MEDICAL ACTIVE IMPLANTABLE DEVICES

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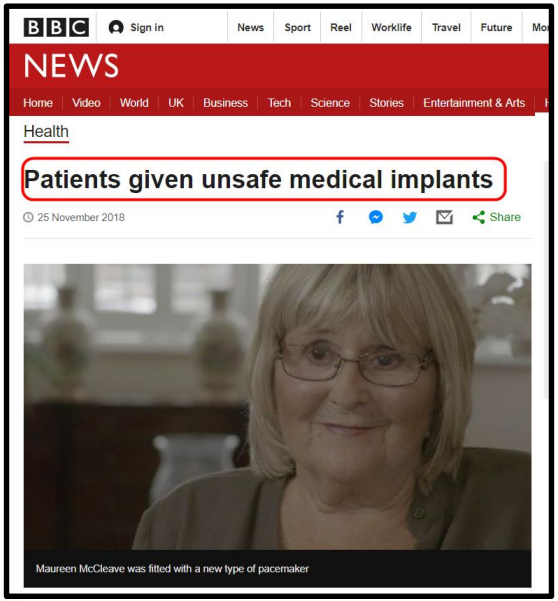
ROHDE&SCHWARZ

Make ideas real

UNSAFE / UNCERTIFIED
MEDICAL IMPLANTS INTRODUCED TO THE MARKET



Medical devices that are unsafe and have not been adequately tested are ending up inside patients' bodies, an investigation has revealed.

The devices include heart pacemakers, rods to correct spines, and artificial knees and hips.

The investigation found implants that had failed in baboons, or were tested only on pigs and dead bodies, were coming onto the market.

The industry says it has transformed millions of lives for the better.

*Source: https://www.bbc.com/news/health-46318445

GROWING CONCERNS TRENDS ON AIMDS

Global Medical Device Testing Markets, 2020-2027 - Focus on Active Implant, Active Medical Device, In-Vitro Diagnostic, Ophthalmic, Vascular and Orthopedic and Dental Medical Devices - ResearchAndMarkets.com

December 11, 2020 05:22 AM Eastern Standard Time

xpected to post a CAGR
vio.

@Technavio predicts the global active implantable medical devices market is expected to post a CAGR of more than 6% by 2022.

Tweet this

A key factor driving the growth of the market is the increasing prevalence of cardiac diseases, neurological disorders, and hearing loss. CVDs are estimated to cause approximately 19 million deaths globally by 2020.

Every year, more than 90,000 patients are diagnosed with heart failure in the US, and three to four million patients are newly diagnosed with heart failure in Europe.

This market research report on the **global active implantable medical devices market 2018-2022** also provides an analysis of the most important trends expected to impact the market outlook during the forecast period. Technavio classifies an emerging trend as a major factor that has the potential to significantly impact the market and contribute to its growth or decline.

This report is available at a USD 1,000 discount for a limited time only: View market snapshot before purchasing

In this report, Technavio highlights the increasing focus on R&D as one of the key emerging trends in the global active implantable medical devices market:

Approximately **19 million death** globally by **2020**

90,000 Patients Diagnosed with **Heart Failure** in US

3 to 4 Million Patients newly Diagnosed with **Heart Failure** in EU

Active Implantable Medical Devices market is expected to **grow 6% by 2022**

*Source: https://www.businesswire.com/news/home/20181004005586/en/Global-Active-Implantable-Medical-Devices-Market-2018-2022

AIMDS ON EMC & WIRELESS

DIRECTIVE REGULATION 2017/745

6.1. Pre-clinical and clinical data

(a) results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;

(b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:

- the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;
- physical, chemical and microbiological characterisation;
- electrical safety and electromagnetic compatibility;
- software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer);
- stability, including shelf life; and
- performance and safety.

Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council [1] shall be demonstrated.

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AIMDS ON EMC & WIRELESS

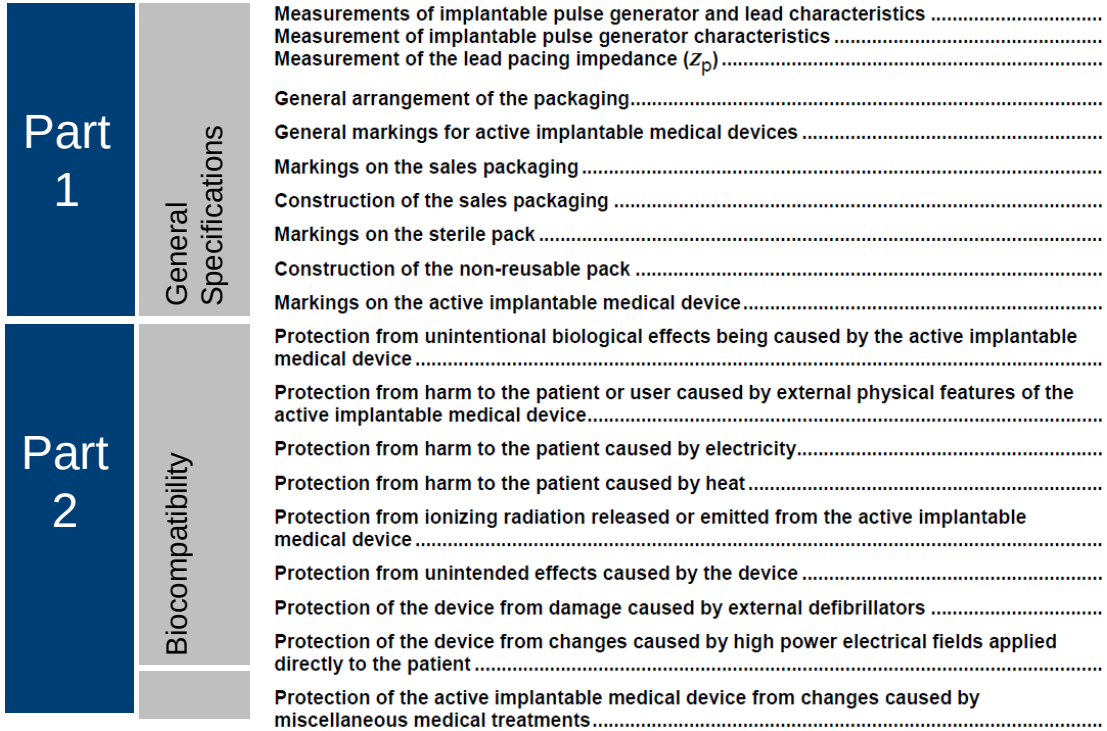
- AIMDs equipped with Wireless Technologies
  - Bluetooth , Wi-Fi , Wireless Induction Charging , RFID Chips
  - Ability to provide correct, secure and accurate medical data transmission to ensure safe operation

- AIMDs EMC Considerations:
  - European Region regulated by Directive 2017/745
  - Test According to ISO 14708
    - Frequency Range: 10Hz to 3GHz
  - Emission is not an issues as its attenuated by the body tissue
  - EMS subjected to more severe levels of EM disturbance than IEC 60601-1-2
    - Due to growing radio frequency and wireless devices

ISO 14708-X SERIES

- Product Standards:
  - ISO 14708-2:2012 – Cardiac Pacemakers
    - Basic Standard:
      - ISO 14117:2012 – Active Implantable Medical Devices (EMC)
  - ISO 14708-3:2008 – Implantable Neurostimulators
  - ISO 14708-4:2008 – Implantable Infusion Pumps
  - ISO 14708-5:2010 – Circulatory Support Devices
  - ISO 14708-6:2010 – Active Implantable Medical Devices Intended to treat tachyarrhythmia
  - ISO 14708-7:2013 – Cochlear Implant Systems

FORMAT OF ISO 14708-X SERIES STANDARDS



FORMAT OF ISO 14708-X SERIES STANDARDS

Part 3	Others	Protection of the active implantable medical device from damage caused by electrostatic discharge
		Protection of the active implantable medical device from damage caused by atmospheric pressure changes
		Protection of the active implantable medical device from damage caused by temperature changes
		Protection of the active implantable medical device from electromagnetic non-ionizing radiation

R&S SUPPORTED TEST CASES IN SUMMARY

Automated testing according to 14708-2, 14708-3, 14708-6 and 14117

- Covered clauses

14708-2

27.2	Test signal 1 (AM modulation) – Induced currents
27.2	Test signal 2 – Inducted currents
27.3	– Test against malfunction
27.4	– EMI test
27.5.1	– Environmental electromagnetic signals
27.5.2	– Environmental electromagnetic signals
27.5.3	– Environmental electromagnetic signals
27.6	– Test against weak magnetic fields

14708-3

27.105.1	Protection from EM disturbances

14117

4.2.2	Test signal 1 and 2 – Induced lead current
4.2.3	Test signal 1 and 2 - Induced lead current
4.3.2.1	Malfunction due to electromagnetic interference
4.3.2.2	Malfunction due to electromagnetic interference
4.3.3.1	Malfunction due to electromagnetic interference
4.3.3.2	Malfunction due to electromagnetic interference
4.4.1	Temporary response to continuous wave
4.4.2	Temporary response to continuous wave
4.5.1	Protection from sensing EMI as cardiac signals
4.5.2	Signal 1 and 2 protection from sensing EMI as cardiac signals
4.5.3	Protection from sensing EMI as cardiac signals
4.5.4	Protection from sensing EMI as cardiac signals

14708-6

27.2	Test signal 1 and 2 induced currents
27.3.1	Test against malfunction
27.3.2	Test against malfunction
27.3.2.1	Test against malfunction
27.4	Test against background EMI
27.5.1	Environmental electromagnetic signals
27.5.2	Environmental electromagnetic signals
27.5.3	Environmental electromagnetic signals
27.6	Test against weak magnetic fields

- Support customization of referenced test case
- Support inhibition signal verification
- Support complex testing methods
- Generate comprehensive test report
- Test logging

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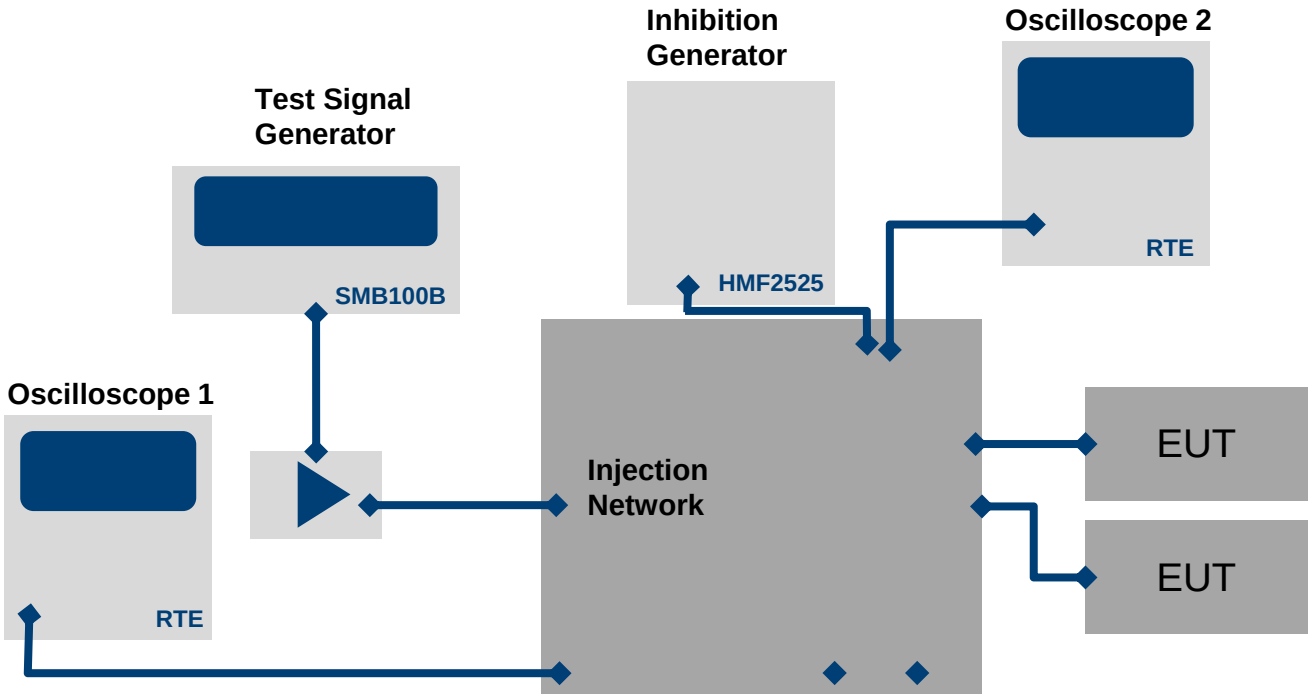
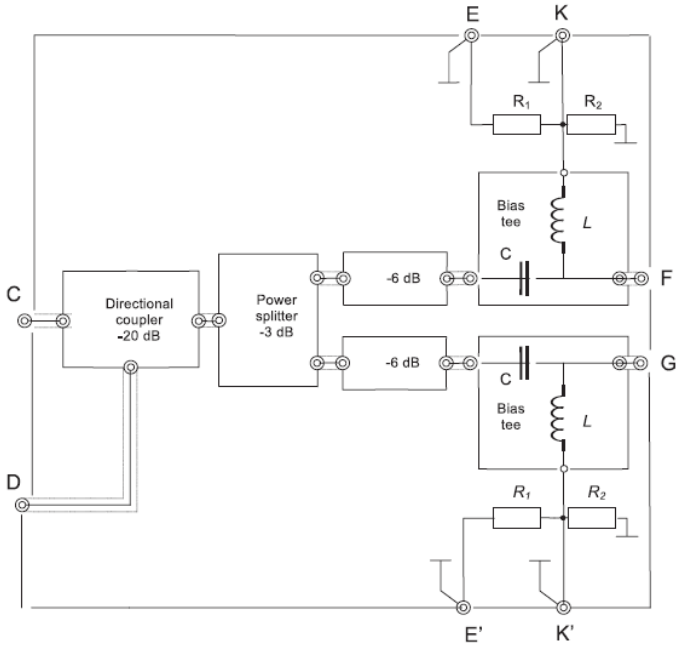
ISO 14708-x Clause 27
Protection of active implantable medical device from electromagnetic non-ionizing radiation
Shifted to ISO 14117 EMC standard for active implants

EXAMPLE OF TEST SET-UP

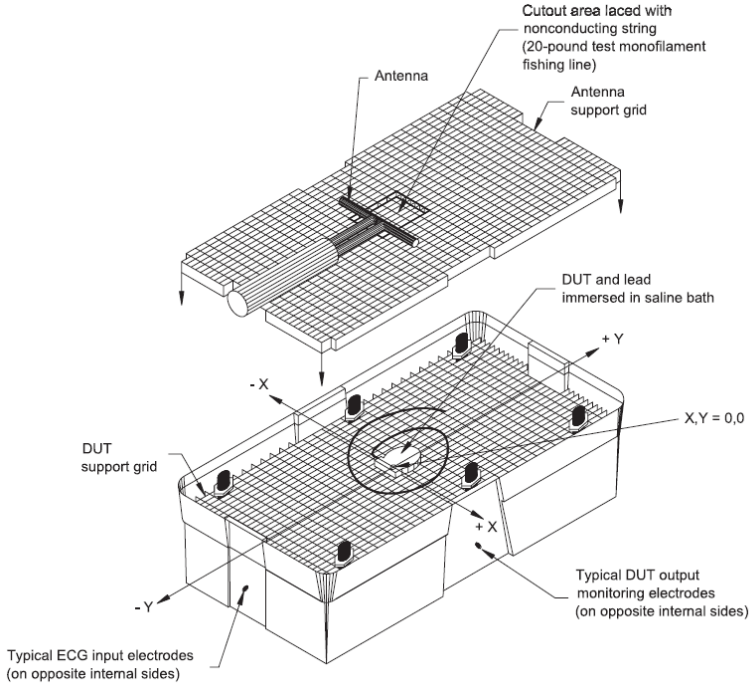
- **Protection from sensing EMI as cardiac signals in the frequency range of 10 MHz to 450 MHz**



EXAMPLES OF TEST JIG

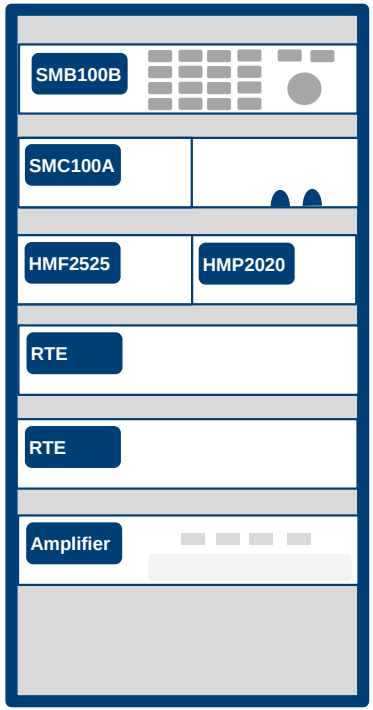


Abstract of Injection Networks specifications

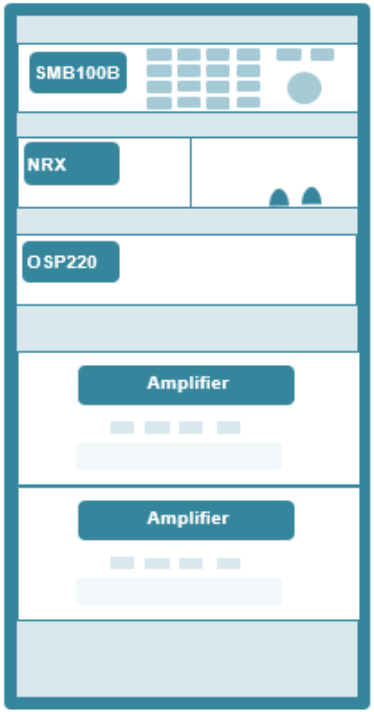


Abstract of Torso Simulator

TA-AIS & TS9982 EMS TEST SYSTEM NEEDS TO BE IMPLEMENTED TOGETHER FOR CLAUSE 27



- **Low frequency magnetic field measurement**
  - Simulated interference signal dependent
    - Static magnetic flux density measurement
    - Magnetic field measurement

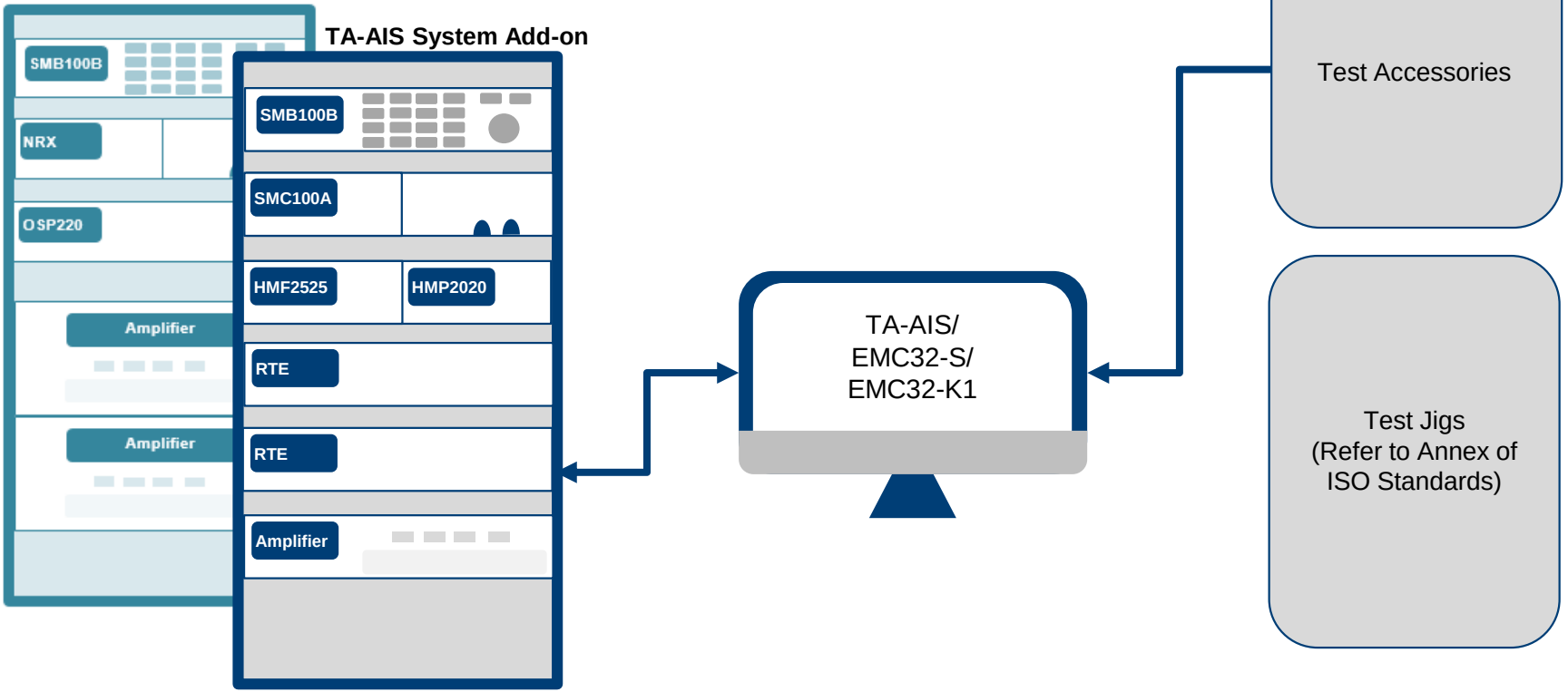


- **Electric field measurement**
  - Frequency range coverage: 30MHz – 3GHz
  - Field strength up to 10V/m, rms
  - Spot frequency range coverage: 10MHz – 3GHz
  - Field strength up to 200V/m, peak

Requires use of EMC chamber

OVERALL SYSTEM SET-UP

TS9982 EMS Test System
(Radiated) Configuration



Additional information

Details | History

Publication type	International Standard
Publication date	2020-09-01
Edition	4.1
Available language(s)	English
TC/SC	TC 62/SC 62A - Common aspects of electrical equipment used in medical practice
ICS	11.040.01 - Medical equipment in general 33.100.10 - Emission 33.100.20 - Immunity
Stability date	2024
Pages	216

Medical electrical equipment Part 1-2:

General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2

UPDATES!

IEC60601-1-2 ED 4.1
EMI REQUIREMENT

CISPR 11

Industrial, Scientific
Medical Equipment

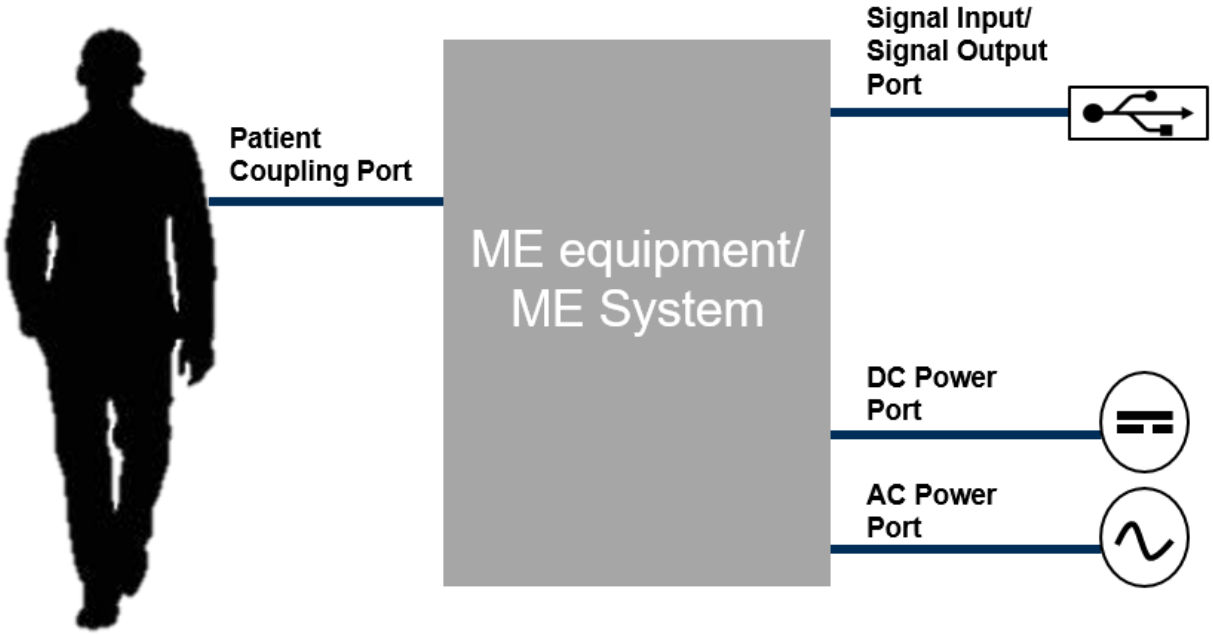
CISPR 14-1

Household/ Motor Driven
Equipment

CISPR 32

Multimedia Equipment

IEC60601-1-2 ED 4.1 (4.0)
MEDICAL EUT DEFINED



IEC 60601-1-2 ED 4.1 (4.0)
CLASSIFICATION OF EM ENVIRONMENT

EM Environment

- **Professional healthcare facility**
  - Clinics
  - Dental office
  - Hospital *(emergency rooms, patient rooms etc.)*

- **Home healthcare**
  - Restaurants
  - Schools
  - Churches *etc.*

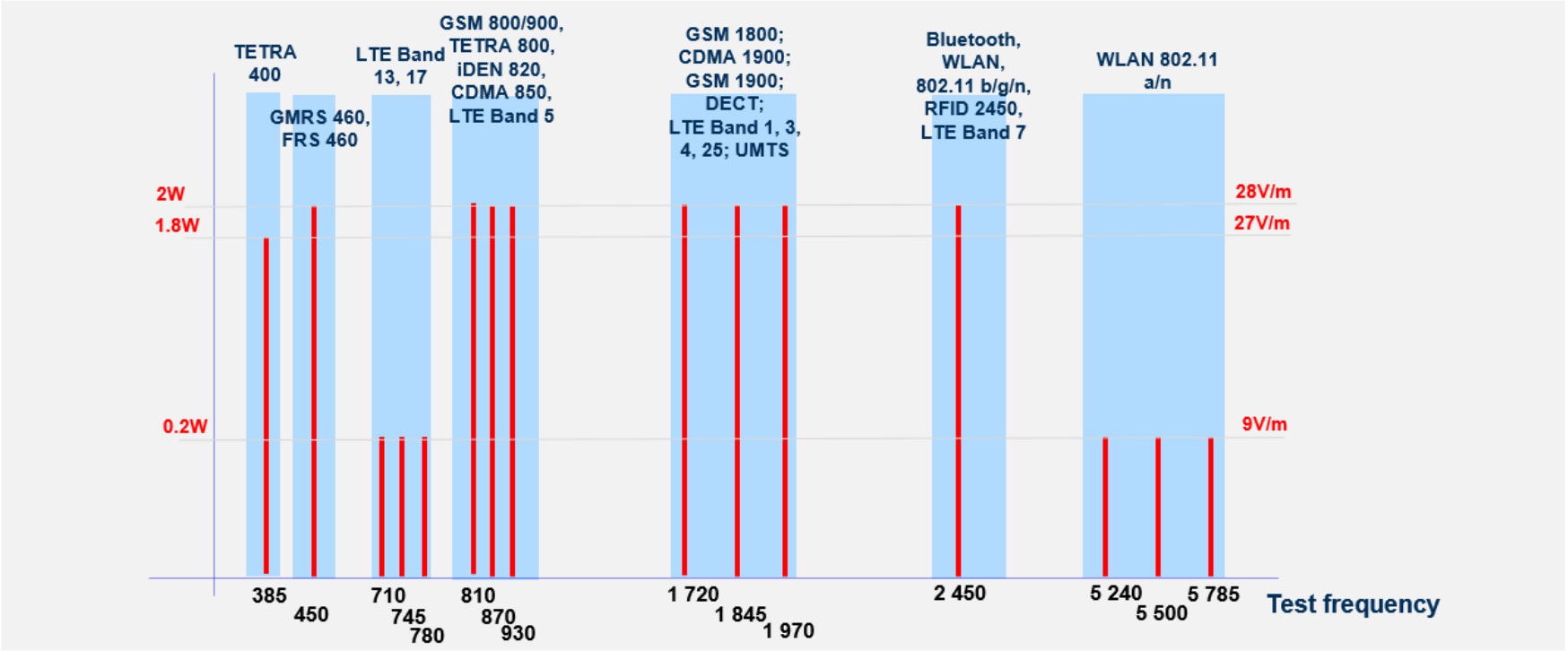
- **Special**
  - Military areas
  - MRI room
  - Transport *etc.*

EMS TEST SUMMARY

Radiated Immunity (IEC 61000-4-3)
EUT Enclosure Port **80MHz – 2.7GHz** **80 % AM at 1 kHz** **Up to 10V/m**
Conducted Immunity (IEC 61000-4-6)
EUT input port, patient coupling port, signal input/ output port **150kHz – 80MHz** **80 % AM at 1 kHz** **Up to 6Vrms**

NO MOBILE PHONE BEYOND THIS POINT

IMMUNITY TO RF WIRELESS COMMUNICATION



IEC60601-1-2 EDITION 4.1 ADDITION FOR IMMUNITY AGAINST MAGNETIC FIELD

Table 11 – Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz [a)]	CW	8
134,2 kHz	Pulse modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse modulation [b)] 50 kHz	7,5 [c)]

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) r.m.s., before modulation is applied.

IEC60601-1-2 EDITION 4.1 ADDITION FOR IMMUNITY AGAINST MAGNETIC FIELD

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Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

An AIM Standard

Table 3 – Test levels

RFID SPECIFICATION	FREQUENCY	TEST LEVEL (RMS)
ISO 14223	134.2 kHz	65 A/m
ISO/IEC 14443-3 (Type A)	13.56 MHz	7.5 A/m
ISO/IEC 14443-4 (Type B)	13.56 MHz	7.5 A/m
ISO/IEC 15693 (ISO 18000-3 Mode 1)	13.56 MHz	5 A/m
ISO 18000-3 Mode 3	13.56 MHz	12 A/m
ISO/IEC 18000-7	433 MHz	3 V/m
ISO/IEC 18000-63 Type C[a]	860-960 MHz	54 V/m
ISO/IEC 18000-4 Mode 1	2.45 GHz	54 V/m

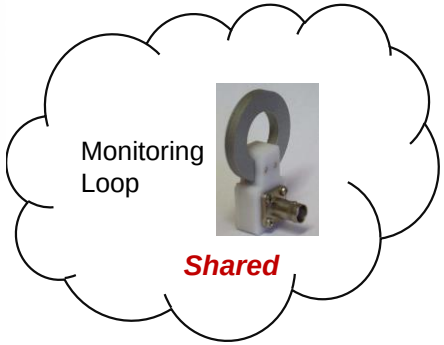
AIM STANDARD 7351731 & IEC60601-1-2 ED 4.1 COMPARISON

Magnetic Immunity Test Case only

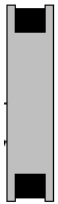
	AIM 7351731	Remarks	IEC60601-1-2 Ed 4.1	Remarks
Frequency range	134.2kHz & 13.56MHz		30kHz, 134.2kHz & 13.56MHz	Higher specifications
Test level	134.2kHz, 65A/m 13.56MHz, 12A/m	Higher specifications	30kHz, 8A/m 134.2kHz, 65A/m 13.56MHz, 7.5A/m	
Modulation	Specific ISO RFID specifications	Higher specifications	CW and Pulse Modulation only	
Illumination area	Not mentioned. * US medical manufacturers propose 10cm coverage @ 0.1m	Higher specifications	9kHz – 150kHz (120mm loop antenna) 150kHz – 26MHz (100mm loop antenna) @ 0.05m	
Specific antenna requirement	Not mentioned. RS101 specifications not able to cover.	Higher specifications	Mentioned (against RS 101)	

PROPOSED MAGNETIC LOOP ANTENNAS FOR TOTAL COVERAGE

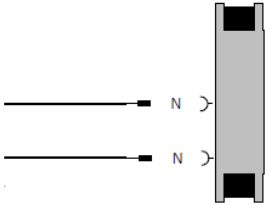
Radiating Loop Set A
134.2kHz
- Covering IEC60601-1-2 Edition 4.1
- Supports AIM 7351731 up to 7.5A/m only
- 5cm test distance



Optional Radiating Loop Set B
134.2kHz
- Covering AIM 7351731
- 10cm test distance



Can be omitted if 10cm coverage not required



Necessary for 12A/m @ 10cm coverage
*** Antenna set A cannot fulfill*

WAVEFORMS RECOMMENDED BY AIM STANDARD 7351731

- ISO 14223 (Annex A)
- ISO/IEC 14443-3 (Type A) (Annex B)
- ISO/IEC 14443-4 (Type B) (Annex C)
- ISO/IEC 15693 (ISO/IEC 18000-3 Mode 1) (Annex D)
- ISO/IEC 18000-7 (Annex E)
- ISO/IEC 18000-63 Type C (Annex F)
- ISO/IEC 18000-4 Mode 1 (Annex G)

Specific waveforms to be used with SMBV100A(B) for generation

Requires EMC32 Software:
EMC32-S/ EMC32-K7/
TA-AIM

WHAT DOES THIS MEAN TO LABORATORIES WITH MEDICAL EMC SCOPE OF SUPPLY?

IEC 60601-1-2 Ed 4.1 Table 11

- **Upgrade from existing EMS test system solution**
- **Antenna set compliant to IEC61000-4-39 for radiating loop**
  - Antenna 1: 30kHz, 134.2kHz
  - Antenna 2: 13.56MHz

US FDA AIM Standard 7351731

- **Vector generator for RFID real signal generation**
- **Antenna loop developed by R&S in-house**
  - Optimized test efficiency/ coverage
  - High coverage of up to 10cm
  - Ability to test large standing EUTs in short period of time
- **AIM software for RFID testing**
  - Upgradable from existing EMC32
  - Fulfills **all** RFID waveform listed on Table 3 of AIM Standard 7351731
- Can also cover IEC 60601-1-2 Edition 4.1 field strength (antenna specifications deviation)

ENDLESS POSSIBILITIES FOR MEDICAL EMC SOLUTIONS