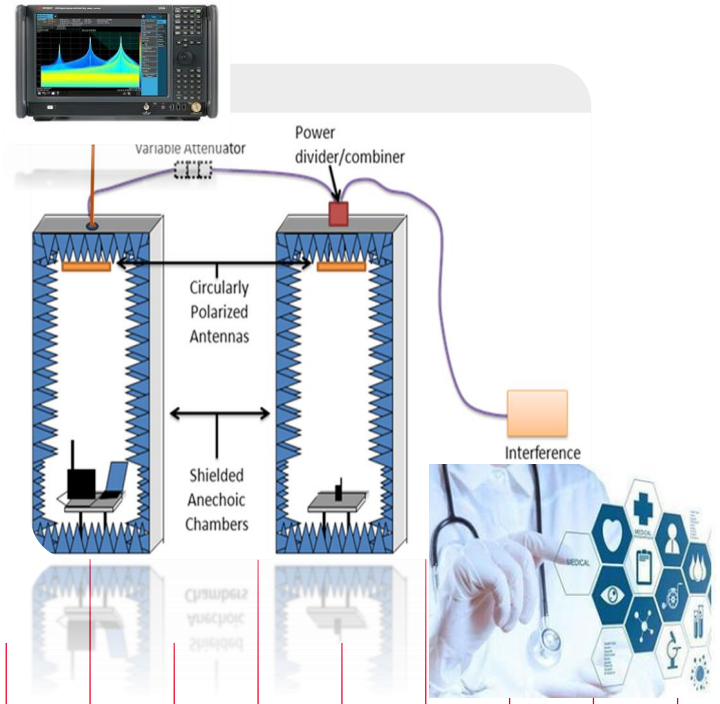
医疗电子产品的无线共存测试



耿如才
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HP时代

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Agilent Technologies years

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在 25 强世界性技术公司中有 **24** 家使用是德科技产品

财富 Fortune 100 的企业中有 **78** 家為是德科技的客户

全球的排名前 **25** 大型的电信运营商/服务提供商全部使用是德科技产品

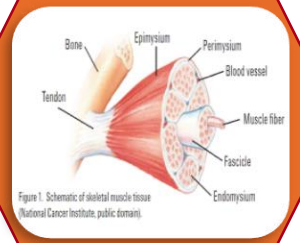
是德科技的医疗测试方案

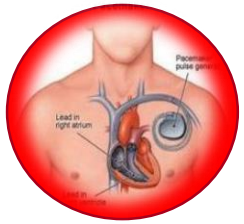
医疗影像设备测试

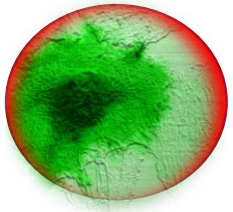
物联网医疗电子测试

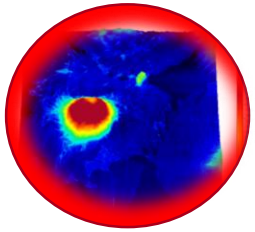
医疗网络安全测试

医学材料测试

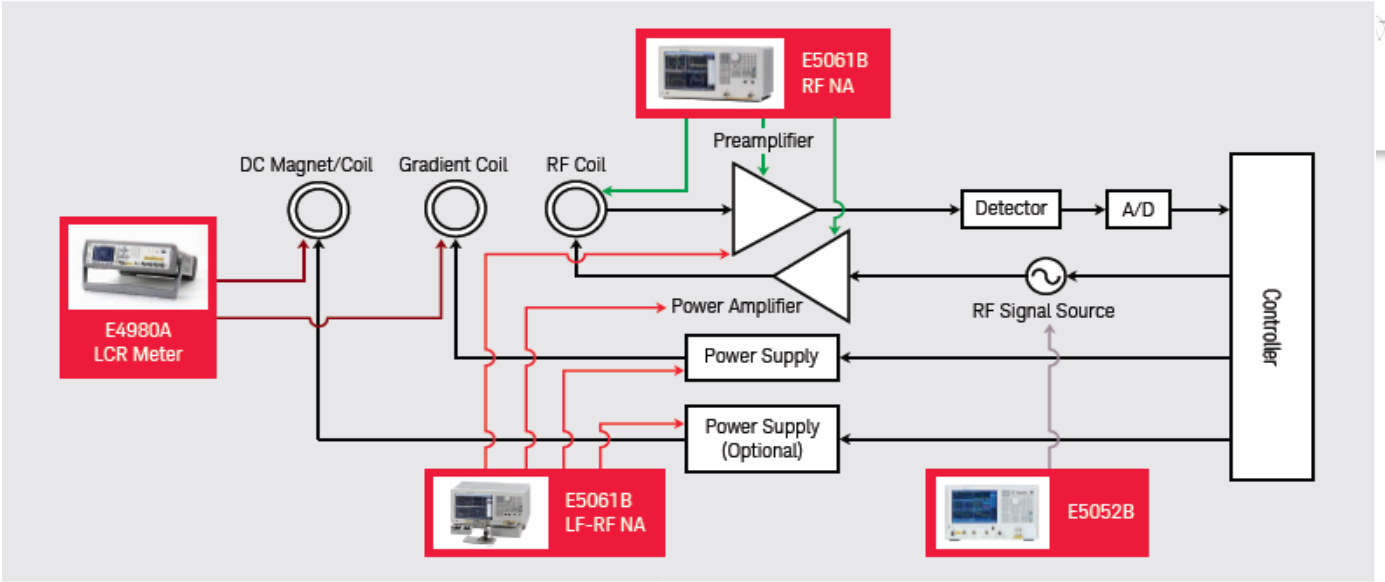








是德科技核磁共振测试解决方案



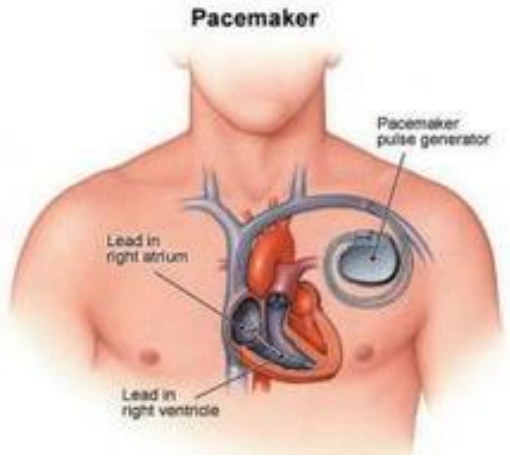
MRI组件	测试内容	推荐测试仪器
MRI 射频线圈	测试共振频率， S11参数	E5071A射频网络分析仪
功率放大器/预放	通过测试S21功率扫频，测试线性度	射频网络分析仪
射频信号源	相位噪声测试	射频信号分析仪
电源	CE认证，通用测试	射频网络分析仪
磁体/梯度线圈	阻抗，转换率和互感测试	E4980A 阻抗分析仪

议程

- 为什么要做无线共存测试 ？
- 什么是无线共存测试？
- 如何进行无线共存测试的？
- 问答

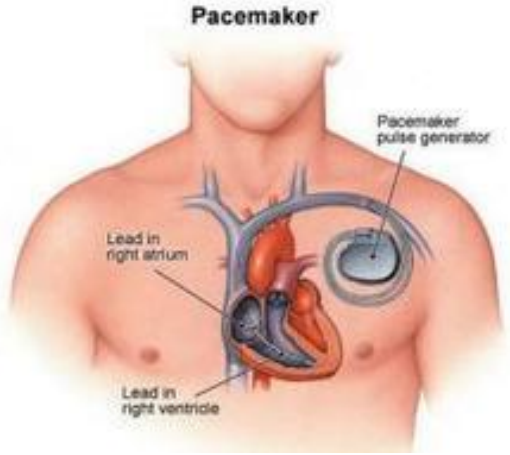
医疗电子设备测试面临的挑战

植入心脏起搏器的病人是否可以接受MRI的检查？



医疗电子设备测试面临的挑战

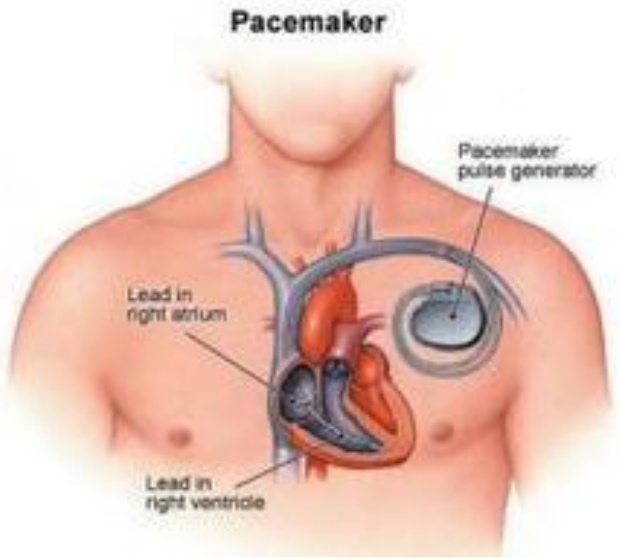
植入心脏起搏器的病人是否可以接受MRI的检查？



研究表明，约 50%-75%的起搏器植入患者需要MRI的扫描检查。然而，为了避免由于磁场的干扰而影响起搏器的正常工作，大量的起搏器植入患者是被禁止接受MRI扫描的.

医疗电子设备测试面临的挑战

植入心脏起搏器的病人是否可以打手机呢？



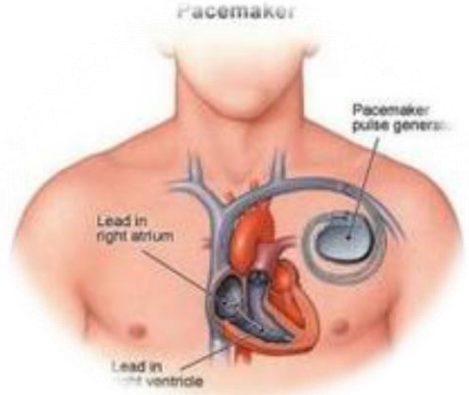
更多便携化和小型化医疗设备

无线B超机

脑起搏器

远程监护仪

无线心电仪

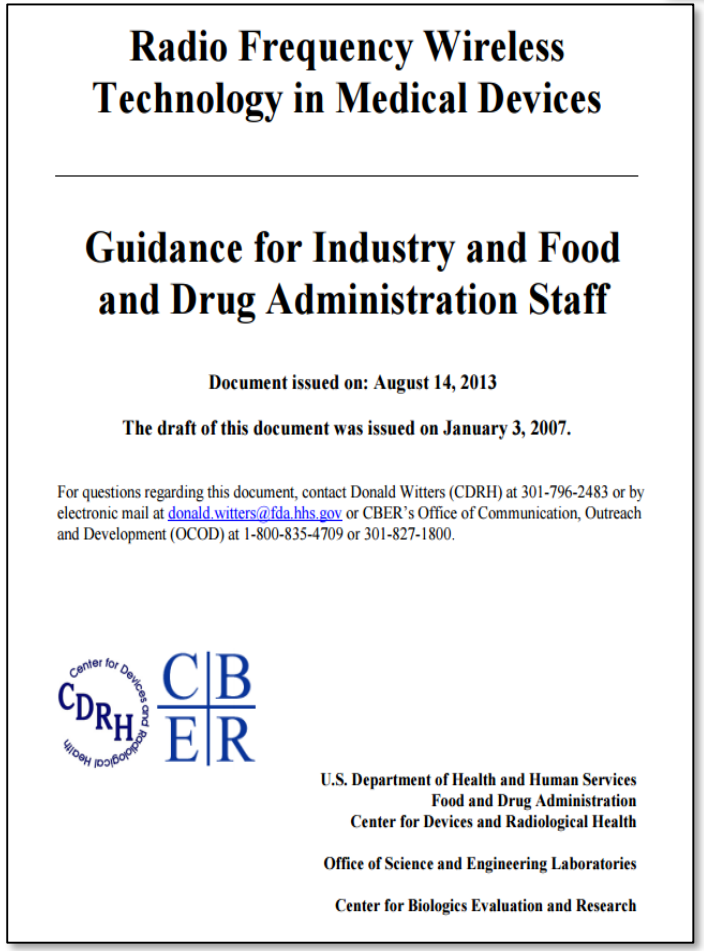


带无线充电起搏器

无线共存

Today's Topic: Only one aspect of the FDA Wireless Guidance

Selection and performance of wireless technology	*Wireless Coexistence*	Quality of Service
EMC of the Wireless Technology	Information for Proper Set-up and Operation	Security of Wireless Signals and Data
	Considerations for Maintenance	



Radio Frequency Wireless Technology in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on: August 14, 2013

The draft of this document was issued on January 3, 2007.

For questions regarding this document, contact Donald Witters (CDRH) at 301-796-2483 or by electronic mail at donald.witters@fda.hhs.gov or CBER's Office of Communication, Outreach and Development (OCOD) at 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Science and Engineering Laboratories

Center for Biologics Evaluation and Research

FDA对射频共存测试的态度

The FDA work began in 2007

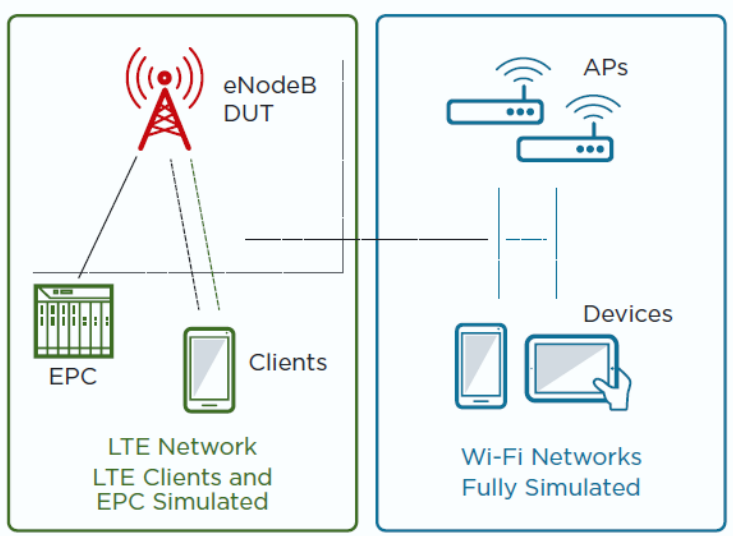
and issued first Guidance in 2013

"If the RF wireless medical device is expected to be used in proximity to other RF wireless in-band (i.e., the same or nearby RF frequency) sources, **FDA recommends addressing such risks through testing for coexistence** of the device wireless system in the presence of the number and type of in-band sources expected to be in proximity to the device."

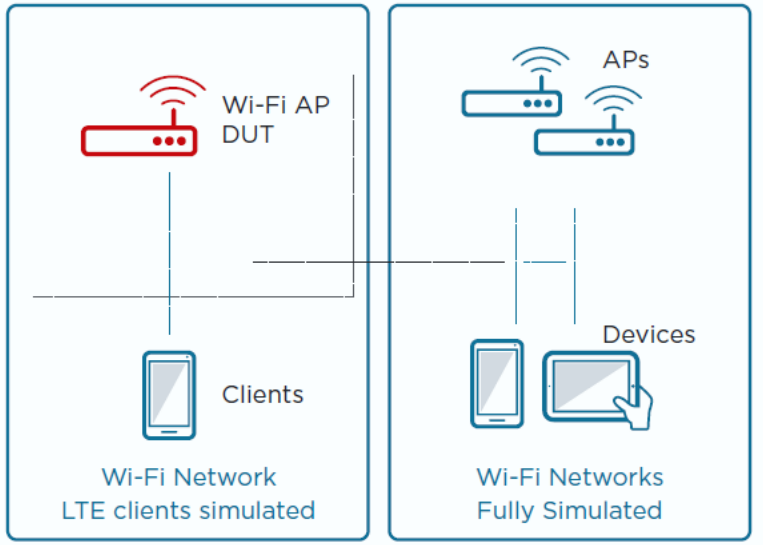
Society of Automotive Engineers (SAE)	Rick Lombardi
	Poul Andersen *(Alt.)*
Telecommunications Certification Body (TCB) Council	Art Wall
	William Stumpf *(Alt.)*
TÜV SÜD America, Inc.	David Schaefer
	Derek Lilla *(Alt.)*
Underwriters Laboratories (UL) LLC	Robert DeLisi
	Jeffrey Moser *(Alt.)*
U.S. Department of Defense—Joint Spectrum Center	Marcus Shellman
	Michael Duncanson *(Alt.)*
U.S. Department of the Navy—SPAWAR	Chris Dilay

	Kermit Carlson *(Alt.)*
Apple, Inc.	Jyun-Cheng Chen
	Michael O'Dwyer *(Alt.)*
Bay Area Compliance Laboratories Corporation	Harry H. Hodes
	Lisa Tang *(Alt.)*
Bureau Veritas	Jonathan Stewart
	Yunus Faziloglu
Cisco Systems	Andy Griffin
	Dave Case *(Alt.)*
Dell Inc.	Richard Worley
Element Materials Technology	Greg Kiemel
	Jeremiah Darden
Ericsson AB	Vladimir Bazhanov
	Kenth Skoglund *(Alt.)*
ETS-Lindgren	Zhong Chen
	Doug Kramer *(Alt.)*
Federal Communications Commission (FCC)	Steve Jones *(Alt.)*
Food and Drug Administration (FDA)	Jeffrey L. Silberberg
	Donald M. Witters *(Alt.)*
Hearing Industry Association	John Becker
	Dave Preves *(Alt.)*
Innovation, Science and Economic Development (ISED) Canada	Jason Nixon
	Horia Popovici *(Alt.)*
Information Technology Industry Council (ITIC)	John Hirvela
	Joshua Rosenberg *(Alt.)*
IEEE Electromagnetic Compatibility Society (EMCS)	John Norgard
	Henry Benitez
Liberty Labs	Mike Howard
	Nate Potts *(Alt.)*
Motorola Mobility	Tom Knipple
Motorola Solutions	Deanna Zakharia
National Institute of Standards and Technology (NIST)	William Young
	Jason Coder *(Alt.)*
Nokia	Dheena Moongilan
PCTEST Engineering Laboratory	Greg Snyder
	Dennis Ward *(Alt.)*
Qualcomm Technologies, Inc.	John Forrester

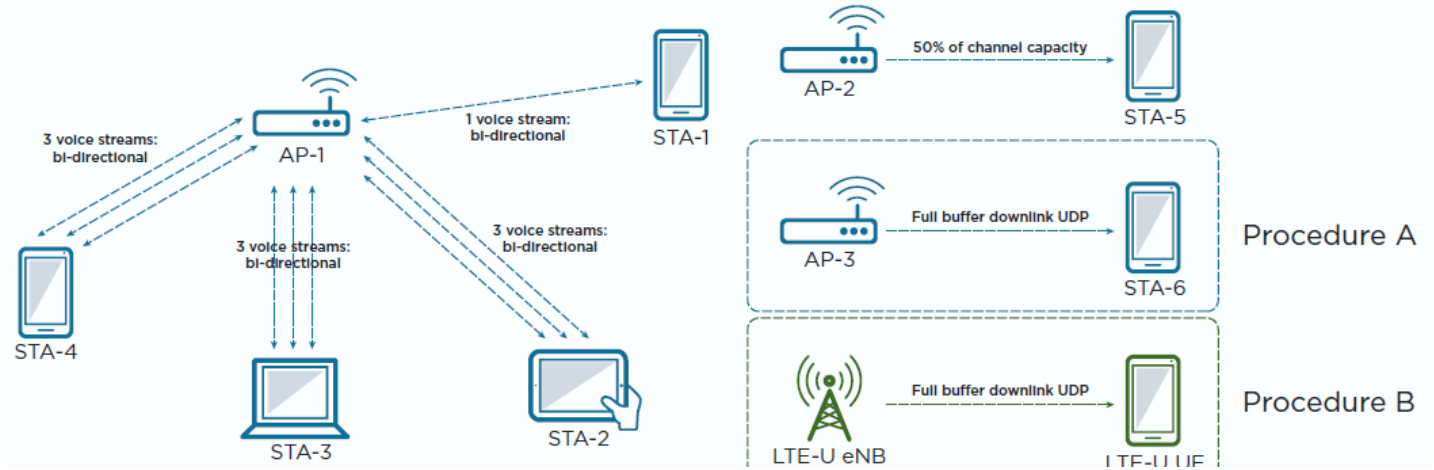
不仅无线医疗电子产品要共存测试



LTE-U/LAA/MulteFire/LWA with Wi-Fi Coexistence



Wi-Fi vs. Wi-Fi Coexistence



WIFI 联盟和LTE-U共存测试计划section4.4 流程A和B

议程

- 为什么要做无线共存测试 ？
- 什么是无线共存测试？
- 如何进行无线共存测试？
- 问答

RF Coexistence 测试规范文件

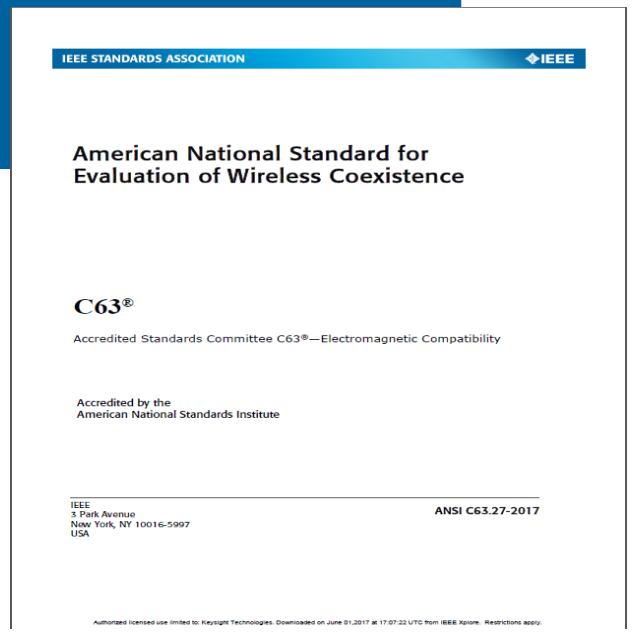
Very recent action from standards group

AAMI TIR69:2017

- Recommendations for the process and guidance on performing a radio-frequency (RF) wireless coexistence evaluation of a medical device as part of an overall medical device risk management approach. Refers to C63.27 as a foundation. **Approved 28 February 2017**
- Includes sample reports and additional information to aid in FDA documentation

C63.27-2017 – ANSI Standard for Evaluation of Wireless Coexistence

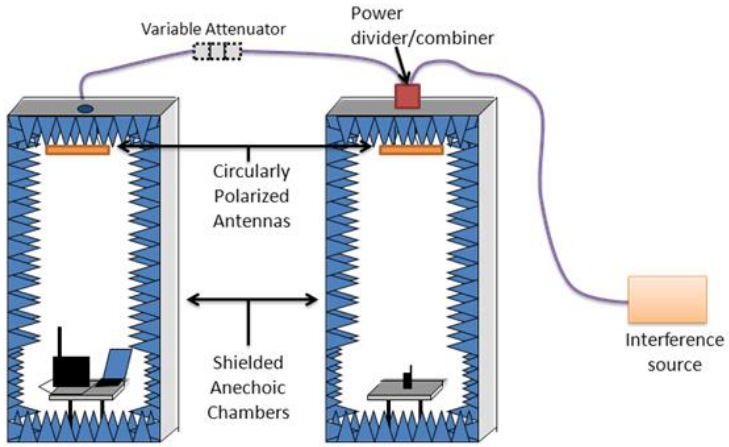
- Provides an evaluation process and supporting test methods to quantify the ability of a wireless device to coexist with other wireless services in its intended radio frequency (RF) environments. **Published 11 May 2017**



什么是共存测试?

It is not traditional EMI/EMC testing

- **EMC Testing:**
  - EMI tests emission of unintended RF signals
  - EMC tests susceptibility to signals other than the intended frequency
- **Coexistence Testing:**
  - Evaluates the ability of a device to maintain its functional wireless performance (FWP)
  - Tests both intended and unintended (interfering) signal impact on the device
  - Both co-channel and nearby frequencies
  - Different radio modulation formats *(concern: WiFi and Bluetooth both at 2.4 GHz)*



共存测试考虑因素

Factors determining coexistence can be divided into two categories: Logical Layer and the Physical Layer

Standard	Frequency	Data Rate	Range
Inductive Coupling	< 1 MHz	1-30 kbps	<1m
Wireless Medical Telemetry System	608-614 MHz 1395-1400 MHz, 1427-1429.5 MHz	>250 kbps	30-60m
Medical Device Radiocommunication Service	401-406 MHz	250 kbps	2-10m
Medical Micropower Networks ("MMNs")	413-419, 426-432, 438-444, 451-457 MHz		<1m
Medical Body Area Networks ("MBANs")	2360-2400 MHz	10Kbps-1Mbps	<1m
802.11a Wi-Fi	5 GHz	54 Mbps	120m
802.11b Wi-Fi	2.4 GHz	11 Mbps	140m
802.11g Wi-Fi	2.4GHz	54Mbps	140m
802.11n Wi-Fi	2.4/5GHz	248 Mbps	250m
802.15.1 Bluetooth Class I	2.4 GHz	3 Mbps	100m
802.15.1 Bluetooth Class II	2.4 GHz	3 Mbps	10m
802.15.4 (Zigbee)	868, 915 MHz, 2.4 GHz	40 kbps, 250 kbps	75m
World Interoperability for Microwave Access (WiMAX)	2.5 GHz	70 Mbps (fixed), 40 Mbps (mobile)	Several km

长用长短距离无线医疗设备用于病人监测和诊断

- Considerations when selecting the Medical Device wireless modality
  - Risk based evaluation and test methods
  - Testing to mitigate the risk to acceptable levels
  - Medically-oriented report formats

考虑因素：逻辑方面 vs 物理方面

Coexistence Factors: Logical Domain vs Physical Domain

OSI Layer	Example
Application	Human Interface
Presentation	Compression
Session	Permissions
Transport	TCP (end-to-end)
Network	IP (addressing)
Data Link	Error Detection, Flow Control
Physical	RF Modulation, Frequency

Logical Domain

Physical

In a wireless network, typical functions in the Logical Domain include Routing, System Capacity, Battery Life, Reliability Margin, Spectrum Utilization, End-to-End Error Correction, Session Connectivity

In a wireless network, functions in the Physical domain include Frequency, Modulation Type, Bit Rate

Interference Analysis now covers more than PHY

物理层需要考虑的因素

- **Dependent on three factors:**

  - Frequency: The probability of coexistence increases as the frequency separation of channels increases between wireless networks.

  - Space (range): The probability of coexistence increases as the signal-to-interference-ratio of the intended received signal increases due to physical separation.

  - Time: The probability of coexistence increases as the channel occupancy of the wireless channel decreases.

- **Coexistence is possible given one of the three following conditions:**

  - Adequate frequency separation between wireless networks
  - Sufficient distance between wireless networks, effectively decreasing the signal-to-interference ratio (SIR) in each
  - Relatively low overall occupancy of the wireless channel.

Problem #1: 频率

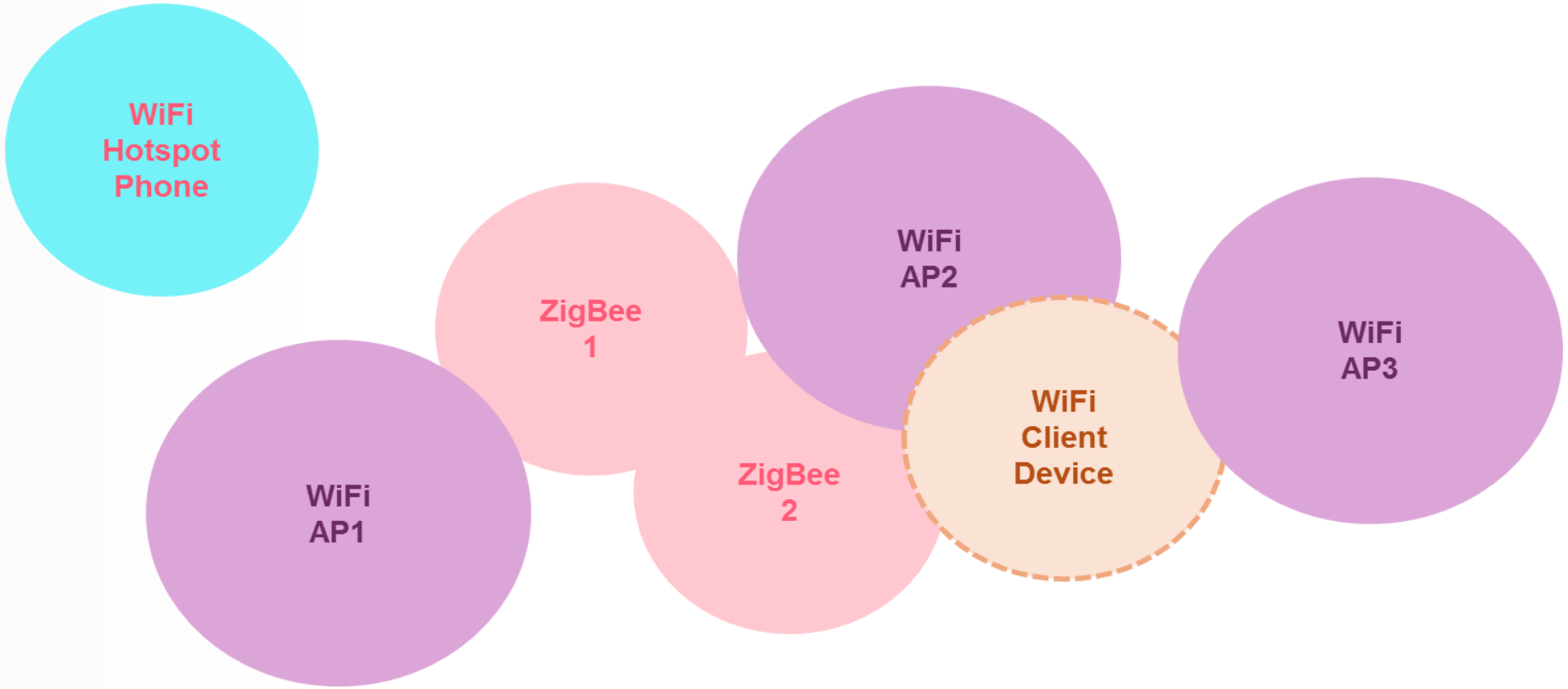
Many devices trying to use the 2.4 GHz ISM Band

	802.11a/g/n.. (WiFi)	802.15.4 (ZigBee)	802.15.2 (Bluetooth)
Non-Overlapping Channels (2.4 GHz):	3	16	79
Bandwidth	22 MHz	5 MHz	1 MHz

- One way to increase the coexistence of heterogeneous networks is to employ *adaptive* frequency hopping.
  - The Bluetooth transmitter and/or the receiver senses the channels to establish which of the 79 Bluetooth channels are free and busy.
  - Bluetooth infers which channels are free and busy by observing the packet error rate of each channel. If a channel has a high packet rate, it is identified as busy.

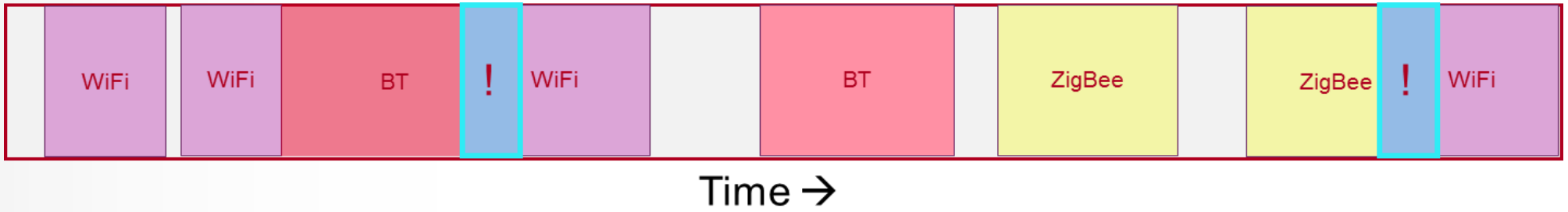
Problem #2: 空间

What is the physical relationship between intended and interfering devices?



Problem #3: 时间

What signals are on the air at the same time?



- 802.11b/g contains abundant white space.
  - 40-50% white space with maximum data rate
- The existing coexistence mechanism for ZigBee, such as carrier-sensing multiple access (CSMA), are inadequate to utilize the white space.
- The default clear channel assessment (CCA) for 802.11b/g is that it only tries to sense other 802.11b/g signals.
  - 802.11b/g does not defer their transmission even when there are existing ZigBee transmissions.

议程

- 为什么要做射频共存测试 ？
- 什么是射频共存测试？
- 如何进行射频共存测试？
- 问答

完成ANSI C63.27 定义的测试

Testing can be done for a variety of reasons – needs help!!

ANSI C63.27
Wireless Coexistence
Evaluation Process

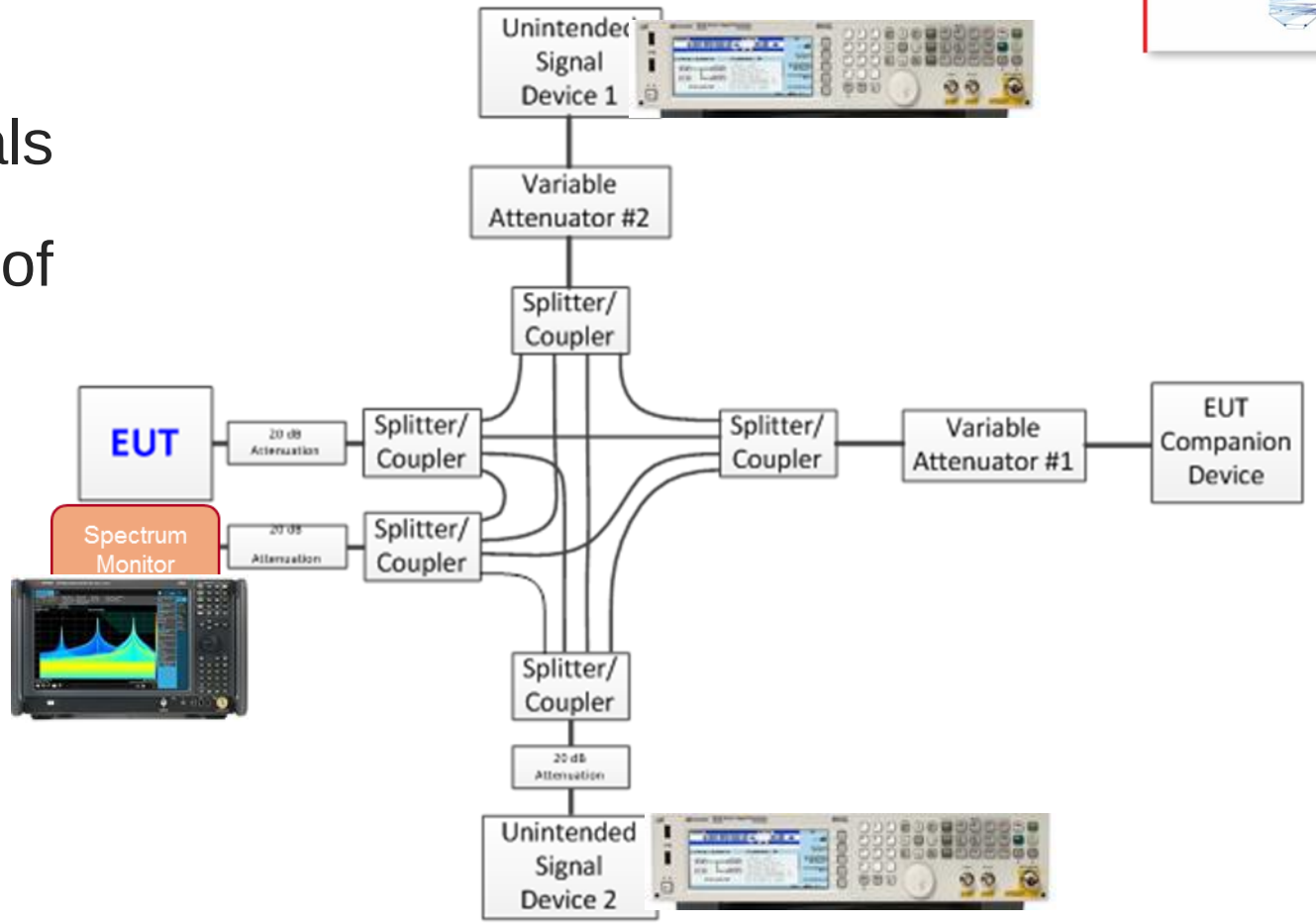
- Clause 5 – Test Plan Development
- Clause 6 - Testing
- Clause 7 – Analysis & Summary of Test Results
- Clause 8 – Analysis of Uncertainties

→ ***Clause 7 provides guidance for the most popular test objectives***

四种基本共存测试方法

1. Conducted (Wired) Method (EUT = Equipment Under Test)

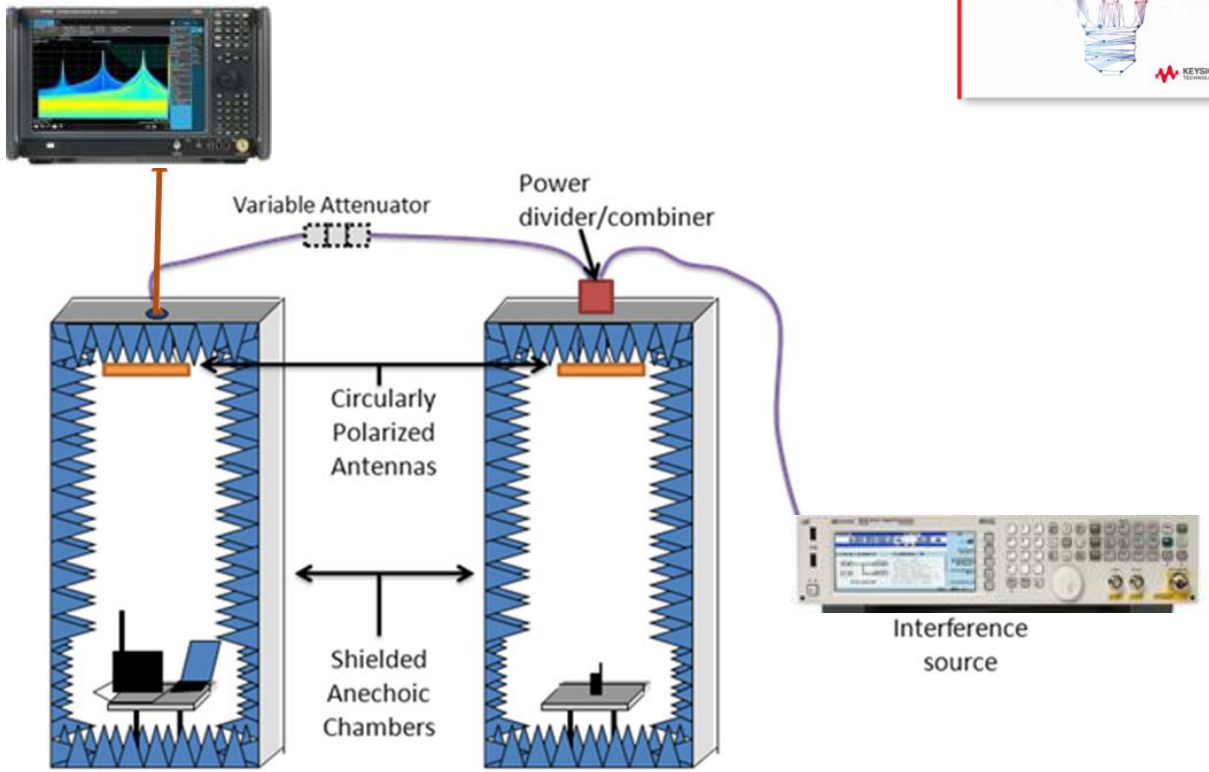
- Performed by combining the intended and unintended signals and connecting them to an access port next to or in place of the antenna
- Effects of the antenna are excluded from testing
- Possible to account for MIMO, beamforming, but difficult
- Most repeatable but least realistic test method



四种基本共存测试方法

2. Chamber/ Hybrid Method

- The signals are generated by actual equipment, which is placed in a separate chamber to allow control over the signal to which the EUT is exposed
- Channel effects can be accounted for.
- Effects of the antennas are included in the testing
- Also used in NFPA radio testing[1]

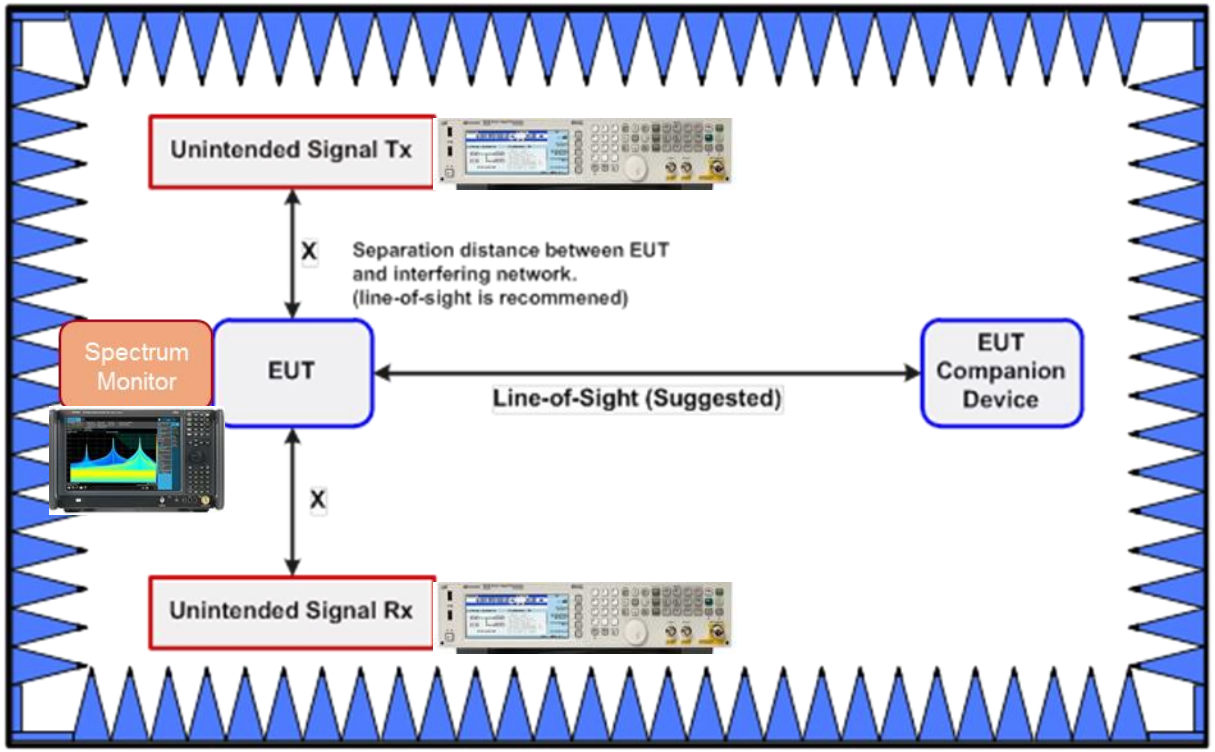


[1] K. A. Remley and W. F. Young, "Test methods for RF-based electronic safety equipment: Part 2 — Development of laboratory-based tests," in *IEEE Electromagnetic Compatibility Magazine*, vol. 2, no. 1, pp. 70-80, 1St Quarter 2013.
doi: 10.1109/MEMC.2013.6512222

四种基本共存测试方法

3. Radiated-Anechoic Method

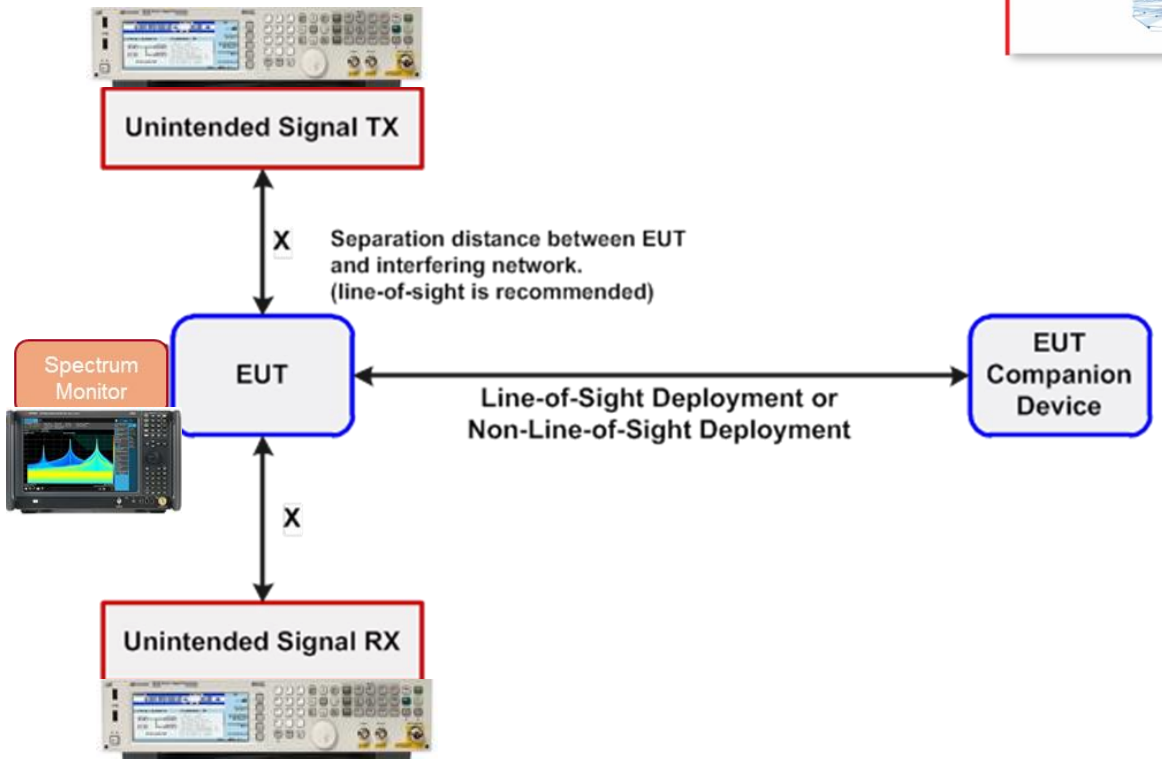
- Semi or fully anechoic chamber
- Ensures that the environment does not decrease the repeatability of the test results
- Antenna effects are accounted for.
- Environment may not resemble the deployment environment



四种基本射频共存测试方法

4. Radiated Open Lab Method

- No shielded room
- Designed to be able to test any wireless device(s)
- Devices can be in LOS or NLOS configuration
  - Enables replication of the deployment environment.
- Testing can be susceptible to ambient signals



评估级别

Based upon Risk Levels (Probability, Severity, etc…)

EUT Using Bluetooth:

Test Tier	Unintended Signal	Recommended Keysight Instruments
Tier 3 Lowest Risk	a single IEEE 802.11n transmission	N5182B MXG Vector Signal Generator or M9381A PXI Vector Sig Gen
Tier 2 Medium Risk	Test A: Two 802.11n transmission	N5182B MXG Vector Signal Generator or M9381A PXI Vector Sig Gen
	Test B: Two Adjacent-band LTE signals	
Tier 1 Highest Risk	Test A: Three 802.11n transmissions	N5182B MXG Vector Signal Generator or M9381A PXI Vector Sig Gen
	Test B: Two Adjacent-band LTE signals	
Spectrum Monitor	n/a	N9020B MXA, or N9914 Field Fox with RTSA

评估级别

Based upon Risk Levels (Probability, Severity, etc…)

EUT Using 2.4 GHz WiFi:

Test Tier	Unintended Signal	Recommended Keysight Instruments
Tier 3: Lowest Risk	a single IEEE 802.11n transmission	N5182B MXG Vector Signal Generator or M9381A PXI Vector Sig Gen
Tier 2: Medium Risk	Test A: One 802.11n transmission	N5182B MXG Vector Signal Generator or M9381A PXI Vector Sig Gen
	Test B: One adjacent-band LTE signal U	
	Test C: One adjacent-band LTE signal L	
Tier 1: Highest Risk	Test A: Two concurrent 802.11n transmissions U and L channels	N5182B MXG Vector Signal Generator or M9381A PXI Vector Sig Gen
	Test B: One adjacent-band LTE signal U	
	Test C: One adjacent Band LTE signal L	
Spectrum Monitor	n/a	N9020B MXA, or N9914 Field Fox with RTSA

非有用信号(Unintended)类别

See Annex A of C63.27 for Band-specific test guidance

To test Bluetooth and BLE:

- Tier 3: single test:
  - Single 802.11n signal 64 QAM
- Tier 2: two tests:
  - Two 802.11n signals 64 QAM
  - Two adjacent-band LTE signals
- Tier 1: two tests:
  - Three 802.11n 64 QAM
  - Two adjacent-band LTE signals

To test WiFi at 2.4 GHz:

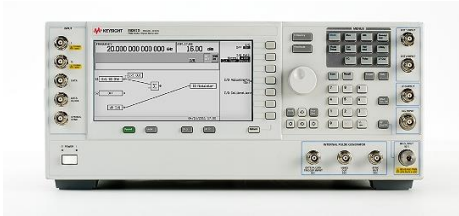
- Tier 3: single test:
  - Single 802.11n signal 64 QAM
- Tier 2: three tests:
  - One co-channel 802.11n
  - One adjacent-band lower LTE signal
  - One adjacent-band upper LTE signal
- Tier 1: three tests:
  - Two concurrent 802.11n lower/higher CH
  - One adjacent-band lower LTE signal
  - One adjacent band upper LTE

测试设备方面的考虑

Signal Simulation, Interactive Signaling, Form Factors

信号模拟需要信号发生器

- Considerations: frequency range, precision, purity of signals, etc.
- N5182B up to 6 GHz, up to 160 MHz bandwidth signals
- M9383A PXIe up to 44 GHz and 800 MHz bandwidth
- E8267D PSG up to 4 GHz Bandwidth



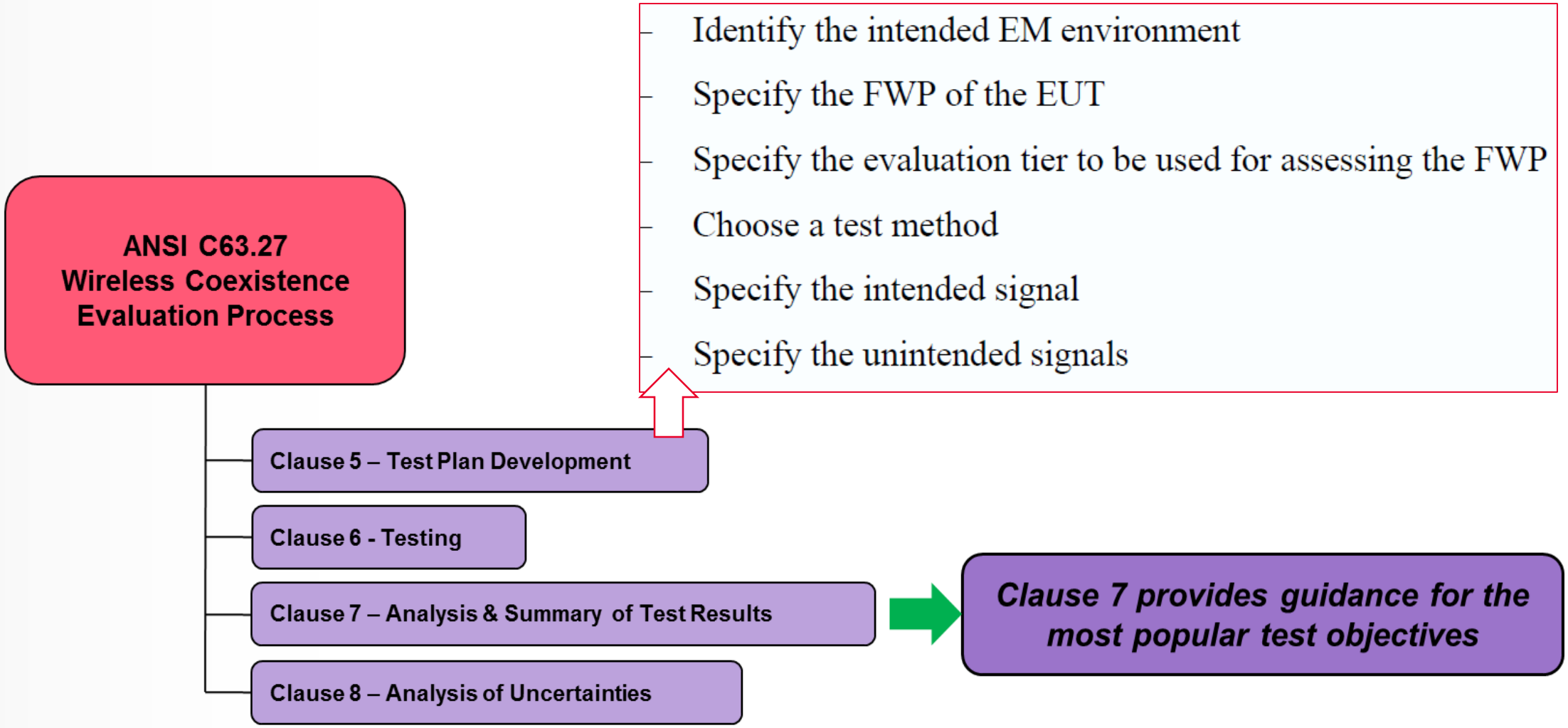
信号模拟需要标准或定制的波形

- Signal Studio N7617B for WLAN, versions for WiMAX, Custom, etc.

交互信令需要具有信令功能的测试仪器

- E7515A UXM Wireless Test Set for LTE up to 1 Gbps down, 100 Mbps up
- E6640A for “faceless” instruments in production test – 6 GHz BW x 4 channels

无线共存测试步骤总结


ANSI C63.27
Wireless Coexistence
Evaluation Process
Identify the intended EM environment
Specify the FWP of the EUT
Specify the evaluation tier to be used for assessing the FWP
Choose a test method
Specify the intended signal
Specify the unintended signals
Clause 5 – Test Plan Development
Clause 6 - Testing
Clause 7 – Analysis & Summary of Test Results
Clause 8 – Analysis of Uncertainties
Clause 7 provides guidance for the most popular test objectives

想了解是德科技更多医疗测试的信息

WHERE TO GO FOR HELP

- 联系我们本地的技术专家或销售
- 参观是德网站: www.Keysight.com
  www.ixiacom.com
- 拨打 800-810-0189 or 400-810-0189 获得支持
- http://www.Keysight.com/find/medical
- https://www.ixiacom.com/resources/wi-fi-and-lte-coexistence-validation-methods

Thanks

KEYSIGHT TECHNOLOGIES