Accredited Standards Committee C63®
Electromagnetic Compatibility
Subcommittee 8 - Medical Device EMC Test Methods
Draft Meeting Minutes

Chair: Bob DeLisi
Vice Chair: Stephen Berger
Secretary: David Zimmerman (Jerry Ramie acting)

11 November 2015 @ 10:00AM – 12:00 PM

UL
12 Laboratory Drive
Research Triangle Park, NC 27709

1. **Call to Order: Chair -** called the meeting to order at 10:12AM-EST
   - **1.1 Opening remarks and Announcements: Chair**
   - **1.2 Meeting logistics announcements: Host**
   - **1.3 Introductions: Secretary -** attendees were Bob DeLisi, Jerry Ramie, Randy Long, Dan Hoolihan, Masud Attayi, Dan Sigouin, Jeff Silberberg, Megan McConnell, Marcus Shellman, Tom Wojtaszek, Chris Dilay, Ed Hare, Greg Kiemel, Dean Ghizzone, Victor Kuccynski, Beth Hackett, Steve Whitesell, Stephen Berger, Nate Potts, Mike Howard, Dheena Moongilan, Victor Bhazonov, Don Heirman, John Norgard, Tom Knipple, Andy Griffin, David Zimmerman, Daoud Attayi, Bob Hofmann, Steve Liu

2. **Approval of the Agenda: Secretary**

3. **Presentation of patent slides: Secretary**

4. **Presentation of meeting attendance fee slides: Secretary**

5. **Approval of minutes of previous meeting: Secretary -** the previous minutes were approved by acclamation.

C63.19: Hearing Aid Compatibility - Working Group Chair: Stephen Berger

5. Provide a brief explanation of the need for the project:	A number of developments, relevant to ANSI C63.19, created a need to review the impact and consider the advisability of revising and updating the standard. Among these developments are: 1. Growing importance of VoIP and VoLTE for telephony services. 2. Hearing aid user satisfaction with HAC. 3. Adequacy of volume control. 4. Adequacy of T-Coil reception. 5. Harmonization with corresponding IEC 60118-13 and IEC 60601-2-66 standards. 6. Cover new technologies, particularly at TVWS devices and cellular at 600 MHz, 3.5 GHz and 5.0 GHz, which may include extending the lower boundary of the frequency range covered. 7. Use of software defined radio (SDR) and other new instrumentation in HAC measurements.

For years we have tried to understand survey responses on VoIP. Volume control and T-coil reception were issues. We have been asked to address 600MHz LTE reception. Use of SDR in HAC measurement has come up. The PINS text was modified to read:

5. Provide a brief explanation of the need for the project:	A number of developments, relevant to ANSI C63.19, created a need to review the impact and consider the advisability of revising and updating the standard. Among these developments are issues with: 1. Growing importance of VoIP and VoLTE for telephony services. 2. Hearing aid user satisfaction with HAC. 3. Adequacy of volume control. 4. Adequacy of T-Coil reception. 5. Harmonization with corresponding IEC 60118-13 and IEC 60601-2-66 standards. 6. Cover new technologies, particularly at TVWS devices and cellular at 600 MHz, 3.5 GHz and 5.0 GHz, which may include extending the lower boundary of the frequency range covered. 7. Use of software defined radio (SDR) and other new instrumentation in HAC measurements.

Further changes in text now show:

7. **This PINS revises a previous PINS submittal:**	☐	Note: A revised PINS is only required if the previously identified stakeholders have changed substantively (see item 6 on this form.)
8. **Description of Contents of Standard:** (Provide a one paragraph description, not to exceed 500 characters.)	The current standard specifies uniform methods of measurement and parametric requirements for the electromagnetic and operational compatibility of hearing aids used with wireless communications devices (WDs) that operate in the 88 MHz to 6 GHz frequency range. This PINS proposes a revision of ANSI C63.19 to address the topics listed under item 5.	
9. **Canvass Developers:** (This request must include a statement of how to obtain a copy of the canvass list.)	☐	Check here to request Canvass Initiation Announcement.
10. **Obtain a Copy of the Canvass List:** (Specify name of contact or a URL address.)		
11. **Consumer Product or Service:**	☐	Check here if standard covers Consumer Product or Service
12. **Accredited Standards Developer Acronym:**	ANSI ASC C63 (EMC)	

Mr. Heirman moved to accept the modified PINS, seconded by Mr. Berger. The motion carried.

5.1.1 Working Group Membership

AI: Mr. Berger to develop roster for C63.19.

5.1.2 FCC NPRM (FCC 15-144)

https://www.fcc.gov/document/hearing-aid-compatibility-standards-nprm

The chair showed this content:

Mr. Berger pointed out that 85% of hearing aids now ship with wireless Bluetooth functionality.
AI: Mr. Berger to develop a response to the 15-44 NPRM by a deadline of 60 days past publication in the Federal Register.

5.1.3 **PINS-C study report and recommendation for initiation of a PINS -** A PINS has now been developed.

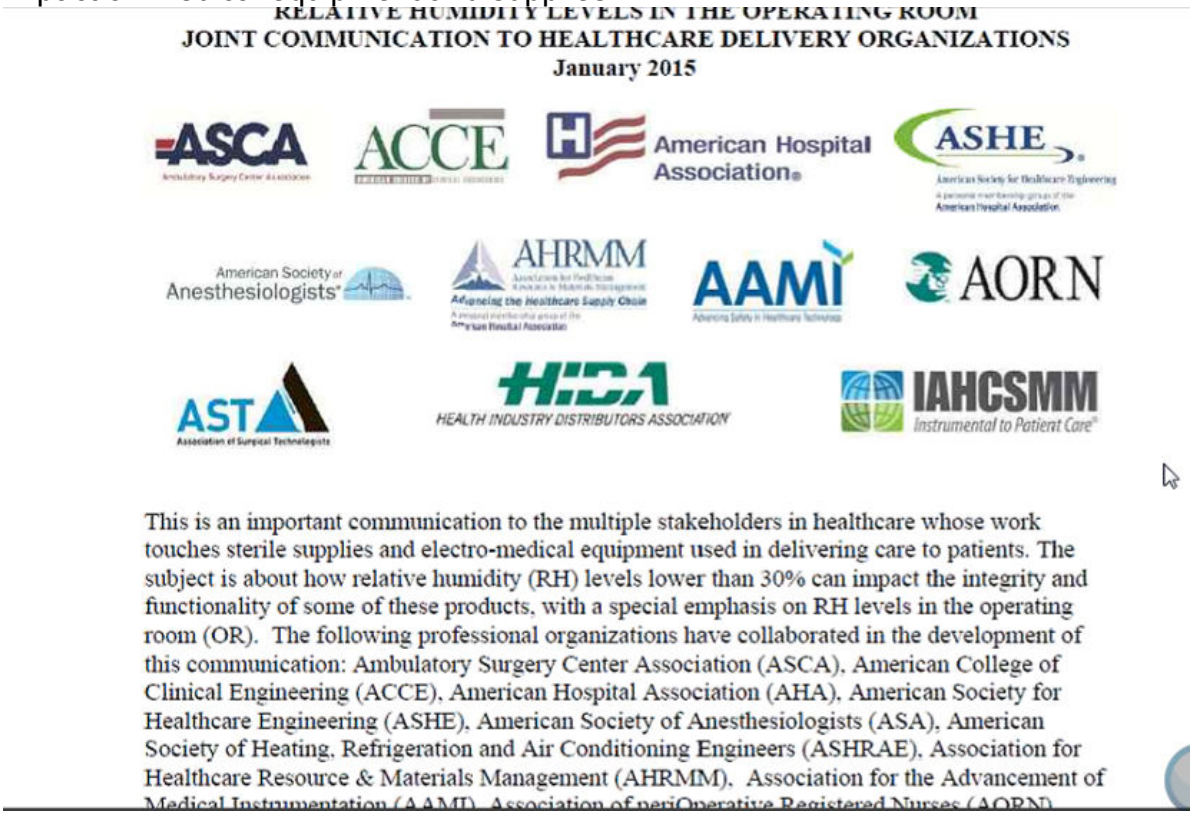
More information about each standard is available on the Standards Status section of the C63® web page.

6. Other Old Business: Chair - none

7. New Business: Chair

7.1 SC8 Leadership for 2016 - Mr. DeLisi's second term is ending. Mr. Hoolihan nominated Mr. Berger, seconded by Mr. Hare. The nominations were closed. Mr. Berger was approved. Mr. Silberberg and Mr. Knipple abstained. Mr. Hoolihan nominated Mr. Whitesell for Vice Chair of SC8, Mr. Hare seconded. Mr. Knipple abstained. Mr. Whitesell is the new Vice Chair.

7.2 AAMI Report - Mr. Heirman showed this presentation:
AAMI undertook to develop the joint communication because ASHRAE had lowered the standard for relative humidity in operating rooms after determining that it would not adversely impact infection control, without any consideration of the potential impact on medical equipment and supplies.


RELATIVE HUMIDITY LEVELS IN THE OPERATING ROOM
JOINT COMMUNICATION TO HEALTHCARE DELIVERY ORGANIZATIONS
January 2015

ASCA ACCE American Hospital Association ASHE

American Society of Anesthesiologists AHRMM Advancing the Healthcare Supply Chain AAMI AORN

AST Association of Surgical Technologists HIDA HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION IAHCSMM Instrumental to Patient Care

This is an important communication to the multiple stakeholders in healthcare whose work touches sterile supplies and electro-medical equipment used in delivering care to patients. The subject is about how relative humidity (RH) levels lower than 30% can impact the integrity and functionality of some of these products, with a special emphasis on RH levels in the operating room (OR). The following professional organizations have collaborated in the development of this communication: Ambulatory Surgery Center Association (ASCA), American College of Clinical Engineering (ACCE), American Hospital Association (AHA), American Society for Healthcare Engineering (ASHE), American Society of Anesthesiologists (ASA), American Society of Heating, Refrigeration and Air Conditioning Engineers (ASHRAE), Association for Healthcare Resource & Materials Management (AHRMM), Association for the Advancement of Medical Instrumentation (AAMI), Association of periOperative Registered Nurses (AORN)

(in fact, EKG electrodes are in foil pouches primarily to protect against changes in external humidity levels). Other consumables for some electrosurgical products also are humidity-sensitive.

→Key Point: It is important for personnel to know and understand the IFUs specific to all supplies and equipment, and in particular know what environmental humidity requirements are specified in the IFU.

- Relative humidity may affect the operation of some electro-medical equipment used in the OR, particularly with older model electro-medical equipment. This equipment may malfunction unexpectedly. Too low humidity levels may also impact calibration. Larger electrostatic discharge (ESD) pulses may create a risk of destruction of parts, premature failure, and erratic behavior of software that is "confusion" from ESD pulses. And, in an environment where humidity is low, a person can more easily become "charged" and receive an electrostatic shock when coming in contact with medical equipment.

- Humidity regulation is difficult to control when weather changes occur. The humidification regulation system in a facility will take some time to compensate by returning the humidity to the nominal "setpoint" range.

Risk Assessment: Steps to Prepare for Lower OR Humidity Levels:

1. What is the desired minimum humidity level and range in the OR and what is the actual level of humidity the HVAC system is able to achieve and maintain in a variety of weather conditions?

2. Have you assessed humidity level data over a sufficient time to know whether, when, and for how long the humidity falls below 30% due to environmental conditions with all seasonal variations? The method of assessment should be conducted in consultation with facilities engineers.

3. Have you determined what the IFUs say about humidity levels for each item in the HDO's existing inventory of supplies and equipment used in the OR?

4. What are the likely risks of using equipment that calls for a humidity level of 30% or higher (which may be especially prevalent with older electro-medical equipment)? What are the potential impacts on performance?

5. Request data from manufacturers documenting the variance of time (excursion data) that products can be out of range before their package integrity or performance are impacted. Learn and understand how integrity and performance are affected when supplies and equipment are stored and used out of range. *Note*: T his data may not be available from all manufacturers as of the date of this communication.

6. For any planned new supplies and equipment, what are the anticipated recommended humidity levels for storage and use?

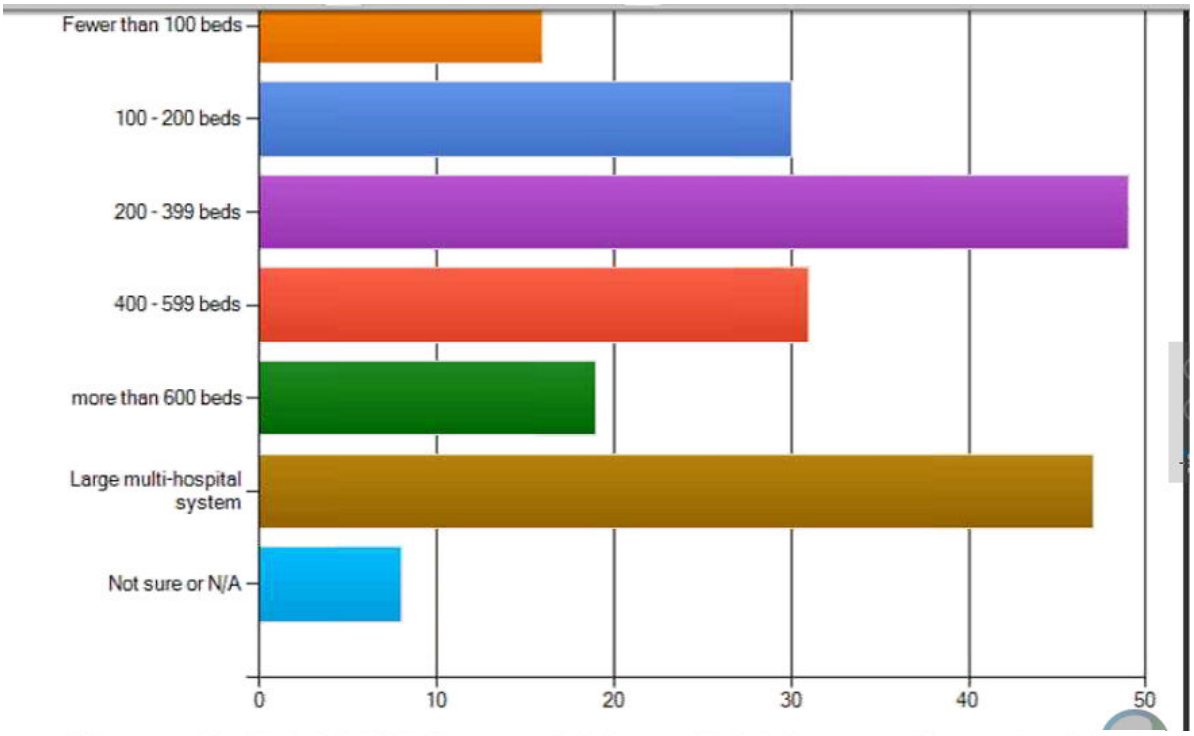
7. Using all of the available information, have you done an overall assessment to determine whether the benefits of lowering the humidity level threshold below 30% override the potential risks?

8. If the decision is made to maintain humidity levels below 30%, consider moving supplies that call for humidity levels of 30% or higher to a humidity-controlled closet.

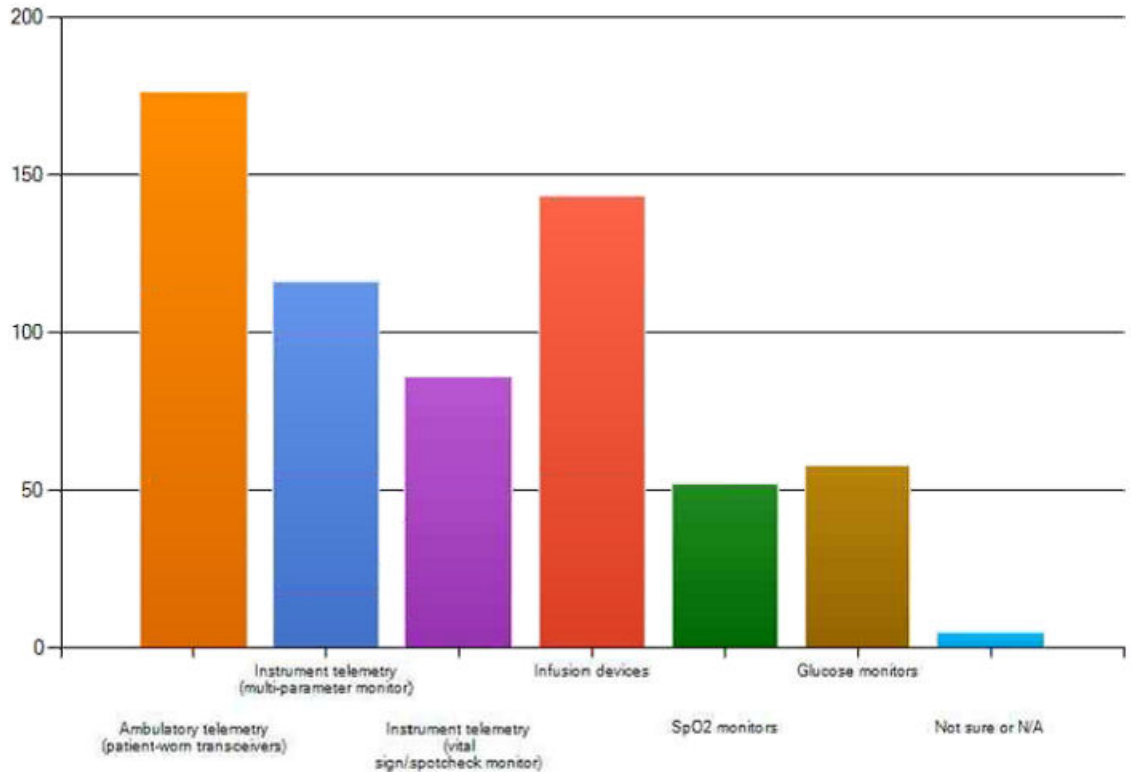
   Note: Supplies that currently require minimum RH levels of 30% or higher are used throughout a healthcare facility (e.g., EKG electrodes). While this risk assessment is specific to the OR, the same process should be considered for other areas where RH levels are going below 30% by design or effect.

Mr. Silberberg pointed out that hospitals wanted lower RH to save HVAC costs. A second presentation was shown by Mr. Heirman:

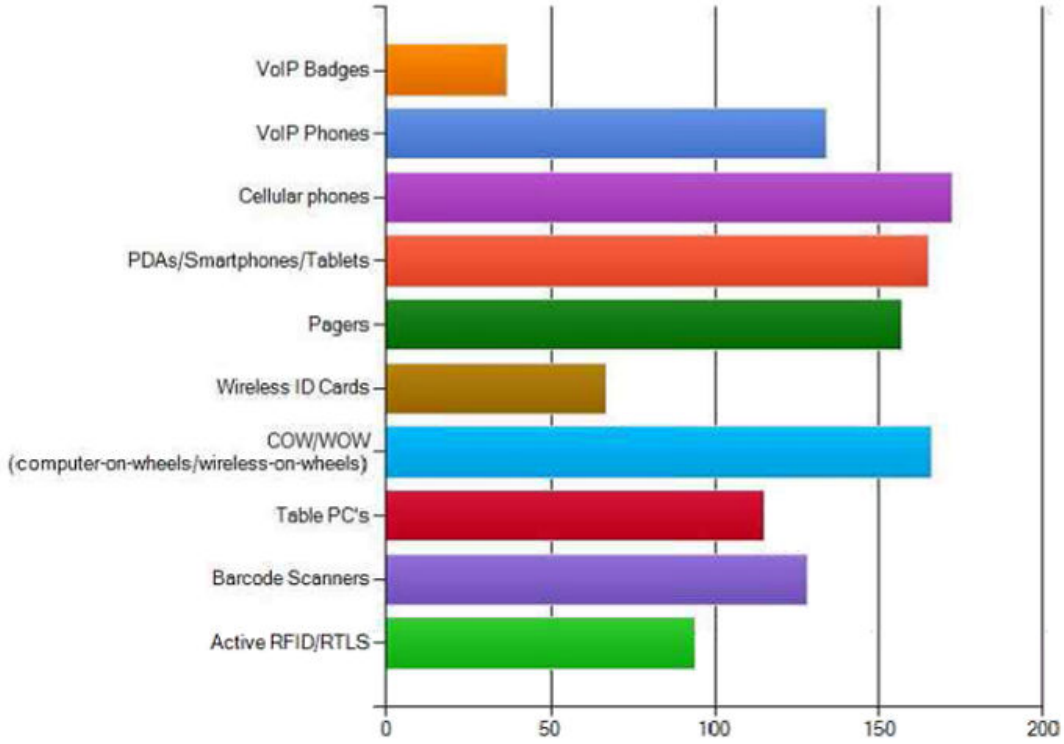
Summary of Results of Wireless Questionnaire



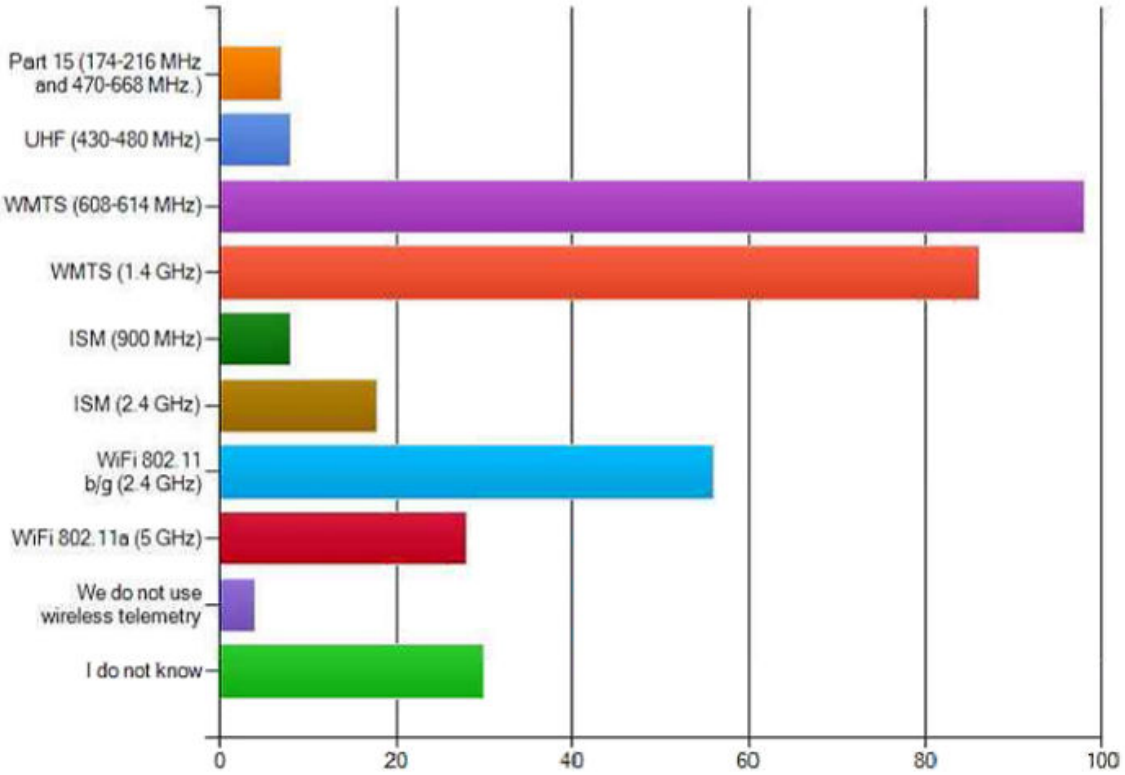
Please specify which of the following types of wireless medical devices are used in your hospital, both currently and those planned for future use.



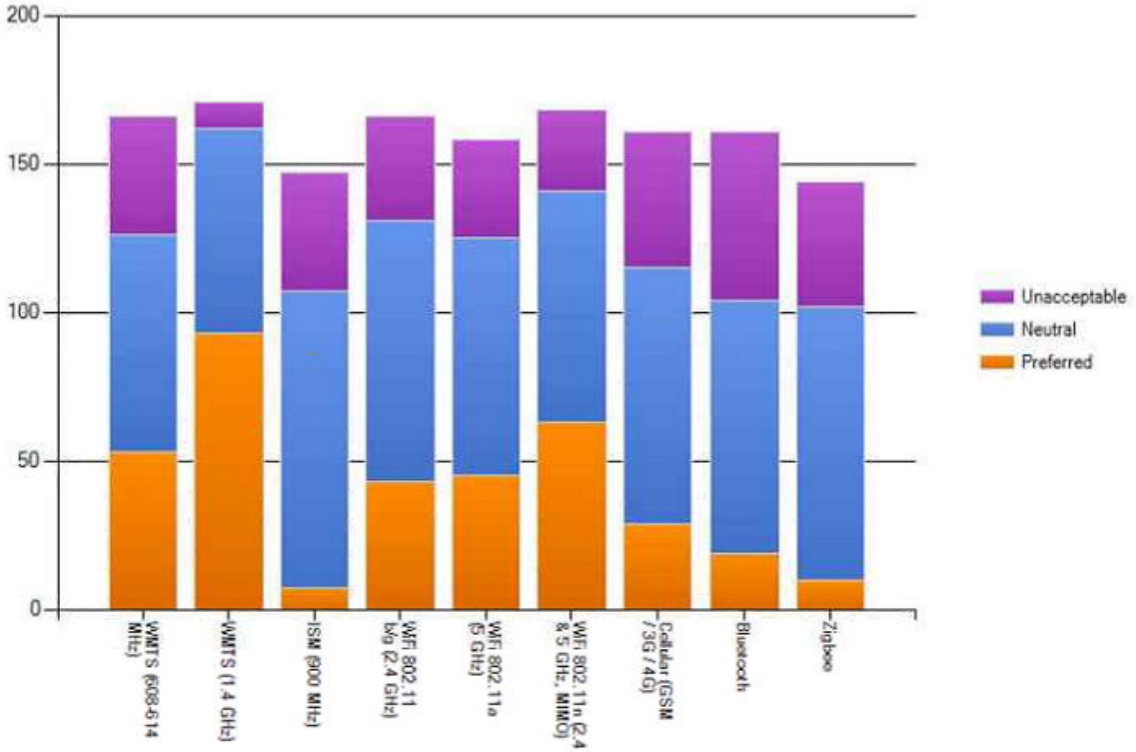
Please specify which of the following other types of non-medical wireless devices are used in your hospital, both currently and those planned for future use.



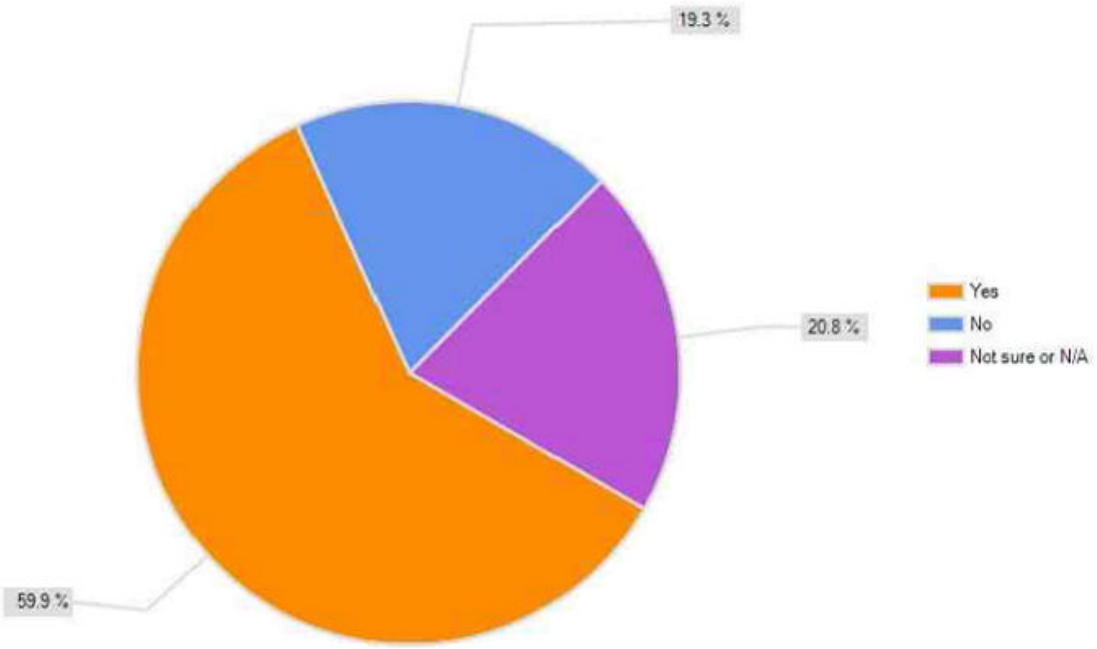
What frequency band(s) do you currently use for ambulatory telemetry (patient worn) and instrument telemetry (bedside monitor)?

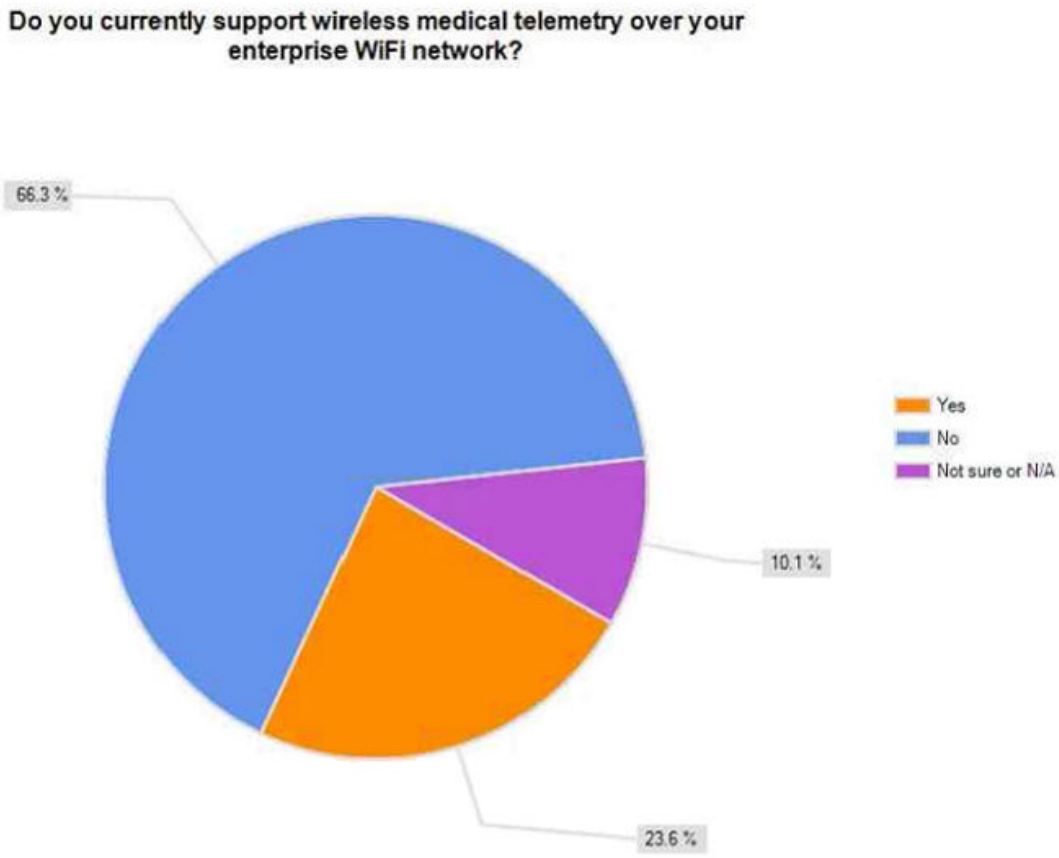


Looking toward the future, please rate the following wireless technologies as "Preferred," "Neutral," or "Unacceptable" for ambulatory telemetry (patient-worn ECG/SpO2):

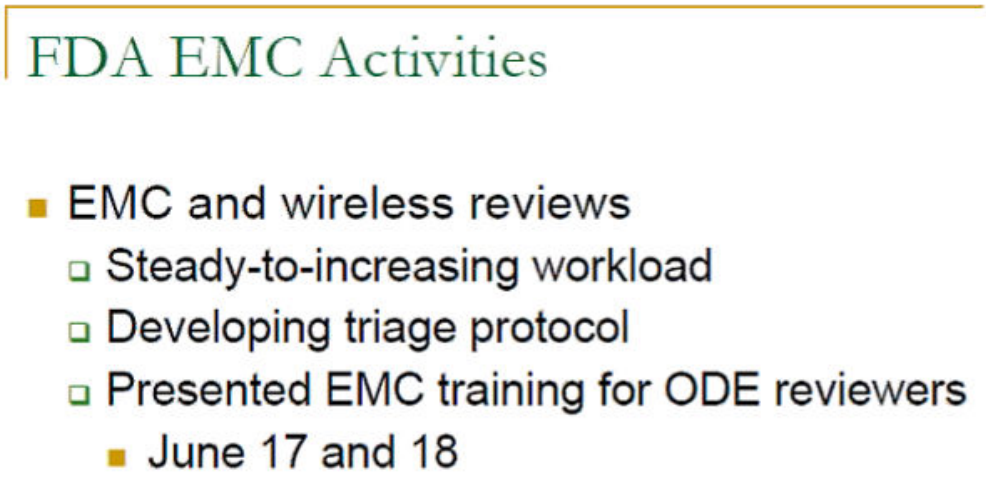


Do you place different medical device types from the same vendor on a shared VLAN?

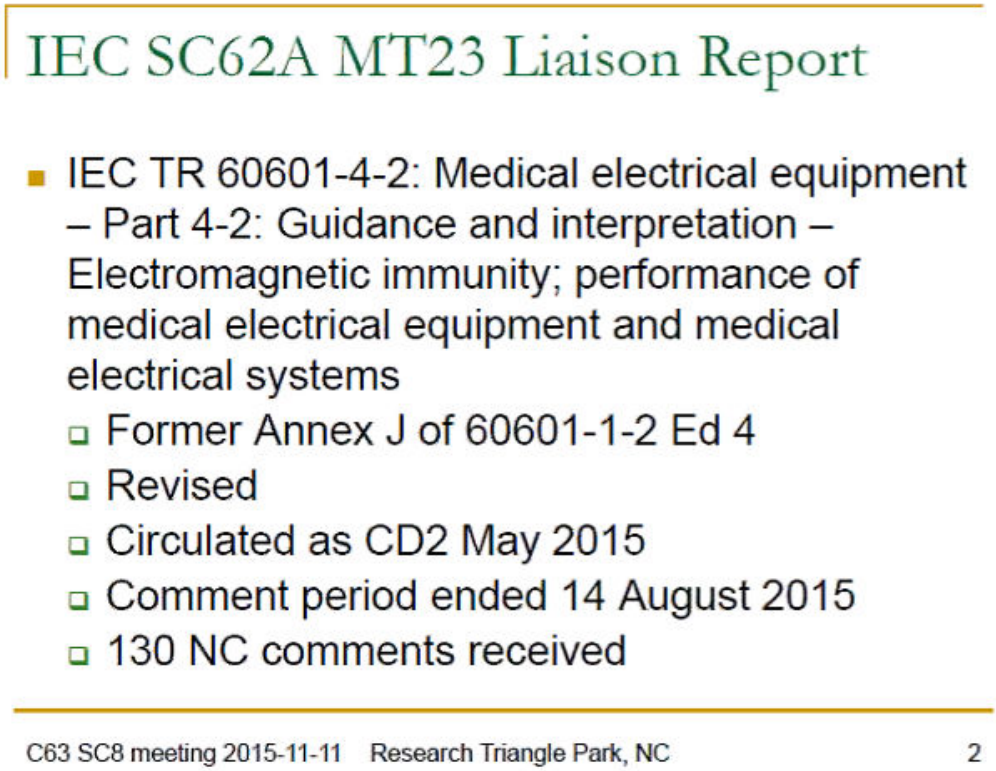




FDA Report - Mr. Silberberg spoke to this presentation:



7.3 IEC SC62A MT23 Report - Mr. Silberberg spoke to this presentation:



8. Review of the action items from previous meetings: Secretary

					ESD. We should keep watch on how this develops as we may want to suggest ESD testing to higher levels for the lower RH.
AI-4:	Send updates to the website to Jerry Ramie with the most current membership and make necessary corrections to member information.	David Zimmerman	Closed	11-30-2014	Done.
AI-5:	Action item given to Bob DeLisi to work with Jerry Ramie to update the link for standards developed by SC8. The link needs to go to a page with only the SC8 standards.	Bob DeLisi	Open	Next Meeting	
AI-6:	Bob DeLisi announced that he will be stepping down as chair at the end of 2015 and he will discuss with the Vice Chair and others about suggestions for incoming leadership.	Bob DeLisi	Open	Next Meeting	
AI-7:	Don Heirman took an action item to look the increased ESD threat with the reduction of relative humidity in operating rooms.	Don Heirman	Open	Next Meeting	
AI-8:	Send updates to the website to Jerry Ramie with the most current membership and make necessary corrections to member information.	David Zimmerman	Open	5-7-2015	

AI-5 closed
AI-6 closed
AI-7 closed
AI-8 closed

9. Time and place of next meeting: Chair - May 9-12, 2016 in Piscataway, NJ

10. Closing remarks and Adjournment: Chair - the meeting was adjourned at 12:00PM-EST.

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End of Meeting