

0Accredited Standards Committee C63®

Electromagnetic Compatibility

Subcommittee 8 - Medical Device EMC Test Methods

Chair: Stephen Berger Vice Chair: John Becker Secretary: Allen Crumm

November 20, 2019; 11:00 AM - 1:00 PM EST

Webex Approved Minutes

- 1. Call to Order: Chair The meeting was called to order at 11:05AM EST.
 - 1.1 Opening remarks and Announcements: Chair Stephen welcomed everyone and thanked them for attending.
- **1.2 Introductions:** Roll Call Dan Hoolihan, Bob Delisi, Jeff Silberberg, Ed Hare, Allen Crumm On Line: Stephen Berger, Dave Case, Don Heirman, Victor Kuczynski, Dave Zimmerman Guests: Randy Long, Jason Nixon, Steve Liu, Pao Thao, Ken Gjerde, Henry Benitez, Jerry Ramie, David Schaefer, Wally Arceneaux, Jeremy Cline, Bill Graff, Ross Quan **Report any roster errors to the ASC-C63 Secretary** (insert <u>SC8 membership roster</u> from the website as shown below)

Subcommittee 8 Membership Roster

#	Name	SC Role	Affiliation		
1	Becker, John	Member	HIA		
2	Berger, Stephen	Chair	TEM Consulting		
3	Case, David	Member	Cisco Systems		
4	DeLisi, Bob	Member	UL, LLC		
5	<u>Hare, Ed</u>	Member	ARRL		
6	<u>Heirman, Don</u>	Member	Don HEIRMAN Consultants		
7	<u>Hoolihan, Dan</u>	Member	Hoolihan EMC Consulting		
8	Kuczynski, Victor	Member	Vican Electronics		
9	Liu, Steve	Member	PCTEST Engineering Laboratory, Inc.		
10	Silberberg, Jeffrey L	Member	FDA Center for Devices & Radiological Health		
11	Zimmerman, Dave	Member	Spectrum EMC, LLC		

- 2. Approval of the Agenda
- 3. Working Group reports Chair More information about each standard is available on the Standards Status Matrix page of the C63® web site.

3.1 C63.18: On Site Medical Device Immunity Testing – No active work.

C63.18-	On-Site Medical	SC 8	Silberberg,	No	Current. No plans for
2014	Radiated RF		<u>Jeffrey</u>	active	further maintenance at
Learn	Immunity testing		-	PINS	this time.
<u>more</u>					

C63.18: C63.18-2014 On-site, Ad-Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio Frequency Transmitters Contact: Silberberg, Jeffrey L (Working Group Chair)

Scope: This recommended practice is a guide to evaluating the electromagnetic immunity of medical devices to radiated radio-frequency (RF) emissions from common RF transmitters (e.g., two-way radios; walkie-talkies; mobile phones; wireless-enabled tablets, e-readers, laptop computers, and similar devices; radio-frequency identification (RFID) readers; networked mp3 players; two-way pagers; and wireless personal digital assistants [PDAs])..

Status: Current. No plans for further maintenance at this time.

Purchase: <u>IEEE Store</u>. To purchase individual standards, go to the IEEE store and search on the standard number. Withdrawn standards can still be purchased. Draft revisions are not yet available for sale.

18 was reaffirmed on July 22nd 2019. Status Matrix to be updated.

3.2 C63.19: Hearing Aid Compatibility maintenance - Stephen Berger

C63.19-	EMC for Hearing	<u>SC 8</u>	Berger,	C63.19	Current. New revision
2011	Aids,		<u>Stephen</u>	<u>PINS</u>	being developed.
<u>Learn</u>					
<u>more</u>					

C63.19: C63.19-2011 American National Standard for Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids

Contact: Berger, Stephen (Working Group Chair)

Scope: Uniform methods of measurement for compatibility between hearing aids and wireless communications devices are set forth.

Status: Current. New revision being developed. An explanation or interpretation is available.

Purchase: <u>IEEE Store</u>. To purchase individual standards, go to the IEEE store and search on the standard number. Draft revisions are not yet available for sale

Published 19 November 2019. Status Matrix to be updated.

4. Other Old Business: Chair

- **4.1 Written reports** Written reports of this Subcommittee meeting shall be presented by the Subcommittee Chair at the Main Committee meeting. These reports shall be made using the PowerPoint template. Prior to the Main Committee meeting, the SC report and approved previous meeting minutes shall be provided to the projectionist for showing on the screen at the Main meeting. The Presentation and any written report shall also be sent by the Subcommittee Chair to the ASC-C63[®] Newsletter editor.
- **4.2 Coordination with SC2 for definitions -** Before any Working Group draft can be submitted to the Subcommittee for approval, the document must be provided to the SC2 Chair for evaluation and coordination of the definitions used.
- **4.3** Coordination with SC3 for harmonization Before any Working Group draft can be submitted to the Subcommittee for approval, the document must be provided to the SC3 Chair for evaluation and coordination of any harmonization effort.

5. New Business: Chair - None.

Discussion of a need for Standards for Immunity of Medical Devices to electronic article surveillance (EAS) systems. David Schaefer raised the issue. FDA has been asking for this testing. The test labs do not know how to perform these tests. Dave took an action item to write the PINS by the next meeting.

Presentations by Jeffery Silberberg to SC8 from the FDA:

FDA Presentation to C63 SC8.

IEC SC62A MT23 Liaison Report to C63 SC8.

- 6. Review of the patent slides No Issues.
- 7. Member Attendance Log:

Name	11/10/16	5/10/17	11/8/17	5/2/18	11/28/18	5/24/19	11/20/19
Andersen, Poul							
Becker, John			X	Х	Web	Х	
Berger, Stephen	Х	Х	Х	Х	Web	Х	Web
Case, David			Web	Х	Web	Х	Web
DeLisi, Bob		Х	Х	Х	Web	Х	Х
Griffin, Andy							
Hare, Ed							Х
Heirman, Don	Х		Х	Х	Web	Х	Web
Hoolihan, Dan	Х	Х	Х	Х	Web	Х	Х
Kuczynski, Victor	Х	Х		Х	Web	Х	Web
Liu, Steve			Х	Х	Web		
Silberberg, Jeffrey L	Х	Х	Web	Х	Web	Х	Х
Zimmerman, Dave	Х	Х	Х	Х	Web	Х	Web

- 7.1 Consideration of new members Application for C63® Subcommittee Membership
- 7.2 Approval of Scope: (Spring meeting only) (Report approval or any changes to the Main Committee)

Scope

Subcommittee 8 is responsible for writing and maintaining existing and proposed C63® standards for medical devices, as assigned by the Main Committee ASC 63®.

- 9. Review of the Action Items: Secretary No new items added.
 - 9.1 Review of Action Items from this meeting:

(read Action Items to Members, who must agree that they understand their meaning)

9.2 Report of Action Items from previous meeting:

Consolidated Action Items from previous Meeting of SC8

Action #	Subject	Responsible Person(s)	Status	Delivery Date	Comments

10. Time and place of next meeting: Chair - ETS Lindgren May 4-8th, 2020.

11.	Closing remarks and Adjournment:	Chair None. The meeting was adjourned at
1:0	OPM EST.	
	******************* End	d of Meeting ************************************

Consolidated Action Items from today's Meeting of SC8

Action Item #	Subject	Responsible Person(s)	Status	Delivery Date	Comments