



Agenda
Anesthesiology Devices Panel
Of the Medical Devices Advisory Committee
Food and Drug Administration

November 1, 2022

Panel Chairperson

Steve Nathan

Designated Federal Officer

Akinola Awojope

8:00 AM Call to Order

Panel Introductions
Conflict of Interest Statement

8:15 AM FDA Opening Remarks

FDA Center for Devices and Radiological Health (CDRH) Jeff Shuren, MD, JD, Center Director
FDA Office of Minority Health and Health Equity (OMHHE) RDML Richardae Araojo, PharmD, MS, Associate Commissioner

8:25 AM FDA Regulation and Pulse Oximeters Technology

Presentation

Pulse Oximeters: Technology, Accuracy Limitations, and Regulation
Standards for Pulse Oximeters: ISO 80601-2-61: 2017
A Systematic Literature Review of the Real-World Performance of Pulse Oximeters

Speaker

James Lee, PhD, CDRH, OHT1
Sandy Weininger, PhD, CDRH, OSEL
Allison O'Neill, PhD, CDRH, OHT1

9:05 AM Considerations for Study Design, Methods, and Analyses

Presentation

Overview of Desaturation Studies in Pulse Oximeter 510(k) Submissions
Premarket Desaturation Studies for Pulse Oximeters
Statistical Considerations in the Evaluation of Pulse Oximeters
Methods for Assessing Skin Pigmentation in Pulse Oximetry Studies

Speaker

Mary Jung, PhD, CDRH, OCEA
Kumudhini Hendrix, MD, CDRH, OHT1
Gene Pennello, PhD, CDRH, OSEL
Josh Pfefer, PhD, CDRH, OSEL

Clarifying Questions from Panel to FDA (15 mins)

10:00 AM Break (5 mins)

10:05 AM Open Public Hearing*

***Open Public Hearing:** Interested persons may present data, information, or views, orally or in writing, on the issue pending before the Panel. Scheduled speakers who have requested time to address the Panel will speak at this time. After they have spoken, the Chair may ask them to remain if the Panel wishes to question them. The Chair may recognize unscheduled speakers if time allows. Only the Panel may question speakers during the Open Public Hearing. Public attendees may not participate except at the specific request of the Panel Chair

11:05 AM Invited Speakers**Presentation**

Adult Patients Perspective about Pulse Oximetry
Pediatric Patients Perspective about Pulse Oximetry
Industry Perspective on Pulse Oximetry, *AdvaMed*
Researcher Perspective on the Conduct of Pulse Oximeters
Desaturation Studies
Professional Societies Perspectives on Pulse Oximetry:

Speaker

Rekha Hagen
Jessica Cocolin, CRNA
Bob Kopotic, RN, RRT
Paul Batchelder, LRCP, RRT, Clinimark
American Academy of Sleep Medicine, Amal Jubran, MD
American College of Chest Physicians, Eric Gartman, MD
American College of Surgeons, Ann G. Rizzo, MD, FACS, DABS
American Medical Association, Jesse Ehrenfeld, MD
American Thoracic Society, Steven Gay, MD, MS
Anesthesia Patient Safety Foundation, Julian Goldman, MD
Society of Technology in Anesthesia, Garrett Burnett, MD
American Association of Critical Care Nurses, Elizabeth Bridges, PhD, RN, CCNS, FCCM, FAAN

Clarifying Questions from Panel to Invited Speakers (10 mins)

12:25 PM LUNCH (35 mins)

1:00 PM Open Public Hearing*

2:00 PM Invited Speakers

Presentation

Real-World Evidence and Pulse Oximetry:

Speaker

Michael W. Sjoding, MD, University of Michigan Medical School
An-Kwok Ian Wong, MD, PhD, Duke University
Ashraf Fawzy, MD, MPH, Johns Hopkins University
Eric Raphael Gottlieb, MD, MS, Brigham and Women's Hospital
Phil Bickler, MD, PhD, UCSF-CERSI
Christopher Almond, MD, Stanford-CERSI
Michael Lipnick, MD, University of California (UCSF)

Clarifying Questions from Panel to Invited RWE Speakers (15 mins)

3:25 PM Break (5 mins)

3:30 PM Panel Deliberations/Discussion

5:30 PM Break (5 mins)

5:35 PM FDA Questions to the Panel

7:20 PM FDA Summation

7:30 PM Adjournment

***Open Public Hearing:** Interested persons may present data, information, or views, orally or in writing, on the issue pending before the Panel. Scheduled speakers who have requested time to address the Panel will speak at this time. After they have spoken, the Chair may ask them to remain if the Panel wishes to question them. The Chair may recognize unscheduled speakers if time allows. Only the Panel may question speakers during the Open Public Hearing. Public attendees may not participate except at the specific request of the Panel Chair