

CRITICAL CARE SOCIETIES COLLABORATIVE (CCSC)



We help the world breathe®
PULMONARY • CRITICAL CARE • SLEEP



March 31, 2021

Jeffrey Shuren, MD, JD
CDRH Center Director
Via email: jeff.shuren@fda.hhs.gov

Michael Ryan
Director, Division of Health Technology 1C
Via email: michael.ryan@fda.hhs.gov

Dear Drs. Shuren and Ryan:

This correspondence is prompted by long-standing concerns regarding the accuracy of pulse oximetry across the spectrum of patient populations, particularly among those with darker skin color. Pulse oximetry is among the most common measures in healthcare, used either intermittently or continuously in millions of acutely and critically ill patients each year. Accurate measurement of arterial blood oxygen saturation via pulse oximetry is vital to the clinical management of patients. The universal use of these devices and the need for accuracy when caring for patients in intensive care make this both urgent and important for clinicians in critical care.

The technology underlying pulse oximetry has evolved since its inception, yet concerns have been raised for more than five decades about the potential inaccuracy of pulse oximetry in people with darker skin.^{1,2} Studies have confirmed differences between arterial blood saturation and pulse oximetry for people with darker skin, sometimes in excess of 5%. These differences were greatest in the setting of hypoxemia—a situation in which accurate information is most important for clinical decision-making.^{3,4} Most recently this finding was re-demonstrated by Sjoding et al, showing in a contemporary cohort of hospitalized patients a higher rate of occult and clinically significant arterial hypoxemia in Black compared to White patients (11.7%-17.0% vs. 3.6%-6.2%).⁵

We are aware of the FDA guidance on this subject issued February 19, 2021,⁶ and we ask that the FDA directly engage the developers and manufacturers of FDA-regulated pulse oximeters to rectify this urgent situation in a timely manner. As noted in the FDA guidance, the agency has authority to regulate the pulse oximeters used in healthcare settings as medical devices. We urge you, through your agency's authority, to ensure that pulse oximeter manufacturers conduct the tests needed to ensure that the devices provide accurate and reliable readings for patients with diverse degrees of skin pigmentation.

We further note that pulse oximeters sold as consumer products are not medical devices and therefore are not subject to FDA oversight. As you know, many individuals have been directed to measure their oxygen saturation levels using consumer-grade pulse oximeters to gauge the severity of their COVID-19 symptoms as a guide for seeking medical help. We are concerned that the consumer-grade pulse oximeters may be giving inaccurate readings for patients with darker skin pigmentation—potentially underestimating the severity of their COVID-19 illness and thereby delaying essential medical intervention. This represents a clear racial health disparity that must be addressed.

We urge the FDA to use its considerable influence to encourage consumer-grade pulse oximeter manufacturers to also participate in the corrective efforts that the FDA seeks from medical device

manufacturers of pulse oximeters. Any response to the challenges with pulse oximeters that does not also include the consumer products would be incomplete.

Thank you for your consideration and your efforts to remove this barrier to high-quality equitable healthcare for all U.S. residents.

The Critical Care Societies Collaborative (CCSC) is a unique partnership comprising the four major professional and scientific societies whose members care for America's critically ill and injured patients. The CCSC leverages its collective and multiprofessional expertise through communication, education, research, and advocacy efforts. The CCSC speaks with a unified voice, representing nearly 200,000 critical care professionals to bring important issues to the forefront in public policy and the healthcare arena.

Sincerely,

Elizabeth Bridges

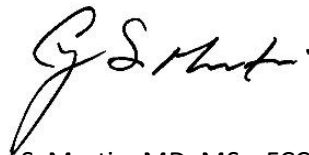
Elizabeth Bridges, PhD, RN, CCNS, FCCM, FAAN
President
American Association of Critical-Care Nurses



Juan C. Celedón, MD, DrPH, ATSF
President
American Thoracic Society



Steven Q. Simpson, MD, FCCP
President
American College of Chest Physicians



Greg S. Martin, MD, MSc, FCCM
President
Society of Critical Care Medicine

References:

1. Saunders NA, Powles AC, Rebuck AS. Ear oximetry: accuracy and practicability in the assessment of arterial oxygenation. *Am Rev Respir Dis*. 1976 Jun;113(6):745-749.
2. Ries AL, Farrow JT, Clausen JL. Accuracy of two ear oximeters at rest and during exercise in pulmonary patients. *Am Rev Respir Dis*. 1985 Sep;132(3):685-689.
3. Bickler PE, Feiner JR, Severinghaus JW. Effects of skin pigmentation on pulse oximeter accuracy at low saturation. *Anesthesiology*. 2005 Apr;102(4):715-719.
4. Feiner JR, Severinghaus JW, Bickler PE. Dark skin decreases the accuracy of pulse oximeters at low oxygen saturation: the effects of oximeter probe type and gender. *Anesth Analg*. 2007 Dec;105(6 Suppl):S18-S23.
5. Sjoding MW, Dickson RP, Iwashyna TJ, Gay SE, Valley TS. Racial bias in pulse oximetry measurement. *N Engl J Med*. 2020 Dec 17;383(25):2477-2478.
6. U.S. Food and Drug Administration. Pulse oximeter accuracy and limitations: FDA Safety Communication. Issued February 19, 2021. Accessed March 22, 2021. <https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication>



April 27, 2021

Elizabeth Bridges, PhD, RN, CCNS, FCCM, FAAN
President
American Association of Critical-Care Nurses
c/o Diana Hughes at dhughes@sccm.org

Dear Dr. Bridges and colleagues,

Thank you for your March 31, 2021 letter from the Critical Care Societies Collaborative regarding the accuracy of pulse oximetry in patients with darker skin color.

We agree that providers and consumers should be aware of the potential limitations of pulse oximetry. All premarket submissions for prescription use oximeters are carefully reviewed by the FDA for evidence of safety and effectiveness. In addition, we ensure that clinical study samples include representation of individuals with darker skin pigmentation, as recommended by the March, 2013 FDA guidance, [Pulse Oximeters - Premarket Notification Submissions \(510\(k\)s\): Guidance for Industry and Food and Drug Administration Staff](#). As we stated in our February 19, 2021 [Pulse Oximeter Accuracy and Limitations: FDA Safety Communication](#), we continue to review the published literature for factors affecting pulse oximeter accuracy and performance, especially research that focuses on oximeter accuracy in individuals with darker skin pigmentation.

The FDA is working with manufacturers and testing laboratories in additional postmarket data analysis to better understand how different factors, including skin pigmentation may affect pulse oximeter accuracy and assure that appropriate testing is performed. We are committed to the continued evaluation of the safety, effectiveness, and availability of medical devices, especially devices in high demand during the COVID-19 pandemic. We also are looking at consumer-grade pulse oximeters.

Based on new findings from published research or post-market data analysis, the FDA may reassess the content of the pulse oximetry guidance document. Should significant new information become available, we will inform healthcare providers and the public.

We very much appreciate the time and effort that you spent in communicating your concerns to us. We value stakeholder input and encourage you to maintain open communication with us as we move forward.

Sincerely,

Jeffrey E.
Shuren -S

Digitally signed by
Jeffrey E. Shuren -S
Date: 2021.04.27
14:44:50 -04'00'

Jeffrey Shuren, M.D., J.D.

Director

Center for Devices and Radiological Health