



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](mailto: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 Shuren, M.D., J.D.  
Director  
Center for Devices and Radiological Health