Presentation to the FDA and Anesthesiology and Respiratory Therapy Devices Panel

In advance of virtual public meeting:
February 2, 2024

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ATS 2024

Disclosure slide

- *I have NO financial disclosure or conflicts of interest with the presented material in this presentation*

Remove bias from pulse oximetry to:
Minimize doubt and address health-care disparities

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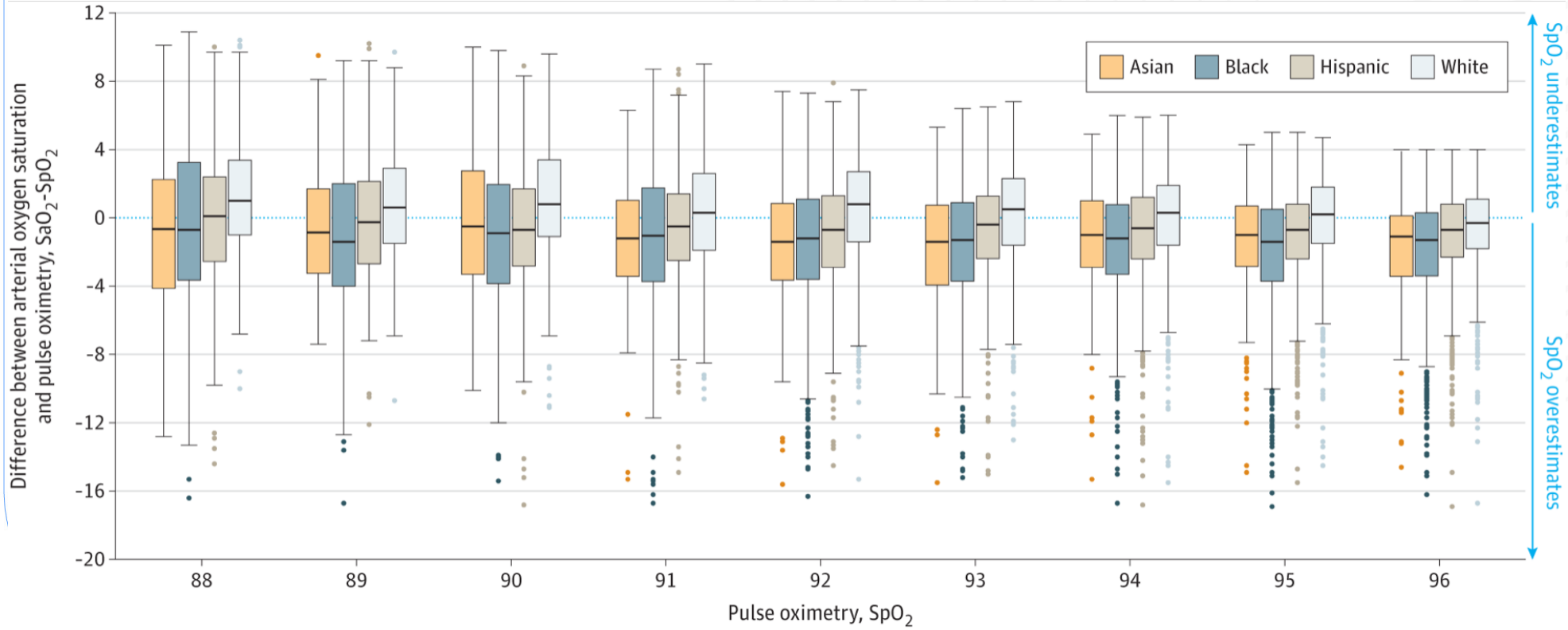
Transparent bias limits across the SpO2 range tested plus standards for precision



Fawzy et al.
JAMA Internal Medicine 2022

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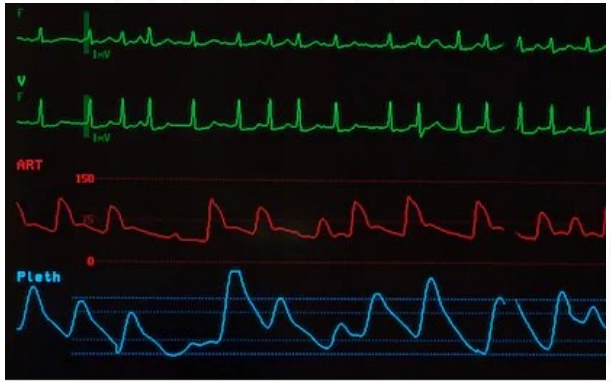
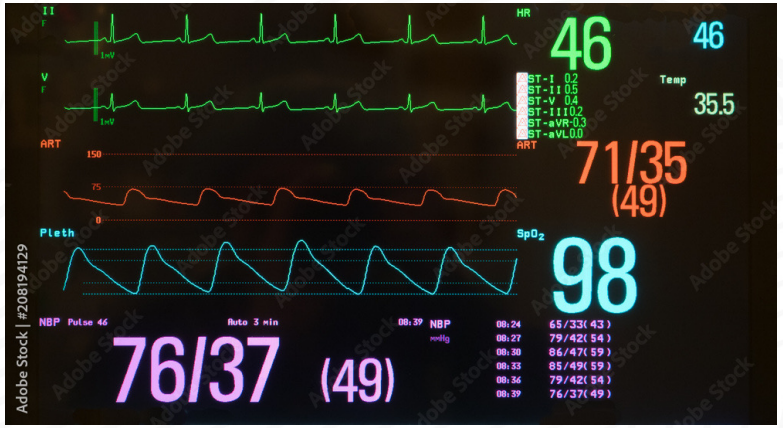
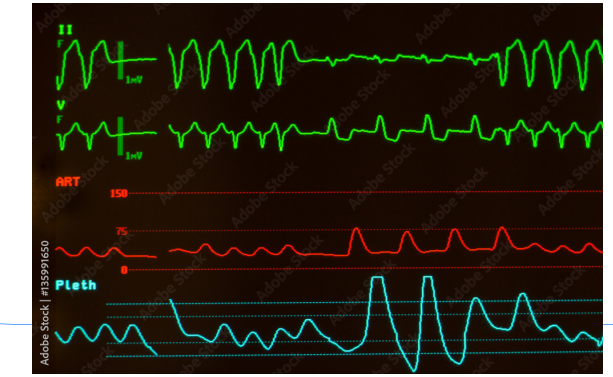
4. There is a need for ongoing post-marketing real-world studies.

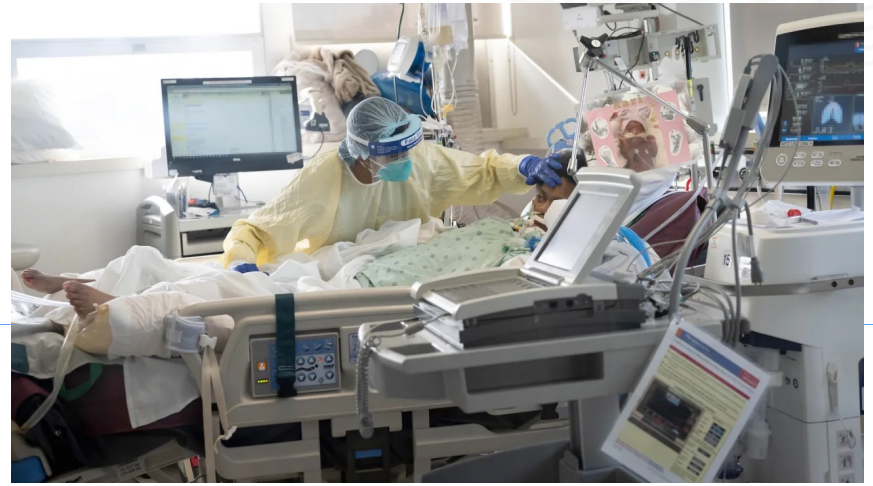
Importance of real-world data and feedback from the front-line





[MAUDE - Manufacturer and User Facility Device Experience]





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4. There is a need for ongoing post-marketing evaluation including real-world studies.
5. There is a need to regulate pulse oximeters sold directly to consumers.

Improve consumer-grade pulse oximeters


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Google image search “consumer pulse oximeters” 1/11/24

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