Medical Device Advisory

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POTENTIAL OXIMETER INACCURACY IN INDIVIDUALS WITH DARKER SKIN

The Health Sciences Authority (HSA) would like to inform users on the potential for oximeters to generate inaccurate blood oxygen saturation readings for dark-skinned individuals. There is a tendency for oximeters to display blood oxygen saturation readings higher than the actual values for these individuals.

Oximeters are usually placed on fingertips to estimate percentage blood oxygen saturation levels. They work by shining light and measuring the amount of light absorbed by blood to determine oxygen saturation. In individuals with darker skin, there is higher amount of skin pigment melanin, which can also absorb the light from oximeters, in addition to their blood. This increased light absorption could potentially cause the oximeters to display higher oxygen saturation levels than the actual values in these individuals, resulting in incorrect or delayed medical decisions or interventions.

Apart from skin pigmentation, accuracy of oximeters can also be affected by factors such as poor blood circulation, skin thickness, and the use of fingernail polish. To date, HSA has not received any local reports of medical device adverse events related to oximeter inaccuracy when used on dark-skinned individuals.

Recommendations for consumers

1. Follow your health care provider's recommendations on when to check oxygen levels.

2. Read the oximeter's user manual thoroughly to ensure the product is used in the correct manner. Understand the accuracy and limitations of the product when taking measurements and interpreting results.

3. Users are reminded not to rely only on oximeter readings to assess their health condition, but to pay attention to other signs or symptoms of low oxygen levels such as difficulty in breathing, bluish lips or nails, or chest pain. If there are concerns about the oximeter readings, or if symptoms persist or worsen, please contact a health care provider.

4. Consumers may report medical device related adverse events (AEs) to the Medical Devices Cluster, Health Products Regulation Group, HSA at Tel: 6866 1048, or report online using the e-form below.

The confirmation of the causality of the AE is not a prerequisite for reporting to HSA. As long as there is a suspicion that a medical device may be related to a serious AE, an AE report may be submitted.

5. HSA will continue to assess any new information pertaining to factors affecting oximeter accuracy and performance and will update the users on any significant safety information that arises.

Thank you.

Yours faithfully,

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