

Date: 19-02-2026

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المَهَيَّةُ الصَّادِمَةُ لِلْفَخَاءِ وَالدَّوَاءِ
Saudi Food & Drug Authority

Medical Devices Sector

National Center for Medical Devices Reporting

Safety Communication

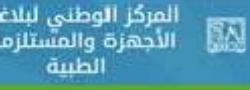
رسالة سلامة

To: Healthcare Providers	إلى: مُقدمي الرعاية الصحية
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Title	<i>Recommendations for Healthcare Providers regarding Pulse Oximeter Accuracy in Individuals with Darker Skin Pigmentation</i>	العنوان:
Medical Device Description	<i>Pulse Oximeter</i>	اسم ووصف الجهاز/المستلزم الطبي:
Manufacturer	<i>All</i>	اسم المصنع
Authorized Representative	<i>All</i>	الممثل المعتمد

Medical Devices Marketing Authorization (MDMA)	<i>All</i>	إذن التسويق
Potential /Associated risks	Based on the SFDA's post-market clinical evaluation study to analyze and evaluate the safety of the current local practices of Pulse Oximeter. The study revealed the below issues associated with using Pulse Oximeter on individuals with darker skin pigmentation: The accuracy of Pulse Oximeter can be affected by skin pigmentation and might overestimate oxygen saturation, particularly in individuals with darker skin pigmentation then it can lead to occult hypoxemia.	المخاطر المحتملة / المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	Recommendations for healthcare providers: <ul style="list-style-type: none">Recognize that pulse oximeters have limitations. Several factors can affect accuracy, including skin pigmentation, poor circulation, skin thickness, temperature, tobacco use, and the presence of nail polish.	النوصيات:

	<ul style="list-style-type: none">• Adequate training should be ensured before using pulse oximeters on patients to promote correct usage and interpretation of readings.• Be aware that pulse oximeters may be less accurate in individuals with darker skin pigmentation, potentially leading to overestimation of oxygen saturation.• When oxygen readings appear inconsistent with the patient's clinical status, arterial blood gas (ABG) testing or other confirmatory assessments should be performed.• All device-related issues or suspected inaccuracies should be promptly reported to the Saudi Food and Drug Authority (SFDA).	
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For Reporting	 SFDA 19999 مركز التحقيق في الأجهزة الطبية	 National Center for Medical Devices Reporting	 المركز الوطني للإبلاغ الأجهزة والمستلزمات الطبية	للإبلاغ
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