

Date: 14 October 2025
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Medical Devices Sector
National Center for Medical Devices Reporting

Safety Communication

رسالة سلامة

To: Healthcare Provider

إلى: مقدمي الرعاية الصحية

Title	Follow Instructions for Safe Use of Hyperbaric Oxygen Therapy Devices	العنوان:
Medical Device Description	Hyperbaric Oxygen Therapy(HBOT) Devices	اسم ووصف الجهاز الطبي:
Manufacturer	All	اسم المصنع

Medical Devices Marketing Authorization	All	إذن التسويق
Potential /Associated risks	Fires that occurred with HBOT devices that resulted in serious injuries and deaths.	المخاطر المحتملة المرتبطة بالجهاز
Recommendations	<ul style="list-style-type: none"> • Make sure the HBOT device is registered and have MDMA. • Review and follow the manufacturer's instructions for use for each hyperbaric oxygen therapy (HBOT) device being used. • Ensure fire prevention and safety measures are followed for HBOT devices. • Be aware that there is a heightened risk of fire with use of oxygen at a high concentration. • Ensure proper grounding equipment is used. • Ensure proper training is provided for staff with use of HBOT devices. • Ensure the patient is properly monitored and supervised for the duration of the treatment with use of HBOT devices. • Ensure that manufacturer recommended cleaning procedures, maintenance intervals, and safety checks are followed for each HBOT device being used. • Ensure patients wear clothing that is made of hyperbaric compatible materials according to the manufacturer's instructions, such as cotton. 	التوصيات

For Reporting	 	للابلاغ
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