

Date: 25 July 2023

Reference Number: SG-2307-408-H

قطاع الأجهزة والمستلزمات الطبية  
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector  
National Center for Medical Devices Reporting

رسالة سلامة  
Safety Communication

To: Healthcare Provider		إلى: مقدمي الرعاية الصحية
<b>Title</b>	Recommendations for Healthcare Providers regarding the safe use of ventilator devices	العنوان
<b>Medical Device Description</b>	Ventilator Devices	اسم ووصف الجهاز/المستلزم الطبي
<b>Manufacturer</b>	All	اسم المصنع
<b>Authorized Representative</b>	All	الممثل المعتمد
<b>Medical Devices Marketing Authorization (MDMA)</b>	All	إذن التسويق
<b>Potential /Associated risks</b>	<p>In accordance with the SFDA's post-market clinical evaluation study about safety concerns of VAP (Ventilator-associated pneumonia) which is an infection of patients during their hospitalization with a ventilator in the Intensive care unit (ICU) at Saudi healthcare providers.</p> <p>The study findings show an association between Ventilator use and lung infection (Pneumonia). During 2022 there have been accumulations of VAP complaints among Saudi healthcare providers.</p>	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
<b>Recommendations</b>	<p>In order to reduce or eliminate the appearance of VAP, here are some recommendations for healthcare providers:</p> <ol style="list-style-type: none"> <li>1. Apply ventilator bundle strategies before the use of ventilator devices.</li> <li>2. Ensure following the manufacturer's guidelines for cleaning and maintaining the ventilator.</li> <li>3. Follow infection control principles.</li> <li>4. Follow hand hygiene between patients.</li> <li>5. Utilize high-flow therapy or noninvasive ventilation.</li> <li>6. Healthcare providers users must be specialized, trained, and qualified to use ventilator devices.</li> <li>7. Ensure to report any complains/ adverse events related to VAP to SFDA through reporting channels.</li> </ol>	التوصيات
<b>For Reporting</b>	  	لإبلاغ