


**Safety Communication**

**رسالة سلامة**

**Overheat/burn cause damages due to possible End-user misuse**

<b>Device/ Product Description:</b>	O2FLO High Flow Heated Respiratory Humidifier
<b>Brand:</b>	VUN-001
<b>Affected Lot Number:</b>	201709, 202002, 202207, 203802
<b>Manufacturer:</b>	Vincent Medical Manufacturing Co., Ltd
<b>Problem:</b>	Reports of Devices had overheated and presented burn damages while in use in hospital.
<b>Recommendation /Actions:</b>	<ul style="list-style-type: none"><li>• Make sure that this document, with accompanying FSNs, are reached to the end-users.</li><li>• <b>Stop using the device to avoid any associated risk with such incident</b></li><li>• Follow the advice on action from the manufacturer:<ol style="list-style-type: none"><li>1. all the machines in the field will be replaced in KSA market.</li><li>2. Contact the authorized representative for replacement of commissioned O2FLO units from affected LOT numbers</li><li>3. If a replacement machine is not available immediately and you do have to use the machine, please ensure trained personnel is operating O2FLO and is following the instructions and accordance to the IFU and operation manual:<ol style="list-style-type: none"><li>a) Always use auto feed with sterile or filter water to fill the chamber</li><li>b) Always switch off oxygen supply when not in use</li><li>c) Only add oxygen supply after machine is switched on and the desired flow rate has been achieved. always add oxygen supply gradually</li><li>d) Never reuse the chamber, breathing circuits and nasal prongs and only to be used for the duration as indicated in the IFU.</li></ol></li></ol></li></ul> <p>For more information, Please click <a href="#">here</a>.</p>

	<p>If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through:  <a href="#">NCMDR</a>  <a href="#">Vigilance system</a>  19999 unified call center</p>	
<b>Devices/Products photo:</b>		
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