

Vincent Medical (Dong Guan) Mfg. Co., Ltd.

东莞永胜医疗制品有限公司

Urgent Field Safety Notice 紧急市场安全通知

Commercial name of the affected product,

受影响产品的商品名

O2FLO High Flow Heated Respiratory Humidifier

FSCA-identifier (e.g. date): FSCA-202012-01

FSCA-识别(如: 日期)

Type of action (e.g. chapter 4 definition of a FSCA).

措施的种类(如第四章定义的FSCA)

Device modification 设备改善.

1. Replacement for the O2FLO device on the KSA market.

Date: 2020-12-09

日期:

Attention: KSA Distributor for O2FLO High Flow Heated Respiratory Humidifier

注意:

Details on affected devices:

受影响器械的细节:

Device name: O2FLO High Flow Heated Respiratory Humidifier

Device model: VUN-001

Lot number:

Lot number	Qty (pcs)
201709	1000
202002	500
202207	34
203802	36

Description of the problem:

问题描述:

On 1st Oct, 2020, we received an incident report on an adverse event involving two O2FLO units of model VUN-001, distributed in the Indian market. Up to 2020-12-9, it has been reported that the sixteen devices had overheated and presented burn damages while in use in a hospital. Total percentage of reported incidents is 0.12% based on units in the field.

Advise on action to be taken by the user:

建议使用者采取的措施:

Corrective action:

1. All machines in the field will be replaced in KSA market
2. Contact your local distributor for replacement of commissioned O2FLO units from the affected LOT numbers listed in the section "Details on affected device"

3. If a replacement machine is not available immediately and you do have to use the machine, please ensure trained personnel is operating the O2FLO and is following the instructions in accordance to the IFU and operation manual
- a) Always use auto feed with sterile or filter water to fill the chamber
 - b) Always switch off oxygen supply when not in use
 - c) Only add oxygen supply after machine is switched on and the desired flow rate has been achieved. Always add oxygen supply gradually
 - d) Never reuse the chamber, breathing circuits and nasal prongs and only to be used for the duration as indicated in the IFU

Contact reference person: Amanda Hu

查询联系人:

Name / organization, address, contact details.: amandahu@vincentmedical.com

姓名/组织、地址、联系方式细节

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

签名即表明已就该通知告知适当的法规机构

(Closing paragraph) (关闭段)

Signature

签名

Issued by 发布人:



Approved by 审批人:

