Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 100 **dated** 19/5/2025 **Regarding SFDA Field Safety Notice of ParaPAC plus™ Model 300 and Model 310 Ventilator from (mfr: Smiths Medical International Limited).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Sultanate of Oman
Ministry of Health
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سلطنة عُمان
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مسقط

Circular No. 100 **/ 2025**

21 -11-1446 H
19 -05-2025

FSN of ParaPAC plus™ Model 300 and Model 310 Ventilator from Smiths Medical International Limited.

Source	SFDA- Saudi Food & Drug Authority https://ade.sfda.gov.sa/Fsca/PublishDetails/361
Product	ParaPAC plus™ Model 300 and Model 310 Ventilator.
Manufacturer	Smiths Medical International Limited.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	ParaPAC plusTM plus kit without internal PEEP & CPAP List Number: P300NXX ParaPAC plusTM kit with internal PEEP & CPAP List Number: P310NXX.
Reason	When a paraPAC plus™ventilator is switched to the operating mode of 'Ventilate', paraPAC plus™ ventilators may intermittently provide continuous positive gas flow instead of the intended cycling like a human breath. This non-cycling and continuous positive gas flow when in the cycling mode, is a malfunction, not allowing the ventilator to properly function as designed.
Action	1. Refer to the "Action to be taken by the user/customer" in the attachment. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Ph. Ibrahim Nasser Al Rashdi
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

smiths medical

6000 Nathan Lane N.
Minneapolis, MN 55442
https://www.icumed.com

URGENT: FIELD SAFETY NOTICE

ParaPAC plus™ Model 300 and Model 310 Ventilator

21st February 2024

Dear Valued Customers:

Smiths Medical is issuing this letter to notify you of a potential issue with the paraPAC plus™ Ventilators. The following information details the issue and the required steps for you to perform.

Issue:
When a paraPAC plus™ ventilator is switched to the operating mode of 'Ventilate', paraPAC plus™ ventilators may intermittently provide continuous positive gas flow instead of the intended cycling like a human breath. This non-cycling and continuous positive gas flow when in the cycling mode, is a malfunction, not allowing the ventilator to properly function as designed.

Potential Risk:
If the ventilator experiences the continuous positive gas flow instead of intended cycling like a human breath, it may result in delay of therapy, no ventilation, excessive tidal volume or excessive pressure. If the device does not allow for adequate expiration of the respiratory cycle, this may lead to hypoxia. These situations may potentially lead to serious patient injury or death, depending on the clinical situation.

To date, Smiths Medical has received eight (8) reports of serious injury, and zero (0) death potentially related to this issue since the launch of this product in 2010.

Affected Models:
This issue impacts all paraPAC plus™ ventilators, refer to Table 1.

Table 1: Affected Products(s)

Product Name	List Number
paraPAC plus™ plus kit without internal PEEP & CPAP	P300NXX*
paraPAC plus™ kit with internal PEEP & CPAP	P310NXX*

* List Numbers are specific to the country level.

Actions to be taken by the User/Customer:

There is no need to return or discontinue using your paraPAC plus™, at this time.
When using the device, all instructions, including warnings and cautions in the User Manual must be followed with heightened awareness. This is inclusive, but not limited to the following:

- Constant monitoring of the patient
- Blood oxygenation and expired carbon dioxide levels should be monitored independently using pulse oximetry and capnography.
- All pre-use checks must be performed before each use.
- Alternative means of ventilation such as bag mask ventilation, must be available in the event of ventilator failure or malfunction.

If the paraPac plus™ ventilator experiences continuous flow, remove the ventilator from clinical use, set the device aside for repair and use another device or alternative means of ventilation Report the continuous flow experience by filing a complaint, per instructions below.

Smiths Medical's Actions:
Smiths Medical is sending this notification to all impacted paraPAC plus™ customers.

Customer Required Actions:

1. Please identify all paraPAC plus™ units in your possession.

2. Share this FSN notification with all potential users of the devices to ensure they are aware of this issue and proposed mitigations. If the devices are used at another location, please ensure that this communication is delivered to these locations.

3. Complete and return the attached Customer Response Form to EMEA-FSN@icumed.com **within ten days of receipt** to acknowledge your understanding of this notification.

4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to **YOU**. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com

Follow-up Actions by Smiths Medical:
Smiths Medical is currently investigating the issue and will provide an update once a solution has been identified.

6000 Nathan Lane N.
Minneapolis, MN 55442
https://www.icumed.com

For further inquiries, please contact Smiths Medical using the following information:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Care	https://www.icumed.com/contact-us/regional-support	Additional information or assistance

Your country regulatory agency has been notified of this action.

Smiths Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Andy Mathein
Vice President of Quality

See below:

- Response Form

smiths medical

6000 Nathan Lane N.
Minneapolis, MN 55442
https://www.icumed.com

URGENT FIELD SAFETY NOTICE: RESPONSE FORM

ParaPAC plus™ Model 300 and Model 310 Ventilator

21st February 2024

Check your inventory and complete the information below, even if you do not have the affected product.

Complete this form and return it by email to *EMEA-FSN@icumed.com*. If you have questions about this form please contact EMEA-FSN@icumed.com or your local sales representative

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

☐ **YES**, I have affected product, I have notified users in my facility and I have followed the instructions provided to me (complete and return this form to EMEA-FSN@icumed.com).

☐ I have **NO** affected product (complete and return this form to EMEA-FSN@icumed.com)

☐ Devices transferred/no longer owned; please indicate new owner contact information:

- Business Name: _____
- Address/City/State/ZIP: _____
- Contact Name: _____
- Contact Phone/E-mail Address: _____

- Have you distributed the product further to the retail level? **YES** ☐ **NO** ☐
  - If yes, have you notified your retail customers?

    YES ☐ **NO** ☐ (if no, explain below)

    _____

If you have distributed the product further, please provide the list of your retail customers, inclusive of customer name, address, city, state, zip code, telephone number and quantity of product distributed along with your completed response form to the contact information listed above **so Smiths Medical can verify effectiveness of the FSN notification to the appropriate level.**

Adverse events and complaints associated with the use of this product should be reported and emailed to Smiths Medical's Global Complaint Management Department at globalcomplaints@icumed.com.