URGENT MEDICAL DEVICE CORRECTION

paraPAC plus™ Model 300 and Model 310 Ventilator

05 February 2024

Dear Valued Customers:
Director of Nursing
Director of Material Management
Director of Risk Management

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 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 Doc. numbers (10018833-003 and/or 10026347-002) 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.

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
Technical Support	TSC.Support@icumed.com	Additional information or technical assistance, including Technical Service Manuals
Field Corrections	AsiaServiceQuality@icumed.com	Questions about this Field Correction Notice

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 recall notification with all potential users of the devices to ensure they are aware of this recall 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 AsiaServiceQuality@icumed.com **within ten days of receipt** to acknowledge your understanding of this notification.

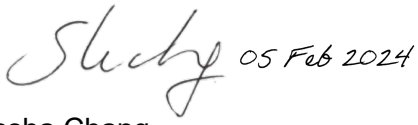
4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to AsiaServiceQuality@icumed.com.

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

General Information
This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

Smiths Medical is committed to providing quality products and service to our customers. We apologize for any inconvenience this situation may cause.

Sincerely,



Sasha Chang
Quality Manager, Hong Kong, Taiwan and Asia Service

Enclosures:
Attachment 1 - Customer Response Form
Attachment 2 - Frequently Asked Questions