

REACTHEALTH
5475 Rings Road
Suite 550
Dublin OH 43017



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PEDIATRIC HOME RESPIRATORY SERVICE, LLC DBA PEDIATRIC HOME SERVICE LLC
2800 CLEVELAND AVE N.
ROSEVILLE MN 55113-1126



Date: September 17, 2026

URGENT: Medical Device Recall**Potential VOCSN Reboot****Affected Product: All VOCSN Devices and Configurations****This document contains important information for the continued safe and effective use of your equipment.**

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Pediatric Home Respiratory Service, LLC DBA Pediatric Home Service LLC
2800 Cleveland Ave N.
Roseville MN 55113

Dear Valued Partner,

Ventec Life Systems Inc. (dba React Health) is voluntarily conducting a recall to inform customers of instances in the VOCSN device family where the device reboots and exhibits recurring System Fault 10 alarms when starting the device, due to a cable within the device becoming partially or fully unseated. Please refer to the "Details on Affected Devices" section of this letter for the specific model numbers affected by this recall.

React Health has identified 213 complaints regarding system reboots (with alarm). All the subject events were identified during servicing or otherwise occurred while the device was not actively providing ventilation therapy to a patient. No adverse events have been reported or identified for this issue during patient therapy. React Health has not received any reports of injury or death associated with this issue.

Patients should not discontinue therapy unless instructed to do so by their treating clinician and an appropriate alternative means of ventilation is available.

No devices are required to be returned to React Health as part of this notification.

Please ensure that you read this notification immediately, and in its entirety.

Indications for Use:

VOCSN Product Family: VOCSN Unified Respiratory System is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. It may be used in invasive and non-invasive applications. VOCSN is intended for pediatric through adult patients weighing at least 5 kg. It is intended for use in home, hospital, institutional, and transport settings, including portable applications.

Details on Affected Devices:

All manufactured VOCSN devices and configurations are affected by this notification starting at SN: 112786. Serial Numbers are available by request.



Device Name	Model Number	Packaged Part Number	UDI-DI
VOCSN+Pro	PRT-00490-001	PRT-00853-000	00855573007792 00855573007006
VOCSN+Pro (Japan)	PRT-00490-100	PRT-00853-100	00855573007761 00855573007204
VC+Pro	PRT-00900-001	PRT-00973-000	00855573007785 00855573007433
VC+Pro (Japan)	PRT-00900-100	PRT-00973-100	00855573007211
VOCSN	PRT-01100-000	PRT-01126-000	00855573007747
VOCSN (Japan)	PRT-01100-100	PRT-01126-100	00850018761130
VCSN+Pro	PRT-01184-000	PRT-01172-000	00855573007860
V+Pro	PRT-01185-000	PRT-01198-000 PRT-01198-010	00855573007877
V+Pro	PRT-01185-001 PRT-01185-002	N/A	00850018761161 00850018761154
V+Pro Emergency	PRT-01201-000	PRT-01173-000 PRT-01222-000	00855573007945
VC	PRT-01098-000	PRT-01125-000 PRT-01125-010	00855573007730
VC (Japan)	PRT-01098-100	PRT-01125-100	00850018761116
V*Home	PRT-01444-000	PRT-01445-000 PRT-01445-010	00855573007822

The affected internal flow transducer cable is used across all device models identified above, regardless of the enabled therapy configuration.

Description of the Issue and under what circumstances it can occur:

React Health provides this notice for all VOCSN device configurations. The internal flow transducer (IFT) cable connector may become partially or fully unseated and result in loss of communication with the internal flow transducer board. This condition can lead to device reboots and recurring System Fault 10 alarms.

No instances of reboots occurring while a patient was receiving ventilation therapy have been reported.

NOTE: Additional investigation indicates that the IFT cable connector may become partially or fully unseated during substantial impacts to the device (e.g., dropping the device), which may exceed the impact limits specified by the IFU and applicable consensus standards. If the device is dropped or experiences an impact, perform the Checkout Procedure in the VOCSN Series Ventilator Portfolio Clinical & Technical Manual, LBL-00001 prior to patient use and to ensure device performance.

NOTE: Ensure that the ventilator is secure during use. Place ventilator on a flat, stable surface or secure it using the VOCSN roll stand or carry bag. Keeping the ventilator secure helps prevent accidental drops or impacts that could affect device operation.

If the subject condition is present the device provides observable indications such as System Fault 10, backup alarms, and reboot behavior are easily identifiable to the user.

Potential Risk:

If an IFT-related reboot were to occur while a patient receives ventilation therapy, the device will alarm (e.g., System Fault 10) and delivery of ventilation from the affected VOCSN device will be interrupted. Appropriate



alternative means of ventilation is recommended to maintain therapy should an event occur. A therapy interruption could result in delay of therapy and/or a serious adverse event (depending on the patient's condition). Patients who are unable to sustain adequate spontaneous ventilation are particularly vulnerable; any interruption in therapy without the prompt initiation of alternative ventilatory support significantly increases the risk of serious injury, permanent impairment, or death, and may require immediate medical intervention to prevent irreversible harm.

React Health has not received reports of any adverse event or patient death. No reports have occurred during patient use associated with the subject reboot events, and no confirmed instances of reboot have been identified while the device was actively providing ventilation therapy to a patient. Based on the available complaint and investigation data, the probability of an IFT-related reboot occurring while the device is actively providing ventilation therapy is considered remote.

Important Care and Monitoring Information:

React Health would like to reinforce the importance of following the VOCSN Series Ventilator Portfolio Clinical & Technical Manual, LBL-00001, including recommendations relating to monitoring, emergency preparedness, caregiver training, and availability of backup ventilation equipment whenever the ventilator is being used.

LBL-00001 Warning: If critical to patient care, always have alternative means of ventilation, oxygen, nebulization, and secretion management available. In case of unexpected VOCSN operation, failure to have alternative means of therapy available may result in patient harm or death.

It is important to ensure that caregivers are appropriately trained, that their training is up to date, and that they are confident in responding to alarms and emergency situations.

Ensure that alternative ventilation equipment is not only available but is functional, regularly checked, and ready for immediate use if required.

Action to be Taken by Healthcare Providers and Distributors:

Note: Healthcare Providers, Distributors, and/or DMEs are responsible for promptly notifying all affected patients and/or caregivers under their care and communicating the applicable Patient/ Caregiver information and Clinical Actions provided in this notice.

React Health requests that customers ensure the clinical action steps below and per the IFU directions. No devices are required to be returned to React Health with this notice.

Clinical Actions for Healthcare Providers, Distributors, and/or DMEs:

1. If your device exhibits the above issue (recurring reboots/ System Fault 10 alarms), utilize back-up ventilation as needed, and contact React Health for device servicing.
2. Reinforce that patients should continue therapy unless otherwise directed by their treating clinician.
3. Ensure that an appropriate, alternative means of ventilation is readily available for all patients.
4. Ensure that the ventilator is secured prior to use and during patient use. Ventilator should be placed on a flat, stable surface or secured using the VOCSN roll stand or carry bag. Keeping the ventilator secure helps prevent accidental drops or impacts that could affect device operation.
5. If the device is dropped or experiences an impact, perform the Checkout Procedure in the VOCSN Series Ventilator Portfolio Clinical & Technical Manual, LBL-00001, prior to patient use to confirm device performance.



6. As indicated in the VOCSN Series Ventilator Portfolio Clinical & Technical Manual, LBL-00001 instructions, always use packaging approved by Ventec Life Systems when shipping devices.
7. Reinforce adherence to the VOCSN Series Ventilator Portfolio Clinical & Technical Manual, LBL-00001 instructions, including ensuring that ventilator-dependent patients are appropriately monitored, care providers are trained and confident in responding to ventilator alarms and emergency situations, and appropriate alternative ventilation equipment is functional, regularly checked, and immediately available where required.

Actions for Patients/Caregivers:

1. Do not stop patient therapy and continue to use the device unless directed by their clinician.
2. If your device exhibits the above issue (recurring reboots/ System Fault 10 alarms), utilize back-up ventilation as needed, and contact your care provider (e.g., Healthcare Providers, Distributors, and/or DMEs).
3. Ensure an appropriate, alternative means of ventilation is readily available for all patients.
4. Ensure that the ventilator is secure during use. Place ventilator on a flat, stable surface or secure it using the VOCSN roll stand or carry bag. Keeping the ventilator secure helps prevent accidental drops or impacts that could affect device operation.
5. If the device is dropped or experiences an impact, contact your care provider prior to reinitiating therapy.
6. Follow existing VOCSN instructions for monitoring and responding to ventilator alarms and emergency situations.
7. Ensure patients and/ or caregivers are trained and confident in responding to ventilator alarms and emergency situations, and appropriate alternative ventilation equipment is functional, regularly checked, and immediately available where required.

Acknowledge Receipt (Healthcare Providers, Distributors, and/or DMEs):

1. Confirm receipt of this notification letter by returning the enclosed Customer Response Form to React Health via email, mail or utilizing the online customer response form within 7 days.
2. If you have distributed or transferred affected devices to other facilities, caregivers, or end users, you must promptly notify them and provide a copy of this notification.

Actions Taken by React Health:

React Health has initiated an investigation and is taking actions to prevent recurrence.

- React Health will support inspection and servicing activities for affected ventilators that meet the criteria outlined in this letter.
- Continue to monitor post-market data and evaluate additional corrective action pathways.
- Provide further communications and updated instructions to customers regarding any additional actions that may be required, as they become available.

If you are no longer the owner of any of these devices, or if a device(s) is no longer in service, please complete an ownership transfer form at [VentecLife.com/tracking](https://www.venteclife.com/tracking) so React Health can follow up with the current owner of the impacted device(s). If you have any questions, please contact React Health at 844-698-6276.

React Health requests your prompt attention to this matter and apologizes for any inconvenience this may cause. We are committed to partnering with you to minimize the effort required to respond to this notice. Patient safety is our number one priority, and there is no impact on React Health's ongoing ability to supply ventilator products with this notice.



22002 26th Ave SE
Bothell, WA 98021
844.698.6276
VentecLife.com



We appreciate your continued trust in us to provide quality respiratory products and are dedicated to supporting you and your patient needs. For any questions, please contact React Health directly at 844-698-6276, Monday through Friday between 8:00 a.m. - 5:00 p.m. Pacific Time (PT) / 11:00 a.m. – 8:00 p.m. Eastern Time (ET).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

To submit your report:

- The voluntary Form FDA 3500 online
- Call 1-800-FDA-1088 to report by telephone

Download the form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178 (Send only page 1 plus any continuation pages – do not send instruction pages).

Regards,

Atul Sinha

Executive Vice President, Quality and Reg Affairs, React Health

Enclosure: Customer Recall Notification Response Form



Urgent Medical Device Recall Response Form:

Potential VOCSN Reboot

All VOCSN Devices and Configurations

RESPONSE IS REQUIRED

Pediatric Home Respiratory Service, LLC DBA Pediatric Home Service LLC
2800 Cleveland Ave N.
Roseville MN 55113

Online Customer Response Form: <https://fs29.formsite.com/M6gPle/MKT-00156/index>



Affected Devices/ Models:

Device Name	Model Number	Packaged Part Number	UDI-DI
VOCSN+Pro	PRT-00490-001	PRT-00853-000	00855573007792 00855573007006
VOCSN+Pro (Japan)	PRT-00490-100	PRT-00853-100	00855573007761 00855573007204
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VC+Pro (Japan)	PRT-00900-100	PRT-00973-100	00855573007211
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VC	PRT-01098-000	PRT-01125-000 PRT-01125-010	00855573007730
VC (Japan)	PRT-01098-100	PRT-01125-100	00850018761116
V*Home	PRT-01444-000	PRT-01445-000 PRT-01445-010	00855573007822

If Applicable: RMA # (Assigned by React Health): _____

Adverse Event / Product Issue Reporting:

Have you identified any adverse events, device malfunctions, or patient safety concerns associated with the affected devices?

☐ No, we have not identified any adverse events or device malfunctions.



22002 26th Ave SE
Bothell, WA 98021
844.698.6276
VentecLife.com



☐ Yes, an adverse event or malfunction has been identified.

If yes, please provide details below:

Device Serial Number: _____

Description of Issue: _____

Date Issue Identified: _____

Organization Branch/ Alternate Location Distribution:

If affected devices were distributed to other branches or locations within your organization, please provide this notice to those locations, and confirm completion in your acknowledgment.

Please acknowledge receipt of this information by checking below:

- ☐ I have read the information within the accompanying **React Health - URGENT: Medical Device Recall Notification Letter**.
- ☐ I am authorized to acknowledge this notice on behalf of the organization.
- ☐ I confirm that this notice has been distributed to all applicable branches and locations. All relevant personnel and all branches/locations that manage any affected devices have been informed of the notice contents, any necessary actions have been taken, and records retained as part of our documentation procedure(s).
- ☐ We do not have the product(s) listed. The products have been removed from service or further distributed:
- ☐ No longer in service SNs: _____
 - ☐ Distributed to: _____

Name: _____

Phone Number: _____

Title: _____

Company Name: _____

Signature: _____

Please return by mail to:

Attention: Recall Coordinator
Ventec Life Systems, Inc. dba React Health
22002 26th Ave SE, Bothell, WA 98021

Or return by email to:

Ventec-Recall@reacthealth.com

Or respond online:

<https://fs29.formsite.com/M6gPle/MKT-00156/index>



For questions, please call:

844.698.6276