

<b>Manufacturer name:</b>	Phillips Respironics
<b>About the Recall:</b>	<p>All devices are required to have a mandatory Software update to version 1.05.10.00:</p> <ol style="list-style-type: none"> <li>1. Accuracy of Oxygen Delivery (2022-CC-SRC-049)</li> <li>2. Environmental Contamination of device sensor (2023-CC-SRC-003)</li> <li>3. Battery Deletion of loss of Power Alarms Triggered (2024-CC-SRC-001)</li> <li>4. Incomplete Contraindications Statement (2023-CC-SRC-001)</li> <li>5. Translation errors in the Korean, Traditional Chinese, and Spanish Instructions for Use (IFU) manuals (2023-CC-SRC-006)</li> <li>6. Flow Sensor Reading Compensation</li> <li>7. Software Alarm Errors</li> <li>8. Labeling-Related Issues-Ozone-Based Disinfection Method</li> </ol> <p><b>Hazard/harm associated with this issue:</b></p> <p>Barotrauma, Hypoventilation/hypercapnia and rebreathing of excessive CO<sub>2</sub>, Hypoventilation/Hypercapnia (AVAPS used invasively)</p> <p>Non-Safety impacted fixes:</p> <ol style="list-style-type: none"> <li>1. Update to HIP/LIP-HEP/LEP technical alarm</li> <li>2. Added priority Vent Service Required Alarm detecting contamination on flow sensor</li> <li>3. Update to address E110 Vent INOP triggered by motor stalls</li> </ol>

	<ol style="list-style-type: none"> <li>4. Update to spontaneous breath percentage calculation</li> <li>5. Updates to floating points calculations</li> <li>6. Updates to translation strings to avoid confusion for customers</li> <li>7. Update to address used interfaces issues</li> <li>8. Adjustment of maximum alarm volume setting to meet standard requirements</li> <li>9. Additional fixes to address software errors, as well as data corruption and transfer of data with Care Orchestrator and Care Orchestrator Essence</li> </ol>
<p><b>Products(s) numbers/models that are affected:</b></p>	<p>Trilogy EVO, Trilogy EVO 02, and Trilogy EV300 ventilators</p>
<p><b>URL Link(s) to Manufacturer Notice/Web Site:</b></p>	<p><a href="http://www.healthcare.philips.com">www.healthcare.philips.com</a> 1-800-345-6443</p>
<p><b>Actions to be taken by customer/Patient:</b></p>	<p>If you have any questions regarding this Urgent Medical Device Recall notice, please contact your home care provider or contact Philips Respironics directly.</p>