Table 8: Appendix 1. Ventilator-Related Adverse Event Taxonomy

Ventilator Category	Subcategory 1	Subcategory 2	Definition	Example
1. Human Factors Issues				
	a. User unable to interpret or adequately respond to alarm/ error code (s)		Issue associated with the use of the device in terms of the user experiencing difficulty in interpreting or responding appropriately to an alarm/ error code (s).	The inspiratory limb of the circuit became disconnected from the humidifier canister. Nurse notified the respiratory therapist, who reconnected the circuit.
	b. Incorrect clinical settings		Issue associated with the use of the device in terms of inappropriate settings (mode, tidal volume, respiratory rate, F_{IO2} and PEEP).	The ventilator settings were not set correctly by the user while running in APRV (airway pressure release ventilation) mode. The patient was connected for 30 hours while settings (Thigh and Tlow) were incorrectly set.
	c. Incorrect alarm settings		Issue associated with the use of the device in terms of inappropriate alarm settings.	While in use with an adult patient, the respiratory therapist discovered that the apnea alarm on the ventilator was incorrectly set at 50 seconds, which was changed to 20 seconds.
	d. Incorrect circuit set up		Issue associated with the use of the device characterized by incorrect assembly of the ventilator circuit.	The nurse was to connect the inspiratory limb of the circuit to the humidifier; however, the expiratory limb of the circuit was connected.
	e. User Interface Concerns		Issue associated with the means by which the operator and the equipment communicate or interact.	The nurse was unable to locate the 100% suction button while suctioning a patient.
	f. Inadequate instructions for use		Issue associated with the accuracy and appropriateness of any written, printed, graphic or audio/visual matter that is supplied with a medical device or its containers, wrappers; with any matter	The respiratory therapist stated that the sequence of steps required to activate the automatic tube compensation option is not clear and incomplete.

			that accompanies a medical device including instructions related to identification, technical description and use of the medical device provided by the device manufacturer.	
	g. Inadequate training		Issue associated with facility not providing satisfactory initial and/or periodic user training covering operation of the device.	Clinician chose the wrong flow sensor to use with a ventilator. As a result, reeducation was conducted with the staff on flow sensor selection and indications for use.
	h. Protocols (manufacturer/organization) not appropriately and/ or adequately followed		Issue associated with the use of the device in terms of nonconforming to that device's intended use, specifications, procedure and process or service instructions and information provided by the device manufacturers. Also includes issues related to staff failure to follow organization's policy and procedures for use.	Patient attached to the ventilator before start up procedure is completed. Startup procedure must be completed prior to attaching the patient to the ventilator.
	i. Backup system unavailable or inadequate		Issue associated with a device system not being available and/ or inability to operate as intended to replace the primary device.	Ventilator stopped working while in use on a patient in the home environment. Back up ventilator was unavailable.
2. Alarm Issues				
	a. Audible Alarm		Issue associated with the inadequate or inappropriate generation of an audible alarm.	Nurse reported that the ventilator screen went blank and did not audibly alarm when it failed.
	b. Visual Alarm		Issue associated with the inadequate or inappropriate generation of a visual alarm.	Customer reported that while on internal battery the unit shut down. A low power alarm warning did enunciate but there was no visual alarm for error.
	c. Audible and Visual Alarm		Issue associated with the inability of a device to generate an audible and visual alarm signal.	While connected to a patient the device shut down and started back up again. The device did not alarm.

	d. Alarm Enunciation		Failed connection and/or notification of ventilator alarm to a secondary enunciation system (e.g., nurse call system, patient monitor, or secondary alert system).	A disconnection occurred in the breathing circuit. The ventilator alarm was not heard because the line which activates the ventilator alarm externally to the room was not hooked up.
3. Power Source Issues				
	a. Electrical power failure/ surges (external to device)		A short or long-term loss of or disturbance in electrical power to an area which supplies power to a ventilator.	During electrical outage, the ventilator shut down briefly.
	b. Device electrical failures		A short or long-term loss of or disturbance in electrical power due to a malfunction in the ventilator evidenced by sparks, smoke or flames from ventilator.	The ventilator was operating and suddenly turned off. Smoke was noted coming from the ventilator.
	c. Failure to power-up		Issue associated with the inability of a device to turn on as intended.	The customer reported that the unit would not power on when activating the power on key.
	d. Device battery power issue	**i.** Failure to run on battery power	Issue associated with the inability of a device to operate from battery power source.	AC power went out and battery did not take over.
		ii. Premature discharge of battery	Issue associated with an early discharge of a battery.	Battery indicator on ventilator indicates a fully charged battery. Within several minutes of use the device alarmed “low battery” and the device shut down.
		iii. Battery issue could not be determined	Issue associated with difficulties in identifying events related to a battery. Insufficient event detail to determine specific battery category.	The customer stated that the ventilator stopped functioning while on battery power.
	1. Disconnection of Power cord		Disconnection of the electrical cord between the ventilator and the power source.	The power cord from the ventilator was accidently disconnected from the outlet when staff was moving equipment.
4. Airway/Breathing Circuit Issue				
	a. Disconnection/ Detachment/Loose Connection		An accidental break in connection in the breathing circuit (tubing/connectors) between the ventilator and the patient's airway/endotracheal tube.	Registered Nurse (RN) responded to ventilator alarm on central monitor, patient's oxygen saturation had dropped and patient's bi-pap tubing was found to be disconnected from bi-pap mask.
	b. Leak (not associated with disconnection)		Leak in patient breathing circuit impeding the proper flow of oxygen to the patient. Does not include leaks associated with disconnection in circuit.	The ventilator was alarming and RN heard an air leak. An area on the ventilator circuit appeared to be melted and a hole was noted.

	c. Unplanned extubation	i. Self-extubation	Patient intentionally pulled out endotracheal tube or caused dislodgment by an action such as coughing up the tube or through bodily movement.	RN responded to a ventilator alarm in patient's room and discovered that the patient had pulled out the endotracheal tube despite being lightly sedated and restrained at time of self-extubation.
		ii. Accidental extubation	Endotracheal tube accidently dislodged during patient care such as turning or lifting.	The patient's endotracheal tube was accidently dislodged during re-positioning. New endotracheal tube was placed without incident.
5. Gas Supply Issue				
	a. Circuit Disconnection/ Detachment/Loose Connection		An accidental break or disruption in connection between the gas supply source and the ventilator.	Patient was placed on the bi-pap machine. Oxygen saturation noted to drop and patient's condition worsened. The oxygen line to the bi-pap was discovered to be disconnected.
	b. Circuit Leak		Leak in the gas supply circuit impeding the proper flow of oxygen to the patient. Does not include leaks associated with disconnection in circuit.	Patient had to be moved to another room because of inability to use bi-pap in assigned room due to a leak in the oxygen outlet.
	c. Inadequate Supply	i. Wall supply	Inadequate supply of oxygen from wall outlet supply	Vent was alarming low O_2 supply. After establishing there was not an issue with the ventilator, the oxygen outlet was changed in same room, but ventilator continued to alarm. Patient was transferred to a different room and connected to wall oxygen outlet and alarm stopped.
		ii. Tank supply	Inadequate supply of oxygen from tank	Patient taken to MRI (Magnetic Resonance Imaging) and on return ran out of oxygen in the tank.
6. Occlusion Issues				
	a. Moisture/ condensation/ humidity		Adverse events related to moisture build-up in a patient breathing circuit or filter associated with a breathing circuit resulting in a blockage of gas flow to the patient.	Respiratory therapist (RT) discovered patient connected to his ventilator. The vent was alarming due to greater than 40 breaths being taken per minute. Further assessment by RT revealed that the patients cuff was deflated and that water was in the circuit.
	b. Tubing issue		Adverse events related to compression or kinking of the patient breathing circuit between the patient and the ventilator or compression or kinking of the tubing between the gas source (e.g., oxygen) and the ventilator.	It was reported to biomed department that the adjustable arm holding the patient circuit could squeeze the inspiration hose if the arm height level is less than the inspiration hose level.

	c. Other/Unknown		Adverse events in which an occlusion is noted in the description of the event but unable to determine if it is moisture or tubing issue.	Ventilator alarming “obstruction” and patient was ventilated manually while ventilator was changed.
7. Stand-by Mode Adverse Events				
			Ventilator standby mode is a feature incorporated into some mechanical ventilators allowing users to prepare the ventilator for use prior to patient connection or temporarily disconnect a patient from the ventilator while maintaining ventilator user-set patient parameter settings and without activating alarms (alarms are suspended, but alarm limits are maintained). When in standby mode mechanical ventilation is paused (i.e., the patient does not receive ventilation therapy).Standby mode adverse events include events in which mechanical ventilators are operating in standby mode either by means of equipment failure or by an individual manually placing the ventilator into standby mode while connected to patients.	Nurse accidentally created a leak with the Oscillator, and this ventilator goes into a standby mode whenever it detects a disconnection or a leak. The nurse taking care of patient did not know how to restart machine and went to find someone who did. Patient desaturated down to the 40's and had to be oxygenated with resuscitation bag to bring oxygen level back up to 90's.
8. Ventilator Malfunction				
	a. Malfunction but continued to ventilate the patient	i. Monitor Settings Not Displaying/ Holding Setting	Monitor screen display blank or setting values not displaying according to what staff programmed.	1. Touch screen of ventilator would not respond, but device continued to ventilate the patient. 2. Ventilator settings changed on own from set value to a different value
		ii. Setting Readings Incongruent With Value Set	Issue in which programmed settings are not being maintained	The actual F_{IO2} reading out was 5 points different than the set value. The set oxygen was 32% but the ventilator performing at only 27%. Check with oxygen analyzer indicates 27% too.
		iii. Vent Alarming and alarms persisted after intervention	Alarms note an issue but attempts to address the issue fail	Ventilator was alarming “circuit disconnect” and replaced with new circuit. Ventilator continued to alarm.
		iv. Other/Unknown	Other malfunction issue in which there is a partial system failure in which the ventilator continues to provide mechanical ventilation to the patient (other issue not described in 9.a.i-iii).	Ventilator alarming and reading “machine default 806.” Ventilator appeared to be operating properly but ventilator replaced.
	b. Malfunction and did not continue to ventilate the patient		Adverse events related to mechanical ventilator malfunctions that prevents mechanical ventilation to patients.	The screen was all black on the vent, the vent was not delivering breaths, and the vent had a red vent “inop” alarm on the top of the screen.

	c. Software Issue	i. Upgrade version, corruption, error	Issue associated with replacing an older operating system to an up-to-date operation system, corruption, and error.	Ventilator upgraded to software version 4.0. After the upgrade the volume, tone, and length of sound from alarms seemed to be altered and unrecognizable by the clinicians.
		ii. Other		
9. MRI/CT Scan Issues				
			Issue associated with the conditions in which the device is being used such as MRI and CT (Computerized Tomography) environment.	Ventilator deemed MRI safe. During patient setup for the MRI exam the ventilator was placed too close to the magnet and was violently attracted, causing minor damage to the MRI machine and severe damage to the ventilator.
10. Foreign Material Issues				
			Issue associated with the presence of materials, which are not part of the documented device specifications and requirements. Does not include occlusion as per category 7.	An oxygen valve was found to contain debris where the plunger seats down onto the body. The debris caused mechanical failure of the valve.
11. Unknown/Ventilator issue could not be determined				
			Issue associated with difficulties in identifying events related to a ventilator. Insufficient event detail to determine specific category.	A patient coded while on a ventilator. It is unclear if the ventilator contributed to the patient's deterioration.