Aestiva Ventilation Mode Selector Switch Failures

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We describe three cases of previously unreported failures of the Bag-Ventilator Switch in Aestiva®/5 anesthesia machines (GE Healthcare/Datex-Ohmeda, Madison, WI). Each failure mode produced a large breathing-circuit leak. Examination of the switches revealed a cracked toggle actuator, residue build-up, and a cracked selector switch housing as causes for the failures. When a leak with no visible cause develops, consider advancing the mode selector switch fully to its mechanical limit or consider that the toggle actuator or its anchoring mechanism may have failed. These cases demonstrate that it is imperative to always be prepared to immediately use an alternate method for ventilation. Cases describing failure to ventilate due to sudden equipment malfunction underscore the need to always have functioning backup ventilation equipment available.

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CASE 1

A hemodynamically unstable patient with multiple injuries was brought to the operating room (OR) for repair of a ruptured pulmonary artery. A thoracotomy was performed and lung isolation requested. The intraoperative course was complicated by multiple desaturations requiring switching modes of ventilation using the Bag-Ventilator Switch. During one of these mode switches it was noted that the Aestiva®/5 anesthesia machine developed a major leak and lost the ability to deliver positive pressure while in ventilator or bag mode. In response, the patient was temporarily disconnected from the breathing circuit and ventilation continued with a self-inflating manual resuscitator. Troubleshooting did not identify or correct the leak and the malfunctioning machine was quickly replaced.

Postoperatively, the malfunctioning machine was inspected and a fracture in the internal Bag-Ventilator Switch toggle actuator was identified. It is believed that a spontaneous fracture occurred and caused the leak because the Bag-Ventilator switch was never forcefully advanced during the case. Replacement of the failed component resolved the issue.

CASE 2

The Food and Drug Administration (FDA) pre-use anesthesia apparatus checkout recommendation (AACR)1 was performed on an Aestiva/5 as a trauma patient arrived in the OR. When the ventilation system and unidirectional valves were checked as described in Step 12 of the AACR, it was noticed that the anesthesia machine's ascending bellows was not returning fully to its prior end-exhalation position and continued to lose volume with each ventilatory cycle, despite a fresh gas flow of 6 L/min. The Bag-Ventilator switch was flipped to bag (manual ventilation) mode position and the machine examined. Despite a visual inspection of the circuit, the seating of the soda lime canisters and the hoses, no source for the leak could be found. Flipping the Bag-Ventilator switch back to ventilator mode failed to reproduce the leak.

Before inducing anesthesia, the availability and functioning of a self-inflating manual resuscitator was confirmed and one more attempt to troubleshoot was made. With the Bag-Ventilator switch set to "bag" there was no leak, but on switching back to ventilator mode, the large leak reoccurred. It was then noticed that the Bag-Ventilator switch did not appear to be fully engaged in the ventilator position (Fig. 1). After pressure was applied to the switch lever so that it moved to its proper position, the leak disappeared. Having established the cause of the variable leak, confirmed that it could be corrected, and that back-up ventilation equipment was available, the case was started and finished without incident.

The machine was taken out of service after the case. Disassembly of the absorber housing revealed a buildup of viscous substance on the internal aspect of the selector switch. We speculate that the source of this residue was cleaning solution (Wex-Cide-128, Wexford Labs, Kirkwood, MO and Virex-Tb, Johnson Commercial Markets, Sturtevant, WI) that had dripped into the Bag-Ventilator switch guide and collected dust. This combination formed a dark sticky, grayish mass that accumulated over time. The residue buildup prevented the switch from fully engaging in the ventilator mode position. Consequently, the manual ventilation sub-system was not pneumatically isolated from the breathing circuit when the selector switch was set to ventilator mode.

CASE 3

A patient for total abdominal hysterectomy was taken to the OR where anesthesia was induced and endotracheal intubation performed. Approximately 5 min after initiation of positive pressure ventilation, exhaled tidal volume decreased. Breath sounds were verified as equal bilaterally. There was no audible tracheal gas leak detected when pressures of up to 30 cm H_2O were applied to the breathing system. Attempts to compensate for the loss of tidal volume by increasing the set tidal volume and by increasing the fresh gas flow to 8 L/min failed, as the bellows continued to lose volume. The patient was temporarily disconnected from

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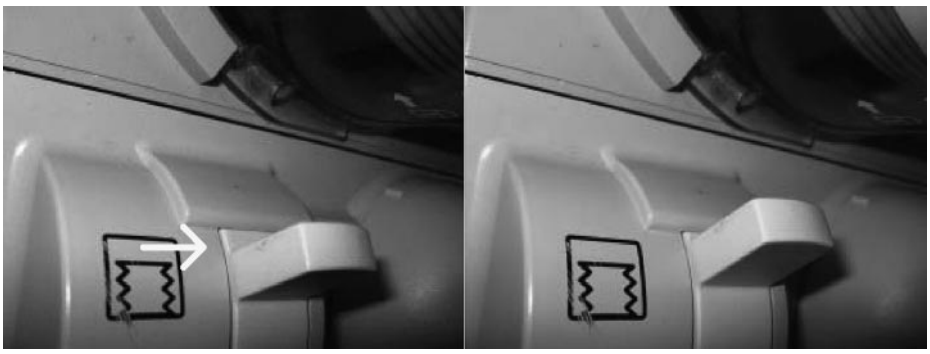

Figure 1. View (from above and left) of the absorber housing and the Bag-Ventilator switch short of its mechanical limit (arrow in left picture) and at its mechanical limit (right picture). From the typical perspective of an anesthesia provider, the difference in selector switch position will be less noticeable.

the anesthesia machine and successfully ventilated with a self-inflating manual resuscitator.

A positive pressure leak test at 30 cm H_2O revealed that fresh gas flow could be reduced to minimal (200 mL/min) with the Bag-Ventilator switch in manual mode and the adjustable pressure limiting (a.k.a. "pop-off") valve fully closed with no discernable circuit leak.

When the Bag-Ventilator switch was set to ventilator with the adjustable pressure limiting valve completely closed from the previous leak test, each mechanical inspiratory breath produced a slight inflation of the reservoir bag. The bag continued to increase in size and it was concluded that the leak stemmed from a pneumatic connection between the mechanical ventilation circuit and the manual ventilation circuit. The Bag-Ventilator switch was very loose. When the lever was advanced to its full mechanical limit, the leak was corrected. The remainder of the surgery was completed without any further issues and the anesthesia machine removed from service.

Inspection of the absorber housing revealed a crack of the internal plastic housing that anchors the Bag-Ventilator selector switch. Replacement of the housing corrected the malfunction.

DISCUSSION

Two actions occur when the selector switch lever is toggled from the bag to the ventilator position in the Aestiva: 1) the ventilator is turned on (ventilator actuation does not appear to require the lever to be at its mechanical limit), 2) the manual ventilation sub-system, including the reservoir bag, is isolated from the breathing circuit. (This action requires the lever to be fully engaged.)

The effect of each of the three different selector switch failure modes (cracked toggle actuator, residue build-up, cracked selector switch housing) reported here was that, when toggled from bag to ventilator mode, the selector switch assembly did not completely seal off the manual ventilation sub-system. Thus, the faulty Bag-Ventilator selector switch produced a three-way connection among the breathing circuit, mechanical ventilation, and manual ventilation sub-systems (Fig. 2). This resulted in a significant amount of gas loss during mechanical ventilation through the partially open Bag-Ventilator selector valve.

A similar failure mode for an Aestiva 3000 has been previously reported (2). In that report, the authors

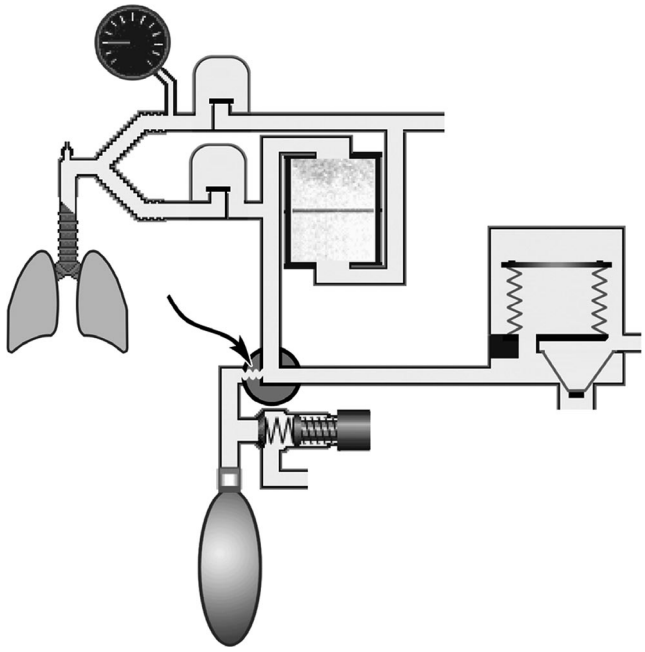

Figure 2. A stylized representation of the leak between the manual and mechanical ventilation sub-systems that occurs only when the failed selector switch is in the mechanical position. Based on the Virtual Anesthesia Machine (VAM) simulation http://vam.anest.ufl.edu (with permission from the VAM authors).

describe a failure of the same plastic component that failed in our Case 3. The earlier report also describes sporadic failures that occurred intraoperatively. Interestingly, all the failures in that report describe leaks that manifested when the Bag-Ventilator switch was in bag mode but failed to fully exclude the ventilator whereas those we describe failed to exclude the bag when set to ventilator mode.

The AACR recommended by the FDA prior to administering anesthesia ascertains, among other elements, the integrity of the ventilator circuit and successfully detected the malfunction in one of the above cases. However, neither the AACR nor the manufacturer's preoperative checkout guarantees against intraoperative equipment failures, nor can they be expected to detect intermittent failures as may occur

from variable forces used to deploy the Bag-Ventilator switch when its movement is impaired by residue. Furthermore, an anonymous web survey indicated that only 20% of anesthesia providers perform anesthesia machine pre-use checks before *every* case, and only 28% believe they do it skillfully (3).

Our report illustrates the value of performing the AACR. That said, this experience also demonstrates that a leak whose source is not readily identifiable by the user may occur intraoperatively, suddenly and without warning. In the Aestiva anesthesia machine, it may not be enough to simply "flip" the Bag-Ventilator switch from bag to ventilator mode. If there is a leak, follow the low pressure algorithm proposed by Raphael et al. (4), check the circuit, CO_2 absorber, vaporizers and all hoses, but also make sure the ventilation mode selector switch has been pushed all the way to its mechanical limit. Even if the leak is resolved, realize that the toggle actuator or its anchoring mechanism may have failed and an alternate method for ventilation must be immediately available. The ventilation options to address an intraoperative selector switch failure are:

1. Attempt to advance the selector switch all the way to the mechanical limit of ventilator (or bag) mode position
2. Flip the selector switch to bag and attempt manual ventilation
3. Convert to ventilating with a self-inflating manual resuscitator
4. Provide alternate means of mechanical ventilation (spare anesthesia machine, transport, or intensive care unit ventilator)
5. Have the machine's selector switch examined by qualified/authorized service personnel as soon as possible.

When contacted, GE Healthcare/Ohmeda acknowledged that the Aestiva User's Reference Manual may not be as clear as necessary about the need to avoid accumulations at or near the Bag-Ventilator switch and indicated that an internal review of the Aestiva User's Reference Manual is in progress (Mitton M, GE Healthcare, personal communication, April 2006).

The anesthesia machine is intended for use in a clinical setting where it should be expected that it will become soiled with biological material and that halogenated anesthetic compounds might be spilled on it accidentally, which will require cleaning. With the current design of the Aestiva, it is not only possible but likely that with normal use these liquids will get into the absorber housing, since this housing is not sealed at the selector switch. These machines were maintained and regularly serviced by trained personnel in accordance with a service contract with the manufacturer. On servicing additional units, we have found similar build-up in 3 of 11 absorber housings.

These cases have been reported to the FDA using the MedWatch Online Voluntary Submission Form 3500 B. Adverse event, Product Problem or error form found at: http://www.fda.gov/cdrh/mdr.

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