

Fig. 1. Gas flow diagram: Dräger Apollo® Anesthesia Workstation. Modified from an original figure in the *Apollo® Operator's Instruction Manual, version 3*. Information furnished courtesy of Dräger. APL = adjustable pressure limiting; AUTO = automatic; exp = expiratory; insp = inspiratory; MAN = manual; P = electronic breathing pressure sensor; PEEP = positive end-expiratory pressure; P MAX = pressure limitation in volume mode; SPONT = spontaneous.

in Germany. Dräger stated they could not find any errors that could explain the failure-to-ventilate problem. They did not specifically mention what the error log might detect in relation to this specific type of problem. Dräger recommended replacing the inspiratory and expiratory flow sensor harness assemblies as well as the analog board and the expiratory sensor in case the problems were related to malfunction of any of the associated components.

We would like to highlight these faults to other users of Dräger Apollo® Anesthesia Workstations. Finally, it is standard practice to have a bag valve mask immediately available, but we would like to emphasize the importance of actually using it. The American Society of Anesthesiologists Recommendations for Pre-Anesthesia Checkout Procedures[#] recommends requirements for safe delivery of anesthesia care. A specific requirement is “Backup ventilation equipment available and functioning.”

[#] Recommendations available at: <http://asatest.asahq.org/clinical/FINALCheckoutDesignguidelines02-08-2008.pdf>. Accessed January 4, 2011.

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In Reply:

In the letter, the authors discuss three cases pertaining to the Dräger Apollo® Anesthesia Workstation (Dräger Medical Inc., Telford, PA). In two of these cases they describe a nonfunctional manual ventilation at the end of a procedure after an otherwise uneventful mechanical ventilation. In a third case, they describe a nonfunctioning manual ventilation during the induction of anesthesia after previous spontaneous ventilation.

In order to better understand what might have happened during these cases, we would like to take the opportunity to provide some detail on the breathing system concept of the Dräger Apollo® Anesthesia Workstation.

Since 1997, Dräger has used a common design of the breathing circuit in combination with the latest generation of electrical piston-type ventilators.

The common circuit diagram is shown in figure 1. It shows that the gas circuit is divided into two parts: the inspiratory part and the nonpressurized rebreathing part.

According to the checklist, the user is advised to check the proper functionality of the adjustable pressure-limiting (APL) valve by a short manual test. This test also allows the user to visually detect leakages in the “Man Spont” part of the breathing system.

During the power-on self-test, the Apollo checks for leakages in the patient and automatic ventilation system, as well as in the Man Spont part of the breathing system. The system tolerates leakages of up to 150 ml/min, including the connected patient hose system, patient filters, absorber canister, and breathing bag.

Dräger recommends performing a self-test every day and a leakage test after changing breathing system components or patients.

Regarding the cases reported by Dr. Hilton and colleagues, a broken O-ring was found at a flow sensor in the breathing system. This generally could cause a leak in the patient system, which would lead to reduced tidal volume delivery to the patient and reduced airway pressure. However, a leak caused by a broken O-ring would have been detected during the automated and manual self-test of the machine. Furthermore, as the authors describe, this damage would affect mechanical ventilation. Because mechanical ventilation was successfully applied uneventfully before on the same patient, the broken O-ring cannot be the root cause of the described situation.

The authors speculate whether a fault of the “Man-Auto Bypass” valve may have caused it to stick in the bypass direction. In addition, the authors describe this valve as an electronic valve. This bypass valve (V2) is not an electronically controlled valve; instead, it is a pneumatic valve, which is activated by vacuum. Mechanically, valve V2 consists of a diaphragm with a base plate, which in its inactive state is pressed on a valve crater by a spring. In this state, which is equivalent to manual ventilation mode, the diaphragm closes the crater and thus the bypass path for the APL valve, which

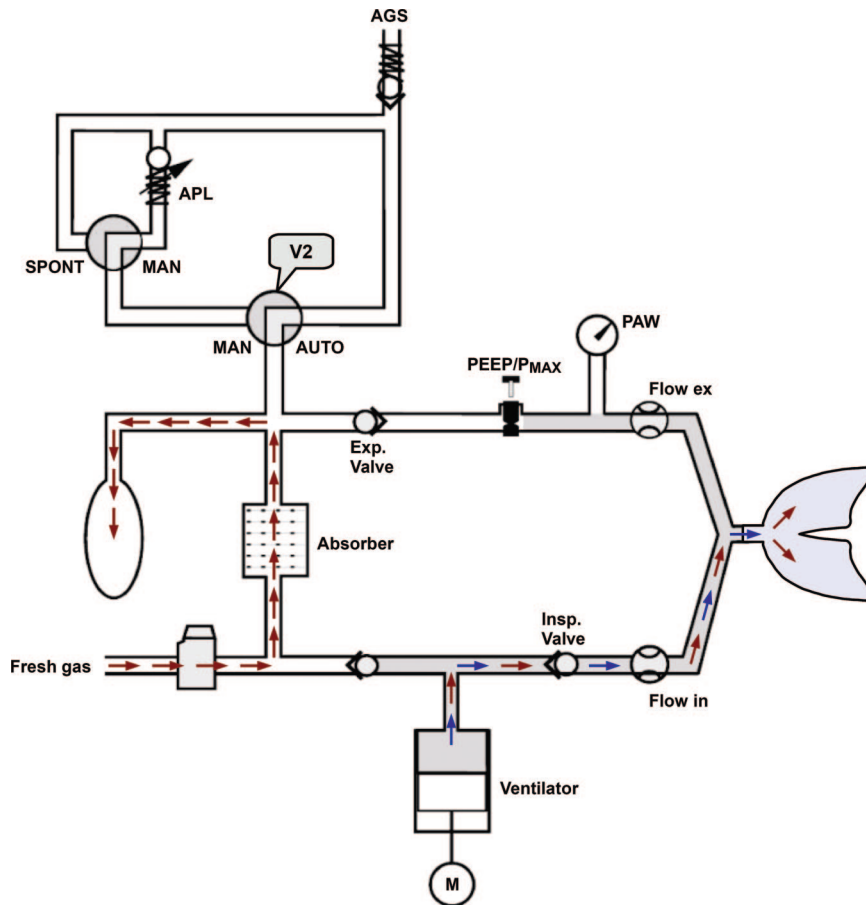


Fig. 1. Gas diagram during inspiration. AGS = anesthetic gas scavenger system; APL = adjustable pressure limitation valve; Exp. Valve = expiratory valve; Insp. Valve = inspiratory valve; MAN/AUTO = reversing valve between manual/mechanical mode; PAW = airway pressure; PEEP/P MAX = positive end-expiratory pressure/pressure limitation valve; SPONT/MAN = reversing valve between spontaneous/manual mode.

results in the APL valve taking control of the airway pressure whenever V2 is closed.

Upon activation of automatic ventilation, a vacuum pump inside the ventilator evacuates a number of sections of the ventilator and breathing system, including the volume set up by the V2 diaphragm and valve housing. This causes V2 to fold back into its housing against the spring's force, resulting in its base being lifted off the crater and thus opening the bypass path of the APL valve. In this state, the APL valve is inactive, and pressure control is solely maintained by the positive end-expiratory pressure valve.

To ensure proper operation of V2 and the ventilator, the vacuum generated by the pump is supervised by an independent pressure sensor, which causes alarms and entries in the electronic device logbook whenever the allowed under-pressure range is out of tolerance. This supervision is maintained in automatic and manual ventilation mode. In this case, the device logs sent to Dräger did not show any failure of this kind in the logbook.

If manual ventilation could not be activated because of the inability to generate sufficient airway pressure, despite the presence of fresh gas, this may have been caused by the following reasons:

- a) *APL valve placed in spontaneous position or blocked in this state.* In this case the direct connection to the gas scavenging system is opened; therefore, all gas provided to the manual section of the breathing system directly leaves it without generating significant airway pressure.
- b) *V2 open in manual ventilation mode.* By construction, this state can be generated only if sufficient under-pressure is present inside V2. If this were the case, data log entries and alarms would be generated, and the ventilator would perform an emergency shutdown, followed by the respective alarms. Because of construction of the vacuum system, a forced ventilation of the evacuated sections ensures that no under-pressure is locked inside the breathing system after the pump is switched off.
- c) *V2 leaky in manual ventilation mode.* In this case, some of the fresh gas would be directed into the gas scavenging system and therefore lost for patient ventilation. But because of the remaining pneumatic resistances, most of the fresh gas would still be available for patient ventilation, so manual ventilation may be impaired but not completely disabled. Because of the centric and flexible construction of V2, such leakages can appear only in the event of mechanical damage.

The highlighted malfunctions of V2 can result only from mechanical or pneumatic damage, which because of their persistent nature, would be reproducible and would not vanish after changing ventilation modes or power cycling the device.

The functionality of mechanical ventilation also indicates that there were no other significant leakages in the pressurized part of the breathing system (see fig. 1).

Furthermore, the authors question whether the APL valve may have been stuck in the open position internally, despite the control knob having been turned to the closed position externally. The APL valve is a mechanical valve with a spring inside. If anything inside the APL would create a mechanical malfunction, this would be a reproducible failure, so it would have been detected during the preuse check and after technical investigation of the APL valve.

As a result, and taking all the above into account, we assume that there was an additional leak somewhere else in one of the areas of the ventilator and breathing system that is pressurized only during manual ventilation.

These areas could include the manual breathing bag, flexible bag arm (including an improperly seated arm as the authors describe), damaged O-ring on the breathing bag connection area, absorber canister, APL valve setting, or improperly seated vaporizer.

However, a leak in one of those areas would have been detected during the automated and manual self-test.

During Man Spont, the following device behavior can be observed in the event of a leak: empty manual breathing bag, insufficient pressurization, minute volume low alarms → carbon dioxide apnea alarm, loss of pressure, and flow-based readings.

Without a physical inspection of the machine, it is difficult to identify which of the situations listed above caused the leak in these cases. However, the letter from Dr. Hilton and colleagues highlights the importance of following the manufacturer's guidelines regarding the preuse checklist, as outlined in the user's manual. In addition, the letter also enforces the importance of performing scheduled maintenance, including the replacement of both preventive maintenance and "wear and tear" parts.

Dräger thanks ANESTHESIOLOGY for the opportunity to respond to the Case Report by Dr. Hilton and colleagues.

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