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Interruption of the breathing gas to a ventilated anaesthetized patient due to accidental disconnection or anaesthesia system malfunction may have serious consequences if not detected quickly. A series of tests which covers the range of foreseeable mechanical problems was developed and used to test the performance of three breathing gas interruption monitors, two commercially available and one developed at Vancouver General Hospital. The tests were designed to evaluate the performance of monitors as installed on anaesthesia systems under a variety of failure conditions, including endotracheal tube disconnection with and without occlusion of the opening, kinks in the inspiratory and fresh gas hoses, disconnection of the fresh gas hose, leaks in the breathing circuit, excessive high or low pressure in the scavenging circuit, continuing high breathing circuit pressure, and kinks in the circuit pressure sensing hose. Ability to detect both significant changes in ventilation variables and faults existing at initiation of ventilation were also tested over a representative range of ventilator and patient variables using circle, coaxial and paediatric circuits.

Only complete endotracheal tube disconnections with no obstruction of the opening were reliably detected by all three monitors. A commercial monitor with a single fixed-threshold alarm level also detected fresh gas interruptions in circle and adult coaxial circuits, but failed to alarm in response to any

#### Key words

EQUIPMENT: ventilators, breathing gas interruption monitors; VENTILATION: mechanical; COMPLICATIONS: breathing circuit interruption.

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# Detection of interruptions in the breathing gas of ventilated anaesthetized patients

other fault condition. A monitor with selectable pressure thresholds and high, low, and continuing pressure limits detected just under half of the fault conditions. A microprocessorbased monitor developed at Vancouver General Hospital detected and correctly identified roughly 80 per cent of the faults.

The series of tests forms the basis for a Canadian Standards Association Preliminary Standard (Z168.10) and will allow hospitals to test the performance of breathing gas interruption monitors in use in their institutions. Comments on the test series are solicited.

Breathing circuit disconnections and mechanical malfunctions of the anaesthesia system are among the most common of preventable anaesthesia mishaps.<sup>1</sup> Most commercially available "patient disconnect" monitors based on breathing circuit pressure fail to detect several common breathing gas interruption (BGI) conditions, although technology exists to make anaesthesia significantly safer.<sup>2</sup> A standard series of tests which could be performed on anaesthesia systems configured for clinical use is needed to allow hospitals to evaluate the performance of their BGI monitors over the full range of foreseeable problems. It is the objective of this article to describe such a scries and the results obtained by applying the tests to typical BGI monitors.

A review of the literature relating to anaesthesia mishaps revealed more than 90 reports of patient anaesthesia incidents unrelated to gas composition or improper drug administration for the five-year period between 1982 and 1986. The incidents fell into ten categories. Disconnections at the endotracheal tube or patient connection,  $^{4-21}$  kinks or partial obstructions of the breathing circuit tubing,  $^{2-27}$  leaks in the circuit,  $^{26-43}$  disconnection of the rash gas hose,  $^{47-50}$  excessive positive pressure in the scaveng-ing system,  $^{51-58}$  excessive negative pressure in the scaveng-ing system,  $^{59-63}$  blocked fresh gas flow,  $^{64-73}$  and continuing high-breathing circuit pressure  $^{74-86}$  comprise

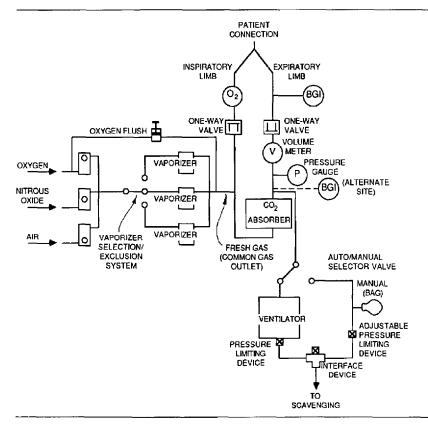


FIGURE 1 (Typical circle breathing system) The preferred site for a breathing gas interruption (BGI) monitor in a circle breathing circuit is in the expiratory limb close to the patient connection. A common alternate site, at the carbon-dioxide absorber, reduces the risk of moisture or kinked tubing interfering with sensing the breathing circuit pressure but removes the sensing site from the point of interest. Some BGI monitors sense the pressure in the ventilator bellows chamber; this site is too far from the patient connection to give an accurate estimate of airway pressure even in normal controlled ventilation.

nine categories which occur after initiation of controlled ventilation. The tenth category covers faults which exist before initiation of automated ventilation.<sup>87–95</sup> For completeness, obstruction of the BGI monitor sensor hose by fluid or by kinking was added to the protocol. These conditions formed the basis for Canadian Standards Association Preliminary Standard Z168.10 "Testing of Breathing Gas Interruption Monitors for use during Anaesthesia,"<sup>3</sup> a user-oriented Standard which outlines a series of tests suitable for evaluating the performance of pressure-based BGI monitors.

No single monitor can detect all of the faults which might occur in an anaesthesia gas delivery system. In recent years a wide variety of monitors have been developed including infrared and mass spectrometer gas analyzers, exhaled volume monitors, and pulse oximeters. All of these systems provide valuable information as to patient status; however, the capital, operating and maintenance costs associated with such devices are significantly greater than those for pressure-based monitors. A well-designed BGI monitor based on breathing circuit pressure can provide a relatively inexpensive, easily used and reliable aid in assuring safe, incident-free anaesthesia. The series of tests described is designed to assist clinicians in identifying those conditions which will not be detected by the BGI monitors currently in use in their institutions.

# Methods

The tests were designed to be performed on an anaesthesia

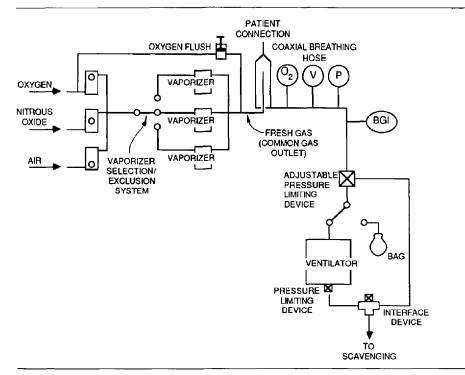


FIGURE 2 (Typical coaxial breathing system) In a coaxial breathing circuit the breathing gas interruption (BGI) monitor sensor hose is generally removed from the patient connection, although it may be inserted into the circuit at the connection to the endotracheal tube. Sensing pressure at the ventilator bellows chamber is not recommended due to the high resistance of the breathing circuit.

system and breathing circuit set up for clinical service, with a BGI monitor installed in accordance with the manufacturer's specifications. For the original series, a calibrated test lung (Manley Ventilator Performance Analyzer; Medishield, Harlow, Essex, England) with adjustable resistance (R) and compliance (C) and an adjustable leak port was attached at the patient connection. A set of adult, paediatric and neonatal lung simulators which can be assembled in-house is described in the CSA Preliminary Standard.<sup>3</sup> A reusable circle breathing circuit (Figure 1) and a coaxial ("Bain") circuit (Figure 2) were used with typical adult R and C values set on the lung simulator: resistances ranged from 0.5 to 5 kPa  $L^{-1}$  s<sup>-1</sup> (5 to 50 cm  $H_2O(L^{-1}\cdot s^{-1})$  and compliances from 100 to 500 ml·kPa<sup>-1</sup> (10 to 50 ml·cm<sup>-1</sup>H<sub>2</sub>O). Fresh gas flow was maintained at 6 L·min<sup>-1</sup> for "adult" tests; an inspiratory to expiratory ratio of 1:2 was maintained throughout. Tidal volumes from 250 ml to 1000 ml and frequencies between 10 and 30 breaths per minute were used. Positive end-expiratory pressure (PEEP) was set at zero or  $1.5 \text{ kPa} (15 \text{ cm } H_2 \text{O})$ .

Paediatric conditions were simulated using the Manley test lung, as a paediatric simulator was not available. A paediatric breathing circuit (Figure 3) and lower fresh gas flows and tidal volumes were used. Compliances of 100 and 200 ml·kPa<sup>-1</sup> (10 and 20 ml·cm<sup>-1</sup> H<sub>2</sub>O) and resistances of 0.5 to 20 kPa·L<sup>-1</sup>·s<sup>-1</sup> (0.05 to 0.2 cm H<sub>2</sub>O·ml<sup>-1</sup>·s<sup>-1</sup>) were used. Neonatal values were beyond the range of the Manley simulator.

The test sequence was as follows. A coaxial breathing circuit was attached to the lung simulator, and the system was set up with the variables shown in the first row of the checklist (Figure 4). The ventilator was allowed to cycle several times until the maximum breathing circuit pressure stabilized, and the BGI monitor was set in accordance with manufacturer's recommended procedures. Fault conditions were introduced one at a time and a maximum of one minute was allowed for the BGI monitor

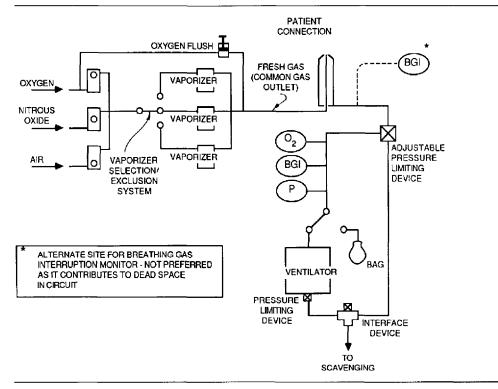


FIGURE 3 (Typical paediatric circuit) Placement of a breathing gas interruption (BGI) monitor in a paediatric breathing circuit presents problems because the sensing tubing typically found on the monitors introduces a relatively large dead space and compliance into the system. Sensing pressure in the ventilator bellows chamber, as for adult coaxial circuits, is not recommended.

to alarm. A check mark was recorded at the appropriate position in the table if an alarm occurred. If the fault was not detected, a zero was recorded. Faults which could not be simulated on the anaesthesia equipment were marked "not applicable."

After each test normal conditions were established before introduction of the next fault. The lung simulator was disconnected at the patient connection with no occlusion of the opening, and with full occlusion. Kinks were made in the inspiratory limb of the breathing circuit and in the fresh gas hose by folding the hoses through  $180^{\circ}$ . The fresh gas hose was disconnected from the common gas outlet of the anaesthesia machine. A leak of the order of 2 L·min<sup>-1</sup> was introduced in the inspiratory line of the breathing circuit. As the vaporizers on the anaesthesia systems in use at Vancouver General Hospital cannot be disconnected without tools, the vaporizer inlet disconnection test was marked "N/A." The hose connecting the ventilator to the scavenging interface device was occluded to produce high positive pressure in the scavenging circuit. A medical vacuum regulator was connected to the scavenging interface device and adjusted to produce between 2 and 3.3 kPa (15 and 25 mmHg) negative pressure in the scavenging circuit. High breathing circuit pressure was created by continuously activating the oxygen flush switch with the ventilator cycling. The hose connecting the BGI monitor to the breathing circuit was kinked through 180°.

After the final fault in the series was corrected, the patient and ventilator test variables were changed to those in the next row of the table, and it was noted whether or not the BGI monitor detected the change in variables. All of the tests were designed to evaluate monitor sensitivity (that is, the ability to correctly identify fault conditions) including the test where ventilation variables were changed suddenly. The ability of a monitor to correctly identify no-fault conditions (specificity) is difficult to assess objectively and is addressed in this series of tests only by

	CHECKLIST									TEST: 1 2 3 4 5 6 7 8 9 10 11 1										
	CKT	PEEP	c	R	FRE	FRG	Vt	$\sim$	$\mathbf{Z}$	$\mathbf{Z}$	Z	Z	$\simeq$	Ž	<u> </u>	$Z^{a}$	<u> </u>	Y	<u> </u>	¥
	B	0	50	5	10	6	500		I										1	4
	6	0	50	5	20	6	1000								L					
	В	15	50	5	20	6	1000							i						J
	ρ	0	5	100	30	3	250													]
ĺ	P	0	20	50	30	3	250													}
	Ρ	0	50	20	15	3	250													]
	¢	0	20	5	20	6	750													]
	С	0	10	5	10	6	750												1	1
	Ç	0	20	50	10	6	500													1
i	Ċ	0	20	50	10	6	1000												Γ	]
	С	15	50	5	10	6	500													]
13	C	0	50	5	20	6	750													]

#### LEGEND

CKT	C, B, P	circle, Bain (coaxial), pediatric circuit							
PEEP	cmH <sub>2</sub> O	positive end expiratory pressure							
с	mL/cmH2O	compliance							
Ŕ	cmH2O/L/S	resistance							
FRE	breaths/min	ventilation rate							
FAG	L/min	fresh gas flow rate							
Vt	mL	tidal volume							
CHECKLIST INSTRUCTIONS									

Record a check mark ( $\lambda$ ) if the monitor alarms in the presence of a fault (tests 1-12), or will not permit startup in the presence of a fault (test 13). Record a zero (O) if the fault is not detected (tests 1-12) or allows startup in the presence of a fault (test 13).

FIGURE 4 (BGI Monitor checklist) The checklist for breathing gas interruption (BGI) monitor performance testing covers a wide range of patient parameters and ventilator settings, and most possible mechanical malfunctions of the anaesthesia system. Other mechanical anaesthesia system failures reported in the literature are generally covered by the tests in the checklist.

recording the number of times a monitor alarmed in the absence of a fault condition. Changes in ventilation variables of the magnitudes given in Figure 4 are considered to be "faults" in so far as they represent significant changes in patient status to which the anaesthetist should be alerted.

Once the coaxial breathing system tests were completed, the circuit was replaced with a paediatric system. Using the paediatric circuit, the relief valve was set to produce a peak pressure of 1.6 kPa (16 cm  $H_2O$ ) for the first test and was not adjusted for subsequent tests. Following the paediatric circuit tests a circle breathing system was assembled and used for the remainder of the series.

The final row of circle system tests checked the ability of the BGI monitor to detect faults introduced before ventilation was begun and the BGI monitor was enabled. A check mark was recorded if the BGI alarmed (did not start under fault condition); a zero was recorded if the BGI did not alarm to indicate a fault condition (started in error).

A full description of the test procedures is given in CSA Preliminary Standard Z168.10.<sup>3</sup>

Three different pressure-based alarms were subjected to the series of fault conditions described. The lowpressure alarm built into a Fraser-Harlake 701 ventilator was tested with a Boyle MS anaesthesia machine (Ohmeda Division, The BOC Group, PO Box 1550, Madison WI) and Boehringer 1.5 kPa PEEP valve (Boehringer Laboratories Inc, PO Box 337, Wynnewood PA). The Drager DPM-S built into a Narkomed 2A anaesthesia machine (North American Drager, 148B Quarty Rd, Telford PA) with adjustable PEEP was tested. A prototype BGI alarm developed by the Vancouver General Hospital (VGH) Biomedical Engineering Department was tested on a Drager Narkomed 2A anaesthesia unit. All

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	CKT	PEEP	С	R.	FRE	FRG	Vt	/4	$\mathbb{V}$	\$/\$	8/4	8% (	9%	ų.	18/63	5/ 0	9/¥	8/¢	9/c	<u>š'/</u>
	В	0	50	5	10	6	500	1	0	0	0	1	0	4	0	0	0	A	0	[
	В	0	50	5	20	6	1000	<	Q	0	0	1	0		0	0	0		0	]
	В	15	50	5	20	6	1000	1	0	0	0	1	0		0	0	0			]
	P	0	5	100	30	3	250	1	0	0	0	0	0		0	0	0	[ ] [	0	]
	Р	D	20	50	30	3	250	1	0	0	0	0	0		0	0	0		0	]
	P	D	50	20	15	3	250	<b>v</b>	0	0	0	0	0		0	0	0			]
	_C	0	20	5	20	6	750	1	0	0	0	1	0	NA	0	0	0	NA	0	
	С	0	10	5	10	6	750	1	0	0	0	1	0		0	0	0		0	]
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13	С	0	50	5	20	6	750	1	0	0	0	0	0		0	0	0			

FIGURE 5 (Tests results for Fraser-Harlake 701 monitor on Boyle MS unit) The breathing circuit monitor built into the Fraser-Harlake 701 ventilator senses pressure in the bellows, and thus the sensor line kink test could not be performed. This monitor detected very few of the mechanical faults which may occur in an anaesthesia system.

tests were done in the hospital's surgical suites using clinical anaesthesia machines, ventilators, and breathing circuit components in general circulation. All devices met manufacturer's specifications and had fresh batteries installed before testing (where appropriate). The anaesthesia systems were connected to air-conditioning scavenging as in normal clinical use via 0.5 kPa "pop-off" valves. All tests were performed using medical oxygen as the pressurizing gas.

#### Results

## Fraser Harlake 701 on Boyle MS

A fixed-threshold pressure sensing BGI monitor is builtin to the Fraser-Harlake 701 ventilator. In the standard configuration, breathing circuit pressure is measured in the ventilator bellows chamber. (Alternatively, a flexible tube may be led from the pressure transducer to the patient connection.) The alarm activates unless a pressure over  $0.7 \text{ kPa} (7 \text{ cm } H_2\text{O})$  is detected within two breaths or 30 seconds maximum. No user adjustments to the sensitivity or delay time are possible. Tests were done on the standard (bellows) sensor configuration, and thus sensor line kink tests were omitted for this BGI monitor.

The Fraser Harlake BGI monitor detected fewer than one-fifth of the test conditions: complete patient disconnection, and most but not all disconnections or blockages of the fresh gas hose (Figure 5).

The Fraser Harlake system is typical of simple fixed-

threshold BGI monitors. Conditions which increase the breathing circuit pressure (such as kinked tubing, occluded patient connection and scavenging problems) could not be detected. Similarly, conditions which decreased breathing circuit pressure from the normal level but not below 0.7 kPa (leaks, and fresh gas disconnections where patient airway resistance was high) were not detected.

# Drager DPM-S on Drager Narkomed 2A

The Drager DPM-S BGI monitor has three fixed thresholds at 0.8, 1.2 and 2.5 kPa (8, 12, and 25 H<sub>2</sub>O) with a fixed delay of 15 seconds. The anaesthetist selects the highest alarm level less than peak airway pressure after the patient's ventilation is stabilized. The DPM-S will also alert the anaesthetist if airway pressure remains above 1.5 kPa (15 cm H<sub>2</sub>O) for more than ten seconds (continuing pressure), if it exceeds 6.5 kPa (65 cm H<sub>2</sub>O), or falls below -1 kPa (-10 cm H<sub>2</sub>O). The monitor is enabled whenever the ventilator is in use, and may be turned on by the anaesthetist during manual ventilation. In the standard configuration, the pressure sensing line is connected to the top of the carbon dioxide absorber between the patient connection and the expiratory oneway valve. In all tests the pressure threshold was set according to manufacturer's instructions.

Results of the tests on the DPM-S are given in Figure 6. The DPM-S detected more fault conditions than the simple fixed-threshold monitor as it was sensitive to high pressure conditions and to some of the leaks introduced

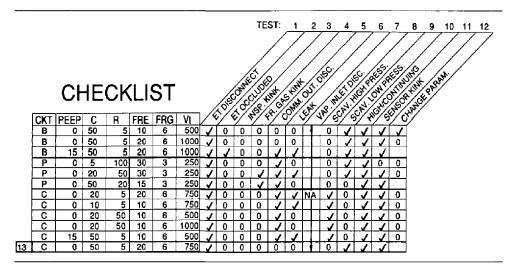


FIGURE 6 (Test results for Drager DPM-S on Narkomed 2A anaesthesia system) The Drager DPM-S monitor detected many more faults than did the single fixed-threshold type, but the results were less predictable. The anaesthetist must choose one of three threshold settings. Faults conditions which reduce airway pressure but do not violate the selected limit will not result in alarms.

into the breathing circuit. The DPM-S also alarmed when the patient connection was occluded in the presence of 1.5 kPa PEEP and detected some of the changing conditions between tests. However, the DPM-S did not detect most instances of endotracheal occlusion, kinked breathing circuit tubing, leaks, or scavenging circuit problems unless the high pressure limit was reached. The DPM-S was also slightly less able than the Fraser-Harlake 701 to detect problems with coaxial and paediatric circuits under certain set-up conditions.

# VGH patient circuit monitor (PCM) on Drager Narkomed 2A

The PCM was designed and built at Vancouver General Hospital following a fatal incident in 1979, when a patient undergoing carotid endarterectomy died following undetected disconnection of the breathing circuit at the patient connection. A Drager Narkomed I anaesthesia machine with DPM (no high, subatmospheric or "continuing" pressure alarms) was in use and correctly set at the time, and when tested immediately following the incident was found to be performing to manufacturer's specifications. It is likely that the disconnected end of the patient wye was partially or fully occluded by the pillow or surgical drapes, preventing a pressure drop, and possibly even increasing the maximum circuit pressure. The VGH PCM is a microprocessor-based device which samples and learns the pressure waveform corresponding to a properly connected patient, and alerts the anaesthetist to changes to

the waveform on a breath-by-breath basis. The PCM sensing line is connected between the patient and the expiratory valve, close to the patient connection.

A software algorithm in the VGH PCM monitor stores the normal breathing circuit pressure waveform, evaluates the ongoing waveform in terms of sets of absolute and relative criteria given in the Table, and warns the operator when the criteria are not met. Thus the sensitivity of the VGH PCM is dependent on the criteria in the Table; the specificity, or ability to tolerate normal waveform variations which are not faults, is determined by the values of the thresholds set for individual criteria. In the design of the prototype VGH PCM, the specificity was set to a level judged subjectively to be clinically acceptable. In the event that parameters of the ventilator must be changed or in the event that the patient's status changes significantly. a "store new data" switch on the VGH PCM can be depressed to cause the device to relearn or store a new pressure waveform as a reference. To prevent the storing of an abnormal waveform, the algorithm is designed so that a new pressure waveform cannot be stored as a reference in the presence of any alarm condition. Further technical information concerning the VGH PCM is given elsewhere.<sup>2</sup>

Figure 7 shows the results of tests done on the VGH PCM. In tests with a circle breathing circuit, the PCM detected almost all faults introduced; exceptions were negative pressure in the scavenging system, and one sensor line link. Other faults were detected on the next

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TABLE Criteria and atarm messages of the VGH PCM

Criterion*	Alarm Message
Internal malfunction monitor	Malfunction
Battery voltage <10.25 volts	Dead battery
Pressure >45 cm $H_2O$	High pressure
Pressure $< -8 \text{ cm } \text{H}_2\text{O}$	Negative pressure
Waveform period >30 second	Period >30 sec
In storing new data, 10 acceptable cycles are analyzed, but no two consecutive cycles are sufficiently similar	Inconsistent cycles
Maximum pressure in current cycle differs by more than 13% from that of reference cycle	Max pressure > reference or Max pressure < reference
Minimum pressure in current cycle differs by more than 17% from that of reference cycle	Min pressure > reference or Min pressure < reference
Period of current cycle differs by more than 17% of reference cycle	Period > reference or Period < reference
Inspiratory/expiratory ratio not between 0.25 and 4.0	1/E ratio > 4.0 or I/E ratio < 0.25
Inspiratory/expiratory ratio of current cycle differs by more than 25% from that of reference cycle	I/E > reference or I/E < reference
Two minutes have elapsed since was turned on without "store new data" switch being activated	Press "store new data" when ready

\*Note: Criteria are listed in decreasing order of priority.

breath. The PCM alarmed whenever patient variables were changed.

The PCM performed well in tests using a coaxial (Bain) circuit, failing to detect only some circuit leaks and one kinked line condition. In tests which simulated paediatric conditions, however, the PCM gave "negative pressure" alarms during tests with the patient connection fully occluded, and with the inspiratory or fresh gas hoses kinked, rather than the expected alarms. The negative pressure alarm on the PCM occurs whenever a pressure less than -0.8 kPa (-8 cm H<sub>2</sub>O) is sensed at any time during the breathing cycle, and has a higher priority than most other waveform messages (see the Table).

As may be seen from comparing the three sets of test results, the PCM was only slightly better than the other two monitors at detecting abnormal conditions existing before initiation of automatic ventilation (test 13). It would "learn" and accept baseline conditions which included a totally blocked patient connection, kinked hoses, leaks, high pressure conditions, and a blocked or completely disconnected fresh gas hose. The design of the PCM is such that the anaesthetist decides when the patient is properly connected and initiates waveform "learning"; incorporation of certain absolute limits on the initial waveform could improve PCM performance in detecting fault conditions existing at initiation of automated ventilation.

### Discussion

The series of tests described yields valuable information about the performance of BGI monitors in clinical use and covers the full range of mechanical problems reported in the literature. During development and refinement of the tests, a number of other fault conditions were introduced: patient disconnection with 50 per cent occlusion of the opening, kinks in the expiratory hose, vaporizer outlet disconnection and gross leaks due to disconnection of an ancillary device (such as an oxygen analyzer). The data provided by these tests was found to be redundant, as the results were always predictable from other tests. Specifically, there were no differences in performance seen whether the patient connection was fully open or 50 per cent occluded, whether a kink was in the inspiratory or expiratory hose, whether the vaporizer inlet or outlet was disconnected, or whether a leak was introduced at the patient connection or the site of an oxygen analyzer. Therefore, the latter of each pair of fault conditions detailed above was omitted from the final series. Similarly, the original series of tests included many more simulated patient resistance-compliance combinations; the values described are an optimized set which cover the range of usual variables and provide all the information obtained from the more lengthy and time-consuming series

Disconnection at the patient connection of a breathing circuit is one of the most frequent preventable anaesthesia mishaps. Endotracheal (ET) disconnections are so common, and so serious, that many anaesthetists routinely tape the endotracheal tube to the patient connection. Complete ET disconnection with no occlusion generally reduces circuit pressure to zero unless tubing resistance is high, as may occur in coaxial or paediatric circuits. All monitors tested were able to detect complete disconnection with no occlusion. Only the VGH PCM reliably detected endotracheal disconnections with 100 per cent occlusion of the patient connection. The Drager DPM-S did alarm in one such test due to violation of the high pressure limit. ET disconnection is especially serious in procedures of the head and neck, where the patient connection may be hidden from the anaesthetist's view by the surgical drapes.

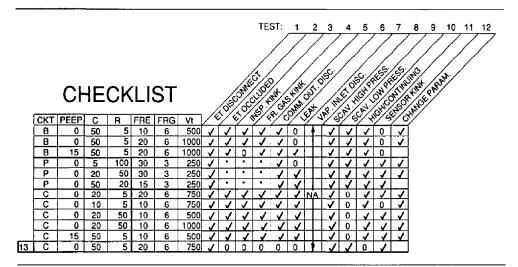


FIGURE 7 (Test results for Vancouver General Hospital PCM Drager Narkomed 2A unit) The microprocessor-based VGH PCM detected most fault conditions which occurred after ventilation was begun, but few which were introduced before ventilation was begun. This feature could be corrected with a software change, introducing absolute limits in ventilation parameters. During tests with a paediatric breathing circuit, the "negative pressure" message over-rode other messages (see text).

Kinked inspiratory and fresh gas tubing was generally not detected by either of the fixed-threshold monitors. Kinked tubes may result in decreased patient ventilation and may affect minute volume computations.

Leaks reduce circuit resistance and increase compliance, reducing patient ventilation. The Fraser-Harlake 701 alarm did not detect any leaks in this series of tests, as the breathing circuit resistance was sufficient to generate 0.7 kPa maximum pressure during ventilator cycling. The Drager DPM-S detected some of the leaks; the VGH PCM detected most but not all leaks during testing.

Disconnection at the vaporizer inlet is a special leak. The flow of oxygen and fresh anaesthetic gases to the breathing circuit is interrupted upstream of the common outlet, and room air may be entrained. At Vancouver General Hospital, all vaporizer connections have been secured so as to require special tools for disassembly, following a patient incident of undetected vaporizer outlet disconnection. As it is the intent of the test series to evaluate only faults which might reasonably be expected on a particular clinical system, this test was not done.

Disconnection of the fresh gas hose from the common outlet creates a large leak, greatly increases circuit compliance and alters the breathing gas composition. The Fraser-Harlake unit detected all such disconnections except when a paediatric circuit was in use; the Drager DPM-S detected all except with a coaxial circuit in the absence of PEEP. The VGH PCM detected all fresh gas disconnections.

Most hospitals now scavenge waste anaesthetic gases and direct them to the outside air via a dedicated controlled vacuum system or a non-recirculating air conditioning system. Passive systems (scavenging to air conditioning) incorporate a positive pressure relief valve. Active (regulated vacuum) systems typically include both positive and negative pressure relief. Occlusion of a passive system downstream of the relief valve may expose operating room personnel to potentially harmful gases and vapours but generally does not increase the risk to the patient. Malfunction of an active system may expose the patient to high positive or high negative pressures in the breathing circuit, both undesirable conditions. The Drager DPM-S and VGH PCM both detected high scavenging pressure conditions but not negative scavenging pressure conditions using the circle breathing circuit. The PCM detected high and low pressures with the coaxial and paediatric circuits; the DPM-S gave mixed results. The Fraser-Harlake alarm failed to detect any scavenging problems.

High or continuing pressures in the breathing circuit may be caused by flowmeter leaks, circuit obstructions or mechanical malfunctions, and may lead to decreased patient ventilation or lung barotrauma in extreme cases. The DPM-S and PCM devices performed well in this test; the Fraser-Harlake alarm was incapable of sensing a problem.

The optimum site for sensing airway pressure is close to the patient's ET tube; this site also makes the connecting tubing more prone to obstruction by condensed water vapour or by kinks. Both BGI monitors tested with accessible tubing (DPM-S and PCM) detected sensor line obstructions most of the time.

In most cases, patient resistance and compliance during surgery remain relatively constant. Changes large enough to affect the airway pressure waveform may indicate a problem either with the patient or the anaesthesia system and should be detected by a BGI monitor. The VGH PCM detected most changes; the DPM-S detected a few; the Fraser Harlake detected none. None of the monitors gave any alarm indications in the absence of a fault condition during the tests.

One of the most difficult conditions for BGI monitors to detect is a fault which exists before automatic ventilation is initiated. Most monitors require a baseline "normal" condition for reference. In theory, pre-existing faults are detected by the anaesthetist during pre-use machine checks. In practice, checks are seldom as extensive as those recommended by the manufacturer and are most often done upon first arriving in a room rather than before each case. None of the BGI monitors tested was particularly good at detecting baseline faults, although this could be corrected in the VGH PCM with software revisions.

The tests described provide the hospital with BGI monitor performance data under all foreseeable mechanical system failures, and can be performed in about an hour. The tests will not evaluate errors in gas composition, as caused by pipeline problems, flowmeter leaks, or improperly set controls, and will not evaluate performance under conditions of operator error, such as disabling the BGI alarm.

The current test series does not simulate neonatal and worst-case paediatric conditions. Neonatal compliance values can range from 2 to 50 ml·kPa<sup>-1</sup> (0.2 to 5 ml·cm<sup>-1</sup> H<sub>2</sub>O); resistances can be 0.1 to 4 kPa·L<sup>-1</sup>·s<sup>-1</sup> (0.001 to 0.4 cm H<sub>2</sub>O·ml<sup>-1</sup>·s<sup>-1</sup>). The lung simulator used during test development had a minimum compliance value of 100 ml·kPa<sup>-1</sup> and minimum non-zero resistance of 0.5 kPa·L<sup>-1</sup>·s<sup>-1</sup>. However, using the neonatal/paediatric lung simulator described in the CSA Preliminary Standard<sup>3</sup> and an anaesthesia ventilator equipped with a paediatric bellows, development of a suitable test regimen is available to hospitals which perform neonatal and paediatric surgery.

Applications for high frequency and jet ventilation are not addressed in the standard. However, a similar test series incorporating faults known to occur with these modes of ventilation could be developed.

### Conclusion

A simple, comprehensive series of tests which evaluates the performance of BGI monitors on clinical anaesthesia systems has been developed, based on clinically observed and realistic fault conditions. The tests are designed for use by hospital personnel, as tests performed by manufacturers under laboratory conditions cannot give full information on monitor performance once the unit is integrated into an anaesthesia system. The tests form the basis for Canadian Standards Association preliminary standard Z168.10 "Testing of Breathing Gas Interruption Monitors for use During Anaesthesia," which is designed to promote the development of improved devices to meet the needs of anaesthetists. Comments on the preliminary standard are solicited from clinical personnel.

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#### Résumé

Chez un patient ventilé l'interruption de l'apport des gaz par déconnection accidentelle ou un malfonctionnement du circuit anesthésique peut avoir des conséquences sérieuses si elle n'est pas détectée rapidement. Une série de tests qui couvre les problèmes mécaniques possibles a été développée et utilisée afin d'étudier la performance de trois moniteurs de détection de débit de gaz dont deux sont commercialement disponibles et un développé à l'Hôpital Général de Vancouver. Les tests ont été planifiés afin d'évaluer la performance de ces moniteurs installés sur les machines d'anesthésie dans différentes conditions de bris de circuits incluant la déconnection du tube endotrachéal avec ou sans occlusion de l'ouverture, une coudure des tubulures de gaz frais et inspiré, une déconnection de la tubulure de gas frais, une fuite dans le circuit, une pression excessivement haute ou basse dans le circuit de scavenging, une pression élevée dans le circuit inspiratoire, et une coudure dans le tuyau détectant les variations de pression du circuit. La possibilité de détecter des changements significatifs dans les puramètres de ventilation et des erreurs à l'initiation de la ventilation était aussi étudiée utilisant des circuits pédiatriques, coaxiaux et systèmes circulaires.

Seulement une déconnection du tube endotrachéal sans obstruction de l'ouverture était détectée avec fiabilité par tous les moniteurs. Un moniteur commercial avec un seuil fixe du niveau d'alarme à détecté l'interruption du débit de gaz frais dans le circuit circulaire et coaxial adulte, mais n'a pu déclencher l'alarme en réponse à d'autres bris du circuit. Un moniteur avec des seuils de pression variable a détecté un peu moins que la moitié des conditions du bris de circuit. Un moniteur basé sur un système de microprocesseur développé à l'Hôpital Général de Vancouver a détecté et correctement identifié approximativement 80 pour cent des bris du circuit.

Cette série de tests constitue la base pour l'Association Canadienne des Normes (Z168.10) et permet aux hôpitaux de tester la performance des moniteurs utilisés dans leurs institutions. Des commentaires sur la série de tests sont sollicités.