

THE NEW GENERATION ANAESTHETIC MACHINE

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Disclaimer – the author is a design and development consultant for Dräger. He has no other financial interest (shares etc) in Dräger or any other medical equipment company.

Background

All of a sudden we have these new machines, they're all different, we don't know what's inside them or how they work, they have lots more alarms, we feel uncomfortable using them, and we had no role in selecting them.

It was all a lot easier when everyone had a Boyles Machine with an Ulco ventilator, wasn't it?

Just 15 or 20 years ago, trainees were taught all about the machines of the day. We learned all about the gas path, from the VIE's, down the pipelines, to the machine and thence to the patient. We knew that there were indexed gas fittings for the hoses and that the cylinder connections were made safe by pin indexing and colour coding. We were taught about how the regulators and rotameters worked in great detail. The internal plumbing of a Boyle's machine was easy to understand. Whether or not gas was flowing into the circuit was immediately obvious, and it was easy to tell if a cylinder was empty. The breathing system was easily understood and all the connections were visible and easily checked. Switching from a bag to a ventilator was intuitively obvious; you just disconnected the bag, closed the APL valve, plugged the hose on to the ventilator, and turned it on. There was a Howison type oxygen supply failure alarm, a pressure based ventilator alarm, and an oxygen analyser. That was about it.

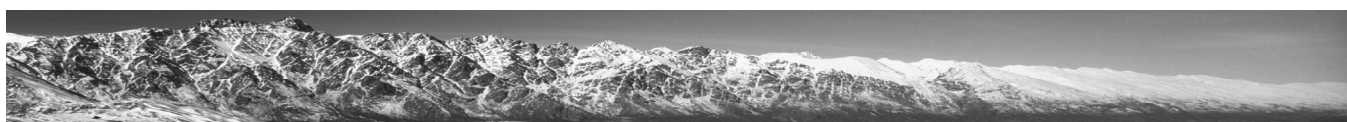
We understood what might go wrong – and how to fix it.

We felt comfortable with these machines because they were simple, their inner workings were understood with a high level of detail and clarity, and because they were all basically the same.

'Anti-hypoxia devices' were the beginning of the end. These mechanically complex and somewhat unreliable additions required second stage regulators and fiddly little components that were tedious to adjust to keep working properly. Most of us had a vague idea of how they worked but didn't appreciate their complexity or the additional hazards they brought to the machine. The bag / vent switch then added another level of complexity. Then international standards mandated monitoring of exhaled volume, and automatic sustained high pressure alarms even in man / spont mode. Bit by bit the complexity of the machine grew and grew, and mechanical solutions became more and more complex and expensive.

At the same time, digital electronic alternatives to mechanical devices became cheaper and more reliable. Calibrated rotameters became costlier than electronic gas mixers. Machines incorporating electronic mixers would prove to additionally provide a huge number of practical benefits over manually-adjusted rotameters, not all of which were anticipated. These included –

- The controls can't be accidentally bumped
- Output can be more precisely adjustable
- Desired values are able to be pre-set
- Current values can be 'held' and 're-activated'
- Confirmation of flow be displayed in novel ways
- Automatic self-testing of the machine for leak
- Quantification of leaks and inefficient gas supply usage
- Delivery of constant fresh gas flow despite variable line pressures (no need for second-stage regulators)
- Provision of automatic leak compensation
- Inclusion of 'smart' anti-hypoxia functionality
- Continuous self-check of the actual delivered gas flow



- Provision of alarms when problems arise
- Prediction of future circuit gas composition
- Provision of feedback control over gas flow and composition

The advent of cheaper computers and flat screens, robust and accurate sensors (many flowing on from industrial, aerospace and automotive applications), cheap programmable micro-controllers, robust two-channel computer control safety algorithms, and finally the development of graphically rich graphical user interfaces all made the shift to fully electronic machines inevitable.

At the same time, ICU ventilation capabilities increased, and machines that could better support spontaneous breathing and provide ICU ventilator performance in the operating room became more desirable. Some companies re-designed the breathing system to more closely emulate the performance of an ICU ventilator, because it is difficult to get low-resistance flow-responsive breathing systems with the conventional anaesthesia circuit. Just about all the suppliers revamped their ventilators to at least provide the same 'modes' as offered in ICU ventilators, even if they didn't quite have the same underlying performance.

Only in the last 10-15 years have all these factors converged. The result is a massive change in the technology underlying anaesthetic machines.

The new machines are increasingly becoming 'black boxes,' poorly understood at the most fundamental level. We no longer understand their internal workings. We don't know how the gas mixer works, and we sometimes feel uncertain about whether the gas really is flowing. How do we know if the numbers on the screen are actually what is happening? How do we know if the computer running the machine is working properly? When the machine makes all those alarm messages we've never seen before, what should we do?

If something goes wrong with the machine during the case, our professional responsibility is to know enough about it to promptly follow the appropriate corrective actions. We therefore have the unenviable task of learning about each of the new anaesthetic machines from the ground up.

Factors to Consider When Evaluating a New Anaesthetic Machine

When a new machine is released, it's different from when a new drug is released. New drugs are carefully studied by independent researchers, and the companies give us lots of information as well. As a result it's easy to figure out how and when to use a particular drug soon after its release. If it's not helpful, it's easy to not use it any more. But new anaesthetic machines are totally different. There is no reliable independent review or assessment service available to us. Once they're purchased, we are stuck with them for a long time. All too often, equipment purchases go to whatever machine is cheapest that meets the specification. But who writes the specification? What should be in it? Clearly it's difficult for people with limited experience of electronic machines to write a tender document that would get them the best machine. Some tenders are written by biomedical engineers or administrators. How does a tender get written that effectively values a clear, intuitive user interface, or a breathing system that better supports spontaneous breathing? Who should evaluate the machines? Should the clinicians or the administrators have the final say?

Some might argue that they all the same, like Boyle's machines. Are the differences between them clinically irrelevant?

That question can be best answered, perhaps, by identifying the differences, thinking about which differences really matter, and finally deciding how we would identify them.

I've personally been a close participant in the development of three new electronic anaesthetic machines, all by Dräger – the Primus, Zeus and Perseus – over a period of almost 20 years. I've assisted with safety concepts, algorithms, display technologies, alarms and so on. During this time I've reached a number of conclusions of particular relevance to people seeking replacements for old machines, and the purpose of this talk is to share them with you.



1. Choose a Manufacturer That is Likely to be Around in 10 Years Time

To design and manufacture a state of the art anaesthetic machine is very costly indeed. Development costs run into many hundreds of millions of dollars. Large companies benefit from economies of scale. It's sensible for them to invest large sums of money in the development of sophisticated, reliable and specialised electronic components only because they know they will sell a lot of them. Smaller manufacturers must use simpler components and often must compete for the 'low end' of the marketplace. They will face a lot of competition from Chinese manufacturers in the years to come, and it will be tough.

2. Up-front Cost Should Not Be the Main Issue

A typical anaesthetic machine would do between 10,000 and 20,000 anaesthetics in its lifetime. The acquisition cost per case is therefore small, much less than the disposables and drugs required for the case, let alone all the surgical and labour costs.

If a new machine prevented one significant adverse outcome in its lifetime it would pay for itself many times over.

The extra cost per case between the new machines on the market is very small.

Administrators always worry about purchase price, and it is important that they factor in savings related to reductions in adverse outcomes. Potential cost savings from reduced volatile agent or oxygen consumption, fewer ICU admissions, etc are typically much greater than the cost of the hardware.

Clinicians should not, in my opinion, worry greatly about cost. We are the patient's advocate. No-one else is. If a particular monitor, ultrasound machine, or anaesthetic machine seems to be markedly better from a clinical perspective than the others, the additional per-case extra cost of having that 'better' machine is trivial over the life of the machine. We should try our best to get the best equipment to care for our patients. This will only happen when clinicians are integral to purchasing decisions.

3. Basic Ergonomics

This is very important; after all, you'll be working with the machine for the next 10 years or so.

Where does the sucker go? What happens if we have to use the machine the other way around? Is there enough desk space to put the notes, the phone and your laptop? Is it easy to clean? Easy to move around? Are cable guards integrated into the wheels? Where does the breathing bag go, and all those cables? Can you reach all the controls while seated? Can the screens swivel to face you? Can you reach the ventilator controls easily on induction? Where do we fit an extra computer screen, or some additional monitoring?

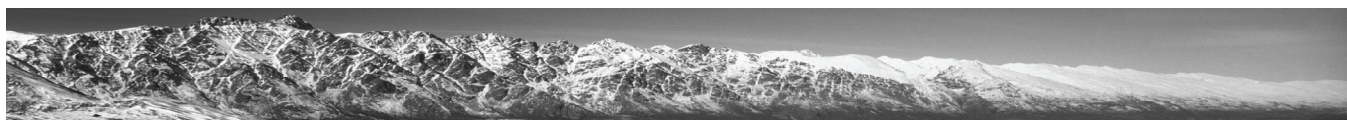
All these issues are not 'new.' Some 'new' machines were so focused on design or technology that ergonomics was not their strong point. We should expect a return to more ergonomically appropriate designs as technology becomes less of a differentiator.

4. User Interfaces

Electronic machines have complex graphical user interfaces. Some are far more sophisticated than others.

The specifications of new machines generally list a range of features. Most machines have 'similar' feature lists but very different levels of technical, ventilator performance and user interface sophistication.

User interface 'superiority' cannot be readily evaluated by a standard tender process that just lists 'features.' A good user interface is intuitive, consistent, and easy to read at a distance, easy to understand, easy to operate, free from needless alarms, readily customised to suit different user expectations, and readily upgraded. It helps you get where you want to go quickly and efficiently and is a pleasure to use. It's important to define these factors in the tender documents, figure out an evaluation process, and ensure they receive a significant weighting in the decision making process.



Who should actually take part in a User Interface (UI) assessment process? Clinicians will always favour 'familiar' user interfaces over 'new' user interfaces – even if the old 'familiar' interface may prove to be very limiting down the track, it will often 'get the nod.' When evaluating machines, it can take months or even years to really get comfortable with an entirely different user interface. Sometimes the evaluation group should be a subgroup of the more visionary, lateral thinking and technologically savvy anaesthetists in a department. Remember that you are buying a machine that you'll still want to use 10 years down the track.

First up, before the trial, someone has to go through all the configuration options and set the machine up the way that is likely to work best in your department. Many electronic machines are highly customisable. Figure out in advance which alarms should be 'active' in each mode, and what the alarm set points should be. Touchscreen interfaces are often full of tricks and shortcuts. Find out what they are in advance. Make sure that each machine is set up in what you think is the simplest and most approachable way.

If after an introduction to the machine, there are any UI aspects you think might be improved, and so long as the tender doesn't prevent you doing so, seek out the manufacturer's feedback on each point. There may be a way to modify that behaviour, or in case there are shortcuts or work-arounds you don't know about, or if a software update is on the way to address that particular issue.

Having all the trial machines available in the department at the same time, to directly compare the user experience of one machine directly against the other, can be very effective. Get them all in the same room, and do the same things to each of them. Find out which responds most quickly and intuitively and is easiest to use. Rate things like –

- Start-up time
- The self-check 'experience' when there is a leak or a loose vaporiser or an empty cylinder
- What happens when the oxygen supply fails
- What happens when the electrical supply fails and when the internal backup supply fails
- If the screen organised logically
- Whether the display is legible at a distance
- Are the trends clear, legible and helpful?
- Are the waveforms of flow and pressure detailed and accurate?
- Does the machine display loops, and if so how well are they displayed?
- Is it obvious which numbers are 'monitored' values, and which are 'settings'?
- Whether in one glance we can confirm that it is working 'normally'
- Can we easily tell which mode the machine is in?
- How easy it is to switch from man / spont to PS and back
- How sensible are the alarms, eg for a leak or a disconnection

Try doing the everyday tasks you'll do every day, like starting and stopping cases, switching ventilator modes, dealing with alarms, and find out which machine lets you do these things most efficiently. Think about things you might not do now, but may do in the future, such as ending every case or even inducing every patient with pressure support, using very low flows (and having to deal with leaks in low flow settings), using feedback control, looking at trends or loops, etc.

Have a robust discussion about how each machine manages a particular issue and decide which you think is best.

Make a list of all the factors that seem to differentiate between the machines, do a 'secret ballot' style formal UI assessment after a sufficient evaluation period, and ensure that the outcome of this evaluation is part of the tender process.

5. Ventilator Capabilities

Most modern machines provide 'new' ventilation modes such as pressure support (PS) and pressure control. Some also include volume-preset pressure control (auto-flow) type modes, where the machine attempts to deliver a fixed tidal volume but with a constant pressure during inspiration. Some may provide 'mandatory minute volume' or other ICU type modes.

Technically it is not particularly difficult to implement these modes on even a simple machine. There can be very significant differences in how effectively these ventilation modes are implemented from machine to machine,



particularly when it comes to supporting spontaneous respiration in such patients. So in a tender situation, a simple list of modes isn't enough to differentiate between machines that can actually perform very differently.

How then can we identify the differences in ventilator performance? It's actually very difficult. There are no particularly helpful papers in the literature.

Manufacturers with a core competency in ventilation are likely to get the ventilation part of a machine 'right,' but that is a generalisation that can't be applied to a tender process.

Pressure Support is probably the most useful new mode of ventilation. Well implemented, it markedly improves ventilation during spontaneous breathing anaesthesia. Adding PEEP should actually provide the benefits of CPAP during spontaneous breathing, and can minimise airway obstruction on induction due to negative intra-pharyngeal pressures.

Some of the things that need to be considered when evaluating a machine's ability to provide effective pressure support include –

- Ease and reliability of triggering, eg for very small children
- Peak inspiratory flow rate
- Time to achieve peak inspiratory flow rate after a trigger
- Time to drop airway pressure after end-inspiration is detected
- Inspiratory flow resistance
- Expiratory resistance
- Resistance compensation

A machine that performs a little bit better on each of these parameters can be much better overall at supporting spontaneous breathing.

When supporting spontaneous breathing, the machine must detect inspiratory effort and respond immediately by increasing circuit pressure to the desired support level. There should be no detectable 'blockage' or 'delay' in providing that increase in pressure. Delays in response can be seen as a fall in airway pressure at the start of inspiration. If a machine cannot deliver flow fast enough, the patient will feel difficulty breathing in, and not get the reduction in inspiratory effort that we are seeking.

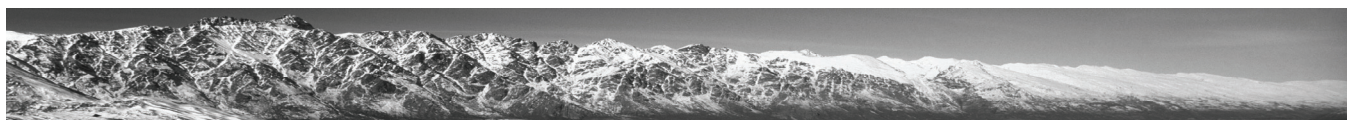
At the end of inspiration, the machine must accurately detect the loss of inspiratory effort, and rapidly open a low-resistance exhalation pathway. Any delay in detecting the end of inspiration and any significant expiratory resistance will add considerably to work of breathing, and reduce the overall effectiveness of pressure support modes.

Generally most machines do a satisfactory job in pressure support modes for relaxed breathing in healthy patients. Not all machines, however, are able to effectively assist someone who is gasping for breath, or for infants at high respiratory rates, or patients in respiratory failure, for example.

Fortunately it is relatively easy to compare, in an A-B fashion, any two machines. Put a filter on each machine, block your nose, sit comfortably in a chair, and configure each machine with identical settings. First breathe normally in Man / Spont. Become familiar with the inspiratory and expiratory resistance of each machine. Note that expiratory resistance increases when the bag gets full, and is very uncomfortable if the APL valve is partly shut. Then swap to Pressure Support mode with, for example, 5 cmH₂O of pressure support and 2 cmH₂O of CPAP / PEEP. There should be an obvious improvement in the level of perceived resistance to both inspiration and expiration, although CPAP feels strange at first. Compare the two machines. The same settings on one may be much more effective, in practice, and not the other. Try rapid shallow gasping inspiratory efforts, and get a feel for how quickly the machine responds. A good machine will effortlessly and 'invisibly' support your breathing and make it easier.

Although it's not so easy to test, not all machines trigger reliably in small children. You can try making very shallow respiratory efforts. In clinical practice, some machines will easily manage 10 kg children on adult circuits, others won't.

Also find out what happens in Pressure Support mode when the patient becomes apnoeic for a time and then starts breathing again. This happens often in practice. Does the machine stay in the same mode, or switch to another mode? Do you have to do something, like respond to an alarm? Does the machine alert you in a sensible,



helpful way? If they start breathing again, does the machine get back to pressure support or does it remain stuck in some other mode?

Finally, is it easy to select a given mode, and switch to another? How are the default settings altered and stored. Is there a 'pause' mode? Are settings shared across the modes sensibly? A machine that requires several key presses to get from one mode to another can be frustrating to use. All these small details make a big difference to the usefulness of a 'feature' on a machine.

Our ability to effectively manage people with respiratory failure is made much easier if we have a machine with ICU quality ventilation abilities. A machine with excellent spontaneous breathing support makes supported ventilation techniques much easier than ever before. It sometimes takes quite a while before you realise how good a job you can do. Before I learned how to use effective pressure support and CPAP in spontaneously breathing obese patients, I would not uncommonly get a phone call from Recovery saying, "Your patient's saturations are only 89-90%, what do you want us to do." These days it just about never happens.

If you do A-B testing, it is usually fairly easy to rank the machines in terms of how effectively they support spontaneous breathing, and how easy it is to use the new modes in practice.

6. Feedback Control of Vapour Delivery

Feedback control of inspired oxygen and volatile agent concentration in the circuit, particularly at low or minimal flow during the maintenance phase of an anaesthetic, has a number of attractions. The main benefit is to reduce the annual cost of volatile agents. This benefits the hospital. The benefits to us and the patient include more stable agent and oxygen levels, less 'drift' over time that requires correction, and smarter anti-hypoxia systems that can target end-tidal oxygen, for example. However they add a number of hazards to contend with to gain those benefits, and the technical challenges in dealing with them are considerable.

The major manufacturers all have machines with feedback control capabilities in an attempt to make low flow or closed circuit anaesthesia safer and easier. First let's think about feedback control of volatile agent.

Administrators may be inclined to assist with the purchase of an expensive new machine on the basis that it will save a lot of money on volatile agents. If feedback control is effective and easy to use, such that a significant proportion of the department's staff will use it, then you should anticipate saving money on volatile agents.

Savings won't be effectively realised in rapid-turn-over type cases, because highish flows (and / or concentrations) are still required at the beginning of the case to 'load' the patient. Conversely, greater savings will accrue when longer cases are the norm.

Using sevoflurane throughout the case at minimal flow requires a low-hydroxide type CO₂ absorbent that makes little or no compound A. Fortunately these are now easy to obtain. I'm not sure it makes a lot of sense to switch back to isoflurane for feedback control, because it doesn't have such an ideal offset characteristic in long cases. Feedback controlling desflurane, particularly to end-tidal values, puts special demands on the controller algorithm to avoid abrupt and significant increases in inspired desflurane levels.

Feedback control of volatile agent adds greatly to the software complexity of the machine, and probably requires additional hardware (backup or 'second channel' agent and oxygen analysers) as well.

I personally think that it is essential to have two independent gas analysers in the machine, one to do the feedback control, and an independent analyser to measure the circuit concentration from a monitoring or checking perspective. If the same gas analyser is used for both monitoring and control, and that single transducer drifts or becomes faulty, then the anaesthetist will get no warning that the agent concentrations are in fact not being delivered correctly. The analyser doing the feedback control may operate from the sample line at the Y-piece, but if, for example, there is air entrainment via a leak in the sample line, then the control mechanism would start to overdose the patient, and the data presented to the operator would give them no clue as to this error. The only way that the operator would know about this problem would be if there was a second gas analyser internal to the circuit that confirmed that the mean agent concentration in the circuit was not consistent with the mean concentration at the Y-piece. If the two didn't match sufficiently, the machine should stop trying to do feedback control. Without an independent 'second channel' to monitor the controller, the risk of a dangerous failure is



unacceptably high. The additional agent analyser in the circuit adds to the cost of the system, and can itself drift or fail.

Alveolar deadspace causes end-tidal gas to look more like inspired gas, and this may cause an end-tidal feedback design to under-administer anaesthetic agent while increasing volatile concentration, though not to a huge extent in most cases. In steady state there would be little or no effect. Likewise, 'smart' anti-hypoxia devices that target end-tidal oxygen may over-estimate functional alveolar oxygen. If the anaesthetist knows that high levels of alveolar deadspace are likely, they can evaluate end-tidal anaesthetic agent or oxygen levels more critically than automated controllers.

If a blower is present in the circuit to provide continuous basal mixing of the vapour in the circuit, it is possible, though difficult, to get prompt and stable control of anaesthetic concentrations in the circuit, at near-zero flows, even when the patient's tidal volumes are small or if the patient becomes apnoeic. Without a blower, and if the agent concentration is controlled at the Y-piece, there can be delays from agent delivery into the circle and when those gases reach the analyser, and these can cause instability.

Conventional variable-bypass vaporisers – including the Aladdin cassette system – have a limit on the maximum output vapour concentration, and therefore cannot deliver vapour under true closed circuit conditions. To deliver vapour at zero flow, a direct vapour injection type vaporiser such as on the Zeus is required, and this is a complex and specialised vaporiser.

The vaporiser used in a feedback control system must be electronic, and therefore vapour delivery is impossible without electrical power. This is kind of obvious, and is an acceptable hazard unless there is a reasonable probability that the power may fail for a long time, such as an unintended extended power failure or in a disaster type situation. In these situations, mechanical vaporisers can be used on some machines with manual ventilation for extended periods of time without any electrical power. In reality, however, this is not a practical issue; not much surgery can be performed without electricity, so without electricity we might as well just close up and wake the patient up anyway.

Additionally, the gas blender must be electronic, because the machine may have to increase flow to wash agent in or out to keep the agent concentration where you want it, and then return it to a lower number under some kind of algorithm. Again, this is self-evident and not a particular drawback in a practical sense, particularly if the machine provides and emergency gas flow through a vaporiser that can be used with hand ventilation.

The user interface must clearly indicate whether or not you are in manual control mode or feedback control mode, and whether it is controlling inspired or expired values. Confusion over the mode of operation of the machine can be a safety issue. When using desflurane, the maximum inspired concentration the machine may generate in the inspiratory limb of the circuit when a step increase in the desired exhaled desflurane concentration is requested. You also need to know what happens to gas flows when a reduction or increase in agent concentration is requested, and how that may affect inspired oxygen or nitrous.

As for volatile agents, feedback control of inspired oxygen requires a second sensor independent of the gas sample line sensor used to monitor inspired / expired oxygen, and this sensor must be internal to the breathing system and independent of the gas sample line. Without that second sensor, the machine is intrinsically very unsafe, in my opinion.

Having the gas continuously circulated in the breathing system by a blower greatly simplifies feedback control of oxygen. It is particularly important in spontaneous breathing modes, should apnoea occur.

The need to tightly control oxygen around 30% more common in the past when nitrous oxide was intended to provide the majority of the anaesthetic. This technique is becoming archaic, and the most common carrier gas in our institution is now air. Controllers capable of tightly controlling inspired oxygen with nitrous as a carrier can be a challenge to design.

The optimal inspired oxygen value for anaesthetic maintenance in air is debatable. Eighty percent has been suggested to reduce infection rates, and 30-40% in air to minimise collapse. Hypoxia due to V/Q inequalities should be almost completely eliminated with inspired oxygen levels of 40% or more. Tight control of inspired oxygen during anaesthesia is probably only required for premature neonates and people particularly susceptible to hyperoxic damage, eg after chemotherapy.



To make a rapid change in oxygen concentration while at low flows, the machine must increase gas flow. If agent control is active at the same time under very low flow conditions, and if variable bypass vaporisers are used, the internal set point for the vaporiser will have to be turned down a great deal from the previously stable setting and the new value won't be obvious to the machine. The user needs to be aware of how the machine reacts to step changes in oxygen set point, and what effect that will have on vapour delivery.

It's interesting that the Dräger Perseus, the latest machine from Dräger, does not have feedback control of agent or oxygen, despite Dräger's extensive experience with feedback control in the Zeus and the fact that the machine has a blower and electronic gas delivery that 'should' make it easy. Not implementing feedback control in the Perseus has simplified the design of the machine, both from a software and hardware perspective, and with it the user experience. The vaporiser may be used with man / spont mode for prolonged periods without any electricity, and this is important in some markets. The Perseus can predict, based on measurement of uptake and pharmacokinetic modelling, what the likely future equilibration values will be for agent and oxygen, in near real-time as you adjust the settings. This can be a very useful guide to setting the vaporiser and the inspired oxygen at low flows. The intent is to facilitate the use of very low flows by minimising the number of adjustments required to get where you want to be, without the hazards and cost of feedback control.

It will be interesting to see whether the advantages of feedback control of agent using variable bypass vaporisers at very low flows proves to be a success in the marketplace. A lot will depend on reliability, field experience and user interface issues. Most likely a good controller would be very useful especially in longer cases, and would probably save money. There is limited experience with 'future prediction' technologies as in the Perseus, so we just don't know at this point whether it will be almost as useful as feedback control or not.

7. Integration with IV Pumps

Propofol, narcotic and relaxant infusions are commonplace in modern anaesthetics. The smooth integration of pumps into the anaesthetic workstation would be a big step forward. It hasn't happened mostly because of the simple fact that no anaesthetic machine manufacturer make their own pumps.

Often the user finds that there is nowhere to effectively put the pumps on the machine and not enough power points on the machine to provide power to them.

It makes sense to be able to control, record, and monitor a propofol infusion in a manner not dissimilar to a volatile agent. Some new machines do properly integrate data from pumps into their data architecture, and some permit control of the pump from within the user interface of the machine. I remain frustrated that better IV pump integration has not become a mainstream focus of the anaesthetic machine manufacturers.

The Dräger 'Smart Pilot' is one manufacturer's attempt to display drug interactions, both volatile and intravenous, in a clinically helpful manner. The system collects data from syringe pumps, the anaesthetic machine and the monitor automatically.

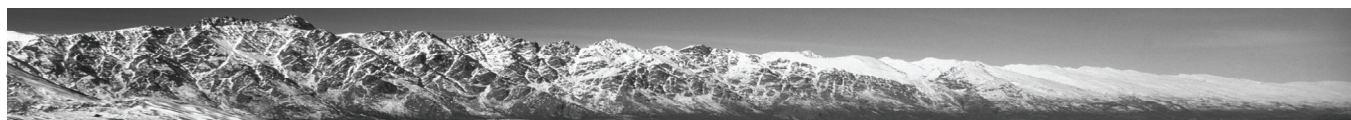
In the future we may be able to choose any point in a two-dimensional touch-screen space to set the desired 'anaesthetic / hypnotic' and 'narcotic / analgesic' levels required for our patient, and have the machine dutifully do whatever is needed to get us to that point, using feedback control of vapour and TCI algorithms for the IV agents. At the same time the machine could calculate the predicted wake-up time, and fine-tune the pharmacodynamic estimate with data from the BIS or Entropy monitor.

But for now the level of IV pump integration is something that can be done better by most manufacturers.

8. Neonates and Paediatrics

The use of a T-Piece circuit with uncuffed tubes for premature babies and neonates remains standard practice.

Not all the new machines support ventilation through a T-piece, and if this is important to you, then make sure it is possible. All support an external 'common gas outlet' to which a lightweight T-piece may be connected for hand ventilation on induction, and all are capable of very precise pressure and volume control ventilation with quite light-weight circle circuits.



Increasingly, infants are being induced and managed on circle systems with lightweight hoses and being intubated with cuffed tubes. Volume control ventilation as for adults is now quite easy. Pressure support can be very effective with children. It's surprising to see a 10 kg child breathing effortlessly on an adult circle system while triggering pressure support without any difficulty!

Rise time when increasing volatile agent differs slightly amongst the new machines, depending on their circuit characteristics. GE machines have 'conventional' circle systems that behave like Boyles machines. In Man / Spont modes, most machines are much the same. The Dräger Primus has a piston ventilator in the inspiratory limb of the circuit. In Pressure Support and other control modes, the fresh gas has a greater time constant because it has to mix in the piston before getting to the patient. It makes very little practical difference in adults, but with small tidal volumes in children there can be a noticeable lag between dialling up the vaporiser setting and seeing it at the Y-piece. Dräger's newer Perseus machine has a low-deadspace blower instead of the piston which additionally provides a continuous basal flow around the circle, so it is now faster than any of the Boyle's type machines.

9. Oxygen Consumption

Machines with electrically-driven ventilators require much less oxygen than those with oxygen-driven ventilators. For example, when ventilating an adult to normocarbida at 500 ml/min FGF and a 50% inspired target, an electrically driven ventilator would only require about 0.4 L/min of oxygen, whereas a demand-valve oxygen-driven ventilator would typically consume 6-7 L/min and a venturi type oxygen-driven ventilator may use 15 or more. Oxygen is cheap, but if the mains oxygen supply fails, your cylinders will last a lot longer with an electrically-driven ventilator.

10. Computers and Micro Controllers

Increasingly, ventilators, monitors and anaesthetic machines are being programmed on computers using specialised versions of desktop operating systems. We all know that domestic computer operating systems can crash unexpectedly. So how do we make an anaesthetic machine 'safe' if we use a similar operating system?

The answer is not to use more reliable software. No software is perfect.

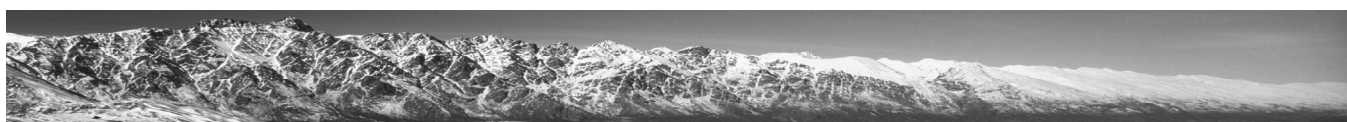
The usual design requirement is to assume that a thread or even the whole computer will crash and figure out how to manage that effectively.

A reliable design uses two separate computers and a bunch of micro-controllers. A micro-controller is the dedicated 'computer on a chip' that for instance operates the modern electronic watch, clock radio, or even your car. It has a set of instructions that it must loop through; if it 'freezes' and doesn't get to the end of the instruction within a certain time, it automatically resets itself and starts again from the top. These things are super-reliable. They can have any number of analogue inputs and outputs.

In a modern machine, there will be a dedicated micro-controller driving the ventilator, one on the gas bench, one on the power supply management board and another one decoding user interactions like when you click a button or press a knob. These micro-controllers are 'free-running' or autonomous to some extent. Usually they 'talk' over an internal network, getting instructions from the main computer, and reporting back to it all the time.

The use of micro controllers makes things much simpler for the main controlling computer. For example, the computer simply tells the ventilator micro controller to deliver a certain tidal volume in a certain mode, so that it does. The ventilator echoes the instructions back to the computer, to be sure it heard the message right, and also reports waveforms, measured values, and so on back to the computer for display on the screen. The ventilator micro controller can be highly optimised in ways that the computer cannot.

The key thing is that there is a verified two-way communication between the ventilator or gas bench controller and the main computer. The main computer focuses on how to draw the screen, how to manage trend data, integrating data, managing alarms, and the micro-controllers do the tedious repetitive stuff with a limited code base that is highly optimised and very unlikely to crash.



To guard against the main computer 'freezing' without any alarms being generated, a second CPU running a specialised monitoring application that 'supervises' the main computer is required. This provides the second channel of safety required by the standard. The 'supervisor' computer gets the same inputs as the main computer because it is connected to the same network, so it receives all the same user inputs and all the feedback from the micro controllers. Additionally it monitors the screen display driver memory and uses algorithms to ensure that the content of that display is what it should be by reverse-engineering the characters on the screen. It does all the calculations performed by the primary CPU and should reach the same conclusions. If the two reach different conclusions, the monitoring computer decides what to do. It may require the main computer to reset the ventilator or enter a 'failsafe' mode, but if the main computer is not responsive it may reset the main computer and take over the user interface until the main computer restarts.

Designing this level of safety into the computers within a machine is based on the Standards requirement that a single fault shall not result in an unacceptable risk. The designers of these machines must be certain that any failure is brought to the attention of the operator. They are required to test every possible fault and verify that the outcome is acceptable.

While it may seem like these machines are just a bit of software running on a computer, the reality is far more complex than this. To design, implement and verify all the software and safety requirements of the modern anaesthetic machine is a hugely difficult task. There may be new machines on the market from time to time, however I would be cautious about buying an anaesthetic machine from a new player until they had demonstrated the level of reliability required by our environment. It is reasonable to request in a tender that all machines provide a 'second channel' in computing terms to ensure that a freeze or crash of the main CPU will be immediately identified and appropriately reported to the operator.

11. Service and Reliability

Service contract pricing is a significant part of the overall cost of any machine with sensors and moving parts. Some companies have extensive experience of component failure rates and these are factored into their preventative maintenance schedules. I strongly recommend paying for preventative maintenance, just as it is important to maintain your car according to the recommended schedule.

Bear in mind that all software driven devices come to market with some bugs they missed, and some features or nice things that they just didn't have time to put into the release version. If you do purchase a Version 1 software machine, be prepared to discover some things that could be done better than you expected. Try to gauge the manufacturer's likelihood of responding to your feedback. Find out how often the manufacturer has provided software updates for their other products and whether they actively address problems with updates.

When evaluating new machines, find out the level of residual functionality should a sub-system fail. For instance –

- If the electronic mixer fails, is there an emergency oxygen system that delivers oxygen through the vaporiser into the circuit? Can the ventilator be used in this situation?
- If the ventilator fails, is hand ventilation still possible?
- If a valve in the ventilator fails, can the entire valve block be changed easily? In some machines, all the 'moving parts' are on one sterilisable block, and this can be replaced in a few minutes

Fault tolerance and field replacement of modules or parts by local biomedical engineers are important considerations in remote areas. Find out whether the internal construction is modular, and how easy or difficult it is to replace a module. If there is a part that can be readily replaced, it should be kept on site, particularly if it has moving parts.

Unexpected downtime is a significant issue for electronic machines, both administratively and clinically. Many machines just don't have a 'limp-home' mode, and cannot be used at all if some vital parts (eg the main CPU or the power supply) fail. Generally there is a need to have a back-up machine of some kind in case of an abrupt failure of a machine.

Preventative maintenance, especially in the early and late phases of a machines life-span, is important, and I would strongly recommend using the manufacturer's preventative maintenance contract. Make sure the contract has time-frames for support. Think about how the contract should address a failure to fix a failed machine after a specified time.



12. Integrated Data Collection and Anaesthetic Charting

Preparing an anaesthetic chart predominantly from automatically acquired data makes a lot of sense. The greatest challenge of any charting solution is to make it easy for the anaesthetist to quickly enter drugs and annotations that can be displayed in as good a manner as a paper record. Many print-outs lack the clarity of a carefully maintained hand-written record. The ideal solution would provide the benefits of automated collection with a high-quality, scalable, easily annotated visual display.

Most likely, high-resolution iPad type touchscreen tablets will make this possible within the next 10 years. Current software applications for 'paperless' anaesthetic records still seem a bit cumbersome to me at this point in time, but they are definitely becoming far more sophisticated.

Near-field wireless identification of patients, staff and equipment is likely to radically change how the anaesthetic record might be generated. It is feasible for a machine of the future to automatically identify the patient that has just been wheeled into the room, and prepare a report including their pre-op evaluation and all relevant lab tests, and then start adding any monitored data to their anaesthetic chart without any human interaction. When the anaesthetist enters the room, the machine may offer to automatically configure itself to their favourite settings.

13. Hospital-wide Integration

Automated logging of anaesthetic agent usage, start and finish times, parameters used and monitored data is not uncommon. Some suppliers provide tools to log data over a network and provide a range of reports.

Provision of integrated access to hospital information systems for pre-operative assessment, lab data, x-ray images, theatre management applications and the entire internet is increasingly helpful. Some systems permit this data to obscure monitored data, but I think most of us would agree that it should be presented on a separate monitor screen.

Remote viewing of anaesthetic machines and monitors, and remote diagnosis of error messages and problems, is now possible. These offer clear benefits when something seems wrong with the machine. If the operator has basic video-conferencing functionality in their smartphone, or included in the machine, it is possible to share real-time audio and video of what is happening around the patient to an on-line support person. These technologies can profoundly affect the level of support available to anaesthetists in relatively remote areas, especially if they are not familiar with a new machine.

Sometimes the networking infrastructure for these features can be provided by an 'open' hospital network, but some manufacturers require the use of dedicated networks and servers, which can be very expensive to implement. Increasingly we should anticipate wireless infrastructure solutions.

Machines of the future may record a lot more than is currently recorded. They may record every operator interaction with the machine. If they also record the occurrence of an alarm, it becomes possible to determine the attentiveness of the operator and the suitability of their responses. It is quite feasible for medical devices to incorporate mobile phone type cameras in their front panels, and to record whatever happens in front of the machine. These recordings could be effectively continuous, or just for periods of time when alarms are present. Such a black box recorder would be associated with significant privacy and medico-legal issues, but at the same time would be indispensable for post-hoc 'root cause' analysis after a problem case.

14. Training

It would be medico-legally difficult to defend an adverse outcome arising from the use of a new drug on the grounds of unfamiliarity with that drug. Before using a new drug on a patient, our professional responsibility is to know not just what the drug does most of the time, but to know about the adverse reactions it may cause and how to deal with them. The same responsibility probably extends to a new anaesthetic machine. In some European countries, the release of a new machine is associated with a formal training and accreditation process before a staff member may operate the machine. In Australia and New Zealand, it can be difficult to get any such training before arriving at a theatre to find that you have to use a machine you've never used before. If something went wrong that day and unfamiliarity with the machine contributed, what then?



This is a challenging problem. Generally the manufacturers will support training and education of anyone who asks, however the educators are typically not anaesthetists, and the focus is mostly on 'normal' usage rather than what may go wrong. There are very few clinicians who know enough to 'train the trainers' effectively.

We are very fortunate indeed that mostly the new machines are as very, very reliable, and relatively easy to use. It's amazing to think that we expect them to work 12 hours a day, five days a week, for 10 years or more – and generally they do! No car, toaster, washing machine or ordinary computer would.

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Summary

Increasingly sophisticated anaesthetic delivery and monitoring systems are inevitable. They are great when everything works well. Understanding enough about those systems to know what to do when things go wrong is a significant challenge. Anaesthetists should ensure that they are familiar with a new anaesthetic machine before they first use them. This poses a number of important questions about how that familiarity may be achieved.

