WHITEPAPER

Anaesthesia Gas Monitoring: Evolution of a de facto Standard of Care

INTRODUCTION

The overriding concern for patient safety during surgery has given rise to the development and adoption of a number of technologies, whose use is taken for granted every time a patient undergoes general anaesthesia. These technologies include airway pressure monitoring and breathing system disconnect alarms, monitoring of inspired oxygen, monitoring of expired CO_2, and pulse oximetry. The ongoing technical advancements in the field of respiratory gas monitoring of the 5 potent inhaled anaesthetic agents, N_2O, CO_2, and O_2, the valuable information they provide to the anaesthesia caregiver, the shrinking of the physical attributes (ie, size and weight) of these sensors and monitors, and their lower purchase cost has seen their use in most modern operating rooms in the world. The feedback they provide to the clinician has made them indispensible tools designed to ensure the patient's safety during the perioperative period. Monitoring the anaesthetic gases delivered by the anaesthesia system can alert the caregiver to a number of potentially adverse conditions such as inadvertent agent overdose, timing to reach MAC awake (pseudo awareness detection), or a vaporizer filled with incorrect agent; the systems also allow monitoring of uptake and distribution, and assurance that the desired agent concentration is being delivered, especially when low flow anaesthesia is administered.[1]

In his ASA refresher course Hazards of the Anesthesia Workstation, Dr. James Eisenkraft, Professor of Anesthesiology at the Mount Sinai School of Medicine in New York City, points out that hardware failures in modern anaesthesia delivery equipment are rare. Rather, more common adverse occurrences relate to the unintentional misuse of the equipment, human error, or equipment failing without the user being aware that a failure had taken place.[2] This assertion is further reinforced by a study published in 1997 analysing the ASA Closed Claims Database regarding the role of equipment related problems to malpractice litigations in the United States.[3] The study observes that problems with gas delivery equipment were associated with 72 (2%) of 3,791 claims in the database, and that death and permanent brain damage accounted for almost all adverse outcomes.[4] Of the 72 equipment related claims, 21% related to vaporizers, and the predominant injury causes were excessive airway pressure and anaesthetic agent overdose.[5] The study also reports of two cases where vaporizer failures were associated with intraoperative awareness. Both claims were caused by the delivery of inhalation agents at concentrations that were lower than intended. The study concluded that in most of the cases, patient injury was "deemed preventable with the use or better use of monitors."[6]

Interestingly, in October, 1986, the American Society of Anesthesiologists (ASA) first approved Standards for Basic Intraoperative Monitoring, last updated in 2004.[7] The standards have evolved over time; however, at this point there is no ASA requirement for monitoring of N_2O and/or the inhaled anaesthetics. The ASA's published standard not withstanding, the monitoring of nitrous oxide and the 5 potent volatile inhaled anaesthesitic agents has become a de facto standard because of its ubiquitous presence in the operating room. Anaesthesia caregivers have come to depend on these monitors in the practice of safe anaesthesia.

This article will guide the reader through a historical overview of anaesthetic gas monitoring technology and market evolution, culminating in today's state-of-the-art products.

HISTORICAL PERSPECTIVE

As always, industry recognises a need and actively seeks to fill it with a technological solution. Good examples of where industry has made a difference in the practice of anaesthesia, and has advanced the cause of patient safety, include the development of pulse oximetry and capnography. Both are now published and accepted standards of care. With the advent and general use of modern potent inhaled anaesthetics such as halothane (Fluothane, 1956), enflurane (Ethrane, 1966), and isoflurane (Forane), along with the introduction of modern vaporizers such as Dräger's Vapor 19.n series and Ohmeda's Tec 4 and 5 series, the benefits have outweighed the risks to the patient. However, the risks were tangible and frequent. For some time, these vaporizers were filled by pouring the

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agent from the bottle into a funnel, and early generation key-index fillers were not always effective. Inadvertent filling of vaporizers with the wrong agent or accidental mixing of agents was always a possibility. Figure 1 shows a funnel-filled Dräger vaporizer. To mitigate these risks and provide the clinicians with the feedback needed to avert patient injury, monitors capable of measuring anaesthetic agent and nitrous oxide concentrations were needed.

Figure 1. *Funnel-fill vaporizer.*

One of the earliest examples of a commercially available anaesthetic gas monitor was the North American Dräger Narko-Test. The device worked on the principle of measuring the relaxation produced by anaesthetic agents in lightly tensioned silicone rubber bands; the degree of relaxation is mechanically transmitted to a pointer by a lever system.[8,9] The instrument was factory-calibrated for use with halothane but could be recalibrated for use with other agents such as enflurane. The instrument was generally considered accurate and linear in the range of 0%–3%. The Narko-Test was, however, influenced by presence of water vapor and nitrous oxide and had other limitations which had to be kept in mind during clinical use. The device could be placed in either the airway's inspiratory or expiratory limbs.[10] A schematic representation of the device is shown in Figure 2.

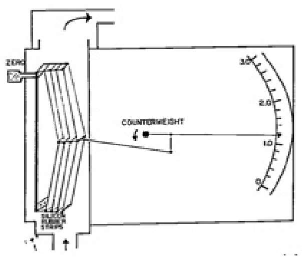

Figure 2. *Schematic representation of the North American Dräger Narko-Test.*

Outside the OR, mass spectrometry was routinely used to identify the chemical composition of various substances. In 1981, the Perkin Elmer Company (later Marquette) introduced a time-shared mass spectrometer capable of monitoring anaesthetic gases on breath-by-breath basis in as many as 31 operating rooms. Essentially a sidestream sampling system, gas samples from the various operating rooms were directed by a multiplexing valve into a centrally located mass spectrometer for analysis. The sample flow when the room was selected was 250 mL/min.[11] The Perkin Elmer system (later Marquette Advantage 1100) was designed to measure and quantify up to eight unique gases.[12] A competitive system, the PPG (Pittsburgh Plate Glass) SARA (System for Anaesthetic and Respiratory Analysis), was introduced a few years later (Figure 3). The sample flow for the SARA, when a room is selected, could be as high as 330 mL/min.[13] It has been shown, however, that the mass spectrometer will display erroneous readings if a gas was present in the mixture, that it was not designed to identify, such as aerosol propellants, helium, and anaesthetic agents. For example, the Advantage 1100, if not programmed for desflurane (Suprane), would identify it as isoflurane, and the PPG SARA would identify desflurane as enflurane.[14] At the institutional level, the risk with a centralised multiplexed mass spectrometry system is that if the central processor part of the system failed, all the rooms served by the system lose that functionality.

Figure 3. *SARA Respiratory Monitor.*

Stand-alone mass spectrometers, like the Ohmeda 6000, mitigated that risk and provided continuous, nearly instantaneous, readings instead of intermittent readings of a few seconds at a time (2 breaths analysed or for 30 seconds if Stat button was pressed) obtained from a central system. Furthermore, the Ohmeda 6000 was found to be as accurate as a centralised/multiplexed mass spectrometer.[15] In addition, its adjustable flow rate of as little as 30 mL/min facilitated its use with infants. Another advantage of the Ohmeda 6000 was that it could be software programmed to be used with any gas or new agent.[16]

The 1990s saw the emergence of a number of competing, more affordable sidestream gas monitoring technologies which further promoted the use of stand-alone anaesthetic multigas monitoring in each operating room. These technologies include infrared spectrometry, RAMAN spectrometry, infrared photoacoustic spectrometry, and piezoelectric crystal agent analysis. Agent identification, either singly or in a mixture, a significant technological advance, was also introduced into the market by a number of manufacturers. The importance of agent specificity, or identification, becomes apparent in cases where vaporizers may have inadvertently been misfiled, thereby creating agent mixtures. This may lead to anaesthetic overdose not detectable by agent analysers lacking an agent identification function. One such example was the case where isoflurane was mistakenly added to a halothane vaporizer, causing the agent analyser to behave erratically and creating the initial incorrect impression that it was malfunctioning.[17, 18]

In contemporary anaesthesia practice, however, anaesthetic agents are routinely and intentionally exchanged in mid-case. Frequently, induction is started with a rapidly acting (insoluble) agent such as desflurane or sevoflurane; the agent is then replaced for maintenance with a less expensive agent such as isoflurane. The safe practice of this technique provides additional rationale for the use of anaesthesia gas analysers that provide agent identification.

For a variety of technical and commercial reasons, anaesthesia gas analysers based on innovative technologies such as Raman spectroscopy, infrared photoacoustic spectrometry, and piezoelectric crystal agent analysis have not succeeded in the marketplace. Raman scattering of laser light was used to identify and quantify oxygen, nitrogen, carbon dioxide, nitrous oxide, and the potent volatile anaesthetic agents. Briefly, when monochromatic light strikes gas molecules, most of the energy scattered is absorbed and re-emitted at a shifted longer wavelength based on the constituent gases in a mixture.[19] The measured shifted wave spectrum, using photomultiplier tubes, quantifies and identifies the gases in the mixture. Raman spectroscopy provides functionality equivalent to mass spectroscopy but at a much lower cost. The best known product based on the Raman scattering principle was the Ohmeda RASCAL II, which is no longer on the market although some are still in clinical use.

Infrared photoacoustic spectrometry and piezoelectric crystal agent analysis were technically innovative but suffered from certain limitations which ended their commercial viability. The infrared photoacoustic gas bench was marketed as the Brüel & Kjaer 1300. Two piezoelectric benches were introduced into the market. The first, the Siemens GM 120 monitor, shown in Figure 4, and the second, developed by ICOR of Sweden, were marketed in the United States by BCI and Vital Signs Inc. Neither the infrared photoacoustic nor the piezoelectric devices were agent-specific.[20] In addition, the photoacoustic device was sensitive to external noise and vibration,[21] and the piezoelectric technology exhibited a pronounced sensitivity to water vapor.[22]

Figure 4. *Siemens Servo Gas Monitor 120.*

Of the various competing anaesthetic gas measurement technologies, the infrared photospectrometer emerged as a commercial and, for the most part, technical success. There are two main reasons for this. The first is that the technology could be implemented at a lower cost, thus reaching a larger customer base, and second is that agent identification functionality could be readily added to these analysers. The number of competing infrared-based products on the market since the mid 1980s has greatly proliferated, but many are no longer being marketed due to obsolescence or commercial failure.

Infrared-based gas analysis products such the Puritan-Bennett/Datex 222 Anesthetic Agent Monitor, Figure 5, came on the market circa 1984. The Datex 222 was the company's first generation (non-ID) infrared gas bench (Jan Ekström: personal communications). The 222 was soon followed by the Datex Normac, Dräger's IRINA, Andros 4600 (analyser bench)/4700 (agent ID bench), Datex Capnomac, Nellcor 2500, Ohmeda RGM, and Criticare's POET II.[23]

Figure 5. *Puritan-Bennett/Datex Anesthesia Agent Monitor 222.*

SIDESTREAM INFRARED MULTIGAS ANALYSER OPERATING PRINCIPLES OVERVIEW

Respiratory gases can be potentially analysed according to different measuring principles. Most commonly, either a dispersive infrared (DIR) method or a non-dispersive infrared (NDIR) method is used to isolate the absorbance characteristics of the gas sample. The dispersive method uses a single optical filter and either a prism or a diffraction grating to separate the component wavelengths for each agent; the non-dispersive technique incorporates multiple narrow-band optical filters through which the infrared emission is passed to determine which gas is present in the mixture.[24,25] The NDIR technique is predominantly used in most of the analysers described below, and the DIR technique is used in the LumaSense/Andros 4800. Both techniques are technically effective; the difference manifests itself in device complexity and manufacturing cost.

As previously noted, the most common method of gas analysis is implemented through the medium of NDIR spectroscopy. This measuring principle is based on the fact that many gases absorb infrared energy at a wavelength specific to the gas being analysed. Figure 6 shows the infrared absorbance spectra for CO_2, N_2O, and the 5 potent inhaled anaesthetic agents, halothane, enflurane, isoflurane, sevoflurane, and desflurane. It can be seen from this figure that the absorbance peaks for CO_2 and N_2O are located at the 4-5 µm range, and the anaesthetic agents are found at the 8-13 µm range, in five different wavelengths. It can be further seen that the agent absorbance spectra overlap, requiring complex methods of discriminating between their spectral components, along with advanced mathematical techniques involving solutions to multiple simultaneous equations to measure and identify them.

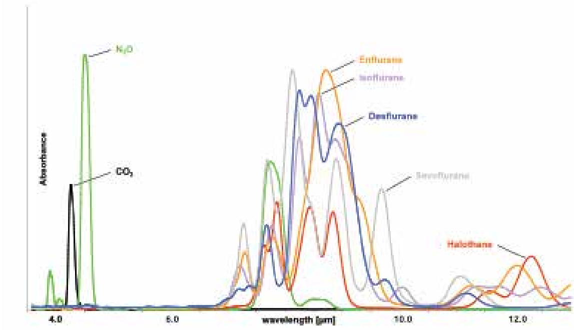

Figure 6. *Absorbance spectra for commonly monitored respired gases and anaesthetic agents.*

Sidestream sampling infrared multigas analysers typically continuously aspirate a sample of the gas of interest from the patient circuit, usually at the point where the breathing circuit is connected to the airway device (eg, facemask, tracheal tube, or laryngeal mask airway). In modern gas analysers, the gas sampling rate from the breathing circuit is in the range of 50 mL/min to 250 mL/min.[26] The sample gas flow is directed, using a cuvette (a sample cell), between the infrared emitter, an optical filter, and the infrared detector, which outputs a signal proportional to the remaining infrared energy not absorbed by the gas. To quantify and identify multiple gases simultaneously, such as N_2O, CO_2, and the five potent inhaled anaesthetic agents, multiple optical filters are utilised. The detected signal is then amplified and interpreted by sophisticated microprocessor algorithms. It is important to note that oxygen cannot be detected or measured using infrared photospectroscopy. Gas analysers which measure oxygen utilise ancillary technologies such as paramagnetic or fuel-cell oxygen sensors in conjunction with the infrared sensor.

A number of architectures are used to accomplish how the optical filters are positioned between the infrared emitter and the detector. Furthermore, depending on the specific architecture, different infrared emitter and detector technologies and structures are incorporated in the various designs. The following examples represent common anaesthesia gas analyser architectures that are currently commercially available.

Datex TPX gas analyser (GE Healthcare, Helsinki, Finland): A ubiquitous gas analyser module utilised by a number of patient monitoring brands. Developed in 1997, this gas analyser measures the standard complement of gases administered during general anaesthesia (N_2O, CO_2, and the 5 possible anaesthetic agents, with agent identification). (Author's note: when researching what 'TPX' stood for, I learned that it actually does not stand for anything. Rather, it is an indirect reference to the thermopile detectors used in the sensor.) The TPX is a nondispersive infrared analyser, measuring absorbance of the gas sample at seven infrared wavelengths which are selected using optical narrow-band filters. The infrared radiation detectors are thermopiles. Concentrations of CO_2 and N_2O are calculated from absorbance measured at 3-5 µm. Identification of anaesthetic agents and calculation of their concentrations is performed by measuring absorbances at 5 wavelengths in the 8-9 µm band. A conceptual schematic of the TPX analyser is shown in Figure 7. The gas sample flow rate for the TPX analyser is specified as 200 mL/min.[27]

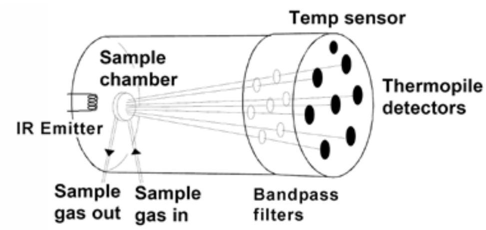

Figure 7. *TPX Analyser schematic.*

Andros/LumaSense 4800 anaesthesia gas analyser (LumaSense, Richmond, CA): A technically novel optical configuration that utilises an elongated sample cell internally coated with reflective gold. As the sample gas flows through the tube, it is illuminated with an infrared light source. The infrared light is then dispersed onto an internal stationary mirror that directs the light onto an oscillating diffraction grating. The position of the grating is encoded and known to the internal microcomputer. The light emerging from the oscillating grating is then reflected onto an infrared detector. This scanning process results in a spectral curve determined by the gases present in the mixture within the sample tube. The instantaneous position of the grating is the curve's location on the abscissa, and the signal received by the infrared detector is the amplitude of the spectral curve. The shape of the curve is determined by the relative concentrations of the gases in the sample mixture. Figure 8 is representation of the Andros 4800 optical structure. The gas sample flow rate is 200 mL/min.[28]

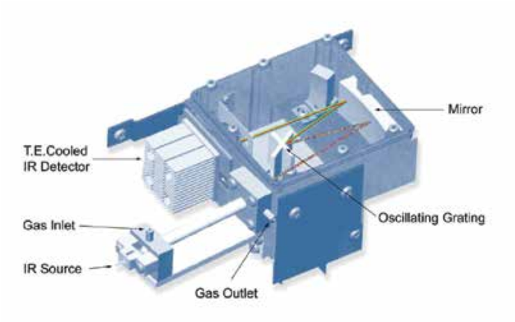

Figure 8. *Representation of the Andros 4800 Analyser.*

Dräger ILCA2 infrared anaesthesia gas analyser (Dräger Medical, Lubeck, Germany): This gas analyser is based on the use of a pulsed infrared source and a multispectral detector. The infrared light is reflected in four directions after which it passes through infrared narrow-band filters, which transmit only at a particular absorbance wavelength of the gases of interest onto a pyroelectric detector chip, as illustrated in Figure 9. The unit also provides an agent identification function. This measurement method is not susceptible to cross-sensitivities from gases such as water vapor, ethanol, and acetone. The sample flow for this gas analyser is 200 mL/min.[29]

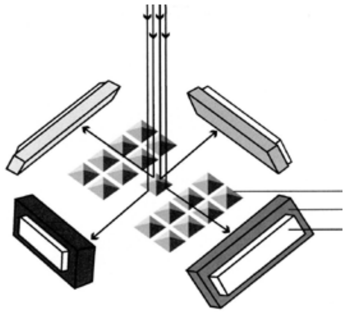

Figure 9. *ILCA2 gas sensor topology.*

Artema AION anaesthesia gas analyser (Artema Medical AB; now Mindray of China; Sundbyberg, Sweden): This gas analyser is a single-beam, eight-channel, non-dispersive infrared (NDIR) gas analyser. The sensor head measures infrared absorbance at eight different wavelengths. To measure the absorbance of light at wavelengths ranging from 3.9 μm to 12 μm, a broadband infrared radiation source is used. The light transmitted from the infrared source is filtered using a set of narrow optical band pass filters. The individual filters are mounted in a rapidly rotating filter wheel that interrupts the light path. The filtered light then passes through the measurement chamber before reaching the infrared detector. The filter wheel in this gas analyser contains eight optical filters facilitating accurate analysis of all respiratory gases in any mixture. The AION gas analyser is capable of identifying anaesthetic agents singly or in a mixture. Figure 10 is a schematic representation of the AION optical path. The sample flow rate for this gas analyser is 250 mL/min.[30]

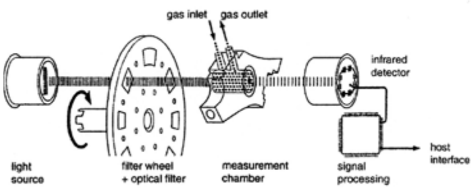

Figure 10. *Schematic representation of Artema AION gas analyser.*

ISSUES COMMON TO CONVENTIONAL ANAESTHESIA GAS ANALYSERS

Conventional anaesthesia sidestream gas analysers discussed up to this point share two functional and usability limitations. The first issue is the relatively high sample flow rate (which can exceed 200 mL/min) required to achieve an acceptable response time of less than 300ms. The high sample flow rate impedes the use of these analysers with infants whose inspiratory and expiratory gas flow rates are close to or less than the analyser's sampling gas flow rate. So if the patient exhales at a flow rate less than the sampling rate, then inspired gas will contaminate the sample. In addition, in instances where low-flow or closed circuit anaesthesia is used, or in special cases such as cardiopulmonary bypass when fresh gas flow is significantly reduced, the possibility exists for more gas to be removed from the patient circuit than is added to it by the anaesthesia delivery system. Such circumstances, if vigilance is not maintained, could lead to the development of subatmospheric pressures in the airway.[31, 32]

The second issue is one of the more daunting challenges facing the design of a sidestream analyser. It is essential that water vapor, liquid water, and patient secretions be controlled and prevented from reaching and damaging the measuring instrument, influencing the accuracy of the measurements, or becoming a nuisance to the anaesthetist. This task is usually accomplished in the specific design of the sample line and/or with use of a water trap on the instrument side.

This challenge stems from the fact that the patient's expired gases are usually saturated with moisture at 97.6°F (37°C). As the sample flow traverses the sample line towards the gas analyser, its temperature is cooled by the external environment. The water vapor within the sample flow therefore naturally condenses in the breathing circuit as well as in the gas analyser sampling tubing. If allowed to reach the gas analyser sample cell, the condensate may permanently damage the instrument or affect measurement accuracy. In order to protect the instrument from the effects of condensed water vapor, patient secretions, and bacterial contamination, a sidestream gas analyser must be fitted by a device that can block, remove, or separate these contaminants from the gas sample. Sidestream gas analyser manufacturers deal with this problem in various ways. GE Healthcare (Madison, Wisconsin), Dräger Medical and Criticare Systems (Waukesha, Wisconsin), as well as other manufacturers utilise a water trap in addition to Nafion tubing in the designs of their analysers. Nafion removes gases based on their chemical affinity for sulfuric acid. Nafion is basically Teflon with sulfuric (sulfonic) acid groups interspersed within it. Sulfuric acid has a very high affinity for water, so it absorbs water into the Nafion. Once absorbed into the wall of the Nafion tubing, the water migrates from one sulfonic group to another until it reaches the outside wall of the tubing, where it evaporates into the surrounding gas (air or other gas).[33] It is commonly used in tubing form as part of some sampling line configurations; it is typically used in high humidity applications. Its effectiveness is affected by the humidity gradient between the inside and outside to the tubing (eg, the outside relative humidity). Nafion does not remove any water in liquid form that may have accumulated within the sampling line. Furthermore, Nafion sampling lines must be handled with care due to the fragile nature of the material.

In certain instances, such as cases of long duration or when high levels of humidity exist in the airway, the gas sampling circuit is prone to frequent occlusions and vigilance must be maintained to empty the analyser's water trap as necessary. If the trap is not emptied, or water vapor condenses within the analyser's optical core, the unit may cease to function (Dr. James Eisenkraft: personal communications), or even be permanently damaged.

STATE-OF-THE-ART SIDE-STREAM RESPIRATORY GAS ANALYSIS

Of special note is the ISA™ (Infrared Sidestream Analyser) family of sensors developed by Masimo Corporation, Irvine, CA, formerly PHASEIN AB.

The ISA sidestream multigas analyser is a 9-channel NDIR gas analyser measuring at 4–10 μm spectra with compensation for pressure, temperature, and the broadening effects on CO_2. It is very compact (23 x 64 x 39 mm), weighs only 70 g, features low gas sample flow (50 mL/min), and integrates a sampling pump, a zeroing valve, and a flow controller. The analyser, shown in Figure 11, is functionally fully self-contained, requiring only power (1.6W) and a communication port from the host monitor. In addition, this analyser is complemented by a sample line design that totally eliminates the need for a traditional water trap by removing both water and water vapor from the line. This sampling line provides fluid protection technology and was specifically developed to eliminate the traditional water condensation problems associated with other sidestream sampling systems.

Figure 11. *Masimo ISA multigas analyser.*

The technological achievements represented by the ISA module have their roots in the infrared spectrometer, based on the micro-optical rotor technology, first developed by the company for its IRMA™ (InfraRed Mainstream Analyser).[34]

MICRO-OPTICAL ROTOR TECHNOLOGY

In order to achieve multigas measurement capability in an ultra compact form, the measurement principle chosen by Masimo is that of an infrared analyser that uses an infrared source; a sample chamber in series with the patient's airway connection through which the respiratory gas flows; a micro-optical rotor (MOR) with appropriate optical filters; and a detector to acquire the optical energy specific to the gases being analysed. However, that is where similarities to previously designed multigas analysers end.

Conceptually, a spectrometer incorporating a rotating filter wheel offers the potential to be reduced in size and weight if the filter elements could be made smaller and be spaced closer together. However, in order to maximise signal output at the detector when a particular filter is coincident with the emitter, sample cell, and detector, and to prevent cross-talk between the channels, it may be necessary to keep the respective spacing between the filter openings of the filter wheel sufficiently large in order to be able to determine a reference intensity. If the respective spacing is made smaller, for example, in order to create a smaller filter wheel or to enable the analysis of more than three gases, it might give rise to cross-talk between the filters (ie, the detector signal does not decrease to its reference level during the periods between two consecutive filters). This may, for example, lead to a degraded signal-to-noise ratio, which, in turn, decreases the accuracy and reliability of the measurement. The problem is compounded when a large number of filters are needed to resolve and identify five or six different gases.[35] The dependence on inter-filter spacing to maximise detector signal and minimise cross-talk is a limiting factor to reduce size of the infrared spectrometer.

The enabling technological development by Masimo facilitates the use of a miniature micro-optical rotor integrating a six-pole magnet and a number of circumferentially arranged infrared narrow-band optical filters. The rotor is driven by a software-controlled stator coil and offers significant advantages compared to conventional solutions involving a filter wheel driven by a motor. The fully integrated optical rotor/motor assembly is mechanically much smaller than a discrete motor with a filter wheel appended to its shaft. Furthermore, this arrangement facilitates full software control of the micro-optical rotor and its synchronisation with the signal processing elements of the photospectrometer. With this arrangement, the spacing between the optical filters has been reduced to the point where 9 filters (7 filters for the quantification and identification of the gases in the mixture and 2 reference filters) can be incorporated in a 14 mm-diameter rotor weighing 0.75 grams, as shown in Figure 12. A patented signal-processing algorithm that uses detection of the signal peaks corresponding to the coincidence of a filter element with the IR emitter and detector determines the intensity of the measured signal. This algorithm allows for the accurate determination of the signal intensity passing through each filter without requiring the signal to diminish to its zero-reference level. In conventional chopper-wheel analysers, this is created by the space between consecutive filters.[36]

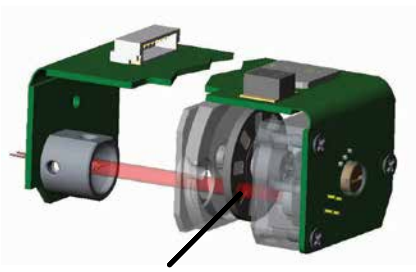

Figure 12. *The micro-optical rotor.*

FROM MAINSTREAM TO SIDESTREAM

Although Masimo's Micro Optical Rotor-based infrared spectrometer was first developed for use in mainstream applications, its use in an ultra-compact sidestream configuration required further technological developments. The spectrometer was integrated with a small measurement chamber, a zeroing valve, a miniature sample pump, and a gas sampling line connector to form a completely integrated sidestream gas analyser module, as shown in Figure 13.

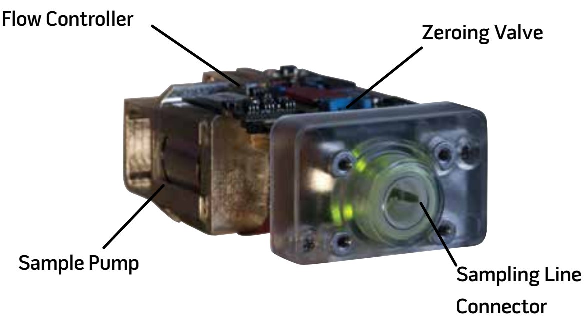

Figure 13. *The ISA (Infrared Sidestream Analyser) sidestream multigas analyser module.*

Measurement chamber: The low flow and high breath-rate capability of the ISA sidestream analyser requires a very small gas measurement chamber design with high transmission characteristics over the entire 4–10 μm range. These requirements were addressed with a 50 μl measurement chamber that has a primary CaF_2 window and a ZnSe lens as secondary window (see Figure 14). The sample chamber design and gas sampling line arrangement allows ISA to be the first multigas sidestream analyser to use a 50 mL/min sample gas flow rate for all patient categories ranging from neonates to adults.

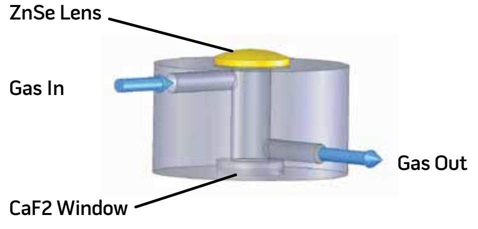

Figure 14. *ISA Measurement chamber.*

Sample Micro Pump: The gas sample is drawn from the patient breathing circuit using a small diaphragm pump integrated in the sensor body. This type of pump is very power-efficient and has a wide working pressure range. The pump is driven by a high-reliability brushless motor to ensure maintenance-free operation. Modulation in the gas sample flow created by the micro pump is eliminated using a pneumatic filter consisting of a flow restrictor and a small volume buffer chamber.

Sample Flow Controller: In order to facilitate monitoring of both tracheally intubated and non-intubated patients using sampling lines of different lengths, the sample pump must be able to adapt to varying ambient conditions. The required real-time feedback is (in ISA) generated by a flow controller consisting of 3 pressure transducers and 2 flow restrictors (see Figure 15). Two of the pressure transducers are configured as a mass flow sensor that measures the pressure change created by the gas sample flowing through the restrictors while the third pressure transducer continuously measures ambient barometric pressure. Data from the flow controller are used by the internal microprocessor to regulate pump power so that a stable flow of 50 mL/min is maintained through the gas analyser independent of the patient's airway and exhaust pressure conditions.

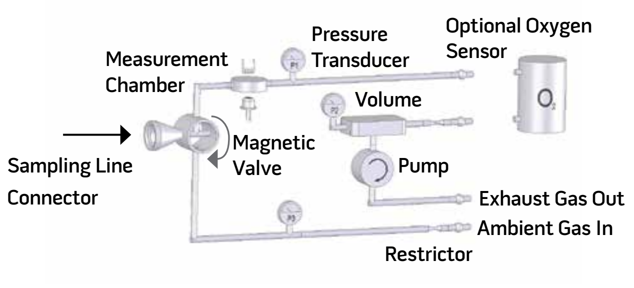

Figure 15. *ISA sidestream multigas analyser gas path.*

Zeroing Valve and Field Calibration: The spectrometer used in the ISA sidestream analyser was, as previously stated, first developed for mainstream applications where stable operation over a wide temperature range is imperative. Similarly, ISA is able to function without zeroing for long periods of time. However, long-term drift could potentially degrade accuracy if zeroing is never executed. A zeroing valve is therefore included in the ISA multigas analyser module and automatically activated once every 24 hours, thus eliminating the need for regular calibration in the field.

Sampling Line Interface: The characteristic of the gas sampling line and its pneumatic interface is very important for the overall performance of a sidestream gas analyser. ISA is designed for use with the Nomoline™ sampling lines (Figure 16), a new concept in sampling lines for gas analysis, combining the extended service cycle of a traditional water trap with the low-flow characteristics and rapid response time of disposable water collecting sampling lines (such as Respironics' LoFlo and Oridion FilterLine). Nomoline's water handling performance is achieved by eliminating liquid water from the gas sample rather than collecting it in a reservoir or blocking it with an integrated filter.

Figure 16. *The Nomoline sample line*

The water removal function of the Nomoline sampling line is based on the physical properties of the Nomoline cover [Fig. 17, 2]. The Nomoline is able to "sweat" the water collected from the gas sample flow to the outer surface of the cover and actively remove the water without user intervention. The Nomoline is also fitted with a hydrophilic wick [Fig. 17, 3] with a volume of about 1.2 mL. The wick has the dual function of a buffer against sudden bursts of aspirated water and of a water distributor, spreading the collected water over a sufficiently large area of water transpirant material. This area is chosen to be large enough to continuously remove all the water that the gas analyser may collect during normal operating conditions. In addition, the Nomoline is designed for applications where the gas sample may be returned to the patient circuit. For these applications, analyser cross-contamination is an important consideration. To address this requirement, Nomoline is fitted with a reliable 3 μm hydrophobic bacteria filter [Fig. 17, 4] that has a Bacteria Filtration Efficiency (BFE) > 99.99996%, as defined in MIL-M-36954C.

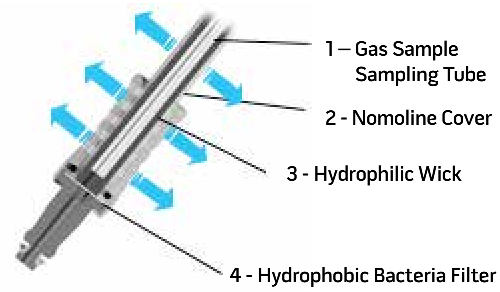

Figure 17. *Nomoline water removal internal structure.*

The Nomoline sampling line interfaces to the ISA multigas analyser module using a proprietary connector that has an optical detector mechanism which senses if a sampling line is securely plugged into its socket. This connector also provides positive tactile feedback (over-center click) to the user when engaged by the sample line, and can be rotated, thus minimising the risk of kinks. Its uninterrupted flow characteristic signifies a seamless, turbulence-free flow, where the Nomoline connector and socket are completely transparent to the sample flow dynamics. The Nomoline's uninterrupted flow design facilitates the ability to monitor anaesthetic and respiratory gases, including oxygen with an ancillary oxygen sensor, at a low gas sampling flow rate and high respiratory rates.[37]

System Integration interface: Like its mainstream cousin, the IRMA, the Masimo sidestream analyser family of products implement the Plug-in and measure...™ concept, where the device does not require any hardware internal to the host patient monitor other than a RS-232 or USB data port. The analyser's integrated microprocessor calculates, formats, and serially transmits, via the communication port, the gas concentration values, waveform data and status information ready to be displayed on the host monitor display.

CONTEMPORARY ANAESTHESIA MULTIGAS ANALYSER PERFORMANCE

The table on the following page charts the performance and other relevant characteristics of 5 popular anaesthesia gas analysers on the market today. Information for the Philips, GE, Dräger, and Datascope (now Mindray) devices was summarised from "Multiple Medical Gas Monitors, Respired/Anaesthetic: ECRI Institute Recommendations"; ECRI Institute Europe, published 2009. Information for the ISA AX+ device was summarized from "Sigma Multigas Technology" published by Masimo. The ECRI Institute's recommended specifications listed in the above-referenced publication can provide context to device performance, but do not address the importance of criteria such as size, weight, field calibration requirements, and water removal performance.

SUMMARY

The ability to monitor anaesthetic gas concentrations being respired by a patient under general anaesthesia has made an immeasurable contribution to patient safety. The introduction of North American Dräger's Narko-Test in 1971, primitive by today's standards, was followed by ever-more-advanced technologies over the next 39 years. From the introduction in 1981 of centralised, time-shared, mass spectrometry gas analysers that were predominantly used in large hospitals to very affordable infrared gas analysers with increasing functionality and performance, these monitors are being used in almost every modern operating room throughout the world. These devices have changed the practice of anaesthesia for the better, and their influence and performance have been well-documented.

As with any technology-centered device, there is always something better around the corner. The market always welcomes products with better performance that are smaller, consume less power, are more robust, more durable, require less operational attention or maintenance, and offer better value. It may be that in the field of anaesthesia infrared multigas analysers, the Masimo ISA AX+ is that product.

Supplier	Masimo		Philips Healthcare		GE Healthcare		Dräger medical		Datascope	
Model	ISA OR+		M1026B Anaesthetic Gas Module		C(AI)O(V)(X)		Scio Four Gas Module		Gas Module 3	
IR Sensor	Masimo ISA AX+		Andros/LumaSense 4800		GE TPX		Dräger ILCA II		Artema AION	
Operating Principles	NDIR, paramagnetic		DIR, paramagnetic		NDIR, paramagnetic sensor		NDIR, paramagnetic sensor		NDIR, paramagnetic sensor	
Sampling Flow	50 ml/min		150 m/min		200 ml/min		200 ml/min		250 / 120 ml/min	
CO_2 Range/Rise Time	0 - 15 vol%	200 msec	0 - 10 vol%	410 msec	0 - 10 vol%	400 msec	0 - 10 vol%	350 msec	0 - 10 vol%	250 msec
N_2O Range/Rise Time	0 - 100 vol%	350 msec	0 - 85 vol%	510 msec	0 - 100 vol%	450 msec	0 - 100 vol%	500 msec	0 - 100 vol%	250 msec
O_2 Range/Rise Time	0 - 100 vol%	450 msec	0 - 100 vol%	640 msec	0 - 100 vol%	400 msec	0 - 100 vol%	600 msec	0 - 100 vol%	500 msec
Hal Range/Rise Time	0 - 8 vol%	350 msec	0 - 7.5 vol%	900 msec	0 - 6 vol%	400 msec	0 - 10 vol%	500 msec	0 - 5 vol%	300 msec
Enf Range/Rise Time	0 - 8 vol%	350 msec	0 - 7.5 vol%	620 msec	0 - 6 vol%	400 msec	0 - 10 vol%	500 msec	0 - 5 vol%	350 msec
Enf Range/Rise Time	0 - 8 vol%	350 msec	0 - 7.5 vol%	610 msec	0 - 6 vol%	400 msec	0 - 10 vol%	500 msec	0 - 5 vol%	300 msec
Des Range/Rise Time	0 - 22 vol%	350 msec	0 - 20 vol%	540 msec	0 - 20 vol%	400 msec	0 - 20 vol%	500 msec	0 - 18 vol%	300 msec
Sev Range/Rise Time	0 - 10 vol%	350 msec	0 - 9 vol%	570 msec	0 - 8 vol%	400 msec	0 - 10 vol%	500 msec	0 - 8 vol%	300 msec
CO_2 Accuracy	±(0.2 vol% + 2% relative)		0-4 vol%: ±0.20 vol%		±(2 vol% + 2% relative)		±(0.45 vol% + 8% relative)		0-1 vol%: ±0.15 vol% 5-7 vol%: ±0.30 vol% 7-10 vol%: ±0.50 vol%	
N_2O Accuracy	±(2 vol% + 2% relative)		±(1.5 vol% + 5% relative)		±(2 vol% + 2% relative)		±(2 vol% + 8% relative)		0-20 vol%: ±2 vol% 20-100 vol%: ±3 vol%	
O_2 Accuracy	±(1 vol% + 2% relative)		±3 vol%		±(1 vol% + 2% relative)		±3 vol%		0-25 vol%: ±1.0 vol% 25-80 vol%: ±2.0 vol% 80-100 vol%: ±3.0 vol%	
Agent Accuracy	±(0.15 vol% + 5% relative)		±(0.10 vol% + 4% relative)		±(0.15 vol% + 5% relative)		±(0.2 vol% + 15% relative)		0-1 vol%: ±0.15 vol% 1-5 vol%: ±0.20 vol%	
Water Trap Volume	1.2 ml, auto water removal		> 20 ml, disposable		No spec, disposable		13 ml, reusable		10 / 5 ml, reusable	
Power	2 W		45 W		14.6 W		No spec.		10 W	
H x W x D	(4.9 x 9 x 10) cm (1.9 x 3.5 x 3.9)"		(9 x 37 x 46.7) cm (3.5 x 14.5 x 18.4)"		(11.2 x 7.5 x 22.8) cm (4.4 x 3 x 9)"		(11.5 x 19 x 27) cm (4.5 x 7.5 x 10.6)"		(7.6 x 30.2 x 26.4) cm (3 x 11.9 x 10.4)"	
Weight	0.4 kg / 0.9 lb		6.3 kg / 13.9 lb		1.6 kg / 3.5 lb		3.5 kg / 7.6 lb		2.8 kg / 6.1 lb	
Note	ISA AX+: 70 g / 0.15 lb									

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