

SIGMA Σ *MULTIGAS*
TECHNOLOGY



*phase***in**

Bringing new dimensions to multigas monitoring

Since its founding in 2002, PHASEIN has taken pride in bringing its medical OEM market customers breakthrough multigas technologies every year. In 2003 PHASEIN raised the competitive bar by introducing a new concept in the field of gas monitoring – the IRMA probe, a high-performance ultra-small multigas analyzer. IRMA is capable of measuring and quantifying five anesthetic agents, nitrous oxide, CO₂ and O₂, thus creating a new dimension in the fields of anesthesia, intensive care, emergency and home care. This has been equivalent to the paradigm shift from fixed, table-top, telephony to mobile hand-held technology in the field of telecommunications. The IRMA multigas probe which weighs only 30 grams, and is small enough to fit in the palm of your hand, has made the concept of a “plug-in and measure” gas analyzer a reality.

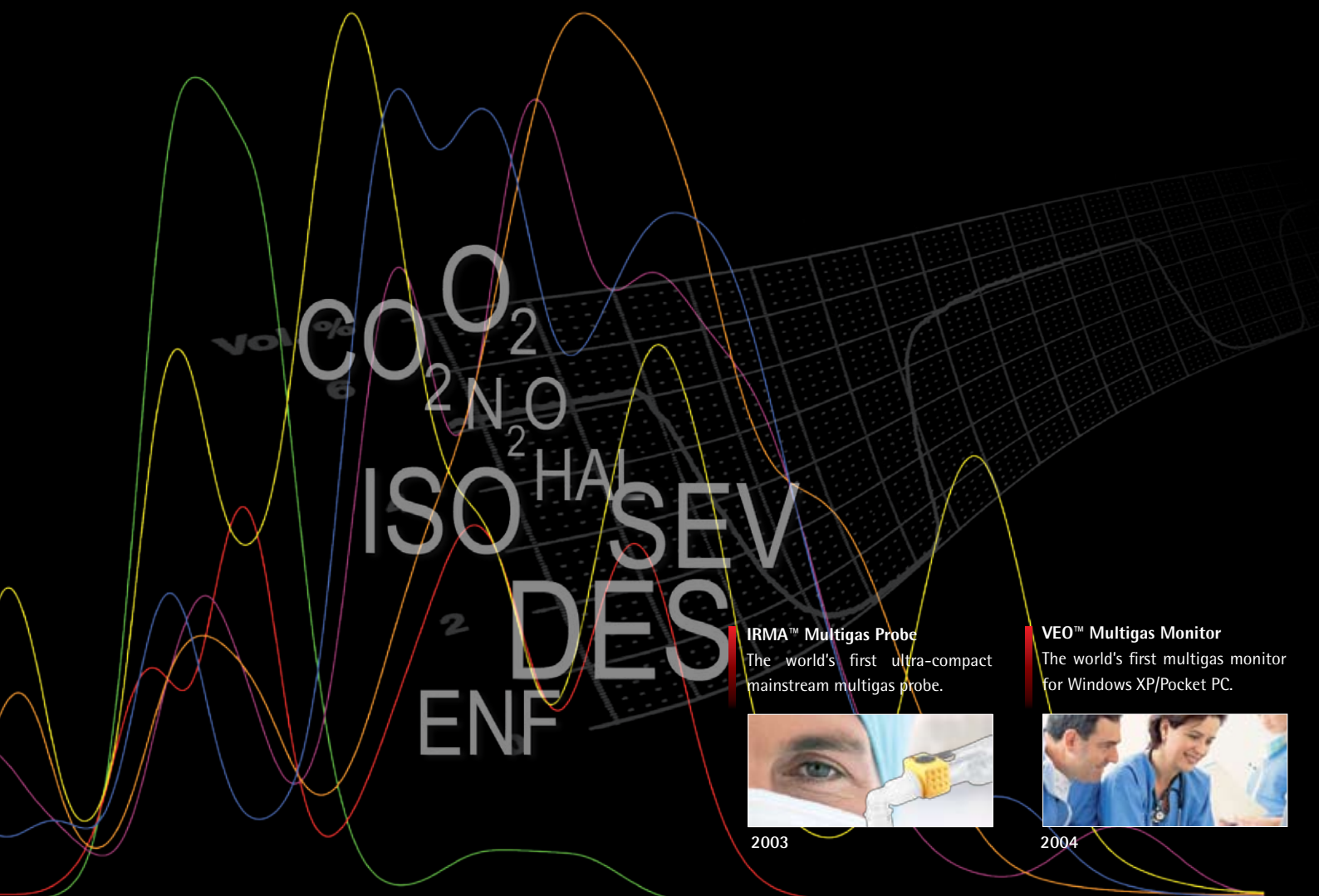
Now, again, the ISA analyzers, launched in 2008, add a new dimension to PHASEIN's product portfolio, and reinforces PHASEIN's irrevocable commitment to its OEM customers as the premier provider of innovative, ultra-compact, mainstream and sidestream multigas technologies in the world. PHASEIN's enabling technologies facilitate the development of cost effective, highly competitive, sophisticated patient monitoring products with multigas monitoring features previously unattainable with other gas monitoring technologies on the market today.

The elegant, well thought out, and robust implementation of the ISA analyzers simplifies the engineering and system integration tasks for OEM customers, thus providing opportunities to reduce a new product's time to market. In addition, the flexible design of PHASEIN's multigas sensors can deliver other tangible benefits to the OEM customers, including low cost of ownership to end user and the system integrator.

PHASEIN's commitment to its customers goes beyond its ability to deliver technically superior gas monitoring sensors. PHASEIN's support of its OEM customers is its highest priority. The company dedicates itself to supporting its customers with their OEM design and system integration needs, clinical education, marketing strategies, as well as product testing and validation.

PHASEIN recognizes that its success is derived from the success of its customers. Its commitment to delivering the best value proposition in multigas sensing technology, along with full support of its customers, is unshakeable.

“Plug-in and measure” – you have to see it to believe it, and design it in to realize its benefits; the most technologically advanced OEM multigas sensing system on the market today.



IRMA™ Multigas Probe
The world's first ultra-compact mainstream multigas probe.



2003

VEO™ Multigas Monitor
The world's first multigas monitor for Windows XP/Pocket PC.



2004



“ Nothing is impossible.
If there's a will there's a way. ”

Our customers have come to expect from us not only technical innovation and leadership in the multigas monitoring field, but also to be treated as part of our company. We would never have it any other way.

We have been working in the fields of anesthesia and intensive care for almost 30 years. Our goal was to create the smallest, best performing plug-in multigas analyzer in the world. With the experience of bringing three generations of infrared gas measurement technology to life we embarked on what may have appeared to be an impossible challenge. With the best technical team in place and firm determination, we ultimately succeeded, and the result was the IRMA family of multigas sensors. Weighing only 30 grams, it was born in 2003, and was followed by new products every year since then.

We also know that technology for its own sake is not a means to an end, and we believe that our ultimate achievement will be measured by the success of our customers. For that reason, PHASEIN's commitment to our customers is as strong as it is to our technology. We are committed to assisting our customers with the integration of PHASEIN technology into their products.

Working together with your engineering team, engineering costs and time to market can be minimized. PHASEIN's staff is always ready to support our customers with their marketing, clinical education, training, and regulatory activities. Once our customers' products are on the market, PHASEIN will always be there for them. Whenever the need arises, we are ready to provide responsive support, because we expect our customers to consider us as part of their team.

In the meantime, our work continues to address the next technical challenges before us. We believe that nothing is impossible, and if there's a will – there's a way.

Robert Zyzanski
CEO

Anders Eckerbom
Director of Technology Development

IRMA™ OR/AX Multigas Probe

The world's first multigas probe measuring CO₂, N₂O, O₂ and anesthetic agents.



2005

EMMA™ Emergency Capnometer

The world's first and smallest portable emergency capnometer.



2006

IRMA™ AX+ Probe

The world's first mainstream multigas probe with automatic agent ID.



2007

ISA™ CO₂, ISA™ AX+ Nomoline™

The world's smallest sidestream analyzers. The world's first sampling line with water removal properties.



2008

A new heart for the ultimate multigas performance

If you are considering adding gas monitoring to your system then there are many considerations you should take into account. Some are of obvious importance while others are subtle, yet critical for your ultimate satisfaction and success. When it comes to SIGMA technology, each detail and function is engineered to facilitate a successful design into your product.

The SIGMA spectrometer

At the heart of any ISA multigas analyzer lies PHASEIN's sophisticated SIGMA spectrometer. This state-of-the-art spectrometer detects the slightest changes in infrared radiation at nine different wavelengths in the LWIR spectrum to precisely determine gas concentrations in a mixture. The SIGMA spectrometer has a true single-beam design, thus eliminating frequent zeroing common for older designs using dual beam sensors or beam splitters.

SIGMA can be tailored to a variety of applications ranging from single gas capnography in the ICU (ISA CO₂) to state-of-the-art multigas measurements of carbon dioxide (CO₂), nitrous oxide (N₂O), and mixture of binary anesthetic agents, with agent identification, in the OR (ISA AX+). Irrespective of the application, the SIGMA spectrometer delivers state-of-the-art performance in a package weighing less than 5g!

No cross interference or broadening effects

The SIGMA spectrometer uses the 4 to 10 μ m LWIR wavelength band to precisely measure the infrared absorption caused by molecules in the gas sample. The LWIR wavelength band contains strong absorption peaks for CO₂, N₂O and the anesthetic agents, with negligible interference from alcohol, acetone, and other gases and vapors that could potentially degrade measurement accuracy. In the multigas version, seven carefully selected narrow band optical filters are used to trace the gas sample composition, while two filters are used for temperature compensation. The precisely tuned optical filter set provides for high signal-to-noise ratio gas measurements, as well as automatic compensation for cross interference and broadening effects caused by oxygen, nitrous oxide, anesthetic agents and for pressure broadening effects.

Crisp waveforms in any clinical situation

Every single detail in an ISA analyzer has been engineered to precisely depict the clinical situation, even for young patients with very high breathing rates. To be able to measure under such extreme conditions, the measuring chamber of the SIGMA spectrometer has been compressed to 50 μ l (microliters)! ISA is the world's first multigas sidestream analyzer with a 50 ml/min sampling flow for all patients, from adults to neonates.

Patented gas measurement algorithms

The SIGMA spectrometer, the flow controller and the micro pump are controlled by a 32-bit RISC microprocessor. Analog pressure, temperature and flow signals combined with data from the SIGMA spectrometer are processed using complex, matrix calculations. The latest advances in digital signal processing provide unparalleled gas measurement accuracy and reliable agent gas identification in any clinical situation.

Temperature stabilized gas analysis

The ISA analyzers are designed without the need for heaters or coolers. Instead, three temperature sensors and two optical filters in the SIGMA spectrometer are used to compensate for temperature variations and gradients. The result is not only an impressive low power consumption, but also "instant on" performance. Accurate data is available within 10 seconds, and full accuracy for anesthetic agents within 20 seconds from power on.

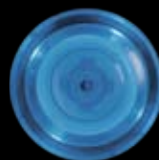
High efficiency LWIR light source

PHASEIN's has engineered its own infrared source to provide excellent power efficiency and stability. A specially designed parabolic reflector focuses the infrared beam so that no energy is lost. That means the ISA analyzers can deliver high fidelity gas data while maintaining micropower operation.

CO₂
N₂O
ISOHAL
SE
DES
ENF



System OK



Anesthetic agent present



Alarm warning

Light emitting gas inlet – LEGI™

The advanced LEGI gas inlet and status indicator detects the presence of the Nomoline sampling line, and conveys color-coded information about the bench status and the alarm system. LEGI interfaces directly to PHASEIN's Nomoline for optimal performance and protection from water, mucus, and bacterial contamination. When no sampling line is connected, ISA automatically enters into a low power, standby mode. Once the sampling line is connected, ISA enters into a measuring mode and starts delivering gas data. The LEGI can be easily detached from the ISA body to add flexibility to the monitor design.

No moisture, no water traps

The ISA analyzers interface to PHASEIN's Nomoline family of gas sampling lines; the world's first sampling lines that remove both water and water vapor from the sample flow.

Integrated flow controller

The ISA analyzers, despite their very small size, integrate an advanced flow controller that secures a stable low flow of 50 ml/min for all applications, and under varying ambient conditions. Unlike other less sophisticated solutions, ISA automatically handles both patient and exhaust pressure variations, as well as a wide ambient temperature and pressure range. A gas reference valve is also provided to facilitate automatic span calibration of the optional oxygen sensor.

Durable micro pump

The integrated high reliability micro pump is fitted with a low power brushless motor. Three miniature ball bearings ensures trouble free operation without any regular maintenance. The balanced shaft design and integrated pneumatic filter virtually eliminates pressure and flow variations.

Universal interface protocol

ISA uses PHASEIN's proprietary interface protocol, common to all our products, ranging from mainstream CO₂ sensors to sidestream multigas analyzers. Changing from a mainstream to a sidestream option in your design is as simple as plug-in and measure...

RS232 or USB interfaces

The ISA analyzers are available with either a standard RS232 or a USB interface.

Rugged design

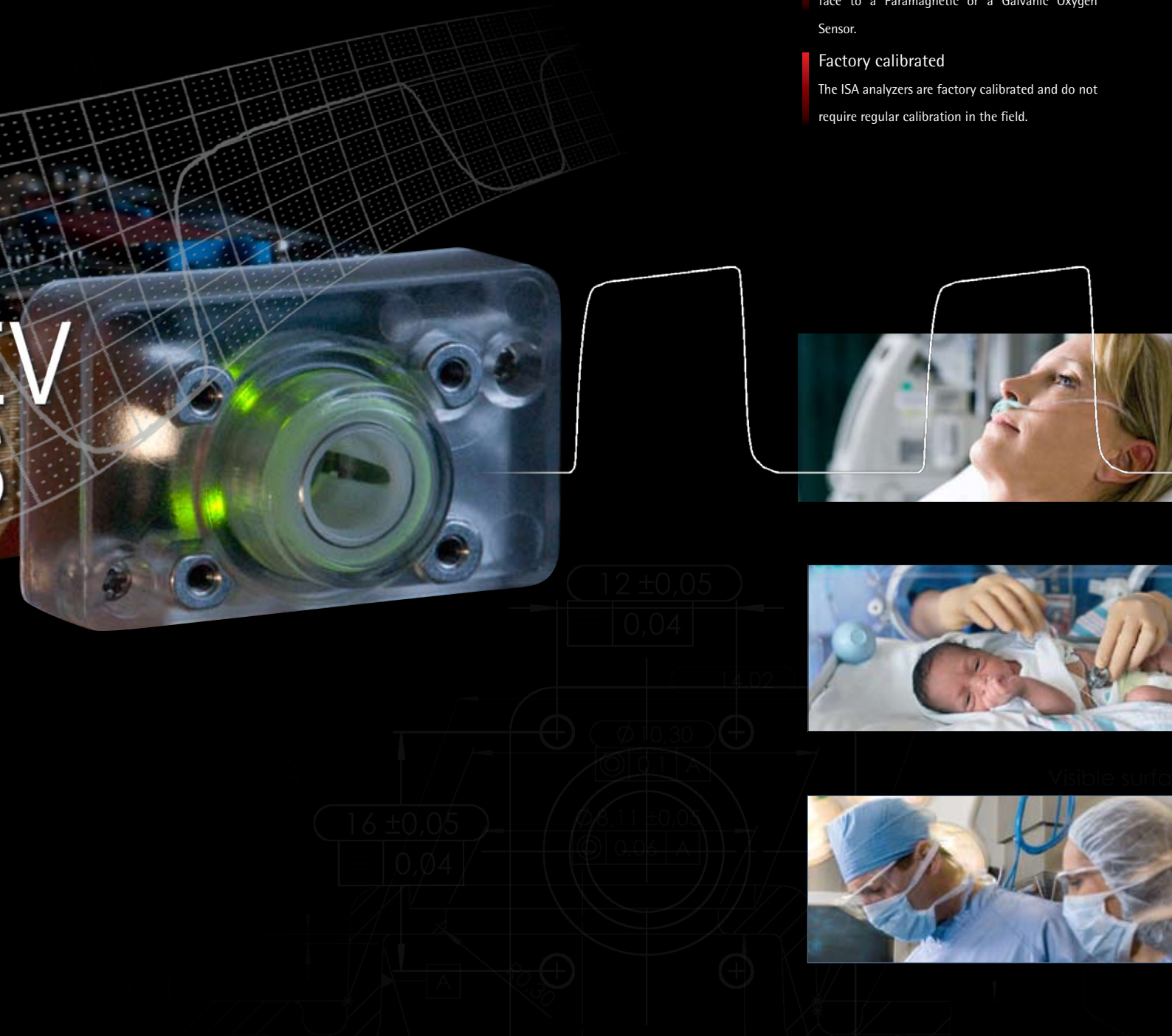
The ISA analyzers are lightweight, have a rugged design and are engineered for a wide temperature range for any clinical application including emergency and transport applications.

Oxygen options

For oxygen measurement, the ISA analyzers interface to a Paramagnetic or a Galvanic Oxygen Sensor.

Factory calibrated

The ISA analyzers are factory calibrated and do not require regular calibration in the field.



ISA™ Sidestream Analyzers and Modules

Precision engineered to deliver ultimate performance

The ISA sidestream analyzers combine innovative PHASEIN technologies with advanced features to optimize all aspects of gas monitoring. The ISA analyzers are available as stand-alone "plug-in and measure" analyzers or as easy to integrate build-in modules. Recognizing that every clinical application is unique, the intelligent features of the ISA analyzers enable you to extend the clinical application range for your products.

- **Anesthesia gas monitoring**



ISA AX+
(CO₂, N₂O, 5 AA, AA ID)
CAT.NO. 800601

ISA OR+
CO₂, O₂*, N₂O, 5 AA, AA ID
CAT.NO. 800401

* Paramagnetic oxygen sensor

- **ETCO₂ monitoring:**

- Respiration mechanics
- Procedural sedation
- Capnography for ventilator management and weaning
- Metabolic measurements and nutritional assessment
- Automated drug infusion safety



ISA CO2
(CO₂)
CAT.NO. 800101

The ISA sidestream modules have, despite their miniature size, all functions needed for a complete multigas analyzer. From the intelligent light emitting gas inlet to an advanced flow controller and a rugged micro pump.

- Low system integration complexity
- Micropower operation
- RS232 or USB interface
- Intelligent light emitting gas inlet
- Interfaces with a paramagnetic or galvanic oxygen sensor
- Utilizes the Nomoline sampling lines
- Integrated flow controller and a micro pump
- 50 ml/min sampling flow for all applications
- Permanently factory calibrated



ISA CO2 Module*
(CO₂)
CAT.NO. 700101

ISA AX+ Module*
(CO₂, N₂O, 5 AA, AA ID)
CAT.NO. 700601

*Interfaces to a paramagnetic or galvanic oxygen sensor

Nomoline™

The no moisture sampling line for all clinical applications

Sidestream systems sample respiratory gases through a sampling line for analysis within the patient monitor. The sampled gas is usually warm and humid and cools down in contact with the wall of a sampling line and condenses in form of water droplets. These droplets could potentially occlude the sampling line and interfere with the gas measurements. To protect the monitors from occlusion, special water vapor permeable solutions and water traps are frequently being used.

Eliminates both water and water vapor

The Nomoline fluid protection technology incorporates a standard sampling tube, a unique water separation section, the *nomo* section, made of a special polymer and a hydrophobic bacterial filter. Unlike traditional solutions, that remove water vapor or collect water in a plastic container, the Nomoline removes water vapor and aspirated or condensed water. Water and water vapor passes through the membrane-like surface of the Nomoline and evaporates into the surrounding air, while leaving oxygen, carbon dioxide and anesthetic gases unaffected.

No cross contamination

The Nomoline contains a bacterial filter (BFE \geq 99.9980 %) to protect the ISA analyzers and modules from water intrusion and cross contamination.

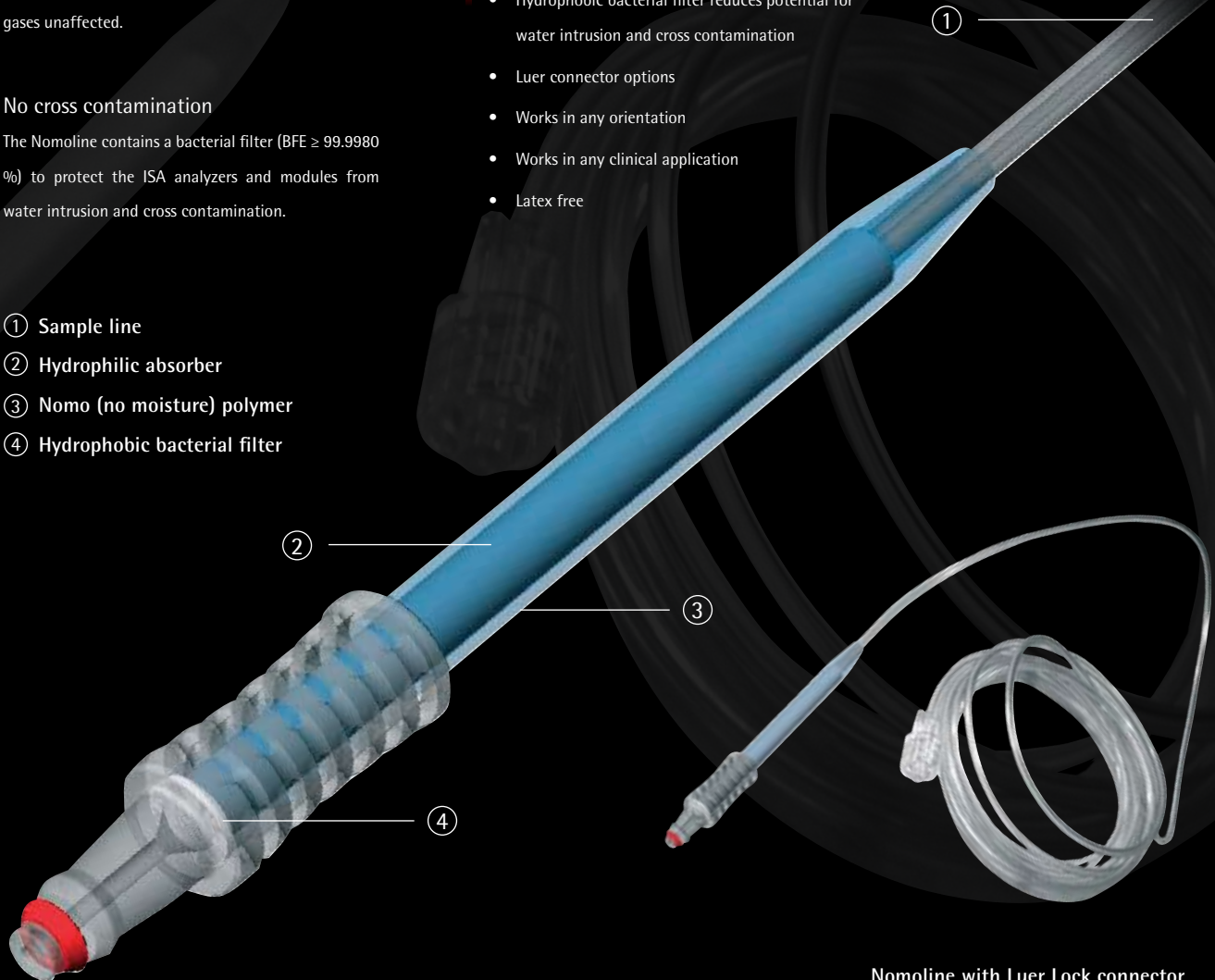
Specially designed for low-flow applications

The Nomoline is specially designed for low flow applications. It has excellent response time making CO₂, N₂O, and anesthetic agents measurement possible even at high respiratory rates. The Nomoline can be used for all type of patients from adults to neonates.

Key features

- Removes water and water vapor from sample line
- Hydrophobic bacterial filter reduces potential for water intrusion and cross contamination
- Luer connector options
- Works in any orientation
- Works in any clinical application
- Latex free

- ① Sample line
- ② Hydrophilic absorber
- ③ Nomo (no moisture) polymer
- ④ Hydrophobic bacterial filter



Nomoline with Luer Lock connector
Box of 25
CAT.NO. 108210

Technical Specifications

Description	Ultra-compact, low flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.	
Dimensions (WxDxH)	ISA CO2/AX+:	33x78x49 mm (1.3"x3.1"x1.9")
	ISA OR+:	49x90x100 mm (3.3"x5.6"x1.6")
	ISA CO2/AX+ Module:	23x64x39 mm (0.9"x2.5"x1.5")
Weight	ISA CO2/AX+:	130 g excluding cable
	ISA OR+:	400 g excluding cable
	ISA CO2/AX+ Module:	70 g
Operating temperature	ISA CO2/AX+:	0 to 50 °C (32 to 122 °F)
	ISA OR+:	5 to 50 °C (41 to 122 °F)
Storage temperature	-40 to 70 °C (-40 to 158 °F)	
Operating humidity	< 4 kPa H ₂ O (non-condensing) 95% RH at 30 °C	
Operating atmospheric pressure	52,5 to 120 kPa (corresponding to a max altitude of 4572 m / 15 000 feet)	
Ambient CO ₂	≤ 800 ppm	
Mechanical robustness	ISA CO ₂ : Meets the shock and vibration requirements for transport of SS-EN ISO 21647:2004 clause 21.102 and SS-EN 1789:2007 clause 6.3.4.2. ISA OR+ / AX+: Meets the shock and vibration requirements for transport of SS-EN ISO 21647:2004 clause 21.101.	
Power supply	4.5-5.5 VDC, ISA CO ₂ : < 1.4 W (normal op.), < 1.8 W (peak @ 5 VDC) ISA AX+: < 1.6 W (normal op.), < 2.0 W (peak @ 5 VDC) ISA OR+: < 2.0 W (normal op.), < 2.4 W (peak @ 5 VDC)	
Interface	USB or RS232 serial interface. Software upgrade possible using the RS232 serial interface.	
Water handling	Sampling line with proprietary water removal tubing.	
Sampling line	2 ± 0.1 m	
Sampling flow rate	50 ± 10 ml/min	

Data output

Breath detection	Adaptive threshold, minimum 1 vol% change in CO ₂ concentration.	
Respiration rate	0-150 breaths/min	
Fi and ET	ISA CO ₂ :	CO ₂
	ISA OR+/AX+:	CO ₂ , N ₂ O, O ₂ , primary and secondary agents (HAL, ISO, ENF, SEV, DES)
Automatic agent identification	ISA OR+/AX+: Primary and secondary agent.	
Waveforms	Up to five simultaneous gas concentration waveforms.	
Diagnostic parameters	Atmospheric pressure, Serial number, Software and Hardware revisions.	
Flags	Breath detected, No breath detected, Replace O ₂ sensor, Check sampling line, Unspecified accuracy and Sensor error.	

Gas analyzer

Sensor head	2-9 channel NDIR type gas analyzer measuring at 4-10 µm.	
Compensations	Pressure, temperature and broadening effects on CO ₂ .	
Calibration	No span calibration required. An automatic zero reference calibration is performed once every startup and then once every 24 hours.	
Warm-up time	ISA CO ₂ : < 10 seconds (Concentrations reported and full accuracy) ISA OR+/AX+: < 20 seconds (Concentrations reported, automatic agent identification enabled and full accuracy)	
Typical rise time at 50 ml/min sample flow	CO ₂	≤ 200 ms (≤ 250 ms for ISA OR+/AX+)
	N ₂ O	≤ 350 ms
	Agents	≤ 350 ms
	O ₂	≤ 450 ms ¹⁾
Primary agent threshold (ISA OR+/AX+)	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol%.	
Secondary agent threshold (ISA OR+/AX+)	0.2 vol% + 10% of total agent concentration	
Agent identification time (ISA OR+/AX+)	< 20 seconds (typically < 10 seconds)	
Total system response time	< 3 seconds (with 2 m sampling line)	

Note 1: For a 5 vol % O₂ step.

Accuracy, standard conditions ¹⁾

Gas	Range ²⁾	Accuracy
CO ₂	0-15 vol%	±(0.2 vol% + 2% of reading)
	15-25 vol%	Unspecified
N ₂ O	0-100 vol%	±(2 vol% + 2% of reading)
HAL, ISO, ENF	0-8 vol%	±(0.15 vol% + 5% of reading)
	8-25 vol%	Unspecified
SEV	0-10 vol%	±(0.15 vol% + 5% of reading)
	10-25 vol%	Unspecified
DES	0-22 vol%	±(0.15 vol% + 5% of reading)
	22-25 vol%	Unspecified
O ₂	0-100 vol%	±(1 vol% + 2% of reading)

Note 1: Dry single gases at 22 ± 5 °C and 1013 ± 40 hPa.

Note 2: All gas concentrations are reported in units of volume percent and may be translated into mmHg or kPa using the reported atmospheric pressure.

Compliance

CE marked according 93/42/EEC Medical Device Directive
EN 60601-1:2006, EN ISO 21647:2004, EN 864:1996, EN ISO 5356:2004,
ISO 594-1:1986, EN 1789:2007, IEC 60529:2001 (IPX4)

Data subject to change without notice



few examples of our modern production tools. Manufacturing and material handling areas with complete ESD protection and temperature stabilization together with local laminar flow workplaces secure high class production environment.

PHASEIN's world class product sourcing is a balanced system based on global suppliers and company's own state-of-the-art manufacturing plant. Our flexible sourcing system is optimized to meet our customers' requirements for competitive manufacturing cost, high quality and volume agility.

ERP system based on Microsoft's latest .net platform, ABB robot and computerized production test systems are just