

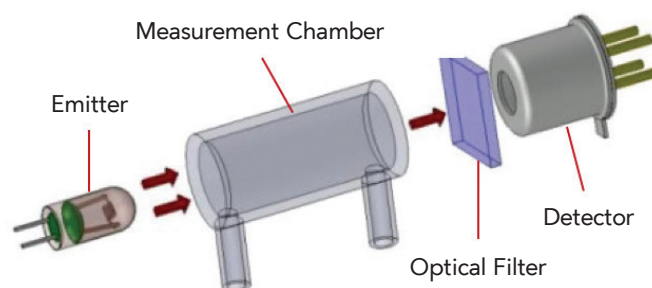
Masimo Capnography and Multi-gas Monitoring

Introduction

Masimo's NomoLine® capnography and gas monitoring technologies complement our breakthrough noninvasive portfolio with innovative, multi-spectral technologies for measuring respiratory gases and inhaled anesthetic agents. The solutions range from integrated OEM solutions, to external "plug in and measure" gas analyzers, to handheld devices. Masimo offers a variety of capnography and gas monitoring solutions, including mainstream and sidestream options, as well as internal and external modules.

Gas Measurements

At the heart of all Masimo capnography and multiple anesthetic gas analyzers lies the multi-channel infrared (IR) spectrometer. The spectrometer uses a broadband infrared radiation source to transmit light through the gas sample, where some of the light will be absorbed. Before reaching the infrared detector, the light path is intersected by narrowband optical filters that only allow light corresponding to selected wavelength peaks of the measured gases to pass. The amplitude of the detector output is an inverse function of the gas concentration. Thus, at a concentration of zero, the amplitude is at its maximum. Below is a basic infrared spectrometer.



End-Tidal Carbon Dioxide Measurements

The analyzer detects end-tidal CO₂ measurements and calculates the respiration rate using a proprietary algorithm. These algorithms are engineered to exclude any breaths that do not meet established thresholds for a valid respiratory cycle. Artifacts that are excluded from being classified as true breaths include noise from cardiogenic oscillations, extremely shallow breathing, and disturbances from non-intubated patients speaking during the measurement.

Breath detection employs an adaptive threshold, requiring a minimum change of 1 vol% in CO₂ concentration. Both FiCO₂ and EtCO₂ values are displayed after each breath and are continuously updated with a breath average through advanced signal processing algorithms. The end-tidal values are determined by the highest CO₂ concentration within a breathing cycle, with a weighting that prioritizes EtCO₂ values nearer to the cycle's end.

Sidestream Analyzers: NomoLine ISA™ Gas Analyzers

Sidestream sampling

The NomoLine ISA Gas Analyzer with the NomoLine sampling lines is specifically designed with a small measurement chamber to provide accurate measurements from 0-150 bpm at a gas sampling rate of only 50 ml/min. This makes it ideal for any patient population.

NomoLine ISA CO₂ Analyzer

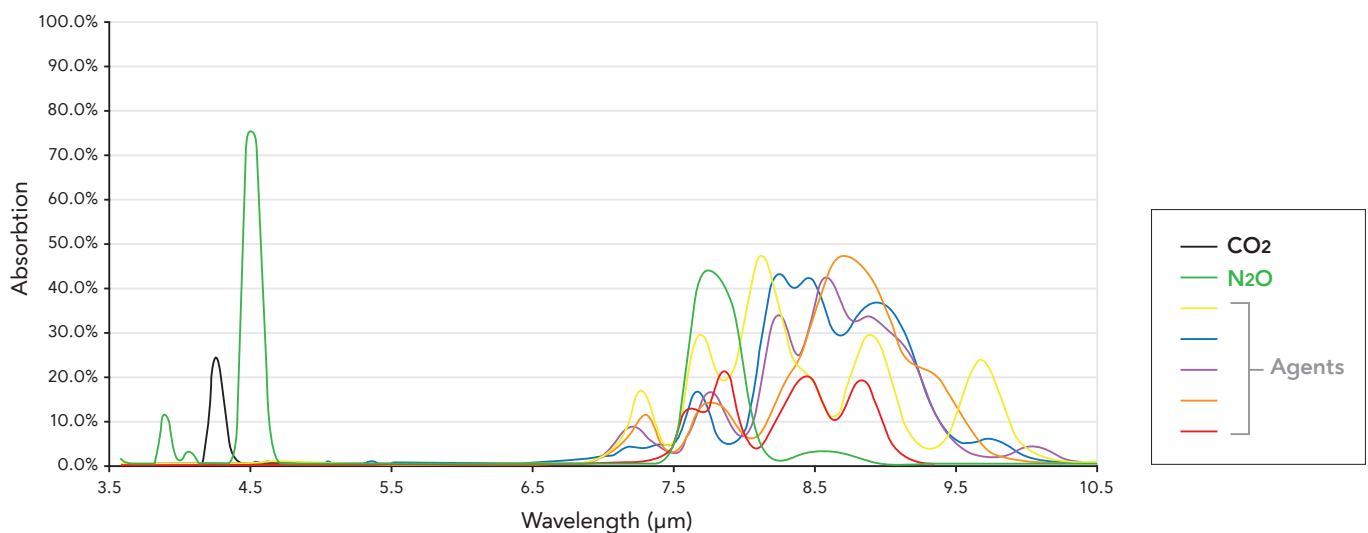
The NomoLine ISA CO₂ analyzer is a solid state, dual-channel spectrometer which uses a proprietary infrared radiation source to transmit light through the gas sample.

The choice of optical filters within the spectrometer is crucial to the characteristics and performance of the gas analyzers. The NomoLine capnography system spectrometer uses the strong absorption peak at 4.2µm for CO₂ measurement. In addition to the measurement filter, a second optical filter, appropriately located within the infrared spectrum, is used as reference. The ratio of the light that passes through the measurement filter to the light that passes through the reference filter is then used to calculate the carbon dioxide concentration.

NomoLine ISA AX+ and OR+ Multigas Analyzers

Different gases absorb infrared light at specific wavelengths so the analysis of respiratory gases by NomoLine ISA gas analyzers is performed by continuously measuring infrared light absorption in the gas flow through an infrared spectrometer. Oxygen, on the other hand, does not absorb infrared light to the same extent as other breathing gases and is therefore measured using alternative methods.

The ISA spectrometer uses the strong absorption peaks at 4.2 and 4.5µm for CO₂ and N₂O measurements and five wavelengths in the 8 to 10µm long wave infrared range (LWIR) for the anesthetic agent calculations, with negligible interference from alcohol, acetone, or other gases and vapors that could potentially degrade measurement accuracy.



In addition to the measurement filters, two optical filters, appropriately located within the 4 to 10 μ m range, are used as references for temperature compensation.

If the gas sample is a mixture of several components that absorb light at the same wavelength, such as a mixture of two anesthetic agents, the absorbed radiation will be the sum of the absorption of the agents. To determine the concentration of each of the individual gases, several filters must be used. The ISA spectrometer incorporates a filter wheel with nine precisely tuned narrowband filters for high signal-to-noise ratio measurements to facilitate simultaneous measurement of CO₂, N₂O, and a mixture of any two of the five anesthetic agents.

A specially designed parabolic reflector focuses the infrared beam so that no energy is lost. That means the analyzers can deliver high-fidelity gas data while maintaining micropower operation.

The NomoLine ISA OR+ analyzer is additionally able to measure the inspired and end-tidal oxygen in the patient's breath with a non-Masimo paramagnetic oxygen sensor. Paramagnetic oxygen analysis is based on measurements of the attractive force exerted by a strong magnetic field applied to the oxygen molecules in a gas mixture. The paramagnetic analyzer distinguishes oxygen from other gases as a function of their magnetic susceptibility. Due to its paramagnetic nature, oxygen is attracted into the magnetic field, while most other gases are not. On a scale of magnetic susceptibility, if oxygen were assigned the value 100, most other gases would have a score of close to zero.

NomoLine ISA Gas Analyzer Features

> Fast Start Up to Full Accuracy

Masimo's gas monitoring technologies have a short warm-up period to full accuracy, enabling fast start-ups with minimal delay in monitoring. Warm-up time is < 10 seconds for capnography (concentrations reported and full accuracy) and < 20 seconds for multigas analyzers. The total system response time for ISA is < 3 seconds (with a 2m sampling line).

> No Zeroing Delays During Monitoring

NomoLine capnography and ISA gas monitoring technologies do not auto zero or calibrate during monitoring, eliminating delays present with other technologies. Automatic zeroing (room air reference measurement) is performed when the NomoLine sampling line is disconnected from the ISA capnography analyzer. Automatic zeroing occurs every eight hours for ISA multigas analyzers. The zeroing procedure lasts < 3 seconds for capnography and < 10 seconds for multigas analyzers.

> Factory Calibrated; No User Calibration Required

Masimo capnography and multigas analyzers are permanently factory calibrated and require no user calibration. The manufacturing and calibration of each analyzer are performed as a part of a fully automated process using robots and specially designed testing and calibration equipment. Each analyzer is characterized in terms of linearity, span, zero, temperature, and pressure sensitivity. An individual calibration matrix is automatically generated and stored in the calibration memory of each analyzer. The analyzer design and full characterization factory calibration process ensure that the analyzer will work in any clinical environment without the need for periodic user calibrations.

Mainstream Analyzers: EMMA®, Radius PCG®, and IRMA™ Gas Analyzers

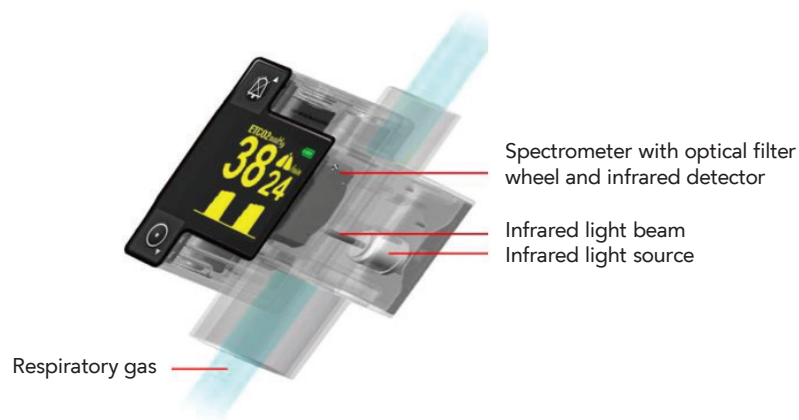
Gas Analysis

The measurement principle for mainstream analyzers is the same as for sidestream. The main difference is that for mainstream analyzers, the measurement chamber is an airway adapter. Respiratory gas measurements are obtained by continuously measuring the infrared light absorption through windows in the adapter.

EMMA, Radius PCG, and IRMA CO₂ Analyzers

The amount of absorbed light is measured by a miniaturized two-channel spectrometer positioned to receive the infrared light beam. The mainstream CO₂ spectrometer incorporates a filter wheel fitted with two different narrowband optical filters. The wavelength ranges of these filters are chosen such that one is located at 4.2µm, where carbon dioxide has very strong absorption, and the other is located where carbon dioxide has no absorption and where interference from condensed water is minimized.

The electrical signal is converted to a digital value that is fed to a microprocessor. The ratio of the light that passes through the measurement filter to the light that passes through the reference filter is then used by the microprocessor to calculate the carbon dioxide concentration in the breathing gas mixture.



IRMA AX+ Multigas Analyzer

The absorbed light is measured by a miniaturized nine-channel spectrometer. The spectrometer, which is the same as for the sidestream multigas analyzers, incorporates a proprietary infrared light source and a filter wheel fitted with nine different narrowband optical filters.