

NomoLine[®]ISA[™] CO₂
Sidestream Gas Analyzer



These operating instructions intend to provide the necessary information for proper operation of the NomoLine® ISA™ CO2 (NomoLine ISA CO2). General knowledge of capnography monitoring and an understanding of the features and functions of NomoLine ISA CO2 are prerequisites for proper use. Do not operate NomoLine ISA CO2 without completely reading and understanding these instructions. If you encounter any serious incident with product, please notify the competent authority in your country and the manufacturer.

Notice: Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

Note: Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) and are CE Marked for noninvasive patient monitoring and may not be used for any processes, procedures, experiments, or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings and precautions.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

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MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
ANSI/AAMI ES60601-1:2005+A1:2012 Cert. to CAN/CSA-C22.2
No.60601.1:2014 Ed.3 Standards for which the product has been found to
comply by Intertek.

Patents: www.masimo.com/patents.htm



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About This Manual

This manual explains how to set up and use the NomoLine® ISA™ CO2. Important safety information relating to general use of NomoLine ISA CO2 appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.

WARNING: This is an example of a warning statement.

A *caution* is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property.

CAUTION: This is an example of a caution statement.

A *note* is given when additional general information is applicable.

Note: This is an example of a note.

Product Description, Features and Indications for Use

Product Description

NomoLine® ISA™ CO₂ is part of the ISA product family and is a sidestream gas analyzer intended to be connected to other medical backboard devices for monitoring of breath rate and carbon dioxide CO₂ gas concentration. NomoLine ISA CO₂ supports various types of host connectors for providing measured data.

Intended Use

NomoLine® ISA™ CO₂ sidestream gas analyzer and accessories including NomoLine, is intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

- CO₂

NomoLine ISA CO₂ is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. NomoLine ISA CO₂ is also intended to be used in road ambulances. The intended patient population is adult, pediatric, infant and neonatal patients.

Safety Information, Warnings and Cautions

CAUTION: NomoLine ISA CO2 is to be operated by, or under the supervision of, qualified personnel only. Read this Operator's Manual, accessories directions for use, all precautionary information, and specifications before use. Refer to the host device operator's manual or user's guide for additional safety information, warnings and cautions.

Safety Warnings and Cautions

WARNING: Do not use NomoLine ISA CO2 if it appears or is suspected to be damaged. Damage to the device can result in exposed electrical circuits that may cause patient harm.

WARNING: Do not adjust, repair, open, disassemble, or modify the NomoLine ISA CO2. Damage to the device may result in degraded performance and/or patient injury.

WARNING: Do not start or operate the NomoLine ISA CO2 unless the setup was verified to be correct. Improper set-up of this device may result in degraded performance and/or patient injury.

WARNING: Do not place the NomoLine ISA CO2 or accessories in any position that might cause it to fall on the patient.

WARNING: Only use Masimo authorized devices with NomoLine ISA CO2. Using unauthorized devices with NomoLine ISA CO2 may result in damage to the device and/or patient injury.

WARNING: Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.

WARNING: Do not lift the NomoLine ISA CO2 by the NomoLine capnography sampling line as it could disconnect from the NomoLine ISA CO2, causing the device to fall on the patient.

WARNING: Do not use the NomoLine ISA CO2 during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: Only use sample lines intended for anesthetic agents if N₂O and/or anesthetic agents are being used.

WARNING: Do not re-use disposable single-patient use NomoLine Family sampling lines due to the risk of cross contamination.

WARNING: Do not use the NomoLine Infant/Neonate Airway Adapter Sets for adults/pediatrics as they may cause excessive flow resistance (0,7 ml dead space).

WARNING: Do not use the NomoLine Adult/Pediatric Airway Adapter Sets for infants/neonates as the airway adapter adds 6 ml dead space.

WARNING: Do not apply negative pressure to remove condensed water from the NomoLine Family sampling line.

WARNING: NomoLine ISA CO2 is not intended to be used for returning exhaust gases to the patient circuit. Exhaust gases should be returned to a scavenging system.

Note: Disconnect the device from AC mains by removing the device cable connection from the host device.

Note: Use and store the NomoLine ISA CO2 in accordance with specifications. See the Specifications section in this manual.

Performance Warnings and Cautions

WARNING: NomoLine ISA CO2 should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: Use of high-frequency electrosurgical equipment in the vicinity of NomoLine ISA CO2 may produce interference and cause incorrect measurements.

WARNING: Do not use the NomoLine ISA CO2 with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.

WARNING: Properly apply sampling lines according to the sampling lines directions for use. Misapplied sampling lines that become partially dislodged may cause no or incorrect readings.

WARNING: Replace the sampling line if the sampling line input connector starts flashing red, or host device displays a *check sampling line* type of message.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.

WARNING: Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the NomoLine ISA CO2 including the cable. Otherwise, degradation of the performance of the NomoLine ISA CO2 could result.

WARNING: Too strong positive or negative pressure in the patient circuit might affect the sample flow.

WARNING: Strong scavenging suction pressure might affect the sample flow.

CAUTION: Do not operate NomoLine ISA CO2 outside of the specific operating environment.

CAUTION: NomoLine ISA CO2 should be mounted securely to avoid risk of damage to the NomoLine ISA CO2.

Cleaning and Service Warnings and Cautions

WARNING: To avoid electric shock, always physically disconnect the NomoLine ISA CO2 and all patient connections before cleaning.

WARNING: Do not attempt to remanufacture, recondition or recycle the NomoLine ISA CO2 as these processes may damage the electrical components, potentially leading to patient harm.

CAUTION: Do not sterilize or immerse NomoLine Family sampling lines in liquid.

CAUTION: To avoid permanent damage to the NomoLine ISA CO2, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.

CAUTION: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the NomoLine ISA CO2. These substances affect the device's materials and device failure can result.

CAUTION: Do not submerge the NomoLine ISA CO2 in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

CAUTION: To prevent damage, do not soak or immerse NomoLine ISA CO2 in any liquid solution.

Compliance Warnings and Cautions

WARNING: Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

WARNING: Use of accessories and cables other than those specified or provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Dispose NomoLine Family sampling lines in accordance with local regulations for biohazardous waste.

CAUTION: Disposal of Product: Comply with local laws in the disposal of the device and/or its accessories.

CAUTION: For FCC compliance information, refer to the host monitor Operator's Manual.

Note: Use the NomoLine ISA CO2 in accordance with the *Environmental Specifications* section in the host monitor Operator's Manual.

Chapter 1: Technology Overview

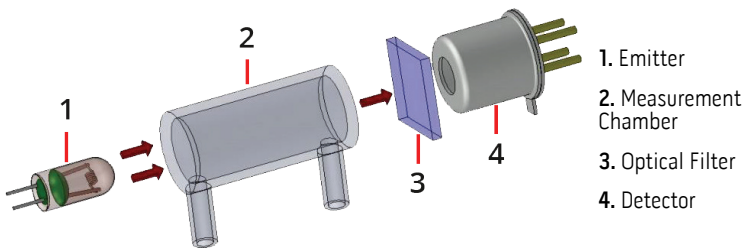
The following chapter contains general descriptions about the technology used by Masimo products.

NomoLine ISA CO₂ Technology Overview

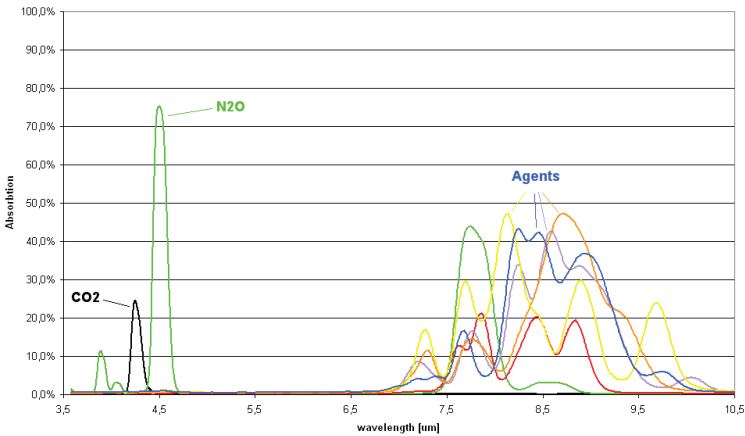
NomoLine capnography computes and analyzes the parameters based on the samples gathered from the patient's breathing circuit, via the NomoLine sampling line.

The heart of the NomoLine capnography system is the solid state, dual-channel spectrometer which uses a proprietary infrared radiation source to transmit light through the gas sample. Before reaching the gas sample, the light path is intersected by a narrow band optical filter that only allow light corresponding to the selected wavelength peak of CO₂ to pass. At the other end of the light path, a sensor detects the portion of the light that is not absorbed by the gas. 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.

Basic Infrared Spectrometer



The selection of the optical filter within the spectrometer is crucial to the characteristics and performance of the gas analyzer. The NomoLine capnography system spectrometer uses the strong absorption peak at 4.2 μm for CO_2 measurement. In addition to the measurement filter, a second optical filter appropriately located within the infrared spectrum is used as reference.



Infrared absorption spectrum for common respiratory gases

Chapter 2: Description

This chapter contains the description of the NomoLine ISA CO2 physical features.

General System Description

The NomoLine ISA CO2 system includes the following:

- NomoLine ISA CO2 Device
- NomoLine Sampling Line

For a complete list of compatible NomoLine sampling lines, cannulas, and related consumables, visit www.masimo.com.

Features

Front View



1. NomoLine Capnography Input Connector

Allows connection to NomoLine® for capnography measurements. Light Emitting Gas Inlet (LEGI) Indicator provides visual indications of capnography status. See *LEGI Indicator* on page 19.

Rear View



2. Capnography Gas Sample Exhaust Port

Exhaust port for gas samples. See *System Setup* on page 17.

NomoLine Sampling Lines

NomoLine ISA CO2 samples gas from the respiratory circuit through the NomoLine Family sampling line at a rate of 50 sml/min, making measurements of CO₂ possible for adult, pediatric, infant and neonatal patients. The NomoLine Family of sampling lines are designed for optimal performance and measurement fidelity when used with the NomoLine ISA gas analyzers.

NomoLine sampling lines include nasal and nasal/oral cannulas for non-intubated patients with and without supplementary oxygen delivery and airway adapter sets for intubated patients.



As long as no sampling line is connected, the NomoLine ISA gas analyzer remains in a low-power sleep mode. Once the sampling line is connected, the NomoLine ISA gas analyzer switches to measuring mode and starts delivering gas data.

For ordering information about NomoLine sampling lines, cannulas, and related consumables, visit www.masimo.com.

Sampling Line Replacement

NomoLine sampling lines should be replaced between each patient or when the sampling line becomes occluded. Occlusion occurs when water, secretions etc. are aspirated from the respiratory circuit to such an extent that NomoLine ISA CO2 cannot maintain the normal 50 ml/min sample flow. This is indicated by a red flashing LEGI indicator and an alarm message; replace the sampling line and wait until the LEGI indicator switches to green, indicating that the NomoLine ISA CO2 gas analyzer is again ready for use.

For ordering information about NomoLine sampling lines and related consumables, visit www.masimo.com.

Chapter 3: Setting Up

This chapter contains information about setting up NomoLine ISA CO₂ before use.

System Setup

During setup, refer to the host device operator's manual or user's guide, in addition to the following procedure.

1. Remove the temporary plug from the NomoLine Capnography input connector.
2. Securely mount the NomoLine ISA CO₂.
Note: A bracket designed to mount NomoLine ISA CO₂ is available, visit www.masimo.com.
3. Connect the gas sample exhaust port on the rear of NomoLine ISA CO₂ to a scavenging system if intended to be used in combination with N₂O and/or anesthetic agents.
4. Connect the NomoLine ISA CO₂ cable to the host device connection port.
5. Connect a NomoLine sampling line to the NomoLine ISA CO₂ input connector. See **Front View** on page 15.
6. Check that host device is powered up and correctly configured.
7. Check that the LEG1 indicator shows a steady green light, indicating that NomoLine ISA CO₂ is ready for use. See **LEG1 Indicator** on page 19.
Note: Without a sampling line connected, the LEG1 Indicator does not illuminate.
8. Attach a NomoLine sampling line to the patient for monitoring. Refer to the NomoLine sampling line Directions for Use.
9. Following connection of the NomoLine sampling line, check that CO₂ values appear on the host device screen. See **Capnography Display** on page 19.

Chapter 4: Operation

The information in this chapter assumes that NomoLine ISA CO2 is set up and ready for use. Do not operate NomoLine ISA CO2 without completely reading and understanding these instructions.

LEGI Indicator



The Light Emitting Gas Inlet (LEGI) Indicator provides visual indications of capnography status. The LEGI Indicator (3) is located around the capnography connector on the front of the device.

The LEGI indicator illuminates in different colors depending on the state of the device as described in the table:

LEGI Indicator	Status
Steady green light	Capnography monitoring in operation and OK
Blinking green light	Zeroing in progress. See Zeroing on page 34.
Steady red light	Sensor error
Blinking red light	Check the sampling line (possible occlusion)

Note: Without a NomoLine sampling line connected, the LEGI Indicator does not illuminate.

With no sampling line connected, NomoLine ISA CO2 stays in a low-power, sleep mode. Once a sampling line is connected, NomoLine ISA CO2 switches to measuring mode and starts delivering gas data.

Capnography Display

Parameters and measurements display on the screen of the host device that NomoLine ISA CO2 is connected to. Refer to the host device operator's manual or user's guide for complete information on displayed parameters, settings, alarms and messages.

Chapter 5: Troubleshooting

To troubleshoot issues with the host device, see the operator's manual for the host device.

Troubleshooting NomoLine ISA CO2

Symptom	Possible Cause	Correction
<i>NomoLine ISA CO2 values are not displayed on host device</i>	<ul style="list-style-type: none">• NomoLine ISA CO2 requires a power cycle• Host device is not configured correctly or is incompatible with NomoLine ISA CO2	<ul style="list-style-type: none">• Disconnect and reconnect the NomoLine ISA CO2 connector at the host device.• Verify that the host device is correctly configured and compatible with NomoLine ISA CO2.
<i>LEGI indicator is dark (indicator is off)</i>	<ul style="list-style-type: none">• NomoLine ISA CO2 is not plugged in to the host device connector• Sampling line not plugged in to NomoLine ISA CO2 completely• Internal error	<ul style="list-style-type: none">• Verify NomoLine ISA CO2 connection to the host device.• Disconnect and reconnect the sampling line to NomoLine ISA CO2.• The NomoLine ISA CO2 requires service. See Return Procedure on page 34.
<i>LEGI indicator blinking red</i>	<ul style="list-style-type: none">• Sampling line obstructed (occlusion)	<ul style="list-style-type: none">• Inspect sampling line for occlusion (blockage, kink in line).• Replace sampling line. See Sampling Line Replacement on page 16.
<i>LEGI indicator steady red</i>	<ul style="list-style-type: none">• NomoLine ISA CO2 requires a power cycle• Internal error	<ul style="list-style-type: none">• Disconnect and reconnect the NomoLine ISA CO2 connector at the host device.• If persistent, the NomoLine ISA CO2 requires service. See Return Procedure on page 34.

Symptom	Possible Cause	Correction
<p><i>Gas readings are questionable</i></p>	<ul style="list-style-type: none"> • Incorrect sampling line used • Sampling line attached incorrectly • Sampling line leaking • Internal error 	<ul style="list-style-type: none"> • Use the correct sampling line with NomoLine ISA CO2. • Disconnect and reconnect the sampling line to NomoLine ISA CO2. • Follow the Directions for Use to properly connect the sampling line. • Inspect sampling line for leaks. • Replace sampling line. See <i>Sampling Line Replacement</i> on page 16. • Perform an Operational Check. See <i>Operational Check</i> on page 33. • Perform the procedures in the maintenance section. See <i>Maintenance</i> on page 33. • If persistent, the NomoLine ISA CO2 requires service. See <i>Return Procedure</i> on page 34.

Chapter 6: Specifications

Accuracy

Standard Conditions

The following accuracy specifications are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa:

Gas	Range*	Accuracy
CO ₂	0 to 15 vol% 15 to 25 vol%	$\pm(0.2 \text{ vol\%} + 2\% \text{ of reading})$ Unspecified

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

All Conditions

The following accuracy specification is valid for all specified environmental conditions except for interference specified in **Effects from Water Vapor Partial Pressure on Gas Readings** on page 27 and **Interfering Gas Vapor Effect** on page 27.

Gas	Accuracy
CO ₂	$\pm(0.3 \text{ kPa} + 4\% \text{ of reading})$

Environmental

Environmental Conditions	
Operating Temperature	0°C to 50°C (32°F to 122°F)
Storage/Transport Temperature*	-40°C to 70°C (-40°F to 158°F)
Operating Humidity**	10% to 95% RH (non-condensing)
Storage/Transport Humidity	10% to 95% RH (non-condensing at ambient temperature)
Ambient CO ₂	≤ 800 ppm
Operating Atmospheric Pressure***	525 mbar to 1,200 mbar (52.5 kPa to 120 kPa)
Storage/Transport Atmospheric Pressure	200 mbar to 1,200 mbar (20 kPa to 120 kPa)
Transient Operating	The device operates according to specification when exposed to -20°C to 0°C (-4°F to 32°F) for 20 minutes.

* A warm up period of 10 minutes is required for the NomoLine ISA CO₂ to fulfill the accuracy specification if immediately put into use after being stored at -40°C. See **Chapter 5: Troubleshooting** on page 21 for additional information.

** Not requiring partial pressure greater than 50 hPa, in accordance to IEC 60601-1-12.

*** CO₂ measurement inaccuracy shall be ± (0.3 kPa + 4 % of reading).

Physical Characteristics

Item	Specification
Dimensions*	91 mm x 60 mm x 37 mm (3.6" x 2.4" x 1.4")
Weight*	Approx. 98 g (0.22 lbs)
Expected Service Life	5 Years

* Excluding cable, tubing and NomoLine.

Electrical

Item	Specification
Power Supply	4.5 to 5.5 VDC ≤ 0.9 W (normal operation @ 5V) < 4 W (power surge @ 5V can last up to 60 ms when entering measurement mode from sleep mode or during start-up)

Compliance

EMC Compliance
See host monitor Operator's Manual.

Safety Standards Compliance
IEC 60601-1:2005/AMD1:2012
IEC 62304:2006/AMD1:2015
EN/ISO 80601-2-55:2018
EN 60601-1:2006/AMD1:2013
IEC 60601-1-12:2014
ANSI/AAMI ES60601-1:2005/A1:2012
CAN/CSA C22.2 No. 60601-1:2014

Equipment Classification per IEC 60601-1	
Type of Protection	Class II
Degree of Protection of Electrical Shock	Defibrillation proof BF-Applied Part
Protection against harm from liquid ingress	IP34, Protection from ingress of particulates ≥ 2.5 mm and against splashing water from all directions
Mode of Operation	Continuous operation

Additional Specifications

General	Specifications
Ambient CO ₂	≤ 800 ppm (0.08 vol%)
Recovery Time After Defibrillator Test	Unaffected
Drift of measurement Accuracy	No drift
Interface	RS-232 and USB
Water Handling	NomoLine Family sampling lines with proprietary water removal tubing.
Sampling Flow Rate*, **	50 ± 10 sml/min

*Volumetric flow rate of air corrected to standardized conditions of temperature and pressure.
 ** Flow accuracy specification for the extended temperature range (-20°C to 0°C) is +15/-10 sml/min.

Data Output	Specifications
Breath detection	Adaptive threshold, minimum 1 vol% change in CO ₂ concentration.
Respiration rate ***	0 to 150 ± 1 breaths/min

Data Output	Specifications
Fi and ET ****	Fi and ET are displayed after one breath and have a continuously updated breath average. The following method is used to calculate end-tidal (ET) values: <ul style="list-style-type: none"> The highest concentration of CO₂ during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. ET will typically decrease below nominal value (ET _{nom}) when respiration rate (RR) exceeds the RR threshold (RR _{th}) according to the following formula for CO ₂ : $Et = Et_{nom} \times \sqrt{95/RR} \text{ for } RR > 95$ (with NomoLine HH Adult/Pediatric Airway Adapter Set)
Flags	Breath Detected, No Breath Detected, Check Sampling Line, Unspecified Accuracy, Sensor Error

*** Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.

**** Measured according to EN ISO 80601-2-55.

Gas Analyzer	Specifications
Sensor head	Dual channel NDIR type gas analyzer measuring at 3.5 to 4.5 μm. Data acquisition rate 10 kHz (sample rate 20 Hz / channel).
Compensations	Automatic compensation for pressure and temperature. Manual compensation for broadening effects on CO ₂ .
Calibration	No span calibration is required.*****
Warm-up time	< 10 seconds (Concentrations reported and full accuracy)
CO2 Rise time at 50 sml/min sample flow *****	≤ 200 ms
Analyzer System Response Time	< 3 seconds

***** An automatic zeroing is performed. See **Zeroing** on page 34.

Effects from Water Vapor Partial Pressure on Gas Readings

When the breathing gas flows through the sampling line, the gas temperature will adapt to the ambient temperature before reaching the gas analyzer. The measurement of all gases will always show the actual partial pressure at the current humidity level in the gas sample. As the NOMO section removes all condensed water, no water will reach the NomoLine Capnography gas analyzer. However at an ambient temperature of 37 °C and a breathing gas with a relative humidity of 95% the gas reading will typically be 6% lower than corresponding partial pressure after removal of all water.

Interfering Gas Vapor Effect

Gas or Vapor	Gas Level	CO ₂
N ₂ O ⁴	60 vol%	- ²
HAL ⁴	4 vol%	- ¹
ENF, ISO, SEV ⁴	5 vol%	+8% of reading ³
DES ⁴	15 vol%	+12% of reading ³
Xe (Xenon) ⁴	80 vol%	-10% of reading ³
He (Helium) ⁴	50 vol%	-6% of reading ³
Metered dose inhaler propellant ⁴	Not for use with metered dose inhaler propellants	
C ₂ H ₅ OH (Ethanol) ⁴	0.3 vol%	- ¹
C ₃ H ₇ OH (Isopropanol) ⁴	0.5 vol%	- ¹
CH ₃ COCH ₃ (Acetone) ⁴	1 vol%	- ¹
CH ₄ (Methane) ⁴	3 vol%	- ¹
CO (Carbon Monoxide) ⁵	1 vol%	- ¹
NO (Nitrogen Monoxide) ⁵	0.02 vol%	- ¹
O ₂ ⁵	100 vol%	- ²

Note 1: Negligible interference, effect included in the specification "Accuracy, all conditions" above.

Note 2: Negligible interference with N₂O / O₂ concentrations correctly set, effect included in the specification "Accuracy, all conditions" above.

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO₂ readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO₂ and 50 vol% Helium, the actual measured CO₂ concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO₂.

Note 4: According to the EN ISO 80601-2-55 standard.

Note 5: In addition to the EN ISO 80601-2-55 standard.

Guidance and Manufacturer's Declaration-Electromagnetic Emissions

This section constitutes the guidance and Masimo's declaration regarding electromagnetic emissions for NomoLine ISA CO2.

The NomoLine ISA CO2 system is expected to be used in professional environments like intensive care units, patient rooms and operating suites except near high frequency electro surgical equipment and magnetic resonance imaging (MRI) systems. The NomoLine ISA CO2 system is also intended to be used in emergency medical services as road ambulances.

The NomoLine ISA CO2 system is intended for use in the electromagnetic environment specified in the tables below. Customers or end users of the NomoLine ISA CO2 system should assure that the NomoLine ISA CO2 system is used within the intended environment.

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
Emission Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The NomoLine ISA CO2 system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The NomoLine ISA CO2 system is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF Emissions EUROCAE ED-14G or RTCA DO-160G, Section 21	Category M	Suitable for use in passenger cabin or in the cockpit of a transport aircraft.

Guidance and Manufacturer's Declaration-Electromagnetic Immunity

This section constitutes the guidance and Masimo's declaration regarding electromagnetic immunity for NomoLine ISA CO2.

Essential performance of NomoLine ISA CO2 is gas measurement accuracy (according to **Accuracy** on page 23) including gas reading alarm conditions, or generation of technical alarm conditions, when exposed to the following immunity levels.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 6 Vrms in ISM and amateur radio bands 80%AM@1kHz 0.15 MHz to 80 MHz	
Radiated RF IEC 61000-4-3	10 V/m 80%AM@1kHz 80 MHz to 2.7 GHz and Table 9 (60601-1-2:2015)	Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the NomoLine ISA CO2 system. Otherwise, degradation of the performance of this equipment could result.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.























WARNING: Use of accessories and cables other than those specified or provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.






WARNING: Make sure that NomoLine ISA CO2 system is used in the electromagnetic environment specified in this manual.

WARNING: Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NomoLine ISA CO2 system including the cable. Otherwise, degradation of the performance of the NomoLine ISA CO2 system could result.

Symbols

The following symbols may appear on the product or product labeling:

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
	Separate collection for electrical and electronic equipment (WEEE)		European Union Conformity Mark
IP34	Protection from ingress of particulates ≥ 2.5 mm and against splashing water from all directions		ETL Intertek certification See Declarations on Page 1 for certifications
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician		Defibrillation-proof. Type BF applied part
	Biohazardous Waste		Serial number
	CO ₂		Catalog number (model number)
	Lot Code		Not made with natural rubber latex
	Storage temperature range		Fragile, handle with care
	Keep dry		Atmospheric pressure limitation
	Storage humidity limitation		Do not use if package is damaged
	Gas inlet		Date of manufacture YYYY-MM-DD
	Gas outlet		Manufacturer

Symbol	Description	Symbol	Description
	Medical Device		Authorized representative in the European community
	Class II Equipment		China Restriction of Hazardous Substances
	Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs Note: eIFU is not available in all countries.		

Chapter 7: Service and Maintenance

Cleaning

Cleaning of the NomoLine ISA CO2 should be performed at regular intervals or in accordance with hospital, as well as local and governmental regulations.

See **Safety Information, Warnings and Cautions** on page 9.

WARNING: To avoid electric shock, always physically disconnect the NomoLine ISA CO2 and all patient connections before cleaning.

CAUTION: To avoid permanent damage to the NomoLine ISA CO2, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.

CAUTION: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the NomoLine ISA CO2. These substances affect the device's materials and device failure can result.

CAUTION: Do not submerge the NomoLine ISA CO2 in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

CAUTION: To prevent damage, do not soak or immerse NomoLine ISA CO2 in any liquid solution.

Note: To prevent cleaning liquids and dust from entering the NomoLine capnography gas analyzer through its sampling gas inlet connector, keep the sampling line fitted while cleaning NomoLine ISA CO2.

NomoLine ISA CO2 may be cleaned using a cloth moistened (not wet) with the cleaning agent. The surfaces of the NomoLine ISA CO2 may be cleaned with the following solution(s):

- 70% ethyl alcohol
- 70% isopropyl alcohol
- Glutaraldehyde Solution
- Quaternary Ammonium Chloride Wipe
- 0.5% Sodium Hypochlorite/Water Solution
- Accelerated Hydrogen Peroxide

Maintenance

Once every year it is recommended to perform maintenance on NomoLine ISA CO2. A NomoLine ISA Maintenance Kit containing components and instructions to perform maintenance procedures is available through www.masimo.com. The NomoLine ISA Maintenance Kit may also be used for troubleshooting.

Operational Check

In addition to the Pre-use check (see **System Setup** on page 17), the Operational check includes a Capnogram check and an Occlusion check. The Operational check shall be performed according to the following procedure before the NomoLine ISA CO2 is taken into operation or as part of troubleshooting.

1. Connect the NomoLine ISA CO2 cable to the host device connection port.
2. Connect a NomoLine sampling line to the NomoLine ISA CO2 input connector.
3. Power up the host device.
4. Check that the LEG1 indicator shows a steady green light, indicating that NomoLine ISA CO2 is ready for use.

Note: Without a sampling line connected, the LEG1 Indicator does not illuminate.

5. Breathe briefly into the sampling line and check that a valid CO₂ waveform and values are displayed on the host device screen.
6. Occlude (obstruct) the sampling line and wait for 10 seconds.
7. Check that an occlusion alarm is displayed and that the LEG1 connector shows a flashing red light.

Zeroing

The highly stable NomoLine ISA CO2 spectrometer requires no regular zeroing. A room air reference measurement is performed when the NomoLine is disconnected from the LEG1 connector, provided that CO₂ measurements are stable. This zeroing procedure is indicated by the LEG1 blinking green.

Repair Policy

Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the instrument repaired.

Please clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in **Cleaning** on page 33. Make sure the equipment is fully dry before packing.

To return the NomoLine ISA CO2 for service, please follow the **Return Procedure** below on page 34.

Return Procedure

Clean contaminated/dirty equipment before returning, following instructions in **Cleaning** on page 33. Make sure the equipment is fully dry before packing. Contact the seller to request instructions on how to return the equipment. Package the equipment securely, in the original shipping container if possible, and enclose or include the following information and items (or other information as the seller requires):

- A letter describing in detail any difficulties experienced with the NomoLine ISA CO2.
- Warranty information, a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the NomoLine ISA CO2 is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.

- A certificate stating the NomoLine ISA CO2 has been decontaminated for bloodborne pathogens.
- Return the NomoLine ISA CO2 to the shipping address provided by the seller.

Sales & End-User License Agreement

This document is a legal agreement between you ("Purchaser") and Masimo Corporation and/or its relevant subsidiary or affiliate ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded software and/or firmware ("Software"). Except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund. BY ACCEPTANCE OR USE OF THIS PRODUCT, YOU ACKNOWLEDGE YOUR ACCEPTANCE OF THESE TERMS.

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Masimo warrants to the original end-user Purchaser that the Product and any Software media contained in the original packaging will conform to Masimo's published specifications in effect at the time of manufacture when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months and any batteries for six (6) months from the original date the Product was obtained by the end-user purchaser.

Masimo's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or Software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact the seller, and follow all instructions and procedures given by the seller. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by Purchaser.

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Possession or purchase of the Product does not convey any express or implied license to use the device with unauthorized sensors or cables that would, alone, or in combination with the device, fall within the scope of one or more of the patents relating thereto.

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