VIAMED

Handheld Mainstream and Sidestream CO_2/SpO_2 Monitors VM-2500-M and VM-2500-S

User Manual

VM-2500 User Manual

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SE519766; SE519779; SE523461; SE524086. Other patents pending

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1 Introduction
1.1 Intended Use

The VM-2500 CO_2/SpO_2 Monitor is intended to provide continuous monitoring of end-tidal CO_2 concentration ($EtCO_2$), inspired CO_2 concentration ($FiCO_2$), functional arterial oxygen saturation (SpO_2), respiration rate (RR) and pulse rate (PR) of adult, paediatric infant and neonatal patients. The CO_2 measurement can be performed either with the mainstream method using the VM-2500-M or with the sidestream method using the VM-2500-S.

It may be used in hospital, hospital type facilities, operating suites, intensive care units, emergency medicine/emergency transport as well as in the home care environment.

The VM-2500 CO_2/SpO_2 Monitor is not intended to be used as the only means of monitoring a patient. It shall always be used in combination with other vital sign monitoring devices and/or professional human judgments of a patient's condition. The VM-2500 is intended to be used by trained and authorized health care professionals only.

1.2 Warnings

Adhere to the following warnings for safe operation of the VM-2500-M mainstream CO_2/SpO_2 Monitor and the VM-2500-S sidestream CO_2/SpO_2 Monitor.

For VM-2500 in General:

⚠ *Warning: The monitor is to be operated only by trained personnel and is for attended monitoring only.*

⚠ *Warning: Do not make any clinical judgments based solely on the VM-2500. The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. The interpretation of the measurement values should be done only by trained health care professionals.*

⚠ *Warning: The monitor should only be used for the purpose and in the manner described in this manual.*

⚠ *Warning: Explosion hazard. Do not use the monitor in the presence of flammable anaesthetic mixtures with air, oxygen, or nitrous oxide.*

⚠ *Warning: Routinely monitor the patient to make sure that the VM-2500 is functioning correctly and the SpO_2 sensor, the mainstream IRMA™ CO_2 analyzer and the CO_2 sidestream sampling configuration are correctly placed.*

⚠ *Warning: Do not place the monitor in any position that might cause it to fall on to the patient.*

⚠ *Warning: Certain environmental and physiological conditions, medical procedures, sensor application errors and external agents may interfere with the monitor's ability to detect and display accurate measurements. (Chapter 9 provides information on possible interferences)*

⚠ *Warning: For the SpO_2 measurement, the monitor uses red and infrared light with specific fixed wavelengths. Consider that these wavelengths might influence diagnostic parameters of other optical applications. The specifications of the wavelengths used are listed in the 'Instructions for Use' of the specific sensor.*

⚠ *Warning: The monitor detects respiratory effort via changes in CO_2 concentration of exhaled air; therefore, the CO_2 measurement can be used to detect apnoea. The device however is unable to discriminate between a patient not breathing and a sensor that is disconnected from the patient circuit. Always monitor and set alarms for SpO_2 when using the VM-2500 to monitor respiratory function.*

⚠ *Warning: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the monitor is functioning correctly.*

⚠ *Warning: The use of accessories, sensors, and cables other than those specified may result in increased electromagnetic emission and/or create invalid readings of the monitor.*

⚠ *Warning: In high ambient light conditions it is required to shield the SpO_2 sensor application site with opaque material. Too much ambient light may result in inaccurate measurements.*

⚠ *Warning: Check all alarm settings and auditory alarm before use of the monitor.*

⚠ *Warning: Do not silence the audible alarm function, or decrease the audible alarm volume if patient safety could be compromised.*

⚠ *Warning: No modifications of the monitor are allowed without authorization of the manufacturer.*

⚠ *Warning: Measurements can be affected by mobile and RF communications equipment. Make sure that the monitor is used in the electromagnetic environment specified in this manual .*

⚠ *Warning: Disconnect the monitor and probes from the patient during computed tomography (CT).*

⚠ *Warning: Disconnect the monitor and probes from the patient during magnetic resonance imaging (MRI) scanning. An induced current could potentially cause burns.*

Additional warnings regarding the power supply system: To prevent the possibility of the Li-ion battery CT-2500 from leaking, heating or explosion, observe the following precautions.

⚠ *Warning: Do not immerse the battery in water or seawater. Store it in a cool and dry environment if not used.*

⚠ *Warning: Do not discard, store or use the battery near a heat source (e.g. a fire or heater).*

⚠ *Warning: Only charge the Li-ion battery CT-2500 while inserted in the VM-2500 monitor using the provided power supply FW 7660M/06.*

⚠ *Warning: Do not connect the positive and negative terminal with metal objects such as wire and do not transport or store the battery together with metal objects such as necklaces or hairpins as this may short-circuit the battery.*

⚠ *Warning: Do not strike, throw or trample the battery or pierce it with a nail or other sharp object.*

⚠ *Warning: Only use the Li-ion battery Model No. CT-2500 provided with the monitor. Contact the manufacturer for replacements.*

⚠ *Warning: Only use the power supply Model No. FW 7660M/06 provided with the monitor. The use of a power supply other than this may result in hazardous situation and effect patient's safety.*

⚠ *Warning: Do not use rechargeable AA sized batteries instead of alkaline AA sized batteries to operate the device, as this may affect the function of the device.*

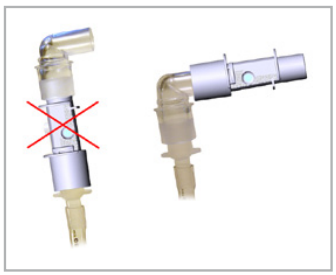
Additional warnings regarding the mainstream device - VM-2500-M:

⚠ *Warning: Disposable IRMA™ airway adapters shall not be reused. Used airway adapters shall be disposed of in accordance with local regulations for medical waste.*

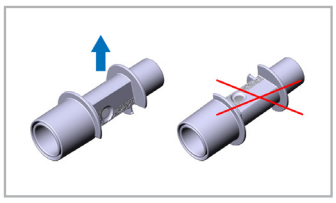
⚠ *Warning: Do not use the IRMA™ airway adapter (adult/paediatric) with infants as the adapter adds 6ml dead space to the patient circuit.*

⚠ *Warning: Do not use the IRMA™ airway adapter (infant) with adults or paediatric as this may cause excessive flow resistance.*

⚠ *Warning: Do not place the IRMA™ airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.*



⚠ *Warning: To keep secretions and moisture from pooling on the windows, always position the IRMA™ CO_2 analyzer in a vertical position.*



⚠ *Warning: Do not use the IRMA™ CO_2 analyzer with metered dose inhalers or nebulised medication as this may affect the light transmission of the airway adapter windows.*

⚠ *Warning: A successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2) in the IRMA™ airway adapter during zeroing. Incorrect zeroing of the IRMA™ CO_2 analyzer will result in false gas readings.*

⚠ *Warning: Replace the IRMA™ airway adapter if condensation occurs inside the adapter.*

Additional warnings regarding the sidestream device – VM-2500-S:

⚠ *Warning: Do not use the VM-2500-S to analyse gasses (e.g. anaesthetics like nitrous oxide etc.) that need to be returned to the patient circuit or a scavenging system. The gas outlet of the sidestream device is not designed to return the exhaust gases to the patient circuit or a scavenging system.*

⚠ *Warning: Excessive positive or negative pressure in the patient circuit might cause incorrect readings and internal damage of the monitor.*

⚠ *Warning: Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.*

⚠ *Warning: Do not lift the VM-2500-S by the sampling line as this could disconnect from the monitor, causing the monitor to fall on the patient.*

⚠ *Warning: Do not use adult or paediatric type sampling line configurations with infants or neonates, as this may add dead space to the patient circuit.*

⚠ *Warning: Do not use infant or neonatal type sampling line configurations with adults or children, as this may result in excessive flow resistance.*

⚠ *Warning: Do not use the VM-2500-S with metered dose inhalers or nebulised medication as this may block the bacteria filter integrated in the Nomo Adapter.*

⚠ *Warning: Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2) in the device, ensure that the VM-2500-S is placed in a well ventilated environment. Avoid breathing near the monitor before or during the zeroing procedure. Incorrect zeroing of the integrated ISA™ CO_2 analyzer will result in false gas readings.*

⚠ *Warning: Replace the blocked part of the sampling line configuration if a sampling system occlusion message is displayed by the monitor.*

⚠ *Warning: Do not re-use the disposable sampling lines and airway adapters.*

⚠ *Warning: Used disposable sampling lines shall be disposed of in accordance with local regulations for medical waste.*

⚠ *Warning: The Nomo Adapter is reusable. It only needs to be replaced if occluded. Replace the Nomo Adapter if "Sampling system occlusion!" is displayed by the monitor whilst only the Nomo Adapter is connected.*

1.3 Cautions

Adhere to the following recommendations to avoid damage or malfunction of the VM-2500-M mainstream CO_2/SpO_2 Monitor and VM-2500-S sidestream CO_2/SpO_2 Monitor.

For VM-2500 in General:

Caution: Do not spray, pour, or spill any liquid on the monitor, its accessories, connectors, switches, or openings in the enclosure as this may damage it.

Caution: Do not immerse the monitor or its accessories in liquid.

Caution: Do not autoclave or steam sterilize the monitor or its accessories.

Caution: Refer to the specific 'Instructions for Use' of the used SpO_2 sensor for correct cleaning and/or sterilization.

Caution: Do not apply excessive tension to any of the monitor cables.

Caution: Do not operate the monitor outside the specified operating temperature environment.

Caution: The monitor requires no routine calibration. A basic maintenance plan conducted by qualified service personnel is recommended. Please refer to the Service Manual for detailed information.

Caution: There are no user-serviceable parts inside the VM-2500. The cover should only be removed by qualified service personnel.

Additional cautions regarding the power supply system:

Caution: Do not use or store the Li-ion battery at very high temperature conditions e.g. strong direct sunlight or in a heated vehicle. Under these conditions the battery can overheat, causing it to burn or its performance will degenerate and its service life will be decreased.

Caution: Do not use the Li-ion battery in an electromagnetic environment other then specified in this manual, as this may damage the safety features of the battery and result in unforeseen danger.

Caution: If the Li-ion battery leaks and the electrolyte gets into the eyes, immediately rinse the eyes with clean running water and seek medical assistance to prevent injury of the eyes.

Caution: If the Li-ion battery gives off an odour, generates heat, becomes discoloured or deformed, or in any way appears abnormal during use, recharging or storage, immediately remove it from the device and stop using it.

Caution: If the Li-ion battery terminals are dirty, clean the terminals with a dry cloth before use, otherwise a power failure or charging failure may occur due to poor connection with the device.

Caution: Discharged batteries may cause fire; tape the terminals to isolate them.

Caution: Remove the batteries if the device is to be stored or not used for a longer period of time.

Additional cautions regarding the mainstream device - VM-2500-M:

Caution: Do not immerse the IRMA™ CO_2 analyzer in liquid.

Caution: The IRMA™ CO_2 analyzer and the IRMA™ airway adapters are non-sterile devices. To avoid damage, do not autoclave these components.

Caution: Use only PHASEIN manufactured IRMA™ airway adapters.

Additional cautions regarding the sidestream device - VM-2500-S:

Caution: The Nomo Adapter, the sampling lines and their patient interfaces are non-sterile devices. To avoid damage, do not autoclave these components.

Caution: Use only Nomo Adapters manufactured by Viamed.

1.4 Symbol Description

	Accompanied with *"Warning: Supplementary text."* within this document. Warnings indicate potential harmful conditions that may lead to injury or death.
	Accompanied with *"Caution: Supplementary text."* within this document. Cautions indicate conditions that may lead to damage to or malfunction of the device.
	Denoted as *"Note: Supplementary text."* within this document. Notes inform the user to relevant facts and conditions in connection with the device.
	Consult User Manual for detailed operating information.
	Consult accompanying documents for important safety-related information
	Manufacturer
	Date of manufacture
	Type BF applied part
REF	Catalogue number
SN	Serial number
P/N	Part number
LOT	Batch code
	Use by [YYYY-MM-DD] (indicates that the device should not be put into service after the date accompanying the symbol)
	Temperature limitation
	Do not re-use
	Fragile, handle with care
	Do not dispose in the consumer waste. Electrical and electronic equipment shall be collected and recycled in accordance with (Directive 2002/96/EC)
CE 0000	European Union approval (complies with 93/42/EEC Medical Device Directive)
IPXY	IP Code (International Protection Rating)

1.5 Terms and Definitions

BTPS	Body Temperature and Pressure Saturated
VM-2500	Handheld CO_2/SpO_2 monitor developed by Viamed. Available as mainstream (VM-2500-M) or sidestream (VM-2500-S) version.
CO_2	Carbon dioxide
$EtCO_2$	End-tidal expired CO_2 gas concentration
$FiCO_2$	Inspired CO_2 gas concentration
Hb	Deoxygenated haemoglobin
HbO_2	Oxygenated haemoglobin
HME	Heat Moisture Exchanger
IR	Infrared
IRMA™	Infrared mainstream CO_2 analyzer.
ISA™	Infrared sidestream CO_2 analyzer
LEGI™	Light Emitting Gas Inlet: Status indicator integrated in the gas sample inlet port.
Li-ion battery	Lithium-ion rechargeable battery
MDD	Medical Device Directive
MRI	Magnetic Resonance Imaging
N/A	Not applicable. Data does not apply to the configuration.
Nomo Adapter	Adapter that is connected between the sidestream VM-2500-S and the selected sampling line. The Nomo Adapter removes water and water vapour from the sampling line and has a hydrophobic bacterial filter to reduce the potential for water intrusion and cross contamination.

Nomo technology	Unique technology to remove water vapour and aspired or condensed water from the sidestream CO_2 gas sample through a membrane-like surface into the surrounding air. (Nomo stands for “no-moisture”)
PR	Pulse rate
RF	Radio frequency
RH	Relative humidity
Rise time	Time required to achieve an increase from 10% to 90% of final value when step function change in concentration occurs at the sampling site.
RR	Respiration rate
Sampling line config.	A sampling line configuration consists of a Nomo Adapter connected to a sampling line with an appropriate patient interface for sampling gas, e.g. a nasal cannula, respiratory mask or the Y-piece of an intubated patient.
SpO_2	Functional arterial oxygen saturation
TBD	To Be Determined. Value or property not yet decided; further investigations may be necessary.
Total system response time	Time from a step function change in gas level at the sampling site to the achievement of 90% of the final gas reading of the capnograph. Total system response time = Delay time + Rise time
USB	Universal Serial Bus
Zeroing	Ambient gas reference measurement used to establish zero concentration level for CO_2. Zeroing needs to be performed ONLY when an offset in gas measurement values is observed, or when an unspecified accuracy message is displayed.

1.6 User Requirements

The user(s) of the monitor shall have an in-depth knowledge of gas analyzing and non-invasive monitoring of functional arterial oxygen saturation.

2 Theory of operation
2.1 CO_2 measurement

Principle

The measurement of CO_2 in gas mixtures with the VM-2500 is based on the fact that different gases absorb infrared light at specific wavelengths. The absorption spectra for CO_2, N_2O and different anaesthetic agents are shown in Figure 1. The CO_2 analyzer of the VM-2500 uses the absorption peak at 4.2µm to determine the CO_2 concentration in the gas. Two additional wavelengths beside this absorption peak are used as reference.

To measure the absorption of light at these wavelengths, a broadband infrared radiation source is used. The light transmitted from the infrared source passes through the gas sample and is then filtered using a set of narrow optical band pass filters. The individual filters are mounted in a rapidly rotating filter wheel that intersects the light path before the light reaches the infrared detector.

The infrared detector 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.

Capnogram

A capnogram is a graph representing the CO_2 concentration in respiratory gasses plotted against time. The capnogram waveform is typically divided into 4 phases (Bhavani-Shankar & Philip, 2000). In the waveform below the inspiration (phase 0) is plotted in blue and the expiration (phase I - III) in red.

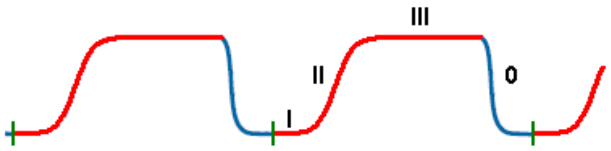


Figure 2: Normal capnogram waveform

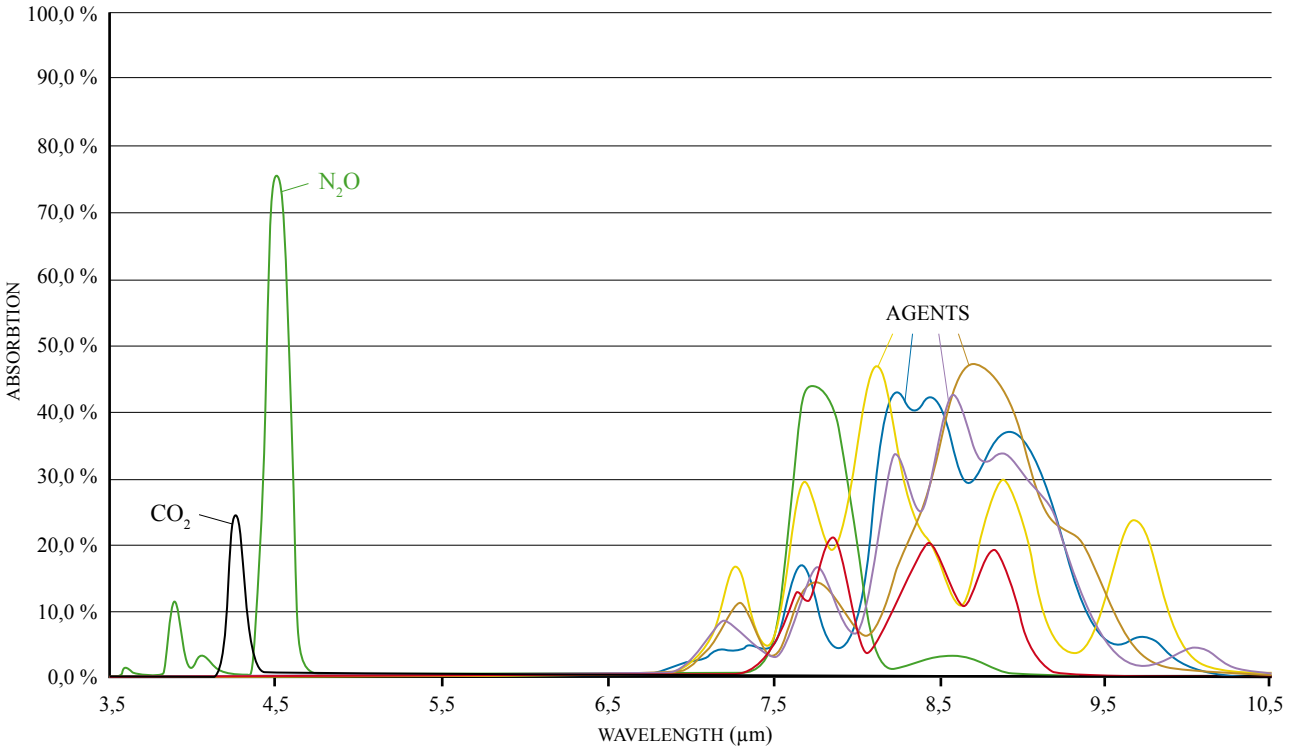


Figure 1: Gas absorption spectra

Phase I: Baseline ($FiCO_2$)
Phase II: Positive expiration slope (alveolar gas)
Phase III: Alveolar plateau ($EtCO_2$)
Phase 0: Inspiration

A capnogram provides valuable information regarding the health situation of patients in respiratory distress.

Measurement methods

Determining the CO_2 concentration of respiratory gases is done either using the mainstream method or

the sidestream method. In both cases the measurement principle is very similar (infrared spectroscopy) the position of the sensor in the measurement setup however differs.

In mainstream capnography an airway adapter is, for example, inserted between the endotracheal tube and the Y-piece of the breathing circuit. The airway adapter has an optical window over which the infrared mainstream CO_2 sensor is positioned. The respiratory CO_2 measurements are obtained by continuously measuring the infrared light absorption, in the gas flow, through the optical windows.

For sidestream capnography a sampling line is connected to an endotracheal tube with the help of a sidestream airway adapter or directly from the nose via a nasal prong. Gas samples are continuously taken from the patient at a constant flow rate (VM-2500-S has a suction rate of 50ml/min) and transferred to the infrared CO_2 sensor incorporated in the capnograph. The CO_2 measurement is taken within the device and after measurement the waste gas is exhausted through the gas outlet.

Typically water traps and bacteria filters are positioned between the sampling line and the device inlet to avoid damage to the device.

2.2 SpO_2 measurement

SpO_2 measurement is performed in transmission mode. The SpO_2 sensor consists of emitters which pass red and infrared light through peripheral sites such as a finger, toe or ear to a light-sensitive detector.

For both wavelengths the change in absorption is continuously measured. In this way the pulsatile signal due to the arterial blood alone is extracted, excluding the offset due to absorption by venous blood, skin, bone, muscle and fat.

This signal is used to determine the functional arterial oxygen saturation (SpO_2) based on the fact that the amount of absorbed infrared light and red light is different for oxygenated haemoglobin (HbO_2) and deoxygenated haemoglobin (Hb).

The amount of red and infrared light received is compared and the percent of haemoglobin molecules bound with oxygen molecules calculated:

$$SPO_2 = \frac{HbO_2}{HbO_2 + Hb}$$

These measurement values are continuously displayed as a waveform (plethysmogram) and also used to determine the pulse rate. Note that the pulse oximeter equipment is calibrated to display the functional oxygen saturation.

Certain physiological conditions, medical procedures, and external agents may interfere with the monitor's ability to detect and display accurate SpO_2 measurements (see chapter 9.2 for detailed information).

3 Product overview

3.1 Available models

Mainstream Capnograph/Pulse Oximeter – VM-2500-M

The VM-2500-M is used together with an IRMA™ CO_2 analyzer, an IRMA™ airway adapter and an application appropriate SpO_2 sensor.

Power is delivered via either the provided power supply, a rechargeable Li-ion battery or 4 x AA batteries.

Mainstream CO_2 monitoring is performed with the IRMA™ CO_2 analyzer. This key technology sets new standards in CO_2 mainstream measurement and provides reliable, safe and easy CO_2 monitoring.

Key features of VM-2500-M:

- Warm-up time < 10s
- Direct measurement without time delay
- Small, light-weight and shock-resistant: IRMA™ CO_2 analyzer weighs less than 30 g
- Adult/paediatric and infant IRMA™ airway adapters available
- Easy plug and measure technology
- IRMA™ airway adapter with XTP™ non-condensing light transmission window
- Maintenance and calibration-free technology
- Wide range of high-quality SpO_2 sensors available
- 2 years warranty

Sidestream Capnograph/Pulse Oximeter – VM-2500-S

The VM-2500-S monitor is used together with a Nomo Adapter, a suitable sampling line configuration (e.g. sampling line, airway adapter, nasal/oral sampling) and an application appropriate SpO_2 sensor.

Power is delivered via either the provided power supply, a rechargeable Li-ion battery or 4 x AA batteries.

Sidestream CO_2 monitoring is performed with the ISA™ CO_2 analyzer incorporated in the VM-2500-S. Together with the Nomo technology that removes water from the sampled gas, the ISA™ CO_2 analyzer with integrated sampling pump delivers the highest performance in an ultra-compact format.

Key features of VM-2500-S:

- Warm-up time < 10s
- Specially designed for all applications using low flow sampling (50 ml/min); from adults to neonates
- For intubated and non-intubated patients
- Nomo technology incorporated in the Nomo Adapter to remove water and water vapour from the sampling line.
- Hydrophobic bacterial filter incorporated in the Nomo Adapter to reduce the potential for water intrusion and cross contamination.
- Maintenance and calibration-free technology
- Wide range of high-quality SpO_2 sensors available
- 2 years warranty

3.2 Mainstream Capnography Accessories

3.2.1 IRMA™ CO_2 analyzer

The IRMA™ CO_2 analyzer is an ultra compact measurement device for mainstream CO_2 measurement with the VM-2500-M. As all necessary calibration constants are stored within each IRMA™ CO_2 analyzer, the analyzer can be replaced without the need for recalibration.

The analyzer has a rugged mechanical design providing reliable shock resistance.

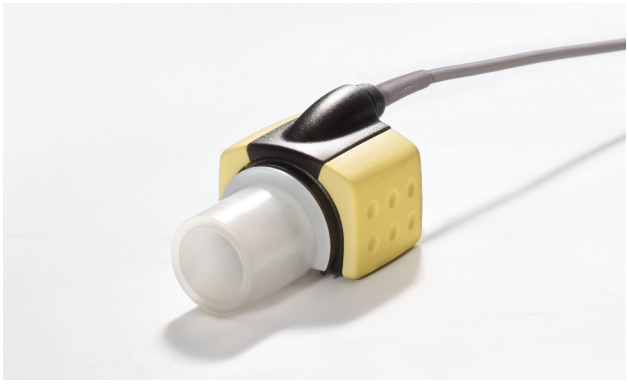


Figure 3: IRMA™ CO_2 analyzer with airway adapter

To perform gas measurements, the IRMA™ CO_2 analyzer requires an airway adapter. The IRMA™ CO_2 analyzer connects in place on top of the IRMA™ airway adapter. This airway adapter is, for example, inserted between the endotracheal tube and the Y-piece of the breathing circuit.

Respiratory CO_2 measurements are obtained by continuously measuring the infrared light absorption, through optical XTP™ windows, in the gas flow through the adapter.

3.2.2 IRMA™ airway adapter

The IRMA™ airway adapter is designed as a single-patient-use disposable product and is available as:

- IRMA™ airway adapter (adult/paediatric) for patients over 1 year of age or 10kg in weight.
- IRMA™ airway adapter (infant) for patients up to 1 year of age or 10kg in weight.

The IRMA™ airway adapter (infant) has specially designed connectors for minimizing the dead space and can be used on very small patients.

Figure 4: IRMA™ airway adapters: Infant (left) and Adult/Paediatric (right)

As the airway adapter is positioned directly in the airway, its performance can be affected by water vapour, patient secretions or nebulised medications that can accumulate on the adapter's windows.

The water vapour can condense on the surface of the adapter windows in the format of small discrete water droplets. This condensation can affect light absorption through the windows, thus affecting the precision of the measurement.

The XTP™ windows of the IRMA™ airway adapter therefore have special features that prevent a decrease in performance when vapour is present. Using the latest advances in material technology they are designed to provide a window minimizing the impact of water vapour on light transmission.

For optimal results, the airway adapter shall not be placed between an endotracheal tube and an elbow, as this may allow patients secretions to block the adapter window.

3.3 Sidestream Capnography Accessories

Sidestream CO_2 measurement is performed by continuously removing a gas sample at a flow of 50ml/min from the respiratory circuit and analyzing it within the sidestream ISA™ CO_2 analyzer incorporated in the VM-2500-S.

To transport the gas sample from the patient to the device, a sampling line configuration is required.

A sampling line configuration consists of a Nomo Adapter connected to a sampling line with an appropriate patient interface for sampling gas, e.g. a nasal cannula, respiratory mask or the Y-piece of an intubated patient.

3.3.1 Nomo Adapter

The gas sample coming from the sampling line is fed through the Nomo Adapter to the VM-2500-S.

The Nomo Adapter is specifically designed for 50ml/min low sampling flow applications. It has a very low dead space that results in an ultra-fast rise time, making CO_2 measurement possible, even at high respiratory rates. The VM-2500-S application therefore ranges from neonates to adults.

The Nomo Adapter contains an unique water separation section and a hydrophobic bacterial filter to protect the ISA™ CO_2 analyzer against water intrusion and cross contamination.

Figure 5: Nomo Adapter

No condensing water:
Because of condensing water within the connected sampling line, droplets can potentially result in occlusion of the sampling system and interfere with the CO_2 measurement. To prevent this situation the Nomo Adapter incorporates an unique water separation section, the NOMO section.

This section is made of a special polymer and a hydrophobic bacteria filter and removes water vapour and aspired or condensed water. Water and water vapour passes through the membrane-like surface of the sampling line and evaporates into the surrounding air, while leaving CO_2 unaffected.

Bacterial filter:
To protect the sidestream ISA™ CO_2 analyzer against cross contamination, the Nomo Adapter includes a filter with bacterial filter efficiency of ≥99.9980%. It is important to be aware that secretion and nebulised medication may be absorbed by the surface of the bacteria filter, and may block the Nomo Adapter.

Replacement of Nomo Adapter:
The Nomo Adapter is reusable as the Nomo technology allows up to two weeks of continuous monitoring with high moisture containing breathing gases.

⚠ *Warning: The Nomo Adapter is reusable. It only needs to be replaced if occluded. Replace the Nomo Adapter if "Sampling system occlusion !" is displayed by the VM-2500-S whilst only the Nomo Adapter is connected.*

3.3.2 Sidestream sampling line, airway adapter and other patient interfaces

Sampling with intubated patient
Sampling with intubated patients is typically performed with an appropriate sidestream airway adapter connected to the Nomo Adapter with a disposable sampling line. The sidestream airway adapter is designed as a single-patient-use disposable product and is available in different sizes ranging from adults through to neonates.

Figure 6: Typical sampling line assembly for intubated patients:
1. Disposable sampling line,
2. Sidestream airway adapter (adult/paediatric),
3. Sidestream airway adapter (infant/neonatal)

Sampling with non-intubated patient
Sampling with non-intubated patients is typically performed with a nasal or oral sampling configuration. This sampling assembly is directly connected to the nose or mouth with a cannula. For further instructions, warnings and precautions refer to the 'Instructions for Use' provided with the selected sampling system assembly.

Note: Our sampling line configurations are continuously updated; please contact Viamed for detailed information. Specific patient sampling line configurations and interfaces are available upon request.

3.4 SpO_2 Sensors

Viamed supplies a large variety of disposable and reusable SpO_2 sensors for use with the VM-2500.

Depending on the sensor type and model, their application ranges from adults to neonates, providing application specific features and design.

The SC 6500 VM Sensor is typically used for adult applications and the W 6500 VM Sensor for infant and neonatal applications (see figure 7). Other sensors are available upon request.

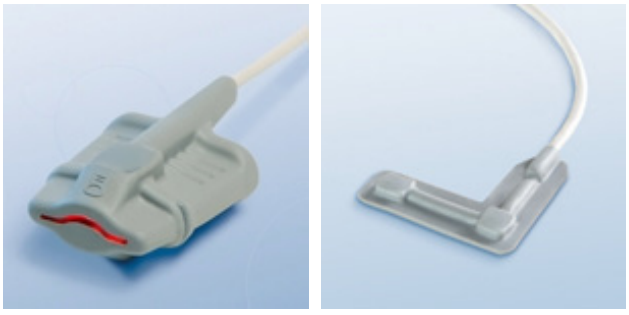
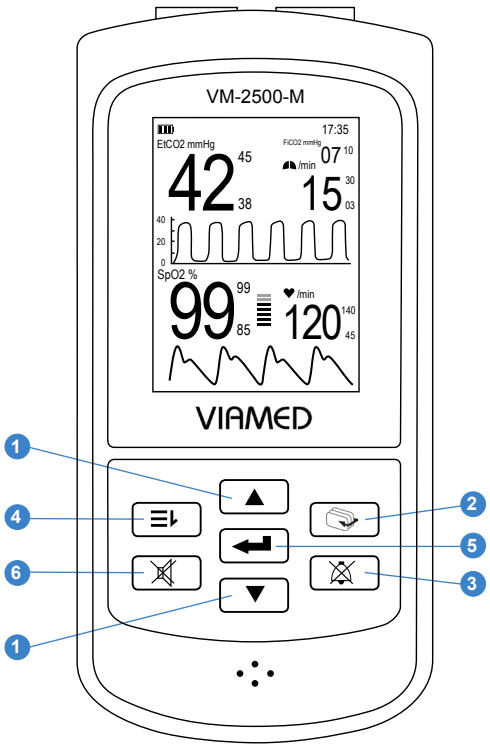


Figure 7: SpO_2 sensor SC 6500 VM (left) and W 6500 VM (right)

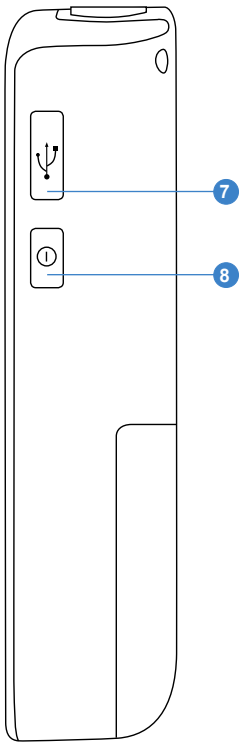
All sensors operate in transmission mode. The light source emits red and infrared light with wavelengths of 660nm and 905nm respectively at a typical radiant power of 3.5mW.

The SpO_2 sensor is applied to peripheral areas of the body such as finger tips and toes for adults, and paediatrics, and the foot or palms for infants and neonates.

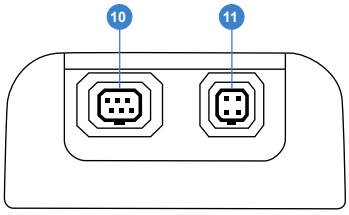
4 Exterior View, Controls and Connectors
4.1 Mainstream Capnograph/Pulse Oximeter – VM-2500-M



Front view



Side view



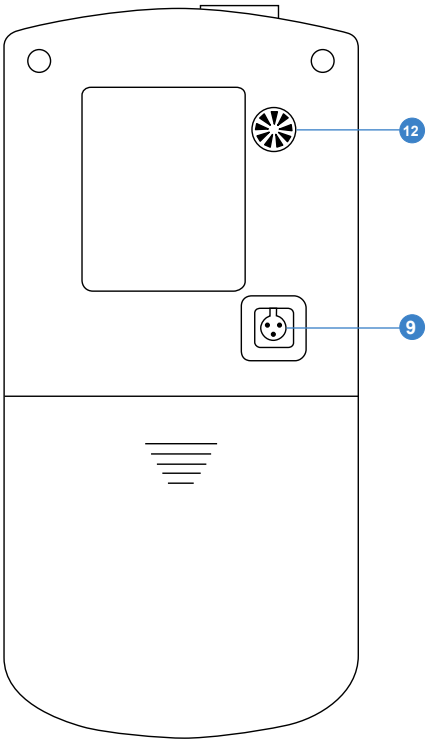
Top View

Rear view is the same as for VM-2500-S but without gas outlet (see Chapter 4.2)

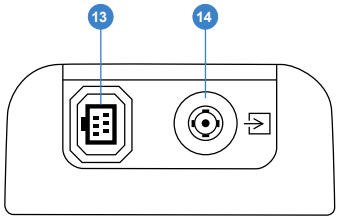
No.	Symbol	Feature/Button	Function
1		Arrow buttons (up/down)	Multifunction buttons used for: 1. Scrolling through menu items 2. Increasing/decreasing parameters 3. Shortcuts to volume/brightness control during monitoring
2		Display mode	Toggles between various display modes. Shortcut to return to display mode during menu mode.
3		Alarm silenced	The audible alarm can be silenced for a maximum period of two minutes. Optical alarm remains activated.
4		Menu	Menu selection. Shortcut to return to the previous menu level during menu mode.
5		ENTER button	Confirms selection
6		Pulse tone	Turns pulse tone on/off
7		USB	USB 2.0 interface
8		On/Off	To turn on the device: press and hold power button briefly. To turn off the device: press and hold power button for approx. 3 seconds.

9		Power input	Port to connect the external power supply (100-240V AC / 50-60Hz, Model No. FW 7660M/06)
10		SpO_2 Sensor port	Port to connect the SpO_2 sensor
11		CO_2 Mainstream port	Port to connect the IRMA™ CO_2 analyzer

4.2 Sidestream Capnograph/Pulse Oximeter – VM-2500-S



Rear view



Top View

Front and side views are the same as for VM-2500-M (see Chapter 4.1)

No.	Symbol	Feature/Button	Function
9		Power input	Port to connect the external power supply (100-240 V AC / 50-60Hz, Model No. FW 7660M/06)
12		Gas outlet port	Gas outlet of the sidestream module (not applicable for mainstream)
13		SpO_2 sensor port	Port to connect the SpO_2 sensor
14		CO_2 Sidestream gas inlet port	Port with Light Emitting Gas Inlet (LEGI™) to connect the Nomo Adapter

5 Preparation for Use
5.1 Selecting Power Supply

Power is supplied to the monitor either via external power supply, rechargeable Li-Ion battery, or 4 x AA alkaline batteries.

5.1.1 Power Supply

The external power supply (100-240V AC / 50-60Hz, Model No. FW 7660M/06) is used for continuous operation of the monitor and to charge the Li-ion battery.

Connecting the power supply (see figure 8):
1. To operate by mains, connect the power supply cable into the power input socket located at the back of the device.
2. Ensure that the correct power supply plug is connected to the power supply. It can be exchanged by pressing the release button (2.1) on the power supply. As standard the device is supplied with a European and United Kingdom plug. Additional plugs are available upon request.
3. Connect the power supply to an AC outlet.

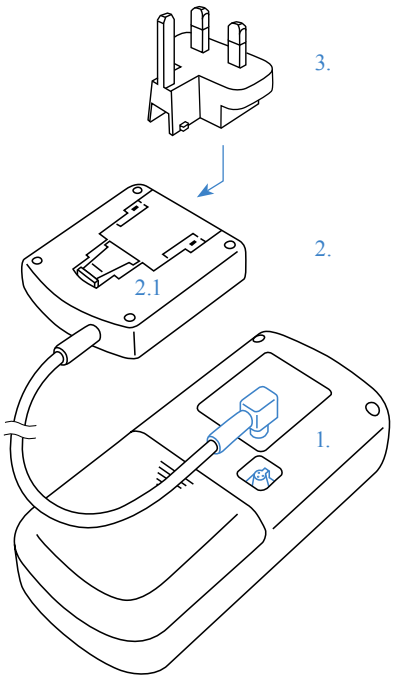


Figure 8: Connect the power supply

⚠ *Warning: Only use the power supply Model No. FW 7660M/06 provided with the monitor. The use of a power supply other than this may result in hazardous situation and effect patient's safety.*

5.1.2 Rechargeable Li-ion Battery or AA Alkaline Batteries

For convenient monitoring in emergency medicine or during patient transport the monitor is supplied by the rechargeable Li-ion battery (3.7 V / 2500 mAh, Model No. CT-2500) or with 4 x AA alkaline batteries.

When the device is connected to an AC outlet the Li-ion battery will begin recharging. This is represented by the three segments of the battery level indicator illuminating in sequence. When the Li-ion battery is completely recharged the three segments of the battery level indicator will be displayed fully.

Note: The charging function is not available at the battery contacts of the 4 x AA alkaline batteries.

Battery Installation (see figure 9):
1. Slide down the cover of the battery compartment on the rear panel of the device.
2. Insert four alkaline batteries (1.5V, AA), ensuring the correct orientation in accordance with the polarity markings.
3. Alternatively, insert the rechargeable Li-ion battery (Model No. CT-2500), orientated according to the guiding grooves.
4. Slide the battery-compartment cover back into its initial position to close.

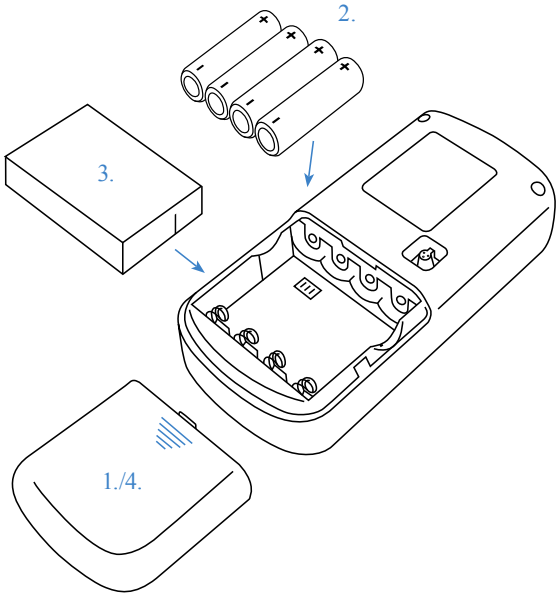


Figure 9: Insert a Li-ion battery or 4 x AA alkali batteries

⚠ *Warning: Only charge the Li-ion battery CT-2500 while inserted in the VM-2500 monitor using the provided power supply FW 7660M/06.*

Caution: Do not dispose the Li-ion battery or the alkaline batteries in the consumer waste, if they are empty or can no longer be recharged. Batteries may contain substances which are harmful to the environment and to the health. Please dispose the batteries at the available battery collecting sites or the recycling yards of the municipalities. Please only dispose discharged batteries into the designated containers. Tape the terminals of the Li-ion batteries at the poles before disposing.

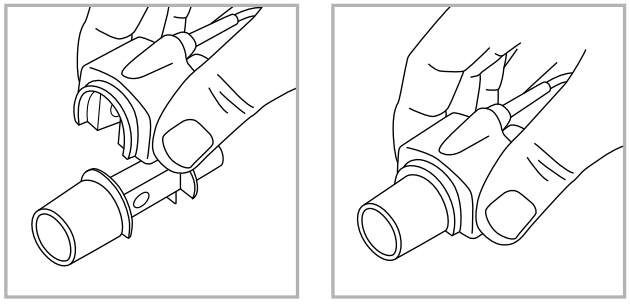
Caution: Remove the batteries if the device is to be stored or not used for a longer period of time.

5.2 Connecting Sensors / Sampling Line Configurations to the VM-2500

5.2.1 IRMA™ CO_2 Analyzer (mainstream)

For CO_2 mainstream capnography with VM-2500-M inspect the IRMA™ CO_2 analyzer and connector cables for any external damage.

Insert the connector of the IRMA™ CO_2 analyzer into the CO_2 Mainstream port located on the top edge of VM-2500-M. Secure the IRMA™ CO_2 analyzer on top of the IRMA™ airway adapter. It will click into place when correctly seated.



Warning: Do not use the IRMA™ airway adapter (adult/paediatric) with infants as the adapter adds 6ml dead space to the patient circuit.

Warning: Do not use the IRMA™ airway adapter (infant) with adults or paediatric as this may cause excessive flow resistance.

Caution: Use only PHASEIN manufactured IRMA™ airway adapters.

5.2.2 Nomo technology sampling line configuration (sidestream)

For CO_2 sidestream capnography with the VM-2500-S inspect the Nomo Adapter and the selected sampling line assembly for any external damage.

a) Insert the Nomo Adapter head into the CO_2 sidestream inlet port (LEGI™) located on the top edge of the VM-2500-S.

b) Now connect the selected sampling line assembly to the female Luer Lock connection at the Nomo Adapter. A typical sampling line assembly for intubated patients consists of a sampling line and a sidestream airway adapter. For non-intubated patients, a sampling line configuration with nasal and/or oral sampling is typical.

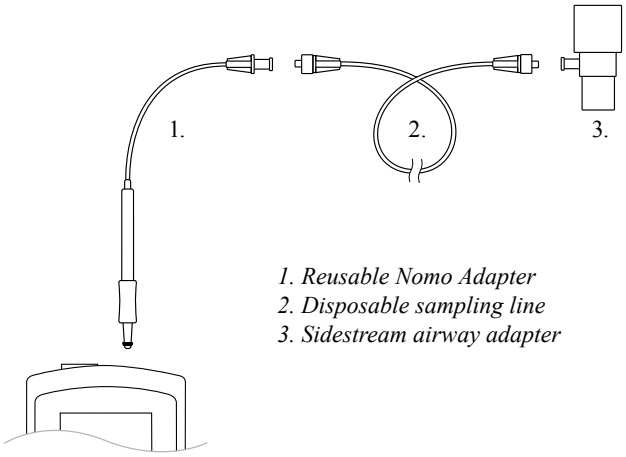


Figure 10: Nomo Adapter with sampling line configuration for intubated patients

Warning: The Nomo Adapter is reusable. It only needs to be replaced if occluded. Replace the Nomo Adapter if "Sampling system occlusion !" is displayed by the VM-2500-S whilst only the Nomo Adapter is connected.

Warning: Do not re-use disposable sampling lines and airway adapters.

Warning: Used disposable sampling lines and airway adapters shall be disposed of in accordance with local regulations for medical waste.

Caution: Use only Nomo Adapters manufactured by Viamed.

5.2.3 SpO_2 Sensor

Inspect the SpO_2 sensor and connector cables for any external damage.

Insert the SpO_2 sensor cable into the SpO_2 sensor port located on the top edge of the device, ensuring correct orientation of the sensor connector and the port.

5.3 Visual Check

Before commencing operation, ensure that the device, power supply, sensors or sampling line configurations are not damaged.

During the visual check of the VM-2500-S sidestream device, ensure that the gas outlet located at the rear part of the device is clear of any obstruction.

⚠ *Warning: Do not use sensors, cables or lines that appear to be damaged. Do not use sensors when optical components are exposed. Do not use a device that appears damaged. Replace the monitor immediately in cases of visible damage.*

⚠ *Warning: Ensure that the speaker is clear of any obstruction and that the speaker holes are not covered. Failure to do so could result in an inaudible alarm tone.*

⚠ *Warning: Ensure that the gas outlet of the sidestream device is clear of any obstruction. Failure to do so could result in CO_2 sidestream measurement errors.*

⚠ *Warning: Check the compatibility of the monitor, probe and cable before use. Incompatible components can result in degraded performance.*

5.4 Switching on the Device

Press and hold the ON/OFF button ⏻ briefly until an opening "welcome screen" appears. The power-on self-test is successfully completed after a single loud tone sounds.

5.5 Connecting Sensors / Sampling Line Configurations to the Patient

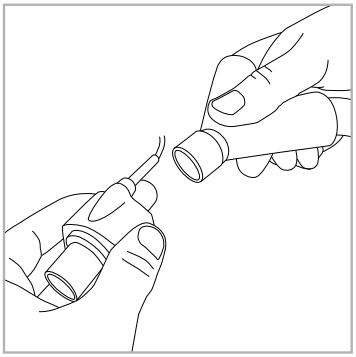
5.5.1 IRMA™ CO_2 Analyzer (mainstream)

A green LED indicates that the IRMA™ CO_2 Analyzer is powered and ready for use.

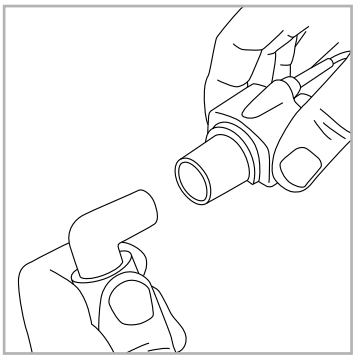
Perform the following tests prior to connecting the IRMA™ CO_2 Analyzer to the patient circuit:

1. Breath into the airway adapter and check that valid CO_2 waveforms and values are displayed by the monitor.
2. Remove the airway adapter and wait for 5 seconds.
3. Check that the airway adapter alarm is displayed and that the LED at the IRMA™ CO_2 Analyzer shows a flashing red light.

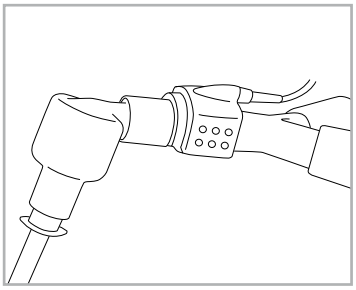
Now connect the IRMA™ airway adapter to the patient circuit:



1. Connect the 15 mm male connector of the IRMA™ airway adapter to the breathing circuit Y-piece.



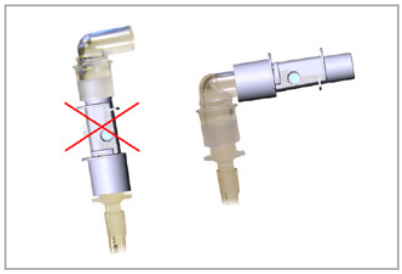
2. Connect the 15 mm female connector of the IRMA™ airway adapter to the endotracheal tube with or without an angled connector.



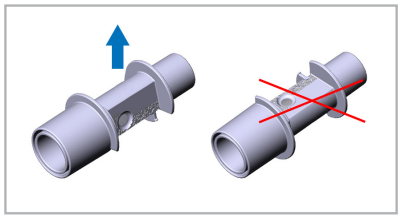
Alternatively, connect a HME (Heat Moisture Exchanger) between the patient's endo-tracheal tube and the IRMA™ CO_2 analyzer. Placing a HME in front of the IRMA™ CO_2 analyzer protects the airway adapter from secretions and effects of water vapour and eliminates the need of changing the adapter. It allows free positioning of the IRMA™ CO_2 analyzer as well.

3. Perform the tightness check of the patient circuit with the IRMA™ CO_2 analyzer connected on the airway adapter.

⚠ *Warning: Do not place the IRMA™ airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.*



⚠ *Warning: To keep secretions and moisture from pooling on the windows, always position the IRMA™ CO_2 analyzer in a vertical position.*



⚠ *Warning: Replace the adapter if condensation occurs inside the airway adapter.*

5.5.2 Nomo Technology sampling line configuration (sidestream)

A constant green light at the Light Emitting Gas Inlet (LEGI™) at the VM-2500-S indicates that the system is working correctly.

Perform the following tests prior to connecting the assembled sampling line configuration to the patient circuit:

1. Breath into the sampling line configuration and check that valid CO_2 waveforms and values are displayed on the VM-2500-S.
2. Occlude the sampling line with a fingertip and wait for 10 seconds.
3. Check that an occlusion alarm is displayed and that the LED shows a flashing red light.

Now connect the selected sampling line configuration to the patient circuit:

A. In the case of intubated patients
The sidestream airway adapter is connected to the tubing of the patient circuit.

- First connect the male connector of the sidestream airway adapter to the breathing circuit Y-piece.
- Now connect the female connector of the sidestream airway adapter to the endotracheal tube with or without an angled connector.

B. In the case of non-intubated patients
The nasal or oral sampling configuration is directly connected to the nose or mouth respectively. For further instructions, warnings and precautions refer to the 'Instructions for Use' provided with the sampling system configuration.

Note: Our sampling line configurations are continuously updated; please contact Viamed for detailed information. Specific patient sampling line configurations and interfaces are available upon request.

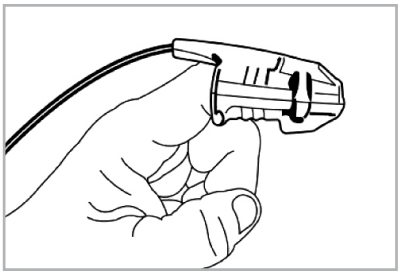
⚠ *Warning: Do not use adult or paediatric type sampling line configurations with infants or neonates, as this may add dead space to the patient circuit.*

⚠ *Warning: Do not use infant or neonatal type sampling line configurations with adults or paediatric, as this may result in excessive flow resistance.*

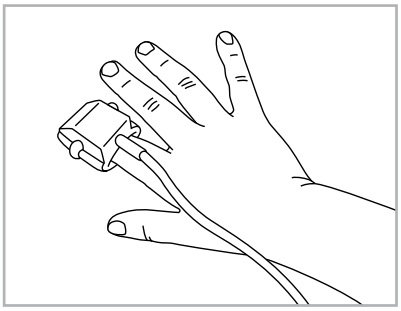
⚠ *Warning: Do not use the VM-2500-S with metered dose inhalers or nebulised medication as this may block the bacteria filter.*

5.5.3 SpO_2 Sensor

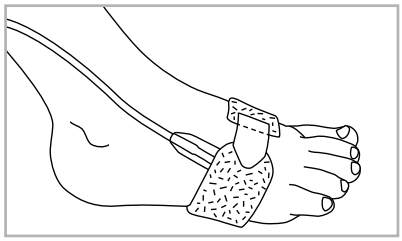
1. Refer to the sensor 'Instructions for Use' to determine if an appropriate sensor is being used, and if it is applied correctly.



Adult



Paediatric



Neonatal

2. Confirm that all connections have been made correctly by verifying an actual SpO_2 waveform on the monitor display.

⚠ *Warning: Avoid application of the SpO_2 sensors to oedematous or fragile tissue.*

⚠ *Warning: Do not use the SpO_2 sensor if it is damaged. Use of a damaged sensor could cause patient injury or equipment failure.*

⚠ *Warning: Excessive patient motion, excessive ambient light, electromagnetic interference, dysfunctional haemoglobin, low perfusion, intravascular dyes, finger nail polish and long or artificial finger nails may affect the sensor performance and the accuracy of the measurement.*

⚠ *Warning: Do not autoclave the SpO_2 sensor.*

⚠ *Warning: For the SpO_2 measurement, the monitor uses red and infrared light with specific fixed wavelengths. Consider that these wavelengths might influence diagnostic parameters of other optical applications. The specifications of the wavelengths used are listed in the 'Instructions for Use' of the specific sensor.*

Caution: Depending on the sensor model, specifications can differ. For sensor specific information on wavelengths and radiant power, please refer to the 'Instructions for Use' provided with your SpO_2 Sensor.

Caution: For further instructions, warnings and precautions refer to the 'Instructions for Use' provided with the SpO_2 Sensor.

5.6 Commencing Monitoring

Once the sensors/sidestream sampling line configuration is connected and correctly positioned on the patient, monitoring begins automatically.

An audiovisual alarm appears, if any of the sensors or the Nomo Adapter is disconnected from the device.

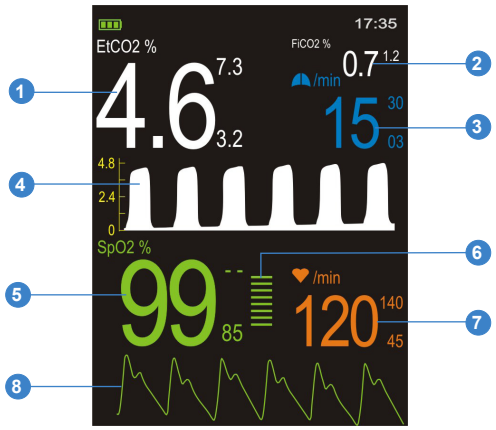
The VM-2500 can be reset to the start-up configuration by resetting the alarms (refer to Chapter 7.6).

5.7 Switching off the Device

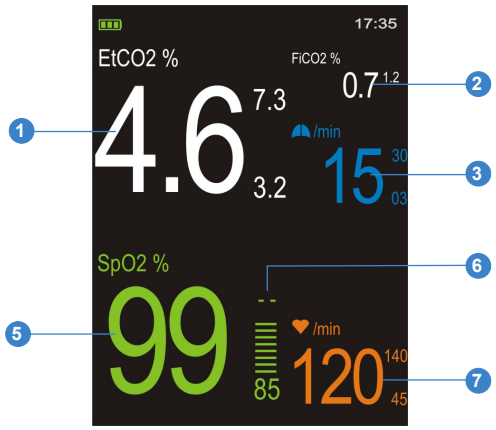
Press and hold the on/off button ⏻ for approx. 3 seconds to switch off the device. The VM-2500 will also power off automatically after 5 minutes when not in use.

6 Display Modes and Displayed Data
6.1 Toggling Between Display Modes

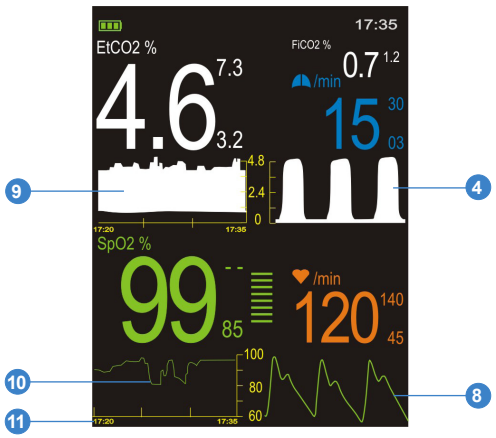
The operator can toggle between various display modes by pressing the button.



Display 1: Standard



Display 2: Numerical

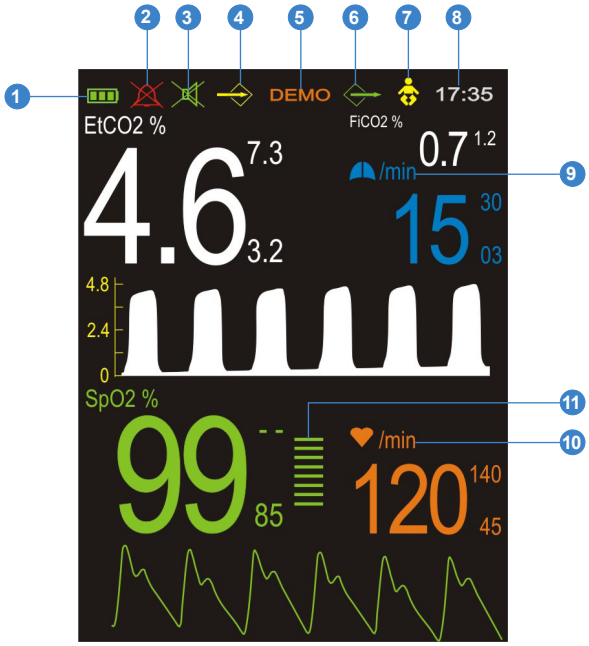


Display 3 to 5: Trend (15 min, 1 h and 6 h Trend, parallel to ongoing measurement)

The small numbers on the right hand side of the measurement value of a parameter indicate the upper and lower alarm limits. In all displays the measurement value, alarm limits, curve, name and unit of each parameter are displayed in the same colour.

1. End-tidal expired CO_2 gas concentration in vol %, kPa or mmHg
2. Inspired CO_2 gas concentration in vol %, kPa or mmHg
3. Respiration rate in breaths per minute
4. CO_2 waveform (Capnogram)
   The default setting of the amplitude scale is Auto scaling. Here the reading is automatically adjusted to the signal strength; therefore, a waveform with strong amplitude should be visible at all times. The scale however can also be defined by the user (refer to chapter 8.1.3).
5. Functional blood oxygen saturation in units of percent SpO_2
6. Bar graph for pulse amplitude
   Indicates the dynamic pulse amplitude and rate. As the detected pulse becomes stronger, more bars light with each pulse. The reverse is true for weak pulses.
7. Pulse rate in beats per minute
8. Pulse waveform (plethysmogram)
   The reading is automatically adjusted to the pulse strength; therefore, a waveform with strong amplitude should be visible at all times.
9. Combined $EtCO_2$ and $FiCO_2$ trend waveform
10. SpO_2 trend waveform
11. Start and end times

6.2 Symbols and Indicators



No.	Symbol/ Indicator	Function
1		**Battery level indicator** The three segments represent the battery charge level. The symbol flashes yellow when the battery capacity is low. During charging of the Li-Ion battery, the three segments of the indicator are illuminated in sequence.
2		**Alarm silence indicator** The audible alarm can be silenced for a maximum period of two minutes. Optical alarm remains activated.
3		**Pulse tone off**
4		**Memory full indicator** The device's memory for measurement data is full. No new data can be stored. Old data can be erased or are overwritten.
5	DEMO	**Demo mode indicator** The device is operated in demo mode. All measurement data are simulated. This mode is accessed via the service menu.
6		**Real-Time Mode indicator** The device is operated in the Real-Time mode. Data is available at the USB port
7		**Neonatal mode** The device is operated in the neonatal mode. On activation the alarm limits are changed to neonatal defaults.
8	17:35	**Current time**, displayed in 12h or 24h format.
9	/min	**Respiration rate**, displayed in breaths per minute.
10	/min	**Pulse rate**, displayed in beats per minute.
11		The colour of the bar graph is an indicator of the signal quality **Green**: good signal quality, very accurate measurement **Yellow**: average signal quality, measurement may be inaccurate **Red**: poor signal quality, unreliable measurement

6.3 Pulse Tone

During monitoring a pulse beep is sounded for every detected pulse. The pitch of the pulse tone is dependent on the measured SpO_2 value. A higher pitch is indicative of higher oxygen saturation.

The pulse tone volume can be adjusted under the menu item 'Volume'. The pulse tone can be also silenced using the  button. Pressing this button for a second time will reactivate the pulse tone.

7 Alarms
7.1 Alarm Priority and Appearance

The VM-2500 differentiates between alarms of high, medium and low priority.

An alarm of higher priority will always overlay alarms of respective lower priority. Vice versa, an alarm of high priority cannot be silenced by an alarm of lower priority. In this way the VM-2500 will always display the alarm with the highest priority, if more than one alarm condition exists at the same time.

7.2 Audible Alarm Volume

The alarm volume is not adjustable; however, it is possible to silence the alarm for a period of two minutes using the button. It has an audibility of at least 55 dB (A) in 1 meter distance of the device.

7.3 Default Alarm Limits

Default settings are active according to the selected device mode “Adult” or “Neonatal”.

Alarm Priority and Appearance

Priority Level	Audio Signal Sequence (repeatedly)	Visual Alarm	Condition
High (Warning)	*5 tone beep + 2 seconds pause + 5 tone beep and 3 seconds pause*	*Red and !!!*	For potentially life-threatening situations
Medium (Caution)	*3 tone beep and 5 seconds pause*	*Yellow and !!*	For potentially serious problems that are presumed to be not life threatening
Low (Advisory)	*2 tone beep and 16 seconds pause*	*Yellow and !*	Advisory alarms

Default Alarm Limits

Limit	Unit	Range	“Adult”	“Neonatal”
$EtCO_2$ High	%	0.1...9.9 / off	7.3	7.3
$EtCO_2$ Low	%	off / 0.1...9.9	3.2	3.2
$FiCO_2$ High	%	0.1...9.9 / off	1.2	1.2
RR High	/min	4...150 / off	off	off
Apnoea	sec	20, 40, 60	20	20
SpO_2 High	%	1...99 / off	off	95
SpO_2 Low	%	off / 1...99	85	85
PR High	/min	1...250 / off	140	150
PR Low	/min	off / 1...250	45	30

7.4 Limit Alarm

The table below shows the limit alarms, alarm conditions and priority of the VM-2500. Depending on the priority of the alarm the respective measurement value will change colour and an audible alarm sounds.

7.5 Alarm Messages

The table below presents the alarm messages, alarm condition and priority of the VM-2500. The colour of the alarm message and its audible alarm depend on the priority of the alarm message.

Limit Alarm	Condition	Priority
$EtCO_2$ High	$EtCO_2$ value above set alarm limit	Medium
$EtCO_2$ Low	$EtCO_2$ value below set alarm limit	Medium
$FiCO_2$ High	$FiCO_2$ value above set alarm limit	Medium
RR High	Respiratory rate above set alarm limit	Medium
Apnoea !!	No breath detected within set terms (if ≤ 1min)	Medium
Apnoea !!!	No breath detected within set terms (if > 1min)	High
SpO_2 High	SpO_2 value above set alarm limit in the standard mode	Low
SpO_2 High (neonatal mode)	SpO_2 value above set alarm limit in the neonatal mode	Medium
SpO_2 Low	SpO_2 value below set alarm limit	Medium
PR High	Pulse rate above set alarm limit	Medium
PR Low	Pulse rate below set alarm limit	Medium

Alarm Messages	Condition	Priority
Bad signal quality !!!	Poor-quality pulse signal, for example as a result of low perfusion	High
No CO_2 Sensor !	No connection to the mainstream IRMA™ CO_2 analyzer	Low
Check CO_2 Adapter !	The mainstream IRMA™ adaptor is dirty, not positioned correctly etc.	Low
No Nomo Adapter !	No connection to the sidestream Nomo Adapter.	Low
Sampling system occlusion !	A component of the sidestream sampling system sampling line, Nomo Adapter or gas outlet) is blocked (occluded)	Low
CO_2 Over range !	Measured CO_2 concentration is outside of the specified accuracy range	Low
No SpO_2 Sensor !	No connection to the SpO_2 sensor	Low
SpO_2 Probe off !	SpO_2 sensor is connected to the device, a signal was detected and then the finger has been removed/slipped off	Low
Excess light !	High ambient light sources near the SpO_2 sensor, e.g. surgical lights	Low
Battery low !	Low battery level at start up results in error message and dysfunction. Critical level during monitoring results in audible alarm and battery indicator to flash yellow. After 3 minutes device switches off.	Low

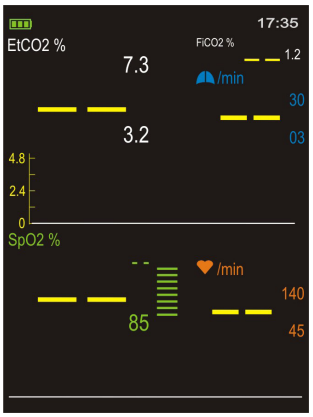
⚠ *Warning: The monitor detects respiratory effort via changes in CO_2 concentration of exhaled air; therefore, the CO_2 measurement can be used to detect apnoea. The device however is unable to discriminate between a patient not breathing and a sensor that is disconnected from the patient circuit. Always monitor and set alarms for SpO_2 when using the VM-2500 to monitor respiratory function.*

7.6 Resetting of Alarm Signals

Once triggered, an alarm will only be reset if the cause of the alarm has been resolved. Individual alarm limits can also be completely deactivated if required.

Alarm signals can be reset by pressing and holding the ↵ button for 3 seconds. If the initial condition for the warning is still present after resetting the warning signals, the warning will return immediately. In case of the alarm signals "SpO_2 Probe off!", "No Nomo Adapter" and "No CO_2 Sensor!" the device reverts to the on-position. Parameters which have been set by the user will remain once an alarm is reset.

Press and hold button ↵



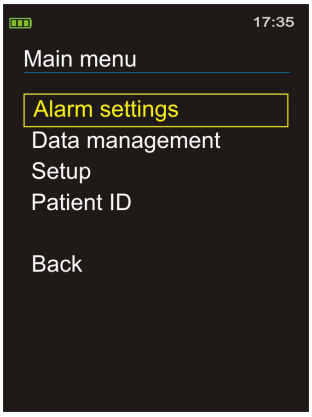
Display after reset of alarms

8 Menu Structure

8.1 Main Menu

Navigating the Menu

Use the ▲▼ buttons to scroll through menu items. The currently selected menu item is highlighted by a coloured frame. Press the ↵ button to confirm your selection. Select the menu item 'Back' to return to the previous menu level. Alternatively use the menu button ☰ as shortcut for "Back".



All important and frequently used settings are accessible through the main menu, which can be accessed by pressing the ☰ button.

Entering Data

In some submenus it is possible to adjust a certain parameter. In this case the parameter can be increased or decreased using the ▲▼ buttons. The value will increase or decrease more quickly when the respective button is held down. Press the ↵ button to confirm the new value.

Exiting Menu and Returning to Display

Press the display button ⏻ at any time, in any menu to return immediately to the monitoring display. If no button has been pressed for more than 30 seconds, the device will automatically return to the monitoring screen.

8.1.1 Submenu: Alarm Settings

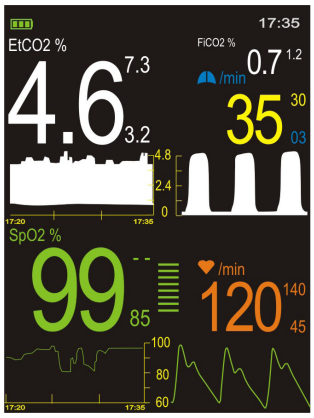
General Information

The VM-2500 alarm limits for $EtCO_2$, $FiCO_2$, SpO_2, respiration rate and pulse rate can be set individually. The current alarm limits are displayed as small numbers on the right hand side of the measurement value. If a measured value either exceeds the upper limit or falls below the lower limit, visual and audible alarms will be triggered immediately.

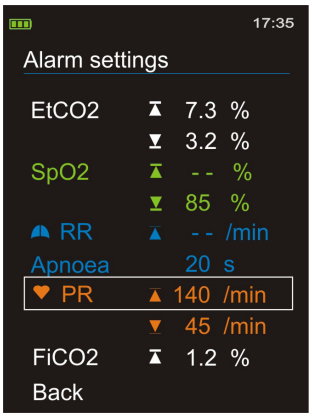
Visual alarm

When an alarm has been triggered the critical value will flash and turn yellow together with the violated alarm limit.

An alarm will also be triggered if the SpO_2 sensor is removed from the patient, the SpO_2 signal quality remains poor over a longer period of time, the mainstream IRMA™ airway adapter is dirty or the sidestream Nomo Adapter is occluded. This is also the case if the SpO_2 sensor, the IRMA™ CO_2 analyzer or the Nomo Adapter is disconnected from the device, provided that valid measurement data has been recorded beforehand.



Visual alarm which was triggered by a violation of the upper respiration rate alarm limit



Selection with ▲▼ buttons / confirmation with ↵ button

Adjusting Settings

Use the Alarm Settings menu to set the upper and lower alarm limit of $EtCO_2$, SpO_2, respiration rate, pulse rate and $FiCO_2$. Select "- -" to deactivate the respective alarm limit. "Apnoea" represents the lower alarm limit of the respiration rate. If no breath is detected within the set time, the apnoea alarm is activated. After restarting the device, the default alarm limits will be reset.

Use the Alarm settings menu to set the upper and lower alarm limit of $EtCO_2$, SpO_2, respiration rate, pulse rate and $FiCO_2$. Select "off" to deactivate the respective alarm limit.

"Apnoea" represents the lower alarm limit of the respiration rate. If no breath is detected within the set time, the apnoea alarm is activated. After restarting the device, the default alarm limits will be reset. This is also the case, if the power supply is interrupted.

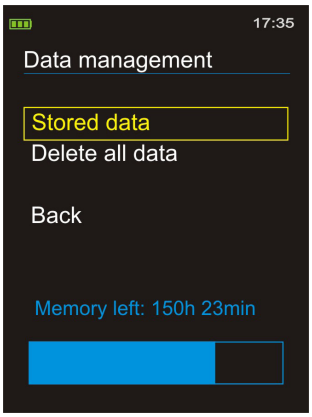
8.1.2 Submenu: Data Management
8.1.2.1 Recording Data

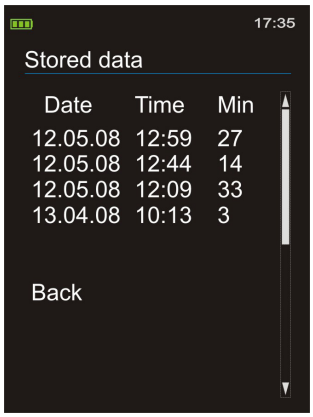
The VM-2500 device can store more than 400 hours of monitoring data. Each individual data set, regardless of its actual length, uses at least 80 minutes of memory space. A new data set is generated automatically each time the device is turned on or the current Patient ID is changed.

When the device is turned off or the current Patient ID is changed, all of the measurements that were taken are automatically stored in the devices memory, together with the respective alarm limits, patient ID, date and time.

The device warns the user when the memory is almost full by displaying the ⇨ symbol. If the memory is full the oldest data set is overwritten upon confirmation by the user. Stored data sets can be retrieved and erased under the menu item "Data management". The data sets can also be downloaded on PC with the user-friendly VM-2500 PC-Software.

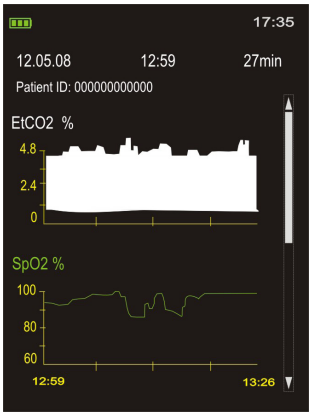
8.1.2.2 Data Management

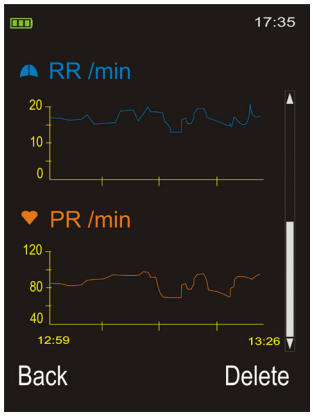




Use the Data Management menu to access the list of stored data sets, to delete all data in the memory or to view the remaining recording time.

Retrieve the selected data set by pressing the ↵ button.

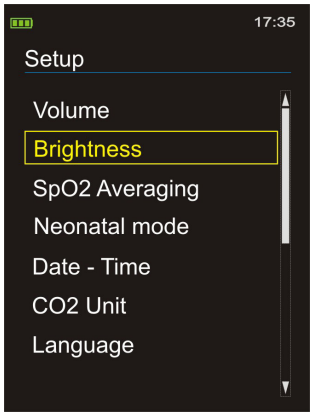


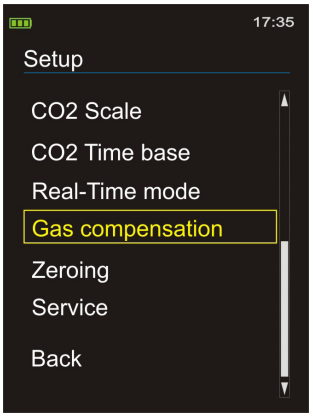


The stored measurements are displayed in graphic form together with the date, start time, duration of the recording and Patient ID. The colour code of the displayed data is as follows: $EtCO_2$ – white, SpO_2 - green, respiration rate – blue, pulse rate - orange.

Select “Back” to return to the list of stored data or “Delete” to erase the data set.

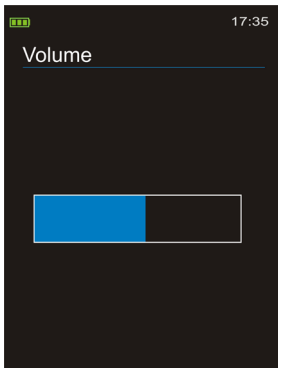
8.1.3 Submenu: Setup
8.1.3.1 General Information





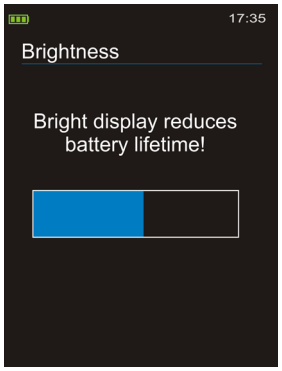
This submenu offers access to various device settings; confirm selection by pressing the ↵ button.

8.1.3.2 Parameters



Volume

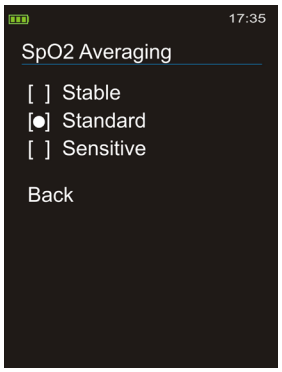
Adjust the pulse tone volume using the ▲▼ buttons. Confirm the new setting by pressing the ↵ button.



Brightness

Adjust the display brightness using the ▲▼ buttons. Confirm the new setting by pressing the ↵ button.

Note: Very high brightness settings will shorten the battery life considerably!



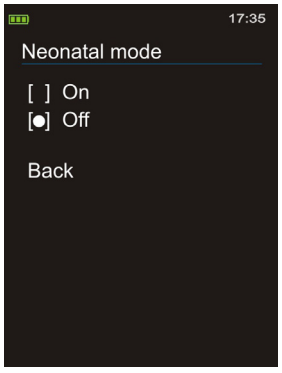
SpO_2 Averaging

Stable: When this setting is selected any strong and sudden variations in data will not immediately affect the reading (data incorporated over time); minor irregularities have little or no effect on the displayed reading.

Standard: Averaging parameters used for this setting are between those of the stable and sensitive settings.

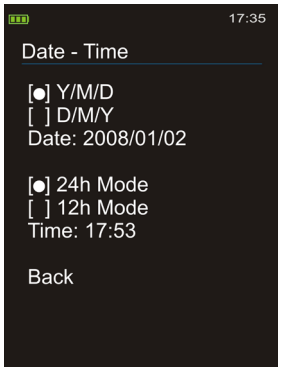
Sensitive: The reading is more sensitive to irregularities but reacts very quickly to any changes in measured parameters.

Refer to Chapter 13 “Technical Specifications” for further details on the influence of the SpO_2 averaging settings on the SpO_2 reaction time.



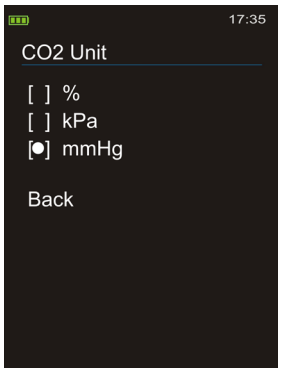
Neonatal Mode

The neonatal symbol indicates that the neonatal mode is activated. In this mode the default alarm limits are adjusted to neonatal default settings (refer to Chapter 7.3). Please ensure that accessories appropriate for neonates are connected.



Date and Time

First, select between Y/M/D and D/M/Y mode (respectively 12h mode and 24h mode), then set the date and time. Settings for the date and time are not erased when the batteries are temporarily removed.

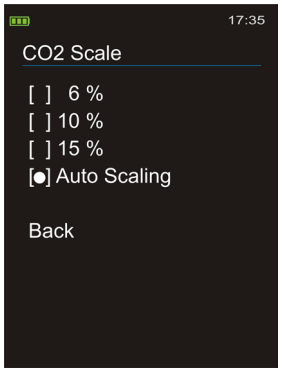


CO_2 Unit

By changing the CO_2 unit, the measurement values and default limits of $EtCO_2$ and $FiCO_2$ are converted accordingly. For conversion to the units kPa and mmHg an automatic barometric pressure compensation is performed.

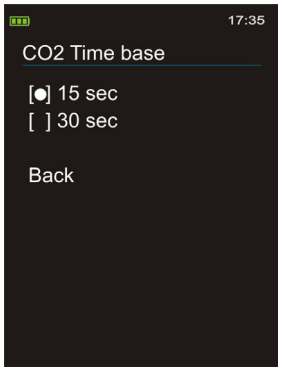
Language

All messages and menus will be displayed in the selected language. The standard language package comprises up to 16 languages. Please refer to the manufacturer for detailed information on the current languages available.



CO_2 Scale

The scale maximum of the capnogram and CO_2 trend can be fixed to 6 %, 10 % or 15 %. Select the option “Auto Scaling” for optimal amplitude scaling of the data. Depending on the selected CO_2 scale, the values will be adjusted accordingly.



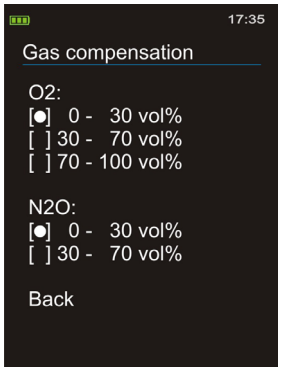
CO_2 Time Base

For an optimal time resolution the time base of the capnogram can be adjusted to 15 seconds or 30 seconds.

Real-Time Mode

The Real-Time mode symbol indicates that the Real-Time mode is activated. Activation of the Real-Time mode enables visualization and storage of measurement data on a PC.

In this mode the ongoing measurement values of $EtCO_2$, $FiCO_2$, SpO_2, respiration rate and pulse rate are available every 4 seconds at the USB port for download to the PC. For more information please refer to the enclosed Software Manual.



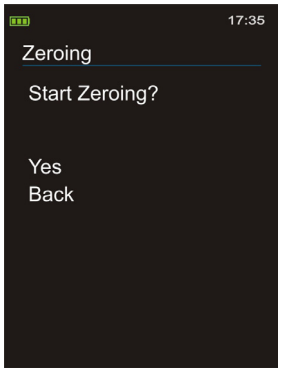
Gas Compensation

The presence of oxygen and nitrous oxide can cause some interference in the CO_2 measurement. These interferences are compensated by setting the range of O_2 and N_2O concentration under the menu point “Gas compensation” accordingly.

When the O_2/N_2O concentrations are set correctly, the measurement is within the accuracy range stated in the Technical Specifications (refer to Chapter 13).

Note: Only the mainstream VM-2500-M may be used to analyse gasses which contain nitrous oxide. Be sure that the IRMA™ airway adapter is correctly connected to the patient circuit.

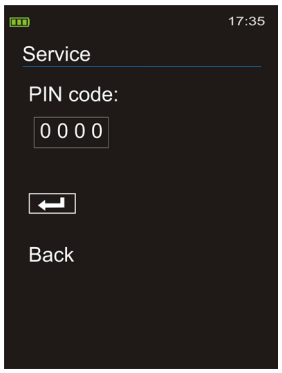
⚠ *Warning: Do not use VM-2500-S to analyse gasses (e.g. anaesthetics like nitrous oxide etc.) that need to be returned to the patient circuit or a scavenging system. The gas outlet of the sidestream device is not designed to return the exhaust gases to the patient circuit or a scavenging system.*



Zeroing

Zeroing needs to be performed only when an offset in $EtCO_2$ and $FiCO_2$ values is observed, or when an unspecified accuracy message is displayed.

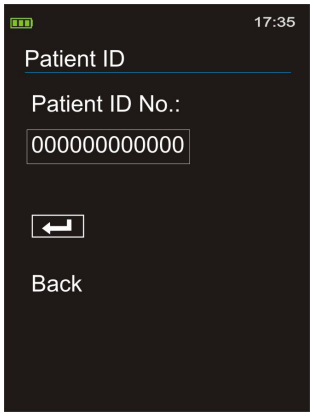
⚠ *Warning: Incorrect zeroing will result in false CO_2 gas readings. Refer to chapter 11.4 for detailed information.*



Service

The Service submenu is protected by a PIN code; only authorized service personnel can access this menu.

8.1.4 Submenu: Patient ID



The VM-2500 features the possibility of saving a 12 digit patient ID together with every created data file. If the Patient ID is changed via the menu during measurement, the current data file is closed and a new data file with the new Patient ID is opened. A message is displayed to inform the user.

8.1.5 Default Start Settings

Changed settings are in effect only as long as the VM-2500 remains switched on. Once the VM-2500 has been switched off, at the next start up, the default settings will be in effect. The start up defaults can be changed in the PIN protected Service Menu. Only authorized service personnel can access this menu.

8.2 Other

8.2.1 Volume Control Shortcut

If the ▲ button is pressed during any monitoring display mode, the volume control screen will open. Adjust the volume using the ▲▼ buttons. Confirm the new setting by pressing the ↵ button.

8.2.2 Brightness Control Shortcut

If the ▼ button is pressed during any monitoring display mode, the brightness control screen will open. Adjust the brightness using the ▲▼ buttons. Confirm the new setting by pressing the ↵ button.

8.2.3 Power-Save Mode

The device's display can be turned off to save power and extend battery life. This can be accomplished by pressing and holding the ▼ button. A countdown will start, after which the display will be switched off. The device is now in economy power mode. The pressing of any button will reactivate the display.

9 Adverse affects on performance

9.1 CO_2 measurements

9.1.1 Humidity or Condensation

The partial pressure and the volume percentage of CO_2 will depend on the amount of water vapour in the measured gas.

Both the mainstream and sidestream devices (VM-2500-M and VM-2500-S) will always show the actual CO_2 partial pressure at the current humidity level.

For sidestream sampling (VM-2500-S) the following has to be considered: In the alveoli of the patient, the breathing gas is saturated with water vapour at body temperature (BTPS). When the breathing gas is sampled, and passing the sampling line, the gas temperature will almost reach the ambient temperature before reaching the VM-2500-S monitor. As the Nomo Adapter removes all condensed water, no water will reach the measurement unit. The relative humidity of the sampled gas will be approximately 95%.

If CO_2 values at BTPS are required, the following equation can be used:
$EtCO_2\ (BTPS) = EtCO_2\ x\ (1-(3.8/Pamb))$

With:

- $EtCO_2$ = $EtCO_2$ *value displayed by VM-2500-S [vol%]*
- *Pamb = Ambient pressure*
- *3.8 = Typical partial pressure of water vapour condensed between the patient circuit and the VM-2500-S [kPa]*
- $EtCO_2$ *(BTPS) =* $EtCO_2$ *gas concentration at BTPS [vol%]*

9.1.2 Interfering gases or vapours

Gas or Vapour	Gas Level	CO_2 Measurement Interference
N_2O [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)	80 vol%	-10% of reading [3]
He (Helium)	50 vol%	-6% of reading [3]
Metered dose inhaler propellants [4]	Not for use with metered dose inhalers propellants	
C_2H_5OH (Ethanol) [4]	0.3 vol%	- [1]
C_3H_7OH (Isopropanol) [4]	0.5 vol%	- [1]
CH_3COCH_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 specifications "accuracy, incl. interfering gases" (refer to Chapter 13)

Note 2: Negligible interference with N_2O/O_2 concentrations correctly set, effect included in the specifications "accuracy, incl. interfering gases" (refer to Chapter 13)

Note 3: Interference at indicated gas level

Note 4: According to the EN ISO 21647:2004 standard

Note 5: In addition to the EN ISO 21647:2004 standard

9.2 SpO_2 Measurement

Physiological conditions, medical procedures, or external agents that may interfere with the monitor's ability to detect and display accurate SpO_2 measurements include:

- Incorrect application of the SpO_2 sensor
- Placement of the SpO_2 sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Excessive patient activity
- Intravascular dyes
- Externally applied colouring agents, such as nail polish
- Failure to cover the sensor site with opaque material in high ambient light conditions
- Venous pulsation
- Dysfunctional haemoglobin, e.g. caused by carbon monoxide intoxication
- Low perfusion

10 Troubleshooting guide
10.1 Error Message – Cause – Corrective Action

Error Message	Cause	Corrective Action
Battery low !	Low battery level at start up results in error message and dysfunction. Critical level during monitoring results in audible alarm and battery indicator to flash yellow. After 3 minutes device switches off.	Replace batteries immediately or connect the external power supply to the AC line.
Device defective !	Defective hardware, e.g. PCB.	Send the device to qualified service personnel.
No SpO_2 Sensor !	No connection to the SpO_2 sensor.	Check sensor connection.
SpO_2 Probe off !	The SpO_2 sensor is connected to the device, a signal was detected and then the finger has been removed/slipped of.	Check that the sensor is correctly attached to the patient.
SpO_2 Sensor fault !	The connected SpO_2 sensor is either defective or not compatible with the device.	Replace sensor.
Excess light !	High ambient light sources near the SpO_2 sensor, e.g. surgical lights.	Shield sensor more effectively from external light.
Bad signal quality !!!	Poor-quality pulse signal, for example as a result of low perfusion.	Check other vital signs to ensure sufficient perfusion. Move the sensor to a different site on the patient or provide more effective monitoring conditions.
CO_2 Over range !	The measured CO_2 concentration is outside of the specified accuracy range.	Ensure that device is used in an environment with a CO_2 concentration within the specified accuracy range.
No Nomo Adapter !	No connection to the sidestream Nomo Adapter.	Check Nomo Adapter connection.
Sampling system occlusion !	A component of the sidestream sampling system (sampling line, Nomo Adapter or gas outlet) is blocked (occluded).	Remove the occlusion by e.g. replacing the sampling line or Nomo Adapter.
No CO_2 Sensor !	No connection to the mainstream IRMA™ CO_2 analyzer.	Check connection.
Check CO_2 Adapter !	The mainstream IRMA™ adaptor is dirty, not positioned correctly etc.	Check airway adapter and replace if required
CO_2 Sensor fault !	The mainstream IRMA™ CO_2 analyzer is defective.	Replace IRMA™ CO_2 analyzer.
Data memory full, overwrite? Yes/No	Message is displayed at every startup of device if the memory is full.	Delete files or overwrite.
Zeroing disabled	The IRMA™ CO_2 analyzer / Nomo Adapter is not connected.	Connect the IRMA™ CO_2 analyzer / Nomo Adapter and try again.
	The CO_2 measurement module has not reached its working temperature after power on or after changing the IRMA™ airway adapter / Nomo Adapter	Wait 10 seconds for warm up of the IRMA™ CO_2 analyzer / ISA module before proceeding with the zeroing procedure.
	Other causes	Send the device to qualified service personnel.

10.2 Failure – Cause – Corrective Action

Failure	Cause	Corrective Action
No response to the power button	Power button is not fully depressed.	Ensure that the power button is fully depressed.
	The batteries may be missing, discharged, or oriented incorrectly or no power supply is connected.	Install new batteries or connect the power supply to the AC line.
Audible medium priority alarm sounds while the device is off and can not be restarted again	Power supply is disconnected during operation while no batteries are installed. Medium priority audible alarm occurs for 2 minutes whereupon device switches off.	Reconnect power supply immediately or insert battery.
No pulse signal found or the pulse signal cannot be found anymore	Patient has no pulse signal.	Check the patient.
	The incorrect SpO_2 sensor is used.	Check the sensor 'Instructions for Use' to determine if an appropriate sensor is being used and if it is applied correctly.
	SpO_2 sensor or extension cable is defective.	Check the sensor and extension cable connections. Test the sensor on another subject. Try another sensor or extension cable.
	Perfusion may be too low for the monitor to track the pulse.	Check the patient. Test the monitor on yourself. Change the sensor site. Try another sensor.
	Interference due to patient activity may be preventing the monitor from tracking the pulse.	Keep the patient still, if possible. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site.
	The sensor may be too tight, there may be interference due to ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.	Reposition sensor, as necessary.
	Electromagnetic interference may be preventing the monitor from tracking the pulse.	Remove the source of interference.
No pulse tone	Pulse beep volume is off.	Switch volume on.
	Speaker/audio has malfunctioned. Sig-nal is corrupted. The VM-2500 has stopped functioning.	Contact qualified service personnel.
$EtCO_2$ values are inconsistent	Physiological reasons.	Check the patient.
	Leakage in the system.	Check the tubes and connections to the patient
$EtCO_2$ values are continuously higher or lower than expected.	Physiological reasons.	Check the patient.
	Zeroing or calibration required.	Contact qualified service personnel.

10.3 IRMA™ LED Status and LEGI™ Status

Indication	Status	Action
Steady green light	System OK	-
Blinking green light	Zeroing in progress	-
Steady red light	System Error	check device error message
Blinking red light at IRMA™ LED	IRMA™ adapter defective	Check IRMA™ adapter
Blinking red light at LEGI™	Sampling system defective	Check sampling system

10.4 Problems with EMI (Electromagnetic Interference)

The VM-2500 has been tested and found to comply with the limits for medical devices according to: EN 60601-1-2, (second edition) and the Medical Device Directive 93/42/EEC.

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Due to the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of performance of this device. Examples of noise sources in healthcare environments that could cause electromagnetic interference include:

- Electrosurgical units
- Cellular phones
- Mobile two-way radios
- Electrical appliances
- High-definition televisions (HDTVs)

The measurement values of VM-2500 can be obscured by electromagnetic interference. During such interference measurements may seem inappropriate or the monitor may not seem to operate correctly.

Disruption may be evidenced by erratic readings, cessation of operation or other incorrect functioning. If this occurs, the operating environment should be surveyed to determine the source of disruption and the following actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reposition or relocate the interfering equipment.
- Increase the distance between the interfering equipment and this equipment.

The VM-2500 will generate, use and radiate radio frequency energy. Failure to follow these instructions may cause harmful interference with other devices in the vicinity.

11 Maintenance

11.1 Maintenance

The monitor requires no routine calibration. If service is necessary, contact qualified service personnel or your local sales representative.

Caution: There are no user-serviceable parts within the VM-2500. The cover should only be removed by qualified service personnel.

Caution: The VM-2500 requires no routine calibration. A basic maintenance plan conducted by qualified service personnel is recommended. Please refer to the Service Manual for detailed information.

11.2 Cleaning

Surface-clean

The VM-2500 and its accessories should be cleaned on a regular basis. Use a soft cloth dampened with either a commercial, nonabrasive cleaner, or a solution of 70% alcohol in water to clean the device. Lightly wipe the surface of the monitor.

To prevent cleaning liquids and dust from entering the VM-2500-S sidestream device through its LEGI™ connector, keep the Nomo Adapter connected while cleaning the monitor.

Caution: Do not immerse the VM-2500 or its accessories in liquid.

Caution: Do not spray, pour, or spill any liquid on the VM-2500, its accessories, connectors, switches, or openings in the enclosure as this may result in damage to the unit.

Disinfection
Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water to disinfect the device housing. Use 70% alcohol to disinfect the IRMA CO_2 Analyzer and the SpO_2 sensor.

Caution: Do not autoclave or steam sterilize the VM-2500 device, or its disposable accessories.

Caution: Do not autoclave or steam sterilize the IRMA CO_2 Analyzer or the Nomo Adapter and sampling configuration.

11.3 Testing

Test of the alarm system
In order to trigger an alarm for test purposes during monitoring set the upper alarm limit of SpO_2 or pulse rate below the currently indicated measurement value. The device will react with a visual and audible alarm.

Test of the measurement accuracy SpO_2
The only reliable method of testing the SpO_2 measurement accuracy of the monitor is the clinical validation of the measurement data, indicated by the system monitor with SpO_2 sensor on the basis of a blood gas analysis. During extensive clinical studies, the monitor combined with the approved sensors evidenced the accuracy required. Verify SpO_2 readings at regular intervals with a reference instrument.

Note that a functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.

Test of the measurement accuracy CO_2
The CO_2 units of the VM-2500 (sidestream and mainstream) are permanently factory calibrated. Reliable testing of the measurement accuracy of the CO_2 measurement requires the use of a suitable calibration gas mixture. During extensive measurements with calibration gas, the CO_2 measurement units (sidestream and mainstream) evidenced the accuracy required. Verify CO_2 gas readings at regular intervals with a reference instrument.

11.4 Zeroing the Capnograph
11.4.1 Mainstream VM-2500-M

Zeroing needs to be performed only when an offset in gas values is observed, or when an unspecified accuracy message is displayed:

- First connect a new IRMA™ airway adapter onto the IRMA™ CO_2 analyzer, without connecting the airway adapter to the patient circuit.
- Allow 10 seconds for warm up of the IRMA™ CO_2 analyzer after power on or after changing the IRMA™ airway adapter before proceeding with the zeroing procedure.
- Select MAIN MENU > SETUP > ZEROING at the monitor.
- Ensure that ambient air (21% O_2 and 0% CO_2) is present in the IRMA™ airway adapter.
- Start the zeroing by selecting “Yes” when the message “Start Zeroing?” is displayed.
- The message “Zeroing completed!” indicates that the zeroing was successful.

Special care should be taken to avoid breathing near the airway adapter before or during the zeroing procedure. Always perform a pre-use check after zeroing the IRMA™ CO_2 analyzer.

Warning: A successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2) in the IRMA™ airway adapter during zeroing. Incorrect zeroing of the IRMA™ CO_2 analyzer will result in false gas readings.

11.4.2 Sidestream VM-2500-S

The VM-2500-S performs zeroing automatically by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed every 24 hours, and takes less than 3 seconds.

Next to the automatic zeroing a manual induced zeroing is also possible, however needs to be performed only when an offset in gas values is observed, or when an unspecified accuracy message is displayed:

- First connect a Nomo Adapter to the VM-2500-S.
- Allow 10 seconds for warm up of the ISA™ module after power on or after changing the Nomo Adapter before proceeding with the zeroing procedure.
- Select MAIN MENU > SETUP > ZEROING at the monitor.
- Ensure that the monitor is placed in a well ventilated environment. Avoid breathing near the monitor housing.
- Start the zeroing by selecting “Yes” when the message “Start Zeroing?” is displayed.
- The message “Zeroing completed!” indicates that the zeroing was successful.

⚠ *Warning: Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2) in the device, ensure that the VM-2500-S is placed in a well ventilated environment. Avoid breathing near the VM-2500-S before or during the zeroing procedure. Incorrect zeroing of the integrated ISA™ CO_2 analyzer will result in false gas readings.*

12 VM-2500 PC-Software

With the user-friendly VM-2500 PC-Software all measurement data, selected alarm limits and occurred alarm can be stored on a PC via the USB interface. Here the data can be viewed and patient data added. The file can be printed or exported as CSV file for processing with additional software.

Furthermore the software can be used to display and save measurement values and alarm messages on a PC, parallel to ongoing measurements.

To enable this function the Real-Time mode has to be selected on the device. During this mode the device sends the current $EtCO_2$, $FiCO_2$, SpO_2, respiration rate and pulse rate measurement values every 4 seconds via USB to the PC.

For more information please refer to the enclosed Software Manual.

13 Technical Specifications

GENERAL

Parameters displayed
- Numerical: End-tidal CO_2 concentration ($EtCO_2$), Inspired CO_2 concentration ($FiCO_2$), Oxygen saturation (SpO_2), respiration rate (RR), pulse rate (PR)
- Graphical: Capnogram, Plethysmogram, trends of numerical data (15min / 1h / 6h)

Indicators
Signal strength and signal quality, pulse amplitude, battery status, alarm mute, pulse tone mute, storage status, Real-Time mode, neonatal mode, time

Alarms
- Limits: Adjustable limits for all numerical parameters
- Alerts: Audible and visual alarms (complies with EN 60601-1-8)

Storing Data
- Communication interface: USB 2.0
- Data memory on device: up to 400 hours in total
- Real-Time mode: Visualise and save numerical parameters every 4 seconds on PC
- PC-Software: VM-2500 PC-Software (for data download and Real-Time mode)

CAPNOGRAPH

Warm up time
< 10 seconds (concentrations reported and full accuracy)

CAPNOGRAPH	Mainstream	Sidestream
Operation principle	State-of-the-art, single path, non-dispersive infrared (NDIR), mainstream sensor	Ultra-compact infrared spectrometer with integrated low-flow pump
Barometric pressure compensation	The total pressure of the gas mixture is estimated by measuring the actual atmospheric pressure in the IRMA™ analyzer. For conversion to the units kPa and mmHg an automatic barometric pressure compensation is performed.	The total pressure of the gas mixture is measured by a pressure sensor in the sidestream CO_2 analyzer. For conversion to the units kPa and mmHg an automatic barometric pressure compensation is performed.
Flow rate	–	50 ± 10 ml/min
Calibration	No span calibration required. Manual zeroing required when offset in gas values is observed.	No calibration required Automatic zeroing is performed at start-up and then every 24 hours.
Rise time	≤ 90 ms (at 10 l/min)	≤ 200ms (at 50 ml/min sample flow)
Total system response time	< 1 second	< 3 second (with 2 m sampling line)
Airway adapter	• Disposable Adult/Paediatric: < 6 ml dead space, < 0.3 cm H_2O pressure drop at 30 l/min • Disposable Infant: < 1 ml dead space, < 1.3 cm H_2O pressure drop at 10 l/min	Disposable Adult/Paediatric: < 6 ml dead space, < 0.3 cm H_2O pressure drop at 30 l/min
Sampling interface	–	Nomo Adapter with female Luer Lock connection
Length of interface	Cable length mainstream sensor: 2.55 m	Sampling line length: 2 m
Water handling	XTP™ windows of the IRMA™ airway adapter with special features that prevent a decrease in performance when vapour is present.	Nomo Adapter with proprietary water removal tubing.

Measurement Range
- $EtCO_2$ and $FiCO_2$: 0 - 15%
- Respiration rate: 0 - 150 breaths/min

Accuracy
- $EtCO_2$ and $FiCO_2$: +/- (0.2 vol%. + 2% of reading), +/- (0.3 vol% + 4% of reading.) incl. interfering gases
- Respiration rate: +/-1 digit

Parameter renews
- $EtCO_2$ and $FiCO_2$: Displayed after one breath and then a continually updated breath average.
- Respiration rate: Displayed after three breaths and then average value updated every breath.

PULSE OXIMETER

Measurement Range
- SpO_2: 0 - 100%
- Pulse Rate: 20 - 300 beats/min

Accuracy
- SpO_2 [1]: +/- 2% (70 to 100%)
- Pulse Rate: +/- 1 digit (up to 100 beats/min) or +/- 1% (> 100 beats/min)

Parameter renews (see Table)
First displayed value after application:
- SpO_2: Between 3 seconds and 7 seconds, depending on measurement conditions.
- Pulse rate: Between 5 seconds and 8 seconds, depending on measurement conditions.

PHYSICAL CHARACTERISTICS

Display
Active OLED colour graphic display,
262 000 colours, 240 x 320 pixels

Dimensions
(L x W x H): 15 cm x 7.5 cm x 3.5 cm

Weight
< 400 g (complete device with batteries)

POWER SUPPLY

Power may be supplied by battery, rechargeable battery or by AC power supply

4 x Batteries
Alkaline battery (AA / LR6 / AM3 / MN1500 / Mignon), 1.5V

Li-ion battery, Model No. CT-2500
Li-ion battery, 3.7V, 2500mAh, charging time and working time with full function: 5-6 hours

AC power supply, Model No. FW 7660M/06
Medical power supply with option for country-specific input plug
- Input: 100-240V AC / 50-60Hz / 250mA
- Output: 6V DC / 1.4 A

PULSE OXIMETER Parameter renews

Measurement dynamics		Beat to beat min/max	Sensitive min/max	Standard min/max	Stable min/max
SpO_2 [2]	First reaction after	N/A	1 sec	2 sec	4 sec
	Determined value reached after another	N/A	4 sec	8 sec	12 sec
Pulse-rate [3]	First reaction after	1 sec / 7 sec	1 sec / 7 sec	1 sec / 7 sec	1 sec / 7 sec
	Determined value reached after another	N/A	1 sec / 4 sec	1 sec / 6 sec	1 sec / 8 sec

1) As inherent to their functional principle, pulse oximetry measurements underlie statistical spread, therefore only two thirds of the measurement data are within the specific range of +/- ARMS
2) Measured at de-saturation / re-saturation between 96 % and 84 % SpO_2 under favourable measurement conditions. The values can be extended by a bad pulsation strength or motion artefacts.
3) Maximum values are measured with sudden change from 40 to 200 beates/minute and vice versa. The reaction depends on the difference (variance) of the beats among themselves.

ENVIRONMENTAL CONDITIONS

Operating conditions
0 - 50°C, 15 - 95% R.H. (non-condensing),
60 - 120 kPa (excl. Li-ion battery [1])

Storage conditions
-30 - 70°C, 10 - 95% R.H. (non-condensing),
60 - 120 kPa (excl. Li-ion battery [2])

CLASSIFICATION

General
- The device is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- No sterile parts are included.
- Mode of operation: Continuous operation

Construction
Water-resistant construction of class IPX1 (with silicone cover)

Classification (according to MDD 93/42/EEC)
Class IIb

Electrical safety
Class of protection II / Type BF – Type and degree of protection against electrical shock

APPLIED STANDARDS

The applied standards are listed in the directory COMPLIANCE on the CD-ROM provided with the device.

14 Component Lists and Ordering
14.1 Packing List

VM-2500-M:

- Mainstream device
- IRMA™ CO_2 analyzer
- IRMA™ airway adapter (adult/paediatric)
- Reusable SpO_2 sensor
  (selectable, see order numbers)
- USB data cable
- Power supply (FW7660M/06)
- Power supply adapter (Europe plug)
- Power supply adapter (UK plug)
- Li-ion battery (CT-2500)
- 4 x Batteries (AA Mignon)
- Silicone protective cover
- User manual + PC software (CD-ROM)

VM-2500-S:

- Sidestream device
- Nomo Adapter
- Disposable sampling line
- Airway adapter (adult/paediatric)
- Reusable SpO_2 sensor
  (selectable, see order numbers)
- USB data cable
- Power supply (FW7660M/06)
- Power supply adapter (Europe plug)
- Power supply adapter (UK plug)
- Li-ion battery (CT-2500)
- 4 x Batteries (AA Mignon)
- Silicone protective cover

User manual + PC software (CD-ROM)

1) Should the device experience condensation it should be stored for more than 24 hours in an environment with relative moisture content below 95%RH (non-condensing).
2) With Li-ion battery the conditions are reduced to: operating while charging at 0 – 45°C and 86 – 106 kPa storage (1 month) at -20 - 60°C and 86 – 106 kPa

14.2 Order Number

Please indicate language version when ordering.

VM-2500 Starter Kit Versions

Device	Language Version	Order number
Mainstream VM-2500-M	Europe	4410500
	Asian	4410501
Sidestream VM-2500-S	Europe	4410520
	Asian	4410521

Language Version [1)]
- Europe: EN, DE, ES, FR, IT, NL, SE, RU (additional languages available upon request)
- Asian: EN, CN, JP (additional languages available on request)

SpO_2 Sensor Style
- SC 6500 VM
- SCP 6500 VM
- W 6500 VM
- EP 6500 VM
- SF 6500 VM

14.3 Accessories

CO_2 Mainstream Accessories

- IRMA™ airway adapter (adult/paediatric), P/N 4420511, Mainstream airway adapter for adult and paediatric use, box of 25
- IRMA™ airway adapter (infant), P/N 4420521, Mainstream airway adapter for infant use, box of 10

CO_2 Sidestream Accessories [2)]

- Nomo Adapter, P/N 4420525, long term use water separator and bacterial filter for sidestream sampling, female Luer Lock connector
- Disposable sampling lines, P/N 4420550, disposable hydrophobic sampling line made of PE, 2m length, male/male Luer Lock connectors, box of 25
- Sidestream airway adapter (adult/paediatric), P/N 4420531, Sidestream airway adapter for adult and paediatric use, female Luer Lock connector, box of 25
- Airway adapter ISO 15mm / I.D. 2.0mm, P/N 4420570, airway adapter for infant and neonatal use, disposable, Luer Lock sideport – FLL, box of 10
- Airway adapter ISO 15mm / I.D. 2.5mm, P/N 4420571, airway adapter for infant and neonatal use, disposable, Luer Lock sideport – FLL, box of 10
- Airway adapter ISO 15mm / I.D. 3.0mm, P/N 4420572, airway adapter for infant and neonatal use, disposable, Luer Lock sideport – FLL, box of 10
- Airway adapter ISO 15mm / I.D. 3.5mm, P/N 4420573, airway adapter for infant and neonatal use, disposable, Luer Lock sideport – FLL, box of 10
- Airway adapter ISO 15mm / I.D. 4.0mm, P/N 4420574, airway adapter for infant and neonatal use, disposable, Luer Lock sideport – FLL, box of 10
- Airway adapter ISO 15mm / I.D. 5.0mm, P/N 4420575, airway adapter for infant and neonatal use, disposable, Luer Lock sideport – FLL, box of 10
- Airway adapter ISO 15mm / I.D. 6.0mm, P/N 4420576, airway adapter for infant and neonatal use, disposable, Luer Lock sideport – FLL, box of 10
- Airway adapter ISO 15mm / I.D. 7.0mm, P/N 4420577, airway adapter for infant and neonatal use, disposable, Luer Lock sideport – FLL, box of 10
- Airway adapter ISO 15mm / I.D. 8.0mm, P/N 4420578, airway adapter for infant and neonatal use, disposable, Luer Lock sideport – FLL, box of 10

1) Refer to the manufacturer for detailed information on the current languages available.
2) Note: Our sampling line configurations are continuously updated; please visit Viamed for detailed information. Specific patient sampling line configurations and interfaces are available upon request.

- Airway adapter ISO 15mm / I.D. 9.0mm, P/N 4420579, airway adapter for infant and neonatal use, disposable, Luer Lock sideport – FLL, box of 10
- Airway adapter ISO 15mm / I.D. 10.0mm, P/N 4420580, airway adapter for infant and neonatal use, disposable, Luer Lock sideport – FLL, box of 20

SpO_2 Accessories

- SC 6500 VM, P/N 0014750, 3rd generation adult soft sensor, 1.2m silicone cable
- SF 6500 VM, P/N 0014650, Fingerclip sensor, 1.2 m long cable, PVC cable
- SCP 6500 VM, P/N 0014751, 3rd generation paediatric soft sensor, 1.2m silicone cable
- SCA 6500 VM, P/N 0014590, 3rd generation adult soft sensor, 1.2m silicone cable, ≥ 200 autoclaving cycles
- SCPA 6500 VM, P/N 0014591, 3rd generation paediatric soft sensor, 1.2m silicone cable, ≥ 200 autoclaving cycles
- W 6500 VM, P/N 0014835, silicone wrap sensor, 1.2m silicone cable
- EP 6500 VM, P/N 0014825, Ear sensor, 1.2m long cable, PUR cable, PUR ear hanger
- XT 6500 VM Extension cable, P/N 0014895, 1.2m cable length, PVC cable
- XT 6501 VM Extension cable, P/N 0014896, 2.4m cable length, PVC cable

Additional SpO_2 sensors are available upon request

Other Accessories

- Universal Mounting Kit, P/N 4420600, V-adapter with female pole-mount thread
- Universal Mounting Clamp, P/N 0121200, Adapter with vertical and horizontal adjustment
- Carry case, P/N 0022170, Carrying bag for main unit and sensor, with shoulder strap
- Europe power supply plug, P/N 4430604, Europe adapter for the power supply FW 7660M / 06
- UK power supply plug, P/N 4430603, UK adapter for the power supply FW 7660M / 0

14.4 Replacement Parts

- IRMA™ CO_2 analyzer, P/N 4420505, mainstream CO_2 analyzer
- Power supply, FW7660M/06, P/N 4420595, Power supply for continuous operation of the VM-2500 and charging of Li-ion battery, Input: 100-240V AC / 50-60Hz, Output: 6V DC / 1.4A
- Silicone Protective Cover, P/N 4420610, Protective cover for the VM-2500 device
- Li-Ion battery, CT-2500, P/N 4420590, special rechargeable battery for use with the VM-2500, 3.7 V / 2500 mAh
- USB Data Cable, P/N 0022174, Data cable for data transfer between the VM-2500 device and PC
- 4 x Batteries (AA Mignon), P/N 9950054
- VM-2500 CD-ROM, CD with the VM-2500 User Manual + PC software