VIAMED

Handheld Pulse Oximeter VM 2160-L

User Manual

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1. Intended Use and Warnings
1.1 Intended Use

The VM 2160-L handheld pulse oximeter is indicated for spot monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate of adult, paediatric and newborn patients in hospital, hospital type facilities, transport, emergency care and mobile environments as well as in the home care environment.

1.2 Warnings

Warnings are identified by the WARNING symbol shown above. Warnings alert the user to potential serious outcomes, such as death, injury, or adverse events to the patient or user.

Warning: *Do not make any clinical judgments based solely on the VM 2160-L. 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: *Explosion hazard. Do not use the VM 2160-L in the presence of flammable anaesthetics mixture with air, oxygen, or nitrous oxide.*

Warning: *Routinely monitor the patient to ensure that the VM 2160-L is functioning and that the sensor is correctly placed.*

Warning: *Pulse oximetry measurements and pulse signals can be affected by certain environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety information.*

Warning: *Certain physiological conditions, medical procedures, and external agents may interfere with the monitor's ability to detect and display accurate measurements. (Chapter 7.1 provides information on possible interferences)*

Warning: *For the measurement the SpO_2 monitor is using red and infrared light with specific fixed wavelengths. Consider that these wavelengths might influence diagnostic parameters of other optical applications. The used wavelengths are listed in the instructions for use of the specific sensor.*

Warning: *If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternative means; then ensure that the VM 2160-L is functioning correctly.*

Warning: *The use of accessories, sensors, and cables other than those specified may result in increased emission and/or create invalid readings of the VM 2160-L.*

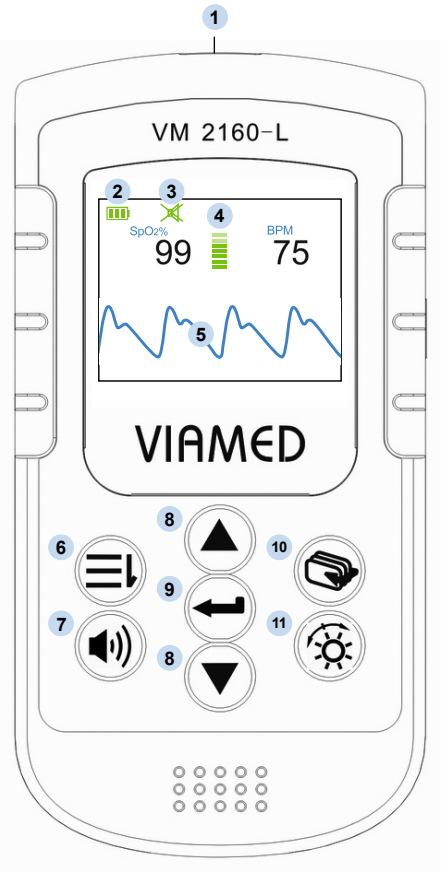
Warning: *In high ambient light conditions it is required to shield the sensor application site with opaque material. Too much ambient light may result in inaccurate measurements.*

Warning: *The VM 2160-L is a prescription device to be operated only by trained personnel. The monitor is for attended monitoring only.*

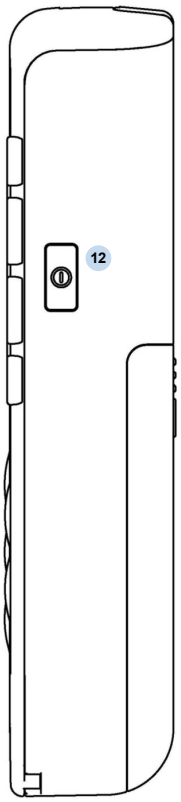
Warning: *The VM 2160-L is not defibrillator-proof. However, it may remain attached to the patient throughout defibrillation or whilst an electrosurgical unit is in use. The measurements may be inaccurate throughout the defibrillation, or use of an electrosurgical unit, and shortly thereafter. To avoid shock, the caregiver should not hold the VM 2160-L while using a defibrillator on a patient.*

Warning: *Disconnect the VM 2160-L and sensor from the patient throughout computed tomography or magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.*

2. Controls – Symbols – Display Modes
2.1. Controls and User Interfaces – Symbols and Indicators



Front view



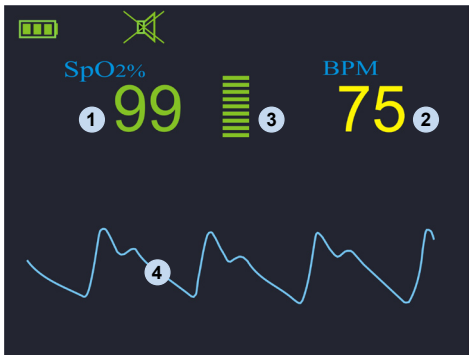
Side view

No.	Symbol/ Indicator	Feature	Function
1		Sensor Port	Port for the SpO_2 sensor
2		Battery Level Indicator	The three segments represent the battery charge level. The symbol flashes red when the battery capacity is low.
3		Pulse Tone Mute	At the lowest volume level the pulse tone is muted.
4		Signal Quality	The colour of the bar graph is an indicator for signal quality. **Green:** good signal quality, very accurate measurement. **Yellow:** average signal quality, measurement may be inaccurate. **Red:** poor signal quality, unreliable measurement.
5		Plethysmogra-phic Waveform	The reading is automatically adjusted to the pulse strength; therefore, a waveform with strong amplitude should be visible at all times.
6		Menu	Menu selection

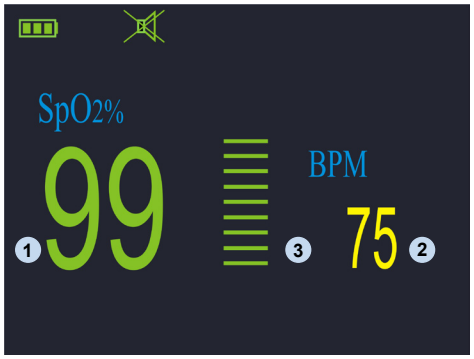
7		Pulse Tone	Gives access to the volume adjustment screen
8		Arrow Buttons (up/down)	Multifunction buttons used for 1. Scrolling through menu items 2. Increasing/decreasing parameters
9		Enter Button	Confirms selection, Resets warning
10		Display Mode	Toggles between various display modes
11		Brightness Adjustment	Gives access to the brightness adjustment screen
12		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.

2.2. Display Modes and Displayed Data

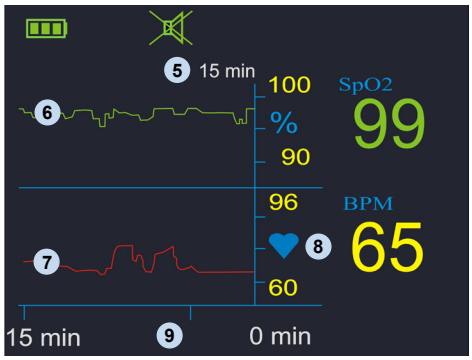
Toggling Between Display Modes
The operator can toggle between various display modes by pressing the button.



Display 1



Display 2



Display 3 to 5
(Example of 15-minute trend)
Display mode showing trend data for 15, 30 or 240-minute time interval parallel to ongoing measurement

1. The SpO_2 value shows the blood oxygen saturation level expressed as a percentage.
2. Pulse rate in beats per minute
3. Bar graph for pulse amplitude. This 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.
4. Pulse waveform (Plethysmogram)
   The reading is automatically adjusted to the pulse strength; therefore, a waveform with strong amplitude should be visible at all times.
5. Time- interval trends
6. Trend waveform for SpO_2
7. Trend waveform for pulse rate
8. Pulse indicator
9. Start and end times

2.3 Audio Indicators
2.3.1 Pulse Tone (Beep)

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 loudness can be adjusted by using the 🔊 button. The lowest volume level will mute the pulse tone.

2.3.2 Audible Warning Signal (Beep, Beep… + 15 seconds pause… Beep, Beep)

In the following conditions an audible warning signal will be generated:

- No sensor!
- Probe off!
- Sensor disconnected!
- Sensor fault!
- Too much ambient light!
- Low battery!
- Device defective!

2.3.3 Battery Alarm

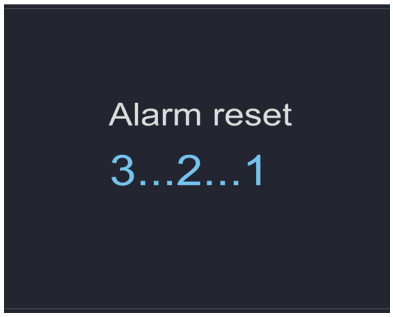
When the device is switched on and a critically low battery level is detected, it will not start operating and a “Low battery” message will be displayed.

If the batteries arrive at a critically low level during monitoring, the battery indicator will start to flash red and an audible warning signal will be generated and the “Low battery” message will be displayed. This warning signal will remain active for 3 minutes, at which point the device will automatically switch off.

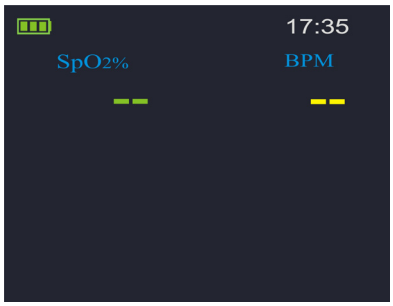
2.4 Resetting of Warning Signals

Once triggered, a warning signal will only be reset if the cause of the warning has been resolved. Some warnings can also be completely deactivated if necessary.

Warning signals can be confirmed and reset by pressing and holding the button ↵. If the initial condition for the warning is still present after resetting the warning signals, the warning will return immediately. In case of the signals “Probe off!” and “No sensor!” the device switches to the on-position. Parameters which have been set by the user will be kept on warning reset.



Display after pressing the ↵ button for approx. 3 seconds.



Display after reset.

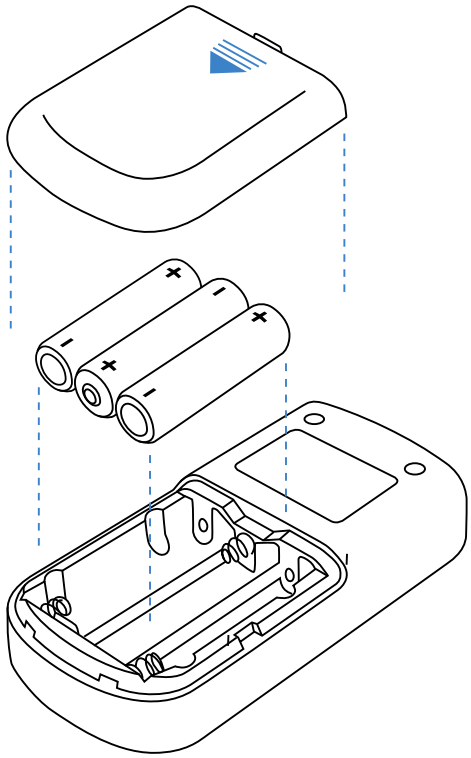
3. Preparation for Use

Caution: *The use of rechargable instead of alkali batteries may cause a shorter operating time of the device.*

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

3.1 Battery Installation

- Slide down the cover of the battery compartment on the rear panel of the device.
- Insert three batteries (1.5 Volt, AA), ensuring the correct orientation in accordance with the polarity markings.
- Slide the battery-compartment cover back into initial position to close.



3.2 Connecting the SpO_2 Sensor

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

Visual check
Before beginning operation, ensure that the device and sensor are not damaged.

Warning: *Do not use sensors or cables that appear to be damaged. Do not use a sensor when optical components are exposed. Do not use a device that appears damaged. Replace monitor immediately in case of visible damages.*

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.*

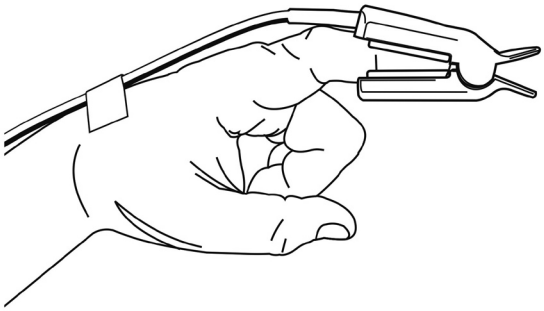
3.3 Switching on the Device

⏻ Press and hold the on/off button briefly until an opening "welcome screen" appears. After the power on self test is successfully completed the device is ready for monitoring.

Warning: *During the power-on self-test of the device a single loud tone can be heard. If not, it is absolutely necessary to ensure that the speaker is not obstructed or defective!*

3.4 Commencing Monitoring

Once the sensor is connected and correctly positioned on the patient, monitoring begins automatically. Refer to the sensor "Instructions For Use" to determine if an appropriate sensor is being used, and if it is applied correctly.

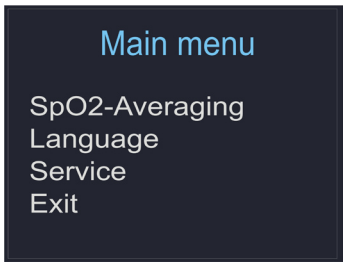


3.5 Switching off the Device

⏻ Press and hold the on/off button for approx. 3 seconds to switch off the device. The VM 2160-L device will also power off automatically after 2 minutes when not in use.

4. Screen Contents – Menu Structure

4.1 Main Menu



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

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.

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

Exiting Menu and Returning to Display
Select the menu item "EXIT" 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 last monitoring screen.

4.2 Adjusting Settings

Default Settings
Changed settings are in effect only as long as the monitor remains on. Once the monitor has been turned off, at the next start up, the default settings will be in effect. The startup defaults can be changed in the PIN protected Service Menu. Only authorised service personnel have access.

The display brightness and language are not reset during a re-start of the device, the settings selected before will be stored.

4.2.1 Submenu: 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.

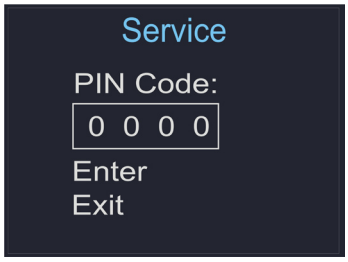
Sensitive: The reading is more sensitive to irregularities but reacts very quickly to any changes in measured parameters.

Refer to chapter 10 "Technical Specifications" for the effects of the SpO_2 mean settings on start and reaction times.

4.2.2 Submenu: Language

Depending on the firmware, up to 10 different language options are available for selection. All messages and menus will be displayed in the selected language.

4.2.3 Submenu: Service



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

5. Brightness Adjustment

Pressing the ☼ button activates the brightness adjustment menu.

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

By adjusting the brightness setting to the lowest level, 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.

The device will always start with the last selected brightness level.

Caution: *Using a high display brightness will consume more battery power than medium or low brightness levels and a more frequent change of batteries may be required!*

6. Volume Adjustment

Pressing the button activates the volume adjustment menu.

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

The pulse tone can be switched off by setting the volume to zero.

Caution: *Warning signals such as "sensor off", or "battery low" can not be muted. The only way to switch these warning signals off is to change the startup default in the PIN protected Service Menu.*

7. Error Messages – Problems – Corrective Actions

7.1. General Information

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

- Incorrect application of the sensor
- Placement of the senor 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 shield the sensor site in high ambient light conditions
- Venous pulsation
- Dysfunctional haemoglobin, e.g. caused by a carbon monoxide intoxication
- Low perfusion

7.2 Error Messages – Causes

"No sensor!" or "Sensor disconnected!"
The sensor is not connected properly to the device. – Check sensor connection.

"Probe off!"
The sensor has been removed from the application site. – Check that the sensor is properly attached to the patient.

"Low battery!" battery symbol blinking red
The battery is almost completely discharged. – Replace batteries immediately.

"Sensor fault!"
The connected sensor is either defective or not compatible with the device. – Check sensor.

"Device defective!"
Fatal device error, e.g. resulting from improper handling, such as use with computed tomography. – Contact qualified service personnel or your local sales representative.

"Too much ambient light!"
High ambient light sources near the sensor, e.g. surgical lights. – Shield sensor more effectively from external light.

"Bad signal quality"
Poor-quality pulse signal, e.g. as a result of low perfusion. – Reposition the sensor to a different application site on the patient or provide more effective monitoring conditions.

7.3 Failure – Causes – Corrective Actions

Problem: No pulse signal found or the pulse signal can no longer be found
Cause – Corrective Action: Check the patient. Check the sensor instructions for use to determine if the appropriate sensor is being used and if it is applied correctly. Check sensor and extension cable connections. Test the sensor on another subject. Try another sensor or extension cable.

The patient's perfusion may be too low for the monitor to track the pulse. Check the patient. Test the monitor on yourself. Reposition the sensor. Replace the 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. Reposition the sensor.

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 the sensor, as necessary.

Electromagnetic interference may be preventing the monitor from tracking the pulse. Remove the source of interference.

Problem: No pulse tone
Cause – Corrective Action: Continue to listen for the pulse beep tone as the monitor is used. If it does not sound with each pulse it indicates one of the following: Pulse beep volume is off. – Switch volume on.

Speaker/audio has malfunctioned. Signal is corrupted. VM 2160-L has stopped functioning. – Contact qualified service personnel or your local sales representative.

7.4 Other Problems

EMI (Electromagnetic Interference)

Caution: *This device 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 pulse 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 monitor generates, uses and radiates radio frequency energy. Failure to follow these instructions may cause harmful interference with other devices in the vicinity.

8. Maintenance – Cleaning – Testing

Maintenance

Caution: *There are no user-serviceable parts inside the VM 2160-L. The housing should only be removed by qualified service personnel.*

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

Caution: *Do not immerse the VM 2160-L in any liquid. Do not spray, pour, or spill any liquid on the VM 2160-L, its accessories, connectors, switches, or openings in the enclosure as this may damage the monitor.*

Surface-clean
Use a soft cloth dampened with either a commercial, nonabrasive cleaner, or a solution of 70% alcohol in water. Lightly wipe the surface of the monitor.

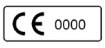
Disinfection
Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water.

Caution: *The device may not to be sterilised neither with superheated steam nor with hot air!*

Test of the alarm system
In order to trigger an alarm for test purposes during the 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 an audible alarm.

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

9. Symbol Definitions

	Attention! See instructions for use!
	Manufacturer
	Date of manufacture
	Alarm inhibit (device has no alarm system)
	Type BF
S/N	Serial number
P/N	Part number
	Observe applicable waste disposal regulations
	European Union approval

10. Technical Specifications

Measurement Range:
SpO_2: 0 to 100%
Pulse Rate: 20 to 300 BPM

Accuracy [1]:
SpO_2: +/- 2% (70 to 100%)
Pulse Rate: +/- 1 BPM (≤ 100 BPM), +/- 1% (> 100 BPM)

LED Power:
Maximum LED Power: 20 mW
Typical: 3.5 mW
Maximum increase of temperature at application site: 2°C

Medium sound pressure level of the audio signal:
69 dB(A) at a distance of 1 m

Display:
- Characteristics: OLED colour graphic display, 262,000 colours, 128 x 160 pixels
- Data displayed: oxygen saturation, pulse rate, plethysmogram, bar graph, trend information
- Indicators: signal strength and signal quality, pulse amplitude, battery status, sensor recognition, sensor disconnection

Reaction Times:
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.

Trend Information:
- Short-term Trends: 15 min / 30 min / 240 min

Environmental Conditions:
- Operating conditions: -20 to 50°C; 15 to 95% R.H.; 600 to 1300 hPa
- Storage conditions: -30 to 70°C; 10 to 95% R.H.; 600 to 1500 hPa

Miscellaneous:
- Construction: water-resistant construction of class IPX2 with silicone cover, splash-proof version of class IPX4 available on request
- Classification: Class IIa device, in accordance with MDD 93/42/EEC
- Electrical safety: Class of protection II / Type BF
- Dimensions (L x W x H): 11.8 cm x 6 cm x 2.5 cm
- Weight: approx. 160 g (with batteries, without sensor)
- Power Supply: 3 batteries (1.5 Volt, Type AA LR6) Alternative: 3 rechargable NiMh batteries, 1.2 Volt, Typ AA HR6, 1200 mAh
- Operational duration: > 2 days continuous operation / approx. 4 days in power economy mode, > 3000 Spotchecks

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 desaturation / resaturation between 96 % and 84 % SpO_2 under favourable measurement conditions. The values can be extended by a bad pulsation strength or motion artifacts.

3) Maximum values are measured with sudden change from 40 to 200 bpm and vice versa. The reaction depends on the difference (variance) of the beats among themselves.

Order Number:
(Please indicate language version when ordering)

- P/N 0012155 - VM 2160-L
  Central European languages,
- P/N 0012156 - VM 2160-L
  Scandinavian languages,
- P/N 0012157 - VM 2160-L
  Special EU character languages
- P/N 0012158 - VM 2160-L
  Asia I languages
- P/N 0012159 - VM 2160-L
  Asia II languages

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

11. Packing List – Accessories and Replacement Parts

Packing List:
- VM 2160-L, main unit
- SF 6500 VM Finger-clip Sensor
  P/N 0014750
- Silicone Protective Cover
- 3 batteries (1.5 Volt, AA)

Accessories and Replacement Parts:

- SF 6500 VM, Finger-clip Sensor, P/N 0014650,
  1.2m cable length, PVC cable
- SC 6500 VM, Soft Sensor, P/N 0014750,
  3rd generation SoftSensor, 1.2m cable length,
  silicone cable
- SCP 6500 VM, Paediatric Soft Sensor,
  P/N 0014751, 3rd generation SoftSensor,
  1.2m silicone cable
- W 6500 VM, Wrap Sensor, P/N 0014835,
  1.2m silicone cable
- 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
- Universal Mounting Kit, P/N 0022171 V-adapter
  with female pole-mount thread
- Universal Pole-Mount Adapter, P/N 0121200,
  Adapter with vertical and horizontal adjustment
- Carrying Bag, P/N 0022170, Carrying bag for
  main unit and sensor, with shoulder strap
- VM 2160-L Silicone Protective Cover,
  P/N 0022160

Additional sensors and accessories are available upon request.

12. Declaration of Conformity

EC Declaration of Conformity

We hereby declare under sole responsibility that the product

VM-2160-L

pulse oximeter for monitoring of functional
arterial oxygen saturation (SpO_2) and pulse rate,

Product No.
0012155

conforms with the essential requirements of Annex II of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

In accordance with Annex IX of the Directive 93/42 EEC the product has been classified as Class IIa

Application of the CE-marking:

CE 0086

Issuer:

Viamed Ltd.
15 Station Road
Cross Hills
Keighley
West Yorkshire, BD20 7DT
United Kingdom

Place, Date: Keighley, 16 September 2008

Legally binding signature:

Steve Nixon (Director)

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VM 2160-L User Manual, Version: EN 1.42
01/2009