VIAMED

Handheld Pulse Oximeter VM 2160

User Manual

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1. Intended Use

The VM 2160 handheld pulse oximeter is indicated for continuous or spot check 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.

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. 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 VM 2160 in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.*

Warning: *Routinely monitor the patient to make sure the VM 2160 is functioning and 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 5.1 provides information on possible interferences)*

Warning: *For the measurement, the SpO_2 monitor uses 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 alternate means; then make sure the VM 2160 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.*

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.*

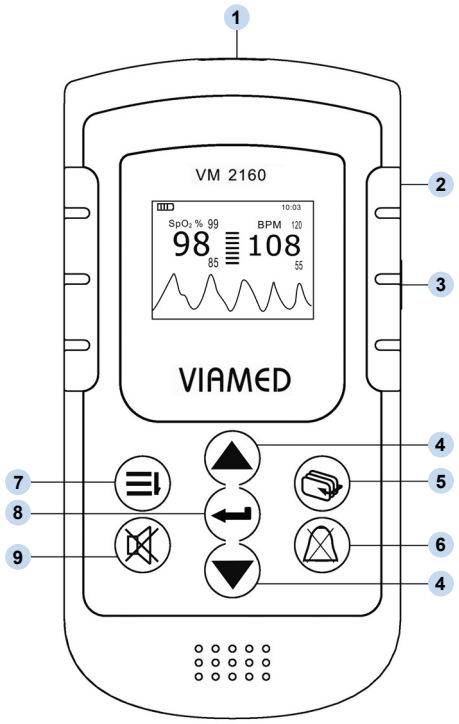
Warning: *Do not silence the audible alarm function or decrease the audible alarm volume if patient safety could be compromised.*

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

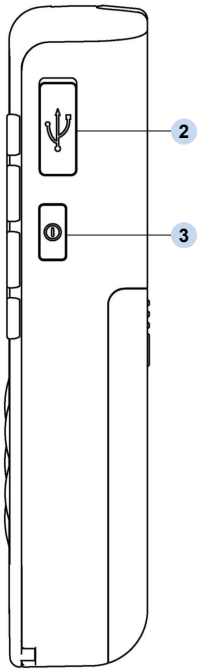
Warning: *The VM 2160 is not defibrillator-proof. However, it may remain attached to the patient throughout defibrillation or while an electrosurgical unit is in use. The measurements may be inaccurate throughout the defibrillation, or use of an electrosurgical unit, and shortly thereafter. To avoid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

Warning: *Disconnect the VM 2160 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



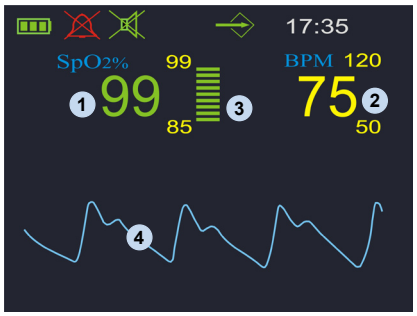
Front view



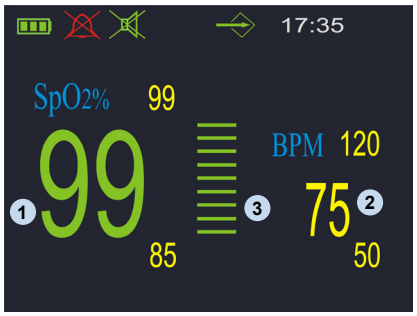
Side view

No.	Symbol	Feature/Button	Function
1		Sensor Port	Port for the SpO_2 sensor
2		USB	USB 2.0 interface
3		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.
4		Arrow Buttons (up/down)	Multifunction buttons used for 1. scrolling through menu items and 2. increasing/decreasing parameters. 3. From monitoring display modes: can be used as shortcuts to volume/brightness control
5		Display Mode	Toggles between various display modes
6		Alarm silenced	The audible alarm can be silenced for a maximum period of two minutes. Optical alarm remains activated.
7		Menu	Menu selection
8		ENTER button	Confirms selection
9		Pulse Tone	Turns pulse tone on/off

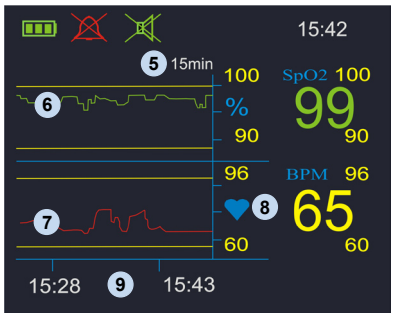
2.2. Display Modes and Displayed Data



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

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

1. The SpO_2 value shows the blood oxygen saturation level expressed as a percentage. The small numbers shown immediately above and below the measured value on the right side indicate the upper and lower alarm limits.

2. Pulse rate in beats per minute. The small numbers immediately above and below the measured value on the right side indicate the upper and lower alarm limits.

3. 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.

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

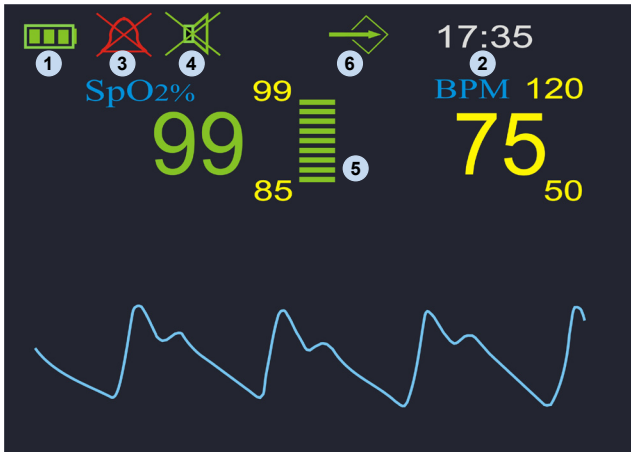
6. Trend waveform for SpO_2 with continuous upper and lower alarm limits in yellow

7. Trend waveform for pulse rate with continuous upper and lower alarm limits in yellow

8. Pulse indicator

9. Start and end times

2.3. Symbols and Indicators



No.	Symbols/Indicators	Definition
1		Battery level indicator. The three segments represent the battery charge level. The symbol flashes red when the battery capacity is low.
2	10:07	Current time, displayed in 12h or 24h format
3		Alarm silenced The audible alarm can be silenced for a maximum period of two minutes. Optical alarm remains activated.
4		Pulse tone off
5		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.
6		Memory symbol The device's memory for measurement data is full. No new data can be stored. Old data can be erased or overwritten.

2.4 Audible Indicators
2.4.1 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 a 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 the button a second time will reactivate the pulse tone.

2.4.2 Alarm Signals

The VM 2160 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 a following alarm of lower priority.

2.4.2.1 Alarm Priorities

High
Alarm Cause: Heart stops beating, no pulse signal found
Audio Signal Sequence (repeatedly): BEEP_BEEP_BEEP___BEEP_BEEP – 2 seconds pause – BEEP_BEEP_BEEP___ BEEP_BEEP – 3 seconds pause

Medium
Alarm Cause: Violation of the SpO_2 or pulse alarm limits, Battery low
Audio Signal Sequence (repeatedly): BEEP_BEEP_BEEP – 5 seconds pause

Low
Alarm Cause: Probe off, No sensor, Sensor fault, Ambient light
Audio Signal Sequence (repeatedly): BEEP_BEEP – 16 seconds pause

2.4.2.2 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.

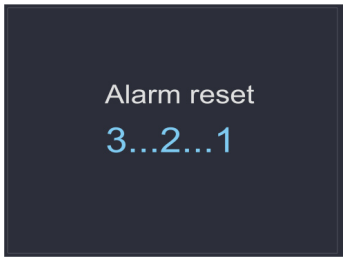
2.4.3 Audible Alarm Volume

The alarm volume is not adjustable; however, it is possible to silence the alarm for a period of two minutes using the button.

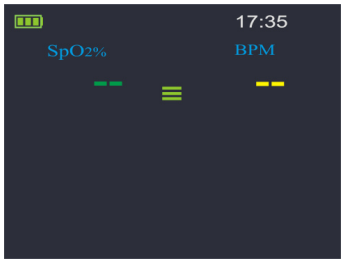
2.4.4 Resetting of alarm signals

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 necessary. Alarm 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 alarm 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 alarm reset.



Press and hold button ↵



Display after reset

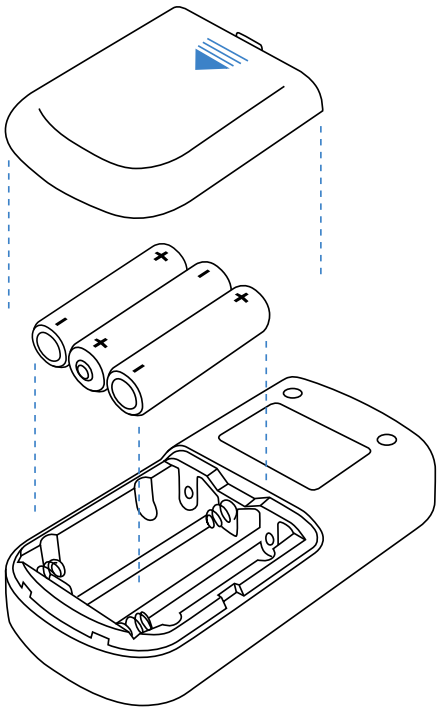
3. Preparation for Use

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 cases 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.*

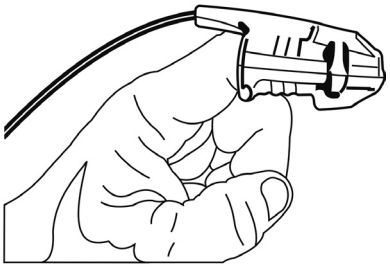
3.3 Switching on the Device

⏻ 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

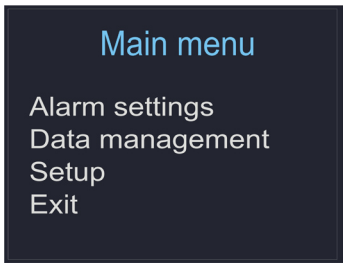
Once the sensor is connected and correctly positioned on the patient, monitoring begins automatically. Refer o the sensor 'Instructions For Use' to determine if an appropriate sensor is being used, and if it is applied correctly.



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 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 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
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 monitoring screen.

4.1.1 Submenu: Alarm Settings
4.1.1.1 General Information

The alarm limits for SpO_2 and pulse can be set individually. The current alarm limits are shown as small numbers above and below the measured values on the right side. 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 red together with the violated alarm limit.

An alarm will also be triggered if the sensor is removed from the application site, if the signal remains poor over a long period of time or if the sensor is disconnected from the device, provided that valid measurement data has been recorded beforehand.

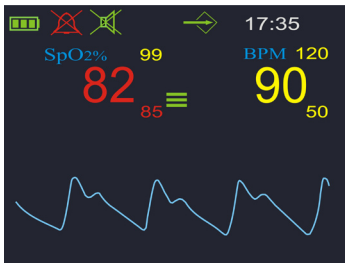


Figure: Visual alarm which was triggered by a violation of the lower SpO_2 alarm limit.

4.1.1.2 Adjusting Settings

Selection with ▲▼ buttons
Selection/confirmation with ↵ button

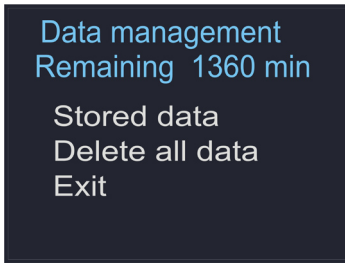
Alarm Settings
Setting of the upper and lower alarm limits of the SpO_2 and pulse rate. "Off" deactivates the alarm limit. After restarting the device, the default alarm limits will be reset.

4.1.2 Submenu: Data Management
4.1.2.1 General Information

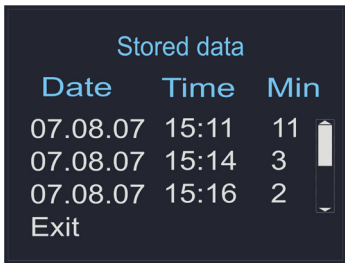
Recording Data
The VM 2160 device can store more than 480 hours of monitoring data. Each individual data set, regardless of its actual length, uses at least 15 minutes of memory space. A new data set is generated automatically each time the device is turned on. When the device is turned off, all of the measurements that were taken are automatically stored in the devices memory, together with the respective alarm limits, date and time. The device warns the user when the memory is almost full by displaying the ⇨. symbol. A maximum of 50 data sets can be stored in the memory. After this maximum has been reached 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 stored and processed with the user-friendly VM 2160 PC-Software.

Stored data will no be erased when the batteries are removed temporarily.

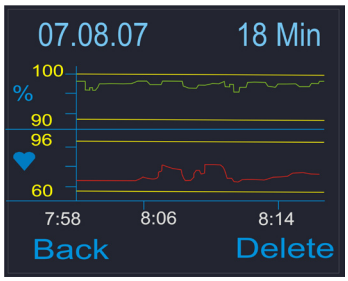
4.1.2.2 Data



Use Data Management menu to
- view remaining recording time in minutes
- access list of stored data sets
- delete all data in memory



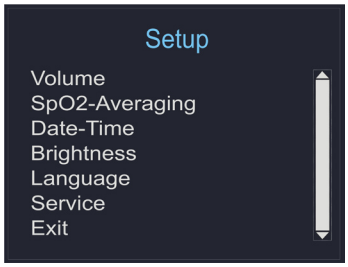
Stored Data menu
List of all stored data sets. Retrieve selected data set by pressing the ↵ button.



Select "Back" to return to the list of stored data or "Delete" to erase the data set shown.

The stored measurements are displayed in graphic form together with the date, start time and duration of the recording. The SpO_2 reading is shown in green, and the pulse reading in red. The yellow lines represent the respective alarm limits.

4.1.3 Submenu: Device Setup
4.1.3.1 General Information



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

4.1.3.2 Adjusting Settings

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

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.

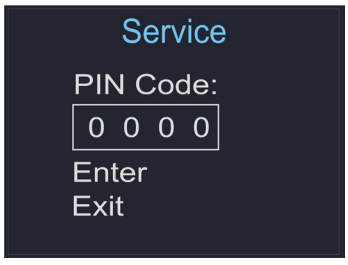
Refer to chapter 8 “Technical Specifications” for the effects of the SpO_2 mean settings on start and reaction times.

First, select between 12h mode and 24h mode; then set date and time. Settings for date and time are not erased when the batteries are temporarily removed.

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

Please note: Very high brightness settings will shorten battery life considerably!

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



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

4.1.4 Default Start 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 Other

4.2.1 Volume Control Shortcut

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

4.2.2 Brightness Control Shortcut

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

4.2.3 Power-Save Mode

The 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. If an alarm is triggered, the display will be turned on automatically.

5. Error Messages – Problems – Corrective Actions

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

5.2 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 monitoring 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, for example as a result of low perfusion. – Move the sensor to a different site on the patient or provide more effective monitoring conditions.

5.3 Failure – Cause – Corrective Action

Problem: There is no response to the Power button.
Cause – Corrective Action: Ensure that the Power button is fully depressed. The batteries may be missing, discharged, or oriented incorrectly. Install new batteries.

Problem: No pulse signal found or the pulse signal cannot be found anymore
Cause – Corrective Action: Check the patient. Check the sensor instructions for use to determine if an 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.

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.

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 has stopped functioning. – Contact qualified service personnel or your local sales representative.

5.4 Other Problems

EMI (Electromagnetic Interference)
This device has been tested and found to comply with the limits for medical devices according to BS EN 60601-1-2:2007, BS EN 60601-1:2006, BS EN 60601-1-1:2001, BS EN ISO 9919:2005 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.

6. Maintenance – Cleaning – Testing

Maintenance and cleaning

Caution: *There are no user-serviceable parts inside the VM 2160. The cover 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.

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.

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

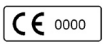
Desinfection
Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water.

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 an SpO_2 monitor is the clinical validation of the measurement data, indicated by the system 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.

7. Symbol Definitions

	Attention! See instructions for use!
	Manufacturer
	Date of manufacture
	Type BF
S/N	Serial number
P/N	Product number
	Observe applicable waste disposal regulations
	European Union approval

8. Technical Specifications

Measurement Range:
SpO_2: 0 to 100%
Pulse Rate: 20 to 300 beats per minute (bpm)

Accuracy [1]:
SpO_2: +/- 2% (70 to 100%)
Pulse Rate: +/- 1 digit (≤ 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 alarm signal:
69 dB(A) at a distance of 1 m

Display:
- OLED colour graphic display, 262,000 colours, 128 x 160 pixels
- Data displayed: oxygen saturation, pulse rate, plethysmogram, bar graph, short-term and long-term trends
- Indicators: signal quality, pulse amplitude, battery status, alarm silenced, sensor detection, 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 measurement conditions.

Trend Information:
- Long-term Trends: up to 48 hours
- Short-term Trends: 15 min / 30 min / 240 min

Environmental Conditions:
- Operating conditions: -20 to 50°C; 15 to 95% RH; 600 to 1300 hPa
- Storage conditions: -30 to 70°C; 10 to 95% RH; 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 IIb device, in accordance with MDD 93/42/EEC
- Electrical safety: Class of protection II / Type BF
- Dimensions (L x W x H): 11.8 x 6 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
- Battery Life: > 2 days of continuous operation, or approx. 5 days in power-save mode
- Data Memory: More than 480 hours, maximum 50 datasets

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	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 0012160 - VM 2160
  Central European languages,
- P/N 0012161 - VM 2160
  Scandinavian languages,
- P/N 0012162 - VM 2160
  Special EU character languages
- P/N 0012163 - VM 2160
  Asia I languages
- P/N 0012164 - VM 2160
  Asia II languages

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

9. Packing List – Accessories and Replacement Parts

Packing List:
- VM 2160, main unit
- SC 6500 VM Adult Soft Sensor
- VM 2160 PC-Software
- USB data cable
- Silicone protector
- 3 AA batteries

Accessories and Replacement Parts:

- SC 6500 VM, Adult Soft Sensor, P/N 0014750,
  3rd generation SoftSensor, 1.2m cable length,
  silicone cable
- SF 6500 VM, Finger-clip sensor, P/N 0014650,
  1.2m cable length, PVC cable
- SCP 6500 VM, Paediatric Soft Sensor,
  P/N 0014751, 3rd generation SoftSensor,
  1.2m silicone cable
- W 6500 VM, Silicone 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 Silicone Protective Cover, P/N 0022160
- USB Data Cable, P/N 0022172
- CD-ROM VM 2160 PC-Software, P/N 0022173

Additional sensors and accessories are available upon request.

10. VM 2160 PC-Software

With the user-friendly VM 2160 PC-Software all saved data can be stored on a PC via the USB interface. This software offers a multitude of functions for more advanced analysis and archiving of the measured data.

For more information please read the enclosed software manual.

11. Declaration of Conformity

EC Declaration of Conformity

We hereby declare under sole responsibility that the product

VM-2160

hand held pulse oximeter for continuous and spot-check monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate,

Product No.
0012160

conforms with the essential requirements of Annex I 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 IIb

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, 26 August 2008

Legally binding signature: .....

Derek Lamb (Managing Director)

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

Tel: +44 (0)1535 634542
Fax: +44 (0)1535 635582
E-mail: info@viamed.co.uk

www.viamed-online.com

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