VIAMED

Finger Oximeter VM-2105
User Manual

VM-2105 User Manual

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The information in this document is subject to change without notice.

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Declaration of Conformity

CE **0086**

Complies with 93/42/EEC Medical Device Directive.

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Patents

Patent pending.

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1. Intended Use and Warnings
1.1 Intended Use

The VM-2105 finger oximeter is indicated for spot monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate of adults and paediatrics in hospital, hospital type facilities, pre and postoperative monitoring, transport, emergency care and mobile environments, sports medicine 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-2105. 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-2105 in the presence of flammable anaesthetic mixture with air, oxygen, or nitrous oxide.*

⚠ *Warning: Routinely monitor the patient to ensure that the VM-2105 is functioning and that the oximeter is correctly placed. Change the sensor application site, check skin integrity and circulatory status at least every 4 hours.*

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

⚠ *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.*

⚠ *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: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then ensure that the VM-2105 is functioning correctly.*

⚠ *Warning: The VM-2105 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 touch the VM-2105 while using a defibrillator on a patient.*

⚠ *Warning: Disconnect the VM-2105 from the patient through-out magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.*

⚠ *Warning: Do not use a device that appears damaged. Do not use the device when optical components are exposed.*

2. Operation
2.1 Power Supply

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

Caution: The use of rechargeable instead of alkali batteries is not advised, due to the lower cell voltage.

1. Release the lip of the battery compartment on the rear side of the device, in the direction of the arrow. Remove the battery-compartment cover (Fig. 1).

2. Insert two batteries (1.5 volt, AAA), ensuring the correct orientation in accordance with the polarity markings. Ensure that the transparent strips remain accessible once the batteries are inserted (Fig. 2).

3. Fold the transparent strips over the batteries and replace the battery-compartment cover, press down until the lip returns to its original position.

4. Depleted batteries can be removed by pulling the transparent strips.

Fig. 1

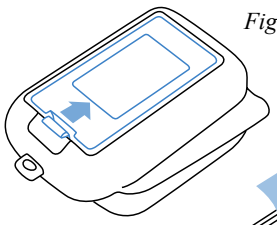
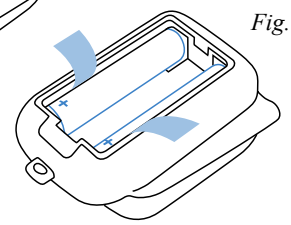


Fig. 2



2.2 Switching on the Device

Press and hold the button on the front panel briefly until the opening “welcome screen” appears. After the power-on self-test is successfully completed the device is ready for use.

Device ready for use, no finger inserted.

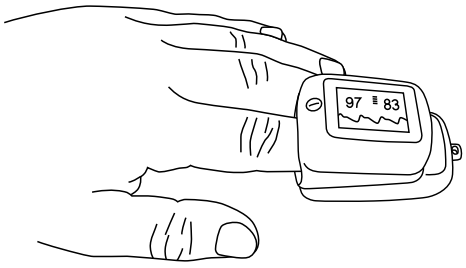
2.3 Inserting the Finger

⚠ *Warning: Externally applied colouring agents, such as nail polish may interfere with the monitor’s ability to detect and display accurate measurements!*

To obtain an accurate reading it is essential that the finger oximeter is placed correctly on the patient’s finger.

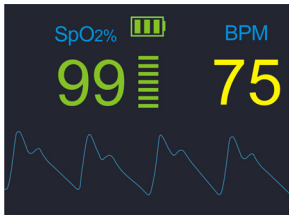
The light that is emitted by the finger oximeter has to transmit from the upside of the finger oximeter through the patient’s finger nail.

- Turn the patient’s hand so that you can see the finger nail.
- Raise the topside of the finger oximeter away from the base slightly, to open.
- Insert the patient’s finger, nail facing the top of the finger oximeter, so that the finger is placed fully on the silicone pad.
- Release the topside of the finger oximeter to secure it on to the patient’s finger.



2.4 Commencing Monitoring

Once the finger oximeter is switched on and the patient’s finger is inserted correctly, monitoring will begin automatically.

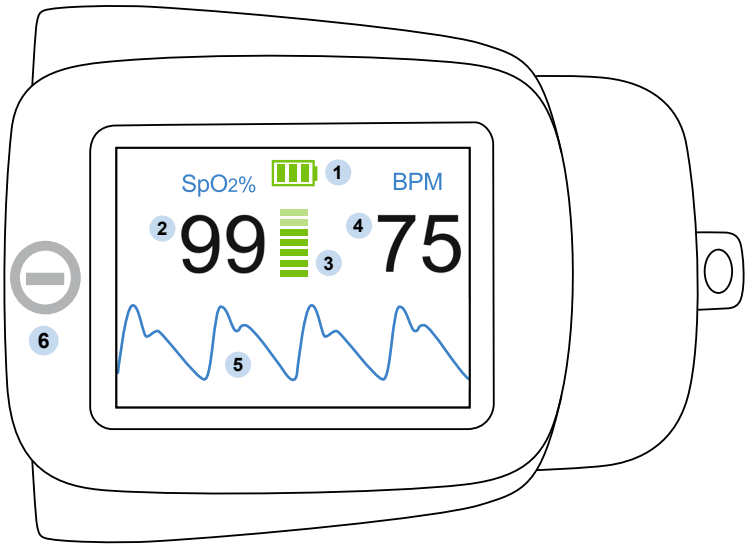


Device in use.

2.5 Switching off the device

The VM-2105 will automatically power off after 15 seconds, when it is removed from the patient’s finger.

2.6 Symbols and Indicators



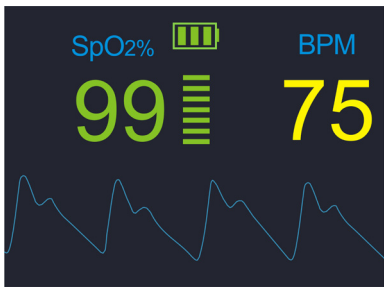
No.	Symbol/Indicator	Definition
1		Battery level indicator. The three segments represent the battery charge level. The symbol flashes red when the battery capacity is low.
2	SpO2%	The SpO_2 value shows the blood oxygen saturation level expressed as a percentage.
3		Bar graph for pulse amplitude. Indicates 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. 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.
4	BPM	Pulse rate in beats per minute.
5	 Pulse waveform	The reading is automatically adjusted to the pulse strength; therefore, a wave-form with strong amplitude should be visible at all times.
6		Multifunctional button - switch device on (short press) - change/rotate display (short press, when the device is switched on) - adjust brightness (press for more than one second, when the device is switched on)

2.7 Alternating between Display Modes – short button press

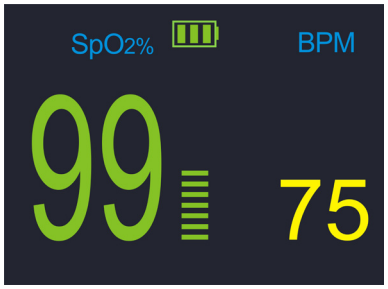
Depending on the personal preferences and application it is possible to alternate between a display with plethysmographic waveform and a display which shows the readings in a larger font size but without the waveform. Additionally it is possible to rotate the screen orientation.

Caution: When the VM-2105 is in operating mode, each short press of the button will change the display mode.

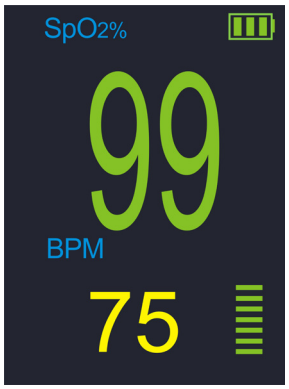
Examples of different display modes



Horizontally orientated screen with plethysmographic waveform.



Horizontally orientated screen with large digits but without plethysmographic waveform.



Vertically orientated display

2.8 Adjusting Display Brightness – long button press

Caution: Using high display brightness will consume more battery power than medium or low brightness levels and result in a shorter operating time!

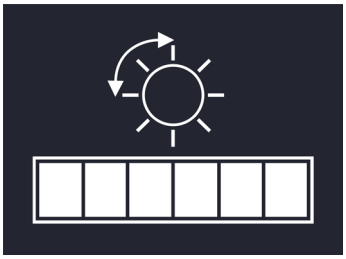
The finger oximeter has 6 levels of adjustable brightness.

If, whilst in operation, the button is kept pressed for longer than one second, the brightness adjustment becomes active and the brightness adjustment screen is shown.

For every second that the button is kept pressed, the brightness increases by one level. Once the highest level is reached the brightness will decrease by one level for every second that the button is kept pressed. When the lowest brightness level is reached the brightness will increase again.

Button pressed toggles the brightness level

Brightness adjustment: lowest level selected



Brightness adjustment: highest level selected

Release the button when the desired brightness level has been reached.

After a few seconds the device returns automatically into measurement mode.

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

3. Error Messages - Problems - Corrective Actions
3.1 General Information

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

- Incorrect application of the finger oximeter
- Placement of the finger oximeter 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 application site with opaque material in high ambient light conditions
- Venous pulsation
- Dysfunctional haemoglobin, e.g. caused by a carbon monoxide intoxication
- Low perfusion

3.2 Error Messages – Causes

Display shows "-- --"
The finger has been removed from the finger oximeter. Check that the finger is correctly inserted into the finger oximeter.

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

"Too much ambient light symbol"
☼ A red sun symbol is shown. There is too much ambient light around. Avoid bright sunlight. Cover the application site with opaque material

3.3 Problems – Causes – Corrective Actions

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. Replace batteries immediately.

Problem: No pulse signal found
Cause/Corrective Action: Check the patient. Check that the finger oximeter is placed correctly. Test the monitor on another subject.

Perfusion may be too low for the monitor to track the pulse. Check the patient. Test the monitor on yourself. Change the application site.

Interference due to patient activity may be preventing the monitor from tracking the pulse.

Keep the patient still, if possible. Change the application site.

There may be interference due to ambient light, or the finger oximeter may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the finger oximeter, as necessary.

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

3.4 EMI (Electromagnetic Interference)

Caution: 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 electro-magnetic interference. During such interference, measurements may seem inappropriate or the finger oximeter 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 the finger oximeter.

4. Maintenance – Cleaning – Disinfection

Maintenance
There are no user-serviceable parts inside the VM-2105. The housing should not be opened.

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

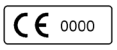
Caution: Do not immerse the VM-2105 in any liquid. Do not spray, pour, or spill any liquid on the VM-2105, its accessories, connectors, switches, or openings in the enclosure as this may damage the monitor.

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 finger oximeter. Please clean the charging station at least once a month to ensure a good power transmission while charging.

Disinfection
Use a soft cloth saturated with a solution of 10% chlorine bleach in water. Lightly wipe the surface of the finger oximeter. Remove any residues of the disinfectant prior to reusing the unit.

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 system on the basis of a blood gas analysis. During extensive clinical studies, the monitor evidenced the accuracy required.

5. Symbol Definitions

	Attention! See instructions for use!
	Device has no alarm system!
IP XY	IP Code
	Manufacturer
	Date of manufacture
	Type BF
S/N	Serial number
P/N	Part number
	Observe applicable waste disposal regulations
	European Union approval

6. Technical Specifications

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

Accuracy*:
SpO_2: +/- 2% (70 to 100%)
Pulse Rate: +/- 1 digit (≤ 100 bpm); +/- 1% (> 100 bpm)

LED:
Wavelenghts: 660 nm, 905 nm

Display:
- OLED colour graphic display, 262,000 colours, 128 x 96 pixels
- Data displayed: oxygen saturation, pulse rate, plethysmogram, bar graph
- Indicators: signal quality, pulse amplitude, battery status

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

Power Supply:
- 2 batteries (1.5 volt, AAA)
- Battery Life: approx. 24h of continuous operation

Reaction time and averaging:
Average reaction time to changes is 1.5 seconds, the averaging uses four pulse waves.

Other:

	VM-2105
Classification (MDD 93/42/EEC)	Class IIa
Degree of protection	IP X2
Type	BF
Dimensions (L x W x H)	65 x 50 x 34 mm
Weight	approx. 58g

Order Number:
VM-2105
- 0012105 - Grey
- 0012106 - Orange

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

7. Packing List

- VM-2105, main unit
- Lanyard
- User Manual on CD
- 2 x AAA batteries, 1.5V

***** *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*