VIAMED


# Silicone Finger Oximeter VM-2105

## User Manual

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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.*

⚠ **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:** *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 throughout 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.*

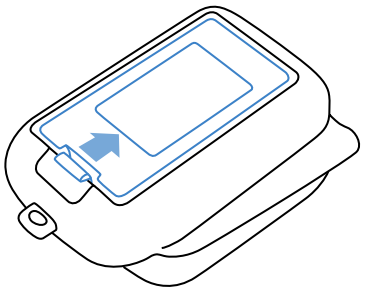
## 2. Operation
### 2.1 Battery Installation

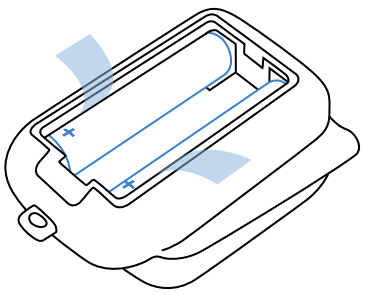
1. Release the lip of the battery compartment on the rear side of the device, in the direction of the arrow. Remove the battery-compartment cover (Fig. 1).

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. Return the battery-compartment cover and press down until the lip returns to its original position.

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





## 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 monitoring.


*Device ready for monitoring, no finger inserted.*

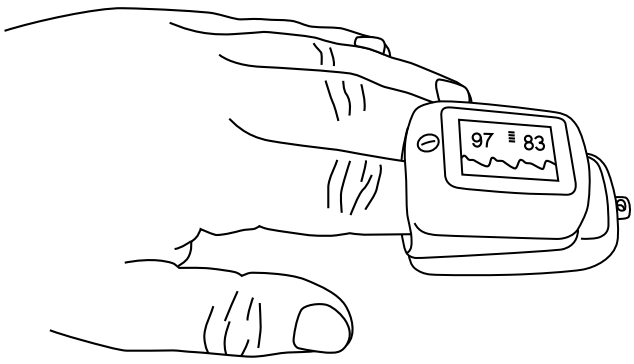
## 2.3 Inserting the Finger

**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.

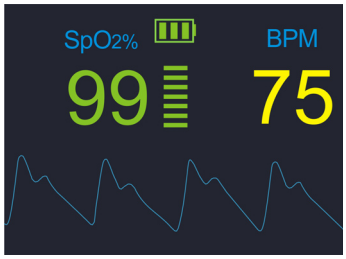
The light that is emitted by the finger oximeter has to transmit from the upside of the finger oximeter through the patient's finger nail.

- 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.

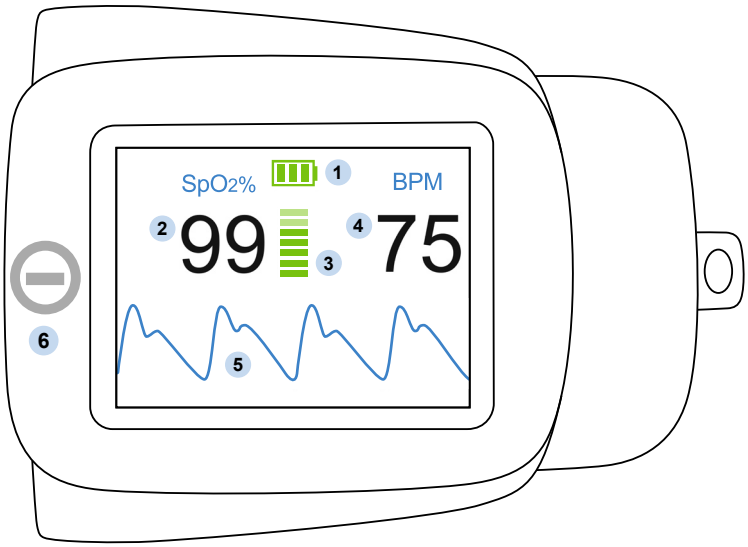



*Monitoring in progress.*

## 2.5 Switching off the Device

The VM-2105 will automatically power off after 15 seconds when the patient's finger is removed.

## 2.6 Symbols and Indicators



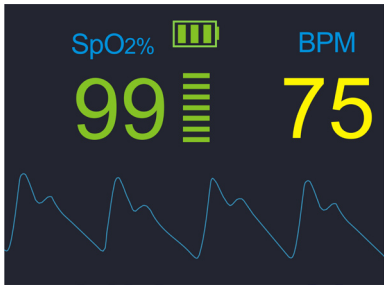

| No. | Symbol/Indicator | Definition |
|---|---|---|
| 1 |  | Battery level indicator. The three segments represent the battery charge level. The symbol flashes red when the battery capacity is low. |
| 2 | SpO2% | The $SpO_2$ value shows the blood oxygen saturation level expressed as a percentage. |
| 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:<br>**Green:** good signal quality, very accurate measurement.<br>**Yellow:** average signal quality, measurement may be inaccurate.<br>**Red:** poor signal quality, unreliable measurement. |
| 4 | BPM | Pulse rate in beats per minute. |
| 5 |  <br>Pleth waveform | The reading is automatically adjusted to the pulse strength; therefore, a waveform with strong amplitude should be visible at all times. |
| 6 |  | Multifunctional button<br>- switch device on (short press)<br>- change/rotate display (short press, when the device is switched on)<br>- Adjustable brightness (press for more than one second, when the device is switched on) |

## 2.7 Alternating Between Display Modes – short button press

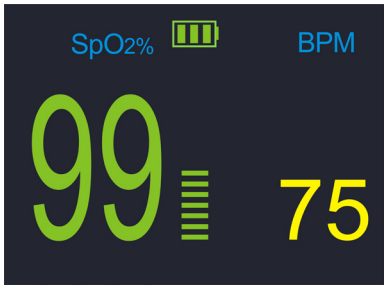
Depending on the personal preferences and application it is possible to alternate between a display with plethysmographic waveform and a display which shows the readings in a larger font size but without the waveform. Additionally it is possible to rotate the screen orientation.

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

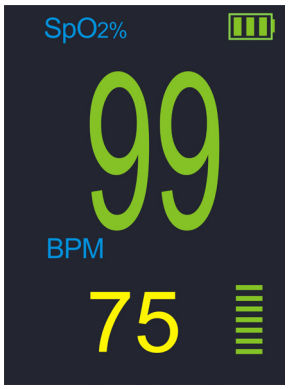
### Examples of different display modes




*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 a more frequent change of batteries may be required!*

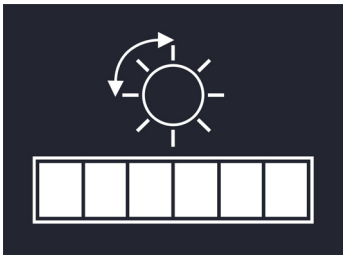
The finger oximeter has 6 levels of adjustable brightness.

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
- 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.

### 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. Install new batteries.

**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 electromagnetic 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

**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 spray, pour, or spill any liquid on the VM-2105 as this may damage the finger oximeter.*

**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.

**Disinfection**
Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water. Lightly wipe the surface of the finger oximeter.

## 5. Symbol Definitions

| | |
|---|---|
|  | Attention! See instructions for use! |
|  | 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)

**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

**Other:**
- Class IIa product
- Water-resistant construction IPX2
- Type BF
- Dimensions (L x W x H): 65 x 50 x 34 mm
- Weight (including batteries): approx. 58 g
- Power Supply: 2 batteries (1.5 volt, AAA)
- Battery Life: approx. 24h of continuous operation

**Order Number:**
- 0012105 - Grey
- 0012106 - Orange

**Applied Standards:**
CE Class IIa in accordance with MDD 93/42/EEC, BS EN 60601-1:2006, BS EN 60601-1-1:2001, BS EN 60601-1-2:2007, BS EN ISO 9919:2005

## 7. Packing List

- VM-2105, main unit
- Lanyard
- 2 x AAA batteries, 1.5 volt
- User manual on CD

## 8. Declaration of Conformity

### EC Declaration of Conformity

We hereby declare under sole responsibility that the product

VM-2105

Silicone Finger Oximeter for monitoring of functional arterial oxygen saturation ($SpO_2$) and pulse rate,

Product No.
**0012105** and **0012106**

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, 29 January 2009

**Legally binding signature:** .....

Derek Lamb (Managing Director)

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