Intended Use

The VM-2160 handheld pulse oximeter is intended for continuous or spot check monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate of adult, paediatric and neonatal patients. To be used by trained healthcare professionals only. For use in the home care environment the user may use the device after instruction by, or under supervision of, a trained healthcare professional.

Depending on the SpO_2 sensor connected, the VM-2160 may be used in hospital, hospital type facilities, transport,

Warnings

⚠ 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.

⚠ Explosion hazard—Do not use the monitoring system in the presence of flammable substances.

⚠ Shock hazard—Use only AA size batteries. Do not use different types or models of batteries, such as lithium ion and nickel-metal hydride batteries, together.

⚠ Routinely monitor the patient to ensure the VM-2160 is functioning and the sensor is correctly placed.

⚠ Pulse oximetry readings and pulse signal can be affected by patient conditions, excessive patient movement, sensor application errors, and certain ambient environmental conditions. See the appropriate sections of the user manual on CD-ROM provide for specific safety information.

⚠ Certain physiological conditions, medical procedures, and external agents may interfere with the monitor's ability to detect and display accurate measurements. The detailed instructions for use on CD-ROM provide information on possible interferences.

⚠ 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.

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

⚠ 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.

⚠ To ensure accurate measurements in bright ambient light, cover the pulse oximetry sensor site with opaque material.

⚠ Do not silence the audible alarm function or decrease the audible alarm volume if patient safety could be compromised

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

⚠ Modification of the VM-2160 or the accessories in not permitted.

⚠ Carefully route the cabling to reduce the possibility of patient entanglement or strangulation

⚠ 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 whilst using a defibrillator on a patient.

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

⚠ 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.

⚠ Tissue damage can be caused by incorrect application or use of a pulse oximetry sensor. Do not apply the sensor too tightly or by using excessive pressure. Do not wrap the sensor, apply supplemental tape, or leave the sensor too long on one place.

⚠ Do not use sensors or cables that appear to be damaged. Do not use sensors with open optical components. Replace monitor immediately in case of visible damages.

VIAMED

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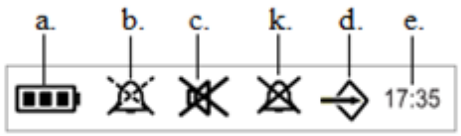
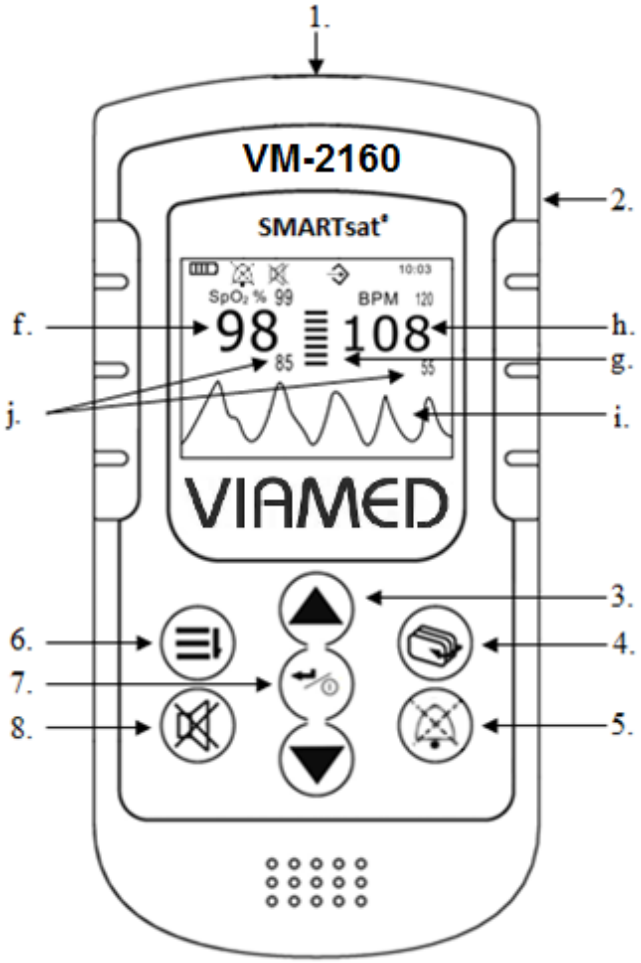
Attention, further warnings, cautions, notes and instructions for use of the device and the sensors are provided on the enclosed CD-ROM.





⚠ **Attention, see user manual for further Warnings, Cautions, Notes and instructions for use**

Controls and User Interfaces

1. SpO_2 sensor port

2. USB 2.0 interface

3. Multifunction buttons:
- Scroll through menu items
- Increase / decrease parameters
- Shortcut to volume / power save mode

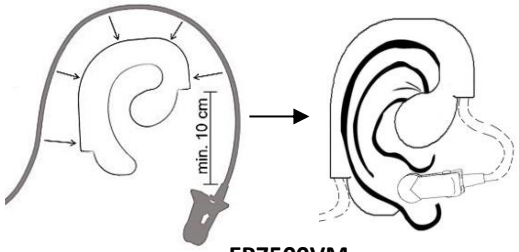
4. Toggles between various display modes /Shortcut to measurement screen

5. Silence audible alarm for a maximal period of two minutes. Optical alarms remain activated. To reset alarms press and hold the button for approx. three seconds

6. Menu selection/ one menu level back

7. On / Off and ENTER button
- To turn on the device: press and hold power button briefly
- To turn off the device: press and hold power button for approx. 3s
- Confirms selection

8. Turns pulse tone and start tone On/Off



EP7500VM

Symbols and Indicators

a. Battery level indicator

b. Temporarily alarm silenced indicator (for 2min.)

c. Pulse tone off indicator

d. Memory full indicator

e. Time displayed in 12h or 24h format

f. SpO_2 Functional blood oxygen saturation

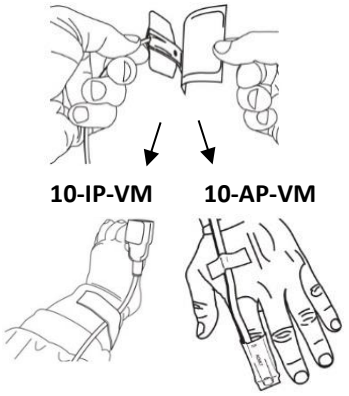
g. Colour coded bar graph to indicate signal quality (green, yellow, red)

h. Pulse rate

i. Pulse waveform (Plethysmogram)

j. Upper and lower alarm limits

k. Permanently alarm silenced indicator (alarm switched off in the Service Menu)



Menu Structure

Alarm settings

Data management

Setup

- Volume
- SpO_2-Averaging
- Date - Time
- Power save mode
- Language
- Service

Connect Sensor