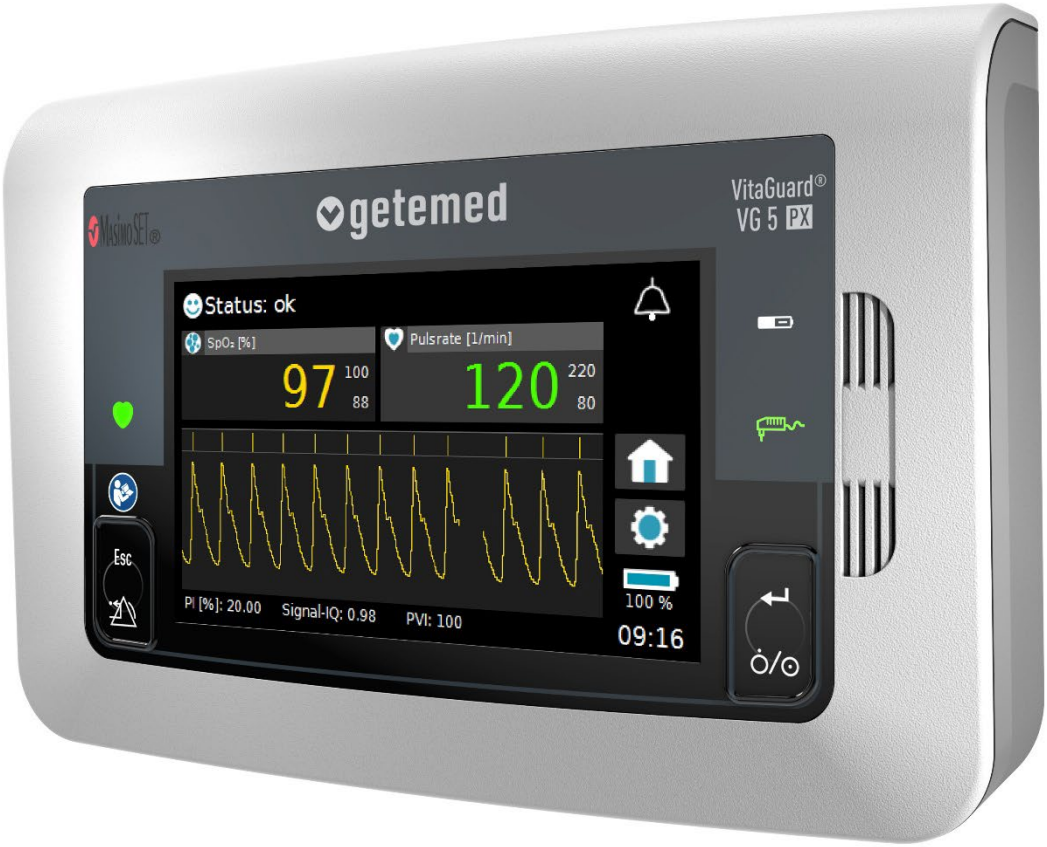
# VitaGuard® VG 5 PX

## $SpO_2$ and Pulse Rate Monitor

## Instructions for Use




Revision 04

getemed

# Legal Information

The information contained in this manual applies only to the VitaGuard® VG 5 PX monitor. Due to continuous product innovation, this manual is subject to change without notice. Refer to the revision history at the back of this document for further details.

# Contents

# 1. Regulatory and Safety Information

## 1.1 Purpose of this Instructions for Use Manual

These instructions for use provide information necessary for the configuration and safe operation of the VitaGuard VG 5 PX patient monitor in accordance with its function and intended purpose, including important information on residual risks and how they can be avoided or minimized. It is not intended as a replacement for, but a supplement to, thorough product training.

In full knowledge of these operating instructions, the prescribing physician must decide:

- whether the caregivers must be trained in the performance of resuscitation measures;
- how the caregivers can be best prepared for monitoring and, above all, for the measures that must be taken in the event of an alarm;
- which views should be displayed on the monitor's display.

Read the complete manual carefully before you use VitaGuard and its accessories.

Caregivers should not hesitate to contact the prescribing physician or the authorized dealer who provided the monitor if they have any questions regarding the monitor and its accessories.

NOTE: Text in **bold font** in these instructions for use also appear on the monitor display.

## 1.2 Intended Purpose of VitaGuard VG 5 PX

The VitaGuard VG 5 family of vital signs monitors are intended to be used for continuous, non-invasive monitoring of physiological parameters and to generate alarms if these parameters lie outside their set alarm limits. Patients are neonates, infants, pediatrics and adults located in home environments, hospitals or hospital-like facilities. The monitors are only for use on one patient at a time. The

monitors are intended to be operated by healthcare professionals as well as by caregivers and adult patients who have received training in the use of the monitor. The monitors are not therapeutic devices and are not intended for use during transport.

## 1.3 Indications and Contraindications

### 1.3.1 Indications for Use

The VitaGuard VG 5 PX is indicated for use on patients (neonates, infants, pediatrics and adults) where a physician recommends continuous, non-invasive monitoring of vital signs, namely to monitor pulse rate and oxygen saturation.

### 1.3.2 Contraindications

The VitaGuard VG 5 PX is contraindicated for use on patients that react allergically to foam rubber products and/or adhesive tape on the $SpO_2$ sensors.

It is not intended to be used as an apnea monitor or to detect cardiac arrhythmia.

## 1.4 Limitations of VitaGuard's Intended Purpose

### 1.4.1 General Limitations

Functional oxygen saturation of arterial hemoglobin ($SpO_2$) and pulse rate are determined by means of photoplethysmography using an optical sensor applied to intact skin on the patient's hand, finger, foot or toe and connected to the monitor using a defined patient cable.

Alarms are triggered by algorithms with adjustable thresholds. Settings or changes to settings are made by a healthcare professional or by a trained service technician on the instructions of a healthcare professional.

Recorded alarm events and compliance data are stored on a non-volatile memory for download and subsequent review by a healthcare professional.

The monitor is powered by the mains supply and incorporates a rechargeable battery for short-term purposes.

Nevertheless, even when operated in accordance with its intended purpose, VitaGuard VG 5 PX cannot detect all life-threatening situations under certain unfavorable conditions. The prescribing physician treating the patient is responsible for the safe application of the monitor.

Qualified training for the caregivers in cardiorespiratory resuscitation techniques is strongly recommended. Clearing the respiratory tract and the resuscitation of infants and small children require special training that the responsible physician should communicate to the caregivers.

It is important that VitaGuard is configured so that false alarms are avoided to the greatest possible extent. Frequent false alarms can greatly reduce the alertness of caregivers.

As the patient gets older, it may be necessary to change the alarm limits. Therefore, follow-up appointments should be arranged with the caregivers if the alarm limits need to be adjusted at a later date.

### 1.4.2 Limitations of $SpO_2$ and Pulse Rate Monitoring

VitaGuard VG 5 PX is not intended to be used as an apnea monitor or for the detection of cardiac arrhythmias.

The method for pulse rate measurement is based on the determination of the peripheral pulse by using optical sensors and can therefore not detect certain cardiac arrhythmia.

The monitoring of $SpO_2$ and pulse rate is adversely affected when the patient moves vigorously or is vigorously moved.

When the sensor is not attached correctly, ambient light can falsify measurements. One remedy is to cover the sensor with dark or opaque material. The monitor can only operate properly when the $SpO_2$ sensor is correctly attached.

Additional detailed safety information on $SpO_2$ and pulse rate monitoring is provided in sections 1.6.6 and 5.2. Read this information carefully before using VitaGuard.

# 1.5 Labels and Symbols

## 1.5.1 Device Label

The device label located on the bottom of the monitor housing serves as a unique identifier for the VitaGuard monitor and includes:

- trade name and model [#];
- manufacturer's name and address;
- serial number [SN];
- catalogue number [REF];
- UDI code with GTIN number (01), date of manufacture (11), serial number (21), and catalogue number (241);
- information about the battery type;
- link to Masimo's patent information.

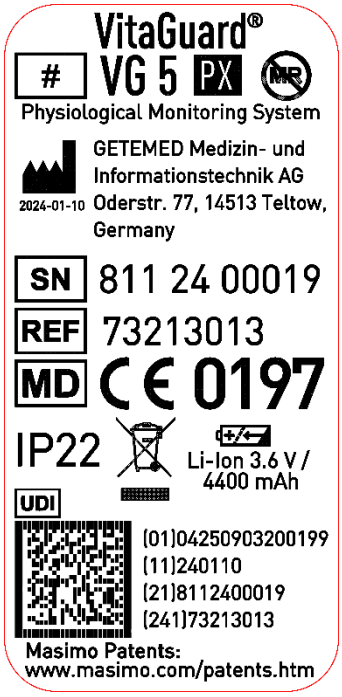



Fig. 1 Example of Label on Bottom of Monitor

The symbols on the device label are explained in section 1.5.5.

## 1.5.2 Transport Case Label

The label located on the outside of the VitaGuard transport case serves as a unique identifier for the VitaGuard monitor and provides important handling and storage information.

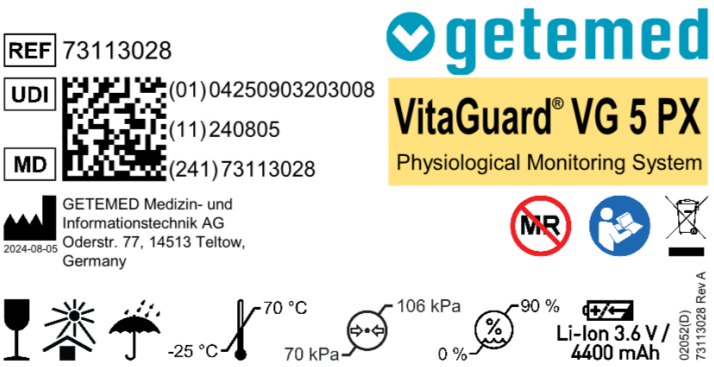



Fig. 2 Example of Label on VG 5 PX Transport Case

The additional symbols on the transport case label not already explained in sections 1.5.3 and 1.5.5 are explained in section 1.5.7.

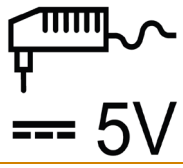
### 1.5.3 Symbols on the Front Panel of the Monitor

The following symbols are located on the front panel of the monitor.

| Symbol | Description |
|---|---|
|  | FOLLOW INSTRUCTIONS FOR USE<br>This symbol indicated that you must read the instructions for use before using the monitor. |
|  | GETEMED Logo<br>This logo is the logo of the manufacturer of the monitor: GETEMED Medizin- und Informationstechnik AG. |
|  | Trade Name and Model<br>This logo indicates the trade name "VitaGuard" and model type "VG 5 PX" of the monitor. |
|  | Masimo SET Logo<br>This logo indicates that the VitaGuard monitor uses the SET technology (Signal Extraction Technology) from Masimo Corp. to determine arterial oxygen saturation (SpO2) and pulse rate. |
|  | Heart Symbol<br>This symbol marks the visual indicator (green LED) that flashes when a heartbeat is detected by the monitor. |
|  | Esc and Alarm Reset<br>These symbols mark the combined Esc and alarm reset key to silence the acoustic alarm for the current alarm condition, and to cancel changes to monitor settings as part of the user interface.<br>The LED behind the triangular alarm symbol changes colour depending on the current alarm situation:<br>White: no alarm; yellow: technical alarm; red: patient alarm |
|  | Enter and On/Off<br>These symbols mark the combined Enter and On/Off key to switch on the monitor and to accept changes to monitor settings as part of the user interface. |
|  | Rechargeable Battery<br>The top symbol marks the visual indicator (green LED) to show the charging status of the rechargeable battery:<br>Permanently on: Battery is charging<br>Permanently off: Battery fully charged<br>Flashing: Error detected<br>Power Adapter<br>The bottom symbol marks the visual indicator (green LED) to indicate that the power adapter is connected to the monitor. |

### 1.5.4 Symbols on the Connector Panel of the Monitor

The following symbols are located on the connector panel beside the individual connectors for attaching the monitor's accessories.

| Symbol | Description |
|---|---|
|  | Type BF (Body Floating) Applied Part<br>This symbol located beside the connector for the SpO2 cable indicates that the input is a type BF APPLIED PART with de-fibrillator protection. This means that the input is floating and electrically isolated from the mains power earth. |
|  | Power Adapter Input<br>This symbol marks the connector for the medical grade 5 V external power adapter supplied with the monitor. |
| USB | USB (Universal Serial Bus)<br>This symbol identifies the connector for a USB Type-C cable required to download stored data to the VitaWin evaluation software, or to download data to a memory stick. |

### 1.5.5 Symbols on the Device Label of the Monitor

The following symbols are located on the device label on the back of the monitor.

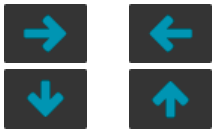
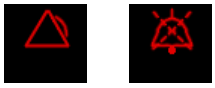
| Symbol | Description |
|---|---|
| CE 0197 | CE Mark<br>The CE Mark with the Notified Body Registration Number (0197) indicates that the monitor conforms to the European Medical Device Regulation (MDR) EU 2017/745 regarding health and safety. The responsible Notified Body is TÜV Rheinland LGA Products GmbH. |
| # | Model Number<br>Indicated the model number of the monitor: VG 5 PX. |
| MD | Medical Device<br>Indicates that the monitor is a medical device. |
| REF | Catalogue Number<br>Indicates the manufacturer's catalogue number for the monitor. |

| Symbol | Description |
|---|---|
| SN | **Serial Number**<br>Indicates the serial number of the monitor for identification purposes. |
| UDI | **Unique Device Identifier**<br>Indicates that the device contains unique device identifier information. The QR code located below the symbol contains the following data:<br>(01) UDI code<br>(11) Date of manufacture YYMMDD<br>(21) Serial number (SN)<br>(241) Catalogue number (REF) |
| YYYY-MM-DD | **Manufacturer**<br>Indicates the name and address of the manufacturer of this monitor as well as the date the monitor was manufactured on: YEAR-MONTH-DAY. |
| IP22 | **Ingress Protection (IP)**<br>Classifies the degree of ingress protection:<br>The first digit (2) represents the degree of protection against the ingress of solid objects. In this case, objects >12.5 mm (finger or similar objects).<br>The second digit (2) represents the degree of protection against the ingress of liquids. In this case, protected against vertically dripping water when the monitor is tilted at an angle of 15° from its normal position. |
| MR | **MR Unsafe**<br>This symbol indicates that neither the monitor nor its accessories are intended to be used in the magnetic resonance (MR) environment. |
| | **Waste of Electrical and Electronic Equipment**<br>The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. |
| | **Rechargeable Li-ion Battery**<br>This symbol indicates that the monitor contains a built-in lithium-ion rechargeable battery pack having a nominal voltage of 3.6 V and capacity of 4400 mAh. |

### 1.5.6 Symbols Displayed on the Monitor Screen

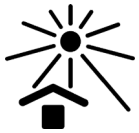
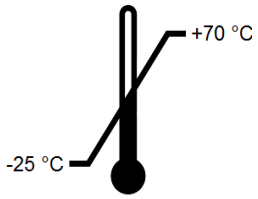
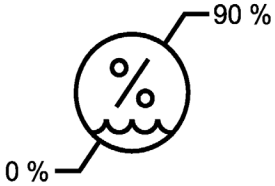
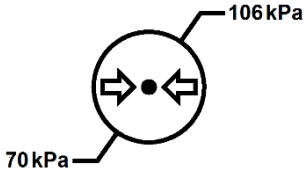
The following symbols appear on the monitor screen and are used for the graphical user interface (GUI). Not all icons may be visible, as the views displayed on the screen depend on the monitor settings.

| Symbol | Description |
|---|---|
|  | Home Screen<br>Touching this icon displays the GUI home screen. |
|  | View 1<br>Touching this icon from the GUI home screen enters View 1. The same applies to the View 2 and View 3 icons. |
|  | $SpO_2$ Icon<br>Touching this icon from the GUI home screen enters the $SpO_2$ view. |
|  | Pulse Rate Icon<br>Touching this icon from the GUI home screen enters the pulse rate view. |
|  | Information Icon<br>Touching this icon from the GUI home screen accesses the information pages. |
|  | System Icon<br>Touching this icon from the GUI home screen enters the system settings menus. |
|  | Memory Icon<br>Touching this icon from the GUI home screen causes the GUI to display the event, trend and USB icons. |
|  | Event Icon<br>Touching this icon displays a list of stored alarm events. |
|  | Trend Icon<br>Touching this icon displays a list of stored trend recordings. |
|  <br>  | USB Icon<br>Touching this icon enters a dialog to download stored data to a USB memory stick.<br>The bottom icon is displayed below the bell icon when downloading data to a USB memory drive. |
|  | Settings Icon<br>Touching this icon enters the settings menu of the selected view ($SpO_2$ or pulse rate). The settings related to the selected view may be selected and changed. |

| Symbol | Description |
|---|---|
|  | **Cancel and Enter Icons**<br>Touch these icons to cancel or accept changes. |
|  | **Navigation Icons**<br>Touch these icons to navigate through the graphical user interface. |
|  | **Bell Icons**<br>These icons show the state of the acoustic alarm system when no alarm is present:<br>Left icon: Acoustic alarm active<br>Right icon: Acoustic alarm silenced. |
|  | **Alarm Icons (Technical Alarm)**<br>These icons show the state of the acoustic alarm system when a technical alarm is present:<br>Left icon: Acoustic technical alarm present.<br>Right icon: Acoustic technical alarm reset. |
|  | **Alarm Icons (Patient Alarm)**<br>These icons show the state of the acoustic alarm system when a patient alarm is present:<br>Left icon: Patient alarm present.<br>Right icon: Patient alarm reset. |
|  | **Battery Status Icons**<br>This icon shows the remaining capacity of the rechargeable battery pack. The percentage value of the remaining capacity is displayed directly below the icon. |
|  | **Nurse Call Unit Cable Icons**<br>This icon is displayed below the bell icon when the nurse call unit cable is connected to the monitor. |

### 1.5.7 Additional Symbols on the Transport Case

In addition to the symbols already described above, the following symbols are located on the monitor's transport case.

| Symbol | Description |
|---|---|
|  | Fragile, handle with care<br>Indicates the transport case and its contents are fragile and could be damaged if not handled with care. |
|  | Keep dry<br>Indicates that the transport case and its contents need to be protected from rain and other sources of moisture. |
|  | Keep away from sunlight<br>Indicates that the transport case and its contents need to be protected from direct sunlight. |
|  | Temperature Limits<br>Indicates the upper and lower limits of temperature to which the transport case and its contents can be safely exposed. The limits are indicated next to the upper and lower horizontal lines. |
|  | Humidity Limitation<br>Indicates the upper and lower limits of humidity to which the transport case and its contents can be safely exposed. The limits are indicated next to the upper and lower horizontal lines. |
|  | Atmospheric Pressure Limitation<br>Indicates the upper and lower limits of atmospheric pressure to which the transport case and its contents can be safely exposed. The limits are indicated next to the upper and lower horizontal lines. |

### 1.5.8 Additional Symbols on Accessory Packaging

In addition to the symbols already described above, the following symbols are located on the accessories supplied with the monitor.

| Symbol | Description |
|---|---|
|  | Non-Sterile<br>This symbol on the packaging of the $SpO_2$ sensors indicates that these are not sterile. |
|  | Single Use Only<br>This symbol on the packaging of the $SpO_2$ sensors indicates that these are suitable for one-time use only. |
|  | Latex Free<br>This symbol on the packaging of the $SpO_2$ sensors indicates that these are not made with natural rubber latex. |
|  | Consult Instructions for Use<br>This symbol on the packaging of the $SpO_2$ sensors indicates that you must consult the instructions for use before using them, |
|  | Use By Date<br>This symbol on the packaging of the $SpO_2$ sensors indicates the date after which they are not to be used. |
|  | Batch Code<br>This symbol on the packaging of the $SpO_2$ sensors indicates the manufacturer's batch code so that the batch or lot can be identified.<br>The manufacturer's batch code is adjacent to the symbol. |
|  | European Authorized Representative<br>This symbol identifies the European Authorized Representative of the manufacturer of the $SpO_2$ sensors and cables, Masimo Corp.<br>The Representative serves as a legal entity designated by non-European Union (EU) manufacturers to represent them in the EU and ensure their compliance with European regulations. |

## 1.6 Warnings, Cautions and Notices

The prescribing physician is responsible for ensuring that the caregivers are able to use VitaGuard for monitoring and that they can implement appropriate measures in the event of an alarm.

This section provides information about the safe use and regulatory compliance of the VitaGuard monitor, including important information on residual risks and how they can be avoided or minimized. Familiarize yourself with this information, and read and understand all instructions before attempting to use it. VitaGuard is a medical device and, as such, was designed and is manufactured to the appropriate medical regulations and controls.

NOTE: Disregarding the safety information provided in this manual is considered abnormal use of the monitor and could result in death, injury, damage to property, data loss, or a voided warranty.

A hazard is a source of potential injury to a person or damage to property or the system. This manual uses the terms WARNING, CAUTION, and NOTICE to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with the following definitions and their significance.

| Convention | Definition |
|---|---|
| WARNING | Indicates a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury. |
| CAUTION | Indicates a potential hazard or unsafe practice, which, if not avoided, could result in moderate or minor injury. |
| NOTICE | Indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property or data. |

### Incident Reporting

A serious incident is a device malfunction that results in death or serious injury, or may lead to death or serious deterioration of health.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

### 1.6.1 Safety Information Related to Caregiver's Tasks

With "caregivers" we mean those persons who are responsible during monitoring for the monitored patient's well-being, and include:

- parents or other members of the family,
- babysitters, once they have been trained for the situation, and
- nurses and other medically trained staff.

WARNING: GENERAL DANGER TO THE PATIENT
Instructions listed in this manual in no way supersede established medical practices concerning patient care.

The potential applications of VitaGuard for high-risk patients are varied such that we cannot give specific instructions on procedures in the event of an alarm. It is the physician's task to inform patients and caregivers about the correct procedure in an alarm situation.

WARNING: GENERAL DANGER TO THE PATIENT
Risk of death or serious injury if you do not operate VitaGuard according to its intended purpose.

VitaGuard is to be operated by, or under the supervision of, qualified personnel only. This manual, all information supplied with the accessories, all safety information, and specifications should be read before use.

WARNING: RESUSCITATION MEASURES
Risk of death or serious injury if you do not react properly to a critical alarm situation.

Regularly check the patient's status, as VitaGuard has no therapeutic effect. You may need to implement resuscitation measures in the event of an alarm. Immediately call the emergency services when the patient is showing signs of a critical situation.

Make sure that you can react to an alarm within a few seconds.

WARNING: SINGLE-PATIENT USE ONLY
Risk of death or serious injury due to overseeing a critical alarm situation if the monitor is connected to two patients simultaneously.

Do not attempt to use VitaGuard on more than one patient at a time.

WARNING: INAPPROPRIATE ALARM SETTINGS
Risk of death or serious injury due to overseeing a critical alarm situation if the monitor alarm settings are not correct.

Never modify any alarm related settings without consulting the responsible physician. The physician is responsible for selecting the correct alarm limits and monitor configuration for each patient.

WARNING: UNINTENTIONAL CHANGES
Risk of death or serious injury due to overseeing a critical alarm situation if the monitor has been tampered with.

Make sure that no siblings or other persons switch off or unintentionally change any settings on the monitor.

WARNING: CHECK DEVICE OPERATION BEFORE USE
Risk of death or serious injury due to overseeing a critical alarm situation if the monitor is not functioning properly, or not properly detecting the patient's vital signs. Always take the following precautions:

- visually inspect the monitor and its accessories before use;
- before leaving the patient alone for any period of time, make sure that the light indicator for pulse rate is flashing (green LEDs described in section 3.4.4);
- test the acoustic alarm unit every time you switch on VitaGuard, as explained in sections 4.2 and 6.5;
- if you suspect that VitaGuard is not in proper working order, check the patient's vital functions and continue to observe the patient until you receive a replacement monitor, or the monitor has been examined by the physician or authorized dealer;
- under no circumstances should you use VitaGuard if it appears or is suspected to be damaged.

WARNING: USING MULTI-MEDIA DEVICES TO RELAY AN ALARM

Risk of death or serious injury due to overseeing a critical alarm situation if relying on a multi-media device to relay the alarm tone.

Software used on multi-media devices such as mobile phones, pads or laptops may implement noise suppression algorithms which prevent the alarm tone from being transmitted. Therefore, never use such devices for remote monitoring of VitaGuard's alarm system.

### 1.6.2 Safety Information Related to the Monitor in General

The following safety information identifies potential risks that apply to the system as a whole.

WARNING: DEVICE SETUP

Risk of death or serious injury to the patient or other persons if the monitor is not setup and configured properly.

We recommend hanging VitaGuard in its pouch such that the display can be easily viewed. Always take the following precautions:

- do not start or operate VitaGuard unless the setup was verified to be correct;
- ensure that alarm limits are appropriate for the patient being monitored by checking the limits each time VitaGuard is used;
- make sure you can clearly hear the alarm signal over any prevailing background noise and set the alarm volume accordingly;
- never set the alarm limits to extreme values that render the monitoring system useless;
- do not place VitaGuard where the controls can be changed by the patient or by siblings;
- do not hang the device directly above the patient's head or place it in any position that might cause it to fall on the patient;
- do not connect the power adapter to an overhead socket, as it could become detached when the cable is pulled;
- avoid stacking multiple devices or placing anything on the device during operation;

- ensure that the sensor packaging is not damaged before use to avoid malfunction from insufficient adhesiveness;
- carefully route patient cables to reduce the possibility of patient entanglement or strangulation and to ensure that nobody can trip over them;
- ensure sufficient air circulation so that toxic substances, which could be emitted in the event of a malfunction, can escape.

WARNING: CHOKING
Risk of death or serious injury from swallowing and choking on $SpO_2$ sensors, or packaging material.

To avoid the risk of choking, always take the following precautions:

- apply $SpO_2$ sensors to the foot of infants and small children;
- keep packaging material out of children's reach.

WARNING: STRANGULATION
Risk of death or serious injury from strangulation on the patient cables or sensor cables.

To avoid possible strangulation, route the patient cable and sensor cable away from the patient's head and throat. With infants and small children, route all cables inside the patient's clothing so that they exit at the foot.

With older children and adults, route the patient cable so that it exits between the trousers and pullover. Secure the cable to ensure that no harm can come to the patient if the patient turns or rolls over during monitoring. Route the cable away from the patient to the monitor.

WARNING: AMBIENT NOISE
Risk of death or serious injury due to overhearing a critical alarm in the presence of ambient noise.

Set up the monitor in such a way that you can hear the acoustic alarm at all times, taking normal day activities such as watching television or listening to a radio into account.

When performing noisy activities, for example, showering, vacuuming, drilling, etc., keep VitaGuard within view in order to see the visual alarm indicators (display and alarm LED) in a critical situation, or ensure that a second person is present to observe the patient and monitor.

Never obstruct VitaGuard's alarm outlet with any objects that absorb sound.

WARNING: HOUSEHOLD PETS AND VERMIN
Risk of death or serious injury due to device malfunction caused by household pets and vermin.

Protect the equipment against contact with household pets and pests, as they could cause safety related damage to it, e.g., by biting it, letting it drop, exposing it to fluids or dirt.

WARNING: ELECTRIC SHOCK
Risk of death or serious injury from an electric shock.

To protect from electric shock:

- always remove the sensor and completely disconnect VitaGuard before bathing the patient;
- do not attempt to clean VitaGuard while monitoring a patient.
- keep the conductive parts of $SpO_2$ sensors and associated parts away from other conductive parts, including earth. Also make sure that no contact to other conductive parts, including earth, is possible should the $SpO_2$ sensor become loose during monitoring.

WARNING: ELECTROSTATIC DISCHARGE
Risk of death or serious injury due to device malfunction from electrostatic discharge.

Electrostatic build-up that, for example, a person may pick up on certain carpets or surfaces must not discharge through the VitaGuard connectors or through the $SpO_2$ sensor's electrically conducting parts. For this reason, avoid directly touching the electrically conducting parts.

Discharge any electrostatic build-up beforehand by, for example, touching an earthed water pipe or heater. Do not touch the device and the patient simultaneously.

If you suspect damage due to electrostatic discharge, return the device to GETEMED or your authorized dealer for inspection.

WARNING: EXTREME TEMPERATURES AND/OR HUMIDITY
Risk of death or serious injury due to device malfunction from extreme temperatures and/or humidity.

Device performance may be compromised at extreme temperatures or due to variations in temperature and air humidity. Always take the following precautions:

- do not use VitaGuard at extreme temperatures below 5 °C or above 40 °C;
- do not place VitaGuard near heat sources such as radiators, ovens, etc.;
- do not expose VitaGuard to direct sunlight;
- if VitaGuard has been stored at a temperature close to the extreme hot or cold storage limits (-25 °C to +70 °C), wait at least four (4) hours for the device to reach ambient temperature before use;
- if external visible dampness or condensation is observed, dry the monitor and wait at least two (2) hours before reuse.

WARNING: EXPLOSION HAZARD
Risk of death or serious injury due to explosions in the presence of certain gases.

Electrical sparks may occur when connecting the cables to the monitor. Therefore, do not use VitaGuard in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide. Establish whether the patient is liable to be in such an environment.

WARNING: MALFUNCTION
Risk of death or serious injury due to device malfunction.

As with any electronic equipment, a fault can occur due to various reasons, including but not limited to:

- component failure;
- electrostatic discharge;
- wear and tear;
- misuse, e.g., dropping the monitor or coiling the cables;
- lack of maintenance.

In order to detect a malfunction as quickly as possible, visually inspect the monitor, the patient cables including their connectors, the external power adapter, and the $SpO_2$ sensor for any visible signs of damage every time you use VitaGuard for monitoring.

If any measurement seems questionable, first check the patient's vital signs by alternate means and then check VitaGuard for proper functioning.

Immediately contact your authorized dealer for replacement of any damaged parts.

WARNING: HEARING DAMAGE
Risk of hearing damage if the monitor is placed too close to the patient's head.

Do not place VitaGuard directly next to the patient's head, as the acoustic alarm could cause hearing damage.

CAUTION: INFECTION RISK
Risk of infection due to reuse of accessories that come into contact with other patients.

To avoid the risk of infection, take the following precautions:

- use disposable parts, such as adhesive $SpO_2$ sensors, on one patient only;
- always use the same patient cable on the same patient;

- disinfect VitaGuard and the patient cable before using it on another patient.

NOTICE: DAMAGE FROM UNCLEAN ENVIRONMENTS
Device performance may be compromised due to debris.

Protect VitaGuard and its accessories against lint, dust, fiber and other sources of pollution. Regularly clean the monitor and its accessories as described in section 1.7.

NOTICE: AIRCRAFT
VitaGuard has not been tested for use in aircraft and, as such, should not be used during flight. Furthermore, VitaGuard has a built-in lithium-ion rechargeable battery pack which should not be transported in your luggage. If you intend to take VitaGuard with you on a flight, consult the airline company in advance for advice.

If the airline company allows you to take VitaGuard with you, transport it in the transport case provided or place it in a hard box to ensure that it cannot accidentally switch on due to pressure on the on/off key from other pieces of luggage. If VitaGuard is accidentally switched on, it will generate an acoustic reminder signal every 20 s.

### 1.6.3 Safety Information Related to Other Devices

VitaGuard is a stand-alone patient monitor primarily intended for home use. Nevertheless, there may be situations where other devices need to be used on the patient or are placed in the vicinity of VitaGuard during use. In such situations, pay special attention to the following warnings and cautions.

WARNING: MULTIPLE MONITORS IN THE SAME ENVIRONMENT
Risk of death or serious injury due to overseeing a critical alarm situation if multiple VitaGuard monitors with different alarm settings are used in the same environment.

Avoid mixing monitors between patients in the same environment and check that the alarm limits are correct for the individual patient every time the monitor is switched on.

WARNING: TRANSCUTANOUS ELECTRICAL NERVE STIMULATORS
Risk of death or serious injury due to overseeing a critical alarm situation if VitaGuard's performance is compromised due to electrical interference from nerve stimulation (TENS) devices.

Do not use VitaGuard together with nerve stimulation devices.

WARNING: ELECTROSURGERY AND ELECTROCAUTERY
Risk of burns and injury to the patient during electrosurgery or electrocautery procedures.

If an electrosurgery or an electrocautery device is used, disconnect the $SpO_2$ cable from the monitor.

WARNING: MAGNETIC RESONANCE IMAGING (MRI)
Risk of burns and injury to the patient during MRI scanning.

It is unsafe to bring this monitor into an area of magnetic resonance imaging (MRI) equipment. The strong magnetic fields generated by MRI scanners can cause injury to the patient and permanent damage to VitaGuard.

WARNING: ELECTROMAGNETIC INTERFERENCE
Risk of death or serious injury due to overseeing a critical alarm situation if VitaGuard's performance is compromised due to electromagnetic interference from other devices.

Electromagnetic interference is frequently emitted by wireless equipment or devices having large electric power consumption. Always take the following precautions:

- keep a safe distance of at least 1 m away from appliances such as induction cookers, washing machines, computers, microwaves, vacuum cleaners, power tools, etc.;
- keep a safe distance of at least 30 cm from mobile wireless communication devices such as mobile phones, tablets, radio equipment, walkie-talkies, etc.;
- avoid placing the monitor directly next to other electrical equipment, and avoid stacking monitors on top of each other.

When it cannot be avoided to place VitaGuard next to or on top of other equipment, check that the monitor operates within its specifications in this environment. We recommend you to regularly check:

- that the displayed signals are plausible and not disrupted when the patient is not moving;
- if the same technical alarm messages are repeatedly displayed.

Should you discover disruptions, switch off the interfering equipment or move VitaGuard away from it.

VitaGuard can be used in the home and in all other environments that public utilities supply directly. It uses high-frequency signals exclusively for its internal operation and has been designed to minimize emitting such signals. As a result, disruption to neighboring electronic equipment is unlikely.

WARNING: LEAKAGE CURRENTS
Risk of burns and injury due to a summation of leakage currents.

VitaGuard's USB port is electrically and mechanically isolated from the patient connectors. Nevertheless, when several devices are connected to each other, e.g., via the USB port, the individual leakage currents may add up and pose a risk to the patient.

When a device is connected to the USB port, the requirements of the general standard IEC 60601-1 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance", chapter 16 "ME Systems" must be met.

To completely avoid this risk, do not connect USB hubs, chargers, printers, cameras, scanners, or any other devices to this port when the patient is connected to VitaGuard.

NOTE: This does not apply to the nurse call cable provided as an optional accessory.

### 1.6.4 Safety Information Related to the Power Adapter

The external power adapter supplied with VitaGuard is a medical grade power supply and should be handled with care to avoid any risks of electrical shock.

Only use the power adapter when it is in perfect working order.

WARNING: OPENING THE POWER ADAPTER
Risk of death or serious injury due to electrical shock from opening the power adapter.

The input voltage of the power adapter is the mains voltage (100 – 240 V). Never open the power adapter or its connecting cable.

WARNING: DAMAGED POWER ADAPTER
Risk of death or serious injury due to electrical shock from damaged power adapter.

Visually inspect the external power adapter for signs of damage before use. Stop using the external power adapter immediately when it has signs of damage, has fallen, or been dropped. Immediately contact your authorized dealer for a replacement.

WARNING: DAMAGED WALL SOCKETS
Risk of death or serious injury due to electrical shock from damaged wall sockets.

Regularly inspect wall sockets for signs of damage. Do not use a damaged wall socket.

WARNING: MOISTURE
Risk of death or serious injury due to electrical shock from moisture inside the power adapter.

To avoid moisture from entering the power adapter, take the following precautions:

- do not operate the external power adapter in a damp environment (e.g. in the bathroom);
- do not immerse the external power adapter in liquids.

WARNING: LIGHTENING
Risk of death or serious injury due to electrical shock from high voltages during thunderstorms.

The VitaGuard power adapter is designed and tested to provide double insulation between the mains power supply and the 5 V output voltage used to power the monitor. Nevertheless, during thunderstorms, disconnect VitaGuard from the external power adapter and pull the plug of the external power adapter from the wall socket. VitaGuard can operate for at least eight (8) hours from the built-in battery pack

CAUTION: EXTENSION CABLES WITH PORTABLE SOCKETS
Risk of injury from stumbling on extension cables.

Use of extension cables with portable sockets is not recommended. However, if it cannot be avoided, do not lie the extension cable on the floor. Caregivers or other persons could stumble over cables lying on the ground and injure themselves or injure the patient if the monitor is pulled from its operating position.

CAUTION: POWER SOCKETS WITH SWITCH OR DIMMER
Device performance may be compromised if the mains power supply is reduced or switched off.

Do not use the external power adapter in sockets that can be switched off or are controlled by a dimmer.

### 1.6.5 Safety Information Related to Accessories

VitaGuard has been designed and tested to operate with the approved accessories listed in section 2.3. Use VitaGuard with these approved accessories only and in accordance with the information contained both in this manual and supplied with the accessories.

WARNING: APPROVED ACCESSORIES
Risk of death or serious injury due to overseeing a critical alarm situation if VitaGuard's performance is compromised due to not using approved accessories.

Safe and reliable operation of the monitor is only ensured when using the approved accessories supplied with the monitor or provided by your authorized dealer. Non-approved accessories may degrade device performance resulting in a risk to the patient, including but not limited to:

- incorrect measurement of vital signs;
- increased emission of electromagnetic interference;
- reduced electromagnetic immunity.

NOTICE: CABLE DAMAGE
Mishandling any of the cables (patient cable and the power adapter cable) can damage them. When handling cables, always take the following precautions:

- treat all cables with care;
- do not use excessive force when connecting and disconnecting them to the monitor;
- make sure not to bend them excessively;
- avoid coiling the cables around the monitor;
- never use any of the cables to lift VitaGuard;
- route all cables in such a way that nobody can trip over them.

NOTICE: SUFFICIENT CONSUMABLES FOR MONITORING
Monitoring can only be performed as long as the required consumables are at hand, i.e., $SpO_2$ sensors. Should you run out of these, contact your authorized dealer, who generally provides 24-hour emergency services. Nevertheless, to avoid unnecessary anxiety for both you and your authorized dealer, please order your consumables in good time.

NOTICE: TROUBLESHOOTING
When more than one monitor is used in the same environment, each monitor should always be connected to the same patient cables and the same power adapter. Faults can therefore be located and remedied faster.

### 1.6.6 Safety Information Related to Monitoring Pulse Rate and Oxygen Saturation

There is a risk of overseeing critical alarm events in certain situations. To minimize this risk, read the following safety information carefully. Refer to section 5.2 for additional warnings on situations that affect the accuracy of $SpO_2$ and pulse rate measurements.

WARNING: A PULSE OXIMETER CANNOT DETECT APNEA
Risk of death or serious injury due to not detecting central apneas when VitaGuard is operated as a pulse oximeter.

A pulse oximeter must NOT be used as an apnea monitor. If the medical indication is to detect central apneas, then the monitor must be configured by the responsible physician accordingly.

WARNING: A PULSE OXIMETER CANNOT DETECT CERTAIN ARRHYTHMIAS
Risk of death or serious injury due to not detecting certain arrhythmias when VitaGuard is operated as a pulse oximeter.

Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis. If the medical indication is to detect arrhythmias, then the monitor must be configured by the responsible physician accordingly.

WARNING: A PULSE OXIMETER IS AN EARLY WARNING DEVICE
Risk of death or serious injury due to not completely understanding the patient's clinical condition.

A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.

A pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: INTERFERING SUBSTANCES
Risk of death or serious injury due to overseeing a critical event due to interfering substances.

$SpO_2$ is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

WARNING: TISSUE DAMAGE
Risk of tissue damage due to incorrect application of the sensor or from allergic reactions to sensor materials.

Tissue damage can be caused by incorrect application or use of an $SpO_2$ sensor, for example, by wrapping the sensor too tightly. Inspect the sensor site regularly to ensure skin integrity and correct positioning and adhesion of the sensor.

Furthermore, tissue damage can be caused by allergic reactions to foam rubber products and/or adhesive tape on the $SpO_2$ sensors. In such cases, consult your responsible physician about the possibility of using a reusable sensor.

CAUTION: PHOTODYNAMIC THERAPY
When patients are undergoing photodynamic therapy they may be sensitive to light sources. VitaGuard may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.

CAUTION: CIRCULATORY CENTRALIZATION
Circulatory centralization, i.e., when the body contracts the vessels to reduce the flow of blood to the extremities, can suppress or otherwise distort the monitored $SpO_2$ values. Circulatory centralization can arise when, for example, patients are anesthetized, suffer from shock, or are under great physical strain. Ear sensors, for example, are available for short-term applications.

CAUTION: HYPOXEMIA
If $SpO_2$ values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

CAUTION: IRRADIATION
If using VitaGuard during full body irradiation, keep the $SpO_2$ sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or VitaGuard might read zero for the duration of the active irradiation period.

CAUTION: VARIATION IN MEASUREMENTS
Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.

CAUTION: LOW PERFUSION
If the "$SpO_2$: Low Perfusion" message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

CAUTION: REPLACE SENSOR AND/OR CABLE
Change the application site or replace the sensor and/or patient cable when a "$SpO_2$: Replace sensor!!" and/or "$SpO_2$: Replace cable!!", or a persistent poor signal quality message (such as "$SpO_2$: Low Signal IQ") is consistently displayed. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.

CAUTION: LIGHT INTERFERENCE
High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse oximeter to obtain vital sign readings.

CAUTION: UPPER $SpO_2$ ALARM LIMIT
High oxygen concentrations may predispose a premature infant to retinopathy. Therefore, the upper alarm limit for oxygen saturation must be carefully selected in accordance with accepted clinical standards.

CAUTION: UPPER PULSE RATE ALARM LIMIT
When setting the upper alarm limit for pulse rate monitoring, be aware that the maximum pulse rate calculated by the $SpO_2$ module is 240 pulses per minute.

CAUTION: MAXIMUM SENSITIVITY
When the $SpO_2$ Sensitivity setting is set to Maximum, performance of the sensor-off detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.

NOTE: A functional tester cannot be used to assess the accuracy of the pulse oximeter.

Carefully read section 5.2 for additional warnings on situations that affect the accuracy of $SpO_2$ and pulse rate measurements.

### 1.6.7 Safety Information Related to Cleaning and Disinfecting

Cleaning and disinfection instructions are provided in section1.7. Please read the following safety information before you attempt to clean or disinfect the monitor or its accessories.

WARNING: LIQUID INGRESS
Risk of death or serious injury due to liquids penetrating the casing.

Ingress of liquids, for example, water or cleaning agents, can cause injury to the patient due to a short-circuit within the monitor, as well as damage the monitor and its accessories. To protect against injury and damage, follow the directions below:

- before cleaning or disinfecting VitaGuard, always turn it off and disconnect all accessories (patient cable and the external power adapter);
- do not attempt to clean VitaGuard while monitoring a patient;
- do not use excessive amounts of liquid or submerge VitaGuard and its accessories into liquids when cleaning or disinfecting them, as this could irreparably damage them;
- avoid placing the monitor or its accessories on surfaces with visible liquid spills;
- use cleaning solutions only as instructed in this manual in section 1.7.

NOTICE: DAMAGE FROM AGGRESSIVE SOLVENTS
Aggressive solvents can damage the device and its accessories.

Do not use solvents such as ether, acetone, or benzene or any cleaning agents containing abrasive substances to clean the monitor or its accessories. These substances can damage the housing material and cause malfunctions.

NOTICE: DAMAGE FROM COARSE CLEANING UTENSILES
Coarse brushes or cleaning pads can damage the device and its accessories.

Do not use any coarse brushes, cleaning pads or hard objects to clean the monitor or its accessories, as such utensils can damage the housing material and cause malfunctions.

NOTICE: DAMAGE FROM STERILIZATION
Sterilization agents and processes can damage the device and its accessories.

Do not sterilize VitaGuard or its accessories by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the monitor.

### 1.6.8 Safety Information Related to Service

Information on service and maintenance is provided in section 1.7.

WARNING: UNAUTHORIZED MAINTENANCE
Risk of death or serious injury due to malfunction from improper maintenance.

Do not adjust, repair, open, disassemble, or modify VitaGuard or its accessories. Injury to personnel or equipment damage could occur. Return VitaGuard to your authorized dealer for servicing if necessary. Maintenance and repair can only be performed by trained and authorized personnel.

WARNING: MAINTENANCE DURING USE
Risk of death or serious injury due to maintenance during use.

As long as VitaGuard is connected to the patient, no service or cleaning tasks may be performed. Remove VitaGuard from the patient before carrying out such tasks.

CAUTION: CONTAMINATION OR INFECTION
The monitor and accessories may be contaminated with bacteria or viruses after use.

If any contamination of the monitor or accessories has occurred, observe the standard procedures for handling contaminated objects and the following precautions:

- use protective gloves to handle the equipment;
- isolate the material by using suitable packaging and labeling;
- contact the addressee before sending the equipment for service;
- disinfect the monitor and its accessories before returning them for inspection or service. Unless otherwise instructed for investigation purposes, please do not return $SpO_2$ sensors;
- clean and disinfect the monitor and accessories after every use. Refer to section 1.7 for instructions.

### 1.6.9 Safety Information Related to the Rechargeable Battery

VitaGuard has a built-in, lithium-ion (Li-ion) rechargeable battery pack to power the monitor when it is not connected to the mains power supply via the external power adapter, or when the mains supply fails. The battery pack compartment is protected by a security screw and is only intended to be opened by trained service technicians. Nevertheless, for regulatory reasons, the following safety information is included in this manual.

Do not attempt to open the battery compartment.

WARNING: TOXIC MATERIALS AND EXPLOSIVE HAZARDS FROM BATTERY PACK
If the battery pack is crushed or disassembled, its cells may leak or release toxic materials. Cells can heat up and cause explosion and / or fire. If the battery pack is disassembled, even partly, the integrated safety unit may not work properly anymore. In this case, charging or discharging the battery could lead to leakage, release of toxic materials, explosion and / or fire.

Also, a short circuit at the terminals of the battery pack could lead to leakage, release of toxic materials, explosion and / or fire.

Furthermore, burning the battery pack will cause explosions and release of toxic materials.

Always adhere to the following instructions:

- do not deform or apply mechanical pressure to the battery pack;
- do not subject the battery pack to mechanical shock;
- do not disassemble the battery pack or its cells and do not cut the external connector of the battery pack;
- do not short circuit the terminals of the battery pack;
- do not store cells or batteries haphazardly in a box or drawer where they may short-circuit each other or be short circuited by other metal objects;
- do not burn or incinerate the battery pack.

WARNING: EXPLOSIVE HAZARDS FROM BATTERY PACK
If exposed to water, battery packs can generate explosive mixtures of hydrogen and oxygen.

Do not wet or immerse the battery packs with / or in any liquids. If the battery pack is exposed to any kind of liquid, stop using it immediately. Keep the battery pack clean and dry.

CAUTION: CHEMICAL BURN FROM BATTERY PACK
In the event of cell leakage, contact with its chemicals can cause skin or eye damage.

Do not allow the cell liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with large amounts of water and seek medical advice.

NOTICE: DAMAGE TO THE MONITOR FROM WRONG BATTERY PACK
Using the wrong battery pack could damage the device.

Do not attempt to replace the battery pack. Replacement of the battery pack must only be carried out by GETEMED or an authorized dealer.

NOTICE: PROLONGED STORAGE
After extended periods of storage, the capacity of the battery pack may be deteriorated. In such cases it may be necessary to charge and discharge the battery pack several times to obtain maximum performance. Furthermore, batteries may leak if left in an unused device for prolonged periods.

If you intend to store the device for longer than one month, regularly connect VitaGuard to the external power supply to ensure that the battery does not fully discharge.

Do not leave the battery on prolonged charge when not in use.

### 1.6.10 Safety Information Related to Cybersecurity

The VitaGuard monitors are stand-alone monitoring devices not intended for use in a computer network. Nevertheless, it is important to adhere to the following safety information.

WARNING: MALWARE
Risk of death or serious injury to the patient if the monitor's software is deleted or modified.

The USB port must only be used to transfer logged alarm data to a PC running the VitaWin evaluation software in the clinic or to a USB memory drive. Do not connect any other peripheral devices to this port, e.g., keyboards, cameras, power adapters, etc.

Before inserting a USB memory drive, ensure that it is from a trustworthy source and free from any malware.

NOTICE: UNAUTHORIZED ACCESS OR THEFT
Risk of breach of data privacy or theft due to unauthorized access.

Keep your device in a secure location to prevent unauthorized access. Do not share physical access to the device with individuals you do not know. Protect your device from theft or physical tampering. Avoid leaving the device unattended in public places.

NOTICE: CONFIDENTIALITY
Risk of breach of data privacy if personal health information is not deleted from the device after use or prior to decommission.

Before using the device on another patient or before decommissioning, execute the "Admit New Patient" function in the System menu to erase all patient-related data from the monitor.

NOTICE: SOFTWARE UPDATES
GETEMED recommends servicing the monitor once every eighteen (18) months. If applicable, the software on the device will be updated. These updates may contain security patches and enhancements.

# 1.7 Cleaning and Disinfecting

## 1.7.1 Preparation

Before reading this section, carefully read the safety information related to cleaning and disinfecting in section 1.6.7.

Before cleaning and disinfecting VitaGuard and its accessories, remove them from the monitor and from the patient.

Do not immerse the monitor, cables, sensors or the power adapter in any liquid solution.

Do not attempt to open the monitor before cleaning or disinfecting.

GETEMED recommends cleaning and disinfecting the monitor and its reusable accessories regularly:

- in clinical environments according to clinical standard operating procedures and immediately before using them on a new patient;
- in home environments, where only one patient is in contact with the equipment, at least once a month; and

to clean immediately when any foreign matter is visible on them.

## 1.7.2 Cleaning

### VitaGuard Monitor

To clean the VitaGuard monitor, proceed as follows:

1 disconnect all sensors and cables from the patient and disconnect them from the monitor;

2 moisten a lint-free cloth or gauze pad with a mild detergent and clean all surfaces by wiping them for 15 seconds with it;
NOTE: Cleaning was validated using "HAKA neutral soap".

3 moisten a second lint-free cloth or gauze pad with sterile or distilled water and wipe all surfaces with it to remove the detergent;

4 dry all surfaces thoroughly by wiping them with a fresh lint-free cloth or gauze pad.

Ensure that all items are completely dry before you reconnect them with each other and reconnect them to the patient.

### $SpO_2$ Cable

To clean the $SpO_2$ cable, refer to the cleaning instructions given in the instructions for use included in the $SpO_2$ cable packaging.

### Pouch

To clean the VitaGuard pouch, proceed as follows:

1 remove VitaGuard from the pouch;

2 moisten a lint-free cloth and gently hand-wash with 30 °C soapy water;

3 clean the outside of the pouch with the moistened cloth. Avoid deforming / squashing the pouch or scratching the transparent window when cleaning;

4 take a second lint-free cloth moistened with fresh water and use it to remove the soapy water from the pouch;

5 allow the pouch to dry completely before you put the monitor back into it.

Do not machine wash or spin dry the pouch, as this will deform the pouch and scratch the transparent window.

Replace the pouch if it is badly soiled or is showing noticeable signs of wear and tear.

## 1.7.3 Disinfection

The monitor and its accessories are not intended for sterilization. Do not sterilize any components by irradiation, steam, autoclave, or ethylene oxide.

When performing the disinfection procedure, wear rubber gloves and protective glasses to protect your eyes and skin from coming into direct contact with the disinfectant.

### VitaGuard Monitor

To disinfect the VitaGuard monitor, proceed as follows:

1 disconnect all sensors and cables from the patient and disconnect them from the monitor;

2 moisten a lint-free cloth or a gauze pad with 70 % isopropanol and disinfect all surfaces by wiping them for 5 minutes with it;

3 moisten a second lint-free cloth or gauze pad with sterile or distilled water and wipe all with it;

4 dry all surfaces thoroughly by wiping them with a fresh lint-free cloth or gauze pad.

Ensure that all items are completely dry before you reconnect them with each other and reconnect them to the patient.

#### $SpO_2$ Cable

To disinfect the $SpO_2$ cable, refer to the instructions given in the instructions for use included in the $SpO_2$ cable packaging.

### 1.7.4 Drying

After cleaning and/or disinfection dry all surfaces thoroughly with a clean cloth or a dry gauze pad. Ensure they are completely dry before you reconnect them with each other and to the patient.

### 1.7.5 Maintenance

The VitaGuard monitor and its patient cables can withstand at least 100 cleaning / disinfection cycles over their service life (see section 11.1) when the procedures described herein are followed.

### 1.7.6 Packaging / Transport Case

To remove any dirt from the transport case, wipe it gently with a moistened cloth and let it dry thoroughly before putting the monitor and its accessories back into it.

### 1.7.7 Storage

Store cleaned and disinfected components in a dust-free and dry place.

If the monitor and its accessories are not in daily use, clean and disinfect them and store them in the transport case supplied.

### 1.7.8 Additional Information

Cleaning and disinfecting by way of a machine is excluded for VitaGuard and its accessories. The instructions listed above have been validated by GETEMED as being suitable for preparing the medical device for reuse. It is the responsibility of the processor to ensure that the cleaning/disinfection tasks performed on the equipment achieve the desired result. This requires verification and/or validation and routine monitoring of the process.

## 1.8 Service Information

Before reading this section, carefully read the safety information related to service in section1.6.8.

Proper service is vital for long-term safety and reliability of the monitor. GETEMED recommends servicing the monitor once every eighteen (18) months. The next service date is generally shown on the service label on the device. Before the end of this period, contact your authorized dealer to organize collection of the monitor and a replacement unit.

Before use, always check VitaGuard and its accessories for any signs of damage and ensure that VitaGuard is working properly, as described in section 4. If you suspect that VitaGuard or its accessories are not in proper working order, take the following precautions:

- under no circumstances should you use VitaGuard or its accessories if they are damaged or are suspected to be damaged;
- contact your authorized dealer immediately;
- check the patient's vital functions and continue to observe the patient until you receive a replacement monitor.

Service and repairs must be performed by GETEMED or its authorized dealers only. Clarify the return procedure with your authorized dealer. For hygienic reasons, clean and disinfect all parts before returning them, as described in section1.7.

Unauthorized personnel have not received proper training and, as such, repairs carried out by unauthorized personnel could pose a

risk to the patient, result in damage to the device or accessories, and loss of warranty.

To help locate the cause of a malfunction, please include a detailed description of the observed malfunction. Remember to include the reusable accessories ($SpO_2$ cable and external power adapter) when returning the monitor for service or repair.

Unless otherwise requested by your authorized dealer, please do not return $SpO_2$ sensors. Should it be necessary to return them, please put them in a plastic bag for hygienic reasons to protect our service personnel.

NOTE TO SERVICE PERSONNEL: The date of insertion of the rechargeable battery into the monitor is printed on the battery pack. The battery must be replaced during service five years after this date at the latest.

## 1.9 Disposal Information

As indicated by the "Waste of Electrical and Electronic Equipment" symbol on the label on the back of the monitor, VitaGuard and its accessories contain substances such as metals and plastic parts that must be disposed of in such a way that they do not pollute the environment after their lifetime has expired.

To ensure that the monitor and its accessories are disposed of in accordance with applicable local and national waste regulations, return the monitor and its accessories to GETEMED or to your authorized dealer for proper disposal. GETEMED or the authorized dealer will disassemble the monitor to ensure that all major parts, i.e.:

- the lithium-ion rechargeable battery,
- the thermoplastic casing, the front panel and the instrument connectors after separating them all from each other,
- the printed circuit boards after removing the lithium coin battery,
- the display,
- and all accessories (patient cables, power adapter, etc.),

are disposed of in conformance with applicable waste regulations.

Disposable $SpO_2$ sensors can be collected in a sealed container or plastic bag and brought to your local recycling center for proper disposal. Do not dispose of them in your household waste. All other reusable accessories must be returned to your authorized dealer together with the monitor when you no longer need to monitor the patient. For hygienic reasons, clean and disinfect all parts before returning them, as described in section 1.7. Place accessories that have had direct contact with the patient, e.g., $SpO_2$ sensors, in a plastic bag beforehand.

If you have any questions concerning the disposal of VitaGuard and its accessories, contact your authorized dealer or GETEMED.

# 2. Sets and Accessories

## 2.1 Complete Sets

The VitaGuard VG 5 PX monitor is available in three standard configurations, which differ only in the type of cable and sensor combination used to measure pulse rate and $SpO_2$:

| Product | REF |
|---|---|
| VitaGuard VG 5 PX with Masimo RD SET technology | 73113029 |
| *NOTE: Canadian kit with French and English IFU* | *73113199* |
| 1 x VitaGuard VG 5 PX monitor | 73213013 |
| 1 x $SpO_2$ RD SET MD14-05 patient cable | 73434080 |
| 1 x $SpO_2$ RD SET Neo sensor | 73434003 |
| 1 x External power adapter NA 5-1 | 73441103 |
| 1 x Device pouch with straps | 73451002 |
| 1 x Instructions for use (English) | 73813022 |
| 1 x Quick start guide (English) | 73823022 |
| 1 x Transport case | 73910010 |

| Product | REF |
|---|---|
| VitaGuard VG 5 PX with Masimo LNCS technology | 73113026 |
| 1 x VitaGuard VG 5 PX monitor | 73213013 |
| 1 x $SpO_2$ LNC-10 patient cable | 70294 |
| 1 x $SpO_2$ LNCS Neo sensor | 70285 |
| 1 x External power adapter NA 5-1 | 73441103 |
| 1 x Device pouch with straps | 73451002 |
| 1 x Instructions for use (English) | 73813022 |
| 1 x Quick start guide (English) | 73823022 |
| 1 x Transport case | 73910010 |

| Product | REF |
|---|---|
| VitaGuard VG 5 PX with Masimo LNCS technology | 73113027 |
| 1 x VitaGuard VG 5 PX monitor | 73213013 |
| 1 x $SpO_2$ LNC-4 patient cable | 70293 |
| 1 x $SpO_2$ LNCS Neo sensor | 70285 |
| 1 x External power adapter NA 5-1 | 73441103 |
| 1 x Device pouch with straps | 73451002 |
| 1 x Instructions for use (English) | 73813022 |
| 1 x Quick start guide (English) | 73823022 |
| 1 x Transport case | 73910010 |

## 2.2 Accessories in Original Packaging

The accessories shipped in the transport case with the monitor are stored in their original packaging as explained below.

The 5 V external power adapter and the $SpO_2$ patient cable are both stored at the bottom of the transport case next to each other.


Fig. 3 Power Adapter (left) and $SpO_2$ Patient Cable (right)

NOTE: The actual $SpO_2$ patient cable supplied with your monitor may be different, but the box is similar to the example shown.

The $SpO_2$ sensor and the straps for the monitor pouch are all stored in the netting of the inside lid after you remove the monitor from the case and open the case fully.

Fig. 4 Storage Area for $SpO_2$ Sensor and Pouch Straps


Fig. 5 $SpO_2$ Sensor

NOTE: The actual $SpO_2$ sensor supplied with your monitor may be different, but the packaging is similar to the example shown.

## 2.3 Accessories and Ordering Information

The following accessories can be used together with the VitaGuard monitor and can be ordered using the catalogue numbers (REF) from GETEMED or authorized dealers. Please consult GETEMED or your authorized dealer for other approved accessories.

Masimo $SpO_2$ sensors and cables are intended for use only with instruments licensed to use Masimo SET technology (Masimo Corporation, 52 Discovery, Irvine, CA 92618, USA).

### 2.3.1 General Accessories

| Product | REF |
|---|---|
| External power adapter NA 5-1 (Friwo) | 73441103 |
| External power adapter NA 5-1 US (Friwo) | 73441106 |
| External power adapter NA 5-2 (Mean Well) | 73441105 |
| External power adapter NA 5-2 US (Mean Well) | 73441107 |
| Device pouch with straps | 73451002 |
| Instructions for use (English) | 73813022 |
| Quick start guide (English) | 73823022 |
| Transport case | 73910010 |
| Nurse call unit cable | 73415012 |

### 2.3.2 Masimo RD SET Sensors and Patient Cables

Adhesive RD SET $SpO_2$ sensors for single-patient use only:

| Product | REF |
|---|---|
| RD SET NeoPt sensor (body weight <1 kg) | 73434004 |
| RD SET NeoPt CS-2 sensor (body weight <1 kg) | 73434474 |
| RD SET Neo sensor (body weight <3 kg) | 73434003 |
| RD SET Neo CS-2 sensor (body weight <3 kg) | 73434473 |
| RD SET Inf sensor (body weight 3-20 kg) | 73434002 |
| RD SET Inf CS-2 sensor (body weight 3-20 kg) | 73434472 |
| RD SET Pdt sensor (body weight 10-50 kg) | 73434001 |
| RD SET Pdt CS-2 sensor (body weight 10-50 kg) | 73434471 |
| RD SET Adt sensor (body weight >30 kg) | 73434000 |
| RD SET Adt CS-2 sensor (body weight >30 kg) | 73434470 |

Replacement tapes are available for the adhesive sensors listed above. Please contact your authorized dealer for more information.

Reusable RD SET $SpO_2$ sensors:

| Product | REF |
|---|---|
| RD SET DCI finger sensor (body weight >30 kg) | 73434050 |
| RD SET DCI-P finger sensor (body weight 10-50 kg) | 73434051 |
| RD SET DBI soft finger sensor (body weight >30 kg) | 73434052 |
| RD SET Y1 multi-site sensor (body weight >1 kg) | 73434054 |

RD SET $SpO_2$ patient cables:

| Product | REF |
|---|---|
| RD SET MD14-05 patient cable (5 ft., 1.52 m) | 73434080 |
| RD SET MD14-12 patient cable (12 ft., 3.66 m) | 73434081 |

### 2.3.3 Masimo LNCS Sensors and Patient Cables

Adhesive LNCS $SpO_2$ sensors for single-patient use only:

| Product | REF |
|---|---|
| LNCS NeoPt sensor (body weight <1 kg) | 70284 |
| LNCS NeoPt-3 sensor (body weight <1 kg) | 70284-1 |
| LNCS Neo sensor (body weight <3 kg) | 70285 |
| LNCS Neo-3 sensor (body weight <3 kg) | 70285-1 |
| LNCS Inf sensor (body weight 3-20 kg) | 70286 |
| LNCS Inf-3 sensor (body weight 3-20 kg) | 70286-1 |
| LNCS Pdtx sensor (body weight 10-50 kg) | 70287 |
| LNCS Adtx sensor (body weight >30 kg) | 70288 |

Replacement tapes are available for the adhesive sensors listed above. Please contact your authorized dealer for more information.

Reusable LNCS $SpO_2$ sensors:

| | |
|---|---|
| LNCS DCI finger sensor (body weight >30 kg) | 70289 |
| LNCS DCI-P finger sensor (body weight 10-50 kg) | 70290 |
| LNCS DBI soft finger sensor (body weight >30 kg) | 70299 |
| LNCS Y1 multi-site sensor (body weight >1 kg) | 70298 |

LNC $SpO_2$ patient cables:

| | |
|---|---|
| LNC-4 patient cable (4 ft., 1.22 m) | 70293 |
| LNC-10 patient cable (10 ft., 3.05 m) | 70294 |
| LNC-14 patient cable (14 ft., 4.27 m) | 70295 |

NOTE: LNCS and RD SET adhesive sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. The sensor will provide up to 168 hours of monitoring time or up to 336 hours for sensors with a replaceable tape. After single-patient use, discard the sensor.

# 3. General Description

## 3.1 Modes of Operation

The VitaGuard VG 5 PX monitor is capable of acquiring the following vital signs:

- functional oxygen saturation of arterial blood ($SpO_2$), displayed as "$SpO_2$"; and
- pulse rate (PR), as calculated from the patient's pulse detected by the $SpO_2$ sensor.

$SpO_2$ and pulse rate are acquired by means of an optical sensor ($SpO_2$ sensor) attached to the patient's foot, toe or finger. As described in section 2.3, various sensors are available to suit the patient's age and weight.

VitaGuard emits an acoustic and visual physiological alarm:

- when the measured pulse rate value exceeds the selected alarm limits for a predefined period; or
- when the measured value of $SpO_2$ exceeds the selected alarm limits for a predefined period.

In addition to fixed alarm limits for pulse rate and $SpO_2$, the responsible physician can also configure percentage deviations as alarm conditions, as explained in sections 8.7.9, 8.8.6 and 8.8.7.

The alarm limits and their respective delay times can be set within defined limits, as described in chapter 8. A table of all patient alarms and their potential causes is provided in section 6.8.1.

VitaGuard continuously monitors the technical state of the monitor and emits an acoustic and visual technical alarm when problems occur that compromise its ability to monitor the vital signs, e.g., when:

- the $SpO_2$ sensor becomes loose;
- the $SpO_2$ cable is removed; or
- the battery capacity is low.

A table of all technical alarms and their potential causes is given in section 6.8.2.

Vital signs data measured for a set period before and after an alarm are logged. The responsible physician can download the logged alarm data through the USB interface for evaluation using the VitaWin software package depicted in section 9.7.

VitaGuard is normally powered using the NA 5-1 external power adapter (5 V) supplied with it. It also incorporates a rechargeable battery pack which serves to power the monitor when the external power adapter is removed, or when the mains power supply fails.

## 3.2 VitaGuard Setup

The following section explains how to set up the VitaGuard and connect its accessories to it.

For safety reasons, only use the approved accessories supplied with the monitor or provided by your authorized dealer. The approved accessories are listed in section 2.3.

The following illustration shows the monitor connected with all accessories connected to it.

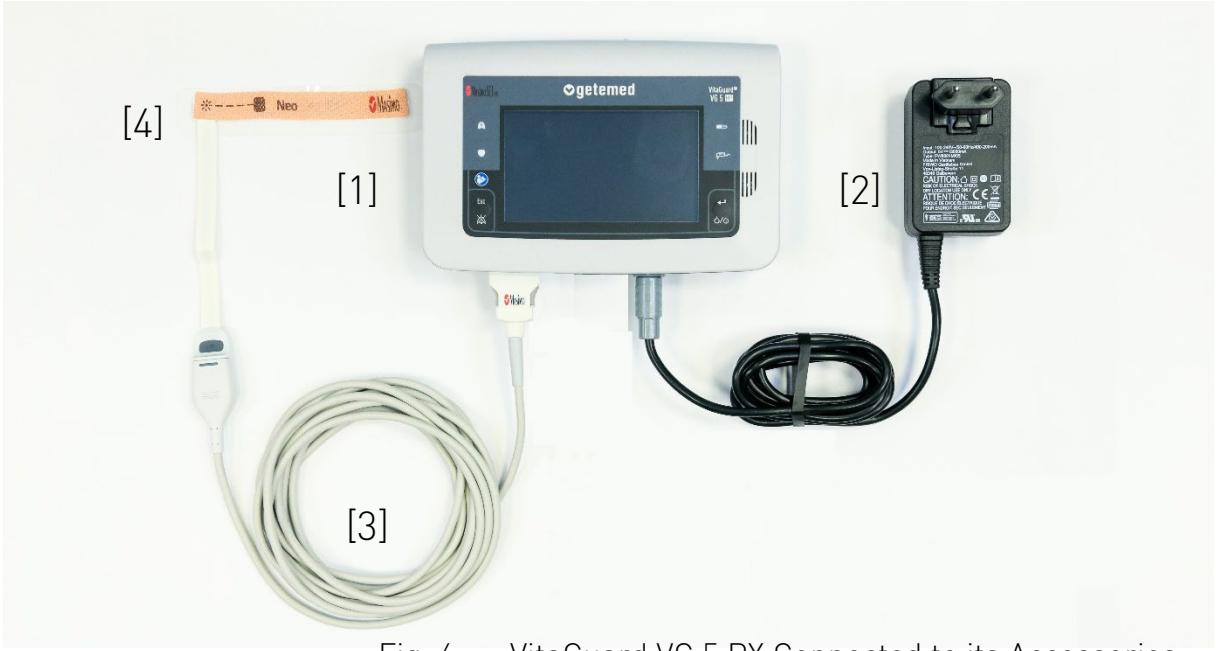



Fig. 6 VitaGuard VG 5 PX Connected to its Accessories

[1] VitaGuard VG 5 PX monitor
[2] External power adapter
[3] Patient cable for $SpO_2$ and pulse rate
[4] Sensor for $SpO_2$ and pulse rate

NOTE: Store the individual boxes and bags for the reusable accessories in the transport case provided so that they can be reused when returning the monitor

## 3.3 Connector Panel

The connectors for the patient cables and the external power adapter are located on the connector panel, as shown below:


Fig. 7 VitaGuard Connector Panel

Hold VitaGuard firmly with one hand when connecting and disconnecting the accessories.

Never use force when connecting and disconnecting cables. Always insert and remove the plugs in line with the connectors to prevent damage to the sensitive contacts, i.e., do not jiggle them left or right, or up and down.

### 3.3.1 $SpO_2$ & Pulse Rate Patient Cable Connector

The $SpO_2$ patient cable is connected to the connector labeled $SpO_2$ on the left-hand side of the connector panel.

The symbol beside the connector informs that the monitor is classified as “body floating” (BF) and that it is protected against defibrillation.

### 3.3.2 Power Adapter Connector

The 5 V external power adapter is connected to the round gray connector labeled with the power adapter symbol described in section 1.5.4 and marked with 5 V.

### 3.3.3 USB Connector

The USB (universal serial bus) port on the right-hand side of the connector panel serves the following purposes only:

- to communicate with the VitaWin evaluation software,
- to download stored data to a USB memory drive for evaluation by the responsible physician, or
- to connect the VitaGuard VG 5 nurse call unit cable (see 11.4).

Do not connect USB chargers, printers, cameras, scanners, hubs, or any other devices to this port.

Do not connect USB cables longer than 1.5 m to the port.

NOTE: While monitoring the patient, data transfer to a PC via the USB port is not permitted.

## 3.4 User Interface Elements on Front Panel

VitaGuard's user interface elements are located on the front panel, as shown below:

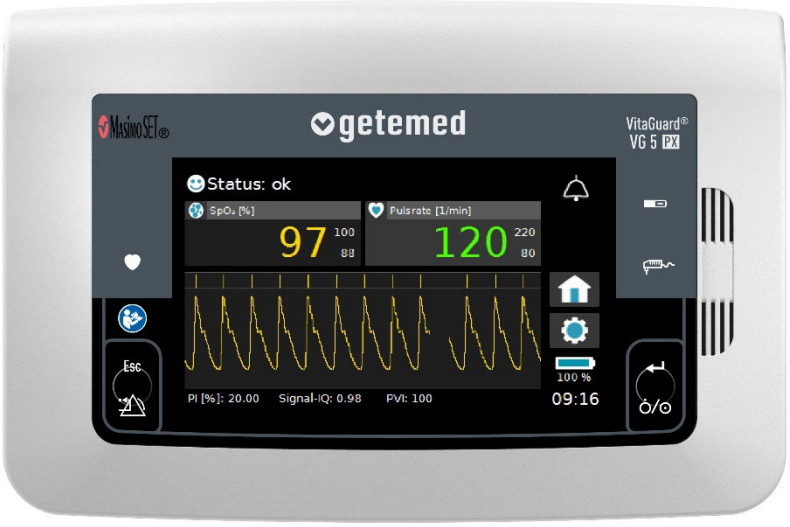



Fig. 8 VitaGuard Front Panel / User Interface

The user interface consists of the following elements:

- a 4.3" TFT touchscreen colour display;
- two pushbutton keys: <Enter> and <Esc>;
- four visual indicators (LED); and
- two alarm buzzer outlets.

NOTE: When using the monitor, do not apply excess pressure to the keys or the touchscreen display.

The symbols on the front panel are explained in section1.5.3.

### 3.4.1 <Enter> Key / On/Off

The <Enter> key serves two purposes:

- to switch VitaGuard on and off; and
- to confirm changes to the monitor settings.

Fig. 9 <Enter> Key

### 3.4.2 <Esc> Key / Alarm Reset

The <Esc> key serves the following purposes:

- when an alarm is triggered, the <Esc> key serves to deactivate the acoustic alarm signal. Pressing the <Esc> key during the alarm condition a second time reactivates the acoustic alarm. During an alarm condition, the red alarm LED flashes and the violated alarm limit on the monitor screen becomes red. The acoustic alarm is again emitted when the next alarm condition occurs;


Fig. 10 <Esc> Key

- NOTE: When an alarm automatically ends (because the vital signs have stabilized back within their allowed limits), the violated alarm limit on the display remains red in colour until the <Esc> key is pressed;
- the <Esc> key cancels unsaved changes to the monitor settings;
- the <Esc> key is used as part of the procedure to switch off the monitor.

### 3.4.3 Alarm LED

The alarm LED integrated into the <Esc> key can flash red or yellow as follows:

- in the event of a high priority alarm, i.e., a patient alarm, the alarm LED flashes red two times per second;

- in the event of a medium priority alarm, i.e., a technical alarm, the alarm LED flashes yellow every two seconds.

### 3.4.4 Pulse Rate LED

The heart symbol LED flashes green each time the patient's pulse is detected.

Fig. 11 Heartbeat LED

The flashing green LED shows you even in complete darkness that monitoring is activated.

NOTE: The System menu provides a setting to switch on and off an acoustic beep tone that is emitted synchronously with each pulse.

### 3.4.5 Power Supply and Battery Charge LEDs

The battery charging symbol LED (top symbol) is green when the rechargeable battery pack is being charged in VitaGuard.

When the battery pack is fully charged, the LED is switched off. A depleted battery pack takes up to six hours to recharge.

Fig. 12 Power Supply and Battery Charge LEDs

If there is a problem with the rechargeable battery, the LED flashes. In this case, please return the monitor for service, as described in section 1.8.

The power adapter symbol LED (bottom symbol) is green as long as VitaGuard is being powered from the external power adapter.

NOTE: When the power adapter LED is off, then VitaGuard is being powered by the rechargeable battery pack.

The battery pack must be fully charged at all times in the event that the power supply from the external power adapter fails.

### 3.4.6 Display and Touchscreen / View 1

VitaGuard's colour display incorporates a touchscreen membrane to interact with the monitor. Various viewing modes are available and are explained in further detail in chapter 7. The following is an explanation of the display content when operated in the View 1 mode.

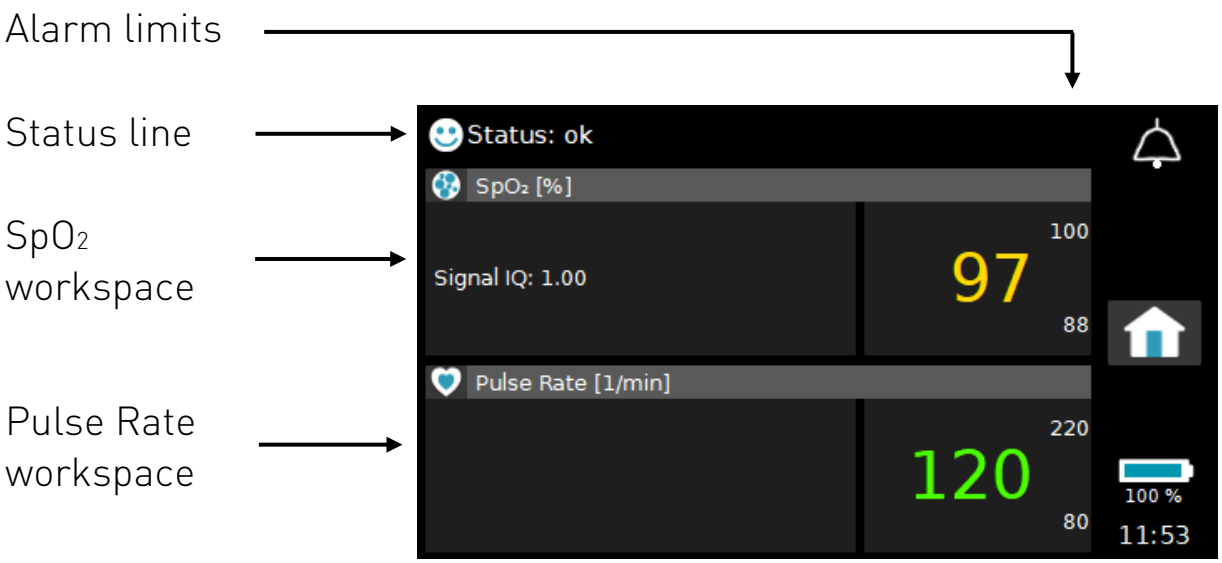



Fig. 13 View 1 Screen Content

Status line: The status line at the top of the screen displays messages about the current status of the monitor. These messages are classified into three categories and are listed in section 6.8:
- patient alarm messages,
- technical alarm messages, and
- informational messages.

$SpO_2$ workspace: The current value of $SpO_2$ in percent is shown in large brown digits. The smaller digits to the right of the current value show the set upper and lower alarm limits. The workspace also displays the current value of Signal IQ, a quality indicator in the range 0.00 to 1.00 of the signal being received from the $SpO_2$ sensor.

Pulse Rate workspace: The current value of pulse rate in beats per minute [1/min] is shown in large green digits. The smaller digits to the right of the current value show the set upper and lower alarm limits.

The following elements are displayed on the right-hand side of the screen:

- Bell icon: The **Bell** icon at the top of the screen indicates that the alarm system is activated and ready to generate an alarm if an alarm situation is detected.

- Home icon: Touching the **Home** icon causes the monitor to return to the top level of the user interface.

- Battery icon: The **Battery** icon provides a visual indication of the current status of the rechargeable battery. The remaining battery capacity is displayed as a percentage value underneath the icon.

- The current time in hours and minutes is displayed in the bottom right-hand corner of the screen.

All the various views and their corresponding screen content are explained in section 7.

NOTE: After the monitor is switched on, it can take up to twenty seconds before the first values are displayed.

### 3.4.7 Alarm Buzzer Outlets

The two alarm buzzer outlets located on the right-hand side of the front panel emit the acoustic alarm tones during an alarm event. Sections 6.2 and 6.4 describe the characteristics of the acoustic tones for patient and technical alarms.

Fig. 14 Alarm Buzzer Outlets

## 3.5 Power Supply

### 3.5.1 External Power Adapter

Before using the external power adapter, carefully read the safety information provided in section 1.6.4.


Fig. 15 External Power Adapter

VitaGuard is powered by the medical grade external power adapter supplied with the monitor, which converts the alternating current (a.c.) mains supply (100-240 V, 50-60 Hz) to a direct current (d.c.) 5 V output. The standard plug on the adapter is for central European supply networks. For other supply networks, contact GETEMED or your authorized dealer for the appropriate plug adapter.

The green LED on the power adapter illuminates when the adapter is connected to a live wall socket. When the power adapter is connected to VitaGuard, the power adapter LED on VitaGuard's front panel also illuminates green, independent of whether the monitor is switched on or off, and charging of the rechargeable battery pack is activated. The green battery charging LED illuminates and switches off once the battery is fully charged.

To minimize the risk of the power adapter being accidentally pulled from the mains socket, only insert the power adapter into the mains socket as shown below: either perpendicular with the cable leading downward (left graphic) or horizontally (right graphic).

Fig. 16 Plugging Power Adapter into Mains Socket

When the external power adapter is connected, VitaGuard automatically operates from the mains power supply. If the power adapter is removed during monitoring or if the mains power supply fails, VitaGuard automatically switches to battery mode and operates from the built-in rechargeable battery pack. If either event occurs, a technical alarm is emitted until the external power supply has been reinserted or the <Esc> key pressed.

Normal voltage fluctuations of ± 10% in the mains supply do not adversely affect monitoring with VitaGuard. Following a mains power supply failure, the current alarm settings are retained for at least thirty days and reappear when the device is switched back on again.

### 3.5.2 Rechargeable Battery Pack

VitaGuard has a built-in Li-ion rechargeable battery pack which powers the monitor when the external power adapter is not connected to it or if the mains power supply fails. Carefully read the safety information provided in section 1.6.9.

NOTE: The rechargeable battery pack may not be sufficiently charged when new or after prolonged storage.

Connect the monitor to the external power adapter to recharge the battery. The maximum charging time is six (6) hours. The battery symbol on the monitor's front panel (see section 1.5.3) indicates the charging status as follows:

- Permanently on: Battery is charging
- Permanently off: Battery fully charged
- Flashing: Charging error detected

The rechargeable battery pack is designed to power the monitor continuously for at least eight (8) hours. It needs to be replaced if any of the following situations occur:

- the operating time with the rechargeable battery is less than eight hours;
- there is a technical problem with the rechargeable battery, as indicated by the charging symbol LED on the front panel flashing;

- the battery has undergone more than 200 full charging cycles, as indicated in the Info screen explained in section 7.5.2.

If one of the above situations occurs, immediately consult your authorized dealer or GETEMED in order to rectify the problem. The battery compartment is sealed with a safety screw. Do not attempt to open the battery compartment and replace the battery on your own.

NOTE: Even if none of the above conditions occur, the rechargeable battery should be replaced after five years at the latest.

The battery icon provides a visual indication of the current status of the rechargeable battery. The remaining battery capacity is displayed as a percentage underneath the icon.

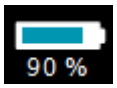



Fig. 17 Battery Capacity Indicator

When the monitor is being powered by the rechargeable battery pack only, check the battery indicator on the screen at least once every hour to ensure that the remaining battery capacity is above 20 %.

In addition to the battery indicator, VitaGuard outputs messages and alarms when the remaining battery capacity reaches critical levels:

- Capacity less than 20 %: The informational message "**Recharge battery**" is displayed on the screen, the remaining operating time is at least 45 minutes;
- Capacity less than 8 %: A medium-priority technical alarm is output along with the message "**Recharge battery!!**", the remaining operating time is at least 30 minutes;
- Capacity less than 5 %: A high-priority alarm is output along with the message "**Connect power adapter NOW!!!**", the remaining operating time is at least 5 minutes.

  **This is the last opportunity to immediately reconnect the external power adapter before the monitor shuts down and stops monitoring.**

NOTE: To maximize the operating time in battery mode, the display brightness behaves as if the **Dimmed Mode** option were selected in the **Display Mode** setting described in section 8.3.1.

### 3.5.3 Power Fail Battery / Reset Button

VitaGuard is fitted with an auxiliary rechargeable lithium cell battery. This provides energy for at least 30 minutes for an acoustic alarm signal that is emitted by an internal alarm buzzer when the monitor shuts down due to a failure in the internal power supply or when the system controllers fail to trigger the internal safety watchdogs. The cell has a nominal voltage of 3 V and is recharged by the power supply from the external power adapter.

The acoustic alarm does not stop until VitaGuard has been switched back on after the power adapter has been reconnected. If this is not possible, the alarm tone can be deactivated by carefully inserting a pin or paper clip into the small 1 mm hole to the left of the USB connector on the connector panel. An internal reset button located directly behind the hole deactivates the power fail alarm tone.

NOTE: The auxiliary internal power fail battery can only be replaced by GETEMED's service department. The current voltage of the battery is displayed in the Info page described in section 7.5.3. If it permanently falls below 2.5 V, return the monitor for service.

# 4. Steps Before and After Monitoring

The following summary shows you all the necessary steps that need to be taken before and after monitoring.

NOTE: The prescribing physician is responsible for all other important activities, including setting the alarm limits.

NOTE: After the monitor is switched on, it may take up to twenty seconds before the first values are displayed.

## 4.1 Steps Before Monitoring / Pre-Use Checks

To set up VitaGuard for monitoring, proceed as follows:

- use the external power adapter supplied to connect VitaGuard to the supply network (do not switch on yet!);
- attach the $SpO_2$ sensor to the patient;
- connect the $SpO_2$ patient cable to VitaGuard;
- connect the $SpO_2$ sensor to the patient cable;
- switch on VitaGuard as explained in the next section;
- make sure that during the power-on sequence all indicator LEDs light up briefly and a short sound is emitted by the alarm buzzers;
- check that the alarm limits displayed on the screen are the same as those specified by your physician.

It is important that VitaGuard is configured so that false alarms are avoided to the greatest possible extent. Frequent false alarms can greatly reduce the alertness of caregivers.

As the patient gets older, it may be necessary to change the alarm limits. Arrange an appointment with your physician if the alarm limits need to be adjusted.

Test the alarm system daily as described in section 6.5.

## 4.2 Switching VitaGuard On

Press the <Enter> key for several seconds to switch on VitaGuard.

VitaGuard performs an internal self-test during the power-on sequence. As part of this sequence, the following displays and signals show you that the monitoring system is fully operable:

- all indicator LEDs illuminate briefly during power-on. During this sequence, the alarm LED first lights up red and then yellow;
- a brief tone is emitted to indicate that the acoustic alarm buzzers are fully operable.

If the alarm buzzers do not emit the acoustic signal during the power-on phase, immediately consult your authorized dealer for a replacement device. Observe the patient carefully until the replacement device arrives. Bear in mind that the patient is not being monitored at this time and that no alarm will be reported in an emergency.

In the first minute of operation after the power-on phase, no acoustic signals are emitted so that you have sufficient time to check all cables. The alarm bell icon is crossed out for this time and the remaining time is displayed below it. The status line on the screen will display messages if there are any actions that need to be taken.

When the first minute of operation has passed and no patient cable has been connected, an acoustic reminder signal is emitted as a short tone every twenty (20) seconds. Acoustic technical alarms for cables and sensors are not activated until the patient cables are connected and the first plausible data have been calculated. Text messages in the status line report from the beginning if the cables or sensors need to be checked.

Check that the acoustic alarm signal is loud enough to be heard over the prevailing or expected noise levels in the monitor's environment. Section 6.5 explains how to test the alarm system.

NOTE: Using the Signal Beep Tone setting in the System menu, a short acoustic signal can be activated to accompany each heartbeat.

## 4.3 Switching VitaGuard Off

To switch off VitaGuard, proceed as follows:

5 Press the <Enter> key and keep this pressed: the message "Press Esc key" appears on the screen.

6 Briefly press the <Esc> key, still keeping the <Enter> key pressed, and then release both keys.

The switch off command is acknowledged by the shutdown sequence on the display. As data and status information must be logged in the monitor's memory before the device finally switches off, VitaGuard needs several seconds after the keys are released before it switches off completely.

## 4.4 Steps After Monitoring

Once VitaGuard has been switched off, proceed as follows:

- carefully remove the $SpO_2$ sensor from the patient, again taking care not to damage the patient's skin;
- make sure that the adhesive $SpO_2$ sensor is stored such that the adhesive surface does not get contaminated with foreign matter.

# 5. SpO2 and Pulse Rate Monitoring

Carefully read the safety information related to SpO2 and pulse rate monitoring in section 1.6.6 before commencing.

## 5.1 General Information on SpO2 and Pulse Rate Monitoring

VitaGuard has been exclusively designed for use with sensors and patient cables manufactured by Masimo Corporation (LNCS and RD SET series). It is not permitted to use sensors and patient cables from other manufacturers.

All Masimo SpO2 sensors are free of latex, not sterile, and cannot be sterilized.

Check that there is no damage to the sensor's packaging before opening it. Do not use the sensor after the expiration date printed on the packaging next to the text "USE BY" hourglass symbol, e.g., 2024-07 = July, 2024, as shown in Fig. 18.


Fig. 18 "Use By" Date of SpO2 Sensor

The SpO2 sensor and cable must be free of visible damage and discoloration. If there are any signs of damage, discontinue use immediately and consult your authorized dealer for a replacement.

NOTE: The SpO2 value displayed by VitaGuard is the functional oxygen saturation value.

For SpO2 and pulse rate monitoring, pay attention to the following important information:

- attach the SpO2 sensor to intact areas of skin only;
- use adhesive sensors on one patient only to avoid cross-contamination between patients;

- avoid wrapping the sensor too tight around the application site. Sensors applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure necrosis;
- secure the sensor and patient cable so that they cannot harm, strangle, or be swallowed by the patient. Always route the patient cable at a safe distance from the patient's head and neck. Route the patient cable when monitoring small children inside their clothing so that it exits at the foot. On larger children and adults you can, for example, route the patient cable so that it exits between the trousers and pullover;
- the sensor site must be checked frequently to ensure adequate adhesion, circulation, skin integrity and correct optical alignment. Remove adhesive sensors at least once every 8 hours and, if used, permanent sensors at least once every 4 hours to inspect and, if necessary, clean the skin covered by the sensor;
- check the application site every (1) hour with poorly perfused patients and relocate the sensor if there are any signs of tissue damage;
- do not use additional tape to secure the sensor to the site as this can restrict blood flow and cause inaccurate readings. Use of additional tape may cause skin damage, and/or pressure necrosis, or damage the sensor;
- if the blood flow at application site is not satisfactory, attach the sensor to a different site, and inspect this site regularly;
- do not attach the $SpO_2$ sensor to a limb that has or will have a catheter or pressure cuff during monitoring;
- do not use adhesive $SpO_2$ sensors on patients exhibiting allergic reactions to adhesive strips or similar materials.

Measurement performance can be impaired if the sensor is improperly secured or misaligned, e.g., when the transmitter and receiver are not exactly located opposite each other.

## 5.2 Reasons for Inaccurate $SpO_2$ or Pulse Rate Values

Inaccurate measurements of pulse rate and/or $SpO_2$ may be caused by various factors. If you suspect inaccurate values, clarify with your physician whether one of the following situations may be the cause of inaccurate values:

- incorrect sensor application or use;
- extreme motion artifacts from excessive patient movement;
- placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;
- intravascular dyes such as indocyanine green or methylene blue;
- interfering substances from externally applied colouring and texture, such as dyes, nail polish, acrylic nails, glitter, or any substance containing dyes that change usual blood pigmentation;
- birthmark(s), tattoos, skin discolourations, moisture on skin, deformed or abnormal fingers. etc.;
- skin colour disorders;
- exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with dark or opaque material);
- venous congestion which may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor);
- abnormal venous pulsation or venous constriction which may cause erroneous low readings (e.g. tricuspid value regurgitation);
- patients suffering from abnormal pulse rhythm;
- pulsations from intra-aortic balloon support which can be additive to the pulse rate on the VitaGuard pulse rate display;

- arterial catheters and intra-aortic balloon
- elevated levels of total bilirubin;
- significant levels of dysfunctional hemoglobins, e.g., carboxyhemoglobin or methemoglobin;
- increases in either COHb or MetHb. $SpO_2$ is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin MetHb). A pulse oximeter cannot measure elevated levels of COHb or MetHb. Therefore, increases in either COHb or MetHb will affect the accuracy of the $SpO_2$ measurement. High levels of COHb or MetHb may occur with a seemingly normal $SpO_2$. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed;
- hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.;
- vasospastic disease, such as Raynaud's, and peripheral vascular disease;
- hypocapnic or hypercapnic conditions;
- electromagnetic interference (including mobile devices);
- very low arterial perfusion at the monitored site so that readings may read lower than core arterial oxygen saturation.

Loss of pulse signal can occur in any of the following situation:

- the sensor is too tight;
- there is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight;
- a blood pressure cuff is inflated on the same extremity as the one with the $SpO_2$ sensor attached;
- the patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;
- there is arterial occlusion proximal to the sensor;
- the patient is in cardiac arrest or is in shock.

## 5.3 Accuracy of SpO2 Sensors

The following adhesive SpO2 sensors are available for use with VitaGuard. Other reusable sensors are also available, as listed in sections 2.3.3 and 2.3.2. For information on additional sensors, contact your authorized dealer or GETEMED.

| RD SET Sensors | Neo Pt<br>Neo Pt CS-2 | Neo<br>Neo CS-2 | Inf<br>Inf CS-2 | Pdt<br>Pdt CS-2 | Adt<br>Adt CS-2 |
|---|---|---|---|---|---|
| Weight | < 1 kg | < 3 kg | 3 – 20 kg | 10 – 50 kg | > 30 kg |
| Application site | Hand or foot | Hand or foot | Thumb or great toe | Finger or toe | Finger or toe |
| Saturation Accuracy, No Motion | ± 3 % | ± 3 % | ± 2 % | ± 2 % | ± 2 % |
| Saturation Accuracy, Motion | ± 3 % | ± 3 % | ± 3 % | ± 3 % | ± 3 % |
| Saturation Accuracy, Low perfusion | ± 3 % | ± 3 % | ± 2 % | ± 2 % | ± 2 % |
| Pulse Rate Accuracy, No Motion | ± 3 /min | ± 3 /min | ± 3 /min | ± 3 /min | ± 3 /min |
| Pulse Rate Accuracy, Motion | ± 5 /min | ± 5 /min | ± 5 /min | ± 5 /min | ± 5 /min |
| Pulse Rate Accuracy, Low perfusion | ± 3 /min | ± 3 /min | ± 3 /min | ± 3 /min | ± 3 /min |

| LNCS Sensors | Neo Pt,<br>Neo Pt-3 | Neo<br>Neo-3 | Inf<br>Inf-3 | Pdtx | Adtx |
|---|---|---|---|---|---|
| Weight | < 1 kg | < 3 kg | 3 – 20 kg | 10 – 50 kg | > 30 kg |
| Application site | Hand or foot | Hand or foot | Thumb or great toe | Finger or toe | Finger or toe |
| Saturation Accuracy, No Motion | ± 3 % | ± 3 % | ± 2 % | ± 2 % | ± 2 % |
| Saturation Accuracy, Motion | ± 3 % | ± 3 % | ± 3 % | ± 3 % | ± 3 % |
| Saturation Accuracy, Low perfusion | ± 3 % | ± 3 % | ± 2 % | ± 2 % | ± 2 % |
| Pulse Rate Accuracy, No Motion | ± 3 /min | ± 3 /min | ± 3 /min | ± 3 /min | ± 3 /min |
| Pulse Rate Accuracy, Motion | ± 5 /min | ± 5 /min | ± 5 /min | ± 5 /min | ± 5 /min |
| Pulse Rate Accuracy, Low perfusion | ± 3 /min | ± 3 /min | ± 3 /min | ± 3 /min | ± 3 /min |

## 5.4 Operation of $SpO_2$ Measurement

$SpO_2$ sensors consist of a transmitter diode (referred to as "transmitter" in the following) and a detector (receiver). The transmitter is identified by the red star symbol on the sensor. The detector is located in the other window on the inside of the sensor.

The transmitter emits light, the detector detects this light. When this light penetrates arterial blood vessels, the composition and intensity of the light picked up by the detector change.

The $SpO_2$ monitor can calculate the percentage level of blood oxygenation from the composition of the light picked up by the detector. However, it is important that no other light, whether daylight or other forms of ambient light, can reach the detector. More detailed explanations on the measuring principle for $SpO_2$ monitoring are provided in section Fehler! Verweisquelle konnte nicht gefunden werden..

## 5.5 Choosing the Sensor Application Site

When selecting the application site for the sensor, take the following considerations into account:

- always select a site that is intact, has good blood flow, and covers completely the receiver window. Information on choosing the right attachment site can be found on the sensor's packaging;
- select a site such that the sensor's transmitter and receiver are aligned exactly opposite each other. The distance between the transmitter and the receiver should not be greater than two centimeters;
- clean and dry the attachment site before applying the sensor;
- select a site where the sensor and patient cable least restrict the patient's freedom of movement.

### 5.5.1 RD SET Adhesive Sensors

RD SET Pdt and Pdt CS-2: Sensor for pediatric patients 10-50 kg: The preferred site is the middle finger or the ring finger of the not dominant hand.

RD SET Inf and Inf CS-2: Sensor for neonates 3-20 kg: The preferred site is the great toe. Alternatively, the toe next to the big toe, or the thumb can be used.

RD SET Neo and Neo CS-2: Sensor for neonates < 3 kg: The preferred site is the foot. Alternatively, across the palm and back of the hand can be used.

RD SET NeoPt and NeoPt CS-2: Sensor for preterms < 1 kg: The preferred site is the foot. Alternatively, across the palm and back of the hand can be used.

RD SET Adt und Adt CS-2: Sensor for patients > 30 kg: The preferred site is the middle or ring finger of non-dominant hand.

### 5.5.2 LNCS Adhesive Sensors

LNCS NeoPt and NeoPt-3: Sensor for preterms < 1 kg: The preferred site is the foot. Alternatively, across the palm and back of the hand can be used.

LNCS Neo und Neo-3: Sensor for neonates < 3 kg: The preferred site is the foot. Alternatively, across the palm and back of the hand can be used.

LNCS Inf und Inf-3: Sensor for infant 3-20 kg: The preferred site is the great toe. Alternatively, the toe next to the big toe, or the thumb can be used.

LNCS Pdtx: Sensor for pediatric patients 10-50 kg: The preferred site is the middle finger or the ring finger of the not dominant hand.

LNCS Adtx: Sensor for patients > 30 kg: The preferred site is the middle or ring finger of non-dominant hand.

## 5.6 Applying the $SpO_2$ Sensor

Your responsible physician should decide which $SpO_2$ sensor is best suited to your particular situation.

### 5.6.1 RD SET Adhesive Sensors

1 Open the pouch and remove the sensor. Remove the protective backing from the sensor, if present.

For PEDIACTRICS (10 - 50 kg)

2 See Fig. 1a in Fig. 19: Orient the sensor so that the detector can be placed first. Place the tip of the finger on the dashed line with the fleshy part of the finger covering the finger outline and detector window.

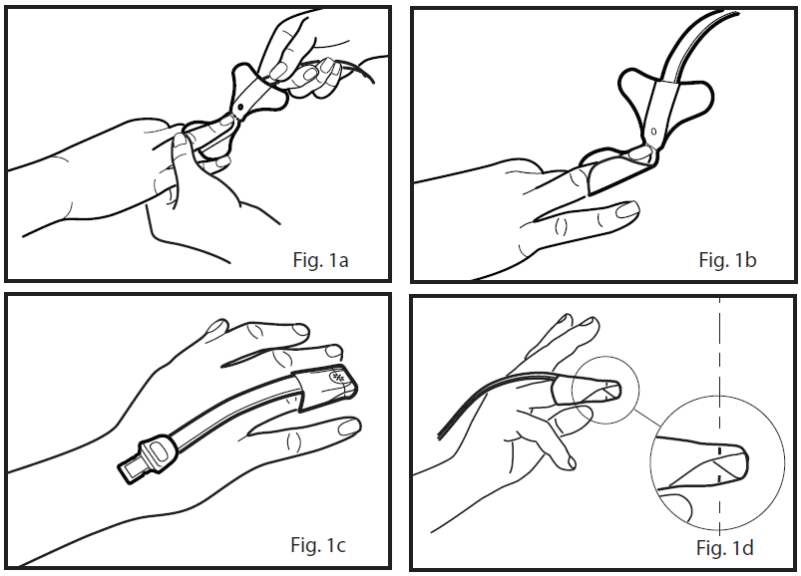



Fig. 19 RD SET Sensor Application for Pediatrics 10-50 kg

3 See Fig. 1b in Fig. 19: Press the adhesive wings, one at a time, onto the finger. Complete coverage of the detector window is needed to ensure accurate data.

4 See Fig. 1c in Fig. 19: Fold the sensor over the finger with the emitter window (red star) positioned over the fingernail. Secure the wings down, one at a time, around the finger.

5 See Fig. 1d in Fig. 19: When properly applied, the emitter and detector should be vertically aligned (the black lines should align). Reposition if necessary.

For INFANTS (3 - 20 kg)

2 See Fig. 2a in Fig. 20: Direct the sensor cable so that it runs along the top of the foot. Position the detector on the fleshy pad of the great toe. Alternatively, the toe next to the great toe, or the thumb can be used (not shown).

3 See Fig. 2b in Fig. 20: Wrap the adhesive wrap around the toe so the emitter is positioned on the nailbed of the great toe. Complete coverage of the detector window is needed to ensure accurate data.

4 See Fig. 2c in Fig. 20: Ensure that the emitter window (red star) aligns on the top of the toe directly opposite the detector. Verify correct positioning and reposition if necessary.

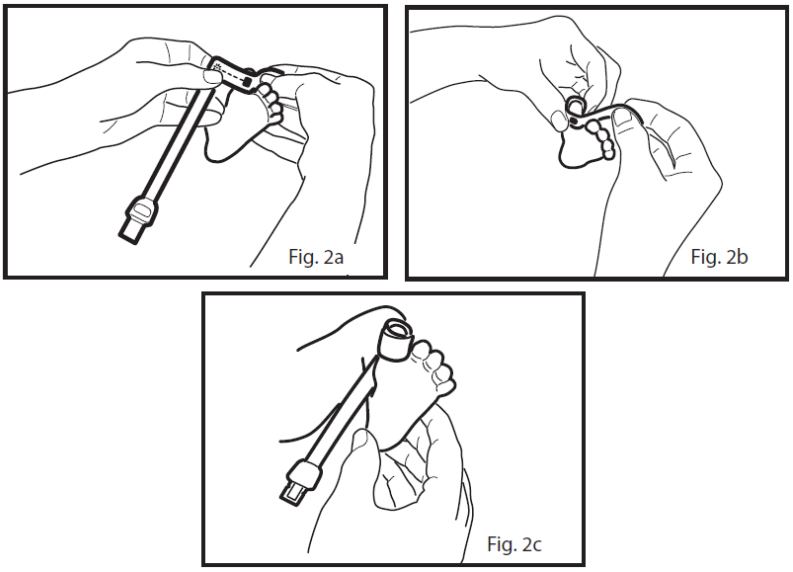



Fig. 20 RD SET Sensor Application for Infants 3-20 kg

For NEONATES (< 3 kg) and PRETERMS

2 See Fig. 3a in Fig. 21: For fragile skin, the stickiness of the medical grade adhesive can be diminished or eliminated by daubing the adhesive areas with a cotton ball or gauze.

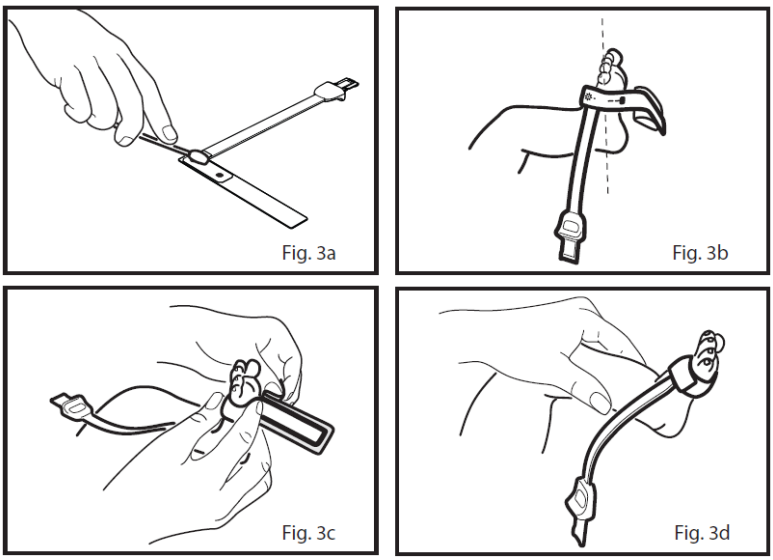



Fig. 21 RD SET Sensor Application for Neonates and Preterms

3 See Fig. 3b in Fig. 21: Direct the sensor cable toward the ankle (or wrist).

4 Apply the sensor around the lateral aspect of the foot (or hand), aligned with the fourth toe (or finger). Complete coverage of the detector window is needed to ensure accurate data.

5 See Fig. 3c in Fig. 21: Wrap the adhesive/foam wrap around the lateral aspect of the foot (or hand) and ensure that the emitter window (red star) aligns directly opposite the detector. Be careful to maintain proper alignment of the detector and emitter windows while attaching adhesive/foam wrap to secure the sensor.

6 See Fig. 3d in Fig. 21: Verify correct positioning.

### 5.6.2 LNCS Adhesive Sensors

1 Open the pouch and remove the sensor. Remove the protective backing from the sensor, if present.

PRETERM (< 1 kg) and NEONATE (< 3 kg)

2 See Fig. 1a in Fig. 22: For fragile skin, the stickiness of the medical grade adhesive can be diminished or eliminated by daubing the adhesive areas with a cotton ball or with gauze.

3 See Fig. 1b in Fig. 22: Direct the sensor cable so that it either points away from the patient or runs along the bottom of the foot. Apply the detector onto the fleshy part of the lateral aspect of the sole of the foot aligned with the fourth toe. Alternatively, the detector may be applied to the top of the foot (not shown). Complete coverage of the detector window is needed to ensure accurate data.

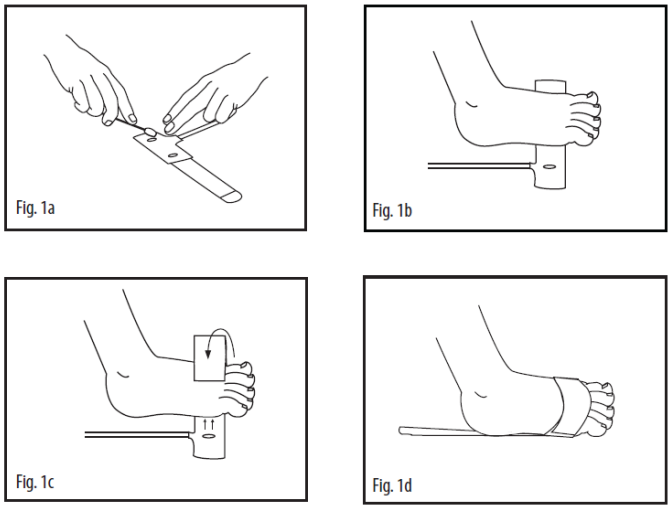



Fig. 22 LNCS Sensor Application for Preterms and Neonates

4 See Fig. 1c in Fig. 22: Wrap the adhesive/foam wrap around the foot and ensure that the emitter window (red star) aligns directly opposite of the detector. Be careful to maintain proper alignment of the detector and emitter windows while attaching adhesive/foam wrap to secure the sensor.

5 See Fig. 1d in Fig. 22: Verify correct positioning and reposition if necessary.

INFANT (3-20 kg)

2 See Fig. 2a in Fig. 23: Direct the sensor cable so that it either points away from the patient or runs along the bottom of the foot. Position the detector onto the fleshy part of the great toe.

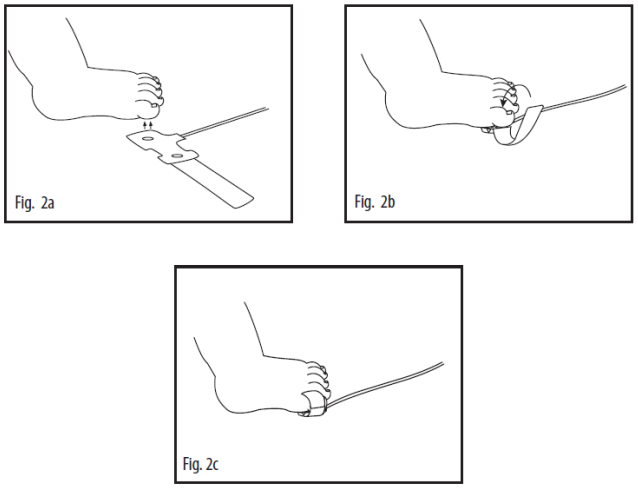



Fig. 23 LNCS Sensor Application for Infants

3 Complete coverage of the detector window is needed to ensure accurate data.

4 See Fig. 2b in Fig. 23: Wrap the adhesive wrap around the toe and ensure that the emitter window (red star) aligns on the top of the toe directly opposite the detector.

5 See Fig. 2c in Fig. 23: Verify correct positioning and reposition if necessary.

PEDIATRIC (10-50 kg)

2 See Fig. 3a in Fig. 24: Orient the sensor cable so that the detector can be placed first. Place the tip of the finger on the dashed line with the fleshy part of the finger covering the detector window.

3 See Fig. 3b in Fig. 24: Press the adhesive wings one at a time onto the finger. Complete coverage of the detector window is needed to ensure accurate data.

4 See Fig. 3c in Fig. 24: Fold the sensor over the finger with the emitter window (red star) positioned over the fingernail. Secure the wings down one at a time around the finger.

5 See Fig. 3d in Fig. 24: When properly applied, the emitter and detector should be vertically aligned.

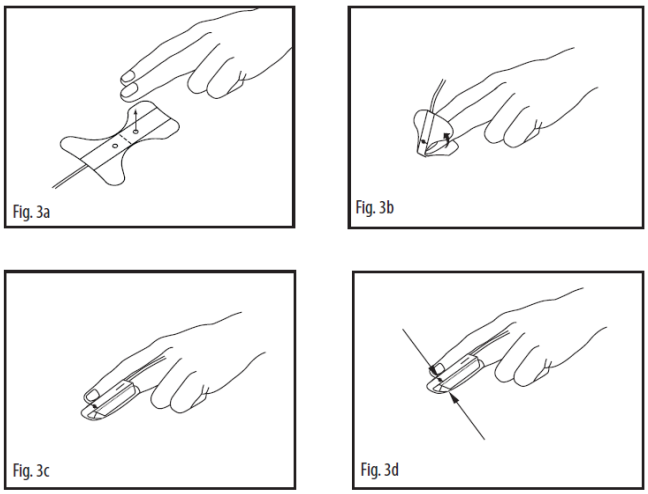



Fig. 24 LNCS Sensor Application for Pediatrics 10-50 kg

6 Verify correct positioning and reposition if necessary (the black lines should align).

## 5.7 Repositioning or Replacing the Sensor

The sensor may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin. Use a new sensor, when the adhesive does not adhere to the skin anymore.

NOTE: Disconnect the sensor from the patient cable before you reattach the sensor to another application site.

If VitaGuard is not displaying plausible values for $SpO_2$ and/or pulse rate, the sensor may have become loose or is not attached to the optimal application site.

- Check the sensor's position, and if necessary, move the sensor to a different site.
- Always replace a sensor when the displayed $SpO_2$ and/or pulse rate remains implausible despite the sensor's new site.

## 5.8 Connecting the SpO2 Sensor and Patient Cable

### 5.8.1 RD SET Patient Cable

1 See Fig. 4a in Fig. 25: Orient the sensor's connector tab so that the side with the "shiny" contacts is facing up. Orient the patient cable with the color bar and finger grips facing up.

2 See Fig. 4b in Fig. 25: Insert the sensor tab into the patient cable until there is a tactile or audible click of connection. Gently tug on the connectors to ensure a positive contact. Tape may be used to secure the cable to the patient to prevent movement.

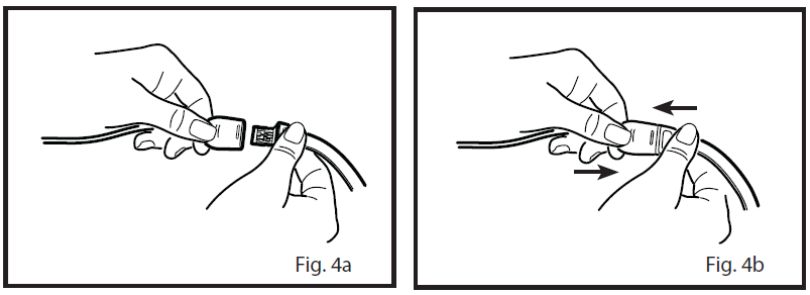



Fig. 25 Connecting RD SET Patient Cable to RD SET Sensor

### 5.8.2 LNC Patient Cable

See Fig. 5 in Fig. 26. Insert the sensor connector completely into the patient cable connector (1). Completely close the protective cover (2).

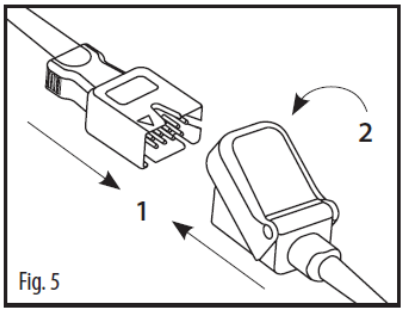



Fig. 26 Connecting LNC Patient Cable to LNCS Sensor

## 5.9 Connecting the SpO2 Cable to VitaGuard

Insert the patient cable's plug into the SpO2 socket on VitaGuard. The Masimo logo on the cable plug must be facing up. The cable plug should snap into the connector.

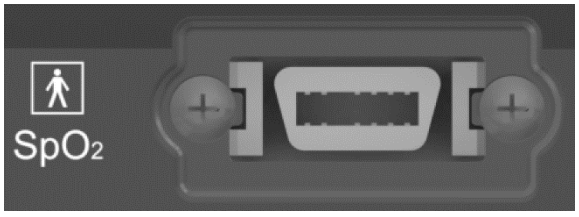



Fig. 27 SpO2 Socket

# 5.10 Disconnecting the SpO2 Sensor from the Patient Cable

## 5.10.1 RD SET Patient Cable

See Fig. 6 in Fig. 28: Pull firmly on the sensor connector to remove it from the patient cable.

NOTE: To avoid damage, pull on the sensor connector, not on the cable.

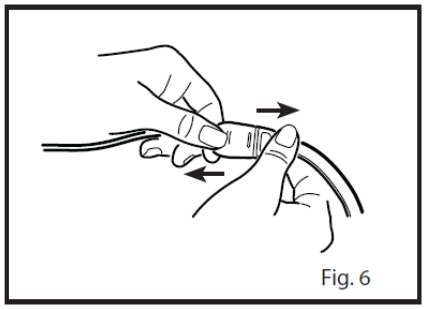



Fig. 28 Disconnecting the RD SET Sensor from the RD SET Patient Cable

## 5.10.2 LNC Patient Cable

See Fig. 8 in Fig. 29: Lift the protective cover to gain access to the sensor connector (1). Pull firmly on the sensor connector to remove from the patient cable (2).

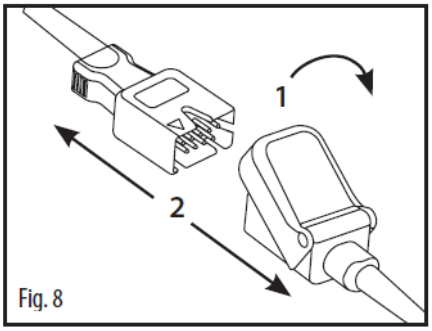



Fig. 29 Disconnecting the LNCS Sensor from the LNC Patient Cable

# 5.11 Disconnecting the SpO2 Cable from VitaGuard

Using your thumb and index finger, carefully press the two levers on the sides of the patient cable's plug and then carefully pull out the plug.

Pull the connector straight out of the socket. Avoid unnecessary up/down or left/right movements.

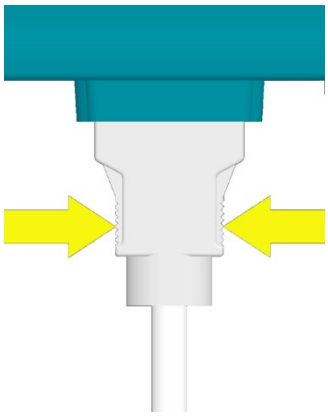


Fig. 30 Levers for Securing and Releasing the Patient Cable Plug

# 6. Alarm System

## 6.1 Introduction

The VitaGuard monitor distinguishes between the following alarm and message categories:

- patient alarms (physiological alarms),
- technical alarms, and
- informational messages,

and, depending on the current situation, outputs feedback to the caregiver through various channels:

- information on the monitor screen,
- flashing visual indicators (LEDs) on the front panel, and
- acoustic signals.

A patient alarm is generated when VitaGuard detects values that violate one or more of the set alarm limits for longer than the corresponding set period. Patient alarms are referred to as HIGH priority alarms.

A technical alarm is generated when VitaGuard detects a technical issue with the monitor itself or with the $SpO_2$ sensor and/or cable during monitoring. Technical alarms are referred to as MEDIUM priority alarms.

Informational messages are displayed when VitaGuard detects a situation about the status of the monitor or its accessories that does not require immediate attention by the caregiver.

This chapter explains the operation of the alarm system and the feedback provided to the caregiver.

## 6.2 Patient Alarms

When the monitor is set to its default settings, patient alarms are generated when one or more of the following conditions are detected by the alarm system:

- the pulse rate falls below the **PR Lower Limit** displayed on the screen for longer than the set **PR Bradycardia Delay**;
- the pulse rate exceeds the **PR Upper Limit** displayed on the screen for longer than the set **PR Tachycardia Delay**;
- the $SpO_2$ value falls below the **$SpO_2$ Lower Limit** displayed on the screen for longer than the set **$SpO_2$ Hypoxia Alarm Delay**; or
- the $SpO_2$ value exceeds the **$SpO_2$ Upper Limit** displayed on the screen for longer than the set **$SpO_2$ Hyperoxia Alarm Delay**.

Go immediately to the patient when an alarm occurs and check the patient's condition.

Depending on the medical condition of the patient, the responsible physician can configure the monitor to generate the following additional patient alarms:

- sudden decrease in the pulse rate value without actually falling below the **PR Lower Limit**;
- sudden increase in the pulse rate value without actually rising above the **PR Upper Limit**;
- sudden decrease in $SpO_2$ without actually falling below the **$SpO_2$ Lower Limit**.

Once a patient alarm is detected, VitaGuard outputs the following acoustic and visual information to inform the caregiver:

- an acoustic alarm, consisting of two sequences of five tones is generated. The interval between each tone packet is approx. ¾ of a second. Also, there is a slightly longer interval between the 3rd and 4th tone of each sequence. The interburst interval is 7 seconds;


Fig. 31 Characteristics of Acoustic Alarm Signal for Patient Alarms

- the alarm reset symbol on the monitor's front panel flashes red twice per second;
- the monitor screen outputs the following visual information, as shown in Fig. 32:
  - a message describing the alarm type is displayed on the status line. The message text for patient alarms ends with three exclamation marks "!!!";
  - the bell symbol in the upper right-hand corner of the screen is replaced by a flashing red triangle symbol;
  - the title bar of the parameter causing the alarm condition is highlighted in red;
  - the alarm limit causing the alarm condition turns red.

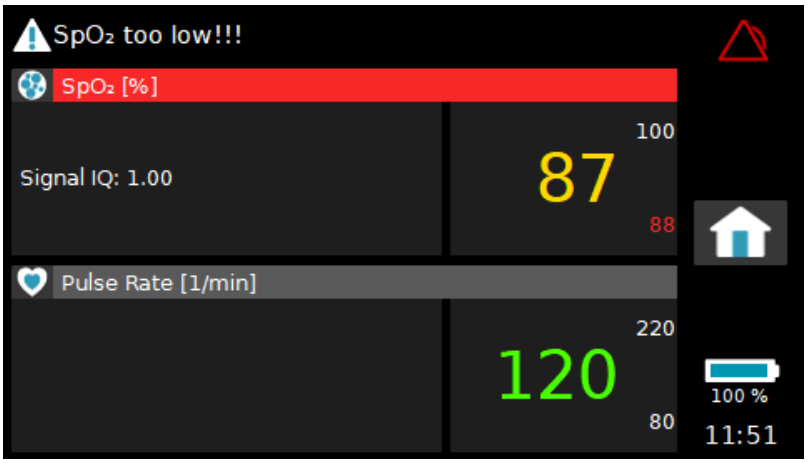



Fig. 32 Information on the Monitor Screen during a Patient Alarm

By pressing the <Esc> key during an alarm condition, the acoustic alarm signal can be deactivated for this alarm situation. In this case, the red triangle is replaced by a flashing crossed-out bell symbol.

By pressing the <Esc> key a second time during the alarm condition, the acoustic alarm is immediately reactivated and the flashing red triangle reappears.

When the alarm condition no longer exists, the affected alarm limit remains red in colour until the <Esc> key is pressed by the caregiver. This function provides instant feedback to the caregiver on the type of alarm condition that was previously detected.

Section 6.8.1 provides an extensive overview of all the patient alarm messages, their priorities in relation to each other, and, if applicable, troubleshooting information if such alarms are being generated due to reasons outside the patient.

## 6.3 Silent Patient Alarms

The responsible physician may wish to configure the monitor to detect less critical events by setting silent alarm limits for the monitored parameters. Silent patient alarms are generated when one or more of the following conditions are detected by the alarm system:

- the displayed pulse rate falls below the PR Silent Lower Limit for longer than the set PR Bradycardia Delay;
- the displayed pulse rate exceeds the PR Silent Upper Limit for longer than the set PR Tachycardia Delay;
- the displayed $SpO_2$ value falls below the $SpO_2$ Silent Lower Limit for longer than the set $SpO_2$ Hypoxia Alarm Delay; or when
- the displayed $SpO_2$ value exceeds the $SpO_2$ Silent Upper Limit for longer than the set $SpO_2$ Hyperoxia Alarm Delay.

The monitor's default settings are such that silent alarms are deactivated. The various settings for activating the silent alarms are explained in section 8.

If a silent alarm condition is detected, an event is logged in the alarm event log without triggering an acoustic or visual alarm, as explained in section 9.1.

## 6.4 Technical Alarms

Technical alarms are generated when a condition is detected which impairs the monitors ability to monitor the patient's vital signs or impairs reliable operation. Such conditions include:

- the $SpO_2$ sensor is off the patient;
- the patient cable is not connected or is faulty;
- the battery capacity is low; or
- an internal fault is detected.

When a technical alarm condition occurs, a life-threatening situation may escape detection. Therefore, go immediately to the monitor when a technical alarm occurs and check the patient's condition.

Once a technical alarm is detected, VitaGuard outputs the following acoustic and visual information to inform the caregiver:

- an acoustic alarm consisting of a sequence of three tones with an interburst interval of 7.2 seconds is generated. The interval between each individual tone in the sequence is identical;
- the alarm symbol on the monitor's front panel flashes yellow twice per second;
- the monitor screen outputs the following visual information, as shown in Fig. 33:
  - a message describing the technical alarm type is displayed on the status line. The message text for technical alarms ends with two exclamation marks "!!";
  - the bell symbol in the upper right-hand corner of the screen is replaced by a flashing yellow triangle symbol.

By pressing the <Esc> key during a technical alarm condition, the acoustic alarm signal can be deactivated for this alarm situation. In this case, the yellow triangle is replaced by a flashing crossed-out bell symbol.

By pressing the <Esc> key a second time during the technical alarm condition, the acoustic alarm is immediately reactivated and the flashing yellow triangle reappears.


Fig. 33 Information on the Monitor Screen during a Technical Alarm

When the technical alarm condition no longer exists, the monitor screen returns to its normal status.

Section 6.8.2 provides an extensive overview of all the technical alarm messages and, if applicable, troubleshooting information to help resolve the situation.

If two technical alarms occur simultaneously, then the alarm with the highest priority will be reported first. Once this condition is resolved, the lower priority alarm will be reported.

If vital signs cannot be measured due to a technical alarm, then the values for that parameter are replaced by a question mark symbol, as shown in Fig. 33.

NOTE: In order to prevent false alarms when the vital signs are being recalculated following a technical alarm triggered by problems with the $SpO_2$ sensor, an alarm pause time of ten seconds automatically follows such technical alarms. During the alarm pause time, the bell symbol in the status line is crossed out.

## 6.5 Alarm Test

The alarm system should be checked daily. To test the alarm system, deliberately trigger a technical alarm when a patient is connected as follows:

1 disconnect the $SpO_2$ sensor from the $SpO_2$ patient cable, and

2 remove the external power supply to confirm switchover to battery mode.

When beginning monitoring at a new site, make sure you can clearly hear the alarm signal over any prevailing background noise. For this purpose, deliberately trigger a technical alarm as described above.

NOTE: The alarm tone volume can be selected in the Alarm Volume setting in the System menu.

## 6.6 Informational Messages

Informational messages are displayed in the status line if a condition is detected that does not require immediate attention. These messages have the lowest priority and will be overwritten should either a patient or technical alarm condition occur simultaneously.

Section 6.8.3 provides an extensive overview of all the informational messages, their priorities in relation to each other, and, if applicable, troubleshooting information to help resolve the condition.

## 6.7 Reminder Signal

After the monitor is switched on, a short acoustic reminder signal is emitted every twenty seconds until the $SpO_2$ sensor is connected and plausible data have been detected.

## 6.8 Alarm Messages and Troubleshooting

The tables in this section list all the text messages that can appear on the VitaGuard display together with more detailed explanations and troubleshooting tips.

### 6.8.1 Patient Alarm Messages

Patient alarms are reported with high priority, as indicated by the three exclamation marks "!!!" at the end of each message.

| Message | Meaning | Troubleshooting |
|---|---|---|
| Pulse rate and $SpO_2$!!! | A pulse rate alarm and an $SpO_2$ alarm have occurred simultaneously. | See the messages and information for "Pulse rate too high!!!/too low!!!" and "$SpO_2$ too low!!!/too high!!!". |
| Pulse rate too high!!! | The calculated pulse rate exceeds the set **PR Upper Limit** for longer than the set **PR Tachycardia Delay**. | When there is no tachycardia:<br>– The sensor is incorrectly attached, e.g. it is too loose or too tight, the transmitter and receiver are too far apart, or they are not exactly opposite each other.<br>– The sensor has become detached<br>– The blood flow is weak or obstructed e.g. by a pressure cuff. |

| Message | Meaning | Troubleshooting |
|---|---|---|
| | | – Strong artifacts caused by excessive movement trigger false alarms.<br>To remedy the above, try a new sensor or a different application site.<br>– The monitor, cable, or sensor is defective.<br>– The set **PR Upper Limit** is too low. |
| Pulse rate too low!!! | The calculated pulse rate has fallen below the set **PR Lower Limit** for longer than the set **PR Bradycardia Delay**. | When there is no bradycardia:<br>– The sensor is incorrectly attached, e.g. it is too loose or too tight, the transmitter and receiver are too far apart, or they are not exactly opposite each other.<br>– The sensor has become detached.<br>– The blood flow is weak or obstructed, e.g., by a pressure cuff.<br>– No pulse is detected.<br>– There are abnormal beats.<br>To remedy the above, try a new sensor or a different application site.<br>– The monitor, cable, or sensor is defective.<br>– The set **PR Lower Limit** is too high. |
| Pulse rate drop detected!!! (when activated) | The current pulse rate has fallen below the value based on the set **PR Deviation Averaging Interval** by more than the percentage deviation value set under **PR Deviation Alarm Limit (–)**. | When there is no pulse rate drop:<br>– The pulse rate and/or the average pulse rate is incorrectly calculated for the reasons given under "Pulse rate too low!!!". |
| Pulse rate rise detected!!! (when activated) | A pulse rate rise is detected in the same manner as a pulse rate drop, but **PR Deviation Alarm Limit (+)** is used instead. | When there is no pulse rate rise:<br>– The pulse rate and/or the average pulse rate is incorrectly calculated for the reasons given under "Pulse rate too high!!!". |
| $SpO_2$ too high!!! | The calculated $SpO_2$ exceeds the set **$SpO_2$ Upper Limit** for longer than the set **$SpO_2$ Hyperoxia Alarm Delay**. | When $SpO_2$ is not too high:<br>– The sensor is incorrectly attached, e.g. it is too loose or too tight, the transmitter and receiver are too far apart, or they are not exactly opposite each other.<br>– The sensor has become detached. |

| Message | Meaning | Troubleshooting |
|---|---|---|
| | | – The blood flow is weak or obstructed e.g. by a pressure cuff.<br>– Strong artifacts caused by movements corrupt the signal.<br>To remedy the above, try a new sensor or a different application site.<br>– The monitor, cable, or sensor is defective.<br>– The set upper alarm limit is too low. |
| $SpO_2$ too low!!! | The calculated $SpO_2$ has fallen below the set **$SpO_2$ Lower Limit** for longer than the set **$SpO_2$ Hypoxia Alarm Delay**. | See "$SpO_2$ too high!!!". |
| $SpO_2$ drop detected!!! (when activated) | The currently measured $SpO_2$ has fallen below the value based on the set **$SpO_2$ Deviation Averaging Interval** by more than the percentage deviation value set under **$SpO_2$ Deviation Alarm Limit (–)**. | When there is no $SpO_2$ drop:<br>– The present $SpO_2$ or the value based on the set **$SpO_2$ Deviation Averaging Interval** is incorrect for the reasons given under "$SpO_2$ too high!!!". |
| Connect power adapter NOW!!! | The monitor is being powered by the rechargeable battery and the battery is exhausted.<br>ATTENTION!!!<br>The monitor will automatically shut down soon. | Immediately connect the monitor to the mains power supply in order to continue monitoring the patient.<br>If the monitor shuts down due to battery exhaustion, refer to 3.5.3 in order to switch off the power fail alarm. |

In addition to the troubleshooting information listed above, refer to section 5.2 for other potential causes of inaccurate $SpO_2$ and pulse rate readings.

### 6.8.2 Technical Alarm Messages

Technical alarms are reported with medium priority, as indicated by the two exclamation marks "!!" at the end of each message.

| Message | Meaning | Troubleshooting |
|---|---|---|
| Check power adapter!! | A fault related to the external power adapter has been detected. | Verify that you are using the power adapter supplied with the monitor.<br>If yes, switch off the monitor, remove and reconnect the power adapter, then switch the monitor back on.<br>If this message persists, replace the external power adapter immediately. |
| Device temperature too high!! | The temperature inside the monitor is above 55 °C. | Make sure the monitor is not exposed to direct sunlight, e.g., on a window ledge, or is not placed on a heat source. Relocate the monitor to a cooler location.<br>If this message persists, return the monitor for service immediately. |
| Device temperature too low!! | The temperature inside the monitor is below 5 °C. | If the monitor has been stored in a cold environment, please wait until it reaches room temperature. |
| Key fault detected!! | A pushbutton key on the front panel is faulty. | Return the monitor for service immediately.<br>If it is not possible to switch off the monitor, use the hardware reset in section 6.8.5. |
| Nurse call cable disconnected!! | The nurse call cable has been disconnected | Reconnect the nurse call cable or press the <Esc> key to stop the technical alarm. |
| Nurse call cable fault detected!! | A communication error with the nurse call cable has been detected. | Remove and reconnect the nurse call cable.<br>If this message persists, replace the cable immediately. |
| Power adapter disconnected!! | The power adapter has been disconnected. | Reconnect the external power adapter or press the <Esc> key to stop the technical alarm. |
| Recharge battery!! | The battery capacity is below 8 %. The monitor will soon no longer be able operate reliably. | Immediately operate the monitor from the external power adapter to recharge the battery. |

| Message | Meaning | Troubleshooting |
|---|---|---|
| Check power adapter!! | A fault related to the external power adapter has been detected. | Verify that you are using the power adapter supplied with the monitor.<br>If yes, switch off the monitor, remove and reconnect the power adapter, then switch the monitor back on.<br>If this message persists, replace the external power adapter immediately. |
| Service: Alarm speakers defect!! | VitaGuard has detected that the alarm speakers are defective. | Return the monitor for service immediately.<br>NOTE: As the speakers are not working, there will be no acoustic alarm. |
| Service: Hardware fault detected!! | The monitor has detected an internal hardware fault. | Switch off the monitor, wait for thirty seconds, and switch it back on.<br>If this message persists, the monitor is defective. Return it for service. |
| Service: Software error detected!! | The monitor has detected an internal software error. | Switch off the monitor, wait for thirty seconds, and switch it back on.<br>If this message persists, the monitor is defective. Return it for service. |
| $SpO_2$: Check sensor!! | A problem with the $SpO_2$ sensor has been detected. | Disconnect and reconnect the sensor.<br>If this message persists, replace the $SpO_2$ sensor. |
| $SpO_2$: Defective sensor!! | The $SpO_2$ sensor is defect or has reached end-of-life. | Disconnect and reconnect the sensor.<br>If this message persists, replace the $SpO_2$ sensor. |
| $SpO_2$: Hardware fault detected!! | The $SpO_2$ module has output a fault message or has stopped communicating. | Switch off the monitor, wait for thirty seconds, and switch it back on.<br>If this message persists, the monitor is defective. Return it for service. |
| $SpO_2$: Incompatible cable!! | $SpO_2$ cable is not compatible with Masimo's SET technology. | Connect a new, compatible $SpO_2$ cable.<br>See section 2.3 for a list of compatible cables. |
| $SpO_2$: Incompatible sensor!! | $SpO_2$ sensor is not compatible with Masimo's SET technology. | Connect a new, compatible $SpO_2$ sensor.<br>See section 2.3 for a list of compatible sensors. |
| $SpO_2$: Interference detected!! | The $SpO_2$ module detects electromagnetic interference. | Locate any interference sources in the direct vicinity and, if possible, remove them. |

| Message | Meaning | Troubleshooting |
|---|---|---|
| Check power adapter!! | A fault related to the external power adapter has been detected. | Verify that you are using the power adapter supplied with the monitor.<br>If yes, switch off the monitor, remove and reconnect the power adapter, then switch the monitor back on.<br>If this message persists, replace the external power adapter immediately. |
| $SpO_2$: No cable connected!! | The $SpO_2$ cable is not connected. | Connect the $SpO_2$ cable to the monitor.<br>If this message persists, replace the $SpO_2$ cable. |
| $SpO_2$: No sensor connected!! | The $SpO_2$ sensor is defective or not connected to the cable. | Check whether the $SpO_2$ sensor is correctly connected to the cable.<br>If this message persists, replace the sensor. |
| $SpO_2$: No adhesive sensor connected!! | The $SpO_2$ adhesive sensor is defective or not connected to the cable. | Check whether the $SpO_2$ adhesive sensor is correctly connected to the cable.<br>If this message persists, replace the sensor. |
| $SpO_2$: Replace cable!! | The $SpO_2$ cable is defective or has reached end-of-life. | Replace the $SpO_2$ cable. |
| $SpO_2$: Sensor off patient!! | The $SpO_2$ sensor has come off the patient. | Check the application site and reattach the sensor. |
| $SpO_2$: Too much ambient light!! | The $SpO_2$ module reports that there is too much ambient light. | Protect the $SpO_2$ sensor from light sources, e.g. by covering it. |
| $SpO_2$: Unrecognized sensor!! | The $SpO_2$ sensor cannot be recognized. | Replace the $SpO_2$ cable. |

If the monitor needs to be returned for service, consult your authorized dealer to organize the return process. Refer to the service information in section 1.8 for further details.

### 6.8.3 Informational Messages

| Message | Meaning | Troubleshooting |
|---|---|---|
| Mechanical shock detected | VitaGuard has been exposed to sudden mechanical shock. | Visually inspect the monitor for any signs of physical damage. If you suspect any fault, return the monitor for service immediately. |
| Service: Auxiliary battery low | The auxiliary battery for alarms during a power failure is depleted. | The auxiliary battery needs to be replaced by a technician.<br>Return the monitor for service. |
| Service: Replace battery | The rechargeable battery pack has reached end-of-life and needs to be replaced. | The rechargeable battery needs to be replaced by a technician.<br>Return the monitor for service. |
| Recharge battery | The battery capacity is below 20 %. | To avoid escalating alarms for low battery capacity, connect the external power adapter immediately. |
| $SpO_2$: Cable near expiration | The cable is getting near the end of its intended lifetime | Replace the $SpO_2$ cable soon.<br>Contact your authorized dealer for a new cable. |
| $SpO_2$: Low perfusion | The $SpO_2$ module reports that the blood flow is too weak. | Either use a different application site, or set **Sensitivity** to **Maximum** in the $SpO_2$ menu. |
| $SpO_2$: Low signal IQ | The $SpO_2$ module reports that the signal quality is low. | Use a different application site, or check for the presence of light or electromagnetic interference sources in the vicinity.<br>Whenever possible, prevent vigorous movements by the patient. |
| $SpO_2$: Pulse search | The $SpO_2$ module is acquiring the patient's pulse. | If this message persists, select a different application site. |
| $SpO_2$: Replace cable next patient | The cable has reached the end of its intended lifetime | Use a new $SpO_2$ cable the next time you switch on the monitor.<br>Contact your authorized dealer for a new cable. |
| $SpO_2$: Replace sensor next patient | The sensor has reached the end of its intended lifetime | Use a new $SpO_2$ sensor the next time you switch on the monitor.<br>Contact your authorized dealer for new sensors. |
| $SpO_2$: Sensor initializing | The $SpO_2$ module is initializing the sensor. | If this message persists, replace the sensor. |

| Message | Meaning | Troubleshooting |
|---|---|---|
| $SpO_2$: Sensor near expiration | The sensor is getting near the end of its intended lifetime. | Replace the sensor soon.<br>Contact your authorized dealer for new sensors. |
| Status: ok | No messages | Monitoring active. |

### 6.8.4 Error Messages during Start-Up

During the start-up procedure, the monitor runs a set of internal tests to check for any hardware faults or discrepancies in the internal file structures.

If an error is reported on the screen, the monitor will need to be returned for service. Contact your authorized dealer to organize the return process.

### 6.8.5 Hardware Reset

If, due to an internal fault, the monitor is not operational, i.e., is not reacting to user actions on the keys or display and is outputting an alarm tone, it may be switched off by carefully inserting a pin or paper clip into the small 1 mm hole to the left of the USB connector on the connector panel. An internal reset button located directly behind the hole switches off the monitor and deactivates the alarm tone generator.

The monitor will need to be returned for service. Contact your authorized dealer to organize the return process, as described in section 1.8.

## 6.9 Alarm Function Test

Healthcare professional operators and/or service technicians can use the following procedure to test the proper functioning of the alarm system for each of the alarm conditions.

Connect the VitaGuard monitor to an $SpO_2$ patient simulator, e.g., Oxytest Plus 7 from Datrend Systems Inc., as described in the manufacturer's instructions for use.

Using the simulator, sequentially select values for pulse rate and $SpO_2$ that exceed and fall below the corresponding alarm limits set on the monitor and confirm that the monitor outputs an appropriate alarm for each alarm type.

# 7. Monitor Views

## 7.1 Introduction

The VitaGuard monitor is designed for use in both home and clinical environments. For safety reasons, certain views are not accessible when the monitor is configured for home use and may only be activated by the responsible physician by entering a four-digit code. There are three Settings Protection modes available:

- On
- Limited
- Off

In the default state, the Settings Protection mode is switched On for home use.

## 7.2 Views (Settings Protection Mode On)

### 7.2.1 Home Screen

With the Settings Protection mode switched On, VitaGuard's Home screen displays the following icons:

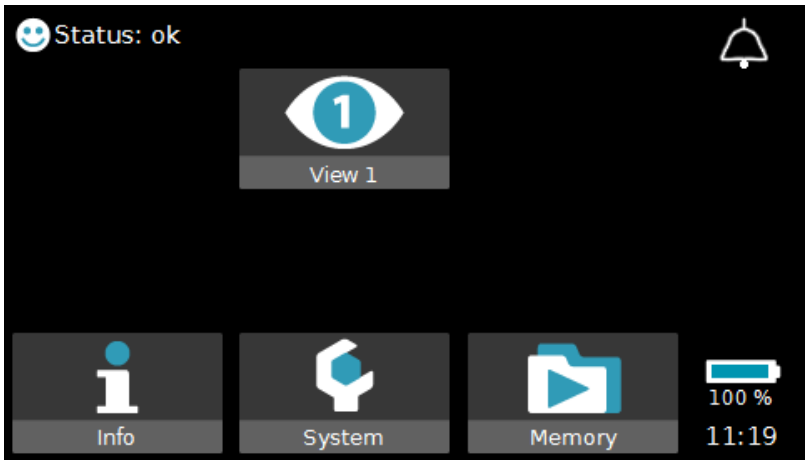



Fig. 34 Home Screen with Settings Protection On

The Home screen is the screen used to navigate through VitaGuard's user interface. Regardless of the currently selected view, the Home screen can be reached by touching the 

Home icon located on the right-hand side of the screen, as explained in section 3.4.6 for View 1, which is the standard view for home use.

In addition to View 1 explained in section 3.4.6, the following views may also be accessed when the settings protection mode is on:

- Info view
- System view
- Memory view

### 7.2.2 Info View

The Info view may be accessed by touching the Info icon. Upon doing so, the first page of information is displayed on the screen. The first page displays a list of the previous 10 messages that were displayed on the status line together with their respective date and time of occurrence.

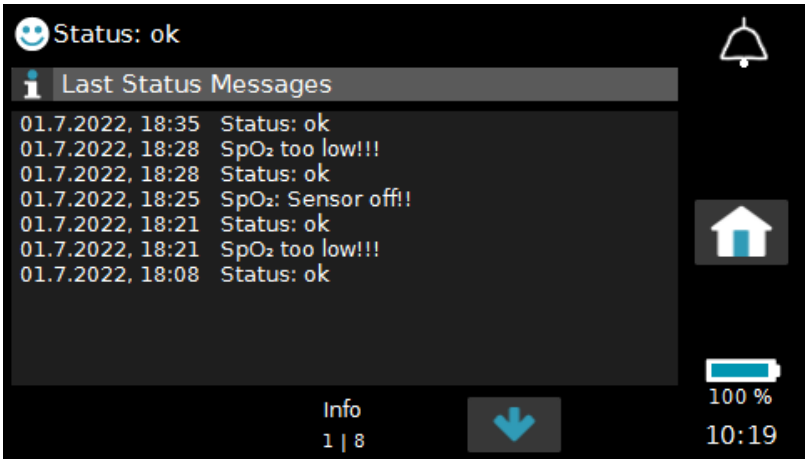



Fig. 35 Info View – Page 1

By touching the arrow at the bottom of the screen, the next page of information is displayed. The two numbers on the bottom of the screen under the title "Info" inform which page of information is currently displayed. In the example above, it is page 1 of 9. The content of the various information pages is explained in detail in section 7.5. To navigate back to the Home screen, simply touch the Home icon on the right-hand side of the screen, as previously explained.

### 7.2.3 System View

The **System** view provides access to the **System** settings that are available when the settings protection mode is **On**. These settings are:

- Screen
- Display Brightness
- Signal Beep Tone
- Alarm Volume
- Settings Protection

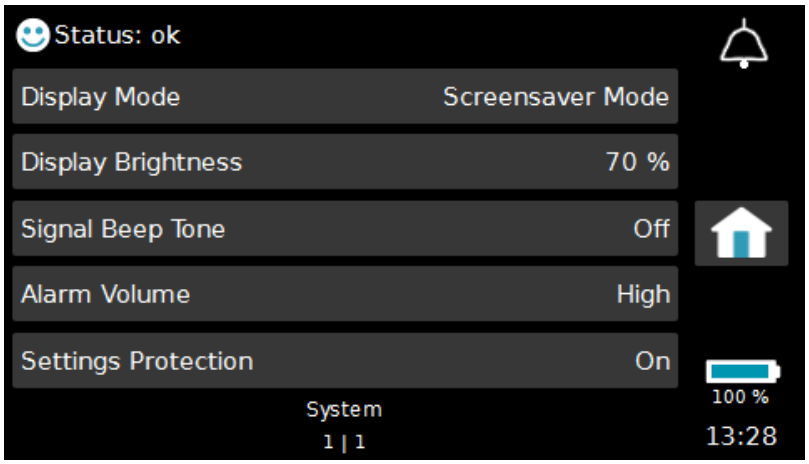



Fig. 36 System View with Settings Protection On

Detailed Information on the individual **System** settings is provided in section 8. The mechanisms for changing a setting are explained in section 8.2.

### 7.2.4 Memory View

The final view available when the settings protection mode is on is the **Memory** view shown in Fig. 37.

This view will always show the **USB Memory** icon. The **Man. Recording** icon will only be displayed if the responsible physician has set the **Manual Event Recording** setting prior to prescribing the monitor.

Data download to a USB memory stick is described in section 9.6; operation of the manual recording function is explained in section 9.1.

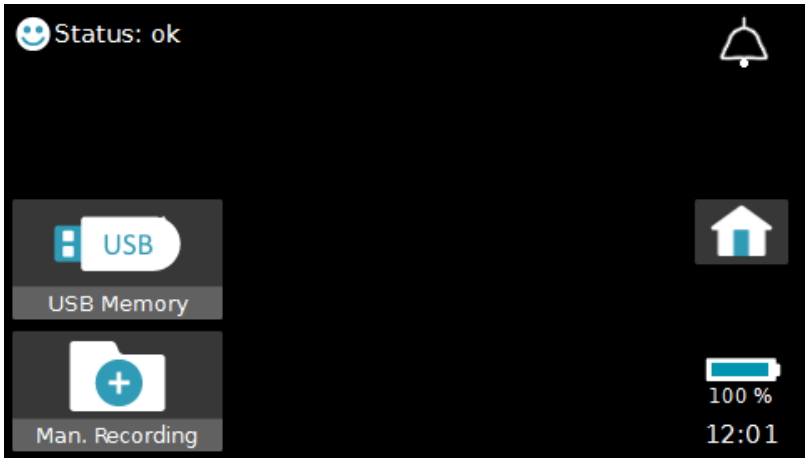



Fig. 37 Memory View with Settings Protection On

# 7.3 Views (Settings Protection Mode Limited)

## 7.3.1 Home Screen

To switch the **Settings Protection** mode to **Limited**, a four-digit code is required. In limited mode VitaGuard's **Home** screen displays the additional icons shown in Fig. 38:

- View 2 icon
- View 3 icon
- $SpO_2$ icon
- Pulse Rate icon

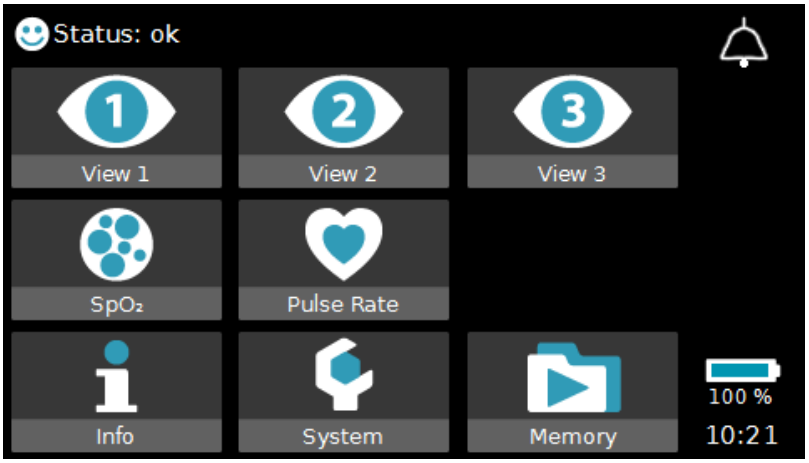



Fig. 38 Home Screen with Settings Protection Limited

## 7.3.2 View 2

**View 2** shown in Fig. 39 differs from **View 1** in that the quality indicators described in section 3.4.6 for **$SpO_2$** are replaced by their corresponding waveforms:

Plethysmogram →

Signal IQ →

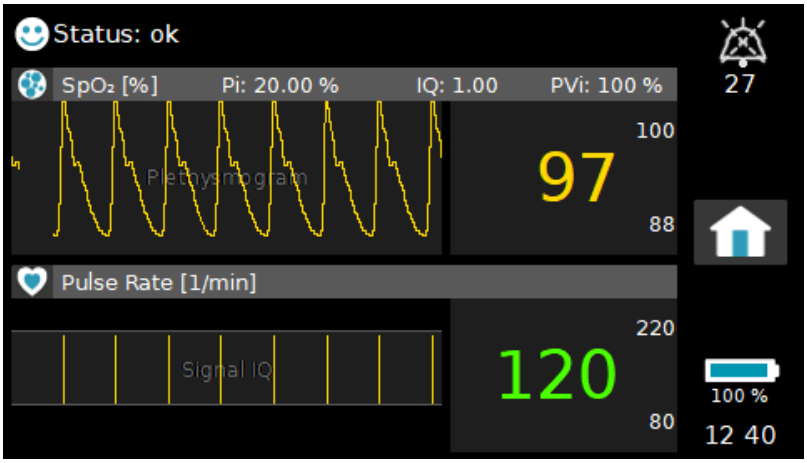



Fig. 39 View 2 Screen Content

The waveform in the **$SpO_2$** workspace is an auto-scaled plethysmogram waveform representing the pulsation of arterial blood detected by the $SpO_2$ sensor. The quality indicators for Perfusion Index (**Pi**)

and Signal IQ (IQ) are displayed in the title bar of the $SpO_2$ workspace, and, if available, the Pleth Variability Index (PVi) calculated by the $SpO_2$ module. More information on these parameters is provided in section 10.2.

NOTE: The plethysmogram is auto-scaled and therefore NOT proportional to the pulse volume. A regular plethysmogram, for example, indicates that the $SpO_2$ sensor is correctly applied.

The waveform displayed in the Pulse Rate workspace is the Signal IQ waveform. This waveform is a horizontal line that corresponds to each pulse detected by the $SpO_2$ module. The height of the line corresponds to the quality of the signal currently detected by the $SpO_2$ sensor: the higher the line, the better the quality, and visa-versa.

The remaining information displayed on the View 2 screen is the same as that described for View 1 in section 3.4.6.

### 7.3.3 View 3, SpO2 View and Pulse Rate View

The main differences in these views compared to View 2 are that the current values for $SpO_2$ and pulse rate together with their corresponding alarm limits are displayed along the top of the screen and the two corresponding waveforms are displayed across the whole width of the screen, as shown in Fig. 40.

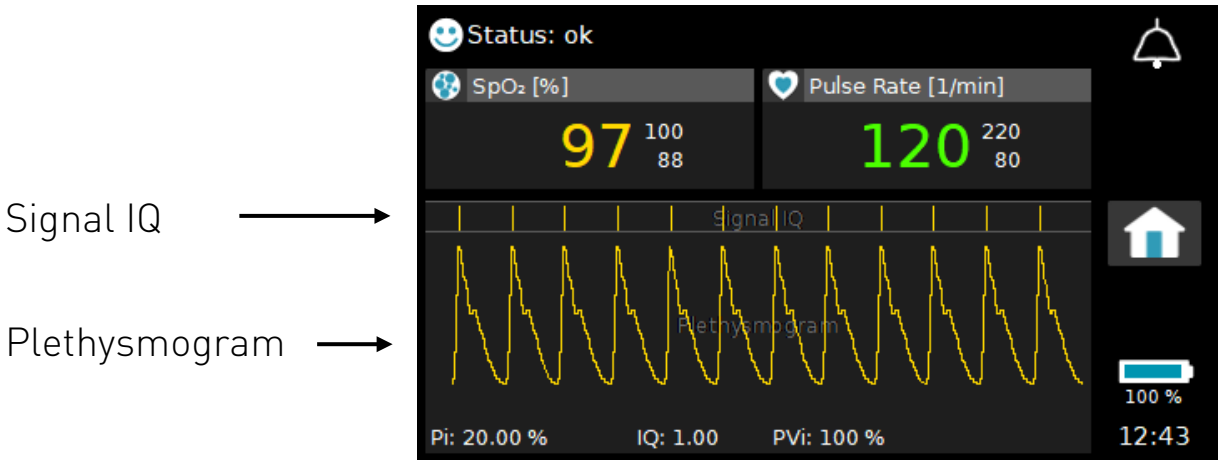



Fig. 40 View 3, $SpO_2$ View and Pulse Rate View Screen Content

The numerical quality indicators for Perfusion Index (Pi), Signal IQ (IQ) and, if available, the Pleth Variability Index (PVi), are displayed along the bottom of the screen.

### 7.3.4 Memory View

When the Settings Protection mode is set to Limited, the Memory view in Fig. 41 contains two further icons along the top of the screen for events and trends. These icons are used to access and view the lists of stored alarm events and trend recordings, and are explained in detail in sections 9.1 and 9.2.

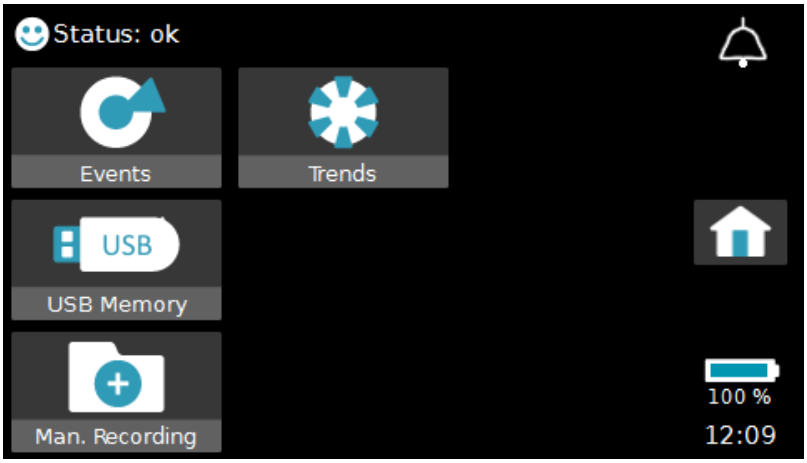



Fig. 41 Memory View with Settings Protection Limited

## 7.4 Views (Settings Protection Mode Off)

To switch off the settings protection mode, a four-digit code is required. There are no additional views available in this mode above and beyond the views already described in the previous sections for the settings protection on and the settings protection limited modes. The only difference in this mode is that all configuration settings are accessible, as explained in sections 8.6, 8.7 and 8.8.

## 7.5 Info Views

This section explains the content of the individual Info pages. Use the up and down arrow icons to scroll through the pages.

### 7.5.1 Info \ Page 1: Last Status Messages

Page 1 of the Info view shows the previous ten messages that were displayed on the status line along with their date and time of occurrence.

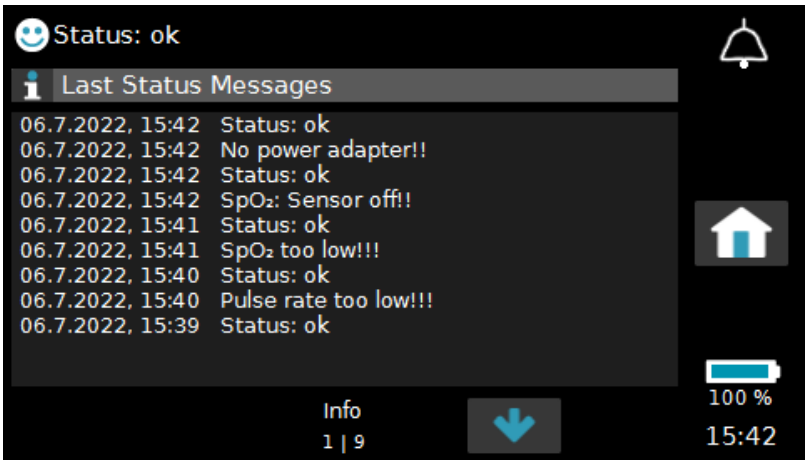



Fig. 42 Info \ Page 1: Previous Status Messages

## 7.5.2 Info \ Page 2: General Information

Page 2 shows the following general information:

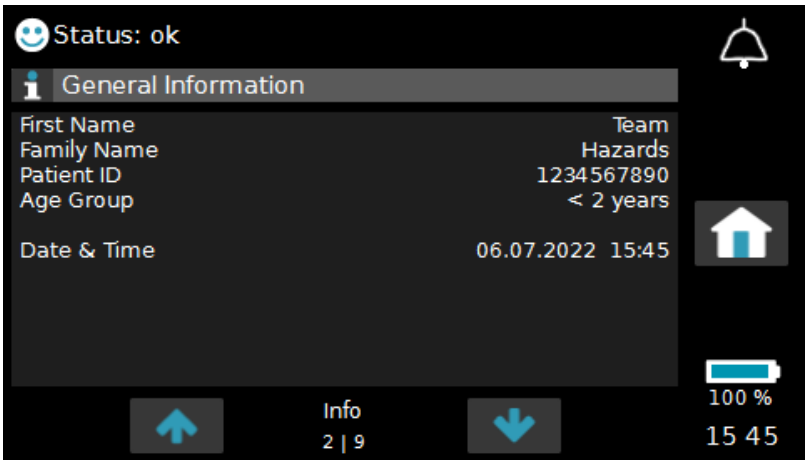



Fig. 43 Info \ Page 2: General Information

- Patient Name & Patient ID: The patient's name and ID are displayed when they have been downloaded to the monitor from a PC running the VitaWin software, or when they have been entered directly into the monitor during execution of the Admit New Patient procedure explained in section 8.6.2.
- Age Group: This displays the age group that was selected during execution of the Admit New Patient procedure explained in section 8.6.2.
- Date & time: This displays the date and time of the internal clock which can be set in the System menu explained in section 8.6.7.

### 7.5.3 Info \ Page 3: System Status

Page 3 provides information on the memory currently used to log data in addition to information about the status of the internal auxiliary battery and the rechargeable battery pack.

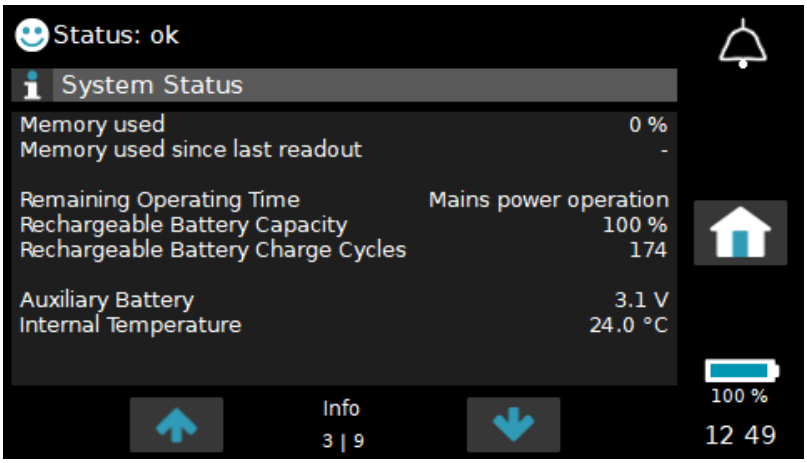



Fig. 44 Info \ Page 3: System Status

The auxiliary battery powers an internal buzzer if the system crashes, as explained in section 3.5.3. If the battery voltage falls below 2.5 V, return the monitor for service.

In addition to the current capacity of the rechargeable battery pack and remaining operating time in battery mode, Page 3 shows the number of charge cycles the battery pack was subject to in the past.

The temperature displayed is the internal temperature of the monitor and should be in the vicinity of the room temperature. If the temperature displayed is too high, check that the monitor is not located beside a heat source or exposed to direct sunlight.

### 7.5.4 Info \ Page 4: Measurements: $SpO_2$

Page 4 displays various average values for $SpO_2$ calculated since the monitor was switched on: last minute, last hour (1h), last six hours (6h), and last twelve hours (12h).

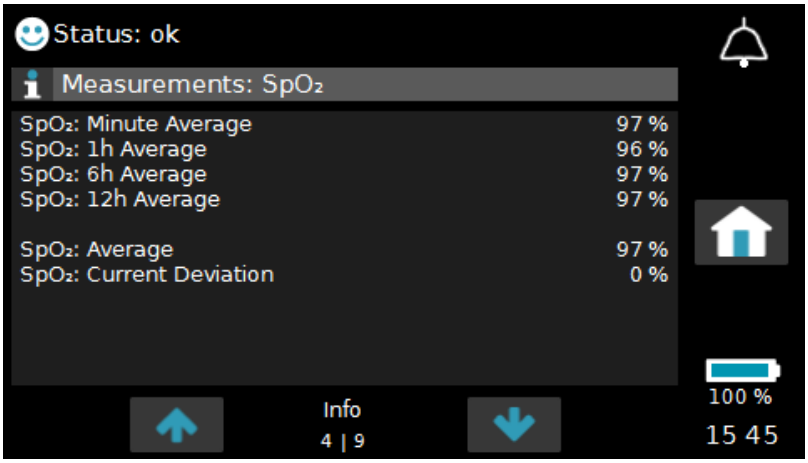



Fig. 45 Info \ Page 4: Measurements: $SpO_2$

In addition, the average value calculated over the interval defined in the SpO2 Deviation Averaging Interval along with the current deviation from this average are shown. This deviation is used for detecting deviation alarms when the SpO2 Alarms setting is set to Limits & Deviations.

NOTE: The above values are lost when the monitor is switched off.

### 7.5.5 Info \ Page 5: Measurements: Pulse Rate

Page 5 displays various average values for the pulse rate (PR) calculated since the monitor was switched on: last minute, last hour (1h), last six hours (6h), and last 12 hours.

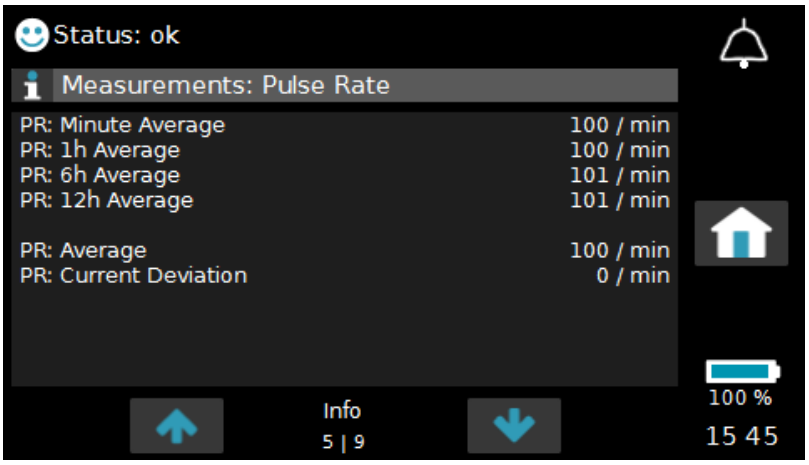



Fig. 46 Info \ Page 5: Measurements: Pulse Rate

In addition, the average value calculated over the interval defined in the PR Deviation Averaging Interval along with the current deviation from this average are shown. This deviation is used for detecting deviation alarms when the PR Alarms setting is set to Limits & Deviations.

### 7.5.6 Info \ Page 6: Current Settings: SpO2

Page 6 provides an overview of all SpO2 related settings.

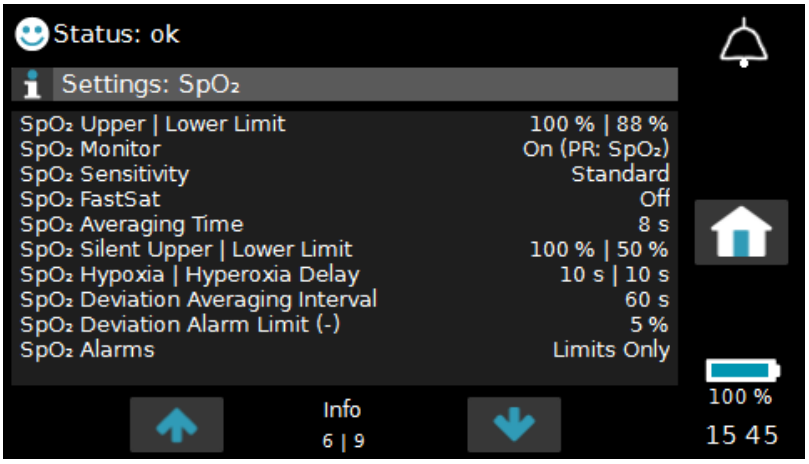



Fig. 47 Info \ Page 6: Current Settings: SpO2

### 7.5.7 Info \ Page 7: Current Settings: Pulse Rate

Page 7 provides an overview of all pulse rate related settings.

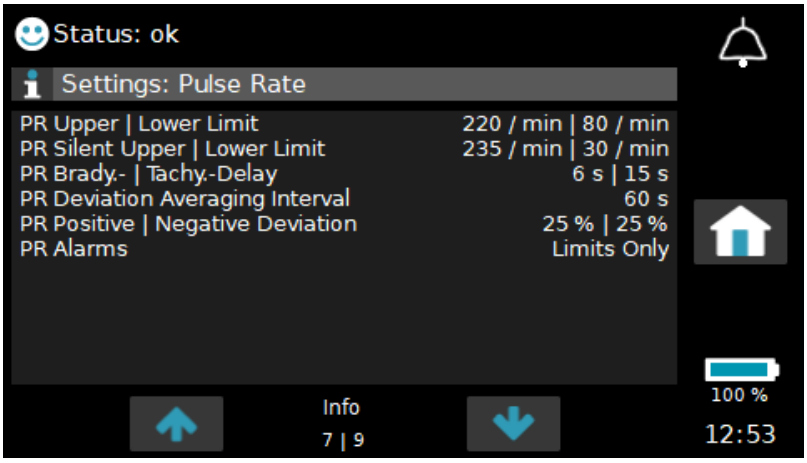



Fig. 48 Info \ Page 7: Current Settings: Pulse Rate

### 7.5.8 Info \ Page 8: Versions

Page 8 provides technical information about the hardware and software versions of the mainboard and the Masimo $SpO_2$ module.

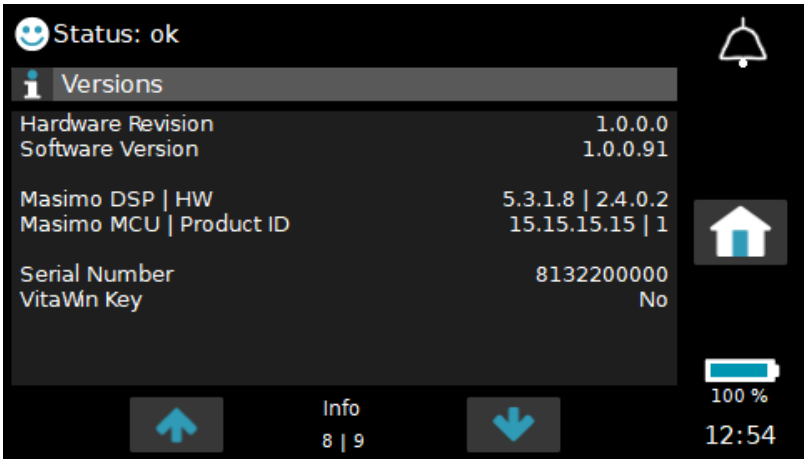



Fig. 49 Info \ Page 8: Versions

### 7.5.9 Info \ Page 9: License Information

Page 9 shows where to find our open-source license information.

This device uses open-source software. The license texts are automatically downloaded to a USB memory drive when downloading logged alarm data, as described in section 9.6. For more information contact us at info@getemed.de.

# 8. Settings

## 8.1 Introduction

The VitaGuard monitor is designed for use in both home and clinical environments. For safety reasons, certain settings are not accessible when the monitor is configured for home use and may only be activated by the responsible physician by entering a four-digit Settings Protection code.

All settings are stored and retained when the monitor is switched off and back on again.

All current settings can be viewed in the Info screens explained in section 7.5.

## 8.2 Changing Settings

This section explains the general mechanism for changing a setting in the monitor menus.

Fig. 36 showed the settings available in the System view when the Settings Protection mode is switched on. To access one of these settings, gently touch the corresponding line on the screen. Upon doing so, a dialog will appear showing the options that may be selected. As an example, if the Display Brightness setting is selected, the following dialog appears:

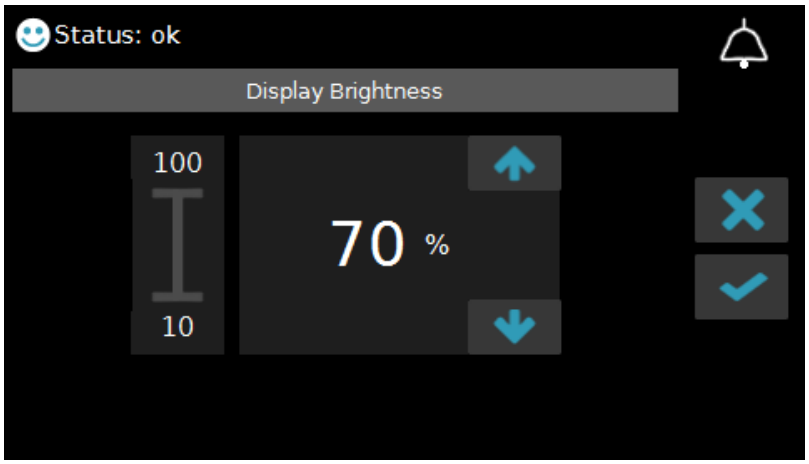



Fig. 50 Settings Dialog for Display Brightness

The bar on the left shows the range of values available for display brightness. The brightness may be selected between the minimum

value of 10 % and the maximum value of 100 %. The current value of 70 % is shown in the middle of the screen. To exit the dialog, touch the "X" icon on the right-hand side of the screen.

To change the value up or down, touch the corresponding arrow beside the current value. The value shown in large digits in the middle of the screen will change accordingly. Once you reach the value you wish to set, touch the **Check** icon on the right-hand side of the screen. This will open a dialog showing the new value and asking you to press either the <**Enter**> key or the <**Esc**> key on the monitor's front panel:

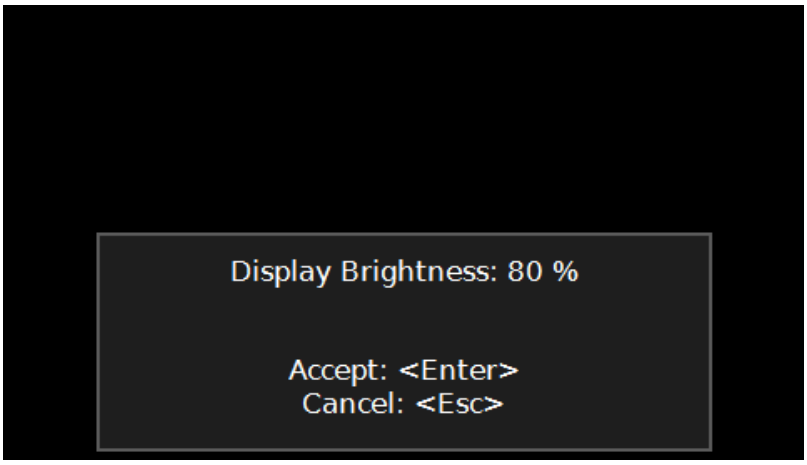



Fig. 51 Dialog to Accept or Reject a Change of a Setting

By pressing the <**Enter**> key, the change will be accepted; by pressing the <**Esc**> key, the change will be rejected. A short message will be displayed confirming the action you have chosen. Once this message disappears, the list of settings shown in Fig. 36 will reappear. If no action is taken, the dialog will automatically disappear after approximately 10 seconds and, again, the list of settings shown in Fig. 36 will reappear. To return to the **Home** screen, simply touch the **Home** icon.

Some menus are designed to change numerical values, as in the brightness example above, whereas other menus are designed to allow you to select from a list of options. As an example, consider the **Signal Beep Tone** setting in the **System** menu:

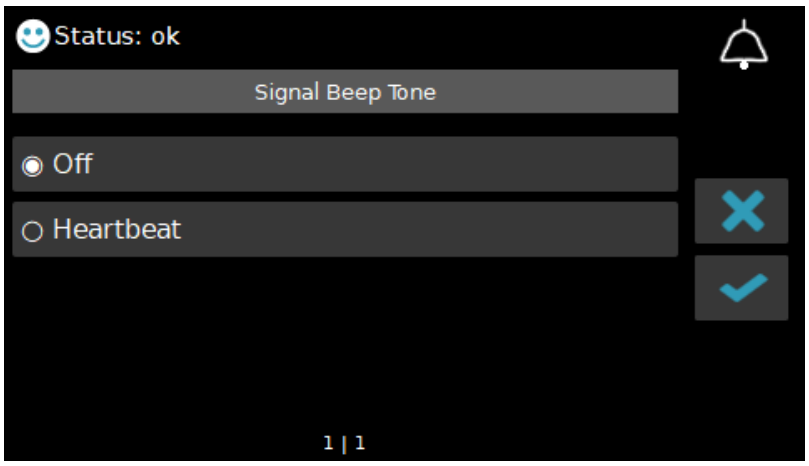



Fig. 52 Settings Dialog for Signal Beep Tone

In this case, there are 2 options to choose from, as shown in Fig. 52. The currently selected option, **Off**, is indicated by the filled circular radio button to its left. To select the other options, touch the line showing the setting. Its corresponding radio button will be activated. To accept this new setting, continue by touching the **Check** icon and following the procedure as described for the brightness example.

Arrows will be displayed on the bottom of the screen if the list of options is longer than the available space on the screen.

In addition to the menus for settings consisting of numerical values and lists, there are dedicated designs for a number of other setting types. These will be explained in the following sections.

## 8.3 System Settings (Settings Protection Mode On)

With **Settings Protection** set to **On**, the **System** view is as follows:

- Display Mode
- Display Brightness
- Signal Beep Tone
- Alarm Volume
- Settings Protection

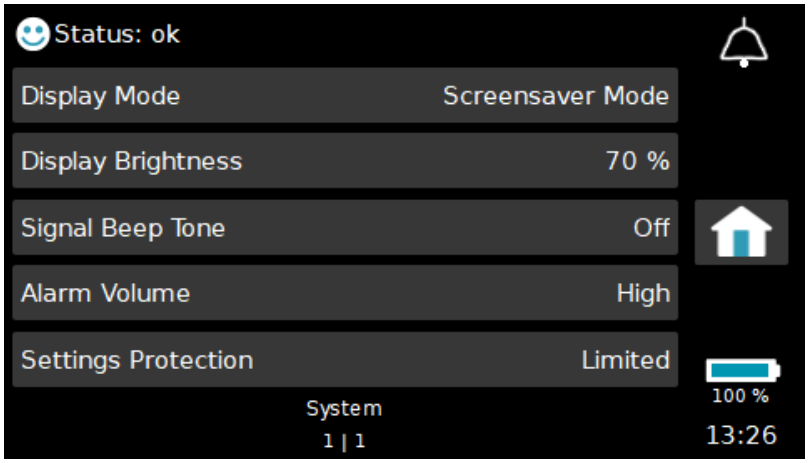



Fig. 53 System Settings with Settings Protection On

### 8.3.1 System \ Display Mode

The monitor display can be configured as follows:

- Normal Mode
- Dimmed Mode
- Screensaver Mode

In **Normal Mode**, the screen content is permanently displayed.

In **Dimmed Mode**, the screen content is the same as for **Normal Mode**, but the screen brightness is dimmed to 20 % after 5 minutes once no alarm occurs and no user interaction takes place.

The **Screensaver Mode** behaves the same as for **Dimmed Mode**, however, the screen content is replaced with an animated GETEMED logo and the current time.

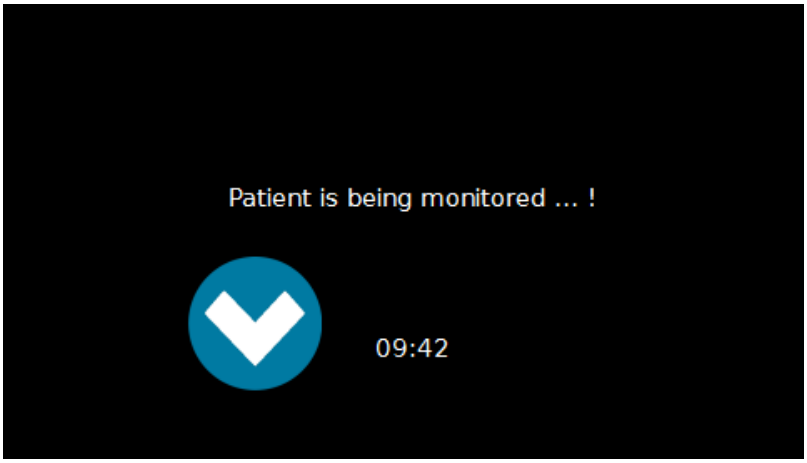



Fig. 54 Display in Screensaver Mode

NOTE: If the **Display Brightness** is already set to less than 20 %, then it is not changed in either the dimmed or screensaver modes.

Any user interaction or an alarm event will cause the display to operate as it would in **Normal Mode**.

### 8.3.2 System \ Display Brightness

The brightness of the display can be set from 10 % to 100 % in steps of 10 %. The default setting is 70 %.

NOTE: The lower the brightness level, the less power the monitor consumes. To extend the operating time when powering the monitor from the rechargeable battery, it may be beneficial to reduce the display brightness level.

### 8.3.3 System \ Signal Beep Tone

The monitor can be configured to output a short beep tone with every detected pulse (Heartbeat). The default setting is Off.

### 8.3.4 System \ Alarm Volume

The volume of the alarm tone can be selected between low and high. The default setting is High.

NOTE: Ensure that you can clearly hear the alarms over the expected background noise. Carefully read the safety information regarding alarms and the risk of hearing damage in section 1.6.

### 8.3.5 System \ Settings Protection

VitaGuard provides the following 3 modes for Settings Protection:

- Settings Protection set to On (default setting) deactivates all options to change monitor settings with the exception of the System settings described in this section 8.3. The available screen views are described in section 7.2.
- Settings Protection set to Limited enables access to all screen views and menus, as described in section 7.3. However, only a small selection of settings may be changed in this mode, as described in section 8.4.
- Settings Protection set to Off enables all screen views and menus, and allows access to all monitor settings.

To change the Settings Protection mode, four-digit codes are required; one for Limited mode and one for Off. The codes are not disclosed in this manual and are available for responsible physicians and authorized dealers only upon request. The codes that protect the monitor settings from unauthorized changes may only be disclosed by the responsible physician to those persons whom the physician judges to be adequately informed about the consequences of changing any settings on the monitor. The physician should point out that the code must be treated as confidential, that settings should be changed at the physician's recommendation only, and that all changes must be confirmed by the physician.

When the Settings Protection menu is selected, a dialog appears requesting input of the respective four-digit code. This dialog always displays “0000” when opened. The most significant zero (left-hand digit) of the code is highlighted and can be changed using the up and down arrows. The left and right arrows are used to select the individual digits of the code. Once the code has been entered, touch the Check icon and progress as explained for changing settings in section 8.2.

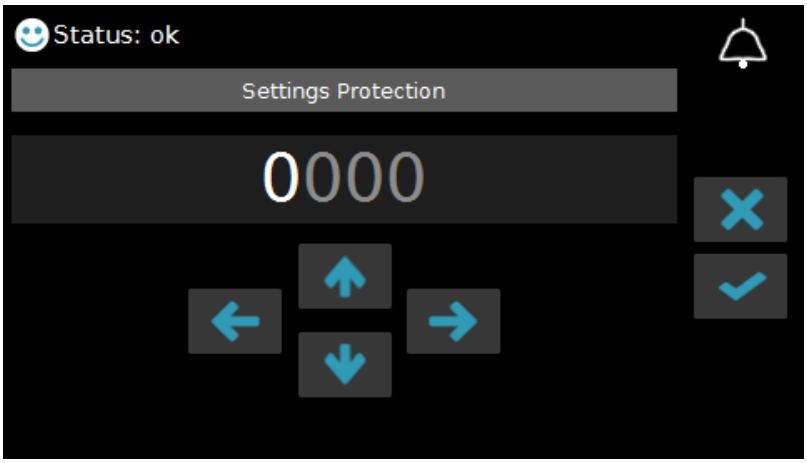



Fig. 55 Dialog to Enter the Settings Protection Code

NOTE: When the wrong code has been entered three times in a row, the dialog for entering the code is blocked. In this case, consult your authorized dealer.

# 8.4 $SpO_2$ Settings (Settings Protection Mode Limited)

To access the $SpO_2$ settings menus, select the **$SpO_2$** view shown in section 7.3.3 and touch the **Settings** icon on the right-hand side of the screen.

With **Settings Protection** set to **Limited**, the following settings are available in the **$SpO_2$** view:

- $SpO_2$ Lower Limit
- $SpO_2$ Upper Limit

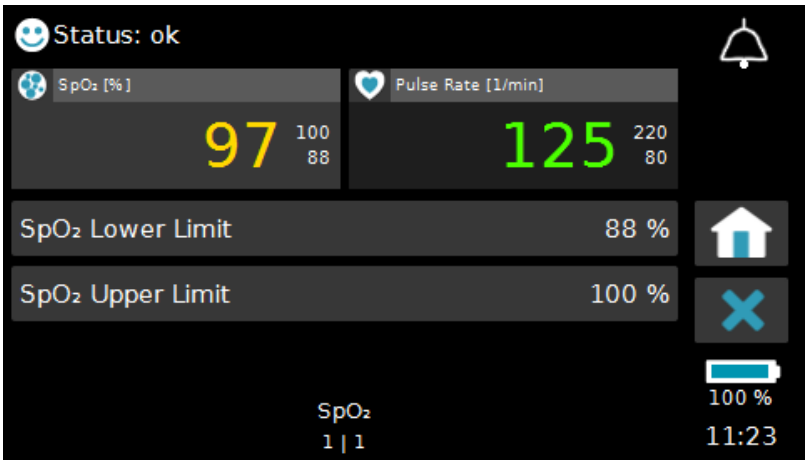



Fig. 56 $SpO_2$ Settings with Settings Protection LIMITED

## 8.4.1 $SpO_2$ \ $SpO_2$ Lower Limit

The lower alarm limit for $SpO_2$ can be set from 70 % to 98 % in steps of 1 %. The default setting is 88 %.

VitaGuard outputs a patient alarm when the value of $SpO_2$ falls below this limit for longer than the set **$SpO_2$ Hypoxia Alarm Delay**.

## 8.4.2 $SpO_2$ \ $SpO_2$ Upper Limit

The upper alarm limit for $SpO_2$ can be set from 70 % to 100 % in steps of 1 %. The default setting is 100 %.

VitaGuard outputs a patient alarm when the current value of $SpO_2$ rises above this limit for longer than the set **$SpO_2$ Hyperoxia Alarm Delay**.

NOTE: The default setting of 100 % deactivates detecting upper limit alarms, as the maximum value of 100 % cannot be exceeded, and, in general, an $SpO_2$ value of 100 % is not a life-threatening condition. However, for patients undergoing oxygen therapy, the responsible physical may lower the upper alarm limit to reduce risks associated with breathing molecular oxygen at increased partial pressures.

# 8.5 Pulse Rate Settings (Settings Protection Mode Limited)

To access the pulse rate settings menus, select the **Pulse Rate** view shown in section 7.3.3 and touch the **Settings** icon on the right-hand side of the screen.

With **Settings Protection** set to **Limited**, the following settings are available in the **Pulse Rate** view:

- PR Lower Limit
- PR Upper Limit

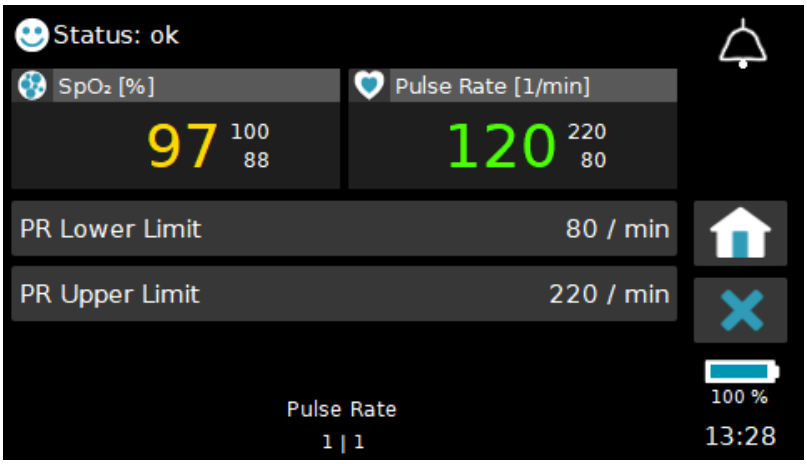



Fig. 57 Pulse Rate Settings with Settings Protection LIMITED

## 8.5.1 Pulse Rate \ PR Lower Limit

The lower alarm limit for the pulse rate can be set from 30 /min to 180 /min in steps of 5 /min. The default setting depends on the age group selected in the **Admit New Patient** function explained in section 8.6.2 as follows:

- Age group 0 – 2 years: Default = 80 /min
- Age group 2 – 6 years: Default = 60 /min
- Age group >6 years: Default = 55 /min

A patient alarm is output when the pulse rate falls below the set limit for longer than the **PR Bradycardia Alarm Delay**.

### 8.5.2 Pulse Rate \ PR Upper Limit

The upper alarm limit for the pulse rate can be set from 100 /min to 250 /min in steps of 5 /min. The default setting depends on the age group selected in the Admit New Patient function:

- Age group 0 – 2 years: Default = 220 /min
- Age group 2 – 6 years: Default = 150 /min
- Age group >6 years: Default = 140 /min

A patient alarm is output when the pulse rate rises above the set limit for longer than the set PR Tachycardia Alarm Delay.

## 8.6 System Settings (Settings Protection Mode Off)

With Settings Protection set to Off, the System settings explained in the following sections are available.

### 8.6.1 System \ Operating Area

The Operating Area menu offers two options: Home or Clinic.

When the Home option is selected, the Settings Protection mode is automatically switched back on once the monitor is switched off.

When the Clinic option is selected, the current Settings Protection mode is retained when the monitor is switched off.

### 8.6.2 System \ Admit New Patient

The Admit New Patient procedure should always be executed before using the monitor on a new patient to ensure that:

- the settings are appropriate for the new patient; and
- there is no mix-up of logged data between patients.

The Admit New Patient procedure begins with the following dialog informing that both the currently logged data in the operator alarm system log (refer to section 9) will be deleted and the current monitor settings will be reset to their default settings.

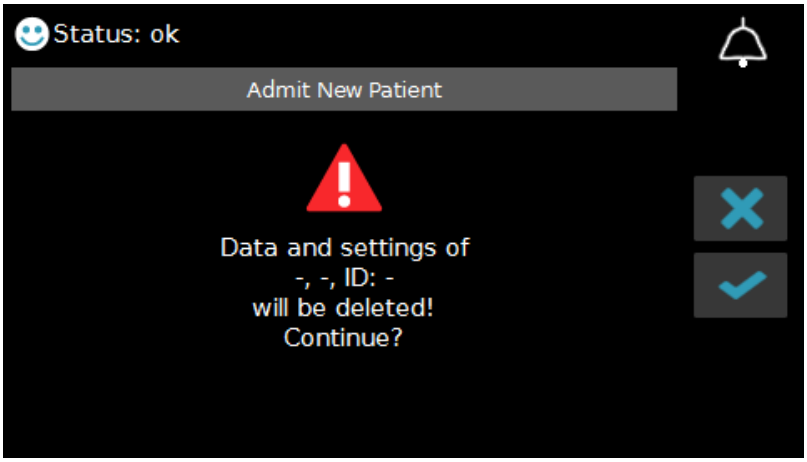



Fig. 58 Admit New Patient Procedure – Step 1: Warning Information

To continue, touch the **Check** icon. This will open the following dialog to select the patient's age group and, optionally, to enter the patient's ID, first name and family name:

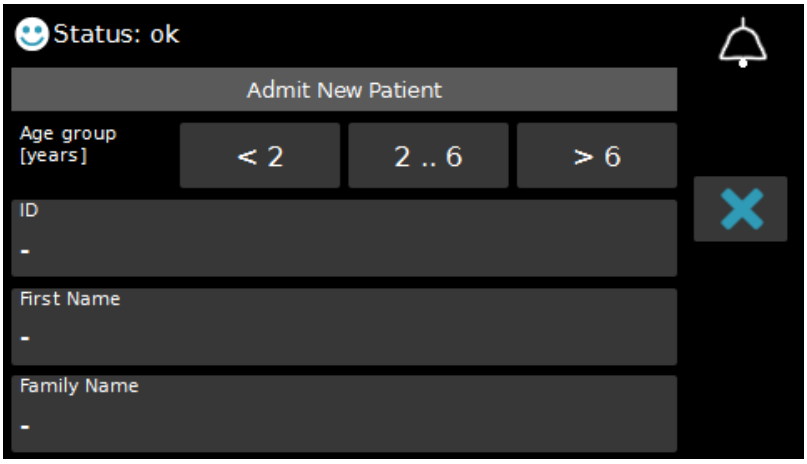



Fig. 59 Admit New Patient Procedure – Step 2: Select Age Group

The **Age Group** selection is used to preset the following settings:

- the **PR Lower Limit** and **PR Upper Limit** in the **Pulse Rate** menu.

| Setting | 0 to 2 years | 2 to 6 years | > 6 years |
|---|---|---|---|
| PR Lower Limit [/min] | 80 | 60 | 55 |
| PR Upper Limit [/min] | 220 | 150 | 120 |

**NOTE**: After completing the **Admit New Patient** procedure, these settings can be changed individually if needed.

Once an age group has been selected, a **Check** icon appears allowing you to proceed to the next step of the procedure. Alternatively, you may enter the patient's **ID**, **First Name** and **Family Name** by touching the corresponding workspaces. Upon doing so, a keypad appears allowing you to enter the information (15 characters for ID and 31 characters for both first name and family name):

The keypad operates similar to a standard keypad. Each character is selected by touching the corresponding digit or letter.

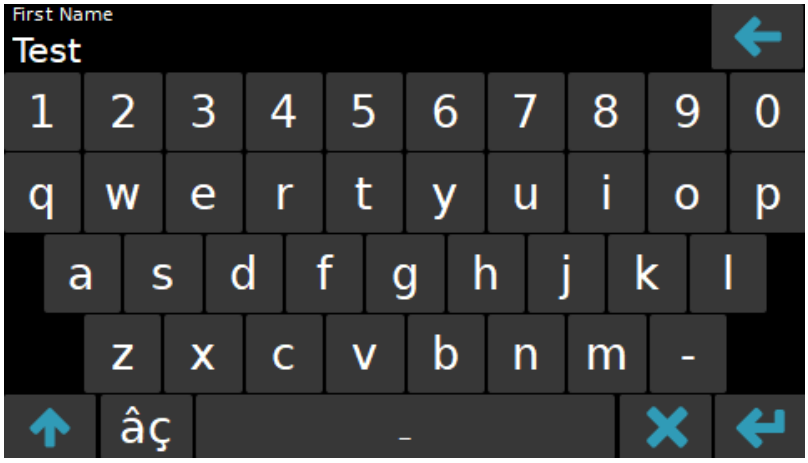



Fig. 60 Admit New Patient Procedure – Step 3: Enter Patient Data

The selected items appear at the top of the screen, as shown for the word "Test" in Fig. 60. The left-facing arrow in the top, right-hand corner of the screen is used to backspace and delete a character; whereas the arrow pointing up in the bottom, left-hand corner is used to change between small and capital letters. The "**âç**" symbol allows selection of special characters. Touching the "**X**" icon exits the dialog and discards the entries made; whereas touching the **Enter** icon in the bottom, right-hand corner closes the dialog and accepts the entries made. Fig. 61 shows the information entered for a fictitious patient.

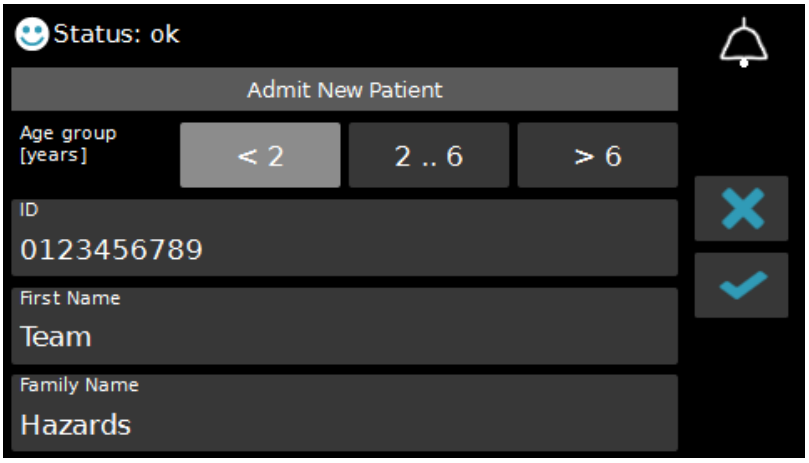



Fig. 61 Admit New Patient Procedure –Example of Patient Data

NOTE: It is not mandatory to enter ID, First Name or Family Name.

By touching the Check icon, the Admit New Patient procedure can be finalized in the same manner as for accepting all changes to settings explained in section 8.2.

The Admit New Patient procedure returns all settings to their default values with the following exceptions:

- Display Mode
- Display Brightness
- Signal Beep Tone
- Pre-Alarm and Post-Alarm Times
- Language
- Date Format

If any of the default settings are not suitable for the new patient, they must be changed individually before starting to monitor the patient.

### 8.6.3 System \ Pre-Alarm Time & Post-Alarm Time

In the event of a patient alarm, the data prior to the event, as defined by the Pre-Alarm Time setting, the data during the event itself, and the data after the event, as defined by the Post-Alarm Time setting, are logged in the operator alarm system log.

These times can be set from 30 to 250 seconds in steps of 10 seconds. The default setting is 60 seconds.

### 8.6.4 System \ Manual Event Recording

Data logging is explained in section 9.1. The default setting for **Manual Event Recording** is **Off**.

By setting the **Manual Event Recording** setting to **On**, the **Manual Recording** icon becomes visible in the **Memory** view described in sections 7.2.4 and 7.3.4 for **Settings Protection** set to **On** and to **Limited** respectively.

To start a manual recording, first touch the **Manual Recording** icon and then touch the **Start** icon when the following dialog appears on the screen:

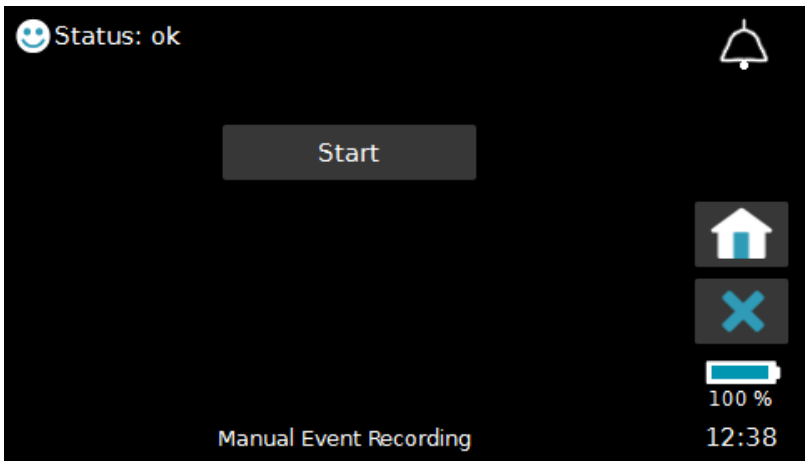



Fig. 62 Dialog to Start a Manual Recording

The manual recording event logs the data already captured in the monitor memory for the set **Pre-Alarm Time** and continues to record data until the **Post-Alarm Time** expires, after which the manual event is finalized and stored in the operator alarm system log. Manual events are displayed in the **M/I** column of the list of logged events shown in Fig. 67.

### 8.6.5 System \ Interval Recording

The **Interval Recording** setting enables systematic logging of data in the operator alarm system log by setting a fixed interval for logging events. The interval can be set between 0 and 240 minutes in steps of 10 minutes, whereby setting the value to 0 minutes (default setting) deactivates interval recording. When the internal interval timer reaches the set interval time, the monitor logs the data already captured in the monitor memory for the set **Pre-Alarm Time** and continues to record data until the **Post-Alarm Time** expires, after which the interval event is finalized and stored in the operator alarm system log. Interval events are displayed in the **M/I** column of the list of logged events shown in Fig. 67.

### 8.6.6 System \ Show Views 2 & 3

In the default state, the **Show Views 2 & 3** setting is **Off**. In this case, **View 2** and **View 3** are not accessible when **Settings Protection** is **On**, as explained in section 7.2.1.

With the **Show Views 2 & 3** setting switched **On**, both **View 2** and **View 3** are accessible when the **Settings Protection** mode is set to **On**, as shown in Fig. 63.

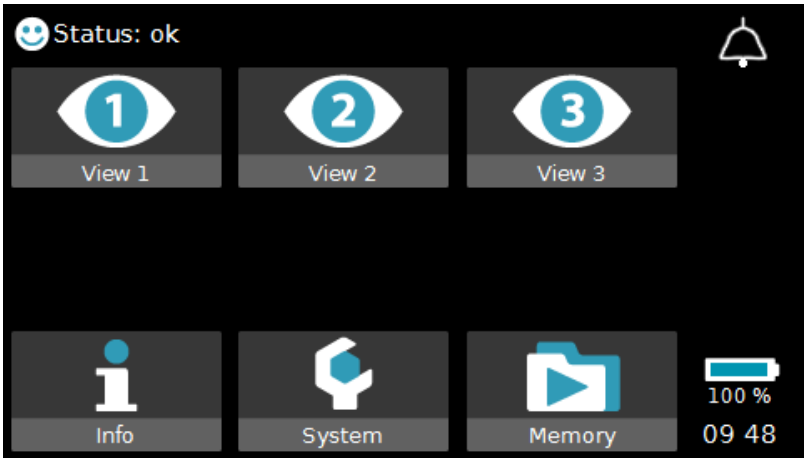



Fig. 63 Home Screen with Settings Protection On and Views 2 & 3 Set to ON

### 8.6.7 System \ Date & Time

Upon selecting the **Date & Time** menu, the following dialog appears on the monitor screen showing the current date and time:

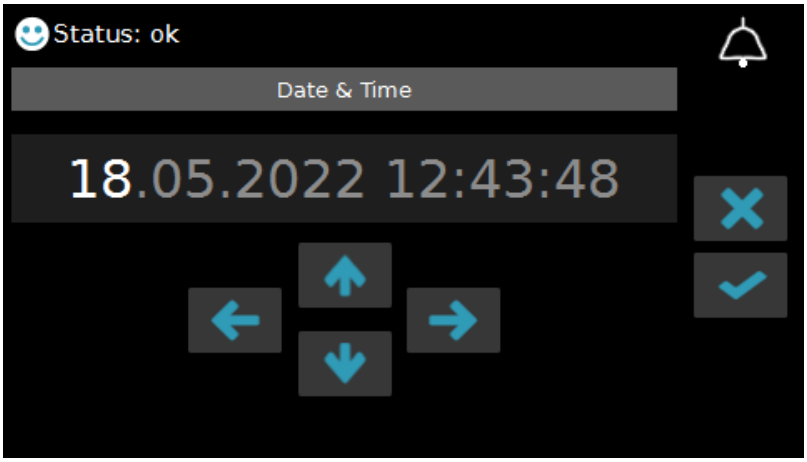



Fig. 64 Dialog to Set the Date and Time

The three left-hand numbers are the current date, whereas the three right-hand numbers are the current time in hours, minutes and seconds. The displayed format for the date will depend on the currently selected **Date Format** explained in section 8.6.9.

The left and right arrows at the bottom of the screen are used to select the individual date and time components; the up and down arrows are used to select the respective values. Once all selections have been made, the new date and time can be logged by touching the **Check** icon and following the steps for changing settings explained in section 8.2.

### 8.6.8 System \ Language

The **Language** menu allows selection of the language displayed on the monitor screen. The flags on the left help to find the language you may be looking for if you do not understand the currently selected language.

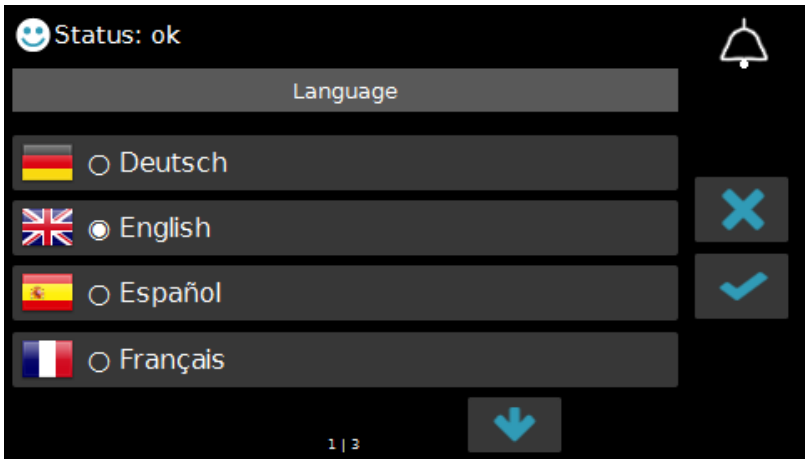



Fig. 65 Language Menu

### 8.6.9 System \ Date Format

The following date formats are available in the **Date Format** menu:

- DD.MM.YYYY (Default)
- DD/MM/YYYY whereby DD = Day
- DD-MM-YYYY MM = Month
- MM/DD/YYYY YYYY = Year
- YYYY-MM-DD

# 8.7 $SpO_2$ Settings (Settings Protection Mode Off)

With **Settings Protection** set to **Off**, the following $SpO_2$ settings are available in addition to those explained in section 8.4.

## 8.7.1 $SpO_2$ \ $SpO_2$ Sensitivity

The **$SpO_2$ Sensitivity** has three settings: **Minimum (APOD)**, **Standard** and **Maximum**. The default setting is **Standard**.

The **Maximum** setting is intended for patients with weak signals (high ambient interference and/or patients with low perfusion) or when a "low perfusion" message displays in **Minimum (APOD)** or **Standard** mode. It is recommended for use during procedures or when clinician and patient contact is continuous.

NOTE: The **Maximum** sensitivity setting is not intended as a permanent setting and is automatically reset to **Standard** when the monitor is switched off and back on again.

The **Minimum (APOD)** setting, on the other hand, is intended for patients who have a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This setting utilizes the APOD™ adaptive probe-off detection algorithm from Masimo Inc. explained in section 10.2.6 with the trade-off that low perfusion patients may trigger technical alarms more often.

## 8.7.2 $SpO_2$ \ $SpO_2$ FastSat

FastSat enables rapid response to fast changes in $SpO_2$ by giving priority to the most recent data. When **$SpO_2$ FastSat** is switched on, the $SpO_2$ monitor effectively takes a pulse-to-pulse measurement, thereby improving its performance to detect sudden, short desaturations. More information on FastSat is provided in section 10.2.4.

NOTE: When the **$SpO_2$ Averaging Time** setting explained in section 8.7.3 is set to 4 or 6 seconds, then **$SpO_2$ FastSat** is automatically activated, even when it has been deactivated in this menu.

### 8.7.3 $SpO_2$ \ $SpO_2$ Averaging Time

This setting can be selected between 4 and 16 seconds in steps of 2 seconds and defines the period over which the $SpO_2$ module uses the sensor data to determine each $SpO_2$ and pulse rate value. The default value is 8 seconds.

### 8.7.4 $SpO_2$ \ $SpO_2$ Silent Lower Limit

The $SpO_2$ Silent Lower Limit can be set from 70 % to 98 % in steps of 1 %. The default setting is 70 %, thereby deactivating the detection of silent lower limit alarms.

VitaGuard logs a silent patient alarm in the alarm event log when the value of $SpO_2$ falls below this limit for longer than the set $SpO_2$ Hypoxia Alarm Delay.

### 8.7.5 $SpO_2$ \ $SpO_2$ Silent Upper Limit

The $SpO_2$ Silent Upper Alarm can be set from 70 % to 100 % in steps of 1 %. The default setting is 100 %, thereby deactivating the detection of silent upper limit alarms.

VitaGuard logs a silent patient alarm in the alarm event log when the current value of $SpO_2$ rises above this limit for longer than the set $SpO_2$ Hyperoxia Alarm Delay.

### 8.7.6 $SpO_2$ \ $SpO_2$ Hypoxia Alarm Delay

The $SpO_2$ Hypoxia Alarm Delay can be set from 1 to 15 seconds in steps of 1 second, and defines the time between when $SpO_2$ falls below the set $SpO_2$ Lower Limit and the corresponding patient alarm is triggered. The default setting is 10 seconds.

### 8.7.7 $SpO_2$ \ $SpO_2$ Hyperoxia Alarm Delay

The $SpO_2$ Hyperoxia Alarm Delay can be set from 1 to 15 seconds in steps of 1 second, and defines the time between when $SpO_2$ rises above the set $SpO_2$ Upper Limit and the corresponding patient alarm is triggered. The default setting is 10 seconds.

### 8.7.8 $SpO_2$ \ $SpO_2$ Deviation Averaging Interval

The $SpO_2$ Deviation Averaging Interval can be set from 10 to 120 seconds in steps of 10 seconds, and defines the length of the moving average window for calculating the average $SpO_2$ used as the reference value for calculating deviation alarms. The default is 60 s.

### 8.7.9 $SpO_2$ \ $SpO_2$ Deviation Alarm Limit

The $SpO_2$ Deviation Alarm Limit can be set from -3 to -25 % in steps of 1 %. The default is -5 %. The current $SpO_2$ value is compared every second with the average $SpO_2$ value calculated over the $SpO_2$ Deviation Averaging Interval. When the value deviates below this average by more than the limit set here and when the $SpO_2$ Alarms setting is set to Limits & Deviations, then a patient alarm is triggered.

### 8.7.10 $SpO_2$ \ $SpO_2$ Alarms

The $SpO_2$ Alarms setting has two options: Limits Only or Limits & Deviations. The default setting is Limits Only. When set to Limits Only, alarms are reported only when the measured values violate the set upper and lower alarm limits. When set to Limits & Deviations, alarms are reported when the measured values violate the set alarm limits and when they deviate from the average $SpO_2$ calculated over the set $SpO_2$ Deviation Averaging Interval.

## 8.8 Pulse Rate Settings (Settings Protection Mode Off)

With Settings Protection set to Off, the following additional Pulse Rate settings are available.

### 8.8.1 Pulse Rate \ PR Silent Lower Limit

The PR Silent Lower Limit can be set from 30 to 180 /min in steps of 5 /min. The default setting is 30 /min, thereby deactivating the detection of silent lower limit alarms. VitaGuard logs a silent patient alarm in the alarm event log when the pulse rate falls below this limit for longer than the set PR Bradycardia Delay.

### 8.8.2 Pulse Rate \ PR Silent Upper Limit

The PR Silent Upper Limit can be set from 100 to 250 /min in steps of 5 /min. The default setting is 250 /min, thereby deactivating the detection of silent upper limit alarms.

VitaGuard logs a silent patient alarm in the alarm event log when the pulse rate rises above this limit for longer than the set PR Tachycardia Delay.

### 8.8.3 Pulse Rate \ PR Bradycardia Delay

The PR Bradycardia Delay can be set from 1 to 4 seconds in steps of 1 second, and defines the time between when pulse rate falls below the set PR Lower Limit and the corresponding patient alarm is triggered. The default setting is 4 s.

### 8.8.4 Pulse Rate \ PR Tachycardia Delay

The PR Tachycardia Delay can be set from 1 to 6 seconds in steps of 1 second, and defines the time between when pulse rate rises above the set PR Upper Limit and the corresponding patient alarm is triggered. The default setting is 6 s.

### 8.8.5 Pulse Rate \ PR Deviation Averaging Interval

The PR Deviation Averaging Interval can be set from 10 to 120 seconds in steps of 10 seconds, and defines the length of the moving average window for calculating the average pulse rate used as the reference value for calculating deviation alarms. The default setting is 60 seconds.

### 8.8.6 Pulse Rate \ PR Deviation Alarm Limit (-)

The PR Deviation Alarm Limit (-) can be set from 5 to 50 % in steps of 5 %. The default setting is 25 %.

The current pulse rate is compared every second with the average pulse rate calculated over the PR Deviation Averaging Interval. When the current value deviated below the average by more than the value set here and when the PR Alarms setting is set to Limits & Deviations, a patient alarm is triggered.

### 8.8.7 Pulse Rate \ PR Deviation Alarm Limit (+)

The PR Deviation Alarm Limit (+) can be set from 5 to 50 % in steps of 5 %. The default setting is 25 %.

The current pulse rate is compared every second with the average pulse rate calculated over the PR Deviation Averaging Interval. When the current value deviates above the average by more than the value set here and when the PR Alarms setting is set to Limits & Deviations, a patient alarm is triggered.

### 8.8.8 Pulse Rate \ PR Alarms

The PR Alarms setting has two options: Limits Only or Limits & Deviations. The default setting is Limits Only.

When set to Limits Only, alarms are reported only when the measured pulse rate violates the set upper and lower alarm limits. When set to Limits & Deviations, alarms are reported when the measured pulse rate violates the set alarm limits and when they deviate from the average pulse rate calculated over the set PR Deviation Averaging Interval.

## 8.9 Changing Settings via VitaWin

All settings may be configured and downloaded to the monitor using the VitaWin evaluation software. However, before being finally accepted by the monitor, confirmation by the responsible physician is required via the confirmation dialog shown in Fig. 66.

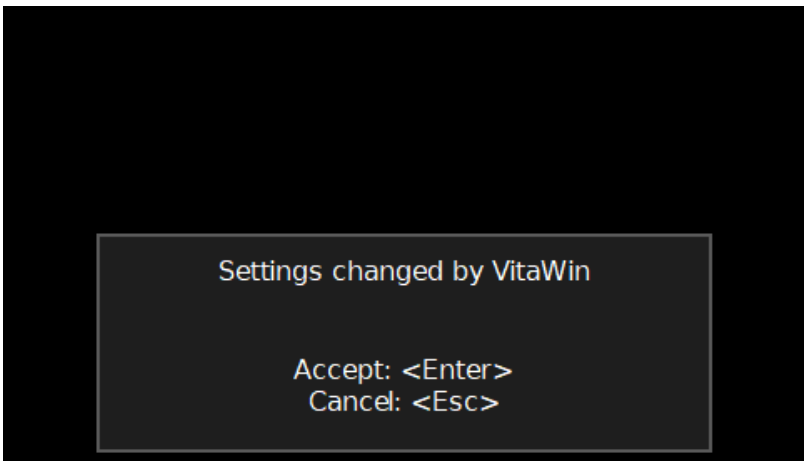



Fig. 66 Confirmation Dialog when Changing Settings via VitaWin

If the settings are not accepted within 20 s, the process is aborted and the monitor retains its original settings.

# 9. Data Logging

VitaGuard implements an operator alarm system log to store physiological data and alarm events, and a responsible organization alarm system log to store compliance information and other data related to monitoring, e.g., changes to settings. The operator alarm system log stores data in the following three categories:

- alarm event data,
- trend data,
- full-disclosure data.

In addition to the above categories, the responsible organization alarm system log stores further data in the compliance log.

NOTE: In addition to restoring the default settings, the Admit New Patient function in the System menu deletes all the data in the operator alarm system log. Therefore, transfer the data beforehand to a PC using the VitaWin software. The compliance log is not deleted by the Admit New Patient function.

NOTE: VitaGuard's memory contents are retained when the power adapter or battery fail.

Section 9.4 provides an overview of the data stored in the operator alarm system log along with their respective sampling rates.

## 9.1 Alarm System Log

The alarm system log stores data when any of the following events occur:

- patient alarm event,
- silent patient alarm event,
- manual event,
- interval timer event.

The log has a capacity to store 1,000 events and will overwrite the oldest events when the limit is reached.

A patient alarm event occurs when any of the alarm limits for $SpO_2$ or pulse rate are exceeded.

Similarly, a silent patient alarm event occurs when any of the silent alarm limits for $SpO_2$ or pulse rate are exceeded. Silent patient alarms are intended for diagnostic purposes by setting non-critical alarm limits for the parameter or parameters of interest. If a silent alarm limit is exceeded, an event is stored in the alarm event log without triggering an acoustic or visual alarm.

A manual event is initiated through user interaction rather than through detection of an alarm event. To access manual event logging through the user interface, the Manual Event Recording setting must be activated in the System menu, as explained in section 8.6.4. As manual events are not triggered by an alarm condition, there may be no alarm event visible in the logged data.

An interval timer event is similar to a manual event in that there may be no alarm event visible in the logged data. By setting an interval time using the Interval Recording setting in the System menu, VitaGuard automatically stores an interval timer event in the operator alarm system log at the intervals defined.

For each event type above, the data prior to the event, as defined in the Pre-Alarm Time setting (default 60 s) in the System menu, the data during the event itself, and the data after the event, as defined in the Post-Alarm Time setting (default 60 s) in the System menu, are logged in the operator alarm system log. Therefore, if the default settings are used, each event covers a time period of two minutes plus the duration of the alarm event itself.

Should a further alarm event occur during the Post-Alarm Time, then the post-alarm timer is reset as long as the alarm condition is present and starts anew when the alarm condition is over, thereby extending the overall duration of the event stored in the log. If alarm conditions continue to occur in quick succession such that the post-alarm timer is continuously reset, then the event is automatically terminated after 15 minutes and a new event is initiated.

The contents of the alarm system log may be viewed directly on the monitor screen. By touching the **Events** icon behind the **Memory** icon on the **Home** screen, a list of logged events is displayed.

Fig. 67 Events Icon

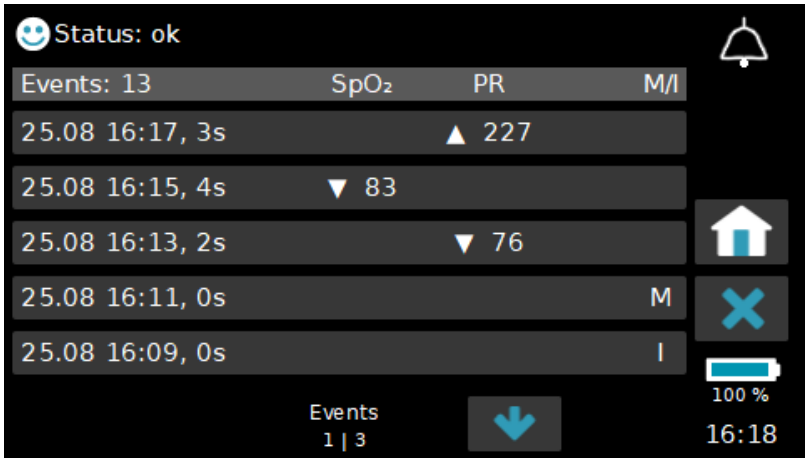



Fig. 68 List of Logged Events

NOTE: The **Post-Alarm Time** after an event has ended must expire before the event can be displayed in the list.

Each line in the list represents one event stored in the log. The date and time of the event followed by the duration of the respective alarm condition in seconds is shown on the left of the line, with the most recent event shown on the top of the list. The large arrows at the bottom of the screen can be used to scroll through the entire list. The two numbers between the arrows inform about the current page of the entire list (left number) and the overall number of pages needed to display the entire list (right number).

The symbols below the columns labeled **SpO2**, **PR**, and **M/I** (Manual/Interval) inform about the type of alarm event. An arrow pointing down in the **SpO2** or **PR** columns shows that the respective lower alarm limit was exceeded. Similarly, an arrow pointing up in the **SpO2** or **PR** columns shows that the respective upper alarm limit was exceeded. The number beside the arrow informs about the minimum or maximum value encountered during the alarm, depending on the alarm type. An "**M**" or "**I**" in the **M/I** column informs that a Manual or Interval event was logged.

Brackets around any of the symbols informs that the event was a silent alarm. More than one symbol on any line in the list indicates that multiple alarm conditions were detected during the event.

By touching on a line in the event list, further information about the alarm event is displayed:

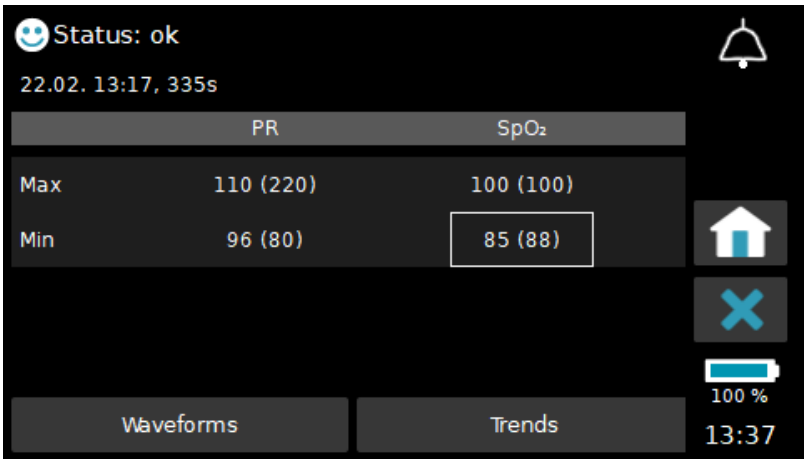



Fig. 69 Minimum and Maximum Values of the Logged Alarm Event

The table shows the minimum and maximum values of $SpO_2$ and pulse rate detected during the alarm condition along with the respective alarm limits in brackets. The entry highlighted inside the rectangular box shows the alarm condition that caused the alarm. In the example above, the $SpO_2$ value of 85 % was below the lower $SpO_2$ alarm limit of 88 %, thereby causing the alarm.

To go back to the event list, touch the "X" icon on the right-hand side of the screen. Alternatively, the plethysmogram waveform logged for the event may be viewed by the touching the **Waveforms** button on the bottom of the screen, or the trend graphs of pulse rate and $SpO_2$ may be accessed by touching the **Trends** button.

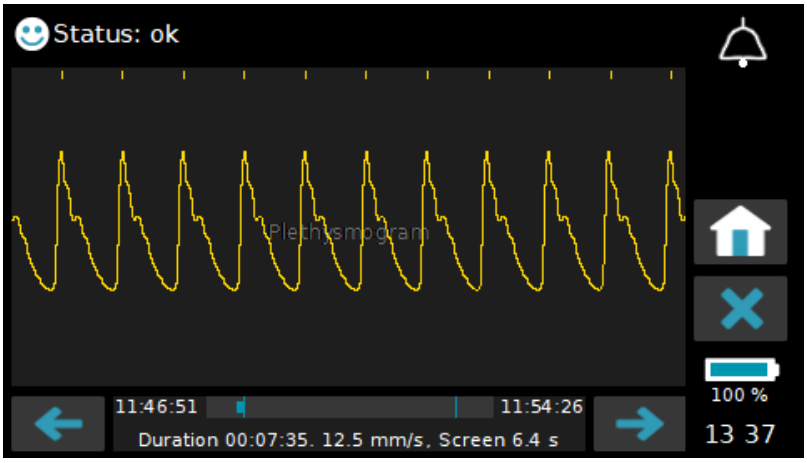



Fig. 70 Event Waveforms

The left and right arrows at the bottom of the screen can be used to scroll through the event waveforms. The bar at the bottom represents the overall duration of the logged waveforms, with the start and end times of the logged data displayed to the left and right of the

bar respectively. The two perpendicular lines mark the duration of the alarm condition. The solid bar moves to the left or right when the arrows are touched to indicate which section of the logged data is currently displayed on the screen. To exit the waveforms, touch the "X" icon on the right-hand side of the screen.

The trend graphs for $SpO_2$ and pulse rate may be viewed by touching the **Trends** button in the same way as the waveforms. The scales in the background indicate the magnitudes of the values displayed in the graphs. Navigation through the data is the same as explained for the waveforms above.

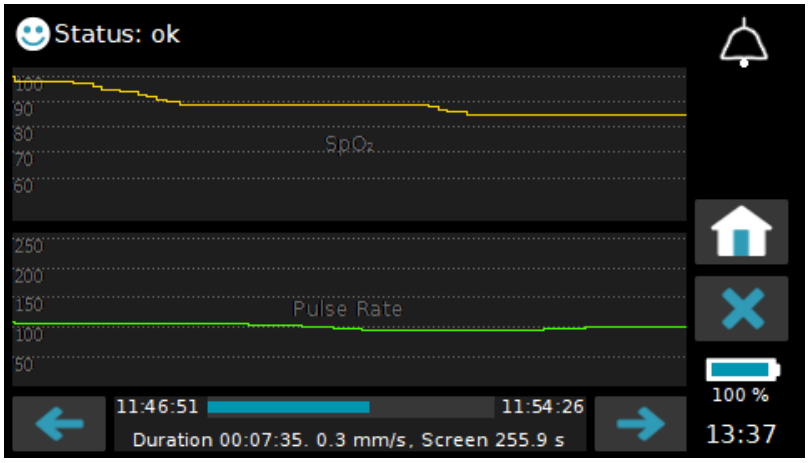



Fig. 71 Event Trend Graphs

In addition, the alarm event log may be viewed using the VitaWin evaluation software after downloading the data via USB.

## 9.2 Trend Log

The trend log is independent of any alarm events and starts storing data once VitaGuard is switched on. The data stored and the sampling rates of the data are given in section 9.4.

The trend log has a capacity to store 168 hours of continuous data and will overwrite the oldest data when the limit is reached. The trend recordings are limited to 24 hours. If the monitor is continuously operated for longer than 24 hours, then the current recording is terminated and a new one is automatically started.

The contents of the trend log may be viewed directly on the monitor screen. By touching the **Trend** icon behind the **Memory** icon on the **Home** screen, a list of trends is displayed.

Fig. 72 Trends Icon

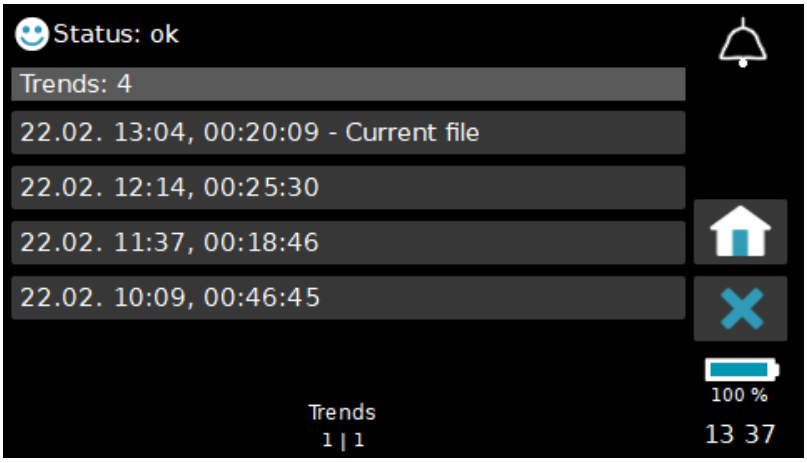



Fig. 73 List of Trend Recordings

In a similar manner as for the event alarm log, each line in the list represents one trend recording in the log. The date and time of the start of the recording followed by the duration of the recording is shown on the left of the line, with the most recent recording shown on the top of the list. The large arrows at the bottom of the screen can be used to scroll through the entire list. The two numbers between the arrows inform about the current page of the entire list (left number) and the overall number of pages needed to display the entire list (right number).

By touching a line in the trend recordings list, further information about the recording is displayed:

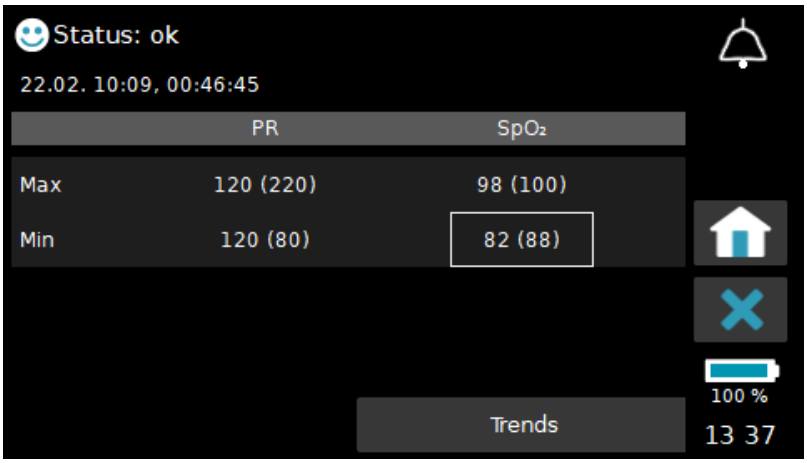



Fig. 74 Minimum and Maximum Values during Trend Recording

The table shows the minimum and maximum values of $SpO_2$ and pulse rate detected throughout the recording along with the respective alarm limits in brackets. Entries highlighted inside rectangular boxes show that these alarm conditions occurred during the recording. These alarms will be individually listed in the alarm event log.

To go back to the list of trend recordings, touch the "X" icon on the right-hand side of the screen. Alternatively, the trend graphs of pulse rate and $SpO_2$ may be accessed by touching the **Trends** button.

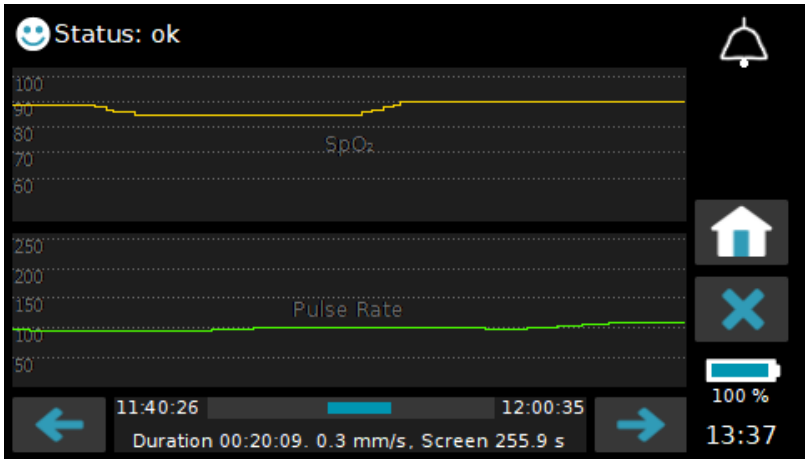



Fig. 75 Trend Recording Graphs

Navigation through the data is the same as explained for alarm events in section 9.1.

In addition, the trend log may be viewed using the VitaWin evaluation software after downloading the data via USB.

## 9.3 Full-Disclosure Log

The full-disclose log is independent of any alarm event and starts storing data once VitaGuard is switched on. The data stored and the sampling rates of the data are given in section 9.4.

The full-disclosure log has a capacity to store 48 hours of continuous data and will overwrite the oldest data once this limit is reached. The full-disclosure recordings are limited to 24 hours. If the monitor is continuously operated for longer than 24 hours, then the current recording is terminated and a new one is automatically started.

The contents of the full-disclosure log may be viewed using the VitaWin evaluation software after downloading the data via USB.

## 9.4 Logged Data and Sample Rates

| Data Type | Sample Rate [Hz] | Alarms | Full-Disclosure | Trend |
|---|---|---|---|---|
| Current $SpO_2$ | 1 | ✔ | ✔ | ✔ |
| Average $SpO_2$ for trend deviations | 1 | ✔ | ✔ | ✔ |
| Average $SpO_2$ over 1 min | 0.2 | ✔ | ✔ | ✔ |
| Average $SpO_2$ over 1 h | 0.2 | ✔ | ✔ | ✔ |
| Average $SpO_2$ over 6 h | 0.2 | ✔ | ✔ | ✔ |
| Average $SpO_2$ over 12 h | 0.2 | ✔ | ✔ | ✔ |
| Current pulse rate | 1 | ✔ | ✔ | ✔ |
| Average pulse rate for trend deviation | 1 | ✔ | ✔ | ✔ |
| Average pulse rate over 1 min | 0.2 | ✔ | ✔ | ✔ |
| Average pulse rate over 1 h | 0.2 | ✔ | ✔ | ✔ |
| Average pulse rate over 6 h | 0.2 | ✔ | ✔ | ✔ |
| Average pulse rate over 12 h | 0.2 | ✔ | ✔ | ✔ |
| Plethysmogram waveform | 64 | ✔ | ✔ | |
| Perfusion index (Pi) | 1 | ✔ | ✔ | ✔ |
| Pleth variability index (PVi) | 1 | ✔ | ✔ | ✔ |
| Signal IQ | 1 | ✔ | ✔ | ✔ |
| Status graph | 0.1 | ✔ | ✔ | ✔ |

## 9.5 Compliance Log

The compliance log registers events and technical information for the responsible organization, including but not limited to:

- monitor on/off,
- admit new patient,
- changes to settings protection,
- technical diagnostic information.

The date and time as well as the current monitor settings are logged with each event. The compliance log has a capacity to store 15,000 events and will overwrite the oldest entries when this limit is

reached. The content of the compliance log cannot be deleted otherwise. The contents of the compliance log may be viewed using the VitaWin evaluation software after downloading the data via USB.

## 9.6 Data Download to USB Memory

To download logged data to an external USB memory, connect a USB memory drive to the monitor's USB-C connector on the connector panel shown in Fig. 7 and touch the **USB Memory** icon shown in Fig. 37. Upon doing so, the following dialog is displayed. Touching the **Start** button starts the copy process.

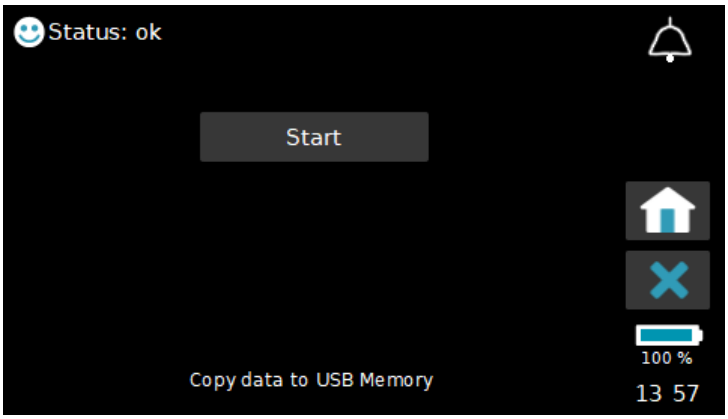



Fig. 76 USB Memory Download Start Dialog

If all files have been successfully copied to USB, the left-hand dialog of Fig. 76 appear. This shows the number of files that were copied and confirms that all files were copied by writing 100% below the USB icon on the right-hand side of the screen. If, on the other hand, an error occurs during the copy process, then the right-hand dialog appears showing a failure message and the number of files, if any, which were copied to the USB memory. Touching the OK button returns to the dialog of Fig. 75.

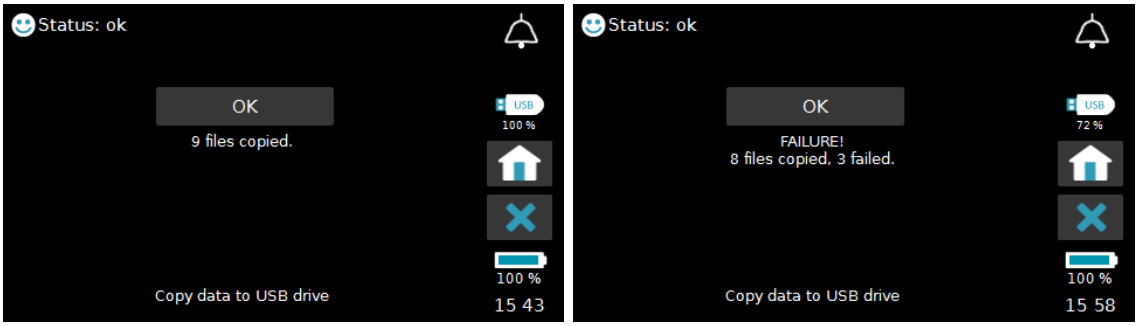



Fig. 77 USB Memory Download Result Dialog

Touching the "X" icon exits the USB download procedure.

**NOTE**: License texts are automatically downloaded once the **Start** button is pressed.

## 9.7 Evaluating Stored Data on a PC

The content of the data logged in VitaGuard can be downloaded directly to a PC via the USB interface and evaluated using the Windows® based VitaWin evaluation software. This software is available to responsible physicians and authorized dealers only.

NOTE: Do not connect USB cables longer than 1.5 m to the port.

VitaWin visualizes each alarm's context by displaying all the stored waveforms and graphs: pulse rate, $SpO_2$, plethysmogram, signal IQ, perfusion index, plethy variability index and status line information.

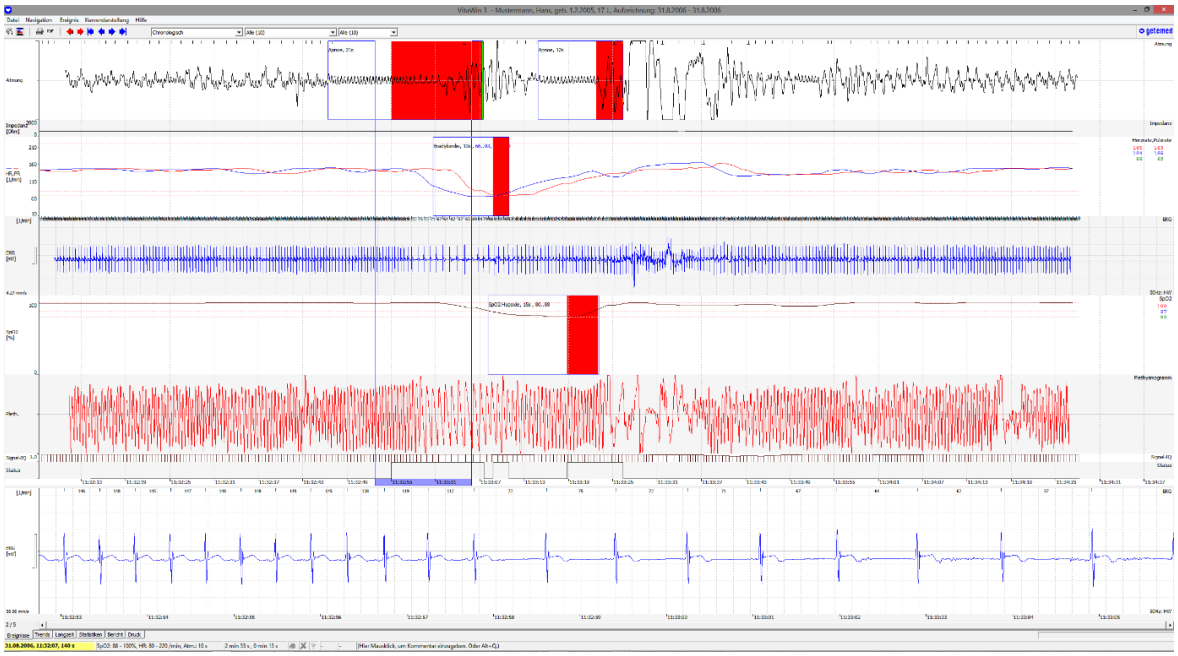


Fig. 78 VitaWin

VitaWin also provides functions for creating reports and assessing the patient's monitored data.

NOTE: While monitoring the patient, data transfer to a PC via the USB port is not permitted.

WARNING: DEVICE SETUP
Risk of death or serious injury to the patient if the monitor is not setup and configured properly.

If VitaWin is used to configure the monitor settings, verify that the selected settings are displayed on the monitor before handing it out to the caregiver.

# 10. Alarm Delays and Measuring Principles

The following information is provided to enable the responsible physician to understand VitaGuard's internal operation.

## 10.1 Alarm Delays

As required by the International Standard IEC 60601-1-8 "General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems", this section informs about the monitor's inherent alarm delay times as an aid in selecting the correct configuration of the alarm limits and monitoring parameters.

- The alarm condition delay is the time from the occurrence of a triggering event on the patient or in the monitor to the decision by the alarm system to confirm an alarm condition.
- The alarm report delay is the time between when an alarm condition is detected and when it is reported.
- The alarm condition delay and the alarm report delay are added to yield the ALARM SYSTEM delay.

The algorithms listed here are based on worst case scenarios, i.e., the calculations represent the maximum delay times.

### 10.1.1 Alarm Condition Delay for $SpO_2$

An alarm condition delay as defined in the International Standard does not apply to $SpO_2$ monitoring. Please refer to the information on alarm report delays below.

### 10.1.2 Alarm Report Delays

The alarm report delays for bradycardia, tachycardia, hypoxia, and hyperoxia can be set within certain limits.

$TA_{(max)}$ for bradycardia: ..... Set PR Bradycardia Delay + 2 s

$TA_{(max)}$ for tachycardia: ..... Set **PR Tachycardia Delay** + 2 s

$TA_{(max)}$ for hypoxia: ..... Set **$SpO_2$ Hypoxia Alarm Delay** + 2 s

$TA_{(max)}$ for hyperoxia: ..... Set **$SpO_2$ Hyperoxia Alarm Delay** + 2 s

The purpose of the selectable alarm report delays is to prevent alarms from being reported every time the alarm limits are briefly violated.

In other words, the maximum alarm report delays correspond to the maximum delays selected by the responsible physician for the individual alarm types plus an inherent delay of maximum 2 seconds to account for the time the monitor needs to update the display.

## 10.2 Measuring Principles of Masimo Technology

### 10.2.1 Measuring Principles of $SpO_2$ Monitoring

The pulse oximeter with Masimo SET® (SET = Signal Extraction Technology®) is based on the following three principles.

1. Oxyhemoglobin (oxygenated hemoglobin) and deoxyhemoglobin (unoxygenated hemoglobin) differ in their absorption of red and infrared light (spectrophotometry).
2. A heartbeat gives rise to a pulse wave that during its cycle changes the volume of arterial blood and therefore its light absorption at the monitoring site (plethysmography).
3. Movements also give rise to blood flows that resemble pulse waves and generate interference signals.

Like conventional pulse oximeters, SET® oximeters determine oxygen saturation by directing red and infrared light through tissue and measuring the absorption of light by the blood flow. Light-emitting diodes (LEDs) serve as light sources and a photodiode as the receiver attached opposite.

Conventional pulse oximetry assumes that all pulsations in the light absorption are caused by the arterial pulse cycle. For this to work, the venous blood in the sensor area must flow completely and there-

fore constantly through the capillary bed. Conventional pulse oximetry then calculates the ratio of the pulsatile to the mean absorption for both wavelengths (660 nm and 905 nm).

The quotient of the two signals is then formed as follows:

$$R = S(660)/S(905)$$

The result R is used to determine the corresponding $SpO_2$ value out of an empirically calibrated table mapped in the oximeter software. These tables were drawn up in trials with volunteers who underwent temporary induced hypoxia. During these trials a conventional pulse oximeter was used for the measurements; at the same time, arterial blood was extracted and examined for its oxygen content.

Unlike conventional pulse oximeters, Masimo SET® pulse oximeters assume that not only the arterial, but also the venous blood flow varies greatly. Changes to venous light absorption are regarded as a significant source of interference to the pulse signal. The $SpO_2$ module separates the signals for both wavelengths S(660) and S(905) into an arterial signal S and a noise component N that are then used to calculate the ratio R:

$$S(660) = S1 + N1$$

$$S(905) = S2 + N2$$

$$R = S1 / S2$$

N1 and N2 are the noise components generated by venous blood.

The DST™ method (Discrete Saturation Transform) isolates and therefore compensates for venous interference components.

The SET® software goes through all the possible values for R (corresponding to $SpO_2$ between 1 and 100%) and calculates the associated interference components. An adaptive noise canceller, or ANC, then takes this value N'(R) to calculate the amplitude of the noise energy, or the so-called output power of the ANC. The result is a DST™ plot (Fig. 78) that exhibits the arterial peak. This peak demonstrates the particularly effective noise suppression for the affected $SpO_2$ value when a precisely defined source of signal fluctuations, the arterial pulse cycle, has been identified. Other peaks can occur during venous fluctuations. Venous blood is saturated less with oxygen, so the

peak with the maximum $SpO_2$ value (in the right side of the graph) always correspond to the arterial oxygen saturation. In Fig. 78 the right peak corresponds to an $SpO_2$ value of 97 %. The DST calculation is repeated every two seconds on the latest raw data over the preceding four seconds.

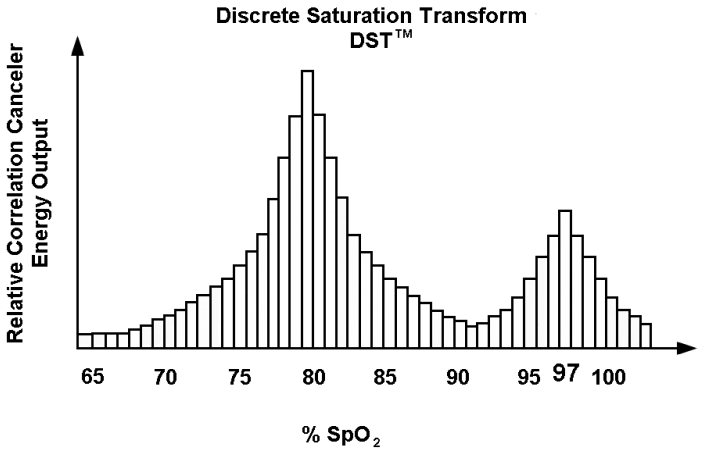



Fig. 79 DST™ Plot: Noise Cancellation as a Function of $SpO_2$

The peak at 80 % is caused by venous blood and would, with conventional methods, completely corrupt the measurement yielding a false desaturation value.

The $SpO_2$ value displayed on VitaGuard is the functional oxygen saturation, which is defined as the percentage saturation given by the oxyhaemoglobin concentration ($cO_2Hb$) divided by the sum of the oxyhaemoglobin concentration and the deoxyhaemoglobin concentration (cHHb)

$$\frac{100 \times cO_2Hb}{cO_2Hb + cHHb}$$

Fig. 80 Functional $SpO_2$ Formula

### 10.2.2 Perfusion Index (Pi)

The Perfusion Index (Pi) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. Pi thus represents a noninvasive measure of peripheral perfusion that can be continuously and noninvasively obtained from a pulse oximeter.

Pi assists clinicians in determining optimal placement of the $SpO_2$ sensor. This parameter is also useful as a troubleshooting tool by helping a clinician rule out whether a questionable value may be due to low perfusion and/or a low signal to noise condition.

Clinicians use Pi to quickly identify the optimal site to place the sensor. Higher Pi values reflect stronger plethysmogram signals which facilitate more consistent measurements. An added benefit is that changes in perfusion can be an indicator to the clinician of important

changes in the patient's physiological status. Pi is a value between 0.00 and 20.00 %. When Pi is very small, $SpO_2$ and the pulse rate are no longer monitored. When the $SpO_2$ Sensitivity setting explained in section 8.7.1 is set to Maximum, the cut-off limit is 0.02 %; when set to Standard, the limit varies from 0.5 to 0.02 % depending on the signal quality.

### 10.2.3 Pleth Variability Index (PVi)

The Pleth Variability Index (PVi) is a measure of the dynamic changes in the perfusion index (Pi) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in Pi over a time interval where one or more complete respiratory cycles have occurred. PVi may show changes that reflect physiological factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions.

PVi may be a useful non-invasive screening tool or early indicator to help clinicians determine whether to administer fluid to patients. PVi has been proven to demonstrate high accuracy in discriminating fluid responders from non-responders—providing a unique opportunity to better manage a patient's fluid volume to optimize cardiac performance and organ perfusion.

The PVi value is displayed as a percentage and encoded within a data range of 0 to 100%.

### 10.2.4 FastSat Algorithm

FastSat enables rapid response to, and display of, fast changes in $SpO_2$ by giving priority to the most recent data. This aids the clinicians in clinical settings requiring fast response time such as those seen with induction, intubation, sleep studies and resuscitation.

As a result of the increased fidelity of this mode, FastSat is not recommended for routine use as there may be an increase of the frequency of alarms caused by rapid, transitory $SpO_2$ changes.

FastSat is always on for 2 - 4 and 4 - 6 $SpO_2$ Averaging modes.

### 10.2.5 Signal IQ Waveform

Signal IQ provides an indicator of the assessment of the confidence in the displayed $SpO_2$ value. Signal IQ can also be used to identify the occurrence of a patient's pulse.

With motion, the plethysmogram waveform is often distorted and may be obscured by noise artifact. Over time, Signal IQ coincides with the peak of an arterial pulsation. Even when the plethysmogram waveform is obscured by artifact, the Signal IQ identifies the timing that the algorithms have determined for the arterial pulsation. The audible pulse beep will coincide with the non-zero value of Signal IQ. The magnitude of the Signal IQ waveform provides an assessment of the confidence in the measurement displayed. A higher value indicates higher confidence in the measurement whereas a smaller value indicates lower confidence in the measurement displayed.

### 10.2.6 Adaptive Probe Off Detection (APOD)

The Minimum (APOD) setting in the $SpO_2$ Sensitivity menu can be selected for patients who have a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.

Further information about FastSat™, APOD™ (Adaptive Probe-Off Detection), Pi, and Signal IQ can be found in Masimo's white papers at www.masimo.com.

### 10.2.7 Validation and Accuracy

The Masimo SET® Technology has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies in the range of 70 %-100 % $SpO_2$ against a laboratory co-oximeter. This variation equals plus or minus one standard deviation which encompasses 68 % of the population.

The Masimo SET® Technology has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark pigmented skin in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70%-100% $SpO_2$ against a laboratory co-oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

The Masimo SET® Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02 % and transmission of greater than 5 % for saturations ranging from 70 % to 100 %. This variation equals plus or minus one standard deviation which encompasses 68 % of the population.

The Masimo SET® Technology has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02 % and transmission of greater than 5 % for saturations ranging from 70 % to 100 %. This variation equals plus or minus one standard deviation which encompasses 68 % of the population.

The saturation accuracy of the neonate and preterm sensors were validated on adult volunteers and 1 % was added to account for the properties of fetal hemoglobin.

Additional information specific to Masimo sensors compatible with the pulse oximeter, including information about measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).

Cables and sensors are provided with X-Cal™ Technology to minimize the risk of inaccurate parameters/readings and unanticipated loss of patient monitoring. Refer to the cable or sensor DFU for the specified duration of the patient monitoring time.

Masimo Corporation offers the “Masimo Tester” so that the proper functioning of the Masimo SET® pulse oximeter module used in VitaGuard can be tested.

NOTE: The “Masimo Tester” is not suitable to evaluate the accuracy.

# 11. Technical Data

## 11.1 General Specifications

| General | Specification |
|---|---|
| Weight | 510 g |
| Dimensions (L x B x H) | 178 x 118.6 x 40 mm. |
| Overall weight of monitor and accessories in transport case | 1.9 kg |
| User interfaces | 4.3" TFT colour display with resistive touch<br>2 pushbutton keys (Esc and Enter)<br>4 LED indicators:<br>- Heartbeat: green<br>- Battery charging: green<br>- External power adapter: green<br>- Alarm: red and yellow<br>2 alarm buzzer outlets |
| Connectors | $SpO_2$: 14-pin 3M connector<br>External power adapter: 2-pin round connector (grey)<br>Communication: USB-C connector |
| Internal power supply | Li-ion rechargeable battery pack:<br>- 2 x Panasonic NCA103450A cells<br>- Nominal voltage: 3.6 V<br>- Nominal capacity: 4400 mAh<br>- Integrated safety mechanism<br>Charging time: Max. 6 h<br>Charging cycles: >200 |
| Operating time with fully charged battery | Min. 8 h |
| Auxiliary backup power supply | Lithium cell VL2330HFN (3 V) |
| External power supply | Medical grade external power adapter:<br>- Manufacturer: FRIWO Gerätebau GmbH<br>- Type: FW 8001M/05<br>- Input: 100–240 V, 50–60 Hz, 400 mA, AC<br>- Output: 5 V, 3000 mA, DC<br>- Ingress protection: IP 42<br>- Safety class: II as per IEC 60601-1<br>- Cable length: 183 cm |

| General | Specification |
|---|---|
| Average power consumption | <2 W, max. 10 W when charging battery. |
| Ingress protection (IP) | IP 22, protection of the housing against the intrusion of solid objects >12.5 mm and dripping water |
| Device safety class | II as per IEC 60601-1 |
| Applied parts classification | BF (body floating) |
| Defibrillator proof | Yes |
| EMC classification | CISPR 11, class B as per IEC 60601-1-2 |
| Medical device classification | IIb as per European Medical Device Regulation EU 2017/745 |
| Operating conditions | Temperature: +5 to +40 °C<br>Humidity: 15 – 90 %, non-condensing<br>Ambient pressure: 70 – 106 kPa |
| Storage and transport conditions | Temperature: -25 to +70 °C<br>Humidity: 0 – 90 %, non-condensing<br>Ambient pressure: 70 – 106 kPa<br><br>NOTE: Refer to the sensors' packaging for the storage temperature of sensors. |
| Calibrating start-up time | < 60 s |
| Display refresh rate | 1 Hz |
| Intervals for calculating average values for $SpO_2$ and pulse rate in the Info view | Minute values: 1 s<br>Hour value: 30 s<br>Six-hour value: 300 s<br>Twelve-hour value: 300 s |
| Data logging | Alarm event log: 1,000 events<br>Trend log: 168 hours<br>Full disclosure log: 48 hours<br>Compliance log: 15,000 events |
| Data retention | > 3 months |
| Communication | USB 2.0<br>WLAN/Bluetooth wireless module |
| Wireless communication module | IEEE 802.11 b/g/n Link Controller Module with Integrated Bluetooth 5.0 |
| Expected service life under normal use conditions | VitaGuard monitor: 7 years<br>RD SET $SpO_2$ patient cable: 2 years<br>LNC $SpO_2$ patient cable: 1 year |
| Recommended inspection and service intervals | 18 months |

| General | Specification |
|---|---|
| Characteristics of HIGH priority acoustic alarm signal | Acoustic signals for HIGH priority alarms consist of two acoustic sequences of five tones each:<br>  <br><br>Number of pulses: 10<br>Effective pulse duration: 155 ± 5 ms<br>Pulse spacing between:<br>- 1st and 2nd pulse: 120 ± 5 ms<br>- 2nd and 3rd pulse: 120 ± 5 ms<br>- 3rd and 4th pulse: 400 ± 10 ms<br>- 4th and 5th pulse: 120 ± 5 ms<br>- 5th and 6th pulse: 725 ± 20 ms<br>- 6th and 7th pulse: 120 ± 5 ms<br>- 7th and 8th pulse: 120 ± 5 ms<br>- 8th and 9th pulse: 400 ± 10 ms<br>- 9th and 10th pulse: 120 ± 5 ms<br>Interburst interval: 7.0 ± 0.5 s |
| Characteristics of MEDIUM priority acoustic alarm signal | Acoustic signals for medium priority are as follows:<br>Number of pulses: 3<br>Effective pulse duration: 150 ± 10 ms<br>Pulse spacing between:<br>- 1st and 2nd pulse: 240 ± 10 ms<br>- 2nd and 3rd pulse: 240 ± 10 ms<br>Interburst interval: 7.2 ± 0.5 s |
| Alarm volume | 78 dB at measurement radius of 1 m |
| Alarm tone frequency | 800 Hz |
| Power-fail alarm signal | 1 Hz signal with tone frequency 1300 Hz ± 100 Hz |

# 11.2 $SpO_2$ and Pulse Rate Monitor Specifications

| $SpO_2$ and Pulse Rate Monitor | Specification |
|---|---|
| $SpO_2$ range | 1 – 100 % |
| Pulse rate range | 25 – 240 /min |
| Perfusion index (Pi) range | 0.02 – 20.00 % |
| Pleth variability index (PVi) range | 0 – 100 % |
| $SpO_2$ accuracy for all age groups during motion* | 70 – 100 %: ± 3 digits<br>< 70 %: unspecified |
| Pulse rate accuracy for all age groups* | ± 3 /min during no motion conditions<br>± 5 /min during motion conditions |
| Accuracy with low perfusion, i.e., pulse amplitude > 0.02 % and transmission > 5 % | $SpO_2$ ± 2 digits<br>Pulse rate ± 3 digits |
| $SpO_2$ resolution | 1 % |
| Pulse rate resolution | 1 /min |
| Surface temperature of sensor | Max. 41 °C at the sensor site at 25 °C ambient temperature |
| Nominal wavelengths | Red LED: 660 nm<br>Infra-red LED: 905 nm<br>This information about wavelength range can be especially useful to clinicians, for example, clinicians performing photodynamic therapy. |
| Radiated power at 50 mA pulsed | ⩽ 15 mW |

* The specified tolerances correspond to a standard deviation of ± 1. This standard deviation encompasses 68% of the population.

# 11.3 Electromagnetic Compatibility Specifications

The following specifications are according to IEC 60601-1-2: 2014 + A1: 2020.

## 11.3.1 Electromagnetic Emissions

| Guidance and Manufacturer's Declaration – Electromagnetic Emissions | | |
|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that the device is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment – guidance |
| RF emissions CISPR 11 | Group 1 | The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |
| RF emissions CISPR 11 | Class B | The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations / Flicker emissions IEC 61000-3-3 | Complies | |

## 11.3.2 Electromagnetic Immunity (Line-Bound Disturbances)

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment. | | | |
| Immunity test | IEC 60601-1-2 test level | Compliance level | Electromagnetic environment – guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact<br>± 15 kV air | ± 8 kV contact<br>± 15 kV air | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electric fast transient / burst IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input / output lines | ± 2 kV for power supply lines<br>± 1 kV for input / output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV outer conductor<br>± 2 kV outer conductor-ground | ± 1 kV outer conductor<br>± 2 kV outer conductor-ground | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | < 5% UT (> 95% dip) for 0.5 cycle<br>< 5% UT (> 95% dip) for 1 cycle<br>70% UT (30% dip) for 25 cycles<br>< 5% UT (> 95% dip) for 5 s | < 5 % UT (> 95 % dip) for 0.5 cycle<br>< 5 % UT (> 95% dip) for 1 cycle<br>70 % UT (30 % dip) for 25 cycles<br>< 5 % UT (> 95% dip) for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | Not applicable | The device has no magnetically sensitive parts according to table 4, Note d) in EN 60601-1-2:2015 |
| NOTE: UT is the AC mains voltage prior to application of the test level. | | | |

### 11.3.3 Electromagnetic Immunity (Conducted and Radiated RF Disturbances)

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment. | | | |
| Immunity test | IEC 60601-1-2 test level | Compliance level | Electromagnetic environment – guidance |
| Conducted RF<br>IEC 61000-4-6 | 3 V effective value<br>150 kHz to 80 MHz | 3 V effective value | Portable and mobile RF devices are not used at closer than 30 cm to the device including leads |
| Radiated RF<br>IEC 61000-4-3 | 6 V effective value in the ISM bands between 0,15 MHz and 80 MHz<br>10 V/m<br>80 MHz to 2,7 GHz<br>Immunity against wireless RF communication devices | 6 V effective value in the ISM bands according to table 5, Note N)<br>10 V/m<br>According to Table 9 of standard | The field strength of stationary radio transmitters is, as determined by an electromagnetic site survey, at all frequencies smaller than the compliance level.<br>Interference may occur in the vicinity of equipment marked with the following symbol.  |
| Proximity magnetic fields<br>IEC 61000-4-39 | Test frequency / Modulation<br>30 kHz / CW<br>134.2 kHz / Pulse modulation 2.1 kHz<br>13.56 MHz / Pulse modulation 50 kHz | Immunity Test Level A/m<br>8<br>65<br>7.5 | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or home healthcare environment. |
| NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. | | | |

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity |
|---|
| NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. |
| a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) tele-phones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.<br>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. |

## 11.4 Nurse Call Unit Cable

The 2.7 m nurse call unit (NCU) cable provides an interface between the VitaGuard VG 5 monitor and an NCU system used in a clinical environment. The cable incorporates a relay which switches to its active position when the VitaGuard monitor detects a technical or patient alarm. The relay returns to its resting position once the alarm condition ends or when the alarm reset key is pressed on VitaGuard's front panel.

The USB-C end of the cable is connected to VitaGuard's USB-C port. Once connected, VitaGuard displays a corresponding icon on its screen to confirm that the cable has been detected. VitaGuard outputs a technical alarm when the cable is removed as a precaution against unintentional removal. Pressing the alarm reset key terminates the alarm.

A biomedical engineer must connect the open-ended wiring at the other end of the cable to the appropriate NCU inputs. The white wire is the relay's common contact which switches between brown and green as follows:

| Alarm Condition | White - Brown | White - Green |
|---|---|---|
| No alarm | Closed | Open |
| Alarm | Open | Closed |

# 12. Glossary

The following is a glossary of medical and technical terms used throughout this manual.

| Term | Description / Definition |
|---|---|
| Amplitude | Amplitude is the peak value of a quantity or wave. |
| Apnea | Central sleep apnea (CSA) is a sleep-related disorder in which the effort to breathe is diminished or absent, typically for 10 to 30 seconds, either intermittently or in cycles. |
| Bradycardia | Slow resting heart rate, typically under 60 beats per minute for adults, and under 100 beats per minute for infants. |
| ECG | Electrocardiogram (ECG), a recording of the heart's electrical activity. |
| Hyperoxia | A condition caused by an excess of oxygen in tissues and organs |
| Hypoxia | A deficiency in the amount of oxygen delivered to the body tissues |
| LED | Light emitting diode, an electronic device that gives off light when it receives an electrical current. |
| Li-ion | A lithium-ion or Li-ion battery is a type of rechargeable battery which uses the reversible reduction of lithium ions to store energy. |
| Oxygen saturation ($SpO_2$) | Oxygen saturation is the fraction of oxygen-saturated hemoglobin relative to total hemoglobin (unsaturated + saturated) in the blood. |
| Pulse oximetry Plethysmogram | A non-invasive method for monitoring a person's oxygen saturation. The waveform displayed depicting the blood volume changes is referred to as a plethysmogram. |
| Tachycardia | A rapid resting heart rate, usually defined as greater than 100 beats per minute for adults. For children it depends on your child's age and physical condition. |

# 13. Table of Figures

# 14. Revision History

These instructions for use have been subject to the following changes:

| Revision | Publication | Description |
|---|---|---|
| 01 | 2024-02-29 | Initial release version. |
| 02 | 2024-06-06 | Chapter 1.2: Intended purpose unified for all VG 5 devices.<br>Chapter 1.5.1: Device label updated.<br>Chapter 1.5.2: Transport case label updated. |
| 03 | 2024-10-15 | Chapter 1.5.2: Transport case label updated (CE 0197 mark removed).<br>Chapter 6.8.2: Check power adapter message added. |
| 04 | 2025-07-25 | Chapter 2: Removed RD SET MD14-08 cable, replaced kit with MD14-05 cable, added additional power adapters to accessory list.<br>Chapter 8.3.1: Brightness dimmed to 20 %.<br>Chapter 8.9: New, confirming settings via VitaWin.<br>Back cover: Feedback information and link added. |

## Your feedback is important to us!

Please take a few minutes to let us know about your experience with the VitaGuard monitor. Your feedback helps us to constantly improve the product.

The survey is anonymous, but at the end of the survey you will have the opportunity to provide us with your contact details if you wish to do so.

Feedback

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