

# VitaGuard® VG 5 CR

## Apnea and Heart Rate Monitor

### Instructions for Use



Revision 04

# Legal Information

The information contained in this manual applies only to the **VitaGuard® VG 5 CR** 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.

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# Contents

|        |  |          |
|--------|--|----------|
| 1.     | <b>Regulatory and Safety Information.....</b>                                | <b>8</b> |
| 1.1    | Purpose of this Instructions for Use Manual.....                             | 8        |
| 1.2    | Intended Purpose of VitaGuard VG 5 CR.....                                   | 8        |
| 1.3    | Indications and Contraindications .....                                      | 9        |
| 1.3.1  | Indications for Use .....  | 9        |
| 1.3.2  | Contraindications.....   | 9        |
| 1.4    | Limitations of VitaGuard's Intended Purpose.....                             | 9        |
| 1.4.1  | Limitations of Apnea Detection .....   | 10       |
| 1.4.2  | Limitations of Heart Rate Monitoring.....                                    | 11       |
| 1.5    | Labels and Symbols .....   | 11       |
| 1.5.1  | Device Label.....  | 11       |
| 1.5.2  | Transport Case Label .....   | 12       |
| 1.5.3  | Symbols on the Front Panel of the Monitor .....                              | 12       |
| 1.5.4  | Symbols on the Connector Panel of the Monitor.....                           | 13       |
| 1.5.5  | Symbols on the Device Label of the Monitor .....                             | 14       |
| 1.5.6  | Symbols Displayed on the Monitor Screen .....                                | 15       |
| 1.5.7  | Additional Symbols on the Transport Case.....                                | 17       |
| 1.5.8  | Additional Symbols on Accessory Packaging .....                              | 18       |
| 1.6    | Warnings, Cautions and Notices.....  | 19       |
| 1.6.1  | Safety Information Related to Caregiver's Tasks .....                        | 20       |
| 1.6.2  | Safety Information Related to the Monitor in General.....                    | 22       |
| 1.6.3  | Safety Information Related to Other Devices.....                             | 27       |
| 1.6.4  | Safety Information Related to the Power Adapter .....                        | 30       |
| 1.6.5  | Safety Information Related to Accessories.....                               | 32       |
| 1.6.6  | Safety Information Related to Monitoring Heart Rate<br>and Respiration ..... | 33       |
| 1.6.7  | Safety Information Related to Cleaning and Disinfecting.....                 | 35       |
| 1.6.8  | Safety Information Related to Service.....                                   | 36       |
| 1.6.9  | Safety Information Related to the Rechargeable Battery.....                  | 37       |
| 1.6.10 | Safety Information Related to Cybersecurity .....                            | 39       |
| 1.7    | Cleaning and Disinfecting .....  | 41       |
| 1.7.1  | Preparation .....  | 41       |
| 1.7.2  | Cleaning .....   | 41       |
| 1.7.3  | Disinfection .....   | 42       |
| 1.7.4  | Drying .....   | 43       |
| 1.7.5  | Maintenance.....   | 43       |
| 1.7.6  | Packaging / Transport Case .....   | 43       |
| 1.7.7  | Storage .....  | 44       |

|       |  |    |
|-------|--|----|
| 1.7.8 | Additional Information .....                                   | 44 |
| 1.8   | Service Information .....                                      | 44 |
| 1.9   | Disposal Information .....                                     | 45 |
| 2.    | <b>Sets and Accessories</b> .....                              | 47 |
| 2.1   | Complete Sets .....  | 47 |
| 2.2   | Accessories in Original Packaging .....                        | 47 |
| 2.3   | Accessories and Ordering Information.....                      | 48 |
| 3.    | <b>General Description</b> .....                               | 50 |
| 3.1   | Modes of Operation .....                                       | 50 |
| 3.2   | VitaGuard Setup.....   | 51 |
| 3.3   | Connector Panel.....   | 52 |
| 3.3.1 | Heart Rate & Respiration Patient Cable Connector.....          | 52 |
| 3.3.2 | Power Adapter Connector .....                                  | 53 |
| 3.3.3 | USB Connector .....  | 53 |
| 3.4   | User Interface Elements on Front Panel .....                   | 53 |
| 3.4.1 | <Enter> Key / On/Off Key .....                                 | 54 |
| 3.4.2 | <Esc> Key / Alarm Reset .....                                  | 54 |
| 3.4.3 | Alarm LED.....   | 55 |
| 3.4.4 | Heart and Respiration LEDs.....                                | 55 |
| 3.4.5 | Power Supply and Battery Charge LEDs .....                     | 55 |
| 3.4.6 | Display and Touchscreen / View 1.....                          | 56 |
| 3.4.7 | Alarm Buzzer Outlets .....                                     | 57 |
| 3.5   | Power Supply.....  | 58 |
| 3.5.1 | External Power Adapter .....                                   | 58 |
| 3.5.2 | Rechargeable Battery Pack.....                                 | 59 |
| 3.5.3 | Power Fail Battery / Reset Button .....                        | 61 |
| 4.    | <b>Steps Before and After Monitoring</b> .....                 | 62 |
| 4.1   | Steps Before Monitoring / Pre-Use Checks.....                  | 62 |
| 4.2   | Switching VitaGuard On.....                                    | 63 |
| 4.3   | Switching VitaGuard Off .....                                  | 64 |
| 4.4   | Steps After Monitoring .....                                   | 64 |
| 5.    | <b>Heart Rate and Apnea Monitoring</b> .....                   | 65 |
| 5.1   | General Information on Heart Rate and Apnea Monitoring.....    | 65 |
| 5.2   | Connecting ECG Electrodes and Patient Cable to VitaGuard ..... | 67 |
| 5.3   | Finding the Optimal Electrode Configuration.....               | 67 |
| 5.3.1 | Standard ECG Electrode Configuration .....                     | 67 |
| 5.3.2 | Optimizing the ECG and Respiration Signals.....                | 69 |
| 5.3.3 | Changing the ECG Lead for Signal Optimization.....             | 70 |
| 5.4   | Basal Impedance.....   | 71 |

|       |  |    |
|-------|--|----|
| 5.5   | Electrode-Off Technical Alarms.....                        | 71 |
| 5.6   | Heart Rate According to Age.....                           | 72 |
| 6.    | <b>Alarm System</b> .....                                  | 73 |
| 6.1   | Introduction.....  | 73 |
| 6.2   | Patient Alarms.....  | 74 |
| 6.3   | Silent Patient Alarms .....                                | 76 |
| 6.4   | Technical Alarms.....                                      | 76 |
| 6.5   | Alarm Test .....   | 78 |
| 6.6   | Informational Messages.....                                | 79 |
| 6.7   | Reminder Signal .....                                      | 79 |
| 6.8   | Alarm Messages and Troubleshooting .....                   | 79 |
| 6.8.1 | Patient Alarm Messages .....                               | 79 |
| 6.8.2 | Technical Alarm Messages .....                             | 81 |
| 6.8.3 | Informational Messages .....                               | 83 |
| 6.8.4 | Error Messages during Start-Up.....                        | 84 |
| 6.8.5 | Hardware Reset .....                                       | 84 |
| 6.9   | Alarm Function Test .....                                  | 84 |
| 7.    | <b>Monitor Views</b> .....                                 | 86 |
| 7.1   | Introduction.....  | 86 |
| 7.2   | Views (Settings Protection Mode On).....                   | 86 |
| 7.2.1 | Home Screen .....  | 86 |
| 7.2.2 | Info View .....  | 87 |
| 7.2.3 | System View .....  | 88 |
| 7.2.4 | Memory View.....   | 88 |
| 7.3   | Views (Settings Protection Mode Limited).....              | 89 |
| 7.3.1 | Home Screen .....  | 89 |
| 7.3.2 | View 2 .....   | 89 |
| 7.3.3 | View 3 .....   | 90 |
| 7.3.4 | Heart Rate View .....                                      | 90 |
| 7.3.5 | Respiration View .....                                     | 91 |
| 7.3.6 | Memory View.....   | 92 |
| 7.4   | Views (Settings Protection Mode Off).....                  | 92 |
| 7.5   | Info Views .....   | 92 |
| 7.5.1 | Info \ Page 1: Last Status Messages.....                   | 93 |
| 7.5.2 | Info \ Page 2: General Information.....                    | 93 |
| 7.5.3 | Info \ Page 3: System Status .....                         | 94 |
| 7.5.4 | Info \ Page 4: Measurements: Heart Rate & Respiration..... | 94 |
| 7.5.5 | Info \ Page 5 and Page 6: Current Settings.....            | 95 |
| 7.5.6 | Info \ Page 7: Versions .....                              | 96 |
| 7.5.7 | Info \ Page 8: License Information .....                   | 96 |

|        |  |     |
|--------|--|-----|
| 8.     | <b>Settings</b> .....  | 97  |
| 8.1    | Introduction .....   | 97  |
| 8.2    | Changing Settings .....                                      | 97  |
| 8.3    | System Settings (Settings Protection Mode On) .....          | 99  |
| 8.3.1  | System \ Display Mode .....                                  | 99  |
| 8.3.2  | System \ Display Brightness .....                            | 100 |
| 8.3.3  | System \ Signal Beep Tone .....                              | 100 |
| 8.3.4  | System \ Alarm Volume.....                                   | 100 |
| 8.3.5  | System \ Settings Protection.....                            | 101 |
| 8.4    | Heart Rate Settings (Settings Protection Mode Limited).....  | 102 |
| 8.4.1  | Heart Rate \ HR Lower Limit.....                             | 103 |
| 8.4.2  | Heart Rate \ HR Upper Limit.....                             | 103 |
| 8.5    | Respiration Settings (Settings Protection Mode Limited)..... | 104 |
| 8.5.1  | Respiration \ Apnea Delay .....                              | 104 |
| 8.5.2  | Respiration \ Apnea Alarms .....                             | 104 |
| 8.6    | System Settings (Settings Protection Mode Off) .....         | 105 |
| 8.6.1  | System \ Operating Area .....                                | 105 |
| 8.6.2  | System \ Admit New Patient .....                             | 105 |
| 8.6.3  | System \ Pre-Alarm Time & Post-Alarm Time .....              | 108 |
| 8.6.4  | System \ Manual Event Recording .....                        | 108 |
| 8.6.5  | System \ Interval Recording.....                             | 108 |
| 8.6.6  | System \ Show Views 2 & 3 .....                              | 109 |
| 8.6.7  | System \ Date & Time.....                                    | 109 |
| 8.6.8  | System \ Language .....                                      | 110 |
| 8.6.9  | System \ Date Format .....                                   | 110 |
| 8.7    | Heart Rate Settings (Settings Protection Mode Off) .....     | 111 |
| 8.7.1  | Heart Rate \ HR Averaging .....                              | 111 |
| 8.7.2  | Heart Rate \ HR Lead Select .....                            | 111 |
| 8.7.3  | Heart Rate \ HR 50/60 Hz Filter .....                        | 111 |
| 8.7.4  | Heart Rate \ HR Pacemaker Detection.....                     | 111 |
| 8.7.5  | Heart Rate \ HR Silent Lower Limit .....                     | 112 |
| 8.7.6  | Heart Rate \ HR Silent Upper Limit .....                     | 112 |
| 8.7.7  | Heart Rate \ HR Bradycardia Delay .....                      | 112 |
| 8.7.8  | Heart Rate \ HR Tachycardia Delay .....                      | 112 |
| 8.7.9  | Heart Rate \ HR Asystole Delay .....                         | 112 |
| 8.7.10 | Heart Rate \ HR Deviation Averaging Interval .....           | 113 |
| 8.7.11 | Heart Rate \ HR Deviation Alarm Limit (-) .....              | 113 |
| 8.7.12 | Heart Rate \ HR Deviation Alarm Limit (+).....               | 113 |
| 8.7.13 | Heart Rate \ HR Alarms .....                                 | 113 |
| 8.8    | Respiration Settings (Settings Protection Mode Off) .....    | 114 |

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|        |  |     |
|--------|--|-----|
| 8.8.1  | Respiration \ Silent Apnea Delay .....                                     | 114 |
| 8.8.2  | Respiration \ Periodic Respiration .....                                   | 114 |
| 8.8.3  | Respiration \ Period T1 (Delay).....                                       | 114 |
| 8.8.4  | Respiration \ Period T2 (Resp.).....                                       | 115 |
| 8.8.5  | Respiration \ Number of Periods .....                                      | 115 |
| 8.8.6  | Respiration \ Minimum Respiration Rate .....                               | 115 |
| 8.9    | Changing Settings via VitaWin.....   | 115 |
| 9.     | <b>Data Logging</b> .....  | 117 |
| 9.1    | Alarm System Log .....   | 117 |
| 9.2    | Trend Log.....   | 121 |
| 9.3    | Full-Disclosure Log.....   | 123 |
| 9.4    | Logged Data and Sample Rates.....  | 124 |
| 9.5    | Compliance Log.....  | 124 |
| 9.6    | Data Download to USB Memory.....   | 125 |
| 9.7    | Evaluating Stored Data on a PC .....                                       | 126 |
| 10.    | <b>Alarm Delays and Measuring Principles</b> .....                         | 127 |
| 10.1   | Alarm Delays.....  | 127 |
| 10.1.1 | Alarm Condition Delay for Heart Rate .....                                 | 127 |
| 10.1.2 | Alarm Condition Delay for Respiration .....                                | 128 |
| 10.1.3 | Alarm Report Delays.....   | 128 |
| 10.2   | Measuring Principle of Heart Rate Monitoring.....                          | 129 |
| 10.3   | Measuring Principle of Apnea Monitoring .....                              | 130 |
| 11.    | <b>Technical Data</b> .....  | 131 |
| 11.1   | General Specifications.....  | 131 |
| 11.2   | Heart Rate Monitor Specifications .....                                    | 134 |
| 11.3   | Apnea Monitor Specifications.....  | 135 |
| 11.4   | Electromagnetic Compatibility Specifications.....                          | 136 |
| 11.4.1 | Electromagnetic Emissions.....   | 136 |
| 11.4.2 | Electromagnetic Immunity (Line-Bound Disturbances). 137                    |     |
| 11.4.4 | Electromagnetic Immunity (Conducted and Radiated<br>RF Disturbances) ..... | 138 |
| 11.5   | Nurse Call Unit Cable.....   | 139 |
| 12.    | <b>Glossary</b> .....  | 140 |
| 13.    | <b>Table of Figures</b> .....  | 141 |
| 14.    | <b>Revision History</b> .....  | 143 |

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# 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 CR 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 need to 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 CR

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 CR is indicated for use on patients (neonates, infants, pediatrics and adults) where a physician recommends continuous, non-invasive monitoring of vital signs, namely to detect central apnea and monitor heart rate.

### **1.3.2 Contraindications**

The VitaGuard VG 5 CR is contraindicated for use on patients that react allergically to ECG electrode gel.

It is not intended for the detection of obstructive apnea. Central apnea can only be detected when the patient is lying on a stable underground.

## **1.4 Limitations of VitaGuard's Intended Purpose**

Calculation of the heart rate is based on the continuous measurement of a single channel electrocardiograph (ECG) signal acquired by applying three ECG electrodes to intact skin on the patient's upper body which are in turn connected to the monitor using a defined patient cable. Respiratory effort detection is based on continuous measurement of the transthoracic impedance measured between two of the ECG electrodes used for heart rate detection.

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 CR cannot detect all life-threatening situations under certain unfavorable conditions.

The prescribing physician treating the patient is responsible for the safe application of the VitaGuard 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.

#### **1.4.1 Limitations of Apnea Detection**

VitaGuard VG 5 CR cannot detect obstructive apneas, i.e., apneas caused by complete or partial obstruction of the upper airway. Occlusion or blockage of the respiratory tract can be caused, for example, by food debris or vomit. The caregiver may have to remove food debris from the patient's oral cavity.

VitaGuard could misinterpret movement as respiration, e.g., during transport in ambulances, cars, and prams, or when a child is held in the caregiver's arms. For this reason, central apneas can only be detected when the patient is sleeping or lying still and is not being moved. Using VitaGuard for detection of central apnea during patient transport is therefore not permitted.

Should a low heart rate alarm occur due to an obstructive apnea event, it may be necessary to perform cardiopulmonary resuscitation.

## 1.4.2 Limitations of Heart Rate Monitoring

The heart rate can be monitored with electrodes during patient motion. However, sudden, vigorous movements can adversely affect the measuring accuracy.

A false heart rate may be displayed during ventricular fibrillation or when the heart rate exceeds 350 beats per minute.

Additional detailed safety information on heart rate and central apnea monitoring is provided in section 1.6.6.

## 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.



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.

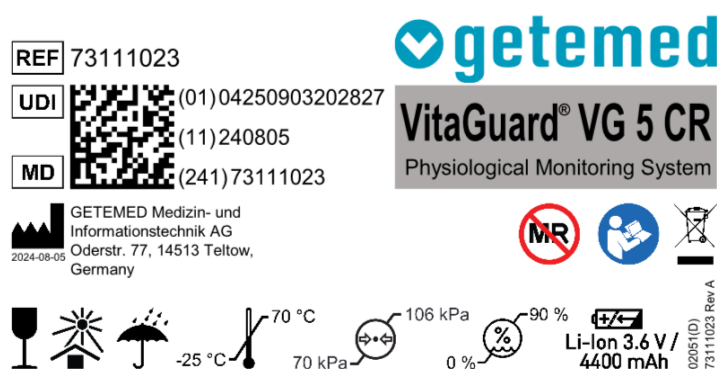




Fig. 2 Example of Label on VG 5 CR Transport Case

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

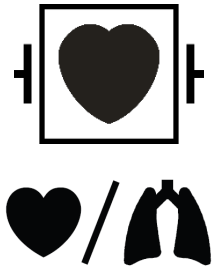

The following symbols are located on the front panel of the monitor.

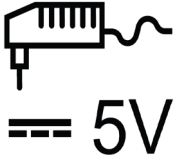
| Symbol | Description   |
|--------|---|
|        | <b>FOLLOW INSTRUCTIONS FOR USE</b><br>This symbol indicated that you must read the instructions for use before using the monitor.   |
|        | <b>GETEMED Logo</b><br>This logo is the logo of the manufacturer of the monitor: GETEMED Medizin- und Informationstechnik AG.   |
|        | <b>Trade Name and Model</b><br>This logo indicates the trade name “VitaGuard” and model type “VG 5 CR” of the monitor.  |
|        | <b>Heart Symbol</b><br>This symbol marks the visual indicator (green LED) that flashes when a heartbeat is detected by the monitor.   |
|        | <b>Lung Symbol</b><br>This symbol marks the visual indicator (green LED) that flashes when a respiration cycle is detected by the monitor.  |
|        | <b>Enter and On/Off</b><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. |

| Symbol  | Description   |
|---|---|
|  | <p><b>Esc and Alarm Reset</b></p> <p>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.</p> <p>The LED behind the triangular alarm symbol changes colour depending on the current alarm situation:</p> <p>White: no alarm<br/>Yellow: technical alarm<br/>Red: patient alarm</p>           |
|  | <p><b>Rechargeable Battery</b></p> <p>The top symbol marks the visual indicator (green LED) to show the charging status of the rechargeable battery:</p> <p>Permanently on: Battery is charging<br/>Permanently off: Battery fully charged<br/>Flashing: Error detected</p> <p><b>Power Adapter</b></p> <p>The bottom symbol marks the visual indicator (green LED) to indicate that the power adapter is connected to the monitor.</p> |

#### 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  |
|---|--|
|  | <p><b>Type CF (Cardiac Floating) Applied Part</b></p> <p>The top symbol located beside the connector for the heart rate and respiration cable indicates that the input is a type CF APPLIED PART with defibrillator protection. This means that the input is floating and electrically isolated from the mains power earth.</p> <p>The heart and lung symbols underneath indicate that both the ECG and respiration signals are acquired through this connector.</p> |
|  | <p><b>General Warning Sign</b></p> <p>This symbol informs that protection of the monitor against the effects of the discharge of a cardiac defibrillator is dependent upon the use of the ECG cable supplied with the monitor.</p>   |

| Symbol  | Description  |
|---|--|
|  | <b>Power Adapter Input</b><br>This symbol marks the connector for the medical grade 5 V external power adapter supplied with the monitor.  |
| <b>USB</b>  | <b>USB (Universal Serial Bus)</b><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  |
|---|--|
| <b>CE 0197</b>  | <b>CE Mark</b><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. |
|  | <b>Model Number</b><br>Indicated the model number of the monitor: VG 5 CR.   |
|  | <b>Medical Device</b><br>Indicates that the monitor is a medical device.   |
|  | <b>Catalogue Number</b><br>Indicates the manufacturer's catalogue number for the monitor.  |
|  | <b>Serial Number</b><br>Indicates the serial number of the monitor for identification purposes.  |
|  | <b>Manufacturer</b><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.   |
|  | <b>Waste of Electrical and Electronic Equipment</b><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.  |





| Symbol  | Description   |
|---|---|
|    | <b>Unique Device Identifier</b><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)  |
| <b>IP22</b>   | <b>Ingress Protection (IP)</b><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. |
|   | <b>MR Unsafe</b><br>This symbol indicates that neither the monitor nor its accessories are intended to be used in the magnetic resonance (MR) environment.  |
|  | <b>Rechargeable Li-ion Battery</b><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.




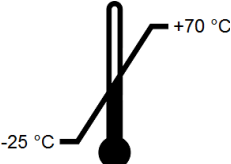
| Symbol  | Description  |
|---|--|
|  | <b>Home Screen</b><br>Touching this icon displays the GUI home screen  |
|  | <b>View 1</b><br>Touching this icon from the GUI home screen enters View 1. The same applies to the View 2 and View 3 icons. |
|  | <b>Heart Rate Icon</b><br>Touching this icon from the GUI home screen enters the heart rate view.                            |

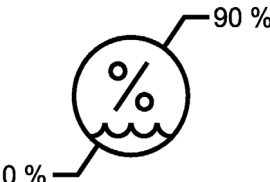
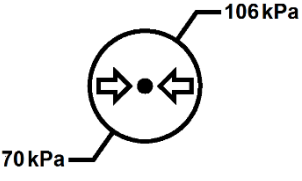
| Symbol   | Description   |
|--|---|
|   | <b>Respiration Icon</b><br>Touching this icon from the GUI home screen enters the respiration view.   |
|   | <b>Information Icon</b><br>Touching this icon from the GUI home screen accesses the information pages.  |
|   | <b>System Icon</b><br>Touching this icon from the GUI home screen enters the system settings menus.   |
|   | <b>Memory Icon</b><br>Touching this icon from the GUI home screen causes the GUI to display the event, trend and USB icons.   |
|   | <b>Event Icon</b><br>Touching this icon displays a list of stored alarm events.   |
|   | <b>Trend Icon</b><br>Touching this icon displays a list of stored trend recordings.   |
| <br>   | <b>USB Icon</b><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. |
|   | <b>Settings Icon</b><br>Touching this icon enters the settings menu of the selected view (heart rate or respiration). The settings related to the selected view may be selected and changed.          |
|    | <b>Cancel and Enter Icons</b><br>Touch these icons to cancel or accept changes.   |
|  <br>  | <b>Navigation Icons</b><br>Touch these icons to navigate through the graphical user interface.  |
|    | <b>Bell Icons</b><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.                    |

| Symbol  | Description   |
|---|---|
|  | <b>Alarm Icons (Technical Alarm)</b><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. |
|  | <b>Alarm Icons (Patient Alarm)</b><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.                           |
|  | <b>Battery Status Icons</b><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.                                      |
|  | <b>Nurse Call Unit Cable Icons</b><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  |
|---|--|
|  | <b>Fragile, handle with care</b><br>Indicates the transport case and its contents are fragile and could be damaged if not handled with care.   |
|  | <b>Keep dry</b><br>Indicates that the transport case and its contents need to be protected from rain and other sources of moisture.  |
|  | <b>Keep away from sunlight</b><br>Indicates that the transport case and its contents need to be protected from direct sunlight.  |
|  | <b>Temperature Limits</b><br>Indicates the upper and lower limits of temperature to which the transport case and its contents can be exposed. The limits are indicated next to the upper and lower horizontal lines. |

| Symbol  | Description  |
|---|--|
|  | <b>Humidity Limitation</b><br>Indicates the upper and lower limits of humidity to which the transport case and its contents can be exposed. The limits are indicated next to the upper and lower horizontal lines.                         |
|  | <b>Atmospheric Pressure Limitation</b><br>Indicates the upper and lower limits of atmospheric pressure to which the transport case and its contents can be 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   |
|---|---|
|   | <b>Non-Sterile</b><br>This symbol on the packaging of the electrodes indicates that these are not sterile.  |
|  | <b>Single Use Only</b><br>This symbol on the packaging of the electrodes indicates that these are suitable for one-time use only.   |
|  | <b>Latex Free</b><br>This symbol on the packaging of the electrodes indicates that these are not made with natural rubber latex.  |
|  | <b>Consult Instructions for Use</b><br>This symbol on the packaging of the electrodes indicates that you must consult the instructions for use before using them.   |
|  | <b>Use By Date</b><br>This symbol on the packaging of the electrodes indicates the date after which they are not to be used.  |
|  | <b>Batch Code</b><br>This symbol on the packaging of the electrodes 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. |

## 1.6 Warnings, Cautions and Notices

The prescribing physician is responsible to ensure 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 indicators for heart rate and respiration are 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 before the setup has been 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 electrode 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 ECG electrodes or packaging material.

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

- keep the upper body of infants and small children covered so that they cannot pull on the ECG electrodes;
- keep packaging material out of children's reach.

**WARNING:** STRANGULATION

Risk of death or serious injury from strangulation on the patient cable or electrode cables.

To avoid possible strangulation, route the patient's cable and electrode cables 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 cables so that they exit between the trousers and pullover. Secure all cables to ensure that no harm can come to the patient if the patient turns or rolls over during monitoring. Route the cables 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.

Setup the monitor in such a way that you can always hear the acoustic alarm, 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 electrodes and completely disconnect VitaGuard before bathing the patient;
- do not attempt to clean VitaGuard while monitoring a patient.
- keep the conductive parts of ECG electrodes away from other conductive parts, including earth. Also make sure that no contact to other conductive parts, including earth, is possible should an ECG electrode 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 ECG electrode'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:** 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.

**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 cable including its connectors, the external power adapter, and the electrodes 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.

**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 ECG electrodes, on one patient only;
- always use the same patient cable on the same patient;
- disinfect VitaGuard and the patient cable before using them 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:** IMPEDANCE PNEUMOGRAPHY

Risk of death or serious injury due to overseeing a critical alarm situation if VitaGuard's performance is compromised due to interference from patient monitors that also employ impedance pneumography to measure respiratory effort.

Do not use VitaGuard simultaneously with other patient monitors that employ impedance pneumography for detecting respiratory effort, as such devices may interfere with each other if they use the same modulation frequency.

**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:** TRANSCUTANEOUS 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 ECG cables 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:** DEFIBRILLATORS

Risk of burns and injury to the patient during defibrillation.

VitaGuard is protected against the impact of defibrillators when used with the ECG cable provided. Nevertheless, before using a defibrillator, disconnect VitaGuard from the patient by removing the ECG electrodes.

**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., ECG electrodes. 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 cable and the same power adapter. Faults can therefore be located and remedied faster.

### **1.6.6 Safety Information Related to Monitoring Heart Rate and Respiration**

There is a risk of overseeing critical alarm events in certain situations. In order to minimize this risk, read the following safety information carefully.

**WARNING:** OBSTRUCTIVE APNEA

Risk of death or serious injury due to overseeing an obstructive apnea event.

VitaGuard is not designed to detect obstructive apnea and should not be used if detection of obstructive apnea is indicated.

**WARNING:** PATIENT MOVEMENT

Risk of death or serious injury due to overseeing a central apnea alarm if the patient is being moved.

Do not move the patient during monitoring and do not sleep in the same bed as the patient. VitaGuard could misinterpret such movement of the patient as respiration and overlook a central apnea alarm.

**WARNING:** SKIN IRRITATION FROM ADHESIVE ELECTRODES

Risk of skin irritation due to prolonged use of adhesive ECG electrodes.

Attach ECG electrodes to intact skin only. In order to avoid skin irritation from prolonged monitoring, vary the position of the electrodes on a daily basis in the vicinity of the optimal site. Refer to section 5 for further information on electrode placement.

**WARNING:** PATIENT PREPARATION

Risk of death or serious injury due to overseeing a critical alarm event resulting from lack of proper patient preparation.

Insufficient patient preparation can result in unsatisfactory signal quality of both the ECG and respiration signals. Whereas VitaGuard incorporates circuitry to detect interference or if an electrode is not properly attached to the patient, and outputs technical alarms accordingly, situations may nevertheless occur that are overlooked. Therefore, carefully follow the instructions on patient preparation described in section 5 of this manual.

**WARNING:** T-WAVE TRIGGERING

Risk of death or serious injury due to overseeing a heart rate alarm due to T-wave triggering.

Large T-waves may be misinterpreted as QRS-waves, causing the monitor to display a higher heart rate value and oversee a bradycardia alarm (low heart rate alarm). When selecting the optimal electrode configuration explained in section 5.3, visually inspect the ECG waveform to ensure that the T-waves are smaller than the QRS-waves.

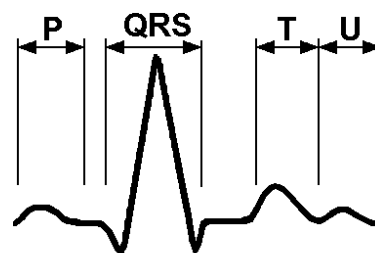


Fig. 3 ECG Waveform

**WARNING: PACEMAKERS**

Risk of death or serious injury due to overseeing a heart rate alarm in pacemaker patients.

VitaGuard can detect pacemaker pulses having amplitudes in the range 2 mV to 700 mV and pulse widths in the range 0.5 to 2 ms, as specified in the International Standard IEC 60601-2-27. Nevertheless, be aware that the calculated heart rate can be influenced by a pacemaker and that a heart rate alarm may be overlooked. Keep pacemaker patients under close observation.

**1.6.7 Safety Information Related to Cleaning and Disinfecting**

Cleaning and disinfection instructions are provided in section 1.7.

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 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 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 ECG electrodes;
- 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 build-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

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, electrodes 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 and ECG Cable

To clean the VitaGuard monitor and the ECG cable, 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.

## 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 surfaces 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.

Do not use undiluted bleach (5 – 5.25 % sodium hypochlorite), as damage to the components may occur.

### ECG Cable

To disinfect the **ECG cable**, use a hydrogen peroxide based disinfection solution such as Sekusept Active (ECOLAB Healthcare), e.g., 2% solution with 15 minutes exposure time for mycobactericidal claim. Remove residues thoroughly with a damp, lint-free cloth and then wipe dry with a fresh lint-free cloth. Please refer to the disinfectant manufacturer's instructions for use for more information.

Do not use agents with high levels of n-propanol or agents containing chlorine on the ECG cable.

### 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 reconnect them 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 section 1.6.8.

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 section 1.7.

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 (ECG cable and external power adapter) when returning the monitor for service or repair.

Unless otherwise requested by your authorized dealer, please do not return ECG electrodes. 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 ECG electrodes 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 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., ECG electrodes, 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 CR monitor is shipped with the following accessories:

| Product .....  | REF             |
|--|-----------------|
| VitaGuard VG 5 CR Set.....   | 73111023        |
| <i>NOTE: Canadian kit with French and English IFU).....</i>        | <i>73111193</i> |
| 1 x VitaGuard VG 5 CR monitor .....                                | 73211013        |
| 1 x ECG patient cable (defibrillator proof) .....                  | 73411004        |
| 9 x Adhesive colour-coded neonatal electrodes (3 packs of 3) ..... | 70219           |
| 1 x External power adapter NA 5-1 .....                            | 73441103        |
| 1 x Device pouch with straps .....                                 | 73451002        |
| 1 x Instructions for use (English) .....                           | 73811022        |
| 1 x Quick start guide (English) .....                              | 73821022        |
| 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 is stored at the bottom of the transport case.



Fig. 4 Power Adapter in Original Packaging

The ECG patient cable, the ECG electrodes 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. 5 Storage Area for ECG Cable, ECG Electrodes and Pouch Straps

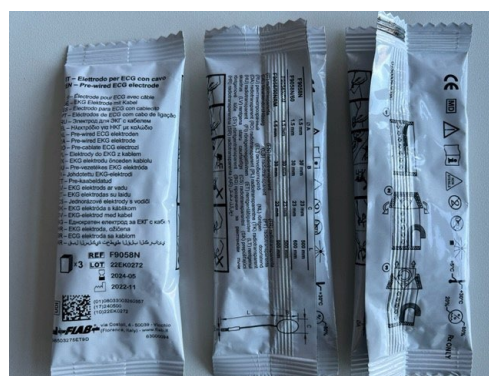


Fig. 6 ECG Cable (left) and ECG Electrodes (right)

## 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.

| Product .....  | REF      |
|--|----------|
| ECG patient cable (defibrillator proof) .....                | 73411004 |
| Adhesive colour-coded neonatal electrodes (3 per pack) ..... | 70219    |
| 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 |

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|  |          |
|--|----------|
| External power adapter NA 5-2 US (Mean Well) ..... | 73441107 |
| Device pouch with straps .....                     | 73451002 |
| Instructions for use (English) .....               | 73811022 |
| Quick start guide (English) .....                  | 73821022 |
| Transport case .....                               | 73910010 |
| Nurse call unit cable .....                        | 73415012 |

## 3. General Description

This chapter provides an overview of the main features of the VitaGuard VG 5 CR monitor.

### 3.1 Modes of Operation

The VitaGuard VG 5 CR monitor acquires the following vital signs:

- respiratory effort to detect central apnea; and
- heart rate (HR), as calculated from the patient's ECG waveform.

Respiration and heart rate are acquired using three adhesive ECG electrodes attached to the patient's thorax.

VitaGuard emits an acoustic and visual physiological alarm:

- when no respiration or movement is detected within a set period;
- when the measured heart rate value exceeds the selected alarm limits for a predefined period; or
- when no heartbeat has been detected for a predefined period.

Depending on the patient's diagnosis, the responsible physician can configure VitaGuard to monitor the above vital signs either individually or in combination. The responsible physician can deactivate apnea alarms in the **Respiration** menu.

In addition to fixed alarm limits for heart rate, the responsible physician can also configure percentage deviations as alarm conditions, as explained in sections 8.7.11 and 8.7.12.

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:

- an electrode becomes loose or the ECG cable is removed;
- 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.



Fig. 7 VitaGuard VG 5 CR Connected to its Accessories

- [1] VitaGuard VG 5 CR monitor
- [2] External power adapter
- [3] Patient cable for heart rate and respiration
- [4] Electrodes for heart rate and respiration

**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. 8 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 Heart Rate & Respiration Patient Cable Connector

The patient cable for heart rate and apnea monitoring is connected to the round, green connector labeled with the heart and lung symbols in the middle of the panel.



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



The general warning symbol informs that protection of the monitor against the effects of the discharge of a cardiac defibrillator is dependent upon the use of the ECG cable supplied with the monitor.

### 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 11.5).

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:

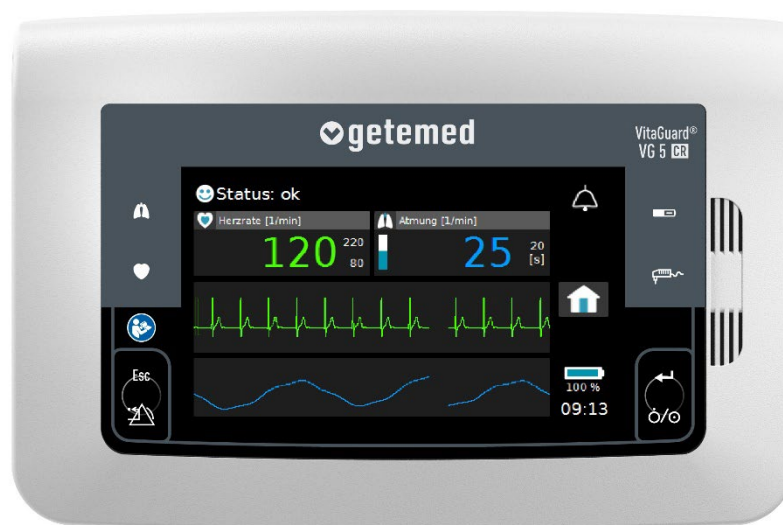


Fig. 9 VitaGuard Front Panel / User Interface

The user interface consists of the following elements:

- a 4.3" TFT touchscreen colour display;
- two pushbutton keys: <Enter> and <Esc>;
- five 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 section 1.5.3.

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

The <Enter> key serves two purposes:

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



Fig. 10 <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. 11 <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 Heart and Respiration LEDs

The lung symbol LED flashes green with every detected breath of the patient when the patient is not moving or being moved.

Similarly, the heart symbol LED flashes green each time the patient's heartbeat is detected.



Fig. 12 Heartbeat and Respiration LEDs

These two flashing green LEDs show 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 either the heartbeat or the respiration cycle.

### 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 re-charge.



Fig. 13 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.

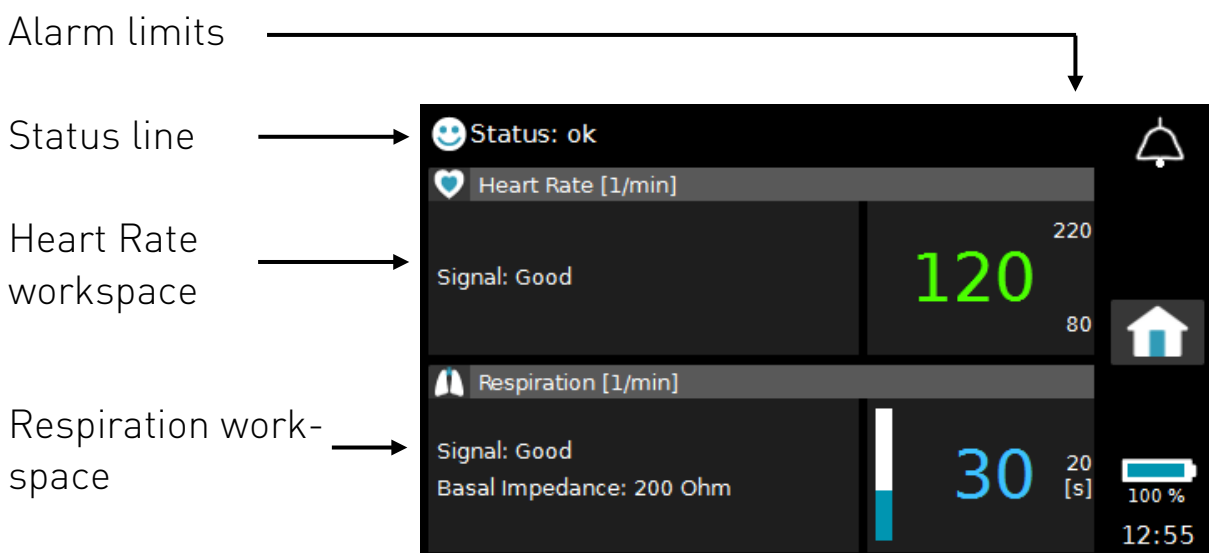


Fig. 14 View 1 Screen Content




**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.

**Heart Rate workspace:** The current value of heart 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 workspace also displays a quality indicator (**Signal**) of the ECG signal being received from the ECG electrodes.

**Respiration workspace:** The current value of respiration rate in breaths per minute [1/min] is shown in large blue digits. The smaller digit to the right of the current value shows the apnea alarm limit in seconds. The workspace also displays a quality indicator (**Signal**) of the size of the respiration signal being received from the ECG electrodes along with the basal impedance in Ohms. This term is explained in further detail in section 5.4. The respiration bar to the left of the respiration rate moves up and down synchronously with the patient's breathing.

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.

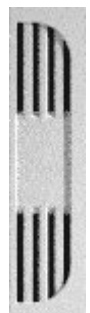


Fig. 15 Alarm Buzzer Outlets

## 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.

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.



Fig. 16 External Power 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. 17 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  $\pm 10\%$  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.

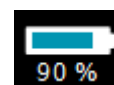


Fig. 18 Battery Capacity Indicator

When the monitor is 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!);
- connect the ECG patient cable to VitaGuard;
- attach the ECG electrodes to the patient;
- connect the ECG electrodes 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 electrodes 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 electrodes 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 or each breath.

## 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 while 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 ECG electrodes from the patient, taking care not to damage the patient’s skin;
- disconnect the ECG electrodes from the patient cable. Avoid pulling the electrode cables.

## 5. Heart Rate and Apnea Monitoring

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

### 5.1 General Information on Heart Rate and Apnea Monitoring

The ECG electrodes supplied with VitaGuard are free of latex, not sterile, and cannot be sterilized. Store the electrodes in a cool dry place. Check that there is no damage to the electrode's packaging before opening it. Do not use electrodes after the expiration date printed on the packaging next to the "Use By" hourglass symbol, e.g., 2024-05 = May 2024, as shown in Fig. 19.

The ECG electrodes 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.



Fig. 19 "Use By" Date of ECG Electrodes

For heart rate and apnea monitoring, pay attention to the following important information:

- attach the ECG electrodes to intact areas of skin only;
- use ECG electrodes on one patient only to avoid cross-contamination between patients;
- secure the electrodes and ECG cable so that they cannot harm, strangle, or be swallowed by the patient. Always route the electrode and patient cables at a safe distance from the patient's head and neck. Route the cables when monitoring small children inside their clothing so that they exit at the foot. On larger children and adults, route the cables so that they exit between the trousers and pullover;

- the ECG electrode sites must be checked frequently to ensure adequate adhesion and skin integrity. Remove electrodes at least once every 8 hours to inspect and, if necessary, clean the skin covered by the electrodes;
- do not use additional tape to secure the ECG electrodes as this may cause skin irritation.

GETEMED recommends replacing the ECG electrodes as soon as the adhesive gel loses its adhesive quality. The special gel on the electrodes has been developed to avoid skin irritation, even after several months of monitoring on newborns. Nevertheless, patients with sensitive skin may suffer allergic reactions in the form of reddened skin or blistering. When the skin exhibits such changes, immediately consult your physician. A change of electrode type may help.

The electrodes provided are designed for short-term applications. Nevertheless, new electrodes may be reattached several times. In order to reuse them:

- peel them gently from the patient's skin starting at the edge;
- avoid touching the adhesive gel surface;
- carefully put them back onto the transparent film from the original packaging. This helps to prevent the electrodes from drying out or becoming soiled.

Using the same electrodes too often will eventually lead to reduced performance. Measurement performance will be impaired if the ECG electrodes become dry, are badly positioned, or become loose.

The responsible physician may decide to deactivate the detection of apnea alarms as described in section 8.5.2. In this case, “Off” is displayed on the monitor screen instead of the respiration rate.

**NOTE:** When the **Admit New Patient** function is executed, apnea detection is reactivated together with the other default settings.

## 5.2 Connecting ECG Electrodes and Patient Cable to VitaGuard

Connect the ECG electrodes only to the ECG patient cable and this only to the corresponding VitaGuard socket.

Insert the three colour-coded ECG electrodes into the corresponding sockets on the ECG patient cable, taking care to match the colours. Make sure that the electrode's plugs are pushed completely into the cable sockets to ensure proper contact.



Fig. 20 Colour-Coded Sockets on the ECG Patient Cable's Distributor

When disconnecting the electrodes from the patient cable, avoid pulling on the cable leads.

Insert the green plug of the ECG patient cable into the green socket on VitaGuard's connector panel marked with the heart and lungs symbol, as shown in Fig. 8.

## 5.3 Finding the Optimal Electrode Configuration

The respiration and ECG signals are detected using the same electrodes. The optimal electrode configuration involves finding good signals for both the respiration and the ECG signals simultaneously.

GETEMED recommends that the responsible physician determines the optimal electrode configuration. In most cases, this configuration can be maintained throughout the whole monitoring period.

In order not to put excessive strain on the patient's skin, the electrodes can be placed in the vicinity of the optimal site.

### 5.3.1 Standard ECG Electrode Configuration

Do not open the electrode's packaging until shortly before the electrodes are to be used. Remove the electrodes and, holding the sides of the electrode, peel off the transparent film. Do not pull on the electrode's cable. Avoid finger contact with the electrode's gel-coated surface as much as possible.

Respiration is always measured between the red and yellow electrodes. In the default state, the ECG signal is also measured between these two electrodes. The black electrode serves as a reference electrode to reduce environmental interference that could corrupt the signals.

Start with the electrode configurations depicted in Fig. 21. Place the gel-coated side of the electrode on the chosen site and carefully press it several times for good contact. First arrange:

- the electrodes on infants as depicted in Fig. 21 a)  
(this electrode configuration has often proved successful because the infant's abdominal wall generally moves synchronously with the respiration),
- the electrodes on all other patients as depicted in Fig. 21 b)

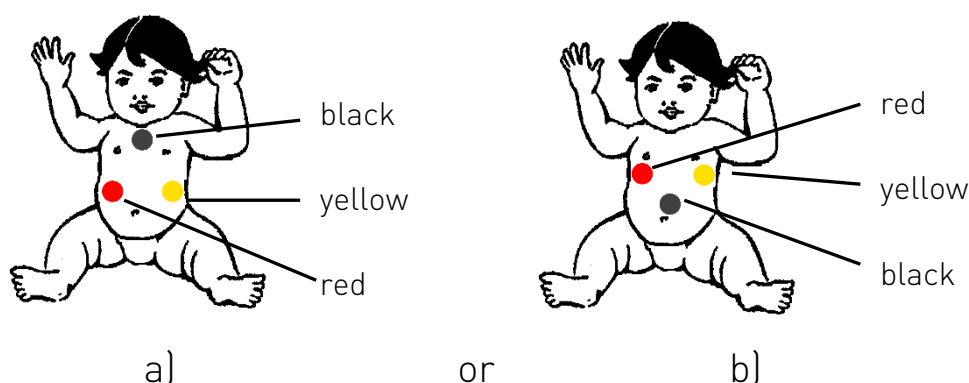


Fig. 21 Recommended Electrode Configurations

If the electrode configuration depicted in Fig. 21 does not yield a good signal, try the alternative electrode configuration depicted in Fig. 22.

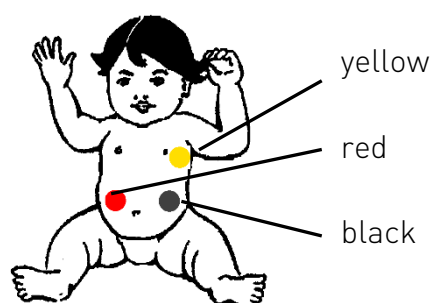


Fig. 22 Alternative Electrode Configuration

**NOTE:** Do not pull on the cables, as this is unpleasant for the patient and can damage the electrodes.

### 5.3.2 Optimizing the ECG and Respiration Signals

With reference to **View 1** on the monitor's screen shown in Fig. 23, the signal indicators for the ECG and respiration are displayed in the **Heart Rate** and **Respiration** workspaces respectively.

The signal indicators (**Signal**) show either poor or good, whereby:

- poor means that the signal is not or only sporadically detected;
- good means that a clear signal is being detected.

As a result, when a poor signal is displayed, the values for heart rate and respiration rate may be imprecise. Furthermore, the monitor may tend to output false apnea alarms due to the low respiration signal.

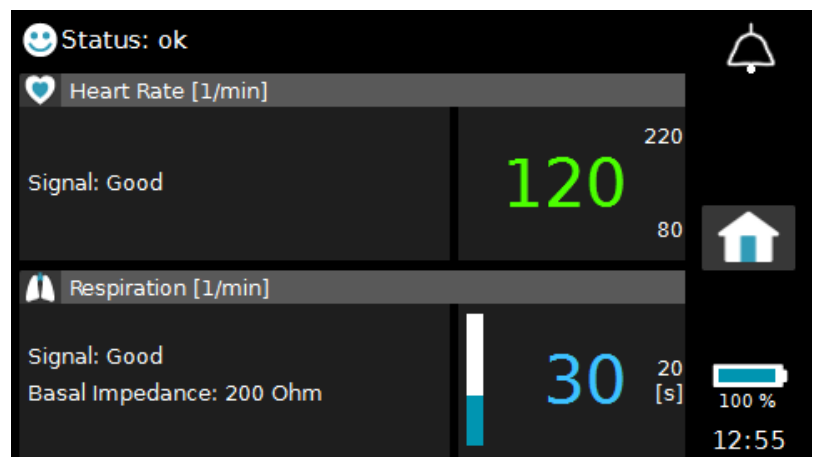


Fig. 23 Signal Indicators in View 1

A correct heart rate is detected when the heart LED flashes green synchronously with the patient's heartbeat. When the signal is good, there should be no deterioration in the detected heart rate when the patient moves normally.



Similarly, the respiration LED with the lungs symbol will flash green synchronously with the patient's breathing when the signal is good. Also, the respiration bar on the VitaGuard screen will move up and down in rhythm with the breathing pattern.



If the respiration signal is poor, change the positions of the red and yellow electrodes with reference to the configurations shown in section 5.3.1. Whenever possible, try to obtain the largest possible deflections in the respiration bar to avoid false apnea alarms.

Once the optimal position for the red and yellow electrodes has been determined based on the respiration signal, check the size of the ECG signal. If the signal indicator for the ECG is “**Poor**”, then further measures explained in section 5.3.3 will need to be taken to improve the size of the ECG signal.

### 5.3.3 Changing the ECG Lead for Signal Optimization

To change the ECG lead configuration, the **Settings Protection** mode must be switched **Off**, as explained in section 8.3.5. Once this has been done, the responsible physician should use **View 2** explained in section 7.3.2 to visually inspect the size of the ECG and respiration signals.

In order to optimize the ECG lead configuration, the patient must be still or sleeping.

Bear in mind when optimizing the ECG lead configuration that there must be no changes to the optimized positions of the red and yellow electrodes for detecting the respiration signal.

First select the **Heart Rate** view and note the size of the ECG waveform displayed on the screen. In the default state, this will be the **Lead I (Yellow-Red)** setting, i.e., the ECG waveform is measured between the red and yellow electrodes. Leaving the electrodes in place, use the **HR Lead Select** setting explained in section 8.7.2 to select the **Lead II (Black-Red)** option. Visually inspect and note the size of the ECG waveform. Now select the **Lead III (Black-Yellow)** option and, again, note the size of the ECG waveform. Finally select the lead setting with the largest signal.

**NOTE:** If two leads have ECG waveforms of similar size, select the lead with the smallest T-wave to avoid T-wave triggering.

When optimization becomes necessary, only the black electrode should be repositioned. If none of the leads produce a particularly large signal, change the position of the black electrode and repeat the procedure. Carefully reapply the black electrode to another position until you obtain the best signal.

## 5.4 Basal Impedance

The basal impedance displayed in **View 1** and in other views is the sum of all impedances in the measurement circuit:

- skin and tissue impedance between the red and the yellow electrodes;
- impedance of the electrode-skin interface; and
- impedance of the electrodes themselves and the patient cable.

When the electrodes are initially applied, the basal impedance value will tend to be high and will slowly fall with time. This is caused by a reduction in the impedance at the electrode-skin interface as the electrode gel acclimatizes to the skin surface.

Generally, the smaller the basal impedance the better, and it should be less than 1000 Ohm for best performance. If the basal impedance stays above this value after 15 minutes, replace the electrodes.

**NOTE:** The basal impedance is displayed in steps of 50 Ohm.

## 5.5 Electrode-Off Technical Alarms

The electrode contact monitor reports an alarm when:

- an electrode has become detached,
- the electrodes are too dry (e.g. the expiration date has been exceeded or the electrodes have been used several times), giving rise to a high basal impedance value,
- one of the electrodes or the ECG cable has a damaged lead, or
- the ECG cable has been removed from the monitor.

**NOTE:** When electrodes have become detached or when the basal impedance between the electrode and skin interface is above 3000 Ohm, the respiration and ECG signals are displayed on the screen as a flat line.

## 5.6 Heart Rate According to Age

Patient's heart and respiration rates drop considerably with increasing age. The responsible physician must check and, if necessary, adapt the alarm limits for each patient's age group.

The average heart rate of an infant is much higher than that of an adult. Accordingly, the lower heart rate alarm limit must be set considerably higher for an infant than for an adult patient. As an orientation aid, the following table lists some medically acknowledged approximate heart rates for various age groups and stress situations.

| Age Group           | Heart Rates (Beats per Minute) |           |                     |
|---------------------|--------------------------------|-----------|---------------------|
|                     | Sleep                          | Rest      | Stress (e.g. fever) |
| Newborns            | 80 – 160                       | 100 – 180 | up to 220           |
| 1 week to 3 months  | 80 – 200                       | 100 – 220 | up to 220           |
| 3 months to 2 years | 70 – 120                       | 80 – 150  | up to 200           |
| 2 to 10 years       | 60 – 90                        | 70 – 110  | up to 200           |
| 10 years and older  | 50 – 90                        | 55 – 90   | up to 200           |

## 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 electrodes and/or cables 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 heart rate falls below the **HR Lower Limit** displayed on the screen for longer than the set **HR Bradycardia Delay**;
- the heart rate exceeds the **HR Upper Limit** displayed on the screen for longer than the set **HR Tachycardia Delay**;
- the ECG signal is not detected for longer than the set **HR Asystole Delay**;
- no respiration signal is detected for longer than the **Apnea Delay** displayed on the screen.

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 heart rate value without actually falling below the **HR Lower Limit**;
- sudden increase in the heart rate value without actually rising above the **HR Upper Limit**.

Furthermore, the responsible physician can configure the monitor to deactivate the detection of central apnea and monitor the heart rate only. Information on configuring the monitor is provided in section 8.

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.  $\frac{3}{4}$  of a second. Also, there is a slightly longer interval between the 3<sup>rd</sup> and 4<sup>th</sup> tone of each sequence. The interburst interval is 7 seconds;



Fig. 24 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. 25:
  - 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.

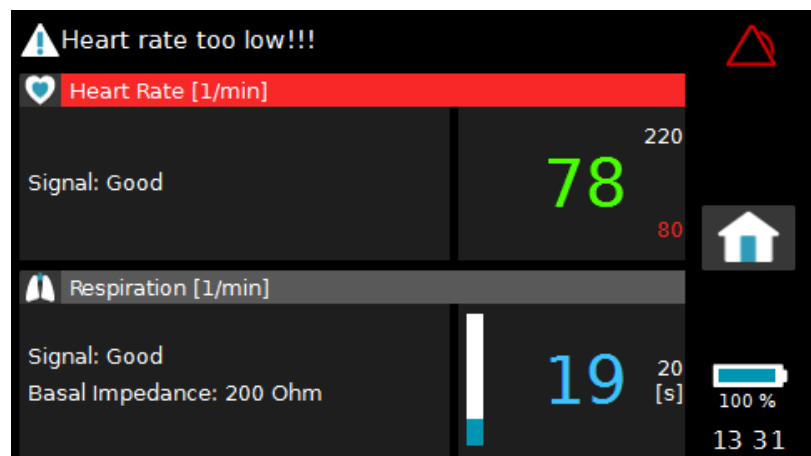


Fig. 25 Information on the Monitor Screen during a Patient Alarm

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 heart rate falls below the **HR Silent Lower Limit** for longer than the set **HR Bradycardia Delay**;
- the displayed heart rate exceeds the **HR Silent Upper Limit** for longer than the set **HR Tachycardia Delay**;
- no respiration signal is detected for longer than the **Silent Apnea Delay**; or when
- periodic respiration is detected.

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:

- an ECG electrode is loose or the patient cable is not connected;
- the battery capacity is low; or
- an internal hardware 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. 26:
  - 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.

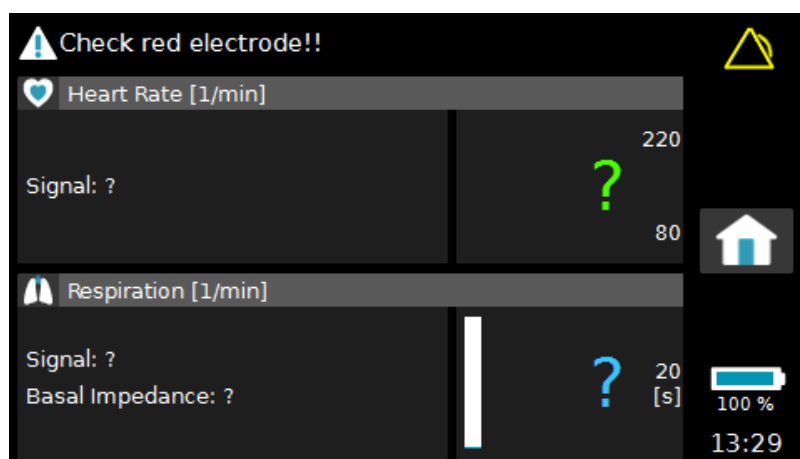


Fig. 26 Information on the Monitor Screen during a Technical Alarm

By pressing the <Esc> key during a technical alarm condition, the acoustic alarm signal is deactivated for this alarm situation and 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.

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

Patient alarms have a higher priority than technical alarms. When, for example, a technical alarm condition relevant to the battery capacity occurs and, at the same time, a patient alarm condition is detected by the heart rate monitor, then the patient alarm condition will be reported. 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. 26 where an electrode is off the patient.

**NOTE:** In order to prevent false alarms when the vital signs are being recalculated following a technical alarm triggered by problems with the ECG electrodes, 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 pull the red electrode plug out of the distributor on the ECG patient cable to test the ECG patient cable,
- 2 disconnect the ECG patient cable, and
- 3 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.

## 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 all electrodes are 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  |
|-------------------|---|--|
| Apnea detected!!! | A respiration signal has not been detected for longer than the set <b>Apnea Delay</b> . | <p>When there is no central apnea:</p> <ul style="list-style-type: none"> <li>– The electrodes are badly placed, i.e. the signal is too small to be detected.</li> <li>– Cardiogenic artifacts are superimposed on the respiration signal so that it is rejected.</li> </ul> <p>To remedy the above, try a different electrode configuration in section 5.3.</p> <ul style="list-style-type: none"> <li>– The monitor, cable, or an electrode is defective.</li> </ul> |
| ECG signal low!!! | The monitor could not detect the ECG signal for   | When there is no asystole (cardiac arrest or delay):   |

| Message                     | Meaning   | Troubleshooting   |
|-----------------------------|---|---|
|                             | longer than the set asystole delay.   | <ul style="list-style-type: none"> <li>– The electrodes are badly placed.</li> <li>– The ECG signal is too small to be detected.</li> </ul> <p>To remedy the above, try a different electrode configuration in section 5.3.</p> <ul style="list-style-type: none"> <li>– The monitor, cable, or an electrode is defective.</li> </ul>   |
| Heart rate and apnea!!!     | A heart rate alarm and an apnea alarm have occurred simultaneously.   | See the messages and information for “Heart rate too high!!!/too low!!!” and “Apnea detected!!!”.   |
| Heart rate too high!!!      | The calculated heart rate exceeds the set <b>HR Upper Limit</b> for longer than the set <b>HR Tachycardia Delay</b> .     | <p>When there is no tachycardia:</p> <ul style="list-style-type: none"> <li>– T-waves are interpreted as R-waves so that the calculated heart rate is too high.</li> <li>– The electrodes are badly placed.</li> <li>– Artifacts caused by excessive movement trigger false alarms.</li> </ul> <p>To remedy the above, try a different electrode configuration, as explained in section 5.3.</p> <ul style="list-style-type: none"> <li>– 50 Hz or other sources of electromagnetic interference trigger false alarms: suspected interference sources must be removed.</li> <li>– An electrode has become detached.</li> <li>– The monitor, cable, or electrode is defective.</li> <li>– The set <b>HR Upper Limit</b> is too low.</li> </ul> |
| Heart rate too low!!!       | The calculated heart rate falls below the set <b>HR Lower Limit</b> for longer than the set <b>HR Bradycardia Delay</b> . | <p>When there is no bradycardia:</p> <ul style="list-style-type: none"> <li>– Heartbeats are not detected.</li> <li>– The electrodes are badly positioned.</li> <li>– Abnormal beats, e.g. extrasystoles, are not detected.</li> </ul> <p>To remedy the above, try a different electrode configuration, as explained in section 5.3.</p> <ul style="list-style-type: none"> <li>– The electrode has become detached.</li> <li>– The monitor, cable, or electrode is defective.</li> <li>– The set <b>HR Lower Limit</b> is too high.</li> </ul>   |
| Heart rate drop detected!!! | The heart rate falls below the value based on   | When there is no heart rate drop:   |

| Message   | Meaning   | Troubleshooting  |
|---|---|--|
| (when activated)                                | the set <b>HR Deviation Averaging Interval</b> by more than the percentage deviation value set under <b>HR Deviation Alarm Limit (-)</b> .                          | <ul style="list-style-type: none"> <li>– The heart rate and/or the average heart rate is incorrectly calculated for the reasons given under “Heart rate too low!!!”</li> </ul>   |
| Heart rate rise detected!!!<br>(when activated) | A heart rate rise is detected in the same manner as a heart rate drop, but <b>HR Deviation Alarm Limit (+)</b> is used instead.                                     | When there is no heart rate rise: <ul style="list-style-type: none"> <li>– The heart rate or its average is incorrectly calculated for the reasons given under “Heart rate too high!!!”.</li> </ul>                                    |
| Connect power adapter NOW!!!                    | The monitor is being powered by the rechargeable battery and the battery is exhausted.<br><br><b>ATTENTION!!!</b><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><br>If the monitor shuts down due to battery exhaustion, refer to section 3.5.3 in order to switch off the power fail alarm. |

## 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 ECG cable!!  | The ECG cable is not connected to the monitor.  | Connect the ECG cable to the monitor.<br>If this message persists, replace the ECG cable.                          |
| Check electrodes!! | One or more of the ECG electrodes are not connected to the ECG cable or have become loose on the patient. | Check all the electrodes on the patient.<br>If this message persists, use new electrodes or replace the ECG cable. |

| 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.  |
| Corrupted respiration signal!!    | The respiration signal is corrupted, for example, by electromagnetic interference.     | Move the monitor away from any potential sources of electrical interference (or visa-versa).   |
| Corrupted ECG signal!!            | The ECG signal is corrupted, for example, by 50 Hz interference from the mains supply. | Try the following actions: <ul style="list-style-type: none"> <li>– Move the monitor away from any potential sources of electrical interference (or visa-versa).</li> <li>– Apply the electrodes as symmetrically as possible.</li> <li>– Replace the electrodes.</li> <li>– Select the <b>Lead I (Yellow-Red)</b> setting.</li> <li>– Reposition the electrodes as described in section 5.3.</li> </ul> |
| 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.   |

| Message                            | Meaning   | Troubleshooting   |
|------------------------------------|---|---|
| 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 to operate reliably. | Immediately operate the monitor from the external power adapter to recharge the battery.  |
| Service: Alarm speakers defect!!   | VitaGuard has detected that the alarm speakers are defective.                                   | Return the monitor for service immediately.<br><b>NOTE:</b> 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. |

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  |
|--------------------------------|---|--|
| Calculating heart rate         | The heart rate is being calculated.   | The heart rate will be displayed after it has been calculated.   |
| 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.                                    |

| Message          | Meaning                             | Troubleshooting  |
|------------------|-------------------------------------|--|
| Recharge battery | The battery capacity is below 20 %. | To avoid escalating alarms for low battery capacity, connect the external power adapter immediately. |
| 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 a heart rate/respiration patient simulator, e.g., AMPS-1 from Datrend Systems Inc., as described in the manufacturer's instructions for use.

Using the simulator, sequentially select values for heart rate 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. Select the apnea alarm function on the heart rate/respiration patient simulator and confirm that an apnea alarm is generated when the apnea is longer than the limit set on the monitor.

## 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:

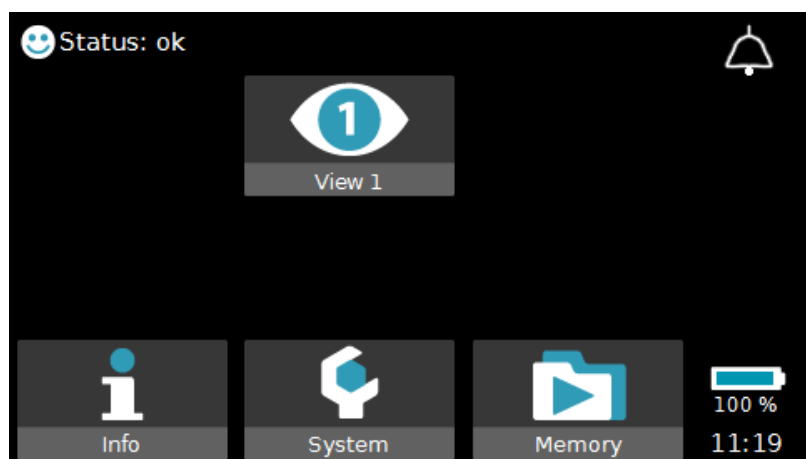


Fig. 27 Home Screen with Settings Protection On

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** already 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.

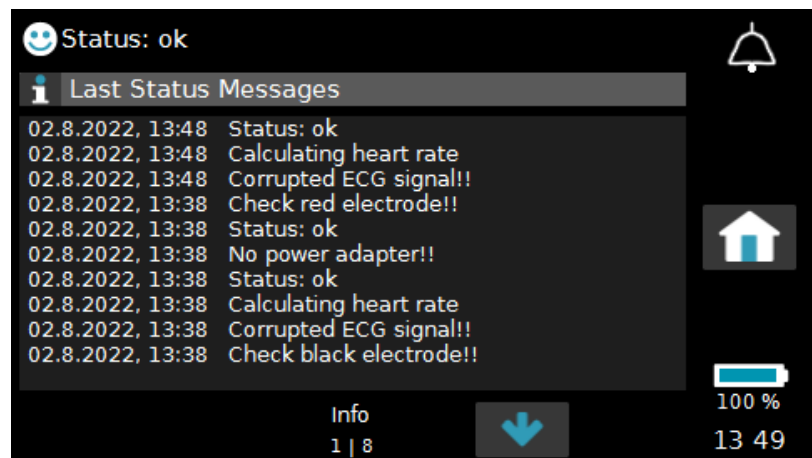


Fig. 28 Info View – Page 1

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 8. 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:

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

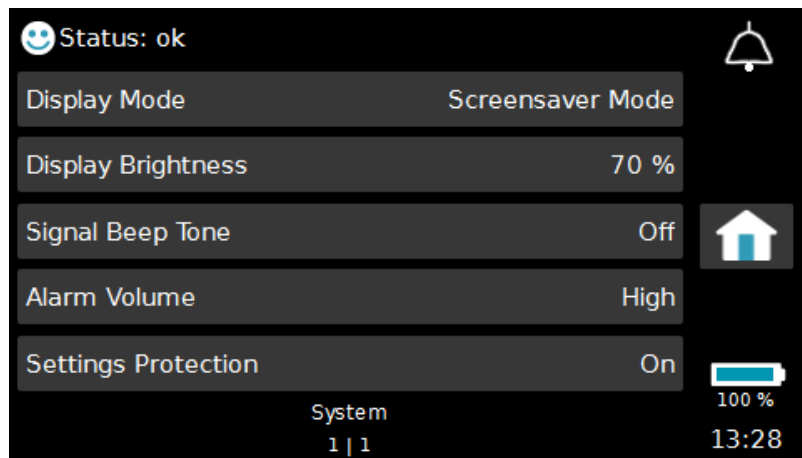


Fig. 29 System View with Settings Protection On

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. 30.

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.

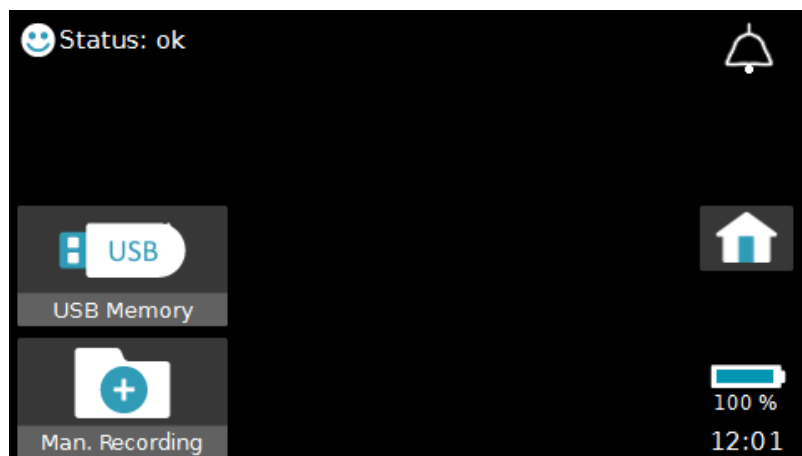


Fig. 30 Memory View with Settings Protection On

## 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. 31:

- View 2 icon
- View 3 icon
- Heart Rate icon
- Respiration icon

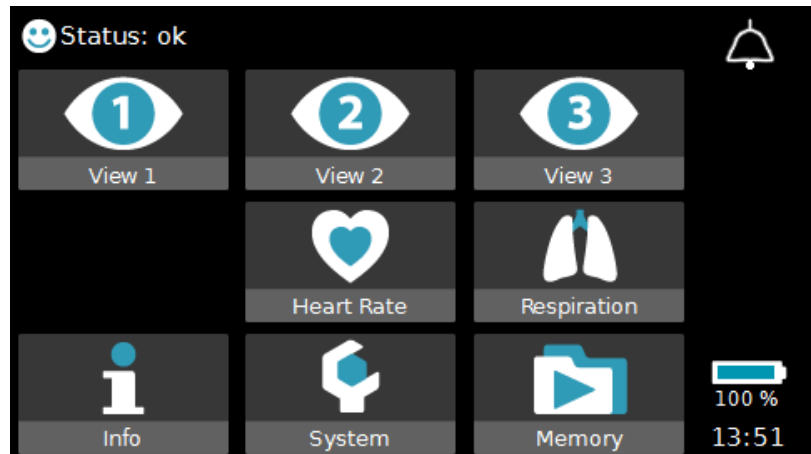


Fig. 31 Home Screen with Settings Protection Limited

### 7.3.2 View 2

**View 2** shown in Fig. 32 differs from **View 1** in that the quality indicators described in section 3.4.6 for **Heart Rate** and **Respiration** workspaces are replaced by their corresponding waveforms:

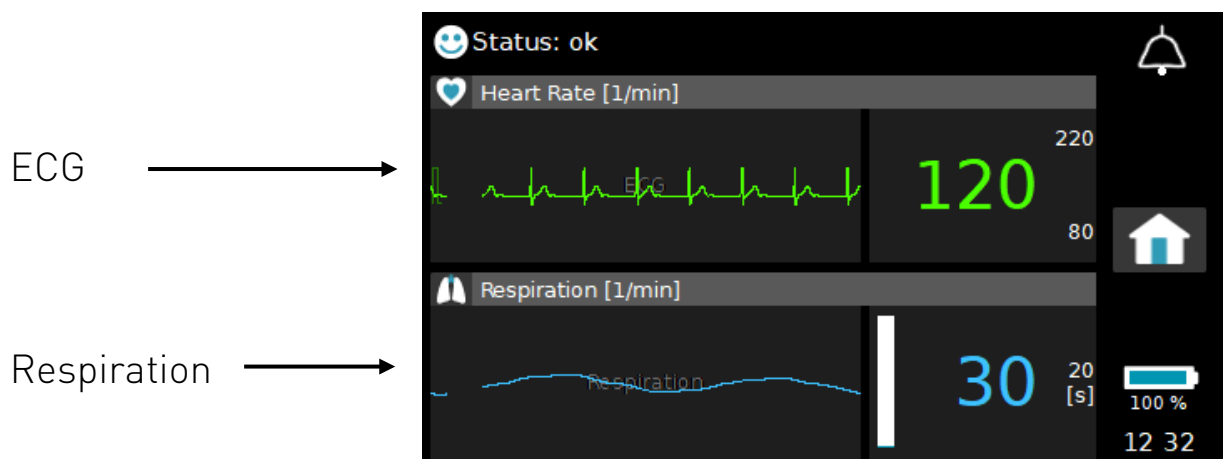


Fig. 32 View 2 Screen Content

The waveform displayed in the **Heart Rate** workspace is the electrocardiogram (ECG) waveform which represents the electrical activity of the heart measured between two of the three electrodes placed on the patient's chest, as explained in more detail in section 10.2.

The waveform displayed in the **Respiration** workspace is the waveform of the respiratory effort of the patient measured between the red and yellow ECG electrodes through the application of impedance pneumography, as explained in more detail in section 10.3.

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

**View 3** content, as shown in Fig. 33, is similar to **View 2**. The main differences are that the current values for heart rate and respiration rate together with their corresponding alarm limits are displayed along the top of the screen and the three corresponding waveforms are displayed across the whole width of the screen.

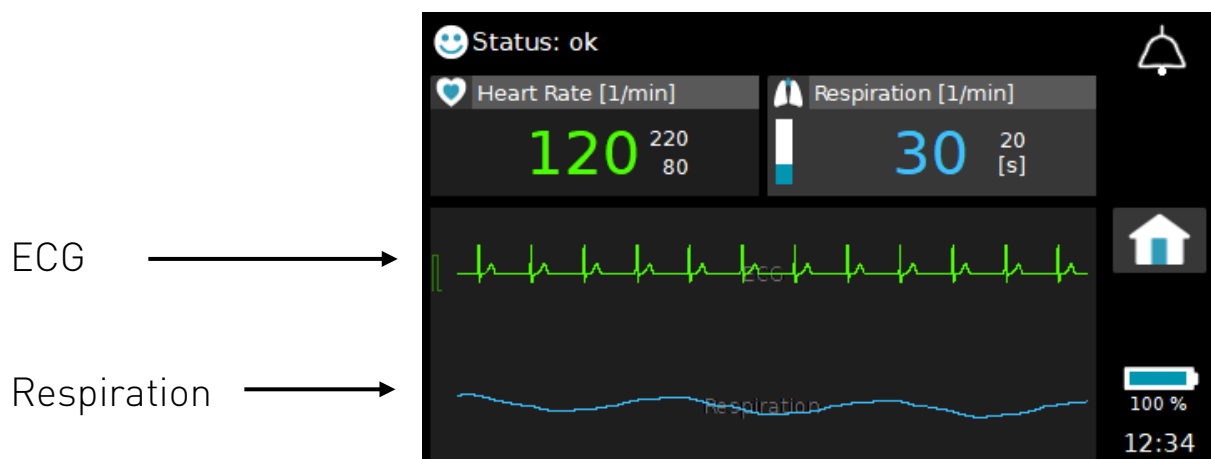


Fig. 33 View 3 Screen Content

Due to space restrictions, the quality indicators for heart rate and respiration are not available in **View 3**.

### 7.3.4 Heart Rate View

The left-hand section of the **Heart Rate** view shows the ECG waveform and green heartbeat markers, as shown in Fig. 34.

**NOTE:** If pacemaker detection is activated, detected pacemaker impulses are identified by yellow markers located directly below the green heartbeat markers.

The settings displayed below the ECG waveform inform about which ECG lead is selected, and whether the pacemaker detection and the 50/60 Hz filter are currently on or off.

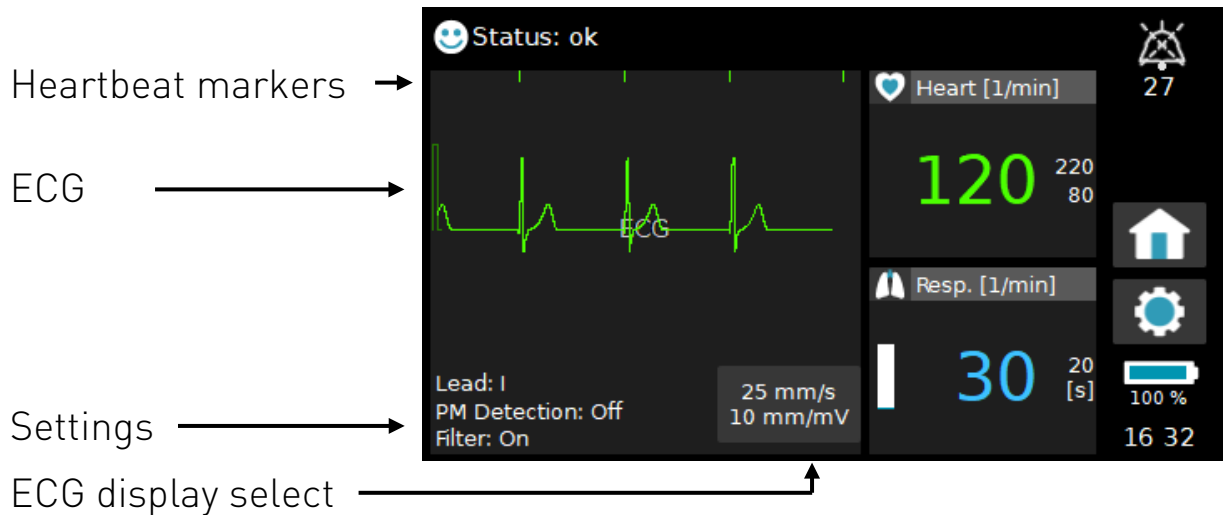


Fig. 34 Heart Rate Screen Content

The ECG waveform is displayed at a speed of 25 mm/s and a resolution of 10 mm/mV, as shown in Fig. 34. By touching the ECG display select icon, other resolutions and deflection speeds may be selected.

### 7.3.5 Respiration View

The top section of the **Respiration** view in Fig. 35 is the same as **View 3**. The bottom section shows a higher resolution representation of the respiration waveform together with the blue respiration detect markers above the waveform for each respiration cycle detected.

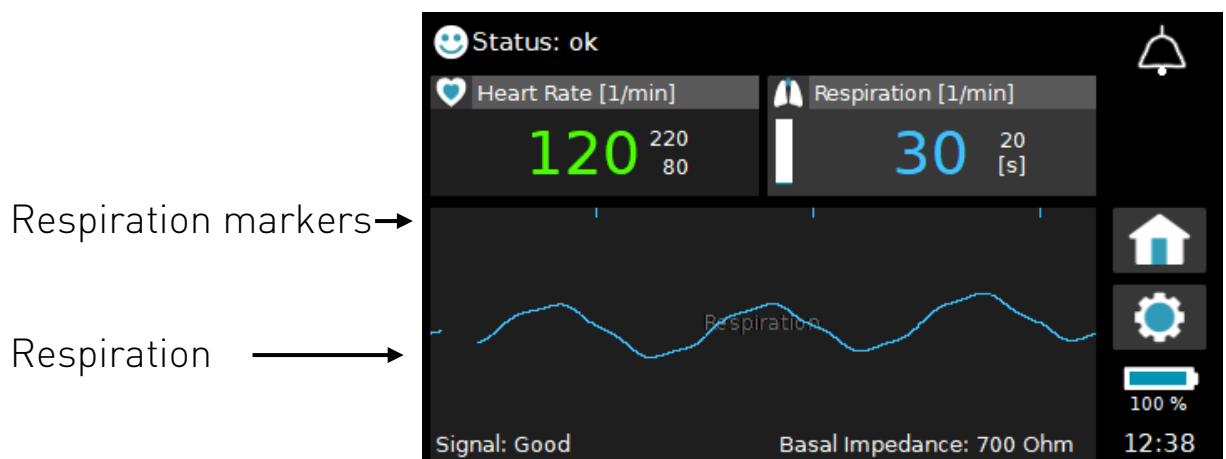


Fig. 35 Respiration Screen Content

The bottom of the screen shows the quality indicator for the respiration signal along with the current value of basal impedance measured between the red and yellow ECG electrodes.

### 7.3.6 Memory View

When the **Settings Protection** mode is set to **Limited**, the **Memory** view shown in Fig. 36 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.

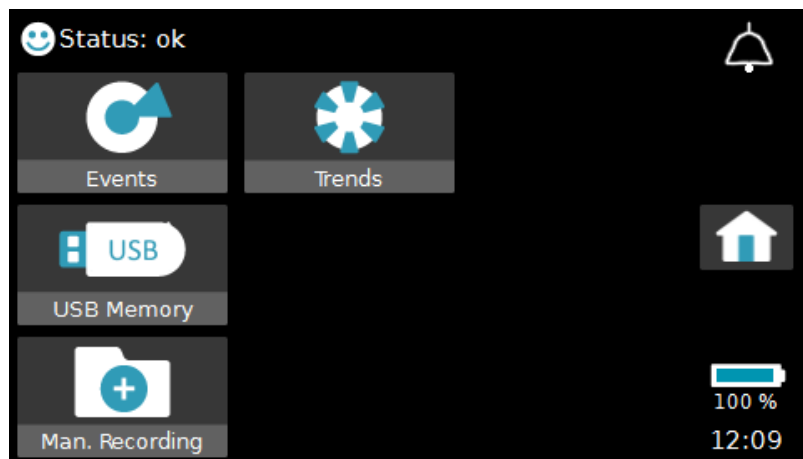


Fig. 36 Memory View with Settings Protection Limited

## 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.

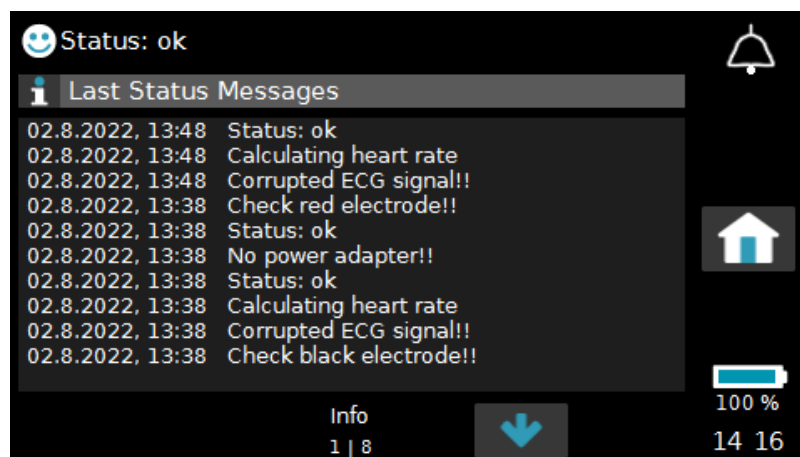


Fig. 37 Info \ Page 1: Previous Status Messages

### 7.5.2 Info \ Page 2: General Information

Page 2 shows the following general information:

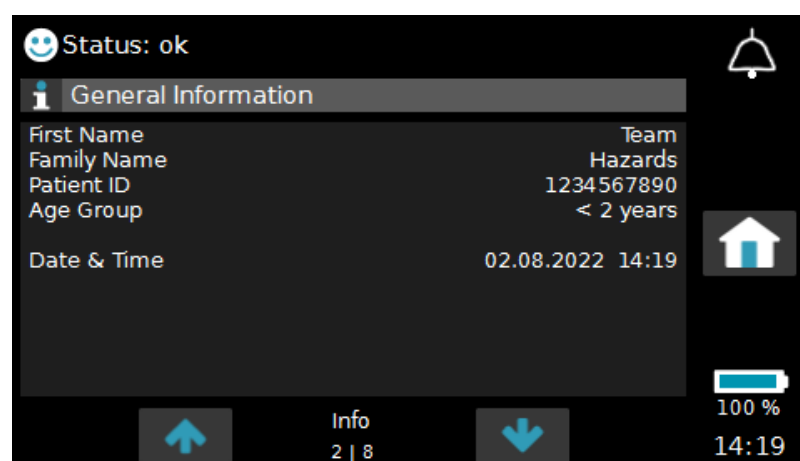


Fig. 38 Info \ Page 2: General Information

- **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.

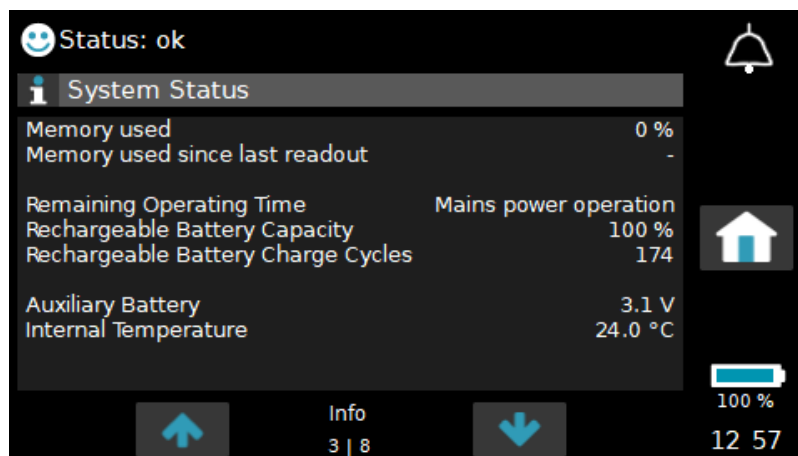


Fig. 39 Info \ Page 3: System Status

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: Heart Rate & Respiration

Page 4 displays average values for the heart rate calculated since the monitor was switched on: last minute, last 1h, last 6h, and last 12h.

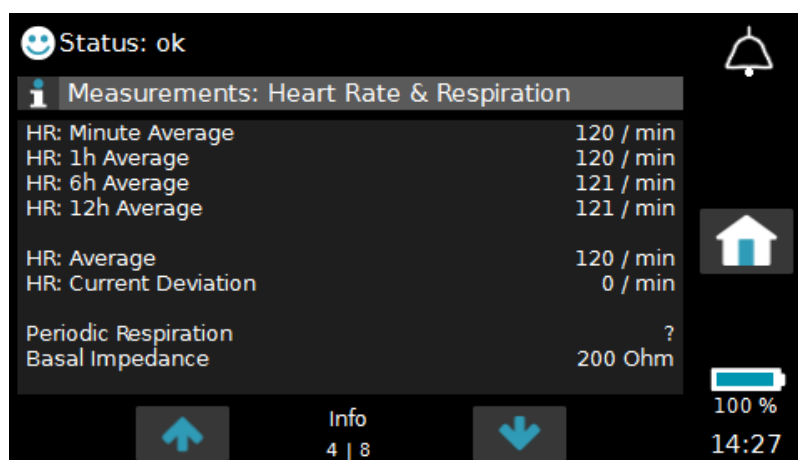


Fig. 40 Info \ Page 4: Measurements: Heart Rate & Respiration

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

**Periodic Respiration** displays the time in percent that periodic respiration has been detected since the monitor was switched on. This value is displayed only when **Periodic Respiration** is set to **On** in the **Respiration** menu and when the **Age Group** selected during the **Admit New Patient** procedure is under 2 years.

**Basal Impedance** displays the current value measured between the yellow and the red electrode explained in section 5.4.

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

### 7.5.5 Info \ Page 5 and Page 6: Current Settings

Page 5 provides an overview of all heart rate related settings.

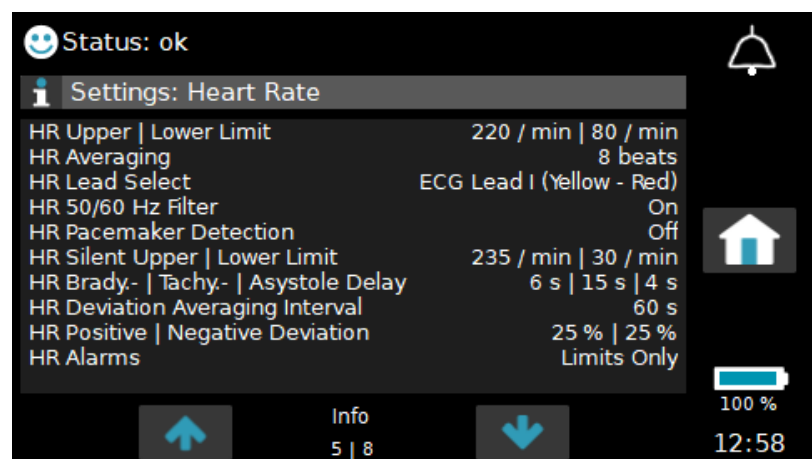


Fig. 41 Info \ Page 5: Current Settings: Heart Rate

Page 6 provides an overview of all respiration related settings.

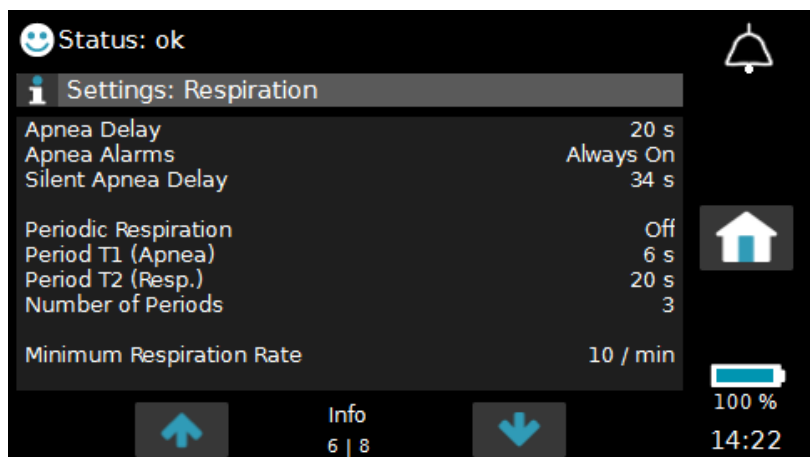


Fig. 42 Info \ Page 6: Current Settings: Respiration

### 7.5.6 Info \ Page 7: Versions

Page 7 provides technical information about the hardware and software versions of the mainboard.

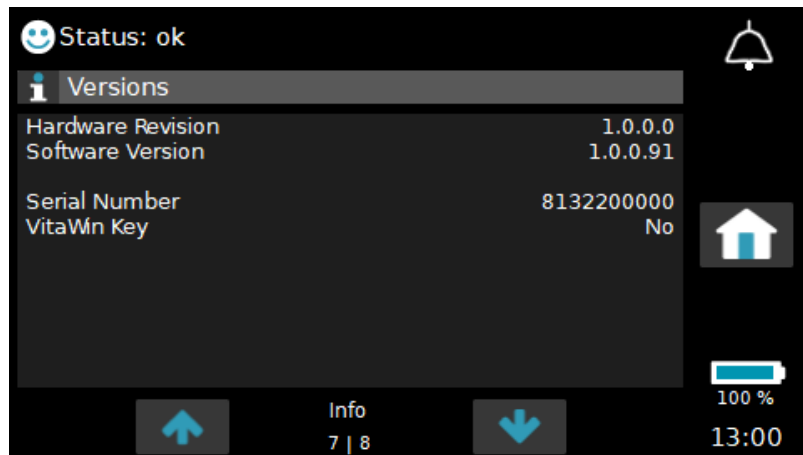


Fig. 43 Info \ Page 7: Versions

### 7.5.7 Info \ Page 8: License Information

Page 8 shows where to find our open-source license information.

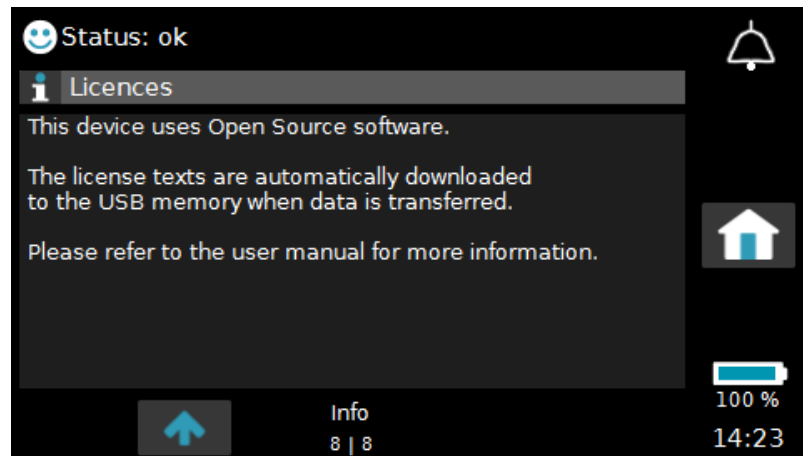


Fig. 44 Info \ Page 8: License Information

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](mailto: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. 29 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:

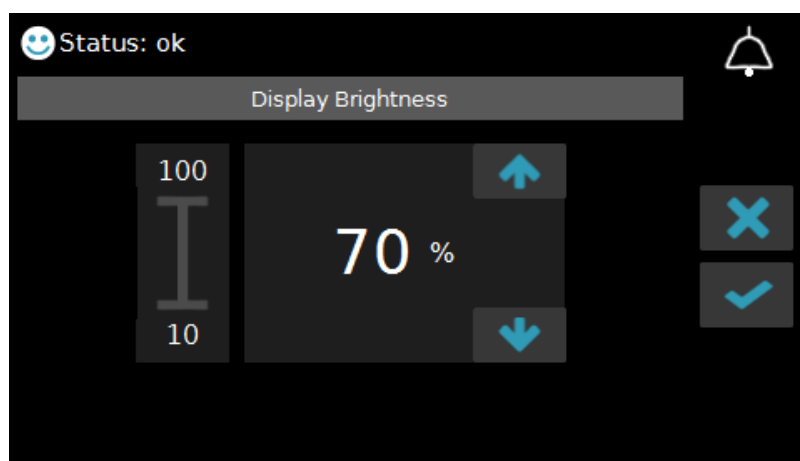


Fig. 45 Settings Dialog for Display Brightness

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:

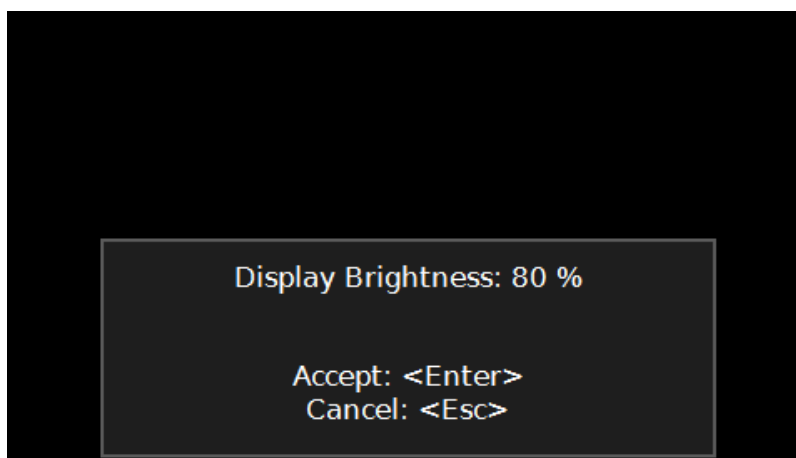


Fig. 46 Dialog to Accept or Reject a Change of a Setting

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. 29 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. 29 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:

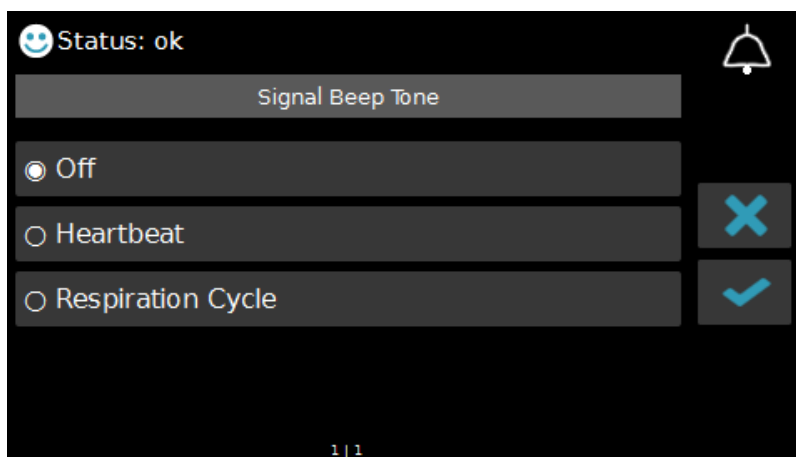


Fig. 47 Settings Dialog for Signal Beep Tone

In this case, there are 3 options to choose from, as shown in Fig. 47. The currently selected option, **Off**, is indicated by the filled circular radio button to its left. To select one of 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

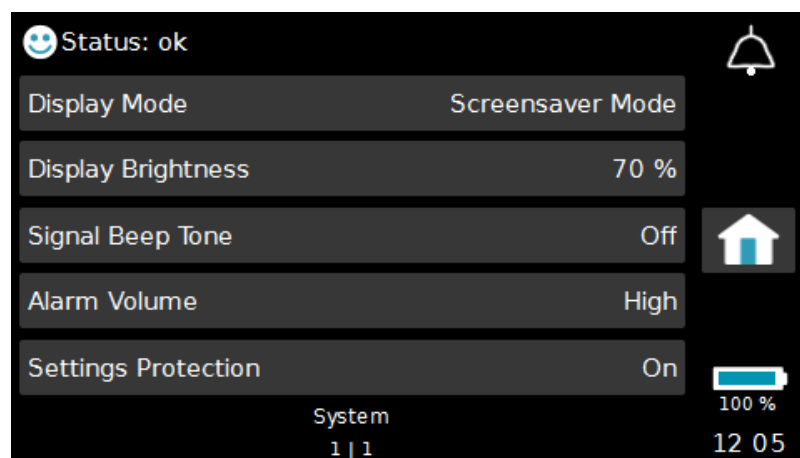


Fig. 48 System Settings with Settings Protection On

### 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.

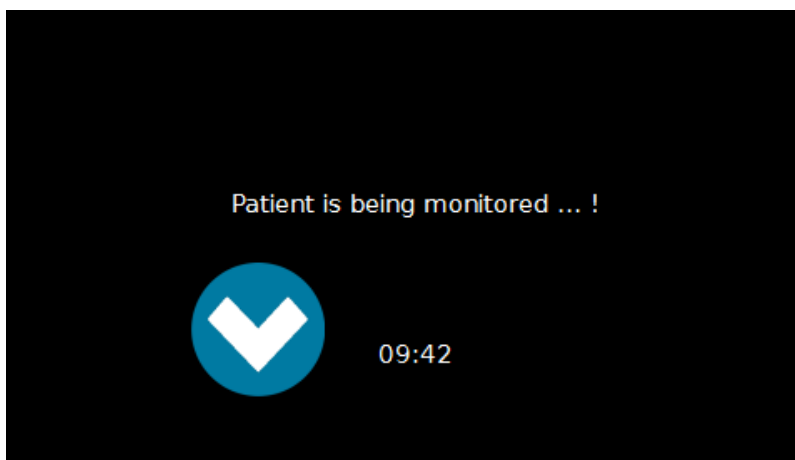


Fig. 49 Display in Screensaver Mode

**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 heartbeat (**Heartbeat**) or with every detected respiration cycle (**Respiration Cycle**). 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.
- **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.

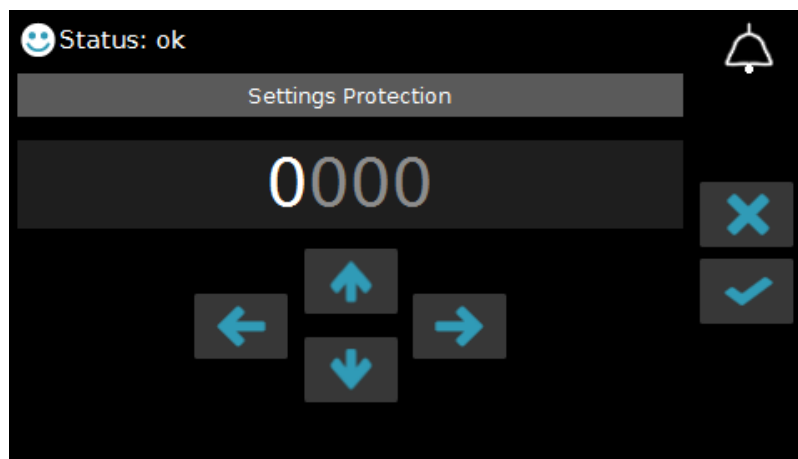


Fig. 50 Dialog to Enter the Settings Protection Code

**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 Heart Rate Settings (Settings Protection Mode Limited)

To access the heart rate settings menus, select the **Heart Rate** view shown in section 7.3.4 and, with reference to Fig. 34, 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 **Heart Rate** view:

- HR Lower Limit
- HR Upper Limit

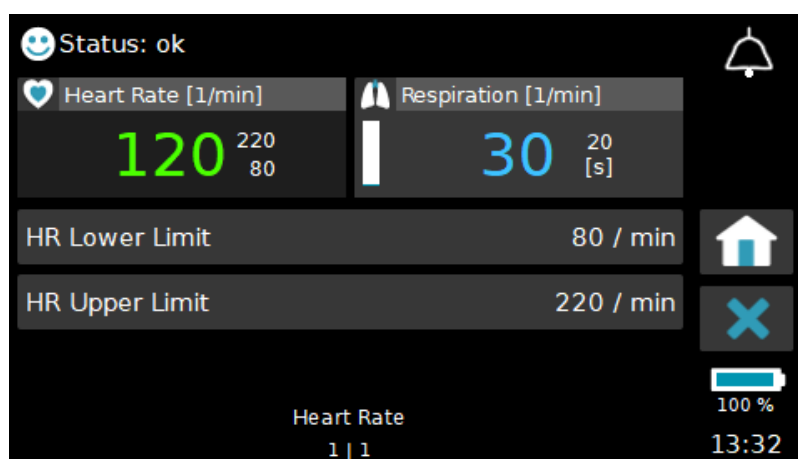


Fig. 51 Heart Rate Settings with Settings Protection LIMITED

### 8.4.1 Heart Rate \ HR Lower Limit

The lower alarm limit for the heart 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 heart rate falls below the set limit for longer than the **HR Bradycardia Alarm Delay**.

### 8.4.2 Heart Rate \ HR Upper Limit

The upper alarm limit for the heart 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 heart rate rises above the set limit for longer than the set **HR Tachycardia Alarm Delay**.

## 8.5 Respiration Settings (Settings Protection Mode Limited)

To access the respiration settings menus, select the **Respiration** view shown in section 7.3.5 and, with reference to Fig. 35, 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 **Respiration** view:

- Apnea Delay
- Apnea Alarms

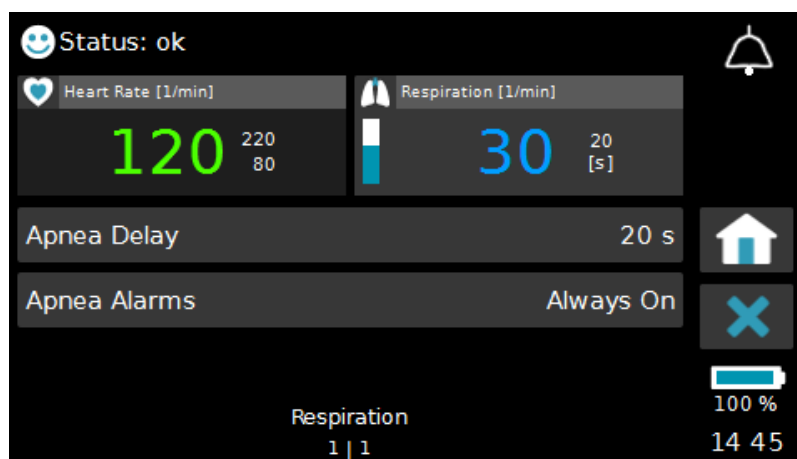


Fig. 52 Respiration Settings with Settings Protection LIMITED

### 8.5.1 Respiration \ Apnea Delay

The **Apnea Delay** for the detection of central apnea can be set from 5 to 20 seconds in steps of 1 second. The default setting is 20 s.

With the **Apnea Alarms** setting set to **Always On** (see next section), VitaGuard outputs a patient alarm when no respiration or movement is detected for longer than the set **Apnea Delay** time.

**NOTE:** The displayed respiration rate is not used as an alarm criterion and is calculated and displayed only when the respiration signal is good and free of movement artifacts. Otherwise, a question mark is displayed. This has no negative effect on either the alarm function or the detection of central apneas.

### 8.5.2 Respiration \ Apnea Alarms

The following selections for configuring the apnea monitor are available:

- Off
- Always On

**Off** and **Always On** switch off and on the detection of central apnea respectively. In both cases the respiration waveform is displayed and stored.

**WARNING:** A deactivated apnea monitor cannot detect apnea!

## 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.

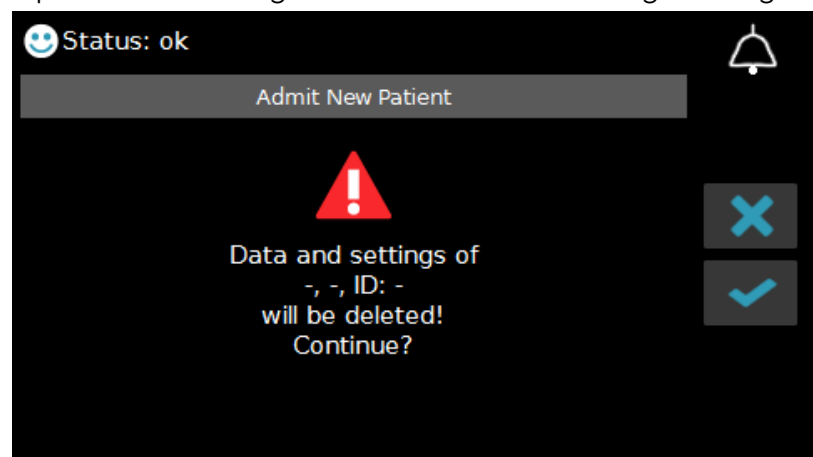


Fig. 53 Admit New Patient Procedure – Step 1: Warning Information

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

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

- the **Minimum Respiration Rate** in the **Respiration** menu;
- the **HR Lower Limit** and **HR Upper Limit** in the **Heart Rate** menu.

| Setting                         | 0 to 2 years | 2 to 6 years | > 6 years |
|---------------------------------|--------------|--------------|-----------|
| Minimum Respiration Rate [/min] | 10           | 5            | 4         |
| HR Lower Limit [/min]           | 80           | 60           | 55        |
| HR 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 work-spaces. 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).

Fig. 55 Admit New Patient Procedure – Step 3: Enter Patient Data

The keypad operates similar to a standard keypad. Each character is selected by touching the corresponding digit or letter. The selected items appear at the top of the screen, as shown for the word “Test” in Fig. 55. 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. 56 shows the information entered for a fictitious patient:

Fig. 56 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 7.3.6 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:

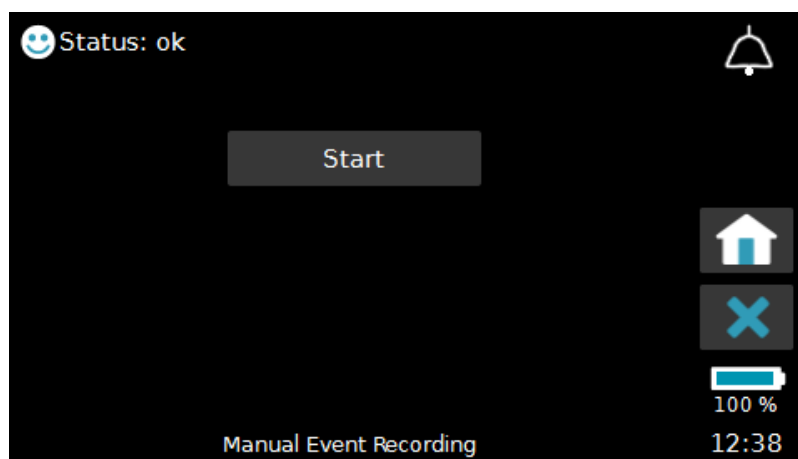


Fig. 57 Dialog to Start a Manual Recording

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. 63.

### 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. 63.

### 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. 58.

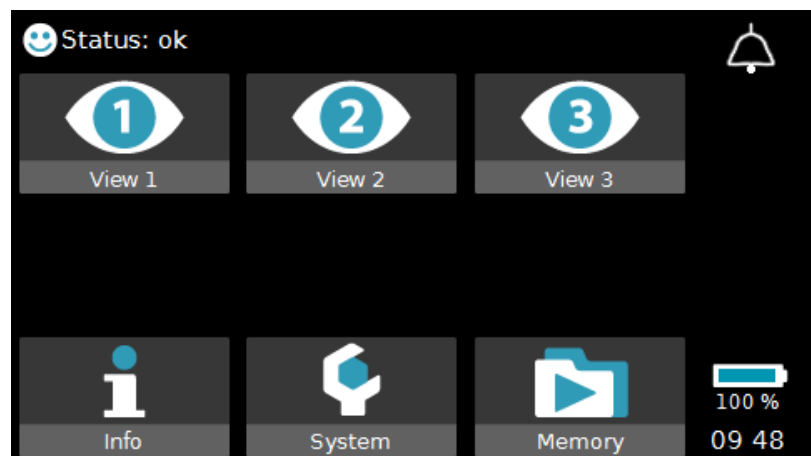


Fig. 58 Home Screen with Settings Protection On and Views 2 & 3 Set to On

### 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:

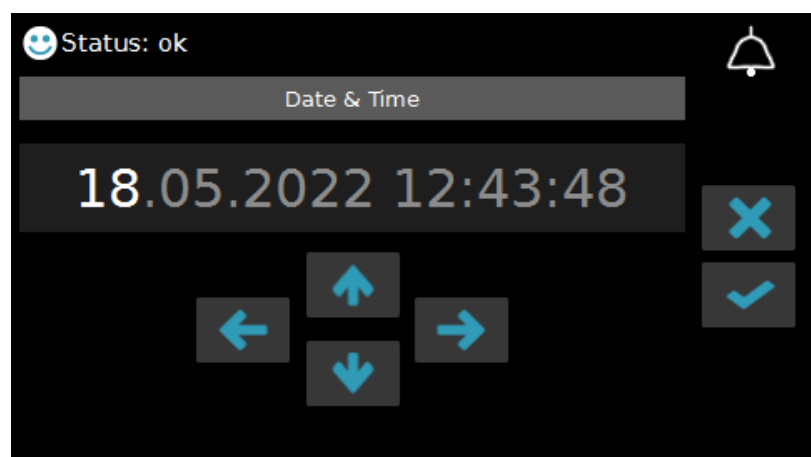


Fig. 59 Dialog to Set the Date and Time

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 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. 60 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 Heart Rate Settings (Settings Protection Mode Off)

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

### 8.7.1 Heart Rate \ HR Averaging

**HR Averaging Delay** can be set from 2 to 8 beats in steps of 1 beat, and defines the number of beats used to calculate the heart rate.

**NOTE:** The higher the value chosen, the slower the system's reaction time to report an alarm, particularly in the event of bradycardia.

### 8.7.2 Heart Rate \ HR Lead Select

The **HR Lead Select** can be set to one of the following three options to determine which electrodes are used to acquire the ECG signal:

- Lead I (Yellow-Red)                      Yellow and red electrodes (default)
- Lead II (Black-Red)                      Black and red electrodes
- Lead III (Black-Yellow)                      Black and yellow electrodes

Section 5.3 provides further information on lead optimization.

### 8.7.3 Heart Rate \ HR 50/60 Hz Filter

This setting can be used to switch on or off a software notch filter used to suppress 50 or 60 Hz interference signals from the mains power supply.

### 8.7.4 Heart Rate \ HR Pacemaker Detection

**HR Pacemaker Detection** must be activated when monitoring patients with pacemakers to avoid misinterpreting pacemaker pulses as heartbeats. The default setting is **Off**.

### 8.7.5 Heart Rate \ HR Silent Lower Limit

The **HR 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 heart rate falls below this limit for longer than the set **HR Bradycardia Delay**.

### 8.7.6 Heart Rate \ HR Silent Upper Limit

The **HR 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 heart rate rises above this limit for longer than the set **HR Tachycardia Delay**.

### 8.7.7 Heart Rate \ HR Bradycardia Delay

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

### 8.7.8 Heart Rate \ HR Tachycardia Delay

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

### 8.7.9 Heart Rate \ HR Asystole Delay

The **HR Asystole Delay** can be set from 1 to 8 seconds in steps of 1 second, and defines the time between when no ECG signal is detected and the corresponding patient alarm is triggered. The default setting is 4 seconds.

### 8.7.10 Heart Rate \ HR Deviation Averaging Interval

The **HR 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 heart rate used as the reference value for calculating deviation alarms. The default setting is 60 seconds.

### 8.7.11 Heart Rate \ HR Deviation Alarm Limit (-)

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

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

### 8.7.12 Heart Rate \ HR Deviation Alarm Limit (+)

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

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

### 8.7.13 Heart Rate \ HR Alarms

The **HR 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 heart rate violates the set upper and lower alarm limits. When set to **Limits & Deviations**, alarms are reported when the measured heart rate violates the set alarm limits and when they deviate from the average heart rate calculated over the set **HR Deviation Averaging Interval**.

## 8.8 Respiration Settings (Settings Protection Mode Off)

With **Settings Protection** set to **Off**, the following **Respiration** settings are available in addition to those explained in section 8.5.

### 8.8.1 Respiration \ Silent Apnea Delay

The **Silent Apnea Delay** can be set from 5 to 20 seconds in steps of 1 second. The default setting is 20 seconds, thereby deactivating silent apnea detection. VitaGuard logs a silent patient alarm in the alarm event log when a central apnea longer than the set delay is detected.

### 8.8.2 Respiration \ Periodic Respiration

This setting is used to activate detection of periodic respiration, which is defined as clusters of breaths separated by intervals of apnea (no breathing) or near-apnea. The default setting is **Off**.

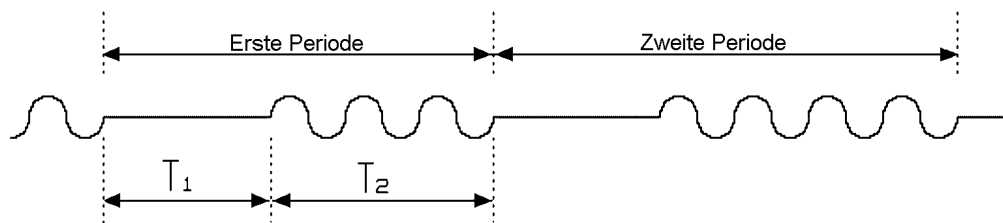


Fig. 61 Periodic Respiration

VitaGuard logs a silent patient alarm in the alarm event log when periodic respiration is detected.

The parameters for detecting periodic respiration can be configured using the three settings explained below.

### 8.8.3 Respiration \ Period T1 (Delay)

The **Period T1 (Delay)** can be set from 5 to 20 seconds in steps of 1 second. The default setting is 6 seconds.

For detection of periodic respiration, apnea must be longer than T1 shown in Fig. 61, but shorter than the set **Apnea Delay** explained in section 8.5.1. If central apnea exceeds the **Apnea Delay**, then an apnea alarm is generated and logged in the alarm event log.

### 8.8.4 Respiration \ Period T2 (Resp.)

The **Period T2 (Resp.)** can be set from 4 to 30 seconds in steps of 1 second. The default setting is 20 seconds. When respiration lasts longer than T2 shown in Fig. 61, then periodicity is no longer assumed and the detection of periodic respiration ceases.

### 8.8.5 Respiration \ Number of Periods

The **Number of Periods** can be set from 2 to 6 in steps of 1 period. The default setting is 3 periods. When the set number of periodic cycles that match the criteria defined for **Period T1 (Delay)** and **Period T2 (Resp.)** above has been reached, a silent patient alarm is logged in the alarm event log.

Periodic respiration events are identified with a “P” in the **Apnea** column of the list of logged events shown in Fig. 63.

### 8.8.6 Respiration \ Minimum Respiration Rate

The **Minimum Respiration Rate** can be set from 4 to 10 /min in steps of 1 /min. This setting is used for detecting central apnea. VitaGuard discards respiration cycles having a rate lower than the set value. For example, when set to 10 /min, respiration cycles slower than 6 seconds will be discarded by the apnea detection algorithm. The default setting depends on the **Age Group** selected during the **Admit New Patient** procedure as follows:

- Age group 0 – 2 years: Default = 10 /min
- Age group 2 – 6 years: Default = 5 /min
- Age group >6 years: Default = 4 /min

## 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. 62.

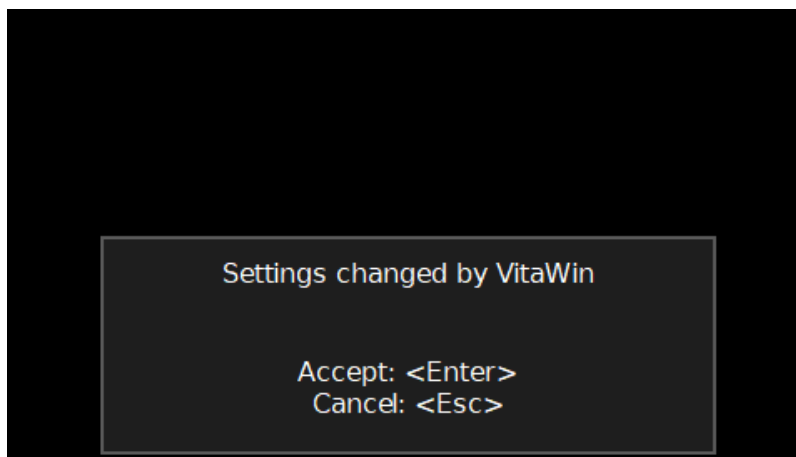


Fig. 62 Confirmation Dialog when Changing Settings via VitaWin

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 heart rate are exceeded, or if a central apnea longer than the set apnea time is detected.

Similarly, a silent patient alarm event occurs when any of the silent alarm limits heart rate are exceeded, or if a central apnea longer than the set silent apnea time is detected. 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. 63 Events Icon

| Events: 27        | HR   | Apnea | M/I |
|-------------------|------|-------|-----|
| 25.08 18:42, 59s  |      | (P)   |     |
| 25.08 18:35, 32s  |      | •     |     |
| 25.08 18:27, 134s | ▼ 70 | •     |     |
| 25.08 18:23, 0s   |      |       | M   |
| 25.08 18:20, 0s   |      |       | I   |

Fig. 64 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 **HR**, **Apnea** and **M/I** (Manual/Interval) inform about the type of alarm event. An arrow pointing down in the **HR** column shows that the respective lower alarm limit was exceeded. Similarly, an arrow pointing up in the **HR** column 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. For apnea alarms, the value shows the duration of the apnea event.

The dot symbol in the **Apnea** column informs that an apnea alarm condition was detected, whereas a “P” in the **Apnea** column marks

Periodic respiration. 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:

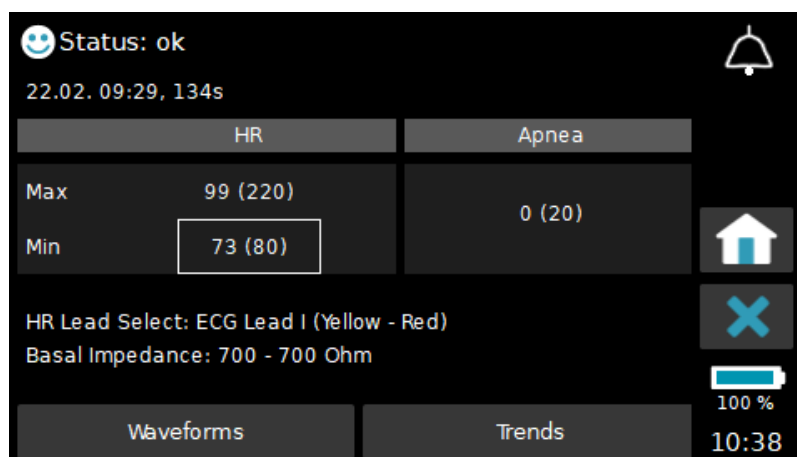


Fig. 65 Minimum and Maximum Values of the Logged Alarm Event

The table shows the minimum and maximum values heart rate and apnea 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 heart rate value of 73 /min was below the lower heart rate alarm limit of 80 /min, thereby causing the alarm.

Below the table, the current ECG lead along with the minimum and maximum values of basal impedance during the alarm condition are displayed for reference.

To go back to the event list, touch the “X” icon on the right-hand side of the screen. Alternatively, the ECG and respiration waveforms logged for the event may be viewed by the touching the **Waveforms** button on the bottom of the screen, or the trend graph the heart rate may be accessed by touching the **Trends** button.

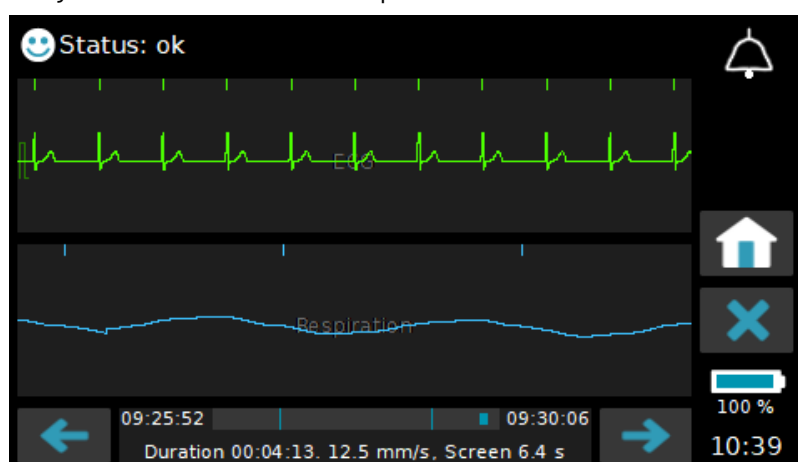


Fig. 66 Event Waveforms

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 heart 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.

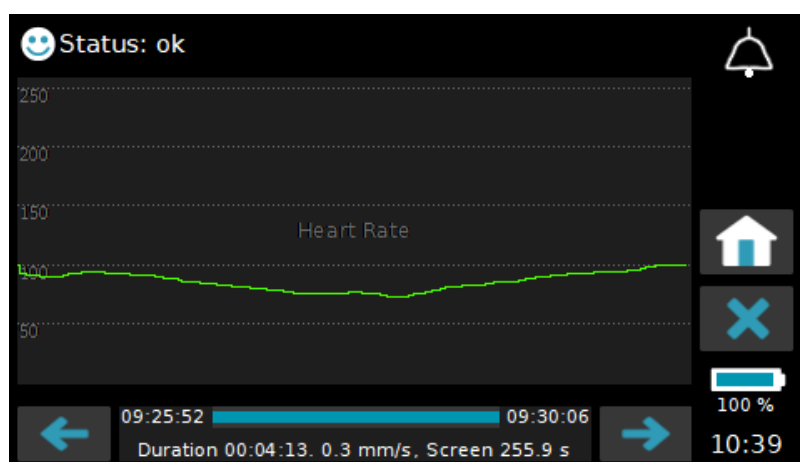


Fig. 67 Event Trend Graphs

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. 68 Trends Icon

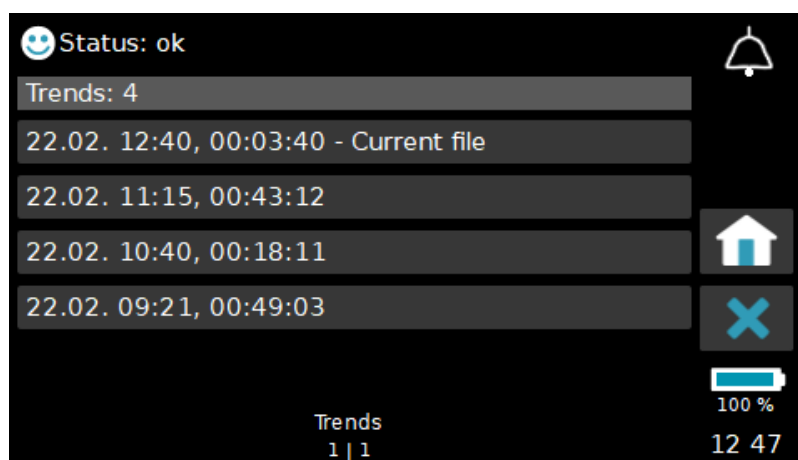


Fig. 69 List of Trend Recordings

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:

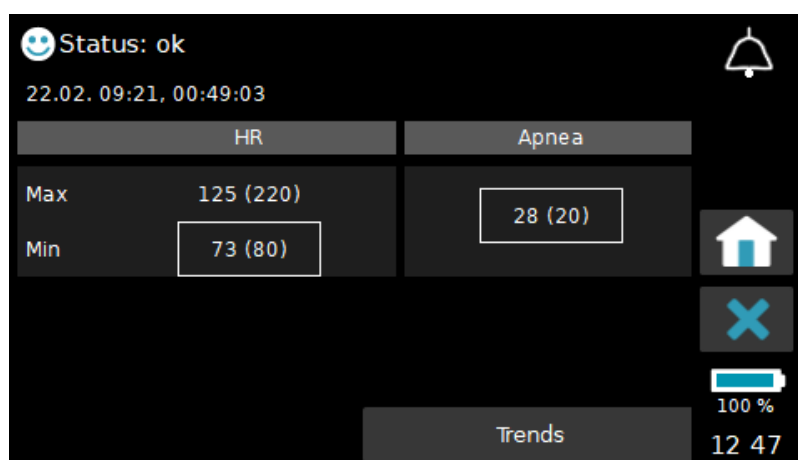


Fig. 70 Minimum and Maximum Values during Trend Recording

The table shows the minimum and maximum values of heart rate and apnea 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 heart rate may be accessed by touching the **Trends** button.

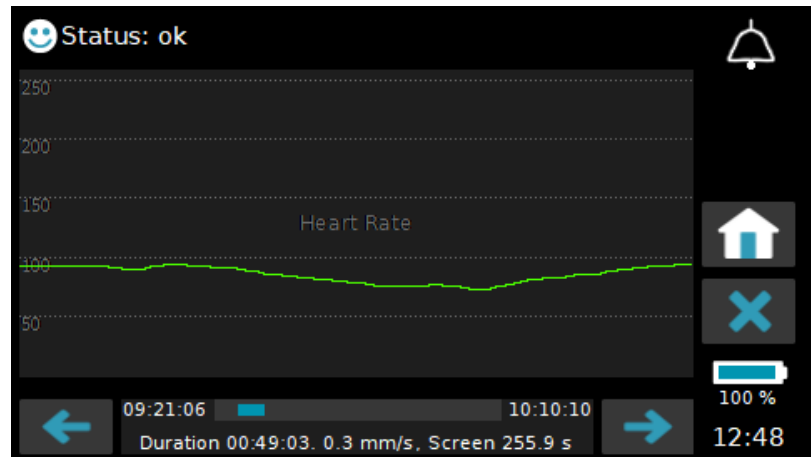


Fig. 71 Trend Recording Graphs

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-Dis-closure | Trend |
|--|------------------|--------|------------------|-------|
| ECG waveform                           | 256              | ✓      | ✓                |       |
| Current heart rate                     | 1                | ✓      | ✓                | ✓     |
| Average heart rate for trend deviation | 1                | ✓      | ✓                | ✓     |
| Average heart rate over 1 min          | 0.2              | ✓      | ✓                | ✓     |
| Average heart rate over 1 h            | 0.2              | ✓      | ✓                | ✓     |
| Average heart rate over 6 h            | 0.2              | ✓      | ✓                | ✓     |
| Average heart rate over 12 h           | 0.2              | ✓      | ✓                | ✓     |
| Respiration waveform                   | 256              | ✓      | ✓                |       |
| Respiration rate                       | 1                | ✓      | ✓                | ✓     |
| Basal impedance                        | 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,
- apnea 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. 8 and touch the **USB Memory** icon shown in Fig. 30. Upon doing so, the following dialog is displayed. Touching the **Start** button starts the copy process.

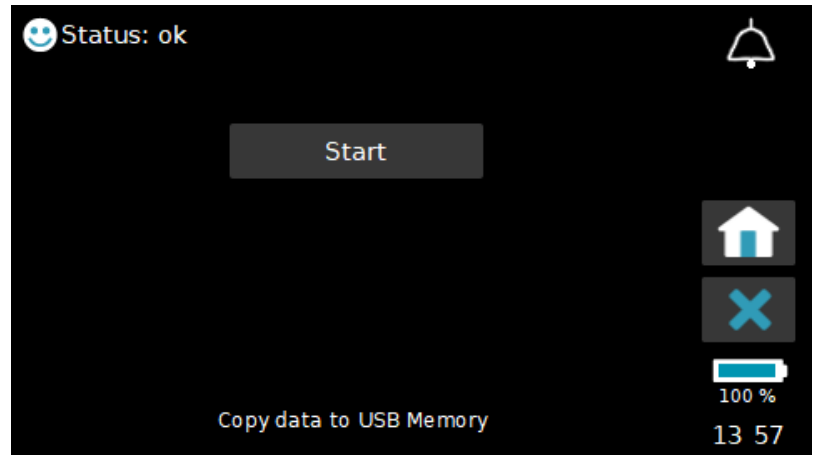


Fig. 72 USB Memory Download Start Dialog

If all files have been successfully copied to USB, the left-hand dialog of Fig. 72 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. 71.

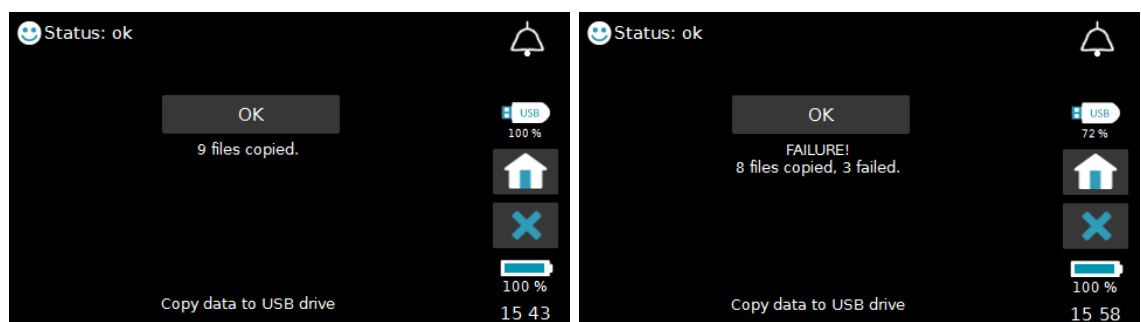


Fig. 73 USB Memory Download Result Dialog

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: respiration, respiration rate, basal impedance, ECG, heart rate, and status line information.

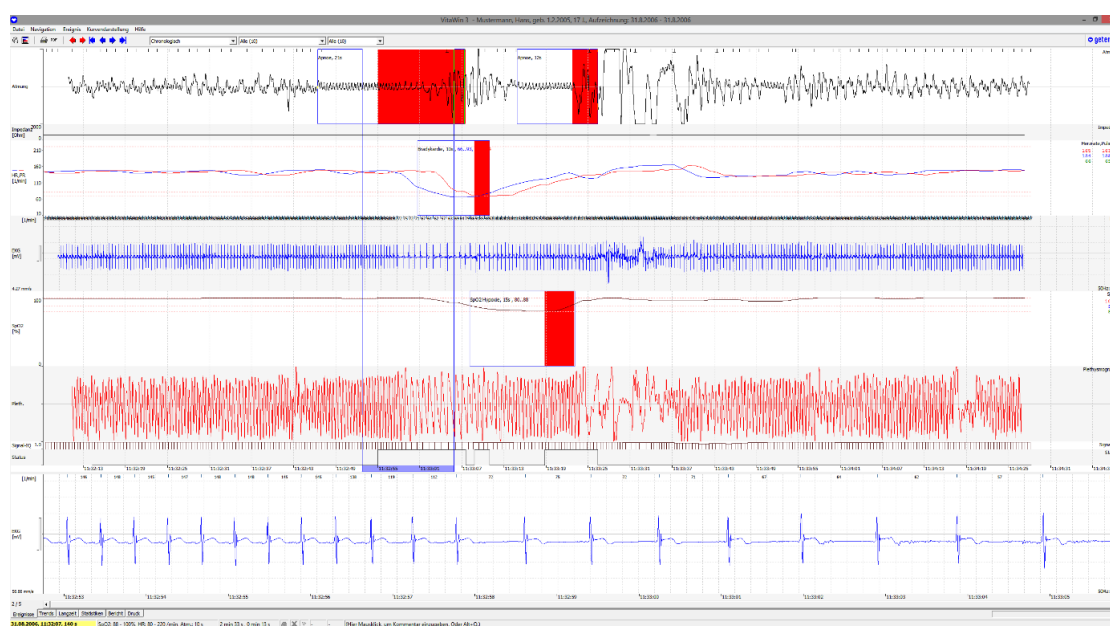


Fig. 74 VitaWin

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 Heart Rate

The current heart rate used for detecting alarm conditions is calculated as the average between two and eight heartbeats as defined in the **HR Averaging** setting explained in section 8.7.1.

The higher the value selected for **HR Averaging**, the longer VitaGuard needs before the displayed heart rate reflects the patient's actual heart rate. When,

for example, a value  $N = 8$  is selected, the displayed heart rate reflects the true heartbeat after eight heartbeats.

$$T_{AC(MAX)}|_{HR} = 60 \sum_{n=0}^{N-1} \frac{1}{HR_n}$$

whereby  $N = \text{AVERAGING}$

The longest alarm condition delay for the heart rate therefore occurs when it is at its lowest. When, for example, the heart rate suddenly drops to thirty beats per minute, a beat is detected every two seconds. With **HR Averaging** set to 8, a heart rate of thirty is not displayed until after a maximum of sixteen seconds.

### 10.1.2 Alarm Condition Delay for Respiration

The impedance pneumography method used to monitor apnea (see section 10.3) must rule out cardiac artifacts as the source of changes in the measured impedance. When central apnea occurs, the applied algorithm detects cardiac artifacts after a maximum of four heartbeats.

In addition, the alarm condition delay for respiration depends on the acquisition amplifier's recovery time. When, in the worst case, the amplifier is saturated owing to sudden, violent movements by the patient directly before the occurrence of a central apnea event, the baseline is reached after a maximum of six seconds, after which a maximum of four beats is needed before cardiac artifacts can be detected. The worst-case alarm condition delay is therefore:

$$T_{AC(MAX)}|_{apnea} = 4 \left( \frac{60}{HR} \right) + 6 \quad (6 = \text{amplifier's max recovery time in seconds})$$

### 10.1.3 Alarm Report Delays

The alarm report delays for bradycardia and tachycardia can be set within certain limits.

TA<sub>(max)</sub> for bradycardia: ..... Set **HR Bradycardia Delay** + 2 s

TA<sub>(max)</sub> for tachycardia: ..... Set **HR Tachycardia Delay** + 2 s

TA<sub>(max)</sub> for asystole: ..... Set **HR Asystole Delay** + 2 s

TA<sub>(max)</sub> for apnea: ..... 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 Principle of Heart Rate Monitoring

Every heartbeat, i.e., contraction of the cardiac muscle, generates a myopotential that propagates through the body as an electric signal that can be measured by two sensing electrodes attached to the surface of the body. The graphical depiction of the measured signal is called an electrocardiogram (ECG).

The amplitude and the polarity (positive or negative) of the measured signal depend on both the placement of the sensing electrodes and the individual location of the heart.

The signal is very small, typically one to two millivolts, so it must be amplified before it can be used to calculate the heart rate.

For this purpose, an instrumentation amplifier is used in conjunction with filter circuitry. This amplifies the ECG signal and suppresses all other unwanted secondary signals such as movement-induced artifacts and electromagnetic interference.

Interference signals can be optimally suppressed when a third reference electrode is used. Without this reference electrode, the ECG measuring circuitry must suppress interference signals solely with the aid of filters. When, however, interference signals exceed a certain limit, suppression is no longer possible and the ECG signal can no longer be measured; false alarms are the consequence. The use of a reference electrode is the most common method for suppressing interference components.

The adhesive quality and the composition of the gel applied to the electrodes have an additional important effect on ECG measurements. The best results are obtained when the electrodes adhere well. Electrodes that have dried out or adhere badly induce further interference into the measurement circuitry.

Irrespective of all interference signals, the heart rate can be measured only when the amplitude of the measured ECG signal itself is large enough to be detected by the monitor. The amplitude of the ECG signal on the body surface cannot be influenced and varies from person to person.

The monitor measures the potential difference between the two sensing electrodes. Depending on where the electrodes are applied, the measured signal can be strong, weak, positive, or negative. It is even possible that a signal cannot be seen at all. This is the case when the electrodes are inadvertently placed on the same potential line. The propagating signal from a heartbeat can be pictured as contour lines around a hill on a map. When two persons are standing on the same line, the difference in height between these persons is zero. Accordingly, no ECG signal can be measured when the sensing electrodes are placed on such a line on the body's surface. To prevent too weak ECG signals from triggering false alarms, it is therefore important that the optimal electrode positions, as explained in section 5.3, are determined before starting monitoring.

### **10.3 Measuring Principle of Apnea Monitoring**

Unlike the heartbeat, respiration is not accompanied by its own electric signal. A different principle must therefore be applied for measuring respiration. The most common method is the so-called impedance pneumography. Fluctuations in impedance are caused by both respiratory movements of the thorax and other movements. For this reason, an apnea monitor can function correctly only when the patient is lying still. Similarly, the measured signals are very weak and must be amplified. To prevent false alarms wherever possible, it is very important that the optimal electrode positions are determined before the start of monitoring.


The essential advantage of the described method is that the same electrodes can be used for monitoring both the heart rate and respiration.

# 11. Technical Data

## 11.1 General Specifications

| General   | Specification   |
|---|---|
| Weight  | 485 g   |
| Dimensions (L x B x H)                                      | 178 x 118.6 x 40 mm.  |
| Overall weight of monitor and accessories in transport case | 1.85 kg   |
| User interfaces   | 4.3" TFT colour display with resistive touch<br>2 pushbutton keys (Esc and Enter)<br>5 LED indicators: <ul style="list-style-type: none"> <li>- Heartbeat: green</li> <li>- Respiration: green</li> <li>- Battery charging: green</li> <li>- External power adapter: green</li> <li>- Alarm: red and yellow</li> </ul> 2 alarm buzzer outlets                       |
| Connectors  | ECG: 8-pin round connector (green)<br>External power adapter: 2-pin round connector (grey)<br>Communication: USB-C connector  |
| Internal power supply                                       | Li-ion rechargeable battery pack: <ul style="list-style-type: none"> <li>- 2 x Panasonic NCA103450A cells</li> <li>- Nominal voltage: 3.6 V</li> <li>- Nominal capacity: 4400 mAh</li> <li>- Integrated safety mechanism</li> </ul> Charging time: Max. 6 h<br>Charging cycles: >200  |
| Operating time with fully charged battery                   | Min. 8 h  |
| External power supply                                       | Medical grade external power adapter: <ul style="list-style-type: none"> <li>- Manufacturer: FRIWO Gerätebau GmbH</li> <li>- Type: FW 8001M/05</li> <li>- Input: 100–240 V, 50–60 Hz, 400 mA, AC</li> <li>- Output: 5 V, 3000 mA, DC</li> <li>- Ingress protection: IP 42</li> <li>- Safety class: II as per IEC 60601-1</li> <li>- Cable length: 183 cm</li> </ul> |

| General  | Specification  |
|--|--|
| Auxiliary backup power supply  | Lithium cell VL2330HFN (3 V)   |
| 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   | CF (cardiac floating) for heart rate and apnea monitor   |
| Defibrillator proof  | Yes, when used with the ECG cable provided   |
| 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><b>NOTE:</b> Refer to the electrodes' packaging for the storage temperature of electrodes. |
| Calibrating start-up time  | < 60 s   |
| Display refresh rate   | 1 Hz   |
| Intervals for calculating average values for heart 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>ECG patient cable: 2 years   |

| General  | Specification  |
|--|--|
| Recommended inspection and service interval              | 18 months  |
| Characteristics of HIGH priority acoustic alarm signal   | <p>Acoustic signals for HIGH priority alarms consist of two acoustic sequences of five tones each:</p>  <p>Number of pulses: 10<br/> Effective pulse duration: <math>155 \pm 5</math> ms<br/> Pulse spacing between:</p> <ul style="list-style-type: none"> <li>- 1<sup>st</sup> and 2<sup>nd</sup> pulse: <math>120 \pm 5</math> ms</li> <li>- 2<sup>nd</sup> and 3<sup>rd</sup> pulse: <math>120 \pm 5</math> ms</li> <li>- 3<sup>rd</sup> and 4<sup>th</sup> pulse: <math>400 \pm 10</math> ms</li> <li>- 4<sup>th</sup> and 5<sup>th</sup> pulse: <math>120 \pm 5</math> ms</li> <li>- 5<sup>th</sup> and 6<sup>th</sup> pulse: <math>725 \pm 20</math> ms</li> <li>- 6<sup>th</sup> and 7<sup>th</sup> pulse: <math>120 \pm 5</math> ms</li> <li>- 7<sup>th</sup> and 8<sup>th</sup> pulse: <math>120 \pm 5</math> ms</li> <li>- 8<sup>th</sup> and 9<sup>th</sup> pulse: <math>400 \pm 10</math> ms</li> <li>- 9<sup>th</sup> and 10<sup>th</sup> pulse: <math>120 \pm 5</math> ms</li> </ul> <p>Interburst interval: <math>7.0 \pm 0.5</math> s</p> |
| Characteristics of MEDIUM priority acoustic alarm signal | <p>Acoustic signals for medium priority are as follows:</p> <p>Number of pulses: 3<br/> Effective pulse duration: <math>150 \pm 10</math> ms<br/> Pulse spacing between:</p> <ul style="list-style-type: none"> <li>- 1<sup>st</sup> and 2<sup>nd</sup> pulse: <math>240 \pm 10</math> ms</li> <li>- 2<sup>nd</sup> and 3<sup>rd</sup> pulse: <math>240 \pm 10</math> ms</li> </ul> <p>Interburst interval: <math>7.2 \pm 0.5</math> s</p>   |
| 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 $1300 \text{ Hz} \pm 100 \text{ Hz}$   |

## 11.2 Heart Rate Monitor Specifications

| Heart Rate Monitor                   | Specification   |
|--------------------------------------|---|
| Heart rate range                     | 30 – 270 /min   |
| Heart rate accuracy                  | ± 3 % for heartbeats of similar morphology (averaged over 2 to 8 beats) under no motion conditions  |
| Heart rate resolution                | 1 /min  |
| Sensitivity                          | 0.3 mV (triangle with 40 ms base width)   |
| Input impedance                      | > 10 MOhm at 10 Hz  |
| Input dynamic range                  | ± 5 mV  |
| Deflection speed on display          | 12.5 or 25 mm/s (in Heart Rate view)  |
| Deflection amplitude on display      | 5 or 10 mm/mV (in Heart Rate view)  |
| Pacemaker pulse display capability   | <p>A pacemaker pulse flag is displayed in the Heart Rate view for pacemaker pulses having the following characteristics when <b>HR Pacemaker Detection</b> = On:</p> <ul style="list-style-type: none"> <li>- Amplitude: ± 2 to ±700 mV</li> <li>- Pulse width: 0.5 to 2 ms</li> </ul>  |
| Pacemaker pulse rejection capability | <p>Pacemaker pulses having the following characteristics will not be interpreted as heart beats:</p> <p>Single-chamber pacemakers:</p> <ul style="list-style-type: none"> <li>- Amplitude: ± 2 to ±700 mV</li> <li>- Pulse width: 0.1 to 2 ms</li> <li>- Overshoot: 0 to 100 ms up to ±2 mV</li> </ul> <p>Dual-chamber pacemakers having intervals of 150 ms and 250 ms between pulses:</p> <ul style="list-style-type: none"> <li>- Amplitude: ± 2 to ±450 mV</li> <li>- Pulse width: 0.1 to 2 ms</li> <li>- No overshoot</li> </ul> |
| T-wave rejection                     | The maximum T-wave amplitude for which the heart rate display is inside the allowed tolerance is 2 mV   |
| Response time of heart rate display  | <p>High rate response from 80 to 120 bpm:</p> <ul style="list-style-type: none"> <li>- Averaging over 2 beats: 1 s</li> <li>- Averaging over 8 beats: 5 s</li> </ul> <p>Low rate response from 80 to 40 bpm:</p> <ul style="list-style-type: none"> <li>- Averaging over 2 beats: 3 s</li> <li>- Averaging over 8 beats: 11 s</li> </ul>  |

| Heart Rate Monitor   | Specification   |                                   |                                   |
|--|---|-----------------------------------|-----------------------------------|
| Heart rate accuracy for the special waveforms A1 to A4 defined in the Standard IEC 60601-2-27:2011 | Waveform  | Rate                              |                                   |
|  | Image A1: ventricular bigeminy, 80 bpm                    | 80 bpm                            |                                   |
|  | Image A2: slowly changing ventricular bigeminy, 60 bpm    | 60 bpm                            |                                   |
|  | Image A3: quickly changing ventricular bigeminy, 120 bpm  | 120 bpm                           |                                   |
|  | Image A4: bidirectional systoles, 90 bpm                  | 60 bpm                            |                                   |
| Time for alarm if tachycardia detected (acc. to IEC 60601-2-27:2011)                               | Waveform  | Alarm delay time = 1 s            | Alarm delay time = 6 s            |
|  | Image B1: ventricular tachycardia, 206 bpm, 0.5 / 1 / 2mV | < 2 s with averaging over 2 beats | < 8 s with averaging over 8 beats |
|  | Image B2: ventricular tachycardia, 195 bpm, 1 / 2 / 4 mV  | < 2 s with averaging over 2 beats | < 8 s with averaging over 8 beats |

## 11.3 Apnea Monitor Specifications

| Apnea Monitor               | Specification                              |
|-----------------------------|--|
| Respiration rate range      | 4** – 90 breaths/min                       |
| Respiration rate accuracy   | ±5 % for rhythmic breathing without motion |
| Respiration rate resolution | 1 /min                                     |
| Sensitivity                 | > 0.2 Ohm with basal impedance 1000 Ohm    |
| Measurement method          | Impedance pneumography                     |
| Measurement frequency       | 50 kHz                                     |
| Measurement current         | < 1 µA                                     |
| Basal impedance             | 50 – 3000 Ohm in steps of 50 Ohm           |

\*\* Minimum respiration rate depends on the setting of the same name in the **Respiration** settings menu.

## 11.4 Electromagnetic Compatibility Specifications

The following specifications are according to IEC 60601-1-2: 2014 + A1: 2020.

### 11.4.1 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<br>CISPR 11  | Group 1    | The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.<br><br>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. |
| RF emissions<br>CISPR 11  | Class B    |  |
| Harmonic emissions<br>IEC 61000-3-2   | Class A    |  |
| Voltage fluctuations<br>/ Flicker emissions<br>IEC 61000-3-3  | Complies   |  |

## 11.4.2 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)<br>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<br>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<br>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<br>IEC 61000-4-11  | < 5% UT (> 95% dip) for 0.5 cycle<br><br>< 5% UT (> 95% dip) for 1 cycle<br><br>70% UT (30% dip) for 25 cycles<br><br>< 5% UT (> 95% dip) for 5 s | < 5 % UT (> 95 % dip) for 0.5 cycle<br><br>< 5 % UT (> 95% dip) for 1 cycle<br><br>70 % UT (30% dip) for 25 cycles<br><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<br>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  |
| <b>NOTE:</b> UT is the AC mains voltage prior to application of the test level.   |   |  |  |

### 11.4.4 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><br>10 V/m<br>80 MHz to 2,7 GHz<br><br>Immunity against wireless RF communication devices | 6 V effective value in the ISM bands according to table 5, Note N)<br><br>10 V/m<br><br>According to Table 9 of standard |  |
| Proximity magnetic fields<br>IEC 61000-4-39   | Test frequency / Modulation<br><br>30 kHz / CW<br><br>134.2 kHz / Pulse modulation 2.1 kHz<br><br>13.56 MHz / Pulse modulation 50 kHz                         | Immunity Test Level A/m<br><br>8<br><br>65<br><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.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## 11.5 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. |
| Asystole             | Cardiac standstill or arrest, absence of heartbeat.   |
| Basal impedance      | Electrical impedance measured between two electrodes, in VitaGuard between the red and yellow electrodes.   |
| Bradycardia          | Slow resting heart rate, typically under 60 beats per minute for adults, and under 100 beats per minute for infants.  |
| ECG                  | <u>E</u> lectro <u>c</u> ardiogram (ECG), a recording of the heart's electrical activity.   |
| Electrode            | A device such as a small metal, gel-coated plate that carries electricity between a patient and an instrument.  |
| 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.  |
| Ohm                  | Unit of measurement of electric resistance / impedance  |
| Periodic respiration | Clusters of breaths separated by intervals of apnea (no breathing).   |
| 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

|         |   |    |
|---------|---|----|
| Fig. 1  | Example of Label on Bottom of Monitor .....                       | 11 |
| Fig. 2  | Example of Label on VG 5 CR Transport Case.....                   | 12 |
| Fig. 3  | ECG Waveform .....  | 34 |
| Fig. 4  | Power Adapter in Original Packaging .....                         | 47 |
| Fig. 5  | Storage Area for ECG Cable, ECG Electrodes and Pouch Straps ..... | 48 |
| Fig. 6  | ECG Cable (left) and ECG Electrodes (right) .....                 | 48 |
| Fig. 7  | VitaGuard VG 5 CR Connected to its Accessories.....               | 51 |
| Fig. 8  | VitaGuard Connector Panel.....                                    | 52 |
| Fig. 9  | VitaGuard Front Panel / User Interface .....                      | 53 |
| Fig. 10 | <Enter> Key.....  | 54 |
| Fig. 11 | <Esc> Key.....  | 54 |
| Fig. 12 | Heartbeat and Respiration LEDs.....                               | 55 |
| Fig. 13 | Power Supply and Battery Charge LEDs .....                        | 55 |
| Fig. 14 | View 1 Screen Content.....  | 56 |
| Fig. 15 | Alarm Buzzer Outlets .....  | 57 |
| Fig. 16 | External Power Adapter.....                                       | 58 |
| Fig. 17 | Plugging Power Adapter into Mains Socket .....                    | 58 |
| Fig. 18 | Battery Capacity Indicator .....                                  | 60 |
| Fig. 19 | “Use By” Date of ECG Electrodes.....                              | 65 |
| Fig. 20 | Colour-Coded Sockets on the ECG Patient Cable’s Distributor ..... | 67 |
| Fig. 21 | Recommended Electrode Configurations.....                         | 68 |
| Fig. 22 | Alternative Electrode Configuration.....                          | 68 |
| Fig. 23 | Signal Indicators in View 1.....                                  | 69 |
| Fig. 24 | Characteristics of Acoustic Alarm Signal for Patient Alarms....   | 74 |
| Fig. 25 | Information on the Monitor Screen during a Patient Alarm .....    | 75 |
| Fig. 26 | Information on the Monitor Screen during a Technical Alarm ..     | 77 |
| Fig. 27 | Home Screen with Settings Protection On .....                     | 86 |
| Fig. 28 | Info View – Page 1 .....  | 87 |
| Fig. 29 | System View with Settings Protection On .....                     | 88 |
| Fig. 30 | Memory View with Settings Protection On.....                      | 88 |
| Fig. 31 | Home Screen with Settings Protection Limited .....                | 89 |
| Fig. 32 | View 2 Screen Content.....  | 89 |
| Fig. 33 | View 3 Screen Content.....  | 90 |
| Fig. 34 | Heart Rate Screen Content .....                                   | 91 |
| Fig. 35 | Respiration Screen Content .....                                  | 91 |
| Fig. 36 | Memory View with Settings Protection Limited.....                 | 92 |
| Fig. 37 | Info \ Page 1: Previous Status Messages.....                      | 93 |

|         |  |     |
|---------|--|-----|
| Fig. 38 | Info \ Page 2: General Information .....                                   | 93  |
| Fig. 39 | Info \ Page 3: System Status .....   | 94  |
| Fig. 40 | Info \ Page 4: Measurements: Heart Rate & Respiration .....                | 94  |
| Fig. 41 | Info \ Page 5: Current Settings: Heart Rate .....                          | 95  |
| Fig. 42 | Info \ Page 6: Current Settings: Respiration .....                         | 95  |
| Fig. 43 | Info \ Page 7: Versions.....   | 96  |
| Fig. 44 | Info \ Page 8: License Information.....                                    | 96  |
| Fig. 45 | Settings Dialog for Display Brightness.....                                | 97  |
| Fig. 46 | Dialog to Accept or Reject a Change of a Setting.....                      | 98  |
| Fig. 47 | Settings Dialog for Signal Beep Tone .....                                 | 98  |
| Fig. 48 | System Settings with Settings Protection On.....                           | 99  |
| Fig. 49 | Display in Screensaver Mode .....  | 100 |
| Fig. 50 | Dialog to Enter the Settings Protection Code.....                          | 102 |
| Fig. 51 | Heart Rate Settings with Settings Protection LIMITED.....                  | 102 |
| Fig. 52 | Respiration Settings with Settings Protection LIMITED .....                | 104 |
| Fig. 53 | Admit New Patient Procedure – Step 1: Warning Information                  | 105 |
| Fig. 54 | Admit New Patient Procedure – Step 2: Select Age Group.....                | 106 |
| Fig. 55 | Admit New Patient Procedure – Step 3: Enter Patient Data....               | 106 |
| Fig. 56 | Admit New Patient Procedure – Example of Patient Data.....                 | 107 |
| Fig. 57 | Dialog to Start a Manual Recording.....                                    | 108 |
| Fig. 58 | Home Screen with Settings Protection On and Views 2 & 3<br>Set to On ..... | 109 |
| Fig. 59 | Dialog to Set the Date and Time .....                                      | 109 |
| Fig. 60 | Language Menu .....  | 110 |
| Fig. 61 | Periodic Respiration .....   | 114 |
| Fig. 62 | Confirmation Dialog when Changing Settings via VitaWin.....                | 116 |
| Fig. 63 | Events Icon.....   | 119 |
| Fig. 64 | List of Logged Events .....  | 119 |
| Fig. 65 | Minimum and Maximum Values of the Logged Alarm Event...                    | 120 |
| Fig. 66 | Event Waveforms .....  | 120 |
| Fig. 67 | Event Trend Graphs.....  | 121 |
| Fig. 68 | Trends Icon .....  | 122 |
| Fig. 69 | List of Trend Recordings .....   | 122 |
| Fig. 70 | Minimum and Maximum Values during Trend Recording .....                    | 122 |
| Fig. 71 | Trend Recording Graphs .....   | 123 |
| Fig. 72 | USB Memory Download Start Dialog.....                                      | 125 |
| Fig. 73 | USB Memory Download Result Dialog .....                                    | 125 |
| Fig. 74 | VitaWin .....  | 126 |

## 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.<br>Chapter 11.2: Lower heart rate range limit changed to 30 /min.   |
| 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: Added additional power adapters to accessory list.<br>Chapter 8.3.1: Brightness dimmed to 20 %.<br>Chapter 8.5.1, 8.8.1, 8.8.3 and 8.8.4: Steps of 1 second.<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.



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