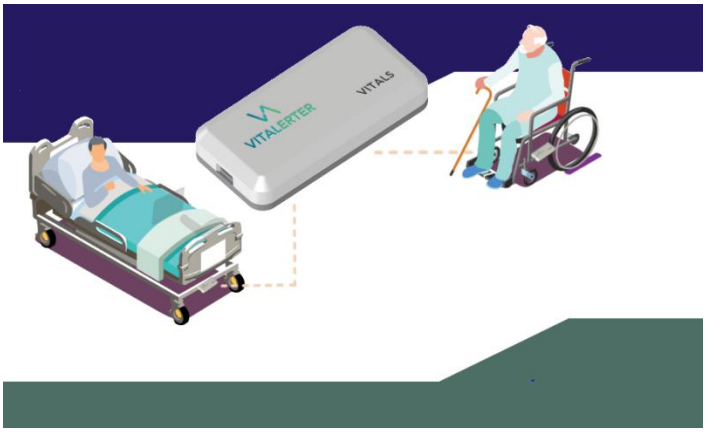
Vitalerter LTD

User Manual

Vitalerter System



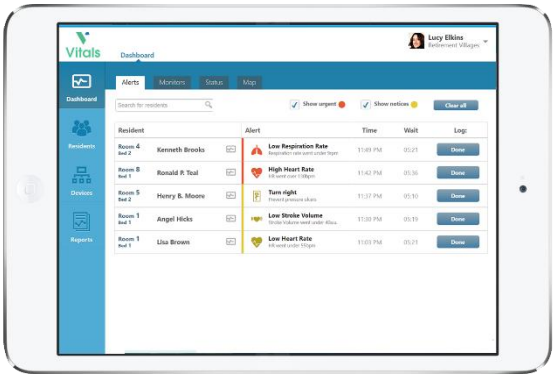


Table of Contents

1. Introduction

The Vitalerter system includes a contact free medical device and integrated care management system intended to provide continuous measurement and monitoring of patient vitals heart rate, respiration rate and body motion for preventive care analysis while patient is at rest or during sleep.

The Vitalerter system continuously acquires patient vital signs data by the Vitals sensor unit. This data is transmitted at real time to the integrated care management system where the data is analyzed and relayed to a central display station or mobile application.

The Vitals sensor is mounted on a bed or a wheel chair and continuously monitoring the patient.

The Integrated care management system presents the monitored data at real time and alerts for fall prevention, pressure ulcers prevention, warning signs in situations of irregular breathing and heart rate incidents.

The Vitalerter system is used in hospital facilities, nursing homes, rehabilitation centers and by authorized private caregivers.

1.1. Intended Use

The Vitalerter System is intended for continuous measurement of Heart rate (HR), Respiration rate (RR) and movement, in an automatic contact-less manner, in hospital or nursing home setting to proactively provide preventive care information.

The Vitalerter system is not intended to permanently store any type of data. The Vitalerter System is not intended to provide automated treatment decisions or as a substitute for professional healthcare judgment. All patient medical diagnosis and treatment are to be performed under direct supervision and oversight of an appropriate health care professional.

1.2. Indications for Use

The Vitalerter system is indicated for residents that require continuous monitoring in a hospital, nursing facility, rehabilitation center or by authorized private caregiver.

1.3. Contraindications

- Patients that require monitoring for life sustaining or life supporting purpose.
- An Magnetic Resonance (MR) environment

2. Safety

2.1. General Safety Guidelines

Please read and adhere to all warnings, cautions and notes listed here and in the associated sections throughout this manual.

 Warning statements alert the user to conditions or practices that could result in injury to a person, or serious adverse events associated with the use or misuse of the Vitalerter System.

 Caution statements alert the user to conditions or practices that could result in problems with the Vitalerter System.

 Read the instructions in this manual before using the device

The Vitalerter system installation shall be performed according to the instructions in this manual.

℞ Only Prescription Use Only

 **Caution**

- The Vitals sensor can be damaged internally if dropped. Avoid dropping and rough handling by proper assembly and placement in an area that is least exposed to mechanical damage.
- The Vitals sensor operating environment is recommended for indoors only to provide least amount of interference.
- Safe decommissioning of the device is required. Sorted disposal of battery according to local regulation or contact local distributor.
- The Vitals sensor is not intended to permanently store any type of data.
- The Vitals sensor is protected against dripping water (IP21).
- Do not expose the Vitalerter Vitals sensor to a wet environment.

- Do not attempt to self-install the Vitals sensor on another bed or chair. All units must be installed by authorized Vitalerter representatives.
- The Vitalerter system is not intended to provide automated treatment decisions or as a substitute for professional healthcare judgment.
- All patient medical diagnosis and treatment are to be used under direct supervision and oversight of an appropriate health care professional
- The Vitals sensor is intended for individual patient, sharing touching or moving bed should be avoided during measurements.

2.2. General Hazards

2.2.1. Electrical Safety

The Vitals sensor has been tested for product safety and is in conformance with IEC/EN 60601-1

Electrical Medical Equipment Classification	
Equipment Classification	Class 1, Internally and continuously powered
Equipment Type	Fixed, Stationary

Only equipment specified in this manual and complying with requirements of EN60601-1 should be connected to the system

2.2.2. EMC

The Vitals sensor is in compliance with EMC IEC 60601-1-2 . This standard is designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed by qualified service personnel.

Emission Test Compliance
IEC 60601-1-2 2007 3rd Edition
FCC Part 15 Subpart B
EN 301 489-1 V2.1.1:2017 EN 301 489-17 V3.1.1:2017

2.2.3. Electrical Fire

Caution

Avoid placing liquids or food on the Vitals sensor. Do not allow conductive fluids to leak into the active circuit components of the sensor as this may cause a short circuit, which could result in an electrical fire. In such an event, only fire extinguishers approved for use on electrical fires should be used. The sensor is not intended for use in the presence of flammable mixtures.

Warning

Do not attempt to connect or power the Vitals sensor with a power adapter and cable other than the ones provided with the device.

2.2.4. WIFI and Bluetooth Communication

All wireless devices are susceptible to radiofrequency interference that can disrupt connectivity. During such interference the Vitals sensor continues to monitor, however relay of information will be halted until the connectivity is restored. A clinician or nurse must always be in direct view of the central display of patient status. If the status appears as blank refer to troubleshooting.

If excessive disconnections are observed please inform your facility administrator to investigate and correct. Always consult with Vitalerter representative before performing any changes to the network. These changes can compromise the communication required for the delivery of status and alerts to the clinicians.

3. System Description

The Vitalerter system consists of:

3.1. The Vitals Sensor

The Vitals sensor containing high sensitivity sensor programmed to sense the patient vitals and motion. Vitals and motion data are collected and transmitted to the cloud and displayed on the integrated care management system. The Vitals sensor contains no display of information.

Figure 1 Vitals Unit Image

The Vitals sensor is powered by:

- **Power adapter**

  The Vitals sensor contains a power adapter and cable supplied with the unit that is connected to the vitals via USB-C. Make sure that the system is always plugged in to the electrical outlet during routine operation.

Figure 2 Vitals Power

- **Battery**

  The Vitals sensor contains a lithium polymer rechargeable battery that provides power in case the unit is unplugged from the electrical outlet, or in case of a power shortage. The battery is not intended to be replaced by the operator. In standard operating mode, the battery is designed to allow approximately 30 hours of operation.

In case the battery no longer maintains the necessary charge, it must be serviced by an authorized Vitalerter representative.

3.2. The Integrated Care Management System (Cloud)

The cloud receives the data from the sensor and analyzes and creates the information presented in real time to the user as it is monitored and displayed in a visual form for appropriate caregiver to directly view patient vitals status and alerts.

4. System Installation and Setup

4.1. Vitals Product Supply

Vitals sensor is supplied in a protective packaging and in bulk to the facility. An individual unit contains the following components:

Quantity	Description
1	Vitals Unit
1	Power adapter
1	Power cord
1	User Manual

Table 1 Product Supply Information

4.2. Vitals sensor Labels

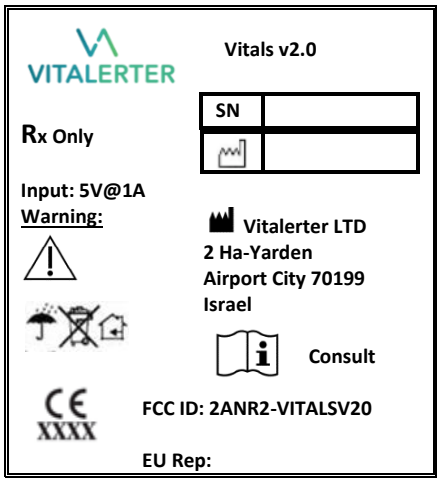


Table 2 System Labels

4.2.1. Vitals sensor Labels Legend

The following explanation of the symbols that appear on the outer packaging and labels of the Vitals sensor.

	Caution
	Warning
	Consult Accompanying Documents
	Manufacturer
Rx Only	Caution: Federal Law prohibits sale by physician order only
	Fragile
	Keep Dry
	Sorted Disposal

4.3. Unpacking

The Vitals sensor should be unpacked and installed only by a Vitalerter authorized representative.

4.4. Installation

The Vitalerter representative performs:

a) The mounting of unit to the residents' bed/chair (4.4.1)

b) The initial powering of the unit (4.4.2)

4.4.1. Mounting

The Vitals sensor may be installed on a bed or a wheelchair.

Patient is to be instructed to lay with upper body in the direction of the USB to allow ideal quality of measurements.

When mounting to bedside the USB Port should be situated in the direction of patient head as follows:

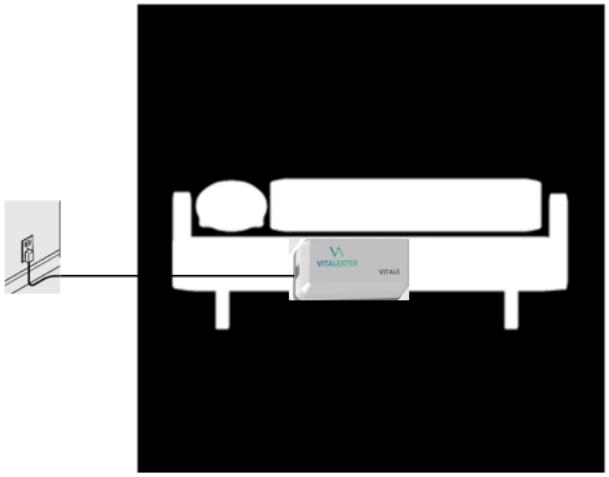


Figure 3 Mounting to Bed

- The device can be mounted by zip tie or double side Velcro.

- Carefully route cables and connections to reduce the possibility of tripping, entanglement or strangulation. This will be done by addition of zip tie to assure securement of cables.
- Install in area that is least likely to be exposed to spillage or ingress of liquids. This can damage the functioning of the device.
- Avoid mechanical damage to device (falling, rough handling) by installing in area that is least likely exposed rough handling. Shaking or falling of device can damage the device internal circuits

Figure 4 Vitals Mounted to Chair

 Avoid assembly under chair for patients with bladder control problems. Ingress of liquids can damage the functioning of the device.

 Inform caretaker of and where the device is assembled.

4.4.2. Power Supply

Use only the power adapter provided in the Vitalerter package. Power supply is necessary for the Vitals sensor performance. The Vitalerter representative will connect the power adapter to the Vitals sensor and to the electrical outlet. At this point the sensor is ON.

4.4.3. Sensor Indications

The unit contains the following LED indication:

4.4.3.1. Power

The green LED will be continuously on when the power adapter is connected. When the power adapter is disconnected and the Vitals sensor is running on batter the green LED will bling every 1 sound.

4.4.3.2. Communication

The yellow LED will indicate the communication status:
If the LED is constantly on or off there is a problem with the communication.
If the LED is blinking the communications is good.

4.4.3.3. Sensor

The orange LED will constantly be on when the sensor is OK.

4.5. Calibration

System Calibration is performed upon device installation.

4.6. Servicing

- Only Vitalerter technicians are authorized to service the device.
- Do not attempt to service the device on your own.
- Servicing of device will not be performed while in use.

In case the Vitalerter Vitals does not operate properly, contact your local distributor or customer service at the address provided ahead.

Please refer to the troubleshooting section 7.

5. Vitalerter Integrated Care Management System

The Vitalerter integrated care management system is operated by users that have read and understood the user manual and are authorized to care for the patient either by profession (a nurse or a physician) or by training (a private caretaker).

5.1. Access to Vitalerter Cloud via Web Browser

Access to the Vitalerter cloud is made possible through the link, user name and password that are provided.

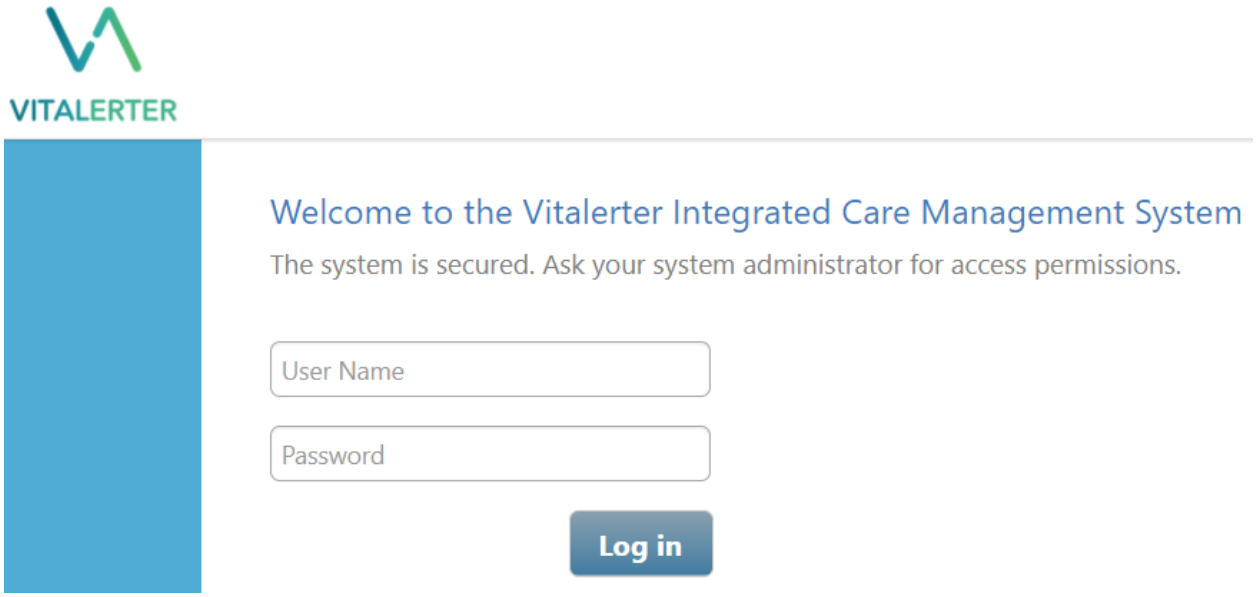
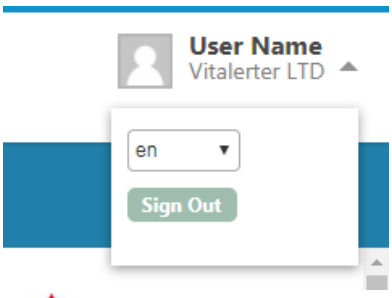


Figure 5 Vitalerter Sign in Screen

Signing out of the system is performed by clicking the “Sign Out” button that is located at the top right corner and appears when clicking on the username.



To prevent settings from being inadvertently changed provide password only to authorized users.

5.2. Residents

5.2.1. Add Resident

The user will add resident by clicking + Add Resident from the “Residents” button at the left side menu. User will be routed to create a patient profile, configure the parameters to be monitored and adding device to the patient.

5.2.2. Patient Profile

A screen for creating patient profile including name, age, gender, room and bed is presented. Enter patient information and click save (see image ahead).

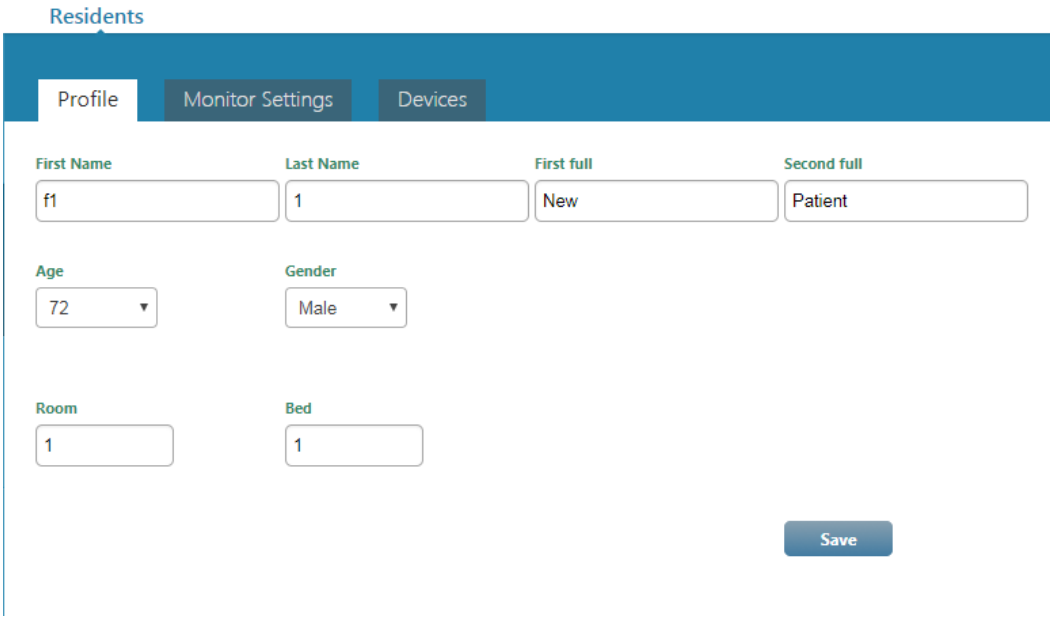


Figure 6 Screen: Patient Profile

Patient information may be edited by returning to the “Residents” tab and selecting the patient and selecting “Edit”.

5.2.3. Monitor Setting Configuration

The following window allows the user to choose the patient alerts:

- Heart Rate
- Respiratory Rate
- Fall Prevention
- Pressure Ulcer

Each option can be turned ON or OFF to activate or deactivate the alert notifications.

Alert settings are configured by clicking on “Edit” at the bottom left of each parameter.

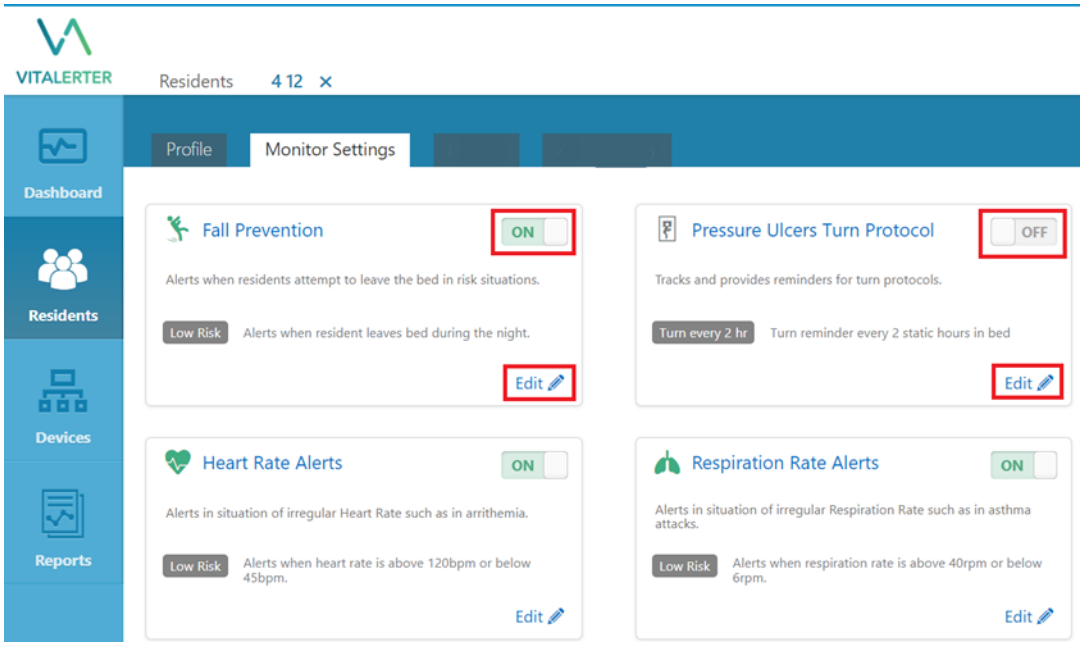


Figure 7 Screen: Monitor Settings

Alert settings can be configured for the following parameters:

5.2.3.1. *Heart Rate*

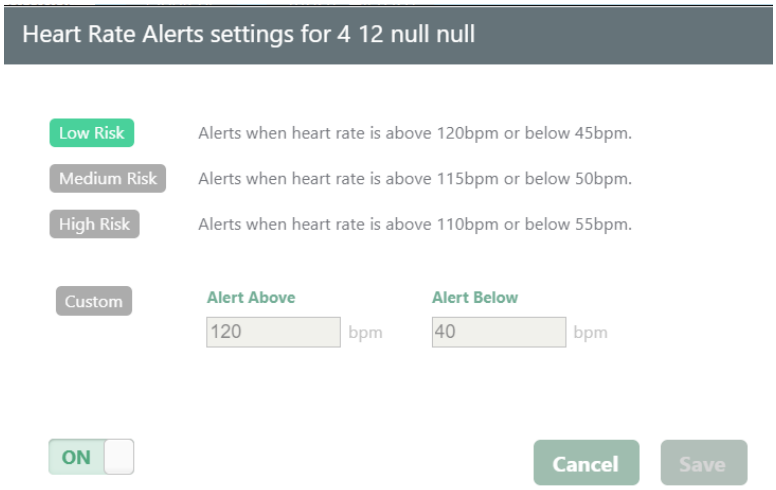


Figure 8 HR Configuration

5.2.3.2. *Respiratory Rate*

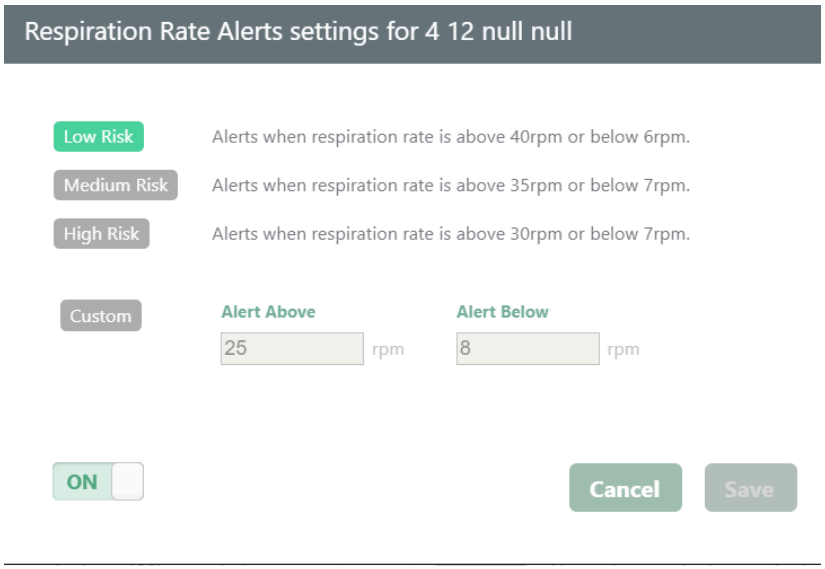


Figure 9 RR Configuration

5.2.3.3. *Pressure Ulcer*

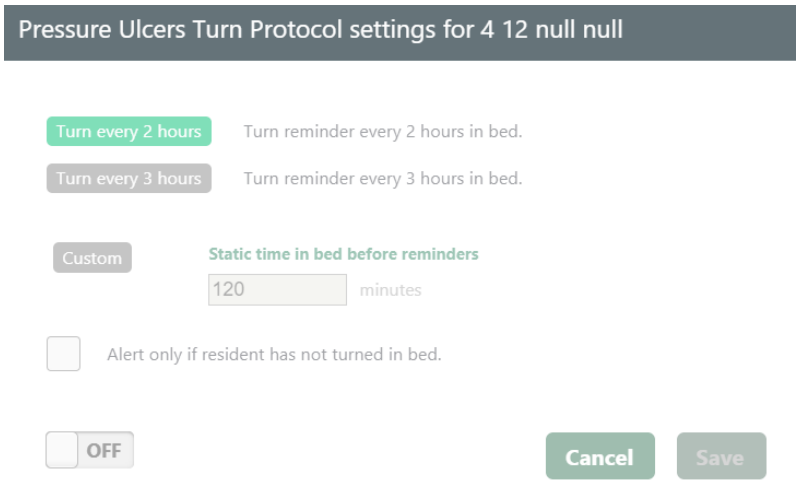


Figure 10 Pressure Ulcer Protocol Configuration

5.2.3.4. *Fall Prevention*

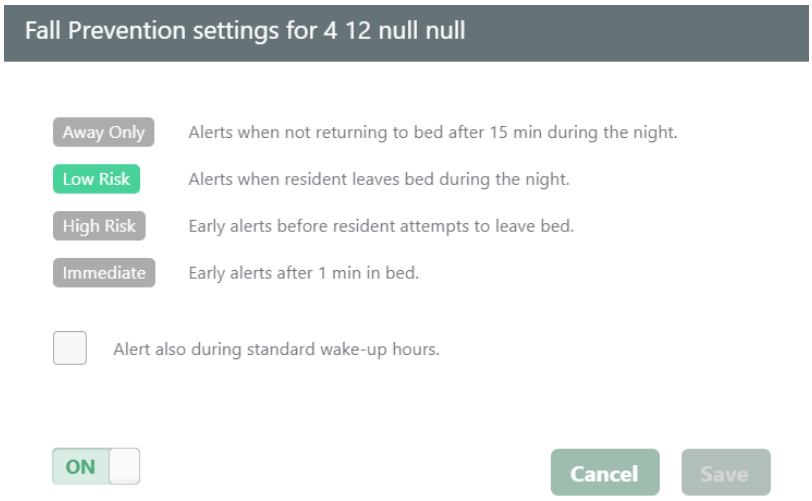


Figure 11 Fall Prevention Configuration

For alert settings to take effect, click “save”.

5.2.4. Devices

The User will select the device assigned to the patient by adding the device from the “Devices” tab.

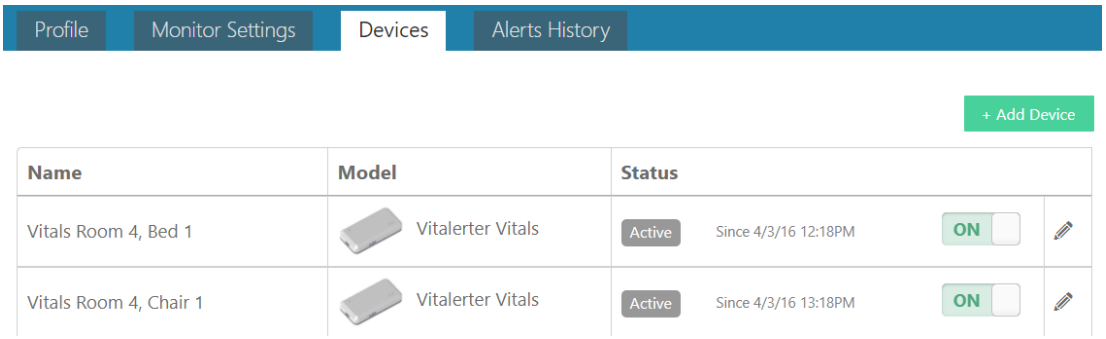


Figure 12 Device Adding

5.3. Existing Resident

The following is an example of an existing resident.

The image below presents the "residents menu" with an existing resident. Information consists of patient name, room and bed and the parameters monitored. By clicking on the "monitors" icons the user can configure the threshold values.

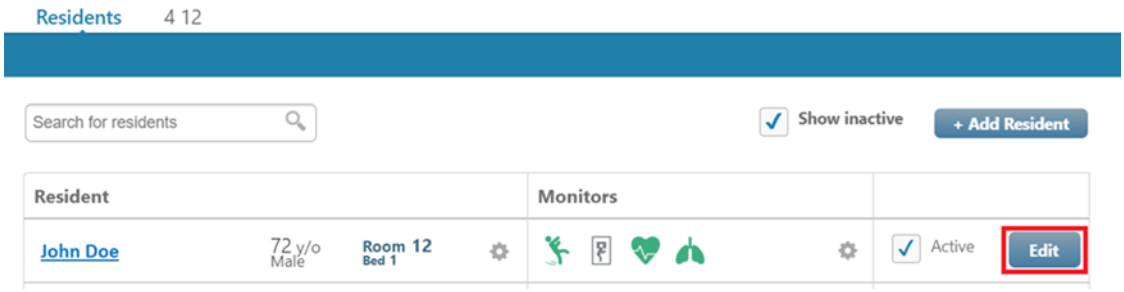


Figure 13 Screen: Residents

5.3.1. Dismissing Resident

When the resident is released, the "active" box should be unchecked 

this will stop the monitoring of the said patient. If patient is admitted again, monitoring is resumed by checking the active box 

.

5.4. Dashboard

The system utilizes color codes that appear on the various screens to indicate the level of alerts. The following color codes are displayed alongside the data presented on the dashboard and are an additional visual indication of patient status

	All Okay	Color code green indicating that patient parameters measured are all within defined threshold and no alerts at the moment
	Take Care	Color code mustard is an alert for patient care
	Urgent	Color code red, alerts that the defined thresholds are exceeded

Figure 14 Status Color codes

The system presents alert icons as follows:

Fall Prevention	
1	 Fall Prevention Resident attempts to leave bed
2	 Fall Prevention Resident sits on bed
Pressure Ulcer Prevention	
1	 Turn Resident Turn left to prevent pressure ulcers
2	 Turn Resident Turn right to prevent pressure ulcers
3	 Turn Resident Turn to back to prevent pressure ulcers
Respiration Rate	
1	 High Respiration Rate Above 13rpm for over 77 seconds
Heart Rate	
1	 High Heart Rate Above 102bpm for over 16 seconds

Figure 15 Legend of Alerts

Through the dashboard tab the user can view the patient data monitored that is continuously measured and presented at the central station (nurses station) by selecting from the various tabs available on the dashboard as follows:

5.4.1. Status

Viewing the current status of all patients including if they are in or out of bed or if there is an alert. Alert level is indicated by a color code. The following figure depicts the status of patients in bed, out of bed and in motion.

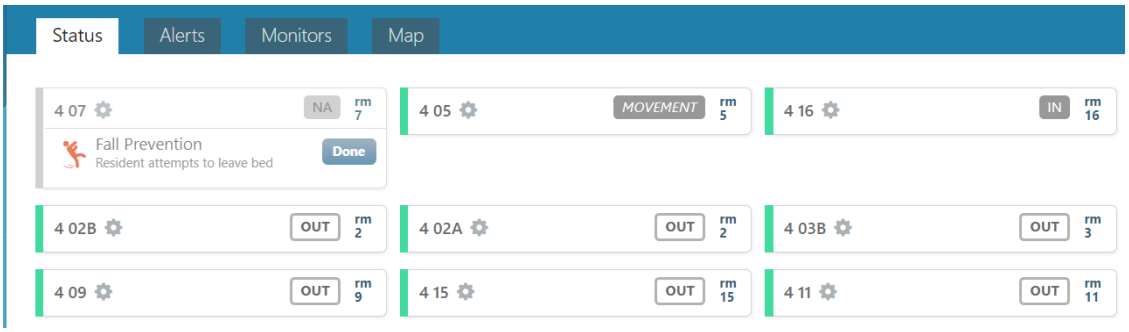


Figure 16 Dashboard: Status

5.4.2. Alerts

Viewing of all the alerts that are set off by the system. The user can view the alert, the time of the alert and the length of time that has elapsed since the alert. Click “Done” after handling the alert.

If “Done” is not selected within an hour then the alert is canceled.

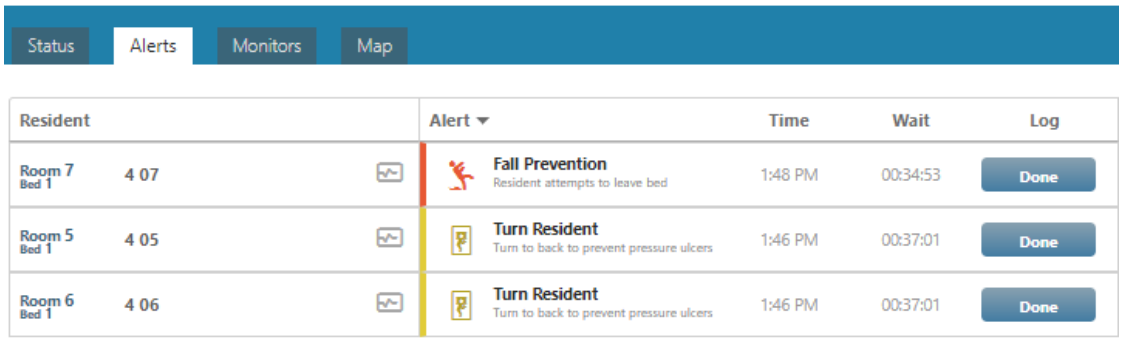


Figure 17 Dashboard: Alerts

5.4.3. Monitors

Viewing of measured parameters in real time of each patient including in or out of bed status, movement, relaxation, HR and RR. The limits defined for the vitals appear aside the actual measurements and each patient appears with a color code indicating alerts if any.

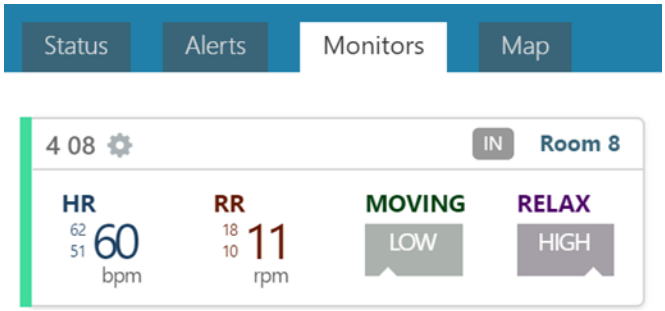


Figure 18 Dashboard: Monitors

5.4.4. Map

Presents view of all resident rooms and their color-coded status

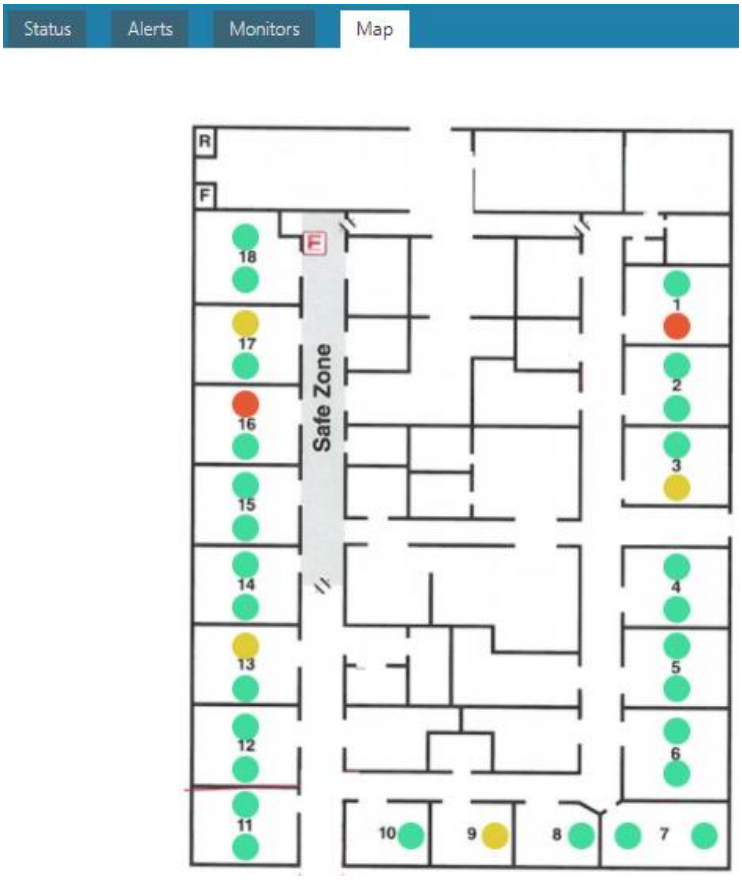


Figure 19 Dashboard: Map

5.5. Trend Analysis Reports

By selecting “Reports” option, the user is presented with a menu from which they may select to view “Alerts” or “Vitals” reports.

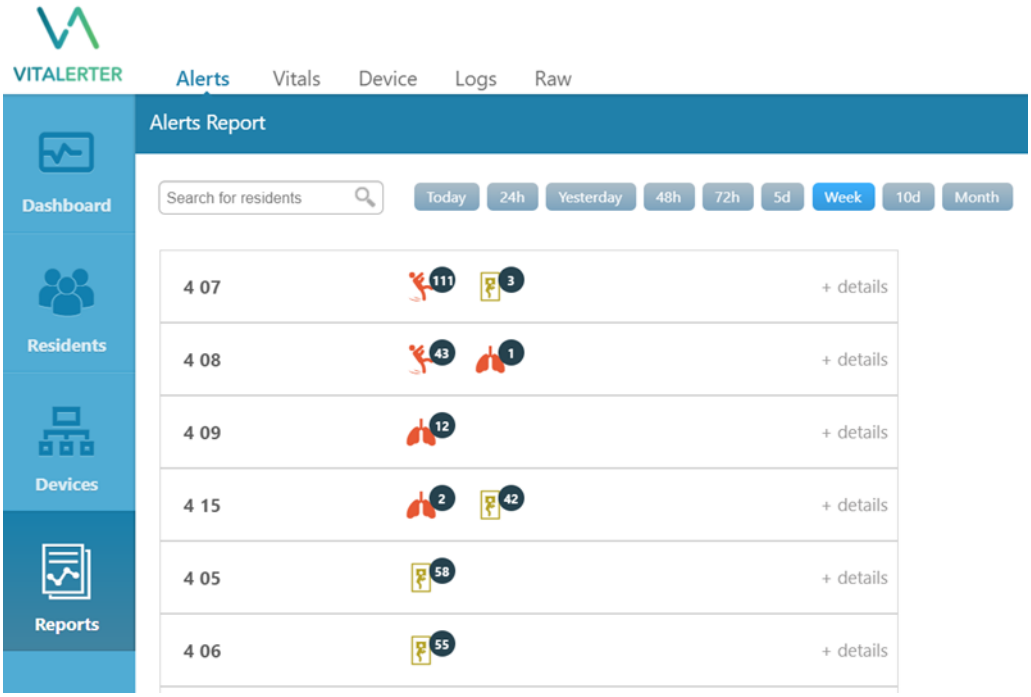
The “Reports” option provides the user with the ability to reviewed the data measured and analyzed for over a period of up to one month.

5.5.1. Alerts

The Alerts provides the user with a list of all patients, the type and the total amount of alerts that occurred indicated by an image from the Vital Alerts legend accompanied by the number of alerts.

The following figure presents several residents, the alerts that occurred over a period of a week and the total amount of times the alerts occurred for each resident.

For instance, resident observed in room 407 had 111 alerts for fall prevention represented by the image  over a period of a week.



Selecting +details will also provide the detail of every alert, the date and time the alert occurred.

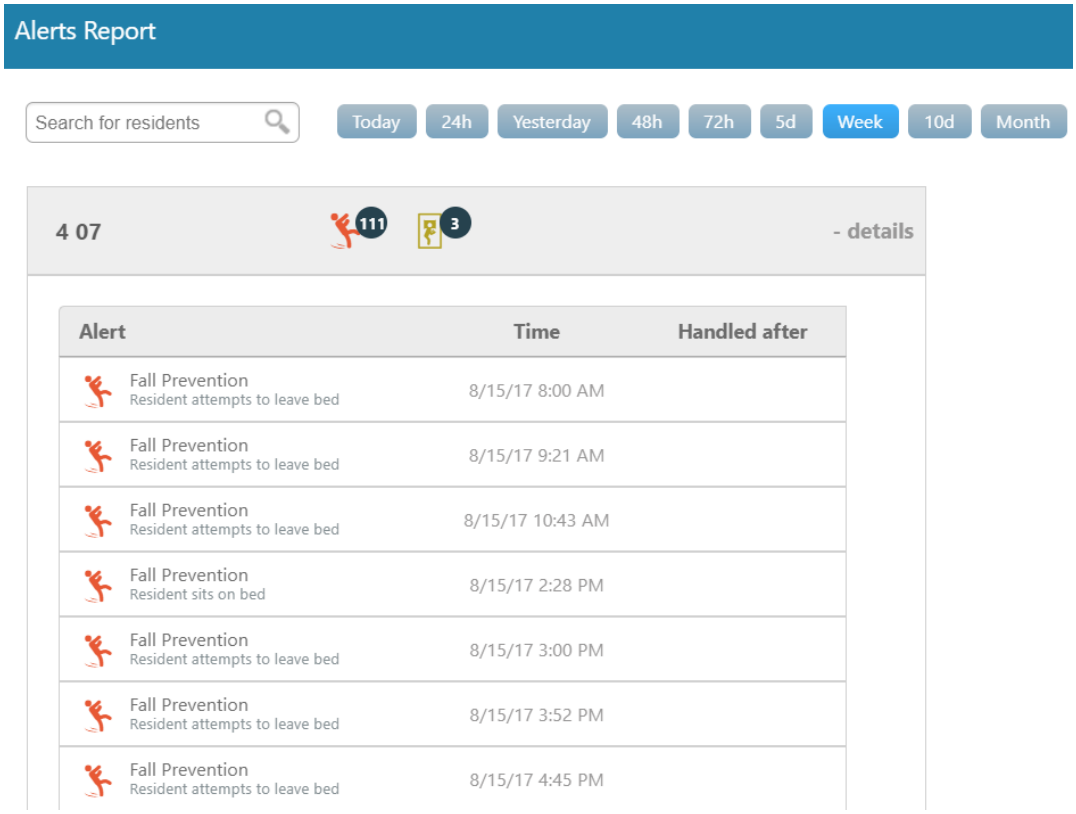


Figure 20 Alerts Trend Analysis Reports

The user can choose to survey the alert trends over a time span of up to a month by selecting from the hours, days, month.

The “Handled after” recordings are available only for alerts that were deactivated by selecting “Done”

5.5.2. Vitals

The Vitals tab, selected from the “Reports” menu allows the user to view trends in the parameters (Vitals) monitored.

Start by selecting the patient/resident for whom the trends report is requested.

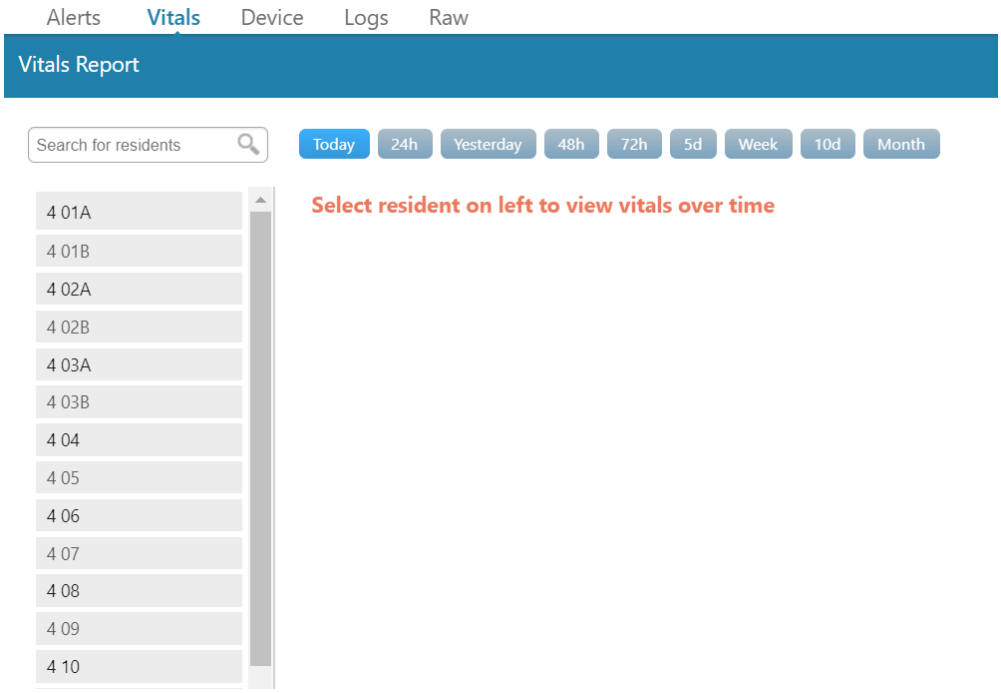


Figure 21 Vitals Trend Analysis Reports

5.5.2.1. Sleep

Selection of “Sleep” below the graph, presents the sleeping pattern of the patient including, “in” and “out “of bed and change of posture. The following report presents the sleeping patterns for patient 401A over the period 0f 48 hours. By placing the cursor over the graph, the user can follow the date, time and hour that the patient is in or out of bed.

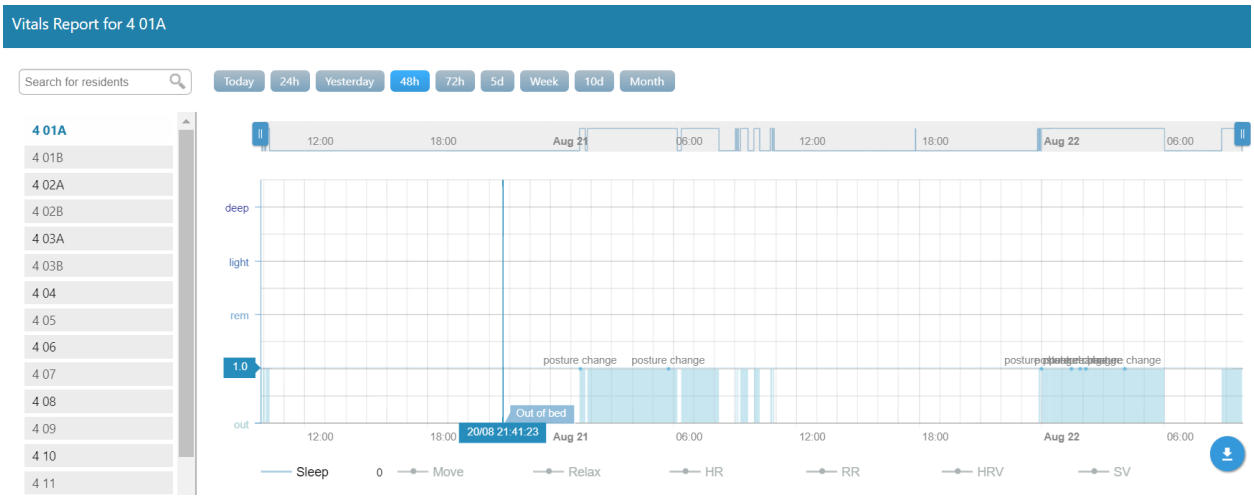


Figure 22 Trend Report Sleep

5.5.2.2. Move

Selection of "Move" presents the user with information on patient activity, patient self-movement. This activity is rated against four scales of activity, presented to the right of the graph. "Move", is the lowest on the activity scale identifying that the patient moved in bed. "Turn", identifies patient turning in bed. "Active", identifies patient increase in movement strength. "Effort" is the highest on the activity scaled and considered more strenuous activity. By placing the cursor over the graph, the user can follow the date, time and hour that the patient is active.

Figure 23 Trend Report Move

5.5.2.3. Relax

Selection of "Relax" presents the user with information on patient state of relaxation. This parameter is rated against a scale from "Rest" being that the patient is fully rested with high rest, normal rest and low rest in between and before "Stress" indicating restlessness. By placing the cursor over the graph, the user can follow the date, time and hour that the patient is at rest.

Figure 24 Trend Report Relax

5.5.2.4. Heart Rate

Selection of “HR” presents the user with measures of patient Heart Rate (BPM).

By placing the cursor over the graph, the user can follow the date, time and actual reading of the heart rate.

Figure 25 Trend Report Heart Rate

5.5.2.5. Respiratory Rate

Selection of “RR” presents the user with measures of patient Respiratory Rate (RPM).

By placing the cursor over the graph, the user can follow the date, time and actual reading of the Respiratory rate.

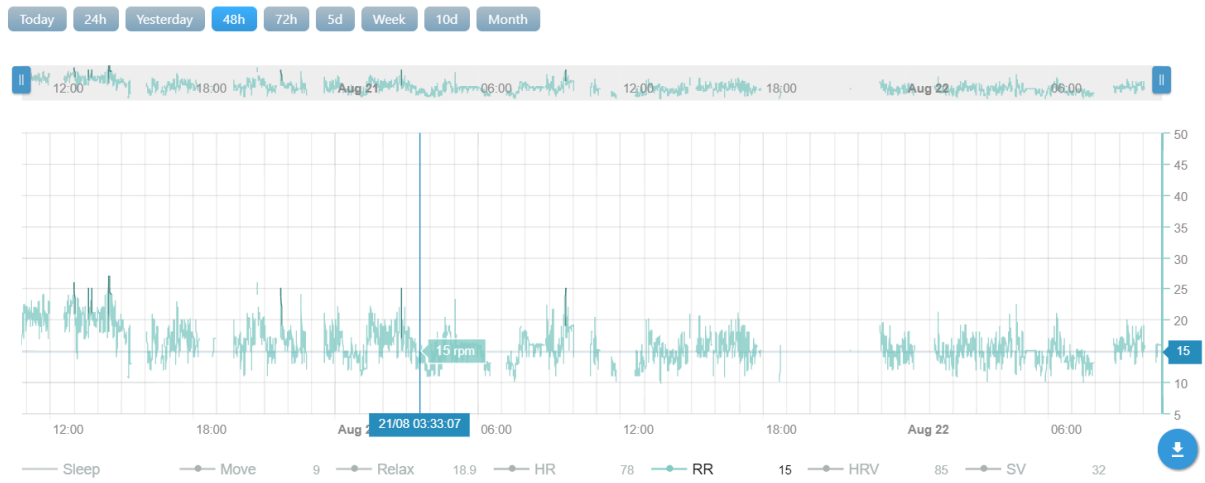


Figure 26 Trend Report Respiratory Rate

5.5.2.6. Heart Rate Variability

Selection of “HRV” presents the user with measures of patient Heart Rate Variability.

By placing the cursor over the graph, the user can follow the date, time and actual reading of the HRV.

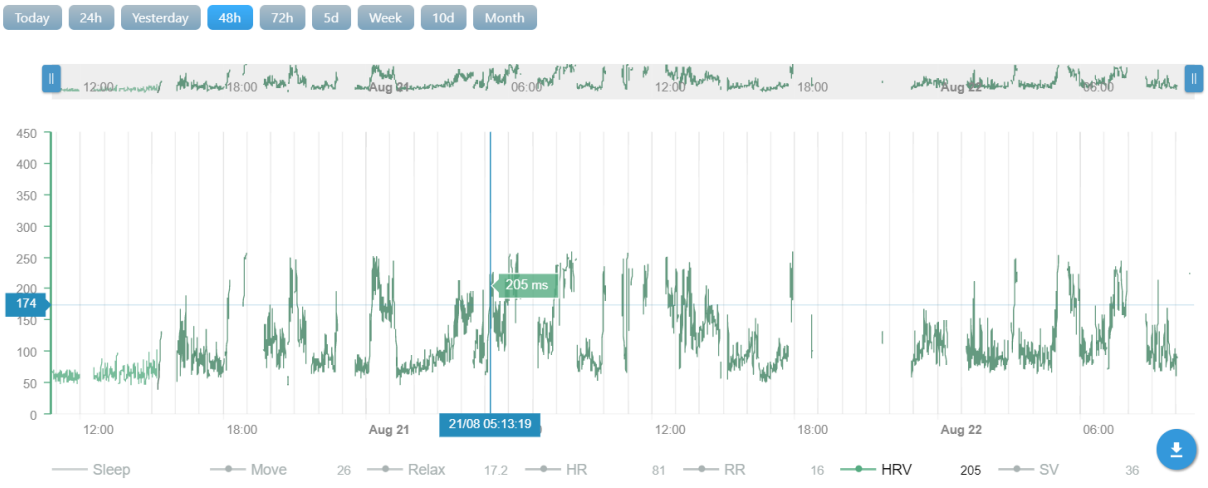


Figure 27 Trend Report Heart Rate Variation

5.5.2.7. Stroke Volume

Selection of “SV” presents the user with measures of patient Stroke Volume. By placing the cursor over the graph, the user can follow the date, time and actual reading of the stroke.

Figure 28 Trend Report Stroke Volume

5.5.2.8. Multiple parameter Viewing

User may select more than one parameter for viewing of trends at the same time. The figure below presents the values measure for HR and RR.

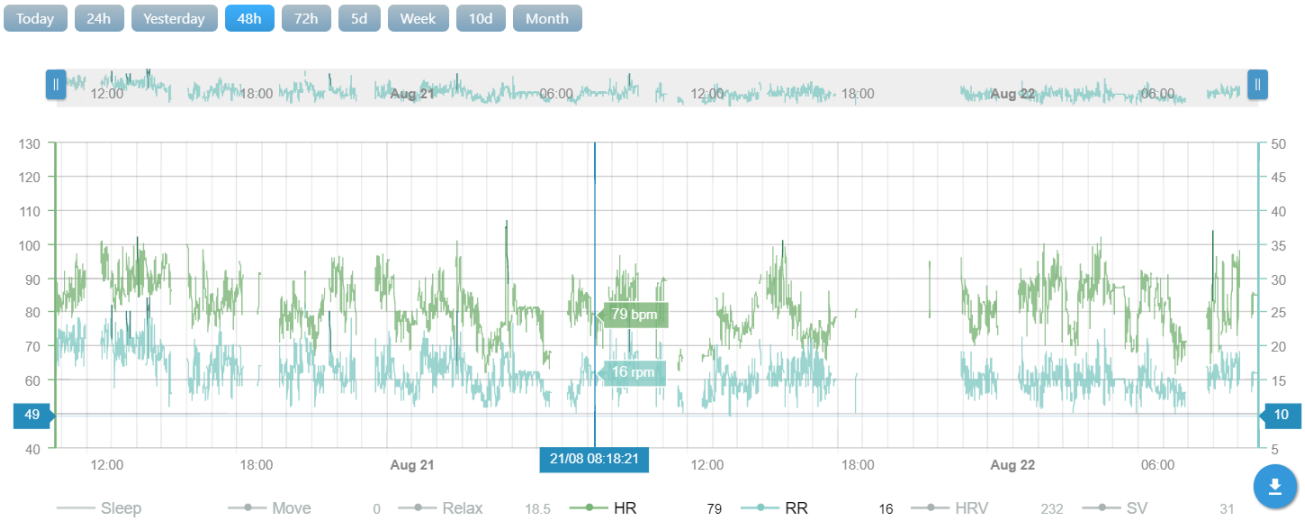


Figure 29 Trend Report Multiple parameters

5.5.2.9. Report Export

The reports may be exported as different formats from the system.

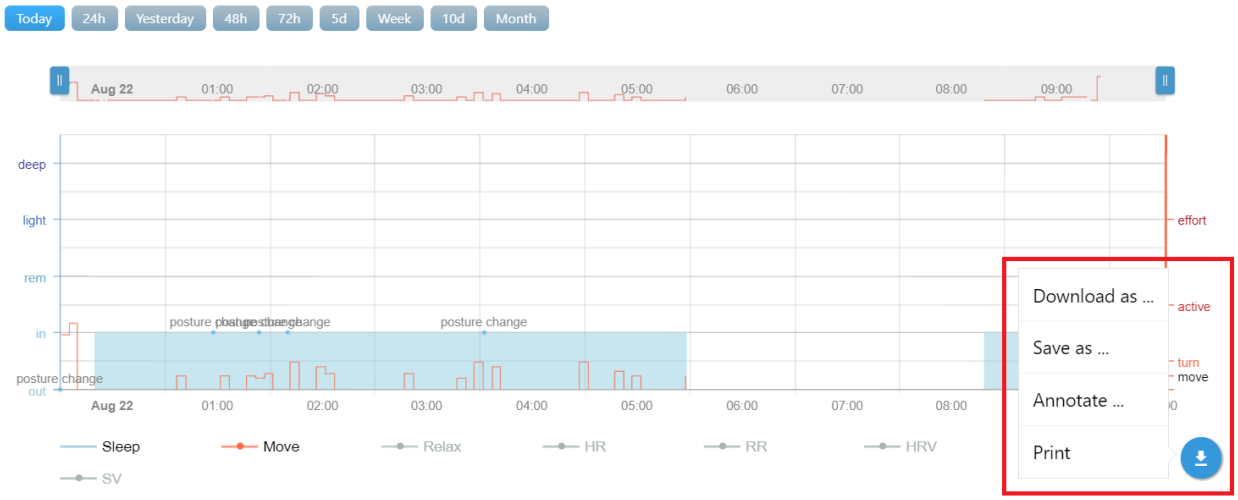


Figure 30Report Export

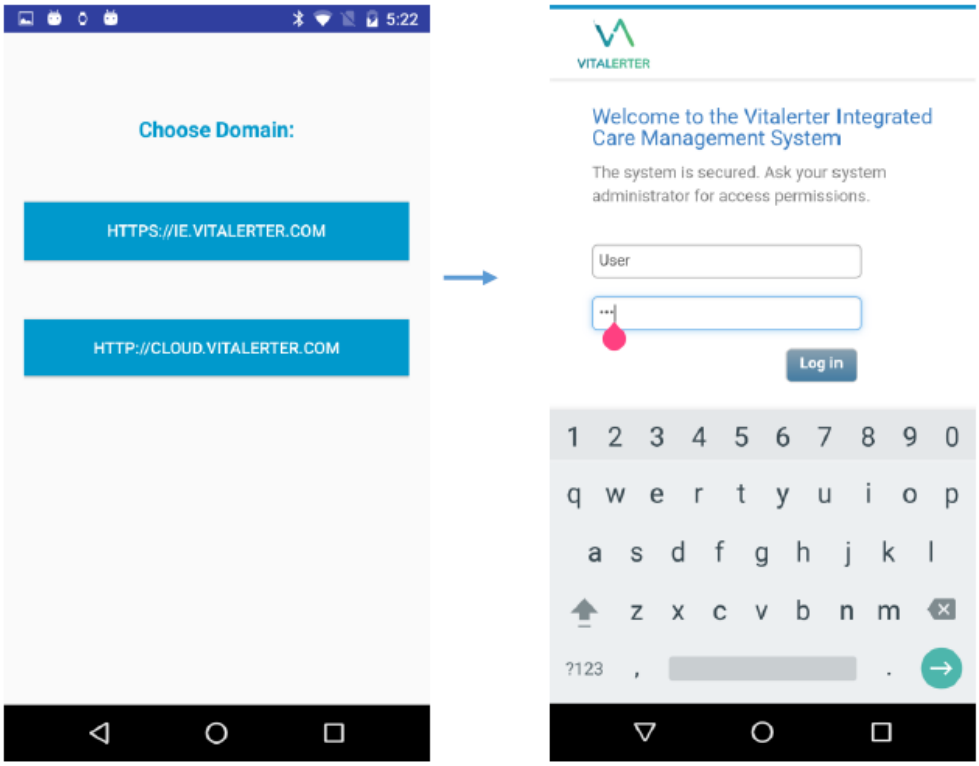
5.6. Access to Vitalerter Integrated Management Care System via Android

5.6.1. Accessing the application

5.6.1.1. Install the Vitalerter application via Google store.

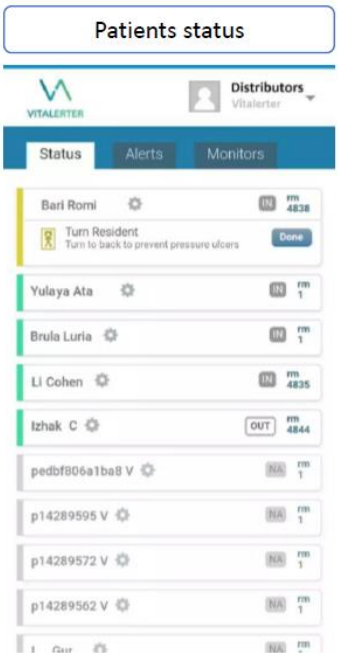
5.6.1.2. Locate the Vitalerter icon (application) and download to your mobile device:

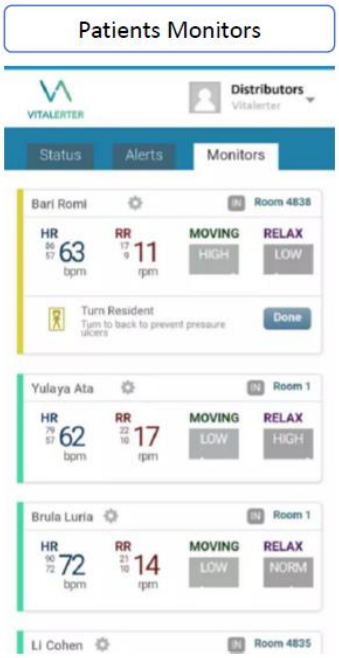
5.6.1.3. When opening the application, following choice of your domain according to the instructions provided with unit, the following welcome window will appear:



5.6.1.4. Type the user name and password provided.

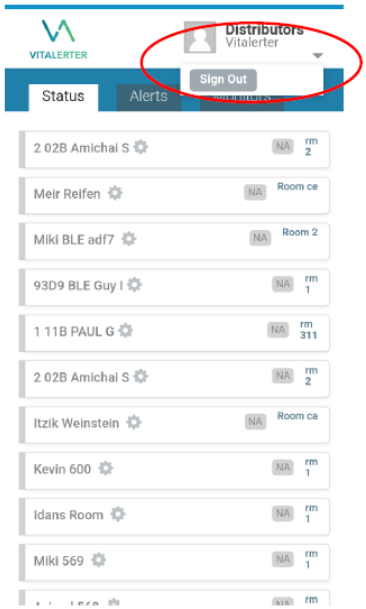
5.6.1.5. Display of the Dashboard main menu will appear, presenting the Status, Alerts and Monitoring as such:





5.6.1.6. After Login, the app will remain open even if it is closed on the screen.

5.6.1.7. To Exit, you need to sign out as follows:



6. Specifications

This section provides specifications regarding measurement ranges, accuracy levels and environmental operating conditions for the Vitals System.

6.1. Vitals Unit

Dimensions	84x41x25 mm (WxLxD)
Weight	80 g
Materials	ABS +Polycarbonate

6.2. Electrical

Power Supply	5V@900 mA
Power Connector	USB-C
Battery	Li-Po 1800mAh
Battery Life	33 hours

6.3. Operating, Storage and Transportation Conditions

	Operations	**Storage and Transportation**
Temperature	5-40 °C | 41-104 °F	0-50 °C | 32-122 °F
Humidity	10% - 95% non-condensing	10% - 95% non-condensing
Atmospheric pressure	540 – 1060 mBar	540 – 1060 mBar

6.4. Wireless Communications /Radio

Frequency	2.4GHz
Protocol	Wi-Fi, BLE
Modulation	
Security	
Power Output (max)	Wi-Fi: 18dBm, BLE: 4dBm
Wi-Fi Alliance Compliant	

6.5. Heart Rate

Display Range	BPM
Accuracy Range	BPM
Accuracy	
Time to alert	

6.6. Respiration

Display Range	BR/MIN
Accuracy Range	
Accuracy	
Time to alert	

6.7. Compliances

FCC Compliance Statement

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in residential installations. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio and television reception.

However, there is no guarantee that interference will not occur in a particular installation. If this device does cause such interference, which can be verified by turning the device off and on, the user is encouraged to eliminate the interference by one or more of the following measures:

– Re-orient or re-locate the receiving antenna.

– Increase the distance between the device and the receiver.

– Connect the device to an outlet on a circuit different from the one that supplies power to the receiver.

– Consult the dealer or an experienced radio/TV technician.

WARNING! *Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.*

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference.

(2) This device must accept any interference received, including interference that may cause undesired operation.

A distance of at least 8cm. between the equipment and all persons should be maintained during the operation of the equipment.

ELECTROMAGNETIC EMISSIONS:

The Vitals sensor is suitable for use in the electromagnetic environment specified in the table below. Ensure that the sensor is used in such an environment.

Emissions Test	**Compliance**	**Avoiding Electromagnetic Interference**
RF Emissions		
RF Emissions CISPR 11	Class B Passed	
Voltage Fluctuations **IEC 61000-3-3:2013**	Pass	

ELECTROMAGNETIC IMMUNITY:

Immunity Test	**IEC 60601-1-2**		
	Test Level	**Compliance Level**	
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for signal lines	±2 kV for power supply lines ±1 kV for signal lines	
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	
Voltage dips short			
Power Frequency			

RECOMMENDED SEPARATION DISTANCE

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	
Conducted RF IEC 61000-4-6	3 VRMS 80%A.M. by 1kHz	3 VRMS 80%A.M. by 1kHz	
Radiated RF IEC 61000-4-3			

6.8. Communication risk mitigation

The Vitals System utilizes the Responsible Organization's network to communicate between the Vitals unit and the Integrated care management system (cloud). The Vitals unit is configured to the responsible organization access point and physiological data that originates from the Vitals Sensor is processed and transmitted through WIFI to the router through LAN and from the router to the cloud through the internet. Any malfunction in one of the computing interfaces described above can prevent data and alerts from be delivered to the display unit. Therefore, reliability of the network is essential in ensuring the Vitals system intended use.

6.8.1. Risk Analysis Summary

The user may at their discretion consider the following residual risks that may interfere with the Vitals system intended use. The end effect of these residual risks may require the user to resort to manual spot check monitoring in the following situations described below.

6.8.2. Residual Risks

- In facilities where uninterrupted power supply is not available (i.e generators), during power shortage the server may be down. The sensor will continue to monitor as it has a battery backup.
- Other RF radiating devices (such as high powered RFID readers and Bluetooth devices) that are in close proximity with the Vitals System may interfere with the wireless communications. During such interference, the Vitals sensor continues to monitor but the data does not reach the integrated management system and will not be displayed during this time. If wireless communication is affected when using the Vitals unit in close proximity with another RF radiating device, move the other device away from the Vitals or discontinue use of the other device under physician's orders only.
- Loss of connectivity, Low internet Quality, network or WIFI failure will influence the Vitals systems ability to display data required to monitor patient data and alerts. Management of this risk is the responsibility of the Responsible Organization for the IT Network.
- For the time span above where the Vitals system is not active alternate monitoring and measuring methods are considered at the discretion and responsibility of the facility.

This risk is minimized with the following mitigations:

Vitalerter Responsibilities

• Vitalerter network assessment prior to installation.

• Vitalerter verification that the Responsible Organization network meets the Vitals System connectivity requirements at the time of installation.

• Hand over protocol with all settings/configurations as installed and configured (Training)

Responsible Organization Responsibilities

• Conduct a risk assessment of the IT Network prior to installation and mitigate technical risk.

• Maintain backup and emergency power resources for Vitals System network components.

• Maintain network configuration post installation of the Vitals System.

• Notify Vitalerter prior to modifications to the network, including any configurations changes that could potentially compromise the IT Network as verified at the initial installation of the Vitals System. For support contact Vitalerter representative directly or through your distributor.

- Perform a risk assessment and verification before implementing a change or modification to the IT infrastructure. Changes to IT network configurations can compromise Vitals units configured to the server

7. Maintenance

NA

8. Troubleshooting

Problem	Possible Cause	Solution
Patient NA	No power (depleted battery, no connection of power adapter)	Call Technical Support
Patient NA	No communication, connectivity lost	Call Technical Support
Unit Fail	Not applicable	Unit replacement
Patient in bed -no reading	The system takes at least a minute for readings to proceed	Readings should proceed

Table 3 Vitalerter Vitals System Troubleshooting

8.1. Technical Support

Email: support@vitalerter.com

9. EU Representative and Contact Information

Contact Vitalerter:

EU Representative: Vitalerter:

2 Ha-Yarden St.
Airport City 7019900
Israel
Website: www.vitalerter .com