VISENSIA®

Visensia Mobile

User Guide

OBS Medical
Data for Life

MD   UDI   5060457930102   UK CA 0120   CE 1639

Contents

Introduction

This guide contains all the information you need to install, configure, and use the Visensia Mobile application as part of the Visensia system. The day-to-day administration of the Visensia system is detailed in the Administration and Configuration User Guide **(Part No. 011-0710-LMAN).**

Visensia System Overview

Visensia is an advanced physiological monitoring system that monitors vital signs to provide early warning of patient deterioration. Visensia has been designed as an accessory to standard patient monitors or medical information systems. Visensia is a client-server computer program, with the client running in a web browser as a Web Application. Visensia operates by forming an aggregate score of patient status based on five vital signs: Heart Rate, Respiratory Rate, Temperature, Blood Pressure, and Arterial Oxygen Saturation.

The aggregate score, the Visensia Index (VSI), is displayed on a scale of 0.0 - 5.0, with 0.0 representing the normal end of the scale and 5.0 representing extreme physiological deterioration.

An audible and visual alert is provided when the Visensia Index (VSI) exceeds a defined threshold value.

Visensia Index (VSI)

The Visensia software calculates the Visensia Index (VSI) based on a non-linear combination of up to five vital sign parameters: heart rate, arterial oxygen saturation, respiration rate, temperature, and blood pressure.

The Visensia Index works by comparing the patient's vital signs against a model of normality for a population of patients from a similar environment. The Visensia Index represents a single measure of the patient's condition. The Visensia Index will update every time new physiological data is received for that patient.

Visensia Mobile Overview

Visensia Mobile is an application that allows authorised users to receive VSI alert notifications and to review assigned units and associated patients via a compatible device as part of the Visensia system.

- Users of Visensia Mobile receive notifications of active VSI Alerts to review as part of the hospital's own protocols.

- The application extends the benefits of Visensia to teams such as Rapid Response or Critical Care Outreach, who are not always located in a specific unit or location within the hospital or have regular access to the Visensia Clinical Dashboard via a PC / Laptop.

Intended Use

Visensia with alert is a software product intended to be used by Clinicians caring for non-paediatric patients routinely monitored by multi-parameter devices.

Visensia is indicated to receive data from multi-parameter devices, Electronic Medical Records (EMR) and Clinical Information Systems (CIS), and to provide the Clinician with a patient status index (Visensia Index) based on a weighted average of five vital signs; heart rate, respiration rate, temperature, oxygen saturation and blood pressure.

The Visensia Index is a single measure of a patient's condition and represents how different the patient's vital signs are with respect to normality enabling recognition of patient deterioration to help drive clinical management. When a Visensia alert has activated, it means that the Visensia Index has reached and/or surpassed the default threshold, highlighting the patient's condition to the clinician for an appropriate response.

Visensia is an adjunct to and is not intended to replace any part of the hospital's device monitoring or electronic data management systems.

Visensia System Safety Information

Users should read and adhere to all Warnings, Cautions and Notes listed here and in the associated sections throughout this manual.

> **Do not use Visensia System before readings these instructions.**

Warnings:

Intended Use

⚠ Visensia software must not be used outside of its intended use.

⚠ Visensia software is not for paediatric use.

⚠ Visensia is an adjunct to and is not intended to replace vital sign monitoring.

⚠ Visensia relies on continuous and accurate physiological data. Use in environments with unstable, intermittent, or unreliable data connectivity may result in delayed, incomplete, or inaccurate Visensia Index calculations.

⚠ Visensia is intended to support clinical assessment. It must not be used as the sole basis for diagnosis, treatment decisions, or escalation of care. Clinical judgement and established hospital protocols must always be applied.

⚠ Visensia does not replace bedside monitoring, clinician assessment, or existing hospital monitoring and escalation systems.

Alerts

⚠ When Visensia Alerts are silenced, there is no notification of a potentially clinically significant change in the patient's status. Observe the patient by other means when Visensia Alerts are silenced.

⚠ If the activated licence has expired, or there are more beds monitored than adequately covered by a license, then the Visensia Index will not be calculated.

Cautions:

Intended Use

⚠ Federal (U.S.) law restricts this system to sale by or on the order of a physician.

Alerts

⚠ Vital Sign Warnings are not intended to be used as a primary alert mechanism.

⚠ Vital Sign Warnings are not a replacement for any primary alerting systems or procedures already in place.

General

- Visensia Mobile is reliant on running via a compatible device with good network connectivity to ensure access to patient data.
- If you cannot access the Visensia system due to poor network connectivity on your compatible device, attempt to review notifications via an alternate device or location, or via a dedicated Visensia Clinical Dashboard.

Visensia System Symbols

Symbol	Title	5	Description
	Manufacturer		Indicates the medical device manufacturer
	Build Date		Indicates the date the Lot / Batch / Software Version was released
LOT	Batch Code		Batch code so the lot or batch can be identified
REF	Catalogue Number		Catalogue number so product can be identified
	Consult Instructions for Use		Indicates the need for user to refer to instructions for use
Rx only	Prescription Use Only (USA only)		Device is prescription use only by a healthcare professional

Visensia Mobile - Symbols

Symbol	Description	Additional Information Provided:
	Visensia Mobile – Status Icon	• Starting Up… • No User Configured. • Connected, Waiting for Notifications. • Network lost. Reconnecting…
	Visensia Mobile – Notification Icon	• A Patient has started alerting. • A Patient alert has been silenced.
	Select Icon – Select a button by touching the Device Screen where shown.	
	Scroll Icon – Navigate the Visensia Mobile Application using the Device Screen.	

Note: All compatible devices used to run the Visensia Mobile application are the responsibility of the hospital.

Note: Compatible devices need to have access to the Hospitals Network to reliably access patient information as part of the Visensia System.

Note: The Visensia Clinical Dashboard and functionality may differ based on regional variations or system configuration.

Please refer to the **Administration and Configuration Guide [011-0710-LMAN]** or speak to your system administrator for more information.

Note: Images used within this manual are provided for reference purposes only.

Trademarks

Visensia® is a registered name of OBS Medical.

Data Protection/ Privacy

Clinicians and other users of the Visensia system should be aware that, in collecting and recording patient names and data, they are responsible for complying with all applicable data protection and/or privacy laws and regulations.

Visensia Mobile - Installation Overview

The Visensia Mobile application will be installed and configured by OBS Medical or an Authorised Representative on compatible devices as supplied by the hospital.

Technical Requirements

Visensia Mobile has been verified to run on the following Operating System and Versions.

Operating System	Versions
Android	13
	14

Application Permissions

Once downloaded and installed, Users will be prompted to **allow certain permissions** pertaining to **Notifications** and **Battery Usage** when first opening the application.

It's advisable all permissions requested by the application are enabled / allowed to ensure the best performance of the application.

However, if you wish to check and configure the applications permissions manually, select the Visensia Mobile app and choose the option – **App Info**

Depending on the device used, the **App Info section** details several options that should be configured as follows:

- Notifications – **Enable** all Visensia Mobile Notifications
- Permissions – **Disable** the Pause app activity if unused.
- Mobile data and Wi-Fi – **Disable** the usage of mobile data in the background.
- App battery usage – **Enable** the option **Unrestricted.**
    - If you leave this option as Optimised, the App on first opening will ask the user to allow the app to always run in the background, so best to set this as the default option first.
- Open by default – **Enable** the option to Open supported links.
- Unused App Settings – **Disable** the option to pause the app if unused.

Server Address Configuration

1. Open the Visensia Mobile App

2. Select the **Address** field and input the **URL** of the **Visensia System** for your hospital.

    e.g. **https://myhospital-visensia.com**

This process is required on the initial set-up of the Visensia Mobile application with the address being retained for future login requests.

Once the Address is configured, Users can then input their login credentials as required.

> **Note:** After initial installation of the Visensia Mobile app, a status notification on the device will be displayed advising **Status: No user configured**. This status notification will automatically clear once the Visensia Server Address and Login credentials for the device user are inputted.

User Roles and Types

All system Users are allocated a **Role** which controls the level of access they have to the various functions and scope of the Visensia system. The **Clinician Role** then has two **User Types** namely:

1. **Web User**. A User who works in a specific department or unit. Has regular access to a laptop/PC.
2. **Mobile User**. A User who works in various departments or units. Has no regular access to a laptop/PC.

User Role	User Type	Scope
Administrator	Super Admin Hospital Group Hospital	Manage Installation, Licences, Inputs, Configurations, Users, Default Algorithm and Vitals Threshold settings. **(See Part No. 011-0710-LMAN for more information)**
Clinician	Mobile Web	View and interact with the systems Clinical Dashboards and functions as configured by the Administrator. **(See Table 1 – Clinical User Type / Function Matrix)**

Table 1: Clinical User Type / Function Matrix

Functions	Mobile	Web
Visensia (VSI):		
View Visensia Index (VSI Value / Date & Time)	x	x
View Visensia Historic Calculations Chart	x	x
View Visensia Contributions and Anomaly Charts	x	x
View Visensia Trend Graph	x	x
View Patient Trend Arrow (PTA)		x
Acknowledge VSI Alerts	x	
Acknowledge Latched VSI Alerts	x	
Silence future VSI Alerts	x	x
Clear VSI Silenced Alerts	x	x
Manage VSI Audible Alert (On / Off)		x
Vital Signs:		
View Vital Sign Data (Vital Sign Value / Date & Time)	x	x
Apply Patient Specific Vital Sign Upper / Lower Thresholds		x
Acknowledge Vital Sign Alerts		x
Silence future Vital Sign Alerts		x
Manually Input Vital Sign Data		x
Patient Lists:		
View Patient Lists for Multiple Units – 'Acuity List'		x
View Patient List for a Single Unit – 'Patient List'	x	x
View 'My List'		x
View 'Drill Down Display'	x	x
View Demographic Data (Name, Age, Gender, Hospital No# and Location)	x	x
View Events (Patient / Algorithm / Vitals)	x	x
ADT Functionality (Standalone):		
Manually Admit, Transfer and Discharge Patient		x
Manage Demographic Data (Name, Age, Gender, Hospital No#, Location)		x

Note: The above listed options can be configured on a per user basis to suite existing workflows.
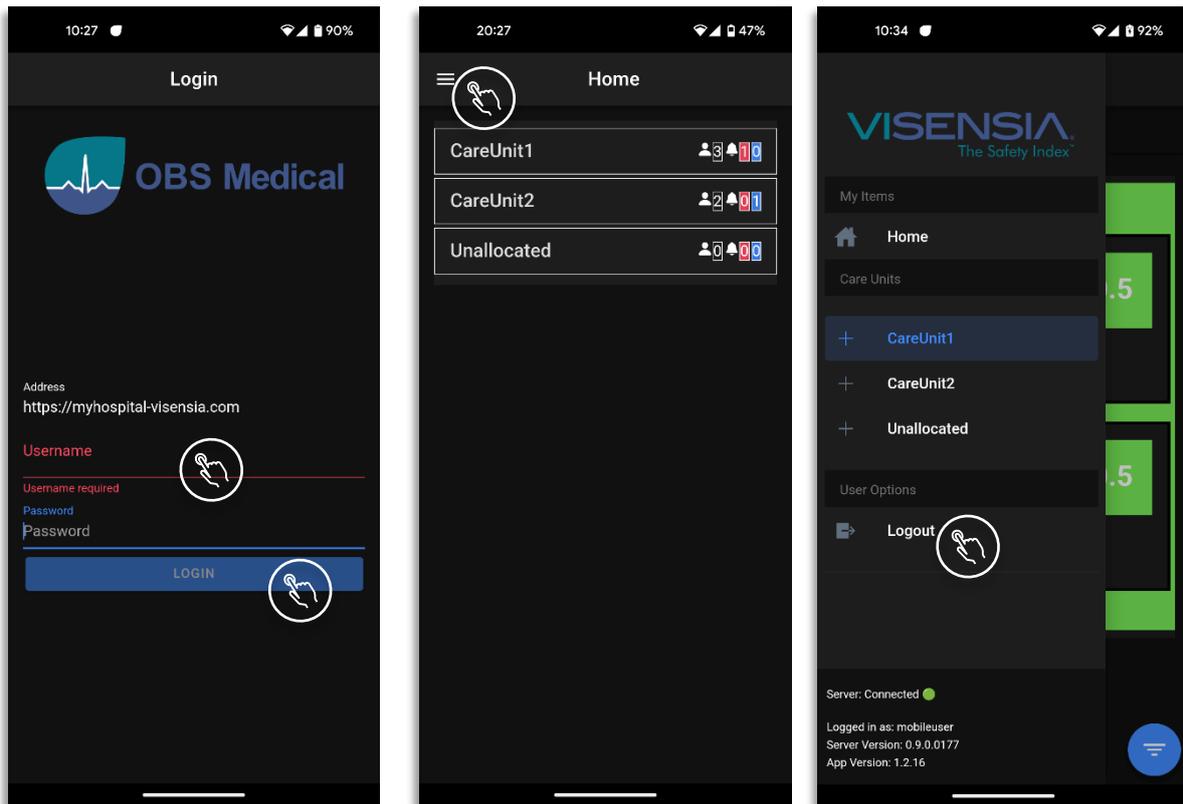
Getting Started

Logging In and Logging Out

Depending on your organisations IT security policy, you will be issued login credentials.

Typically, you will receive a unique **Username** and **Password.**

1. Input your login credentials as required and press the **Login** button.

2. The **Home Screen** and configured Units will be displayed.

You can **Logout** of the system at any time by selecting the ☰ **Menu Icon**, located at the top left of the Home Screen.

- User Options > **Logout**

The **User Credentials**, **Server Status**, **Versio**n and **App Version** are also displayed within ☰ Menu Screen.

> **Note:** The Address field within the Login Screen should be prepopulated with the Visensia Server URL for your hospital e.g. https://myhospital-visensia.com. Please contact your System Administrator if this is not the case.
>
> **Note:** If you forget your login credentials you will need to contact your System Administrator.

Home Screen

The **Home Screen** displays the various **Units assigned you** as a **Clinical Web User.**

The number of **patients assigned to the Unit**, along with any **active VSI Alerts or Silenced Alerts** are detailed for each monitored Unit.

You can select which Units you want to review patients for, by clicking on the relevant Unit within the Home Screen. e.g. **CareUnit1** revealing the **Patient List** and associated **Patient Tiles**.

If you select a Unit which has no patients, a system message is displayed for the User to check and confirm patients have been admitted, and that the patient is using a configured monitoring device.

	The **number of patients admitted** to the Unit.
	The **number of Active <u>VSI Alerts</u> (Red)** and <u>**Silenced Alerts**</u> **(Blue)** for the Unit.
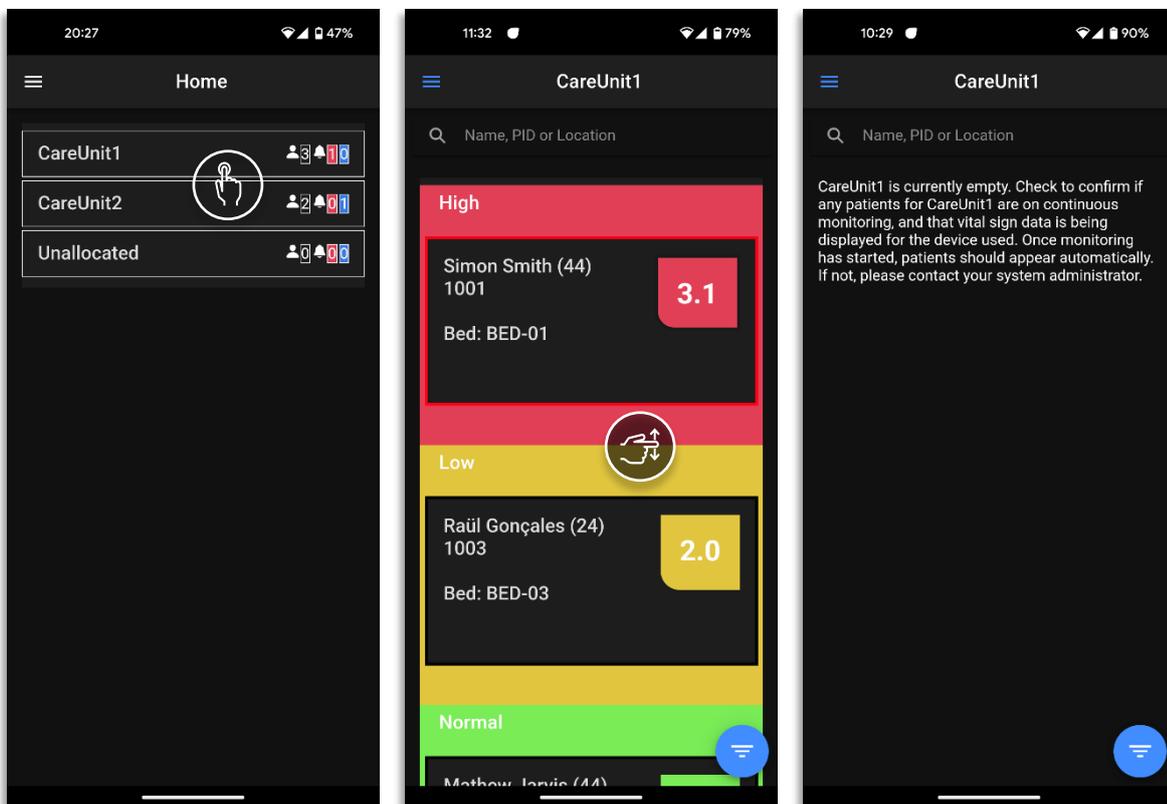
Patient List

The **Patient List** displays all **Patient Tiles** for a selected Unit.

The **Unit selected for review** is detailed at the **top of the Patient list**.

You can switch between the various **Units** and their associated **Patient Tiles** by using the **Home Screen** to focus on a single Unit at a time, or to have an overview of all monitored patients.

Selecting a **Patient Tile** from within the **Patient List** will display more information via the **Drill Down**.

- VSI Section
- Vitals Section
- Events
- Trends

Patient Tiles

The **Patient Tile** can be configured by your Administrator to display various components including:

- **Patient Information** (**Name, Age, Patient ID, Location**)
- The **VSI Index, Threshold Range** and associated **VSI Alert Status.**

The **Patient Tile** will change colour according to the **VSI Threshold Range** and **Alert Status**. Depending on the VSI Index and alert status the Patient Tile will appear as follows:

Example 1 – No VSI Alert	
Normal Rónán O'Gara (68) 1005 **[M]** Bed: BED-05 0.5	Patient Location - Bed: **BED-05**
	Hospital / Patient ID: **1005** — Patient Name: **Ronan O'Gara**
	Age: **68** — Gender: **Male**
	VSI **(0.5)** VSI Alert Status – None Visensia **Normal Threshold Range (0.0 to 2.9)**

Example 2 – Active VSI Alert	
High Simon Smith (44) 1001 **[M]** Bed: BED-01 3.1	Patient Location - Bed: **BED-01**
	Hospital / Patient ID: **1001**
	Patient Name: **Simon Smith**
	Age: **44** — Gender: **Male**
	VSI **(3.1)** VSI Alert Status – **Active Alert Status (Red Flashing Border)** Visensia **High Threshold Range (3.0 to 5.0)**

| Example 3 – VSI Alert Silenced	
High John Stephens (63) 1004 **[M]** Bed: BED-04 3.2	Patient Location - Bed: **BED-04**
	Hospital / Patient ID: **1004**
	Patient Name: **John Stephens**
	Age: **63** — Gender: **Male**
	VSI **(3.2)** VSI Alert Status - **Alert Status Silenced (Blue Border and Fill)** Visensia **High Threshold Range (3.0 to 5.0)**

Note: Visensia requires a minimum of three vital signs to calculate the Visensia Safety Index - VSI. **Grey Marks (- -)** will be displayed when the system is unable to calculate a Visensia Safety Index.

Note: Patient Name and **Patient ID** can be configured to be **hidden or displayed** according to organisations policy.

Drill Down

The **Drill Down** will automatically populate when a **Patient Tile** is selected from the **Patient List.**

The **Drill Down** provides additional information when reviewing a patient.
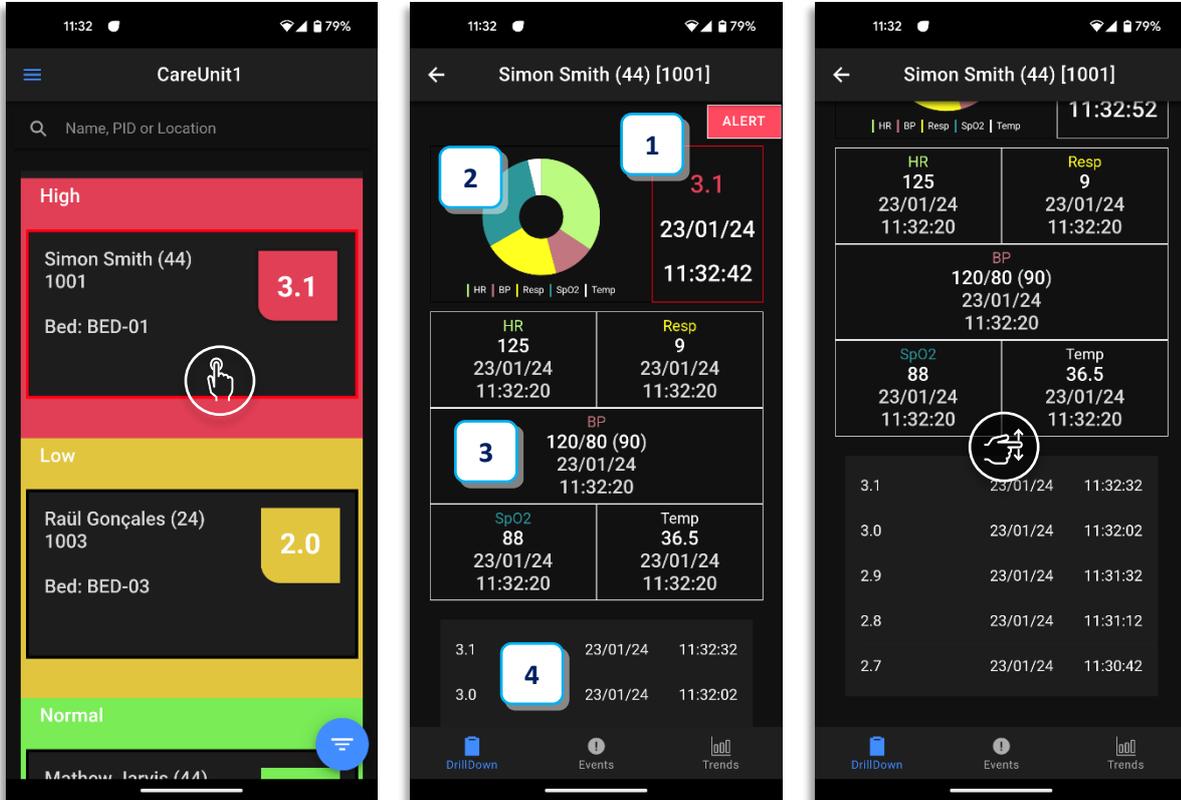
1. **VSI Index and Alert Status**

    The Visensia Index is displayed on a scale of 0.0 - 5.0, with 0.0 representing the normal end of the scale and 5.0 representing extreme physiological deterioration, along with the date and time of the calculation.

    The VSI Index can be segmented in to High, Medium, Low and Normal thresholds with an associated colour for each threshold to aid workflow and protocolised responses as defined by your Organisation.

2. **VSI Contributions Chart or Anomaly Chart**

    o **Contributions Chart**

    Shows how much each current vital sign has contributed to the total amount of the Visensia Index; the larger the pie-slice the greater the contribution of that vital sign.

    o **VSI Anomaly Chart**

    Shows how much each individual vital sign has deviated from the mean value in the training data set. An VSI Alert occurs either when one vital sign is approximately ± 3 standard deviations from its normal value, or when two or more vital signs vary from normality by a smaller amount.

3. Vitals Section

Displays the current vital signs for the patient, their values and the date and times at which the vital signs were recorded.

HR 110 23/01/24 11:25:19	Resp 9 23/01/24 11:25:19
BP 120/80 (90) 23/01/24 11:25:19	
SpO2 97 23/01/24 11:25:19	Temp 36.5 23/01/24 11:25:19

4. VSI History Table

Shows a list of the last five VSI calculations along with the date and time for each calculated risk index.

1.3	23/01/24	11:25:32
1.2	23/01/24	11:24:52
1.1	23/01/24	11:24:12
1.0	23/01/24	11:23:20
0.9	23/01/24	11:20:31

VSI Warning Thresholds

The VSI Index can be segmented into various thresholds with associated colours for each threshold to aid workflow and protocolised responses as defined by your Organisation.

The **VSI** is **Colour Coded** according to the **VSI Warning Threshold Ranges** as configured by your Administrator for each monitored Care Unit. Each threshold range can be **enabled or disabled** as required.

The thresholds provide a clear indication of a patient's risk of deterioration. The default settings are agreed and configured during installation and set-up according to clinical guidance and hospital protocols.

The default set-up is outlined below, with the **High-Risk Threshold Range** enabled.

Enabled	VSI Warning Thresholds		Warning Notification	Enable Latching	Lower Limit	Upper Limit
✓	🟥	**High-Risk Threshold**	✓	✓	**3.0** 🔔	**5.0**
☒	🟧	**Medium-Risk Threshold**	N/A	N/A	1.5	2.9
☒	🟨	**Low-Risk Threshold**			0.8	1.4
The upper limit is auto calculated according to the lower limit of each enabled threshold.					**0.0**	**2.9** (0.7)

- A VSI Alert is generated when the lower limit of the VSI High Risk Range Threshold is reached or exceeded.

Across multiple retrospective analyses and care environments, **VSI ≥1.5 has consistently emerged as a clinically meaningful inflection point** associated with increased risk of deterioration or death.

These findings support a tiered interpretation of VSI values, in which:

- **Higher VSI values (e.g. ≥3.0)** are associated with imminent risk and may warrant urgent escalation or rapid response activation.
- **Lower but elevated VSI values (e.g. ≥1.5)** may indicate early or evolving deterioration and support increased clinical vigilance, reassessment, or enhanced monitoring.

This tiered interpretation is consistent with the intended use of VSI as a clinical decision support tool and does not replace clinical judgement or established escalation protocols.

Note: See the Visensia User Guide [011-0709-LMAN] for more information on VSI Warning Thresholds.

VSI Alerts

Visensia Mobile Users will receive a Notification when the Visensia Index equals or exceeds the defined **Algorithms High Risk Warning Threshold** for a monitored patient in an assigned unit.

Depending on the device used and the permissions enabled / configured for Notifications, the device should display the Visensia Mobile Notification when received from the Visensia system.

- The **devices lock screen** will display the Visensia Mobile Notification.

🔔	⭕ Visensia Mobile • now 🔔	• A Patient has started alerting in care unit – CareUnit1

- **Selecting the Notification** will open the Visensia Mobile App on the **Drill Down for the Patient.**
- The **Home Screen** will update to display an **Active VSI Alert** for the associated Unit.
- The **border** of the **Patient Tile** will begin to **flash red**.
    - When an alerting Patient Tile is selected, the **Drill Down** is displayed.
    - The VSI and VSI Section border is coloured red.
    - An **Alert Button** is clearly visible.
- Review the Drill Down information and follow hospital protocol with respect to the appropriate response for the VSI Alert.

VSI Active Alert Status - Home Screen, Patient Tile and Drill Down
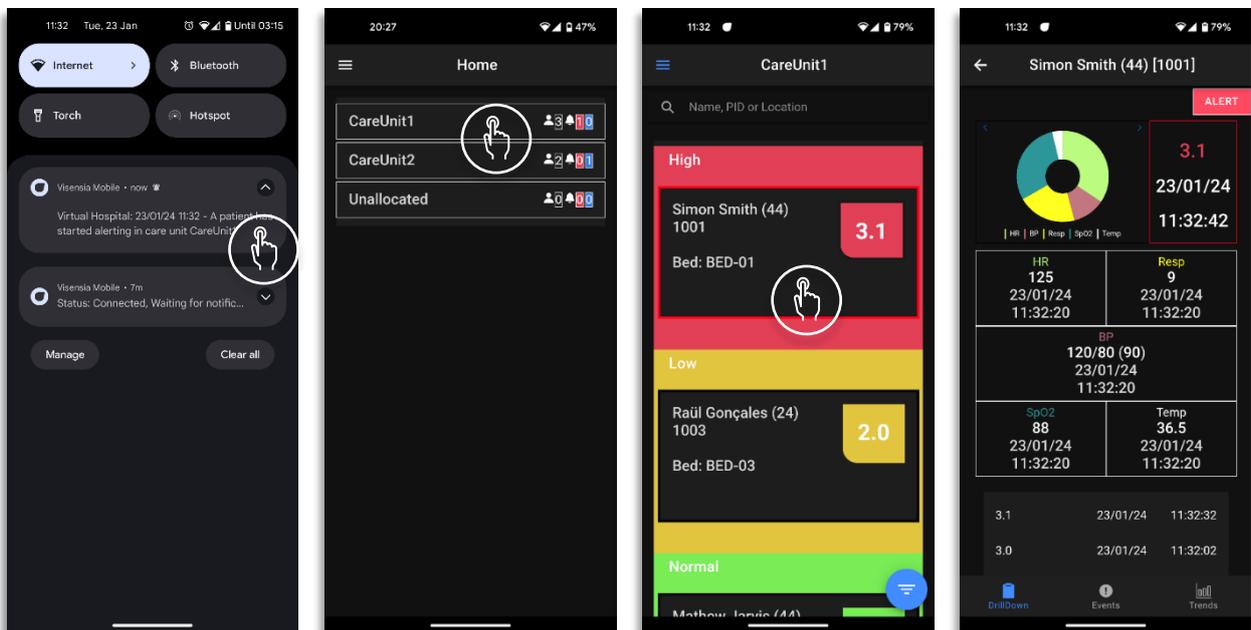
Notification Received → Select Notification → Patient Tile with VSI Alert is displayed → Review the Drill Down Information → Follow Hospital Protocol

Silence future VSI Alerts

Once you have reviewed an active VSI Alert, you can then Silence future alerts for a defined period, while a planned intervention takes effect.

To **silence** future VSI Alerts

1. Select the **Patient Tile**.

2. Using the **Drill Down** – select the **Alert Button.**

3. Scroll and select the desired duration to **Silence future Visensia Alerts** for e.g. **15 Minutes.**

   - Select **Confirm** to apply the Silenced Status.

   - Select **Cancel** if you don't want to proceed with the Silence Status request.

4. The **Patient Information Tile** border will change from an **Alert Status** to the **Silence Alert Status** indicating future Visensia Alerts have been **Silenced.**

5. If configured by your System Administrator, a Notification will be received by Mobile Users assigned to the same Unit, advising the VSI alert has been silenced.

🔔	⚪ Visensia Mobile · now 🔔	• A Patient alert has been silenced in care unit – CareUnit1
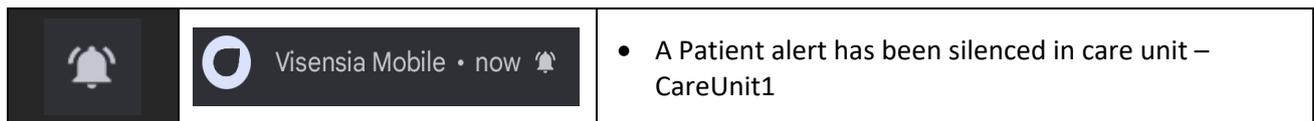
## VSI Silenced Alert Status - Patient Tile and Drill Down
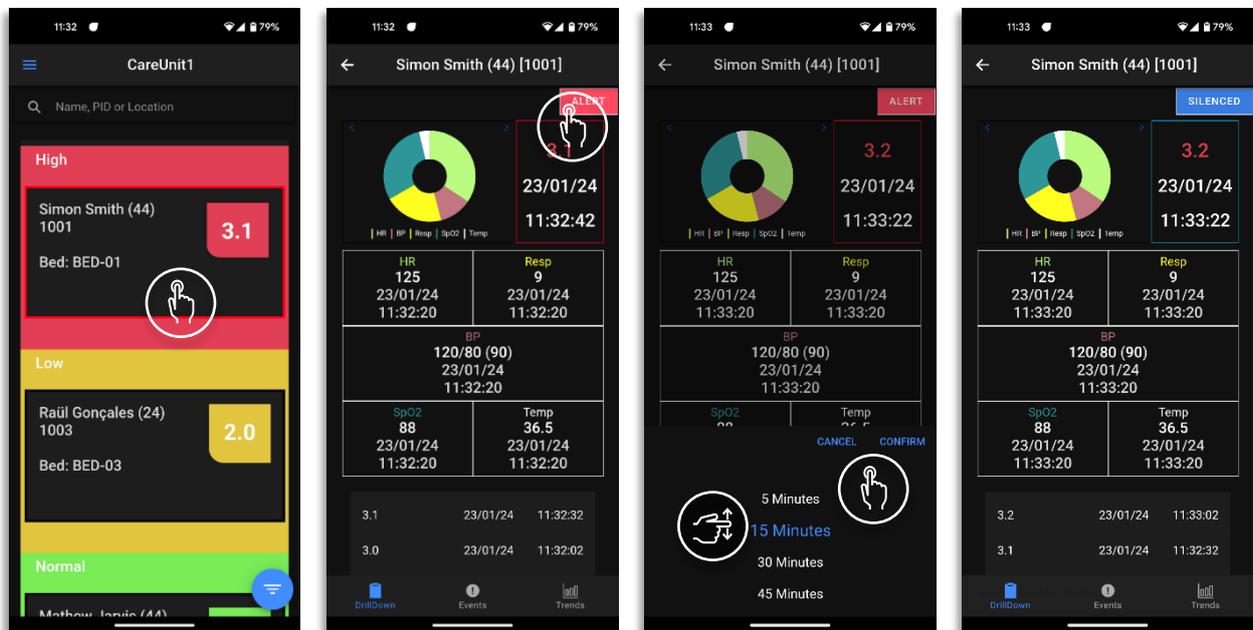
Note: The **Home Screen** will update to show the number of **Silenced VSI Alerts** there are for the Unit.

Clear a VSI Silenced Alert

If for any reason you want to remove the Silenced Status for a Patient, this can be actioned as follows.

6. Select the **Patient Tile**.

7. Using the **Drill Down** – select the **SILENCED Button.**

8. A message will be displayed asking you to confirm actions:

    • Select **Yes** to remove the Silenced Status.

    • Select **No** if you don't want to proceed with the removal of the Silence Status request.

9. The **Silenced Alert Status will now be removed.**

10. If configured by your System Administrator, a Notification will be received by Mobile Users assigned to the same Unit, advising the VSI Silenced Status has been removed.

11. If the VSI Index is still within the High Threshold Range the patient tile will start to Alert again.

12. Apply a new Silence period as required.

Remove a VSI Silenced Alert Status - Patient Tile and Drill Down
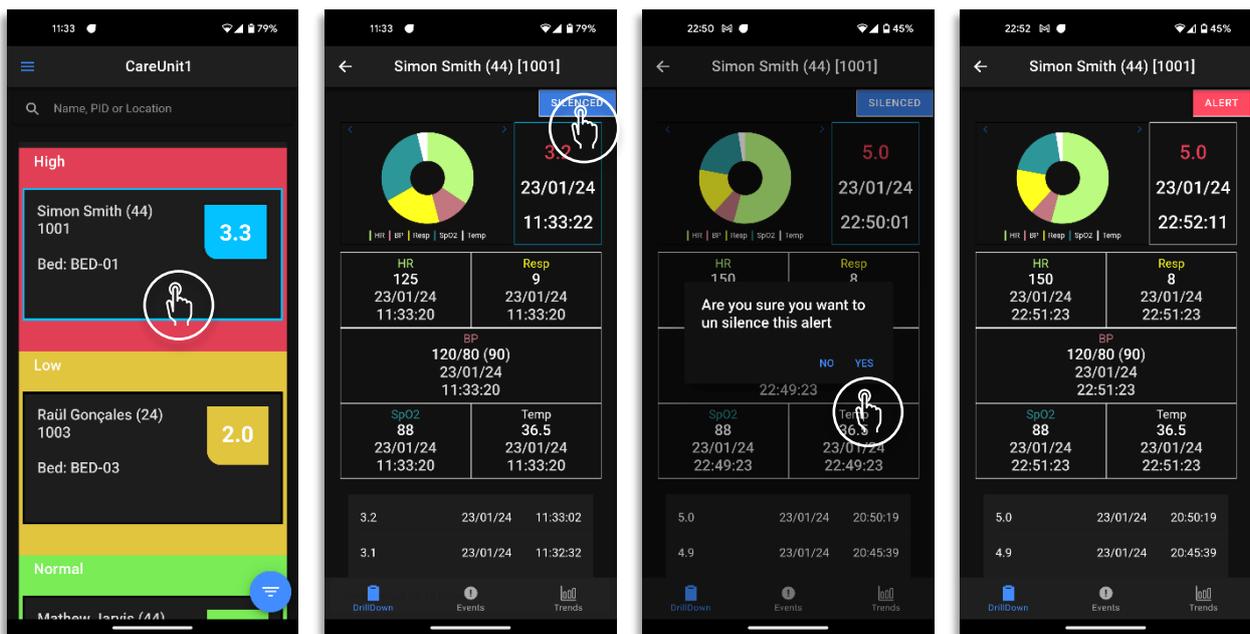
Note: If the **VSI** falls **below the defined High Threshold Lower Limit value**, then the VSI Alert Status (both Visual and Audible) is automatically cleared from the Patient List and Drill Down Tab.

Note: The actions of Silencing and Removing a Silenced Alert are documented via the Events Table.
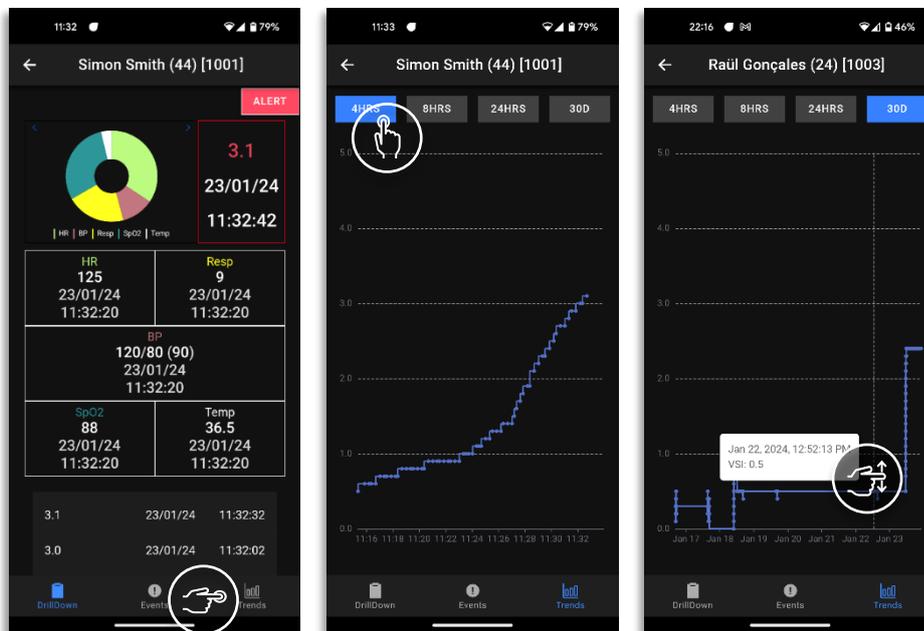
Trends

The Trends Screen details the history of the selected patient's **VSI.**

To **view the VSI Trends Graph** for a Patient

1. Select the **Patient Tile.**

2. Using the **Drill Down** – select the **Trends Button.**

3. Select the **time interval for VSI trend graph** by clicking the options available.

4. Select points along the trend graph to reveal the values for the calculated VSI value and date / time.

| Trend	4hr	8hr	24hr	30Days

VSI Trends Graph

Note: Changing the time interval will cause the selected Trends Chart to be redrawn as required. The graph will also be redrawn every minute to include any additional VSI calculations.

Events

The Events Screen details all historic VSI Alerts, VSI Threshold Warnings and any interventions or changes made by Users.

1. Using the **Drill Down** – select the **Events Table.**
   - A list of all logged VSI Alerts and Vital Sign Warnings is now displayed.
2. Filter the Events Table by selecting the option required and press **OK.**
   - Algorithm Events (VSI Alerts, Threshold Breaches)
   - Vital Events (Threshold Breaches)
   - Patient Events (Admit, Transfer)

Events Table
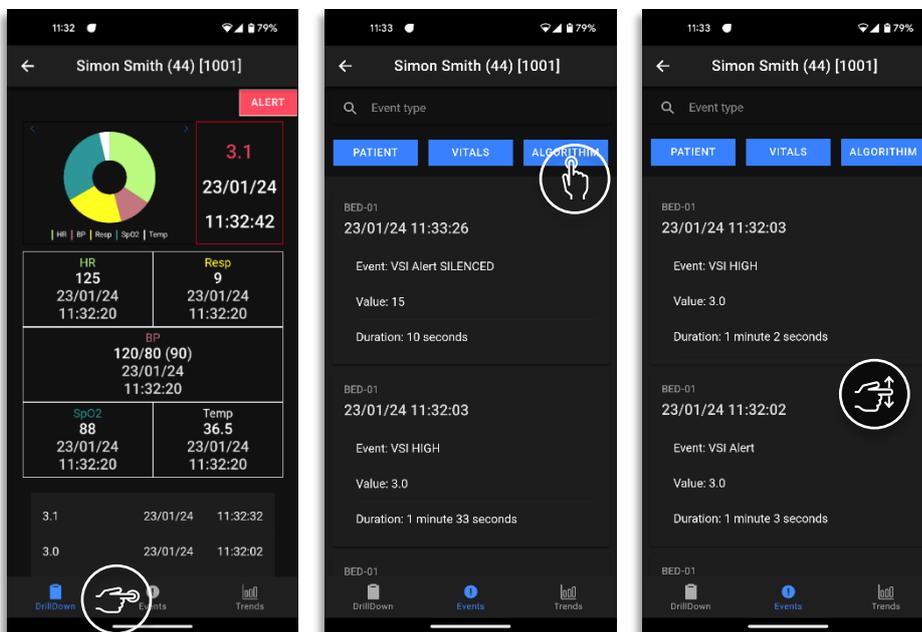
Support

Please contact you **System Administrator** for any technical issues experienced.

You can access an electronic copy of this User Guide via: http://www.obsmedical.com/visensia-user-guides/

Sever Downtime

Server downtime is defined as any time the Visensia server is unavailable or unresponsive.

Various factors, including planned maintenance, hardware failures, power outages, network problems, and software issues, can cause this.

To check the status of the connection with the Visensia Server select the ≡ **Menu Icon**, located at the top left of the Home Screen. The Server Status is displayed at the bottom of the screen.

Visensia Server Status	
🟢	Connected
🔴	Disconnected

- Attempt to log back in to the Visensia Mobile Application to reconnect to the Visensia Server.
- If the issue persists for more than 30 Minutes you should contact your System Administrator.

Visensia Server Connection Status
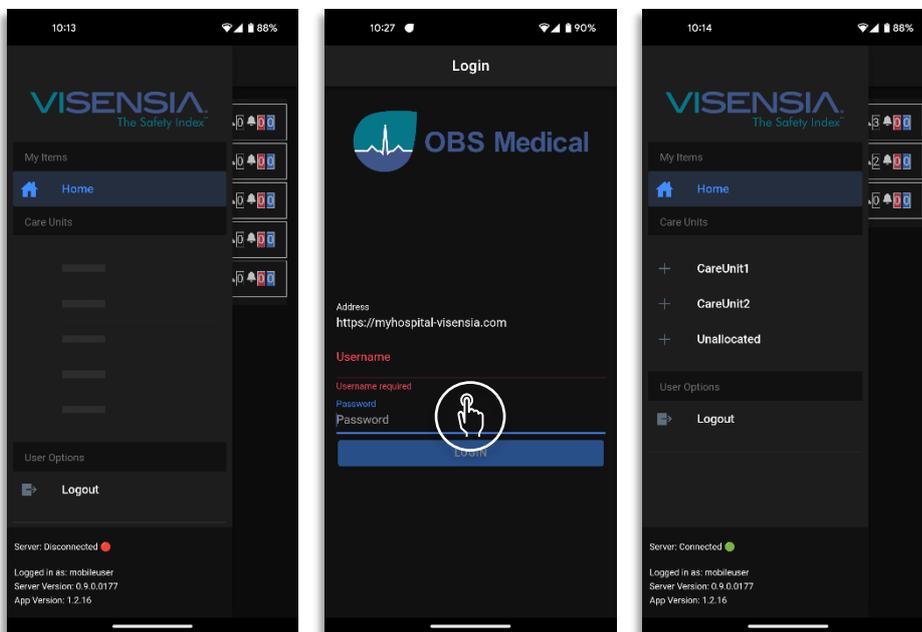
Note: As a mobile application, Visensia Mobile is reliant on running via a compatible device with good network connectivity to ensure reliable access to patient data.

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