



# User Guide

## Version 3.4

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Visensia is a medical device complying with the EU Council Directive 93/42/EEC concerning Medical Devices.

# Welcome

This guide contains all the information you need to operate Visensia®. It is intended for use by trained medical personnel and assumes prior knowledge of the operation of multi-parameter patient monitors.

Configuration and Connectivity of Visensia is detailed in the **Installation and Configuration Guide** (Part No. 011-0130-LMAN).

## Visensia Overview

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Visensia software is a computerised analysis software program designed as an accessory to standard patient monitors or medical information systems. It 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, is displayed on a scale of 0-5, with 0 representing the normal end of the scale and 5 representing extreme physiological deterioration. An audible and visual alert is provided when the Visensia index exceeds a threshold value for a period of time.

The Visensia Index is calculated whenever new data is received.

Visensia is an advanced physiological monitoring system that monitors critical vital signs to provide early warning of patient deterioration.

## Visensia Index

The Visensia software calculates the Visensia Index 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

# Intended Use

Visensia with alert is an accessory to multi-parameter patient monitors (bedside, ambulatory, or centralized location) or clinical information systems and is indicated for use by health care professionals with those non-pediatric high dependency care patients for whom multi-parameter patient monitoring has been routine.

Visensia provides the clinician with a patient status index (Visensia Index) based on a weighted average of five or (four) vital signs namely 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. Visensia is an adjunct to and is not intended to replace vital sign monitoring.

When a Visensia alert has activated, it means that the Visensia Index has reached and/or surpassed the default threshold and indicates that attention should be brought to the patient.

## Safety Information

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Users should familiarize themselves with all warnings and cautions before using Visensia. In addition to the following, other warnings and cautions appear throughout this manual.

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

Visensia software is not for paediatric use.

The abnormal vital warning indicators are not intended to be used as a primary alert mechanism. It is not a replacement for any primary alerting systems or procedures already in place.

**CAUTION: US Law restricts this software to sale on or by the order of a physician.**

## Trademarks

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Visensia® is a registered name of OBS Medical.

## Data Protection/ Privacy

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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 law and regulation.

# The Visensia Display

During normal operation the Visensia screen will display a Visensia Index for each patient and it will update every time new physiological data is received for that patient.

The Visensia display can be configured to show patient information in a variety of formats. This section describes the main elements that are found on each Visensia display.

## Banner

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The banner displays the company and product name and may, or may not be displayed, depending on how your system is configured.



## Status Bar

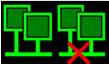
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The status bar, at the bottom of the display, shows the local date and time to the left.

Icons to the right of the status bar indicate whether or not the system is operational and connected to the network.

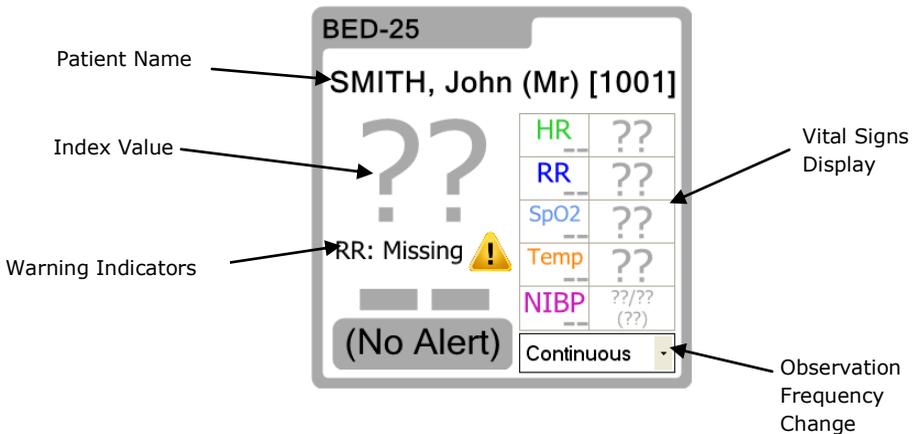
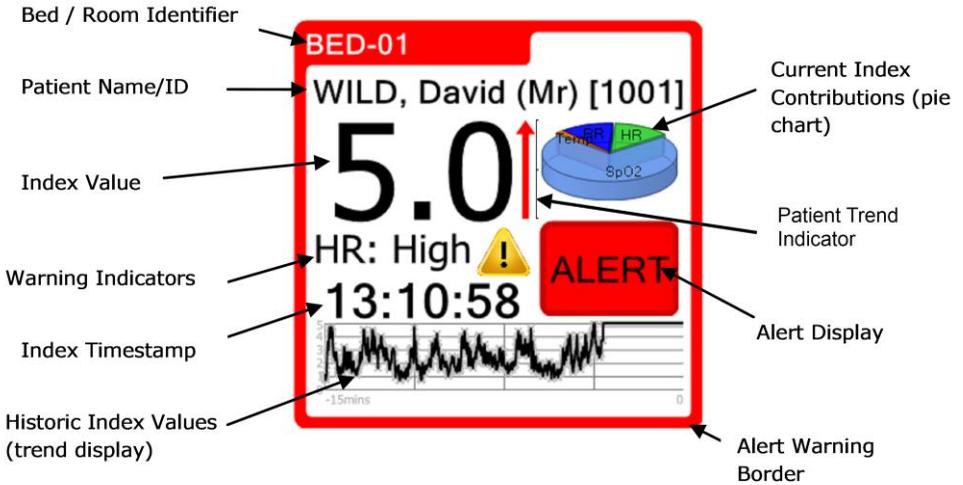
The status bar may, or may not be displayed, depending on how your system is configured.

The icons that display are as follows:

	<p><b>Network connection indicator</b> <i>Indicates whether Visensia client is connected/is not connected to the server.</i></p>
   	<p><b>Activity indicator</b> <i>When this is flashing it indicates that Visensia is operational.</i></p> <p><b>Warning:</b> <i>If this indicator stops then it indicates a system failure. Refer to a Clinical Engineer or IT Specialist immediately.</i></p>

# Patient Information

Each Visensia display shows a grid of cells and each cell shows information for a single monitored patient.



<p><b>Bed / Room Identifier</b></p>	<p><i>The name of the bed / room that is being monitored.</i></p>
<p><b>Patient Name/ID</b></p>	<p><i>The name/ID of the patient being monitored. See <b>Adding a Patient's Name</b> and <b>Removing a Patient's Name</b> for further information. <b>Note:</b> Your IT specialist may have configured Visensia to not show this information</i></p>
<p><b>Index Value</b></p>	<p><i>The latest value of the Visensia Index calculated from the vital signs received from the patient's monitor. The index value is updated when a new vital sign measurement is received for the patient that is being monitored.</i></p> <p><i>If this value displays grey question marks (??) this indicates that there is not enough valid data available, for example, if the data is only available for less than 3 vital signs, if the vital signs have been removed, or if the observation frequency has expired (see <b>Changing the Observation Frequency</b> for further information).</i></p>
<p><b>Patient Trend Indicator</b></p>	<p><i>The latest Patient Trend Indicator display the trend of Visensia Index for a patient, over a period of time.</i></p>

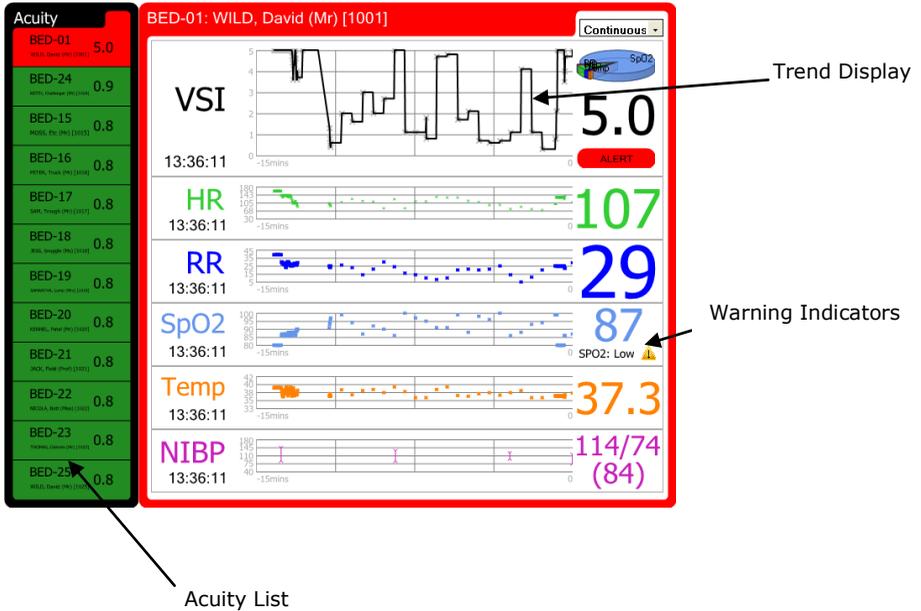
<p><b>Index timestamp</b></p>	<p><i>The time the latest value of the Visensia Index was calculated</i></p> <div data-bbox="395 215 1001 371" style="border: 1px solid black; padding: 5px;"> <p><b>Note:</b> The time stamps shown are in 24 hour clock format only (without a date), the time is limited to the last 24 hours from the point the display is observed.</p> </div>
<p><b>Warning Indicators</b></p>	<p><i>Indicators showing any active warnings for the bed/room being monitored. <b>Note:</b> Your IT specialist is able to configure which warnings Visensa® will display.</i></p>
<p><b>Vital Signs Display</b></p>	<p><i>A list of current vital signs for the patient, their values and the times at which the vital signs were recorded.</i></p> <p><i>If this value displays grey question marks (??) this indicates that there is no valid data available, for example, if the vital signs have been entered, or if the observation frequency has expired (see <b>Changing the Observation Frequency</b> for further information).</i></p> <div data-bbox="395 1026 1001 1182" style="border: 1px solid black; padding: 5px;"> <p><b>Note:</b> The time stamps shown are in 24 hour clock format only (without a date), the time is limited to the last 24 hours from the point the display is observed.</p> </div>

<p><b>Alert Warning Border</b></p>	<p><i>The surrounding cell colour indicates one of the following alert states for the patient:</i></p> <p><i>Red (Flashing) – Alert</i></p> <p><i>Grey – (Technical) Warning</i></p> <p><i>Gold – Silenced (Alert)</i></p> <p><i>Green – Normal</i></p>
<p><b>Alert Display</b></p>	<p><i>If the Visensia Index satisfies the Visensia alerting criteria an Alert state is seen on the Alert control button. The alert may clear if the Index no longer meets the alerting criteria (unless Latched Alerts are configured). The alert may also be ‘silenced’ or ‘adjusted’ if required. See <b>Maintaining Alerts</b> for further information.</i></p>
<p><b>Historic Index Values (trend display)</b></p>	<p><i>Shows a history of the index value for the patient, over a period of time, in graph or table form. The amount of history displayed and whether to use tables or graphs is system configurable.</i></p>
<p><b>Current Index Contributions (pie chart)</b></p>	<p><i>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. The pie chart also scales depending on the index value; a high value displays a larger pie chart.</i></p>

<p><b>Observation Frequency Change</b></p>	<p><i>From here you can set the observation frequency rate for the patient.</i></p> <p><i>This is the length of time that you estimate a patient's reading is valid for.</i></p> <p>See <b>Changing the Observation Frequency</b> for further information.</p>
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# Drill Down Display

The Drill Down display, and displays that are similar to this, show the vital signs and the index value for the patient currently selected, along with any currently active warnings.



## Acuity List

The Acuity List shows the current list of patients being monitored. The list is ordered according to the alert state and then the index value.

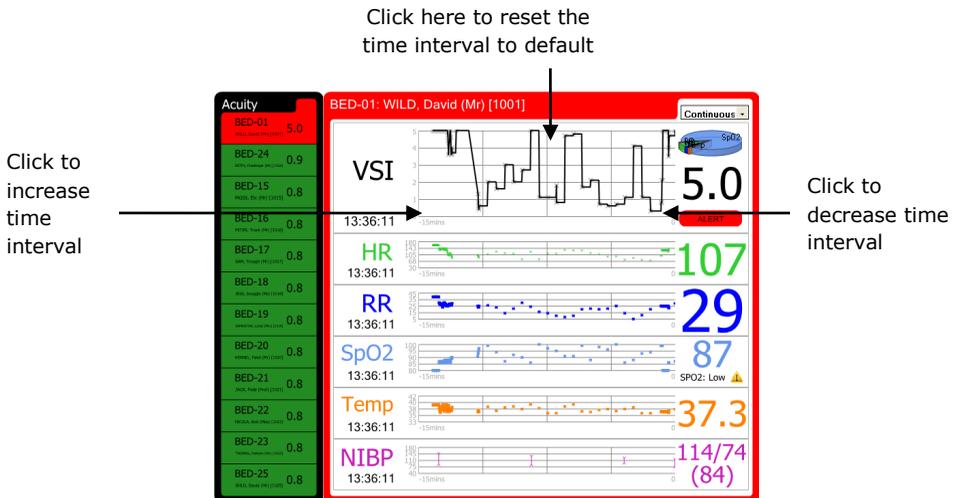
You can select a patient and display their details in the Trend Display by clicking on the patient details from the Acuity List.

## Trend Display

The Trend Display shows the vital signs for the selected patient, including the values for each vital sign and the time on which the values were last recorded.

The display also shows, in graph form, a history of the patient's index value and a history of the values for each vital sign. The maximum time interval for the historic graphs is system configurable. To change the maximum time interval, please see your IT Specialist.

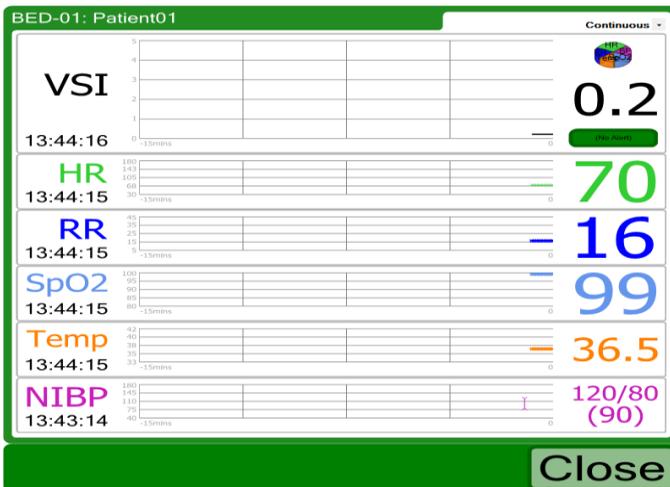
You can temporally change the time interval for the historic graphs by clicking the left and right hand sides of the graphs. Clicking to the right will decrease the time interval, clicking to the left will increase it. The time interval will automatically reset after 10 minutes of no interaction has elapsed. Clicking in the centre of the graph will reset the time interval to its default value.



**Note:** The time interval of all graphs will change, not just the graph you are clicking on

# Pop Up Display (Drill Down)

If configured, the pop up is displayed when the user clicks on the VSI Index value of a given bed in a cell in order to display history of the patient's index value and a history of the values for each vital sign. The pop up is very similar to the Trend Display with the addition of a **Close** button; you can hide the pop up display by clicking on the **Close** button.

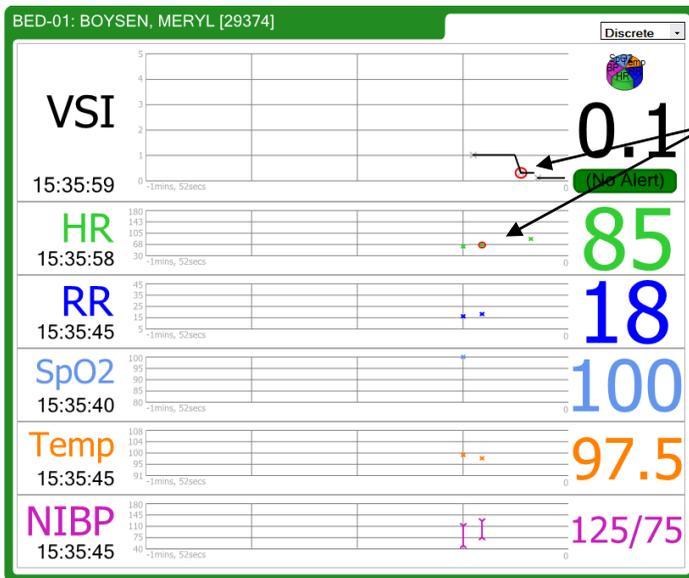


# Corrections and Deletions

If configured, Visensia displays can show corrections and deletions that are made to the vital signs and the calculated VSI index.

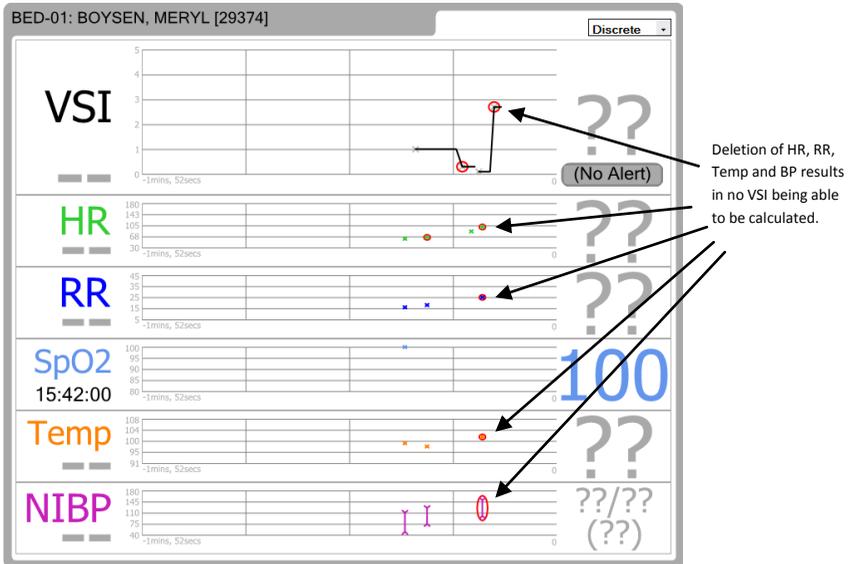
Both Corrections and Deletions result in deleting a previous value, the deletion is visible on those screens that show historical data such as the trend graphs and the history table.

Trend Graphs with Corrections:

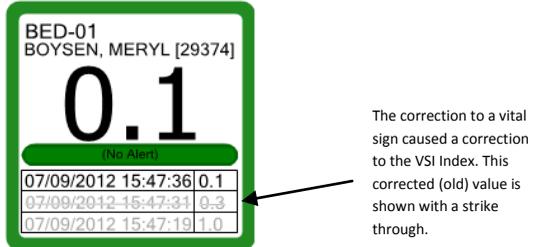


Correction of HR causes a correction of the VSI. The corrected (old) values are shown with a red circled around them.

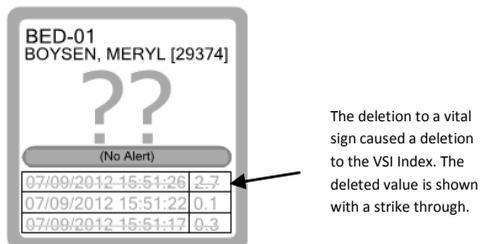
## Trend Graphs with Deletions:



## History Table with Corrections:



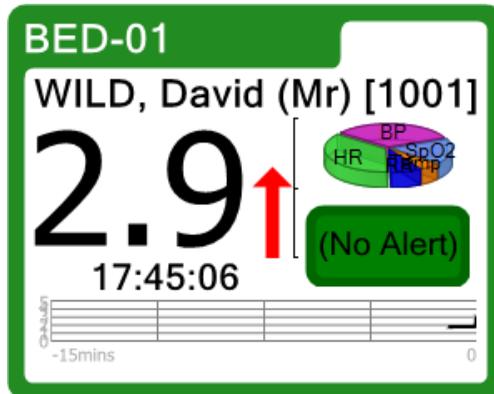
## History Table with Deletion:



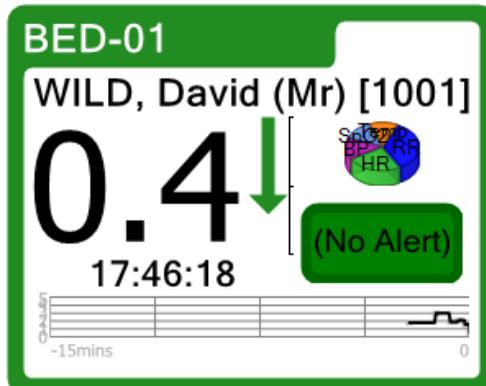
# Patient Trend Indicator

Patient Trend Indicator indicates improvement or deterioration in the Visensia Index trend for a Patient over a period of time. The red arrow indicates deterioration, while green arrow means improvement. The height of the arrow indicates the amount of improvement or deterioration. A horizontal grey arrow means no change. Following figures illustrates the three states mentioned above.

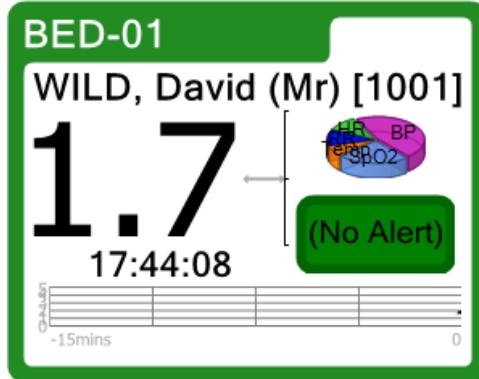
- Deterioration



- Improvement



- No Change



# Using Visensia

You can interact with the main Visensia display by clicking on various areas of the patient information cells.

**Note:** The following data entry screens will timeout after 10 minutes and the main display will be shown so that any alerts can be seen.

## Adding a Patient's Name

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A patient's name can be added to identify the bed / room being monitored, if required.

**Note:** You will only be able to add a patient's name if your system has been configured to enable you to do so.

1. Click on the name of the bed / room for which you want to enter a patient's name.



2. Type in the patient's name or select from a Patient List (depending on Display Configuration).
3. Click the **OK** button.

## Removing a Patient's Name

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If a patient has been discharged, you can remove their name from the bed / room being monitored.

**Note:** You will only be able to remove a patient's name if your system has been configured to enable you to do so.

1. Click on the name of the bed / room for which you want to remove a patient's name.



**BED-01**

2. Click the **CLEAR** button or select “<Remove Current Patient>” from Patient List (depending on Display Configuration).
3. Click the **OK** button.

## Entering Vital Signs Manually

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Vital signs - heart rate, respiratory rate, temperature, blood pressure and blood oxygen – can be manually entered for a patient, if configured to do so. The manual reading entered will be overridden once a new automatic reading is received from the patient's monitoring system.

**Note:** You will only be able to enter a patient's vital signs manually if your system has been configured to enable you to do so.

1. Click on the vital sign for which you want to enter details manually.

For example, click the **HR** vital sign to manually enter the Heart/Pulse Rate details for a patient.



2. Type in the value for the vital sign.
3. Click the **OK** button.

## Changing the Observation Frequency

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You can manually set the period for which the last set of recorded vital signs to remain valid (and displayed) in the system, if required.

**Note:** The frequency selections available will depend on how your system has been configured.

1. Click on the down arrow to the right of the Observation Frequency Change field.
2. Select the frequency option you require from the drop down list.

## Maintaining Alerts

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Visensia displays an alert for a patient when the index value for that patient meets, and/or, exceeds the criteria for alerting. If the vital signs for the patient change and the index value falls to below the alerting criteria, the patient automatically comes off alert (unless your system has been configured to display Latched Alerts).

The alerting criteria can be manually adjusted, if required, but for only a set period of time or silenced (disabled) for a period of time.

**Note:** A patient with an Alert requires immediate attention.

**Note:** The last alert state is maintained when the index goes to grey question marks (??). Only a patient reset or a new index can change this alert state.

Alerts are distinguished in two ways:

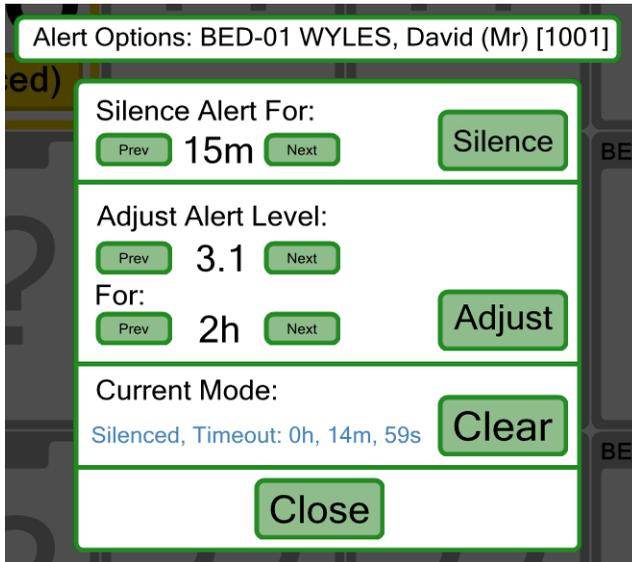
- The border to the patient information cell displays in a colour that reflects an alert state, as follows:
  - Red (Flashing) – Alert
  - Grey – Warning  
(a warning will display when there is an error to the patient’s data feed)
  - Gold – Silenced (Alert)
  - Green – Normal
- An alert control button. The button displays as:
  -  A red Alert button when there is a non-silenced alert.
  -  A gold Silenced button when the alert is silenced for a period of time.
  -  A green No Alert button when there’s VSI available and its neither alerting or silenced.
  -  A green Adjusted button when there’s VSI available and the alerting threshold has been adjusted.

## Silencing/Modifying an Alert

To silence or adjust an alert:

1. Click the **Alert** control button.

The Alert Options screen displays.



2. You can either:

- Set the time interval for the Silence Alert, i.e. the time period after which the Alert will be re-instated, by clicking on either the **Prev** or the **Next** button until the time interval you require displays. The **Prev** or **Next** buttons will not display if the minimum or maximum time intervals have been reached.

or:

- Set the alert index value and the time interval for the Alert adjustment. Until the time period has elapsed and alert will only be generated when the new Alert level has been reached.

Select the alert value by clicking on either the **Prev** or the **Next** button until the alert value you require displays. The **Prev** or **Next** buttons will not display if the minimum or maximum alert values have been reached.

Select the time interval by clicking on either the **Prev** or the **Next** button until the time interval you require displays. The **Prev** and **Next** buttons will not display if the minimum or maximum time intervals have been reached.

3. Click the **Silence** or **Adjust** button when you have selected the required silence alerting criteria.

## Warnings

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Visensia can be configured to display warnings when vital signs fall outside of configured thresholds, or when a vital sign is missing from the patient's feed or generating some kind of "status message". These warnings are indicated on the display by either a visual icon or text indicator.

**Note:** Which warnings are shown is configurable by your IT specialist.

**Note:** The abnormal vital warning indicators are not intended to be used as a primary alert mechanism. It is not a replacement for any primary alerting systems or procedures already in place.



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