ViSIG™

ICU Patient Deterioration System

Version 1

Clinical

User Guide

OBS Medical
Data for Life

Contents

Introduction

This guide contains all the information you need to operate ViSIG™.

ViSIG is intended for use by trained medical personnel and assumes prior knowledge of the operation of multi-parameter patient monitors.

The day-to-day administration of the system is detailed in the Administration and Configuration User Guide **(Part No. 011-0814-LMAN).**

ViSIG Overview

ViSIG™ is a system for assessing the risk of mortality in ICU patients. It works by examining current and past vital sign readings, as well as whether or not the patient is receiving mechanical ventilation (MV).

For each vital sign, specific patterns of readings over the previous 30 minutes that are associated with mortality are identified, summed, and along with ventilator status (room air, on MV, previously on MV), are incorporated into a score (ViSIG Score: "ViS") that indicates a patient's risk of mortality.

A basic ViSIG Score is constructed by adding the scores from each vital sign. The ViSIG Score is correlated with risk of mortality, and can be used to trigger early intervention, with a visual and audible alert highlighting a deteriorating patient for clinicians to respond as protocolized.

ViSIG Score

The ViSIG Score is a single measure of a patient's current risk level for mortality.

It ranges from 0-100 and gives an up-to-date metric of a patient's probability of mortality within the ICU. As the ViSIG Score increases, so does the patient's probability of mortality without timely intervention.

The value of a patient's ViSIG Score is given a corresponding colour code on the User Interface: green for baseline risk, yellow for moderately increased risk, and red for patients at highest risk of mortality.

When a ViSIG alert has activated (patient's tile is red), it means that the ViSIG Score has reached and/or surpassed the default threshold, highlighting the patient's condition to the intensivist for an appropriate response.

ViSIG Alerts

ViSIG Alerts indicate that a patient is at an increased risk of mortality. When a ViSIG alert has activated, it means that the ViSIG Score has reached and/or surpassed the default threshold, highlighting the patient's condition to the intensivist for an appropriate response.

These alerts may change over time for a patient, depending on the ViSIG Score.

Intended Use

ViSIG with alerts is intended to be used with data from already cleared sensors measuring physiological parameters, including heart rate, respiratory rate, oxygen saturation, mechanical ventilation status and blood pressure in patients being monitored in a healthcare facility.

The device provides a time series patient status score (ViSIG Score) based on patterns of change in a patient's monitored vital signs. The ViSIG Score is a single measure of a patient's condition and identifies those patterns in a patient's vital signs that are consistent with subsequent patient deterioration, which has been derived from pre-determined risk scores associated with each pattern, embodying the knowledge of which patterns of vital sign history are associated with high risk, and which are moderate or low risk. The ViSIG Score is based on an integrated computation evaluating changes in the parameters and their relationships to each other.

The ViSIG Score is intended for regular review by a qualified clinician. ViSIG is intended to provide additional information for use during routine patient monitoring. ViSIG is an adjunct to and is not intended to replace vital sign monitoring.

Patient Population

ViSIG is validated for use with patients aged 18 and over being cared for in the intensive care unit setting.

Intended User

The intended user of ViSIG is a tele-ICU or ICU clinician within the hospital who has undergone training in the use of the system.

The ViSIG Statistics Model

The ViSIG Score is a rolling score predictive of a patient's risk of ICU mortality and is updated every thirty minutes. It ranges from 0 to 100, with higher scores implying greater mortality risk.

For each vital sign (Heart Rate, Respiratory Rate, Blood Pressure and Blood Oxygen Saturation), median measurements over the previous 10 minutes are obtained. A set of three median values for each vital sign are concatenated to form a thirty-minute pattern. These patterns are matched against those previously shown associated to be associated with mortality and assigned a score. The scores for the four vital signs are summed, and along with ventilator status (room air, on MV, previously on MV), to produce a total score (ViSIG Index) that indicates a patient's risk of mortality.

A patient's score for a 30-minute time segment ranges from 0 to 100 points: If there was a gap in vital signs of greater than 6 hours, a new ViSIG Score was initiated, as it was felt such a gap would result in a discontinuity of the score.

Summary of ViSIG Clinical Performance

The performance of ViSIG was determined via a three (3) phase prospective multi-centre clinical study.

- o The first phase, ViSIG Recalibration, involved recalibrating the ViSIG Score weights using real-time, live data. This real-time aspect of the data collection ensures the relevance and applicability of our findings to current clinical practice. Six ICUs from two hospitals were enrolled here.

- o Once the new weights for the ViSIG Score were derived, the second phase – "Validation" looked at the performance of the ViSIG algorithm on new ICU admissions at three hospitals and eight ICUs (data from the third hospital was analysed retrospectively). Clinicians were blinded to each patient's ViSIG Score.

- o The third phase, ViSIG Clinical Efficacy, occurred after validation was confirmed. There was a live period of three months, during which the ViSIG Score and its trend were made visible to clinicians via a web-enabled user interface. The resulting change in outcomes between this group of admissions

and the ICUs used in the validation phase (clinicians were blinded to ViSIG) were compared, adjusting for patients' severity of illness.

A total of 7.930 ICU admissions contributed to this study of ViSIG.

The algorithm behind ViSIG was shown to be robust across eight ICUs from three hospital systems, with a sensitivity of 57% and a specificity of 89% as shown in Table 1 below.

Table 1. ICU Mortality in the Validation Phase of the Study

All Three (3) Hospitals					
Risk Group	Alive	Dead	Total	% Mortality	Relative Risk
Low	2,227	57	2,284	2.5%	Baseline group
Moderate	1,199	107	1306	8.2%	3.28
High	421	219	640	34.2%	13.71
ALL	3,847	383	4,230	9.1%	

Sensitivity	57.2%	
Specificity	89.1%	

Data Protection/ Privacy

Clinicians and other users of the ViSIG 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.

Note: While browsers remain largely compatible between versions, full compatibility can only be guaranteed with the listed version.

Note: The various dashboards as used by ViSIG have been designed to work best on a desktop computer or laptop with a minimum screen resolution of 1024 x 768.

Note: All patient names and data used throughout this guide are fictitious.

Trademarks

ViSIG® is a registered name of ViSIG Health LLC.

Symbols

Symbol	Title	Description
	Manufacturer	Indicates the medical device manufacturer
LOT	Batch Code	Batch code so the Lot / Batch / Software Version 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
R$_x$only	Prescription Use Only (USA only)	Device is prescription use only by a healthcare professional

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 ViSIG before readings these instructions.**

Warnings:

Intended Use

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

⚠ ViSIG software is not for paediatric use.

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

Alerts

⚠ When ViSIG 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 ViSIG Alerts are silenced.

Cautions:

Intended Use

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

⚠ The ViSIG Score as output by the ViSIG system should be viewed as one clinical data point that should be integrated by an appropriately trained clinician with the patient's clinical history, continuous monitoring data, diagnostic test results, and clinical judgement.

General

- As a Web application, VISIG is reliant on running via a compatible Web Browser with good network connectivity to ensure access to patient data.

  Verified Web Browsers are listed in the Admin and Configuration Guide **[011-0814-LMAN].**

- Your system administrator will provide you access to ViSIG via a dedicated display, typically located near or at a nurse central station.

- Your system admin can also provide you access to ViSIG via a web link for your organizations computer or laptop.

- If you cannot access the system due to poor network connectivity, attempt to login via another workstation with known network connectivity.

Contraindications

There are no known contraindications for use of the ViSIG system

> **Note:** Images used within this manual are provided for reference purposes only. Screens may differ based on system configuration and available parameters. Please refer to the **Administration and Configuration Guide [011-0814-LMAN**] or speak to your system administrator for more information.
>
> **Note:** Temperature is not used by the ViSIG Algorithm when calculating the ViSIG Score, however this Vital Sign can be displayed via the Vitals Chart within the Patient Tile or Drill Down Display as a configurable option.

Licensing

ViSIG uses a licensing system that provides copy protection, security, algorithm functionality and allows registered clinical users to login and view monitored patients via the various dashboards.

An activated license determines how many beds can be monitored at any given time. It is important to ensure the ViSIG system has enough licenses in place for all monitored beds.

If your system admin has not yet activated the software license, clinical users will not be able to login to view the dashboards.

If the activated license has expired, or there are more beds monitored than adequately covered by a license, then the ViSIG Score will not be calculated. A yellow border will be displayed – highlighting the ViSIG Score cannot be calculated for the additional beds.

Note: Please inform your System Administrator if you are unable to access the system due to Licence Invalid message.

Note: Please inform your System Administrator if you notice the borders for some patient tiles displayed in yellow, indicating the existing Algorithm License requires a review as the ViSIG Score is not being computed due to a License issue.

Getting Started

Logging In

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

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

1. Using a compatible web browser and supplied web link, navigate to the ViSIG homepage, and input your login credentials and Login.

You will now be able to access the system and its various features as per the User Role assigned to you.

You can **Logout** of the system at any time by selecting the logout button, located top right of every dashboard.

Forgotten Password

If you cannot recall your Password, select **Forgot Password** link.

2. Type in your **Username or Email** and press **Submit.**

3. A password reset link will be sent to your registered email. Navigate to your email, select the reset password link, and follow the instructions as required.

4. Using your new login credentials, attempt to login again.

Note: Depending on the systems configuration the "Forgot Password" link maybe disabled. You will need to contact your System Administrator to reset your password if this is the case.

Note: A mail server will need to have been configured by your System Administrator to enable this functionality.

Users

User Roles

All system Users are allocated a **Role** which controls the level of access they have to the various functions and scope of the system as outlined Table 1: Roles / Functions Matrix.

Role	Scope
Administrator	Manage Installation, Licences, Inputs, Configurations, Users, Default Algorithm and Vitals Threshold settings. **(See Part No. 011-0710-LMAN for more information)**
Clinician	View and interact with the systems Clinical Dashboard and primary functionality as configured by your System Administrator.

	Roles	
Table 1: Roles / Functions Matrix	**Administrator**	**Clinician**
Functions		
System Administration:		
Manage System Licences	x	
Manage Users	x	
Manage Care Units	x	
Manage Staff assigned to Care Units	x	
Manage User Groups for Dashboard Functionality Preferences	x	
Patient Information:		
View Patient Demographic Information		x
View ViSIG Score		x
View Vital Sign Data (Vitals / Trend Data)		x
View Events (ViSIG Alerts)		x
View Single or Multiple Care Units – 'Acuity List' or 'My List'		x
ViSIG Alerts:		
Set Default ViSIG Alert Thresholds	x	
Silence ViSIG Alerts		x
Clear ViSIG Silenced Alerts		x
Acknowledge Latched ViSIG Alerts		x
Vital Signs:		
Manually Input Vital Sign Data		x
Set Default Vital Sign Timeouts	x	
Apply Patient Specific Vital Signs Timeouts		x
ADT Functionality (Standalone):		
Manually Admit Patient		
Manually Transfer Patient		x
Manually Discharge Patient		x
Edit Patient Demographic Information		x

Clinical Dashboard

The Clinical Dashboard is configured according to the individual needs of the User. This section describes the ViSIG Clinical Dashboard, its main components and features and various configuration options.
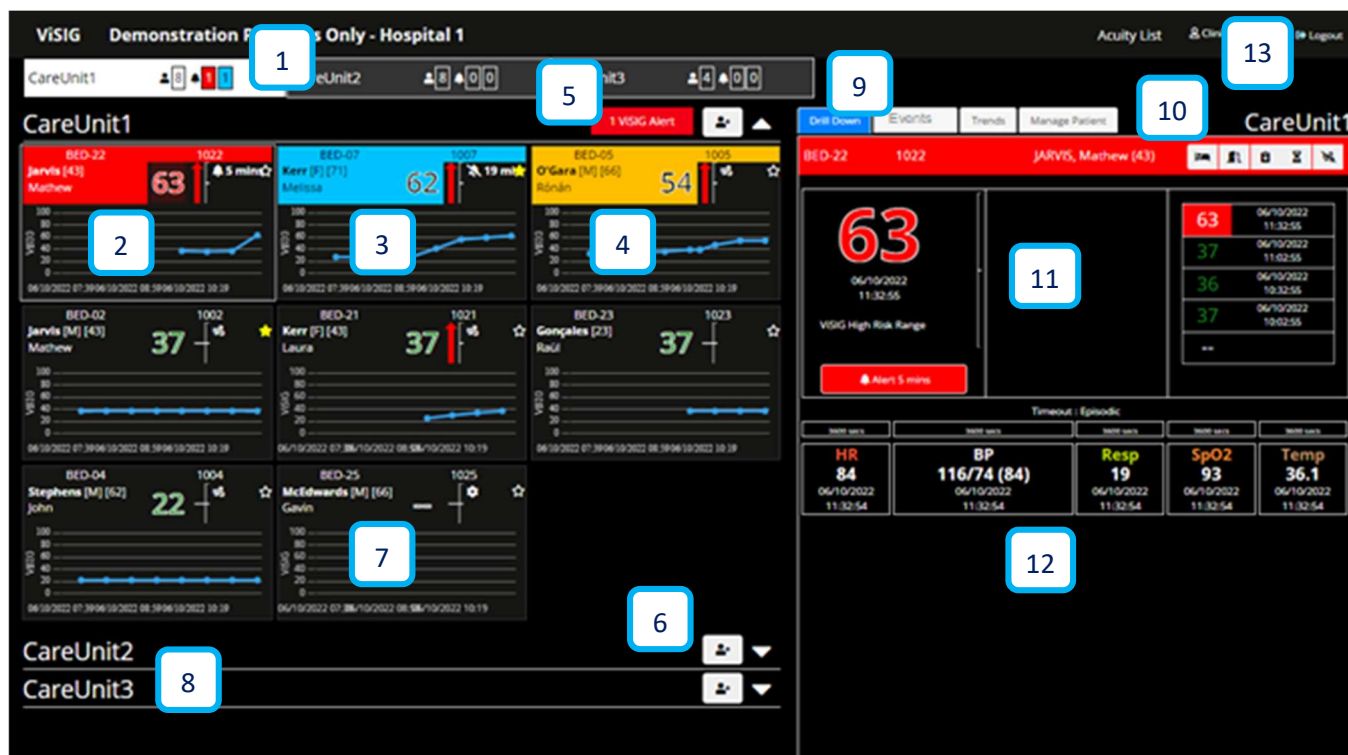
The image above is of the **Clinical Dashboard** with the **Drilldown Display fixed** and the options to **display** the **ViSIG Trend Graph, Patient Trend Arrow,** and **Vital Signs** enabled within the **Patient Tiles.**

|	
1. Unit Selector No# Patients | ViSIG Alerts | Silenced Alerts	**8.** Patient List – Collapsed Care Units
2. Patient Information Tile – High Threshold Patient Info| ViSIG | ViSIG Trend | Patient Trend Arrow	**9.** Drill Down Section and associated Tabs: Events | Trends |Manage Patient
3. Patient Information Tile – Silenced Status Silenced ViSIG Alert - BLUE	**10.** Drill Down Toolbar Discharge | Transfer | Add Vitals | Timeouts
4. Patient Information Tile – Medium Threshold Medium ViSIG Threshold – YELLOW	**11.** ViSIG Section ViSIG | Trend Arrow| ViSIG Historic Table
5. ViSIG Alert Notice Box No# Active Alerts	**12.** Vitals Section Vital Signs | Timeouts
6. Admit Patient Button Care Unit Specific	**13.** Logged in User / Logout
7. Patient Information Tile – Awaiting Data ViSIG First Calculation – Waiting for more data	

Patient List

The **Patient List** displays all received **Patient Information** as individual **Patient Tiles** and can be configured according to the individual needs of the User. **Patient Tiles** are grouped for the various Care Units assigned to you.

Acuity List

The **Acuity List** displays all **Patient Tiles** for a Care Unit assigned to a Clinical User.

Care Units and their associated **Patient Tiles** can be **collapsed or expanded** using the **Unit Selector** or by using the **^ or ˅** for each **individual Unit** to allow you to focus on a single Care Unit at a time, or to have an overview of all monitored patients.

The number of active and silenced VSI High Threshold Alerts for the Care Unit are displayed within the heading of the Care Unit.
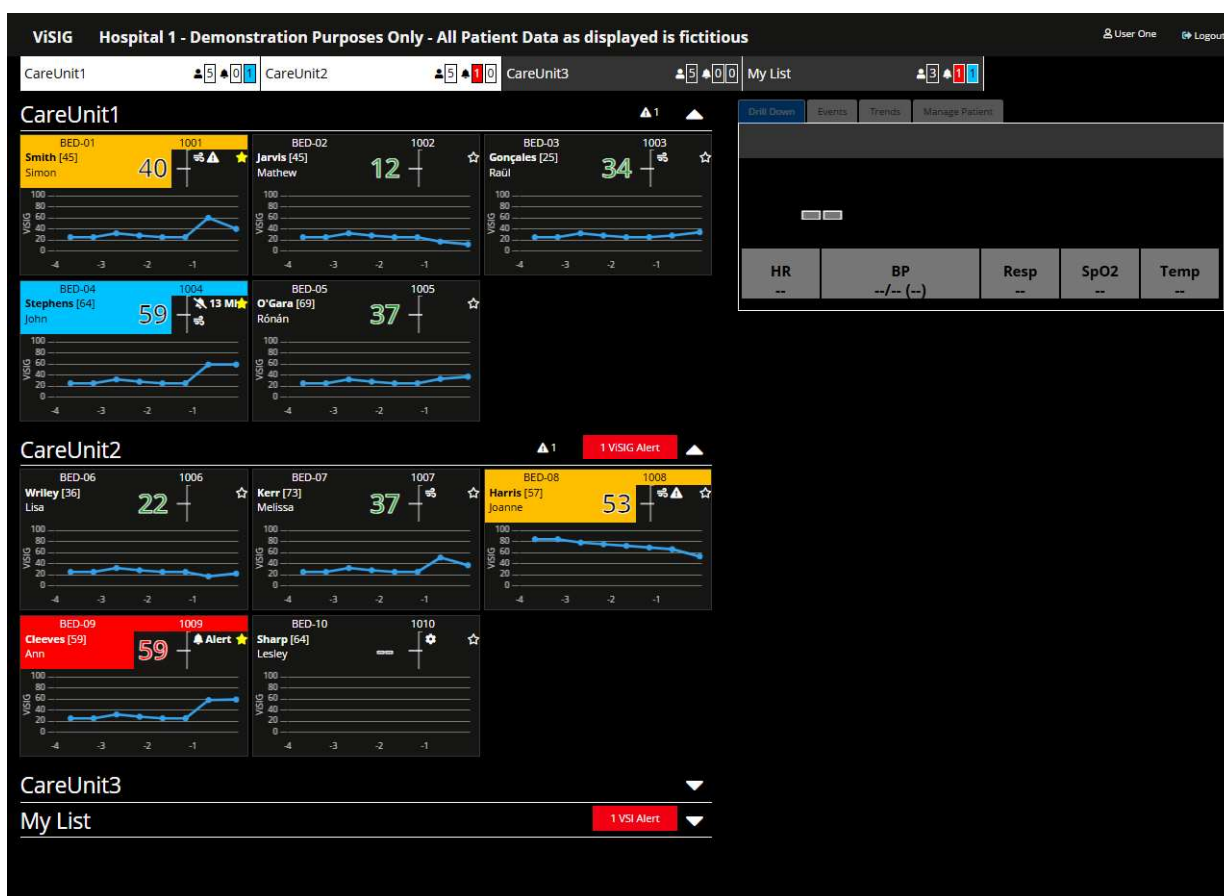
Selecting a **Patient Tile** will bring up more detailed information via the **Drill Down Display**.

- **ViSIG Section**
- **Vitals Section**
- **Events Tab**
- **Trends Tab**
- **Manage Patient Tab**

Note: The Acuity List can be configured to automatically rank patients according to the **ViSIG Score, Admittance Time** or **Room / Bed**.

Note: A **scroll bar will automatically appear** for Users who have been assigned multiple Units with large amounts of monitored patients so that they can easily review patients and their ViSIG Score.

My List

My List allows you to select patients that are assigned to you for specific reasons and to clearly highlight these patients from the Patient information Tiles within the main Acuity List and associated Care Units.

My List is specific to your login and cannot be seen by other Clinical Dashboard Users.

My List displays those Patients within the **Acuity List**, you have **starred** as your favourites.

- If Patients from Multiple Care Units are assigned to a User, **they are not separated** by Care Unit as seen within the Acuity List but simply listed via the Patient List.

- The associated Care Unit name is detailed within the Patient Tile.

Note: Patients that appear in **"My List"** are specific to the individual Clinical User and cannot be seen within the "My List" of another Clinical User.

Note: My List is a configuration option within User / Group Permissions. If enabled, the Unit Selector will only display My List once a Patient Tile has been "Starred" as a favourite. If the Patient Information Tiles do not have a star, the functionality has been disabled.

Unit Selector

The **"Unit Selector"** displays the various **Care-Units assigned you** as a **Clinical User.**

When you first login, all assigned Care-Units within the Unit Selector will be pre-selected (**Active - White Background),** with the associated **Patient List** being expanded to display all **Patient Tiles.**

The **number of patients assigned** to the Unit, along with any **active ViSIG Alerts or Silenced Alerts** for the Unit remain visible. Clinical Users can **activate / deactivate**, which Care-Units they want expanded or collapsed within the Patient List, by clicking on the relevant Care-Unit within the Unit Selector. (**Collapsed – Black Background**)

	Details the **number of patients admitted** to the Unit
	Details the **number of Active ViSIG Alerts (Red) and Silenced Alert (Blue)** for the Unit

Patient Tiles

The **Patient Tile** can be configured by your Administrator to display various components including:
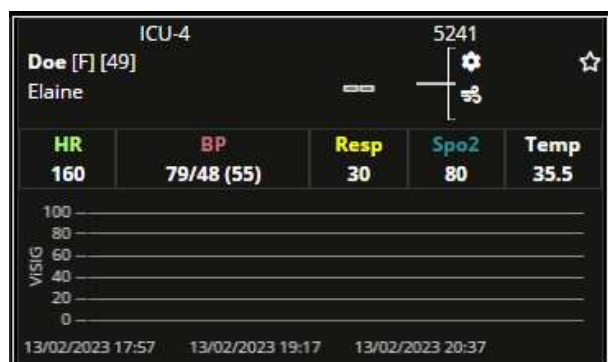
- **Patient Information** (**Name, Age, Patient ID, Location**).

- The **ViSIG Score, Patient Trend Arrow, ViSIG Score Trend Graph**, **ViSIG Warning Notifications** for Threshold Breaches, and **Alert Status.**

- Monitored **Vital Signs**.

A **white border** will be displayed for a Patient Tile selected for viewing via the **Drill Down Display**.

The **Patient Tile** will change colour according to the **ViSIG Alert Status**.

Depending on the ViSIG Score and alert status, the Patient Tile will appear as follows:

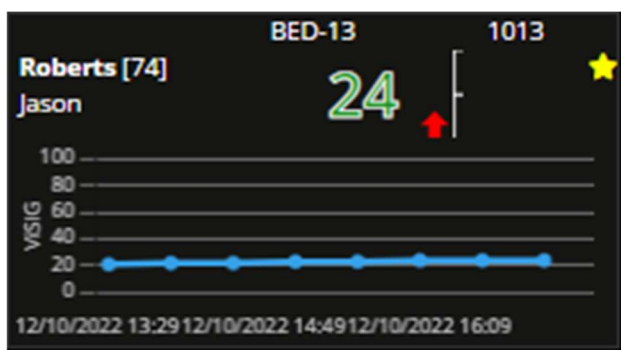| Example 1 – ViSIG Score (--) and associated "First ViSIG Score Calculation" Warning.	
	Patient Location - Bed: **ICU-4**
	Hospital / Patient ID: **5241**
	Patient Name: **Elaine Doe**
	Age: **49** — Gender: **Female**
	ViSIG Score (- -) and associated **"First Calculation Icon"** indicating the system needs more vital sign data to calculate the first ViSIG Score. **Vital Sign** data displayed. **Vent Icon** displayed indicating patient receiving mechanical ventilation (MV).

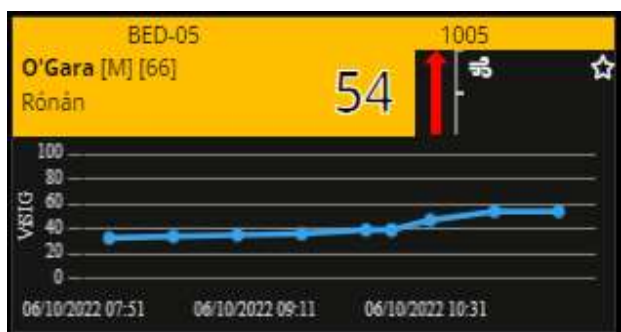| Example 2 – ViSIG Normal Threshold, Vital Sign Threshold Breach.	
	Patient Location - Bed: **BED-13**
	Hospital / Patient ID: **1013**
	Patient Name: **Jason Roberts**
	Age: **74** — Gender: **Not Specified**
	ViSIG Score (24), **Normal Threshold Status (Green).** **ViSIG Trend Graph** and **Patient Trend Arrow (Small Red)** indicating ViSIG Score has increased slightly over defined period**.**

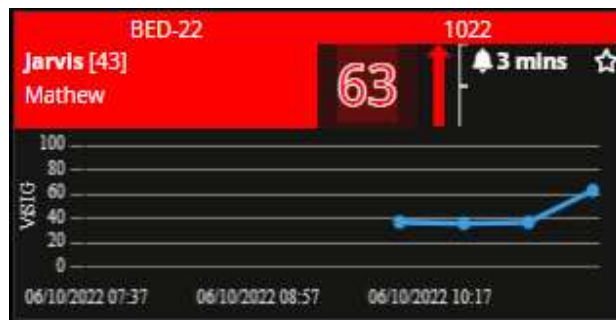| Example 3 – ViSIG Medium Threshold Breach	
	Patient Location - Bed: **BED-05**
	Hospital / Patient ID: **1005**
	Patient Name: **Ronan O'Gara**
	Age: **66** — Gender: **M**ale
	ViSIG Score (54), **Medium Threshold Status (Yellow).** ViSIG Trend Graph and **Vent Icon** displayed indicating patient receiving mechanical ventilation.

Example 4 – ViSIG High Thresold Breach (Active ViSIG Alert)

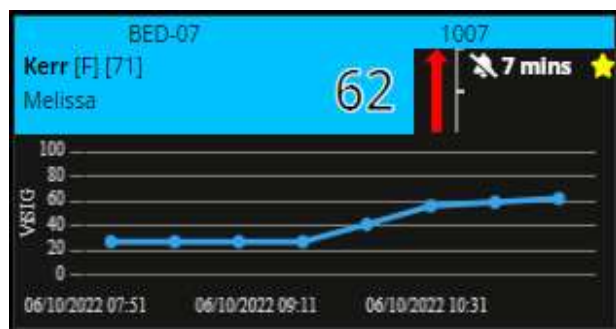|	
Patient Location - Bed: **BED-22**	
Hospital / Patient ID: **1022**	
Patient Name: **Mathew Jarvis**	
Age: **43**	Gender: **Not Specified**

ViSIG Score (63), **Alert Status (Red)** and ViSIG Trend Graph. **ViSIG Alert Active** for **3 Minutes.**

Patient Trend Arrow (Large Red) indicating ViSIG Score increased quickly over defined period**.**

Example 5 – ViSIG Silenced Alert Status

Patient Location - Bed: **BED-07**	
Hospital / Patient ID: **1007**	
Patient Name: **Melissa Kerr**	
Age: **71**	Gender: **Female**

ViSIG Score (62), Alert / Silence Status (Blue) and ViSIG Trend Graph. **7 Minutes remaining before Silence Status times out.** Patient has also been **"Starred"** to appear in **"My List".**

ViSIG Warning Notification Icons

		Flashing Red Fill – Bell Icon. <u>Active</u> **ViSIG Alert** and duration of alert state in hh:mm:ss
		Solid Red Fill – Bell Icon. <u>Acknowledged</u> *ViSIG Alert* and duration of alert state in hh:mm:ss
		Solid Red Fill - Latched Alert Icon. How long in hh:mm:ss since an Active ViSIG Alert has dropped below the High Threshold Limited, without being Acknowledged by a Clinical User.
		Blue Fill – Silenced Bell Icon. Silenced ViSIG Alert and the time remaining before current setting expires in minutes.
- -		**ViSIG Score - - and associated First Calculation Icon.** Indicating the system requires more vital sign data to calculate the first ViSIG Score. A minimum of thirty (30) minutes of data from four (4) vital signs are required to calculate the first ViSIG Score. As the ViSIG Score is calculated every thirty (30) minutes from the time of Admission, the ViSIG Score will timeout after one (1) hour, if no new vital sign data is received during that period.

Vent Status and Starred Patients Icons

	Ven Icon, indicating the patient is **currently receiving mechanical ventilation.** Typically, the vent data is received from a configured interface engine or manually updated via the dashboard using the Drilldown Toolbar.

☆ ★	**Starred Patients,** indicating if a patient has been selected to be viewed via the "My List".

Border Information

	White Border – Patient Selected for **Drill Down Display**
	Yellow Border – Algorithm License Expired or Exceeded Use Limit

Other Symbols

|	
- -	Is displayed when there is no value to be displayed for a Vital Sign or ViSIG Score.
Sys / Dia **(xx)**	Rounded brackets indicate the Mean Arterial Blood Pressure (MAP) value as displayed has been received from the vitals feed. e.g., 130/77 (90)
Sys / Dia **[xx]**	Square brackets indicate the Mean Arterial Blood Pressure (MAP) value has been **estimated using the Systolic and Diastolic values received** from a vitals feed. e.g., 130/77 [90]

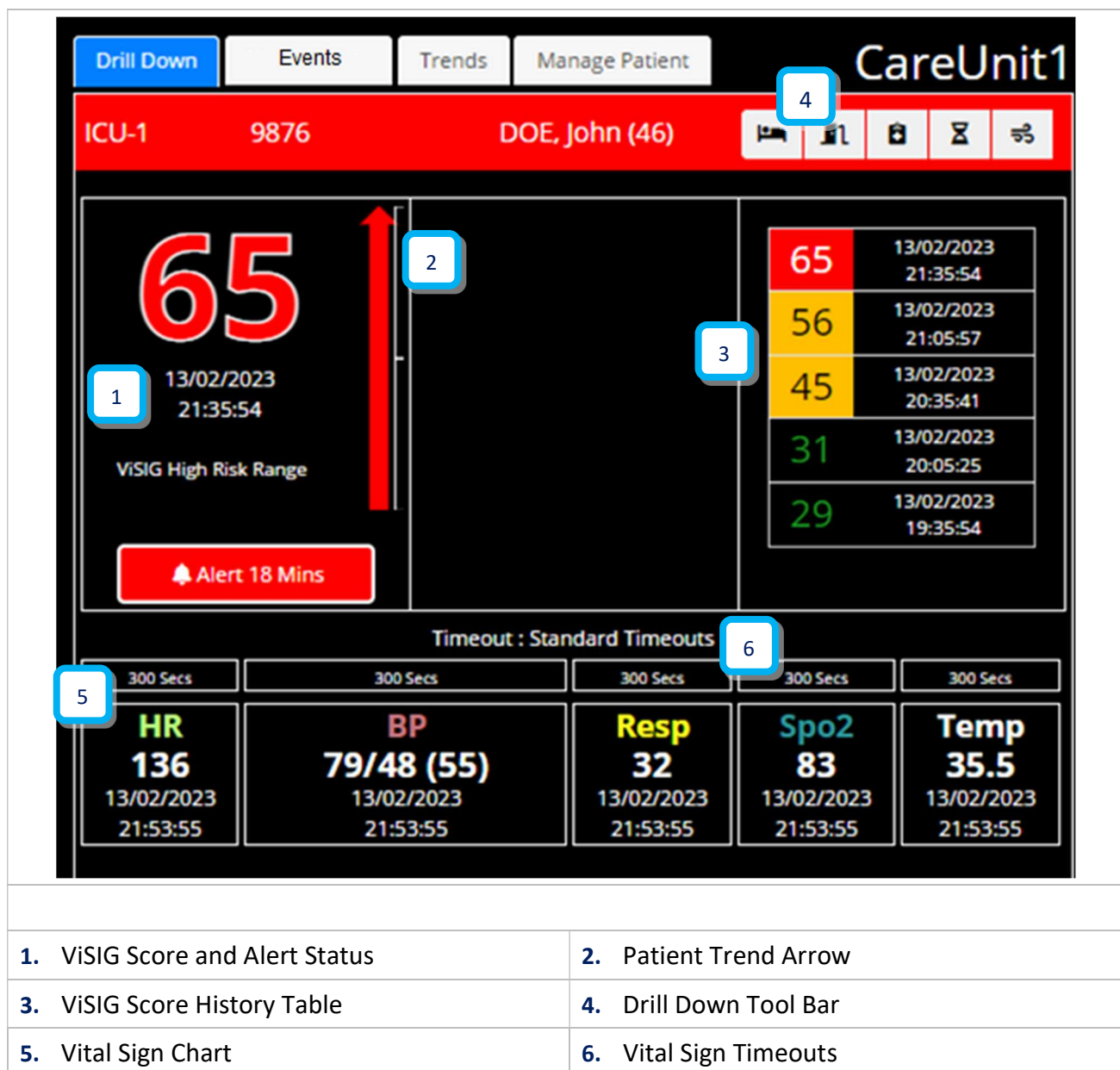## Example Clinical Dashboard and Patient Tiles with all states.
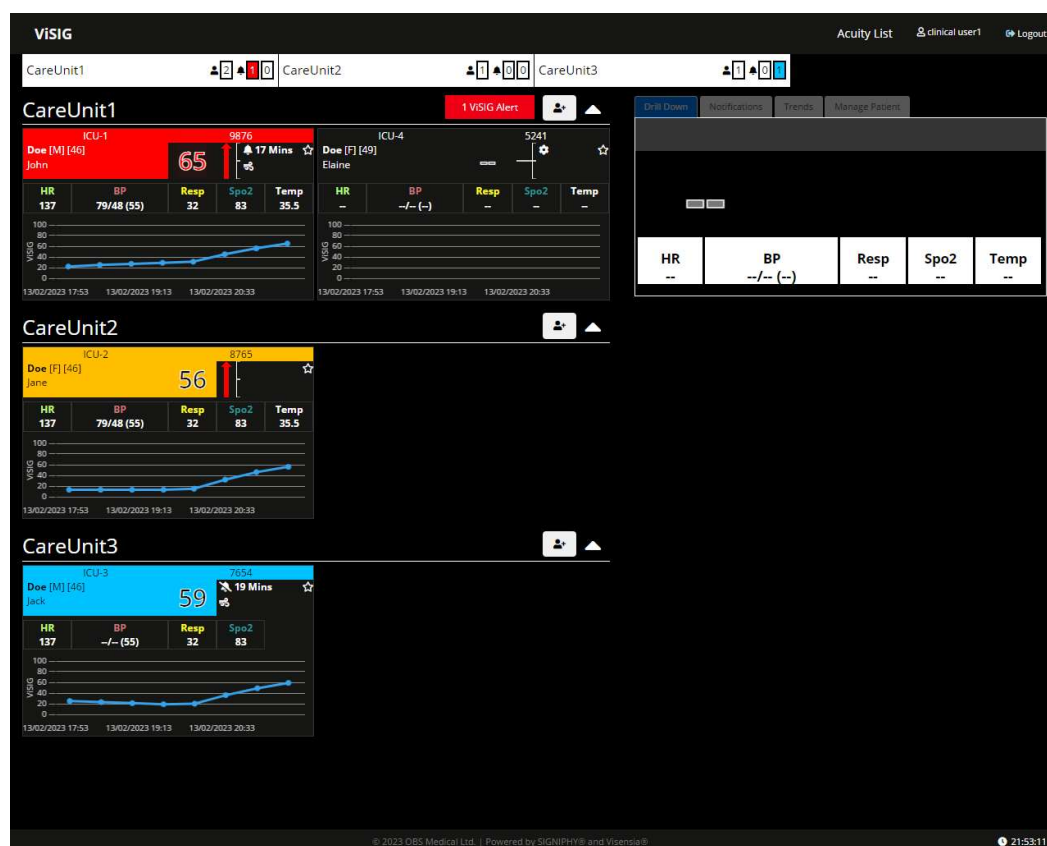
Note: ViSIG requires a minimum of four vital signs over a period of thirty (30) minutes to calculate the first ViSIG Score. During this time the **"First Calculation" Icon** displayed. **Grey Marks - -** will be displayed during this time or when the system is unable to calculate a ViSIG Score.

Note: Users with the authority to **"Input Patient Information"** will still be able to see the Patient Name and Patient ID from the **Manage Patient Tab** even if the PHI information is configured as hidden on the Patient List and Drilldown for that User.

Note: As a Web application, ViSIG is reliant on running via a compatible Web Browser with good network connectivity to ensure uninterrupted access to patient data.

Drill Down

The **Drill Down** display can be a **Fixed area** next to the Patient List or a **Fly In display** that is activated when a **Patient Tile** is selected. The **Drill Down display** will automatically populate when a **Patient Tile** is selected from the **Patient List.**

1. ViSIG Score and Alert Status	**2.** Patient Trend Arrow
3. ViSIG Score History Table	**4.** Drill Down Tool Bar
5. Vital Sign Chart	**6.** Vital Sign Timeouts

The **Drill Down** display provides additional information when reviewing a patient using the following tabs**:**

- **Events Tab**
- **Trends Tab**
- **Manage Patient Tab**

Note: ViSIG dashboards do not support zoom as part of the web application. Zooming may distort or hide certain features so display should be left at 100%.

Note: If you cannot access the system due to poor network connectivity, contact your administrator or attempt to login via another workstation with known network connectivity.

Drill Down Tab

The Drill Down provides more information about the ViSIG Score and patient and consists of the following:

o **ViSIG Score**

The ViSIG Score is a single measure of a patient's current risk level for mortality.

It ranges from 0-100 and as the ViSIG Score increases, so does the patient's probability of mortality without timely intervention.

o **Patient Trend Arrow (PTA)**

The PTA is an score, generated to measure the rate of change of the ViSIG Score over a defined period.
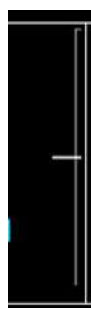
- A Red Arrow indicates an increase in the ViSIG Score
- A Green Arrow indicates a decrease in the ViSIG Score

The larger the arrow, the greater the change to the Score over the defined period.

A grey line indicates no change to the Score during the period.
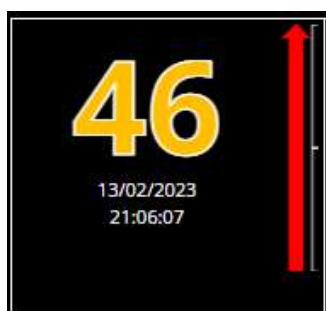
Deterioration – Red Arrow	No Change	Improvement – Green Arrow

o **ViSIG Score History Table**

Shows a list of the last five ViSIG Score calculations along with the date and time for each calculated risk score.

o **Drill Down Tool Bar**

The drill down tool bar allows you carry out various functions via the main dashboard by displaying additional dialogue box for the selected function.

	Transfer Patient	Select the Transfer Patient icon to reassign the selected patient to a new location within the ViSIG System.
	Discharge Patient	Select the Discharge Patient icon to discharge the selected patient from the ViSIG System.
	Manual Observations	Select the Manual Observations icon to manually document a set of vital sign observations for a selected patient.

Icon	Name	Description
	Vent Status	Select the Vent Icon to manually document if a patient has started, stopped, or resumed mechanical ventilation. Typically, the vent data is received from a configured interface engine and as such the icon is then hidden.
	Vital Sign Timeouts	Select the Vital Sign Timeout icon to manually adjust the selected patients vital sign timouts from a configured selection to suite the patients type of monitoring. i.e. Continuous, Episodic or Hybrid.
>	**Close Drilldown**	Select the Close Drill Down icon to return to the Patient List to review another patient as required. Only visible when the Drill Down is active.

o **Vitals Chart**

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

ViSIG Score Warning Thresholds

The **ViSIG Score** is **Colour Coded** according to the **Warning Threshold Ranges defined** for each monitored Care Unit. These are fixed and cannot be altered. Default set-up is outlined below:

Warning Thresholds		Threshold Warning Notification	Enable Latching	Lower Limit	Upper Limit
☑	**High Risk Range**	☑	☑	59 🔔	100
☑	**Medium Risk Range**			38	58
☑	**Normal Risk Range**			0	37

o A **ViSIG Alert** is generated when the **lower limit of the High-Risk Range Threshold (59)** is reached or surpassed.

o ViSIG Alerts generate a **visual (Red Flashing)** and associated **audible sound** when triggered.

You can view the Care-Units **ViSIG Score Warning Thresholds** via the **Drill Down display – Manage Patient TAB.**


Note: How the **VISIG Alerts** and **VISIG Warning Thresholds** are responded to, are defined by your own Organization and Care Unit protocols.
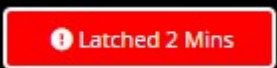
ViSIG Alerts

All Clinical dashboards will provide a **visual alert** when the **ViSIG Score equals or exceeds** the defined **Algorithms High Risk Warning Threshold.**

- The **Unit Selector** will update to display an **Active ViSIG Alert** for a particular Care-Unit.

- The **border** of the **Patient Tile** will begin to **flash red**.
    - When an alerting Patient Tile is selected, the Drill Down Tab, is also colored red and you can then interact with the Alert Status using the **Alert Button** or **Latched Alert Button**.

    - The system can also be configured to **sound an Audible Alert** in addition to the visual alert.
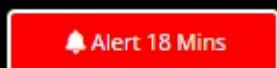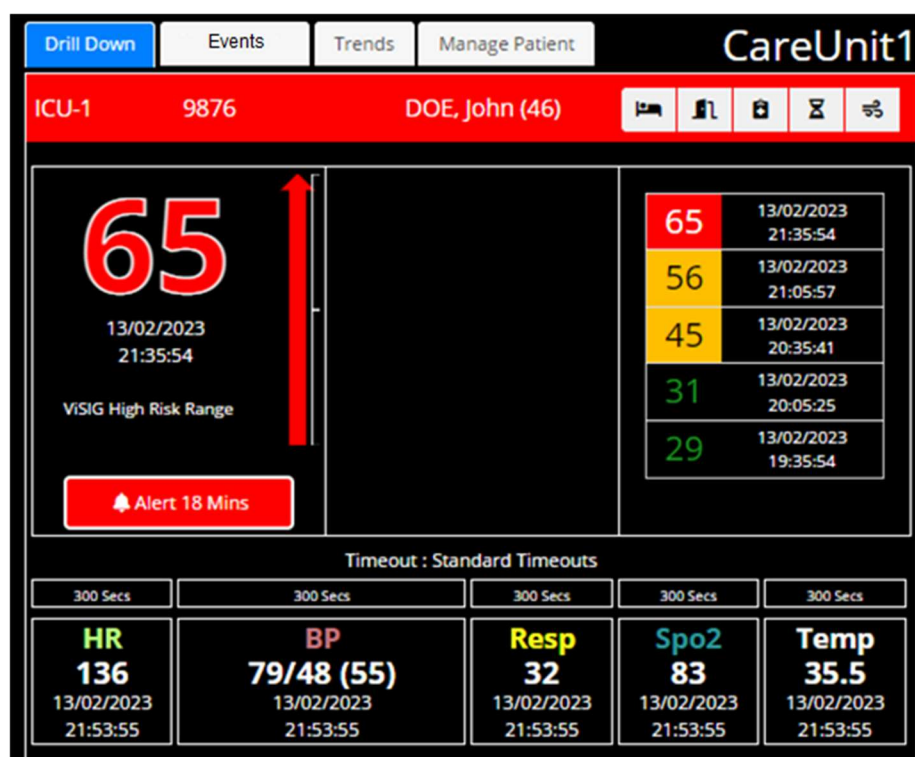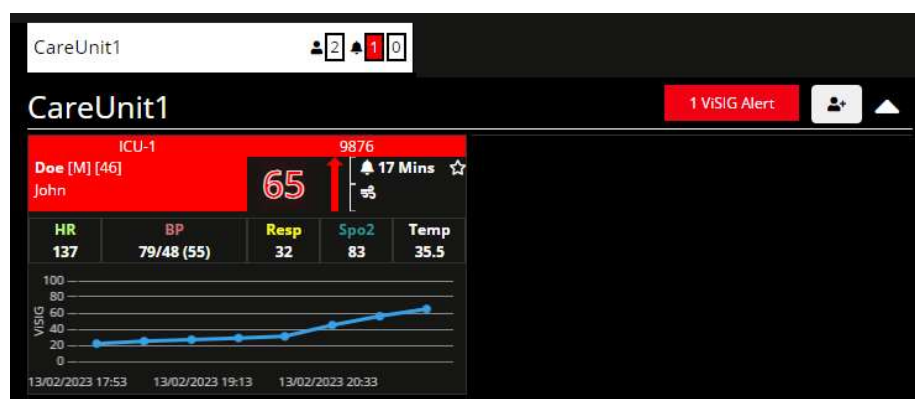
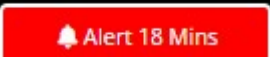|	
	The **Alert Button** and how long the **Alert Status has been active for,** will be displayed.
	If **Latched Alerts** are enabled, the **Latched Alert Button** and how long the Latched Status has been active for, will be displayed.

Silence a ViSIG Alert

Silencing an ViSIG Alert acknowledges a clinical / technical response to the underlying cause of the ViSIG Alert has been carried out according to defined hospital protocol.
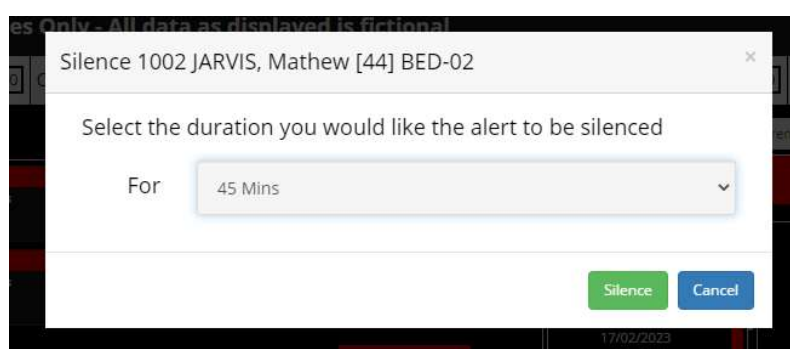
To **silence** an ViSIG Alert

1. Select the **Patient Information Tile** with the **Active ViSIG Alert.**

2. Using the **Drill Down** display – select the **Alert Button** from the **Drill Down Tool Bar.**

🔔 Alert 18 Mins	Select the **Alert Button** to Silence an active ViSIG Alert. From the drop down options available, select the time period required and **select > Silence**

3. A dialogue box will be displayed showing you a list of available time periods to Silence the ViSIG Alert for.

4. The **Patient Information Tile** border will change from an **Alert Status to the Silence Alert Status** indicating the ViSIG Alert has been **Silenced.**

5. The **Time Stamp** will now show time remaining, before the **Silenced Alert will time-out** e.g., 45 Minutes.

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

Note: The **Unit Selector** will update to show the number of Active Silenced Alerts there are for the Care Units assigned to you.
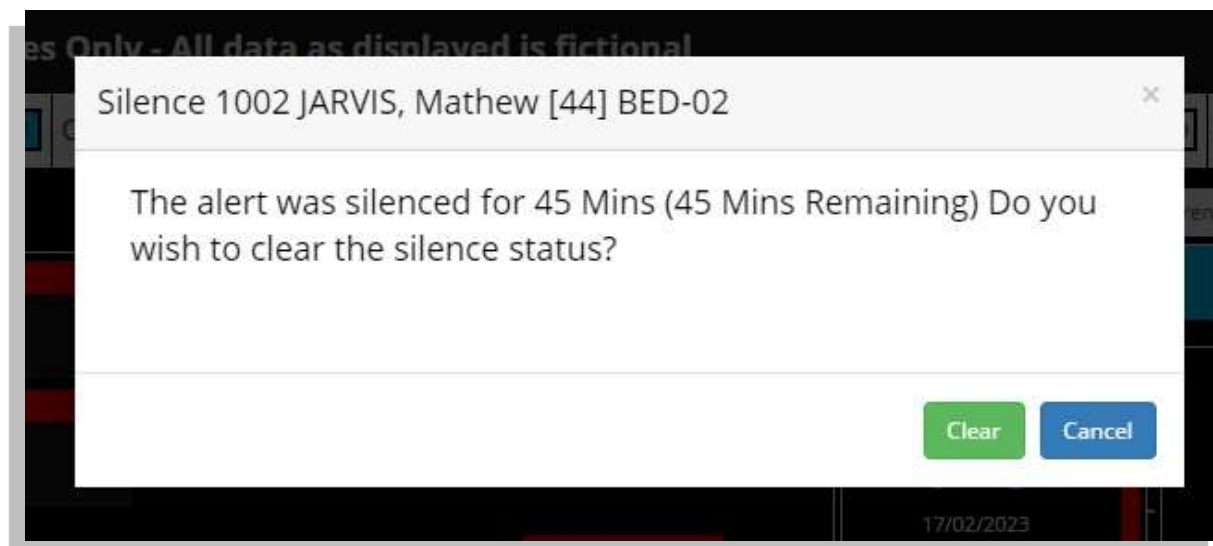
Clear a ViSIG Silenced Alert

Using the **Drill Down** display

1. Select the **ViSIG Alert Icon (Silenced)** from the **Drill Down Tool Bar.**

Silenced 45 mins	Select the **Silenced Button** to clear the Silenced Alert status applied. Check the patient information and **select > Clear.**

2. A dialogue box will be displayed confirming you wish to clear the silence status.

Silence 1002 JARVIS, Mathew [44] BED-02   ×

The alert was silenced for 45 Mins (45 Mins Remaining) Do you wish to clear the silence status?

Clear   Cancel

17/02/2023

3. Select the **Clear** button.

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

5. If the ViSIG Score is still within the High Threshold Range the patient tile will start to Alert again. Apply a new Silence period as required.

> **Note:** If the **ViSIG** falls **below the defined High Threshold Lower Limit value**, then the ViSIG Alert Status (both Visual and Audible) is automatically cleared from the Patient List and Drill Down Tab.
>
> **Note:** If Latching is enabled, then the ViSIG Alert will remain in place until the latched alert is acknowledged.
>
> **Note:** The actions of Silencing and Removing a Silenced Alert are documented via the Events Table.

ViSIG Latched Alerts - Acknowledgment

The system can be configured to Latch ViSIG Alerts to ensure any High Threshold Breaches of the ViSIG Score are acknowledged by a Clinical User if they subsequently drop below the threshold before the original ViSIG Alert is silenced.

Latched 2 Mins	Select the **Latched Alert Button** to acknowledge an VISIG Alert status that was not silenced, before the VISIG dropped below the High Threshold limit set. Only visible when Latched Alert status is active. Select > Confirm to remove latched alert.

Latched Alerts appear the same as an VISIG Alert, however instead of **"Silencing"** the alert, you will need to **"Acknowledge"** the VISIG Alert has occurred in the past.

You should always review the patients' overall condition and risk of deterioration before acknowledging.

Once acknowledged the **Patient Tile** will revert to the current Threshold Status and colour.

ViSIG Alert Notice Box

Each Care Unit listed has an associated '**ViSIG Alert Notice Box'**.

This allows caregivers to quickly identify any **ViSIG Alerts,** even if the Care Unit in question has been collapsed while reviewing patients in another Care Unit.

Trends Charts

The Trend Chart shows, in graph form, a history of the selected patient's **ViSIG** and a history of the values for each monitored **Vital Sign**.

- You can configure the system to display the various **Trend Graphs** and associated **Upper/Lower Threshold limits** for the **ViSIG** and **Monitored Vital Signs** using the **Trend Graph Configuration Icon.** ⚙

    o By unselecting a vital sign or even the VISIG from the Trend Graph Configuration settings, the graphs will be redrawn, and all unselected items will be hidden / removed.

    o You can select the items again for display within the trend graph as required.

- You can temporally change the **time interval for the historic graphs** by clicking the options available.

Trends	4hr	8hr	12hr	24hr	48hr	72hr

- You can expand the trend graph to full screen using the **expand graph icon [ ]**
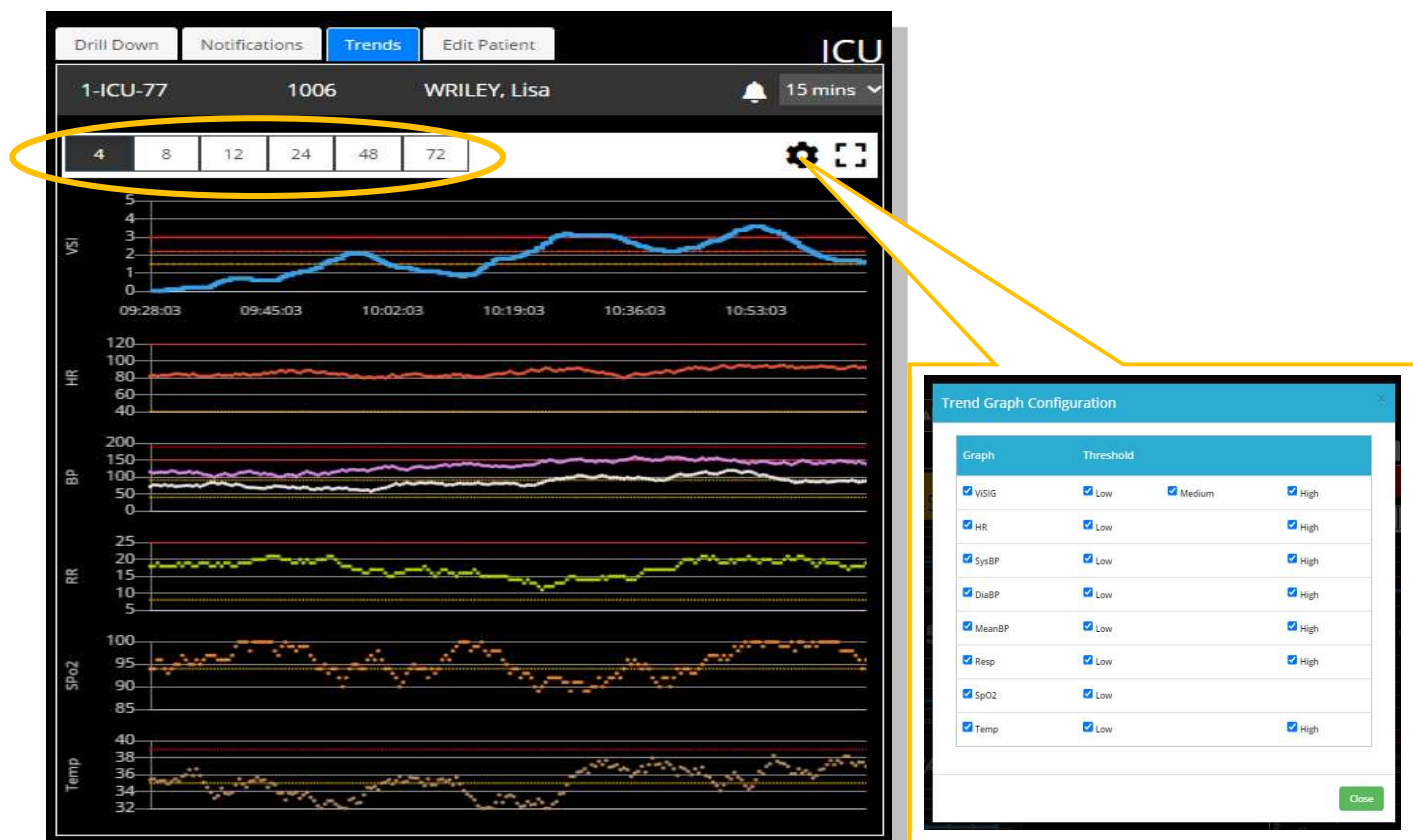
Panning and zooming is available on the both the ViSIG and Vitals graphs.

You may use these features to alter the display to focus on regions of the graph. You will need a mouse and keyboard to use this functionality.

- ▪ **To Pan**
  - o Using your mouse, **left click on the graph and drag the image** (Left or Right) and release when the display shows the portion of the graph that is of interest.

- ▪ **To zoom**
  - o Using your keyboard, **hold down the Alt key** and using the mouse, **left click on the graph and drag the cursor to draw a grey box** around the area into which you would like to zoom. Repeat as required until the display shows the portion of the graph that is of interest.
  - o Select one of the default time intervals to reset the graph.
  - o Hovering your mouse pointer over individual trend graphs will reveal the values for each recorded vital for the date / time.

Note: The available time intervals displayed are defined by your Hospital Admin.

Note: Changing the time interval will cause the selected Trend Chart to be redrawn as required. The graph will also be redrawn every minute to include any additional vital sign data received.

Vitals Chart

The **Vitals Chart** can be configured to display the current vital signs for the patient, their values, and the times at which the vital signs were received.

Not all vital signs may be shown, depending on how ViSIG has been configured.

How long a Vital Sign is displayed via the Vitals Chart and used by the Algorithm when calculating the ViSIG Score, is highlighted in the Timeout box above the Vital Sign.

In this example 300 seconds or 5 Minutes.

In addition, the box for each vital sign will change color to indicate whether data for the configured vital sign has ever been received in the past or stopped (timed out) for whatever reason.

	White Background – No data ever received for this vital sign.
	Grey Background – Data received in the past but has now stopped.
	Black Background – Data is currently being received for the associated vital sign.
_ _	**No available data -** Indicating that there is no valid data available, for example, if the vital signs have not been entered, or the vital sign has timed-out for consideration when calculating the current ViSIG Score.

You should always investigate the underlying causes as to why an expected vital is not being received or has stopped being transmitted to the ViSIG system. Missing vital signs can affect the sensitivity and specificity of the ViSIG Score.

More information about Timeouts and how to change them can be found in the **Vital Sign Timeout Settings section.**

Events Chart

The Events Chart details all historic ViSIG Alerts, Vitals Warnings and any interventions or changes made by Users.

1. Using the **Drill Down** display – select the **Events TAB.**
   - A list of all enabled and logged Events will be displayed.

2. Filter the Events Table by selecting the option required and press **OK.**
   - Algorithm Events
     - VISIG Alerts, Silence Alerts and Latched Alerts
       - Acknowledged Latched Alerts
       - Cleared Silenced Status
     - ViSIG Threshold Breaches
   - Vent Events
     - Start and Stop
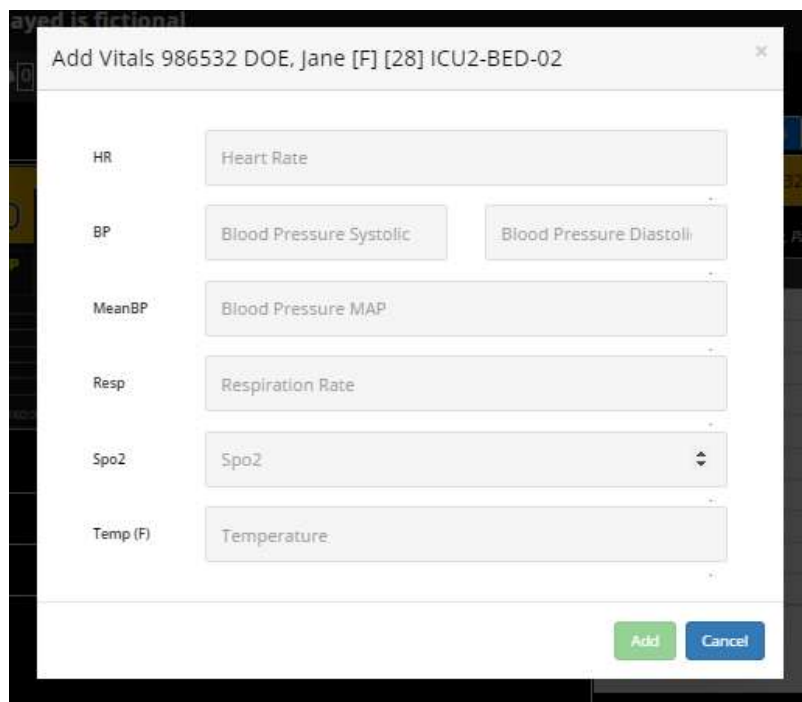   - Patient Events
     - Admit and Transfer

Manually Input Vital Sign Data (Manual Observations)

Vital sign data can be manually inputted for a selected patient as part of a routine observation round, or to supplement a patient monitoring device / solution that does not support that vital sign.

1. Using the **Drill Down display** – select the **Add Vitals Icon** from the **Drill Down Tool Bar**

2. A dialogue box will be displayed, with a list of Vital Signs that can be inputted.

3. Input the value for each vital sign observed, and press **Add** button.

Note: There are validation checks to ensure the value inputted does not exceed the systems expected Maximum and Minimum amounts for the inputted vital sign. You will be required to input an expected value before being able to select Add.

4. The dialogue box will disappear, and the updated Vitals Chart will now be updated to display the observed Vital Sign values and associated Timestamp.

5. The **ViSIG** will then take into consideration the manually updated vital sign when calculating the next ViSIG Score – every thirty (30) minutes.

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.

Note: Any manually entered vital signs will be overridden as soon as new vital sign data is received from a configured patient monitoring system that is outputting continuous vital sign data.

Vital Sign Timeout Settings

Preconfigured Vital Sign Timeouts are available to apply to patients as part of your Care-Units monitoring needs.

Timeouts help Clinical Users to idenitfy vital signs monitored by ViSIG that have for what ever reason been disconnected or are no longer being transmitted by the primary device (Patient Monitor / Sensor) thus not being incorporated in the next calculation of the ViSIG Score.

Use the Vital Sign Timeout icon to manually adjust the selected patients vital sign timouts from a configured selection to suite the patients type of monitoring.

Example TimeOuts:

Option	Monitoing Type	Timeouts Applied
1.	Continuous Monitoring	- All vitals set to time out after 300 Seconds (5 Minutes)
2.	Episodic Monitoring	- All vitals set to time out after 4 Hours
3.	Hybrid Monitoring (Mix of Continuous & Epesodic Vital Signs)	- Some Vitals set to time out after 5 minutes - Some Vitals set to time out after 1 hour

1. Using the **Drill Down display** – select the **Vital Sign Timeout Icon** from the **Drill Down Tool Bar**

Vital Sign Timeouts

2. A dialogue box will be displayed, with a list of pre-configured Timeout Groups.

3. Select the **appropriate Timeout option** for the monitored patient.

4. Select the **Change button** to apply the new Timeout setting.

5. The dialogue box will dissapear and the Vitals Chart will be updated to reflect the new TimeOut option chosen.
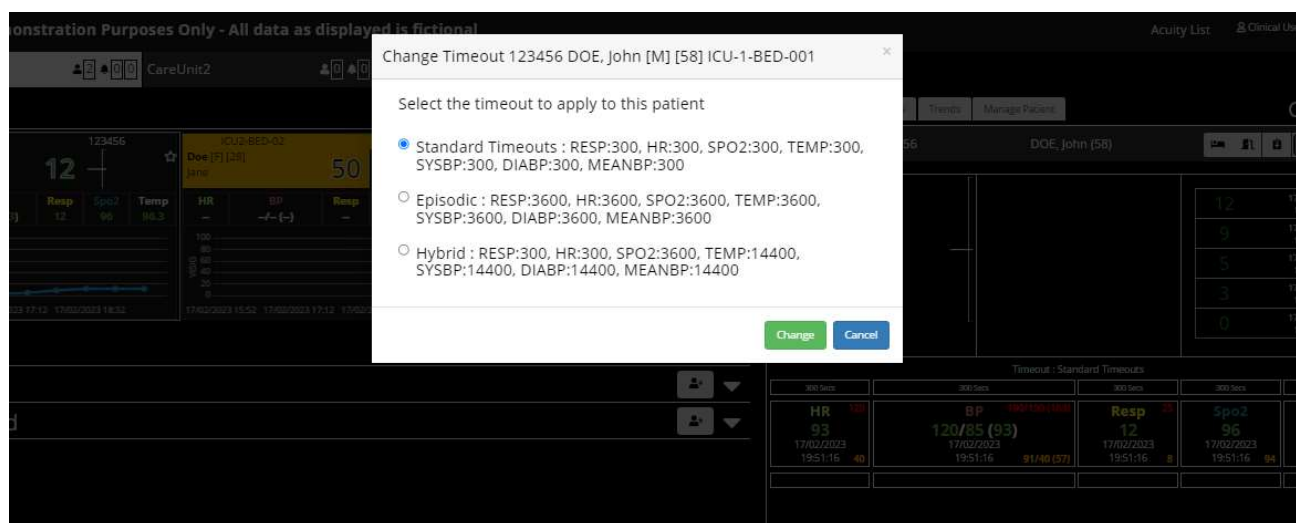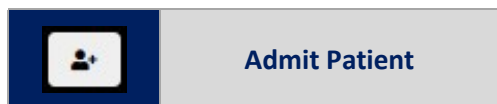
Manually Admitting a Patient to a Care-Unit

Patients should automatically be admitted to a Care-Unit as part of an configured ADT set-up.

However if you wish to **Manually Admit** a patient to a Care-Unit then action the following:

1. Select the **Admit Patient** button from the associated Care-Units Patient List.

2. The **Admit Patient** display is now shown for the **Care-Unit** selected.

3. Enter the **Patient ID, First Name, Last Name, Date of Birth (DOB), Gender, Room No#** and **Bed Location No# as required** and select **Save.**

4. The patient will now be added to the Care-Unit and should be visible in the **Patient List** for the Care-Unit.

5. You can now **manually add vitals** for the patient via the **Drill Down Display** to calculate the VISIG as required.

Note: If ADT is configured for the Care-Unit in question, all ADT information matching **Patient ID** and **Patient Name** received will automatically override any manually entered patient information such as **Location** and **Vital Sign Data.**

Note: Depending on the system configuration, options to Admit, Transfer and Discharge patients manually via the Dashboard may be disabled and as such not displayed via the Clinical Dashboard.

# Transferring a Patient to a different Care-Unit

Patients should automatically transfer between Care-Units as part of an configured ADT set-up.

However if you wish to **Manually Transfer** a patient to a different Care-Unit then action the following:

1. Select the Patient from the **Patient List** you wish to **Transfer.**

2. Using the **Drill Down display** – select the **Transfer Patient Icon** from the **Drill Down Tool Bar.**
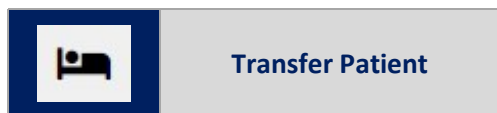
3. A dialogue box will be displayed, with options to **transfer a patient From and To, a new Room and Bed location.**
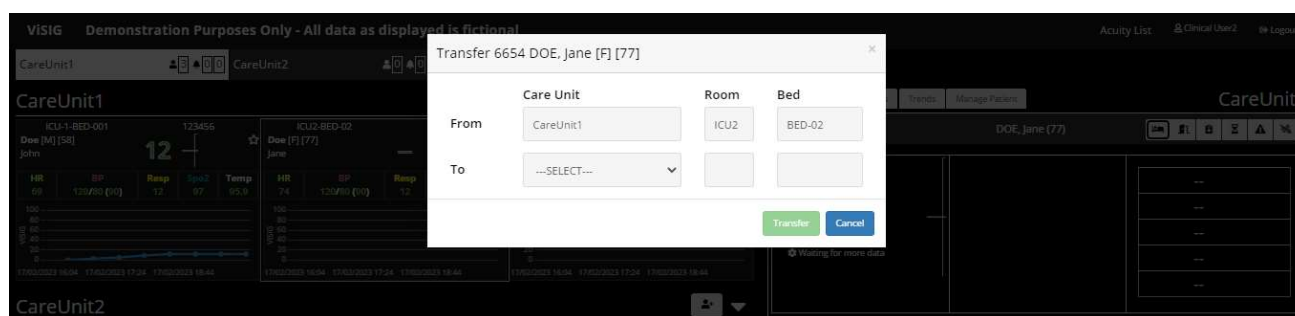
4. Select the Unit you wish to transfer the Patient to and input the Room and Bed location and select the **Transfer button.**

5. The patient will now be transferred to the new Care-Unit and will be visible in the **Patient List** for that Care-Unit.

   ▪ The Events Table will detail the transfer request, as well as the User actioning the request.

Note: All historic information for the monitored patient should still be accessible providing an overview of the patient journey.

Note: Depending on the system configuration, options to Admit, Transfer and Discharge patients manually via the Dashboard may be disabled and as such not displayed via the Clinical Dashboard.

Discharging a Patient

Patients should automatically discharge from a care-unit via ADT functionality, which is configured during Installation and Set-up.

However is you wish to **manually Discharge** a patient from a Care-Unit then action the following:

1. Select the Patient from the Patient List you wish to Discharge.

2. Using the Drill Down display – select the Discharge Patient Icon from the Drill Down Tool Bar.VS
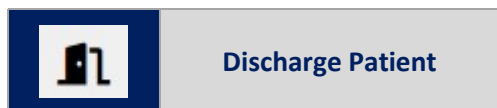
Discharge Patient

3. A dialogue box will be displayed, confirming you wish to discharge the selected patient.
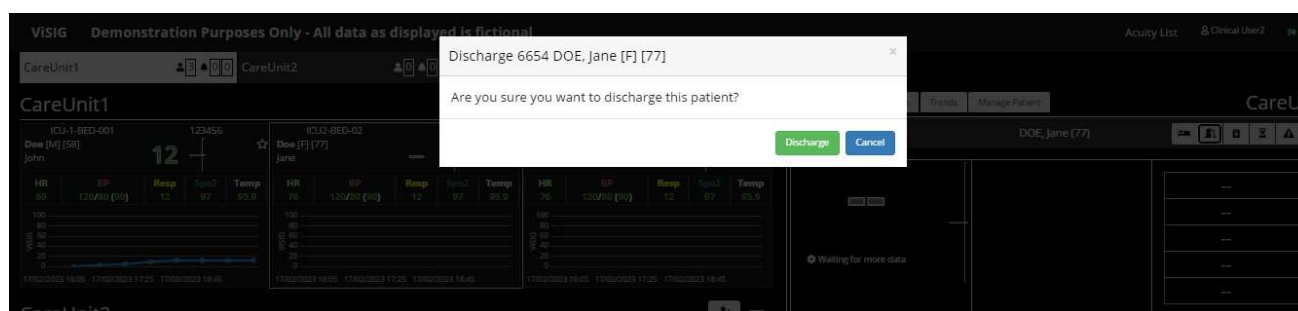
4. Select the **Discharge Button.**

5. The patient should now be removed from the Patient List for the selected Care-Unit.

6. As the patient has now been discharged from the ViSIG system, you can no longer access the Drill Down to review the Events Tab and associated Graphs and Charts.

Note: If ADT receives some information after you have manually discharged the patient, the system will automatically re-admit the patient to the Unit as per the ADT Message and update as per the message received.

Note: Until the configured ADT system sends out Discharge message, the patient could re-appear in the Patient List for the Care-Unit even if you have manually Discharged the patient as ADT takes priority.

Note: Depending on the system configuration, options to Admit, Transfer and Discharge patients manually via the Dashboard may be disabled and as such not displayed via the Clinical Dashboard.

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/ViSIG-user-guides/

Sever Downtime

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

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

Whenever the server is down, the clinical dashboard will display a message informing the Clinical Users the server is currently in downtime and to contact technical support if the issue persists for more than 15 Minutes.

Note: As a Web application, ViSIG is reliant on running via a compatible Web Browser with good network connectivity to ensure reliable access to patient data.

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Issue Date: **25 March 2025**