
Wireless Patient Monitoring System

(SH202001 EU)

(SH202000 US)

User Manual

Sensium®
Wireless Vitals Monitoring

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About this manual

This user manual provides the necessary information for the operation of the Sensium® Wireless Patient Monitoring System (TZ202001 EU & TZ202001 US).

The information contained in this manual is subject to change without notice. No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent of Sensium Healthcare Ltd.

It is intended that the Sensium® system is only to be used by qualified healthcare professionals who have previously received training on the operation of the system.

The Sensium® Wireless Patient Monitoring System is used to monitor a patient's vital signs, including heart rate, respiratory rate, and axillary temperature with a view to detect early patient deterioration.

Symbols

This document uses the following symbols:



Warnings indicate potentially hazardous situations which, if not avoided, could result in injury or death.



Caution indicates conditions that could damage equipment or other property.



Notes contain supplementary information or emphasize a point or procedure.

Please ensure all warning and caution icons noted in this User Manual are reviewed, understood and followed.

Chapter 1 System description

1.1 Intended use

The Wireless Monitoring System is intended for use by health care professionals for routine surveillance of patient physiological parameters to include, heart rate, respiratory rate and axillary temperature, posture, and activity. Data is transmitted wirelessly to a central location. Notifications can be prospectively set to notify healthcare professionals to excursions outside of selected parameters.

The device is not intended to be used on critical care patients and is intended to supplement vital signs monitoring by healthcare professionals, not to replace current standards of care. The device is intended for use on general care patients and on patients who are 18 years of age or older.

Intended Environments

The SensiumVitals System (SH202001 / SH202000) is intended for Professional healthcare facility & Home Healthcare environments.

It is not suitable for use near active HF surgical equipment and the RF shielded room of magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

1.2 Indications

The Sensium® Wireless Patient Monitoring System is intended to supplement vital signs monitoring by healthcare professionals, not to replace it. The device is intended for use on general care patients and on patients who are 18 years of age or older.

Heart rate /MIN monitoring

- Uses single-lead electrocardiogram (ECG) to detect the heart rate (HR) only.
- Provides intermittent HR readings in a range of 30–200 beats per minute (BPM) when conditions are appropriate.

Respiratory rate /MIN monitoring

- Uses impedance pneumography to detect respiratory rate (RR).
- Provides intermittent RR readings in a range of 5–60 breaths per minute (BrPM) when conditions are appropriate.

Axillary temperature monitoring

- Measures the axillary temperature using a sensor placed underneath the axilla.
- Provides intermittent axillary temperature readings in a range of 32 to 44°C (89.6 to 111.2°F) when conditions are appropriate.

Activity/Posture Monitoring

- Uses a 3-axis accelerometer to detect physical movement.
- Provides estimates of activity level (light or moderate), or posture if the patient is inactive.

1.3 Contraindications

DO NOT use the Sensium® Wireless Patient Monitoring System as follows:

- The system is not intended for use on critical care patients.
- The system is not intended to replace routine vital signs monitoring by healthcare professionals.
- The device is not designed for use on patients under the age of 18 years.
- The system is not designed for use with pacemakers, implantable defibrillators, or neurostimulators.
- Do not use to diagnose the absence of a heart rate.
- Do not use to diagnose any forms of arrhythmia or any other conditions usually detected through an ECG.
- Cannot be used to detect rapid drops of core body temperature.
- The system is not intended for home-use patients who are mentally incapacitated, through medical condition or cognitive impairment.

1.4 General warnings and cautions

General warnings

	WARNING—The system is not intended for use on critical care patients.
	WARNING—Remove patch before defibrillating the patient.
	WARNING—Do not apply the patch on breached or compromised skin surfaces.
	WARNING—The patch is a single-use device and cannot be re-used on different patients or after the system requires the patch to be replaced. Patches can be temporarily removed from patients during treatment(s); new electrode pads should be used when reattaching a patch.
	WARNING— Ensure patient checks are carried out upon receiving notification.
	WARNING—Be sure to place the patch exactly as shown in these instructions. An improperly placed patch can return false data.
	WARNING— Patient interference with the patch can cause false data to be sent.
	WARNING—Always verify that the patient's information is correct before any clinical intervention.

	WARNING—Make sure that yellow and red vital sign limits are appropriate to the patient's condition. Improper vitals configuration can cause potential patient safety issues.
	WARNING - Used patches may be contaminated and should therefore be disposed of using local clinical waste procedures.
	WARNING –If for any reason the UI (web) is not working as expected manual observations should continue to be taken and hospital; IT informed using standard hospital procedures
	WARNING –If for any reason a patient is not being monitored by Sensium ensure that manual patient observations are continued in accordance with local hospital procedures
	WARNING - If evidence of suspected electrical damage is identified, do not connect bridge and/or disconnect bridge immediately
	WARNING - Use of this equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
	WARNING - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the Sensium Vitals System (SH202001 / SH202000), including cables. Otherwise, degradation of the performance of this equipment could result.

General Cautions

	CAUTION—The Patch is a radio frequency (RF) emission device and should not be used in RF sensitive areas.
	CAUTION—The system is not designed for use near magnetic resonance imaging (MRI) equipment. Patch must be removed from any patient about to undergo an MRI.
	CAUTION—The system is not designed for use near X-ray computed tomography (CT) equipment. Patch must be removed from any patient about to undergo a CT scan.
	CAUTION—The patch is designed to be shower-proof, but vital sign readings may be temporarily unavailable during a shower dependent on the condition of the ECG electrodes used.
	CAUTION – The Patch is not designed to be immersed in water or any other liquid.
	CAUTION - Electrode selection can significantly affect the quality and reliability of information provided by Sensium®. It is recommended to use high quality disposable

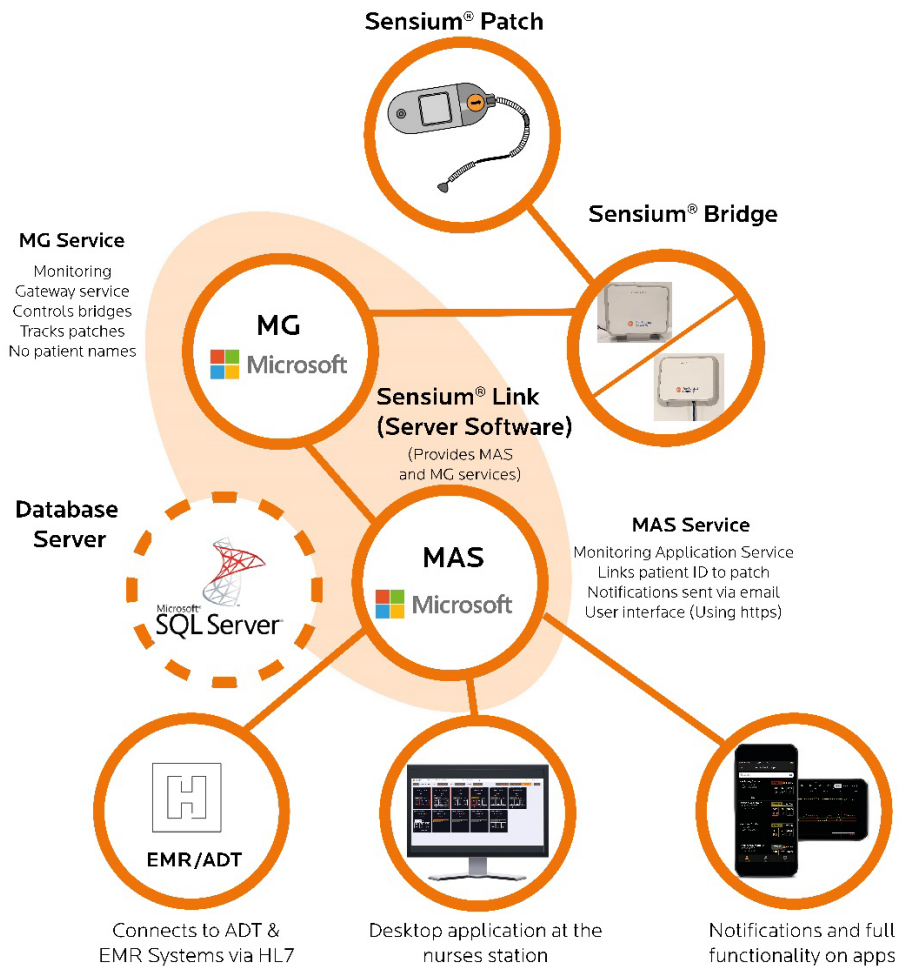
	electrodes designed for continuous ECG monitoring and to regularly replace electrodes. The manufacturers IFU for the selected electrodes must be followed at all times
	CAUTION – Thorough skin preparation can significantly improve the quality and reliability of information provided by Sensium®. It is recommended to ensure good skin preparation prior to electrode application.
	CAUTION — Once a patch has been activated it cannot be manually de-activated.
	CAUTION—Make sure the activation tab opening is properly sealed after the patch has been activated. Doing this avoids patch malfunctions due to moisture ingress.
	CAUTION - It is possible that a loss of communications between parts of the system is lost due to EM Interference. In this case the Clinician is notified that communications is lost and that that the information presented is not current.
	CAUTION- The Sensium Patch is restricted to use on one patient at a time.
	CAUTION - The home system requires a usable mobile coverage.

1.5 System components

This section describes the system components, patch components, and the main screens of the Wireless Monitoring Application.

System components

System components and descriptions are provided in the following graphic and table.



System component descriptions

Item	Description
Sensium® Wireless Patient Monitoring Patch (SH202165 US & SH202166 EU)	Collects and transmits vital signs data from patients to the bridge.
Sensium Hospital Bridge (SH202070 US & SH202071 EU) Sensium Home Bridge (SH202220 US & SH202221 EU)	Sends the vital signs data from each patch to the MG Server.

Item	Description
Application Server Provides MG and MAS Services	Provide a link between the bridges and the Wireless Monitoring Application. Manages vital sign data and notifications.
Wireless Monitoring Application (User Interface)	Displays vital sign data and notifications. Caregivers can use it to access system features.
Sensium mobile apps (iOS & Android)	Displays vital sign data and notifications. Caregivers can use it to access system features.
Other notification Alerts	Can be configured to work with Pagers



It is possible that a loss of communications between parts of the system is lost due to EM Interference. In this case the Clinician is notified that communications is lost and that the information presented is not current.

System component Installation

All system components need to be installed as per SH-FCS-FAE-0002

MAS Installation Guide

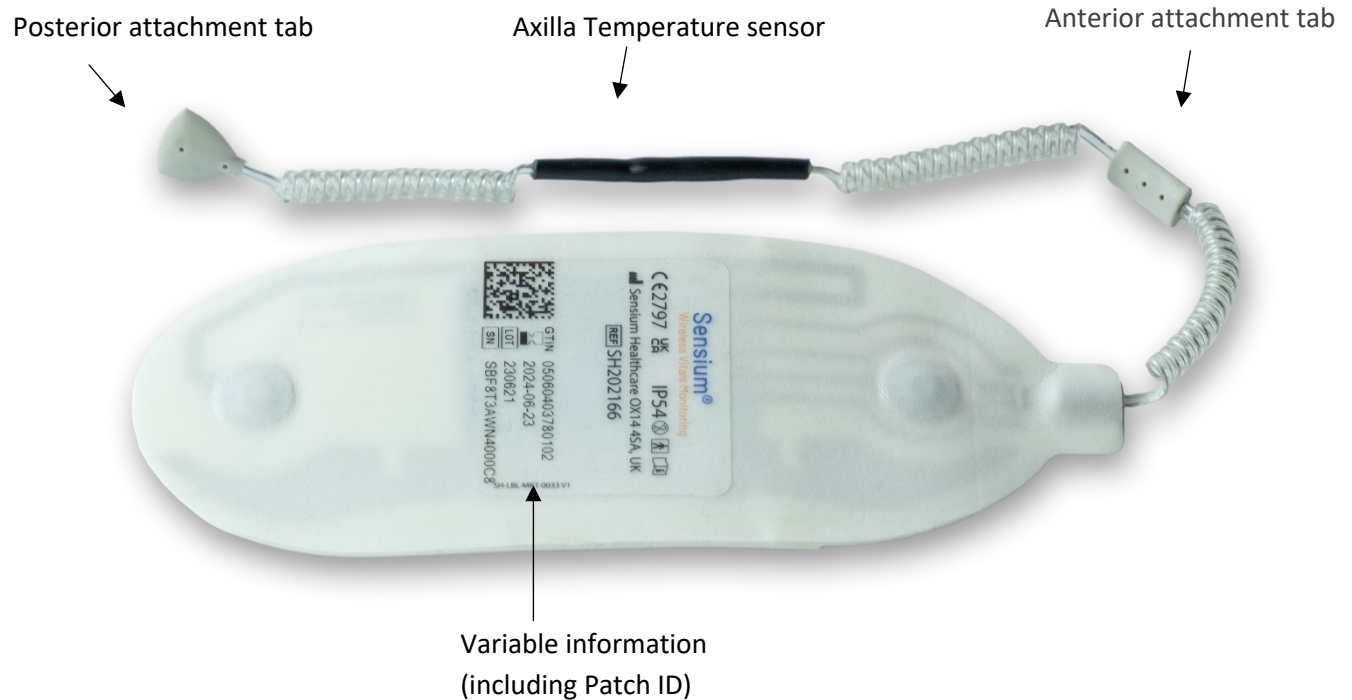
Contact details for persons designated as qualified to perform the installation are available from:

Sensium Healthcare Ltd,
115 Olympic Avenue,
Milton Park, Abingdon,
OX14 4SA, United Kingdom
Tel: +44 1235 438950
Email: info@sensium.co.uk
www.sensium.co.uk

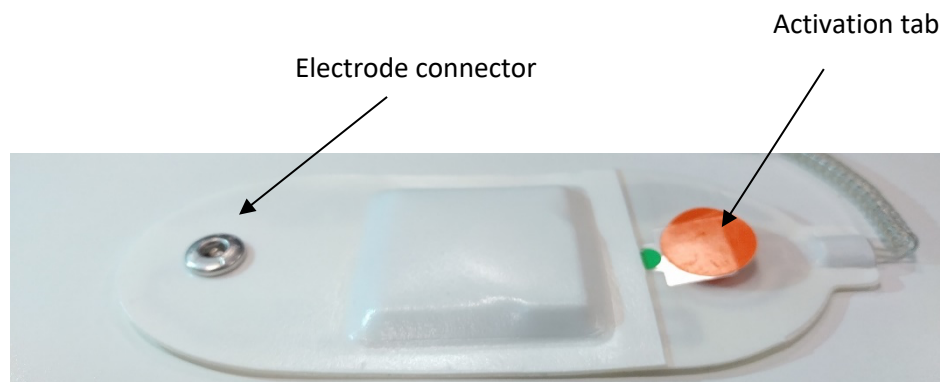
Patch components (SH202165 US & SH202166 EU)

The single patient use disposable patch, when applied to the patient and activated, collects and transmits patient vital sign data: heart rate, respiratory rate, and axillary temperature; and assessment of patient activity/posture. The vital sign data are then displayed on the Wireless Monitoring Application screens.

Font:



Back:



The patch can be turned off by using the replace patch section 2.8.3 or remove patient 2.8.5 functions

Patch component descriptions

Item	Description
Electrode connectors	Connectors on the underside of the patch where monitoring electrodes are attached.
Patch ID	Barcode and number which uniquely identify the patch.
Activation tab	Removing this tab activates the patch.
Axilla temperature sensor	Used to measure the patient's axillary temperature.
Attachment tabs	Used to secure the temperature sensor in the proper location.

1.6 Bridge components

The Bridge units are mounted around the ward and hospital, or placed near a patient in the 'home setting', to communicate with the Patches being worn by patients. LED indicators on the top panel show the status of Bridge power, Server and Patch communications

Bridge Unit

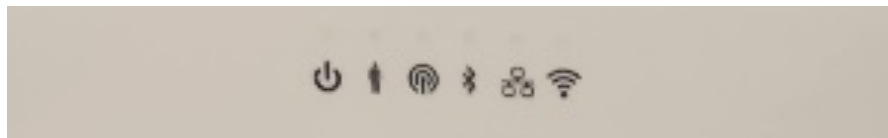


Hospital Bridge
SH202070 &
SH202071



Home Bridge
SH202220 &
SH202221

Bridge indicators



		Colour	Indicates
	Power	Green	On
	Patch	Green	Patch connected
		Amber	Ready for Patch connection
	Cellular	Green	Connected to MG
		Amber	Connected to a network

		Colour	Indicates
	Bluetooth (Hospital only)	Green	Connected to a smart device
		Amber	Interface connection
	Ethernet (Hospital Only)	Green	Connected to MG
		Amber	On network but not yet connected to MG
	Wifi (Hospital Only)	Green	Connected to MG
		Amber	On network but not yet connected to MG



The Bridge can be turned off by removing the ethernet cable or the power supply cable from the device

1.7 Display Information

The optimum screen display for the application is as follows:

Screen resolution: 1920 x 1080 pixels

80-100% zoom

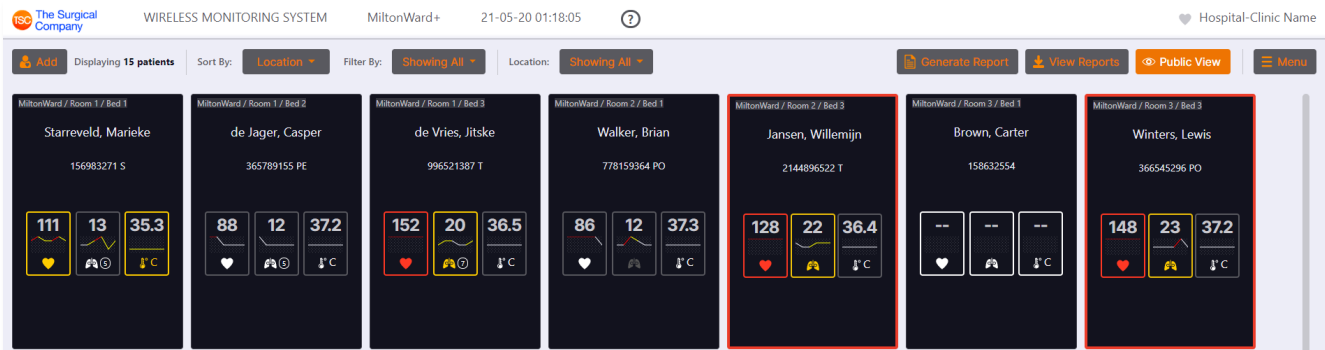


Once the Sensium browser application has been launched, the browser zoom should not be adjusted.

1.8 Wireless Monitoring Application screens

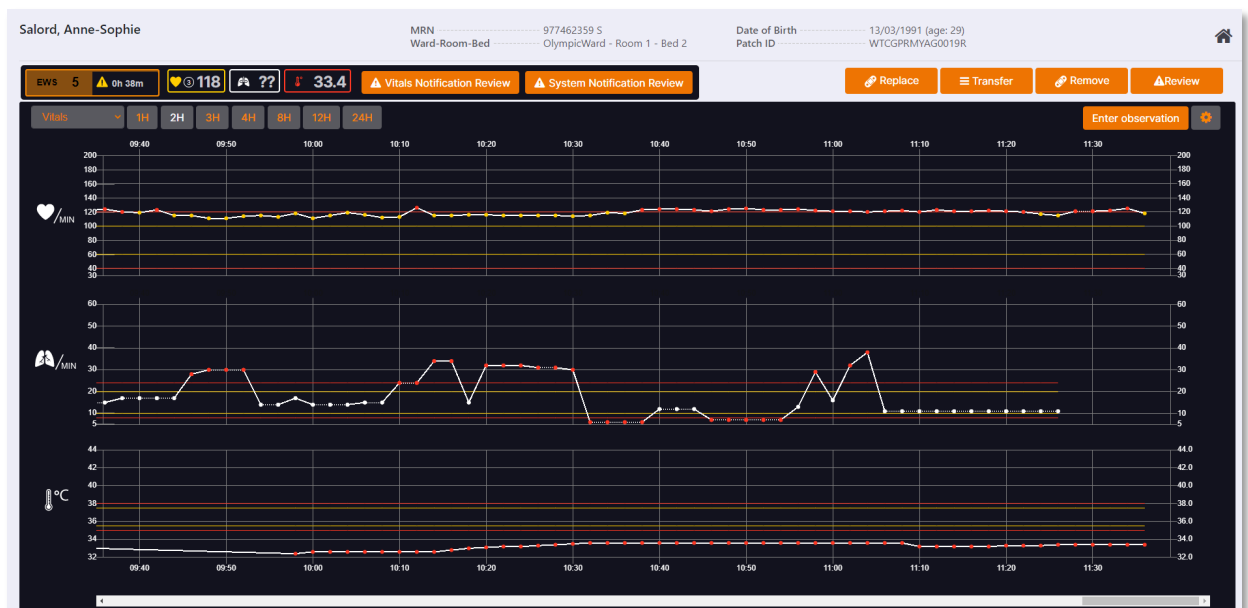
The Wireless Monitoring Application is a web-based application accessed using a web browser.

Main screen



The main screen of the application shows all the patients in the selected locations/filters. The functionality of this page is detailed in future chapters.

Patient Detail screen



The patient detail screen, accessed when clicking on a patient, reveals more information about the specific patient. The functionality of this page is detailed in future chapters.

1.9 User Privileges

Individual caregivers and administrators can be assigned different access to the system by the Hospital IT Administrator. The following table outlines the privileges for each user group.

	Roles						
Privilege	Clerical User	Junior User	Standard User	Senior User	Clinical User	IT Staff	Admin
Application Access							
Access Clinician (Access to Clinician Application)	✓	✓	✓	✓	✓	✗	✓
Access Direct Patient Details (Direct access to Patient Details Screen from URL)	✓	✓	✓	✓	✓	✗	✓
Access Anonymised Clinician (access to Public view Dashboard)	✓	✓	✓	✓	✓	✓	✓
Access Admin	✗	✗	✗	✗	✗	✓	✓
Clinician Application Actions							
View Multiple Wards	✗	✗	✗	✓	✓	✗	✓
Select Multiple Wards	✗	✗	✗	✓	✓	✗	✓
Ack. Notification	✗	✓	✓	✓	✓	✗	✓
Associate Patch (To add a patch to admitted patient)	✗	✓	✓	✓	✓	✗	✓
Create Clinical Data Report	✓	✓	✓	✓	✓	✗	✓
View Clinical Data Report	✓	✓	✓	✓	✓	✗	✓
Deactivate Patch (To remove a patch from monitoring)	✗	✓	✓	✓	✓	✗	✓
Assign Bedgroups (To assign beds to different groups)	✗	✓	✓	✓	✗	✗	✓
Manually Admit Patient	✓	✓	✓	✓	✗	✗	✓

	Roles						
Privilege	Clerical User	Junior User	Standard User	Senior User	Clinical User	IT Staff	Admin
Transfer Patient	✓	✓	✓	✓	✗	✗	✓
Discharge Patient	✗	✗	✓	✓	✗	✗	✓
Replace Patch	✗	✓	✓	✓	✓	✗	✓
Patient Settings							
Set Doc Interval	✗	✗	✓	✓	✗	✗	✓
Set Vital Sign Limits (warning) (To set Yellow Vital Sign Limits)	✗	✗	✓	✓	✗	✗	✓
Set Vital Sign Limits (critical) (To set Red Vital Sign Limits)	✗	✗	✓	✓	✗	✗	✓
View Doc Interval (To view documentation interval)	✗	✓	✓	✓	✓	✗	✓
View Vital Sign Limit (To view Vital Sign Limits)	✗	✓	✓	✓	✓	✗	✓
Escalation							
Escalate patient	✗	✓	✓	✓	✓	✗	✓
Review/Update escalated patient	✗	✓	✓	✓	✓	✗	✓
De-escalate patient	✗	✗	✗	✓	✓	✗	✓
E-Obs/EWS							
Observations Entry	✗	✗	✓	✓	✓	✗	✓
EWS Settings (view)	✗	✓	✓	✓	✓	✗	✓
EWS Settings (update)	✗	✗	✗	✓	✗	✗	✓
Admin Tool Actions							
All Settings Windows	✗	✗	✗	✗	✗	✓	✓

Chapter 2 Using the Sensium® system

2.1 Logging in and out

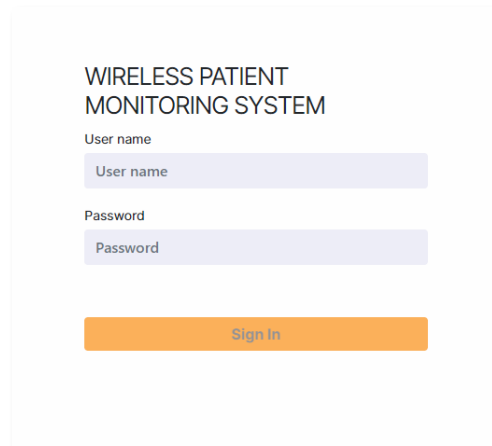
The Wireless Monitoring Application (MAS) is a web-based application accessed using a web browser on a standard hospital PC or laptop. Only authorized personnel can log in to the Wireless Monitoring Application.

2.1.1 To log in

Open a suitable browser on your PC and enter the URL of the Wireless Monitoring Application (this will be defined by your facility's IT department). Alternatively, if a desktop shortcut has been set up on your machine you can simply click on the icon.

You are presented with the login screen.

1. Enter your user ID and appropriate password at the login screen.



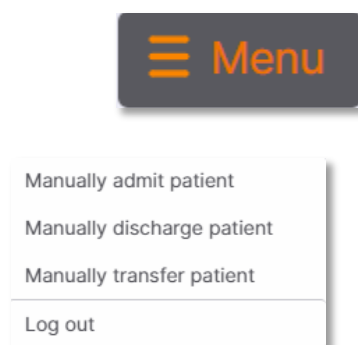
The login screen for the Wireless Patient Monitoring System. It features a white background with the title 'WIRELESS PATIENT MONITORING SYSTEM' at the top. Below the title are two input fields: 'User name' and 'Password', both with placeholder text. An orange 'Sign In' button is located at the bottom of the form.

2. Click Sign in

The main screen appears.

2.1.2 To log out

1. On the patient summary screen, click on 'Menu' then click on 'Log out'



You will be automatically logged out of the application after a specified period of inactivity (configurable by an administrator). Follow the on-screen



messages to log back in again if required.

It is important to log out of the system after performing tasks to avoid unauthorised access to the system

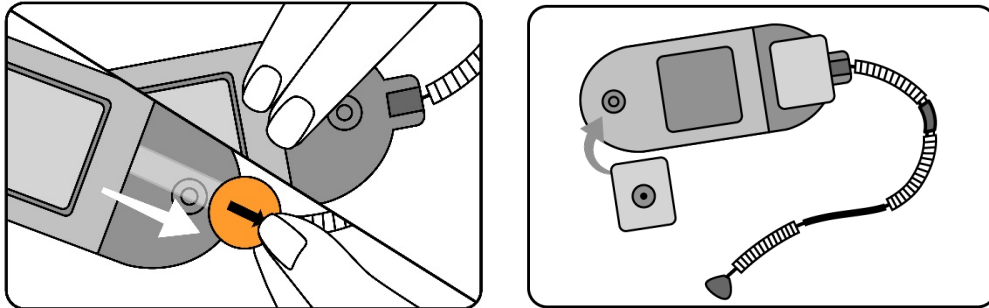
2.2 Starting patient monitoring

2.2.1 Required equipment

- Sensium® Patch
- Monitoring Electrodes (2 required)
- Skin cleaning solution
- Hair clipper
- Water-resistant plastic or paper medical tape such as 3M Transpore™ or 3M Transpore™ White

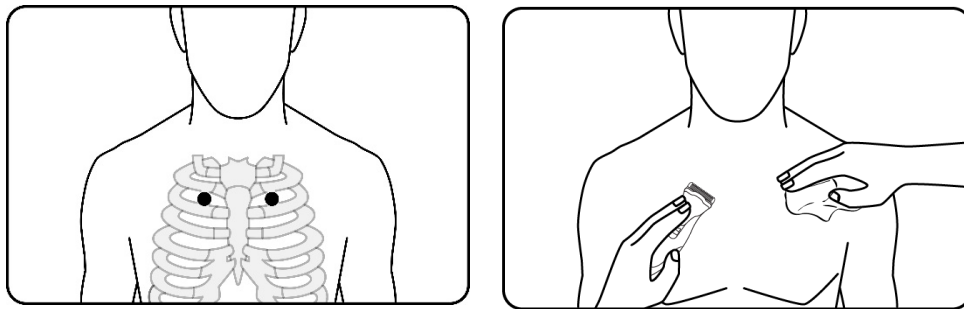
2.2.2 Patching a patient

1. How to prepare the patch

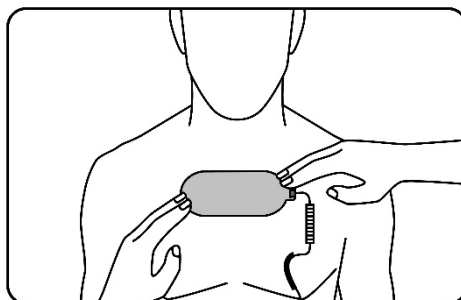


1. Pull out the activation tab and reseal.
2. Connect the long-life, snap fit electrodes to the patch.

2. How to prepare the skin

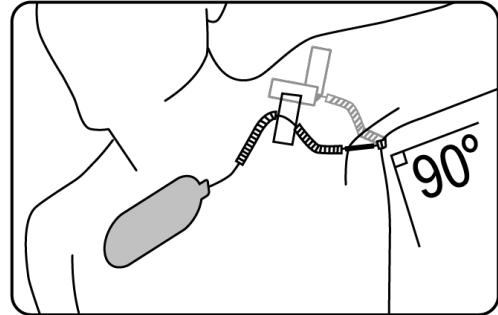
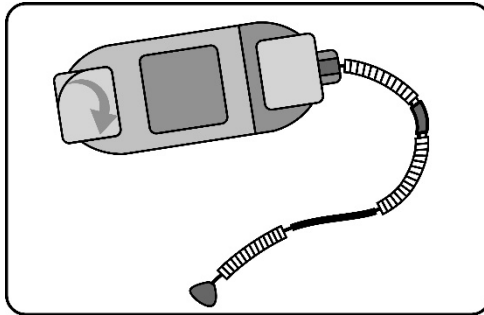


3. Locate the application site, in the first or second intercostal space.
4. Prepare the skin. The application site must be hairless. Clip excess hair and then clean and dry the skin.

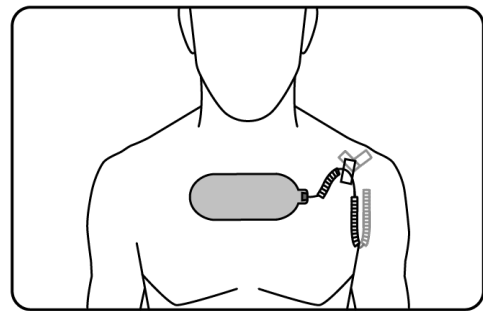
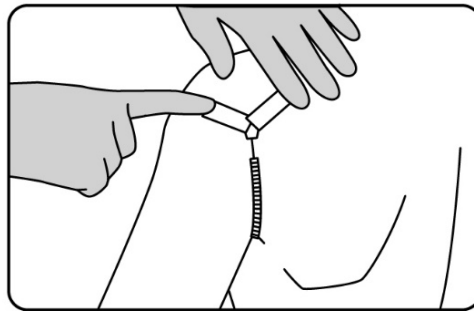


5. Orient the patch so the temperature sensor points toward the patient's non-dominant arm.

3. How to apply the patch

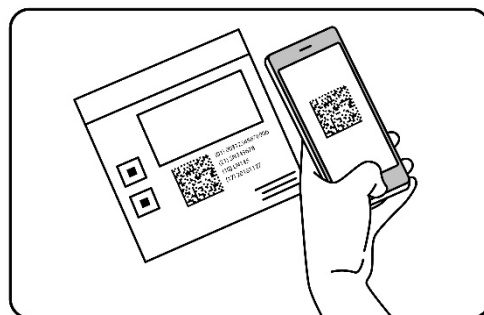


6. Remove the sticky backing from the patch and apply to the patient's skin
7. Tape the first attachment to the front of the shoulder, then secure the temperature sensor with tape under the arm.



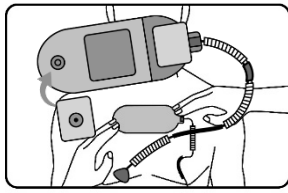
8. Tape the second triangular attachment to the back of the shoulder
9. Advise the patient not to remove or pull on the patch

4. Associate the patch



10. Associate the patch to the system by scanning the patch barcode using the mobile app or desktop (see section 2.3 below).

2.2.3 Patching patient at home



If the patient has taken a shower, the electrodes have come loose, or if the data coming through is, the patients need to be told to follow the steps below (steps are available in the Patient Leaflet SH-TRG-MKT-0046):

Step 1 (Picture 1): Connect electrodes to the patch connectors. If you can, leave the temperature sensor in place.

Step 2 (Picture 2): Before removing the backing from the electrodes, offer up the patch as a guide to locate the electrode application sites. The patch should be centered horizontally on the upper torso, roughly 4 fingers underneath your collarbone. Orient the patch so that the temperature sensor points towards the non-dominant arm, if the temperature sensor is still in place, skip to the next step.

Step 3: Peel off the backing from the electrodes and apply the patch, pressing lightly on the electrodes to secure. Ensure the patch is well centered on the torso with the center of the electrodes, roughly 4 fingers underneath your collarbone.

Step 4: (picture 3) If you need to apply the temperature sensor, apply as follows.

Raise your arm to 90 degrees, center the temperature sensor underneath the axilla (armpit) and tape.

Lift the two attachment tabs of the temperature sensor and position them on either side of the shoulder. Secure each attachment tab to your shoulder using provided tape (picture 4)

When applied correctly, the sensor coils are only slightly extended, and the two attachment points are at approximately the same level as shown.

2.3 Adding a patient to wireless monitoring

1. On the top left of the main screen of the Wireless Monitoring Application, click



2. If multiple wards are available, select the correct ward.
2. Scan the patient's ID tag with a barcode scanner (if available), alternatively type the patient name or Medical Record Number (MRN) into the search box.
2. Select the appropriate patient from the list using the scroll bar or search bar as necessary.

Add patients to wireless monitoring

Select a patient or scan patient wristband

OlympicWard ▾

Location	Name	MRN	DOB
OlympicWard / Room 3 / Bed 2	Kilgariff, Georgia	188653788	08 Nov 1978
OlympicWard / Room 1 / Bed 1	Marchand, Camille	785442318	20 Aug 1984

You can do either of the following to help you find the patient in the patient list:

2. Enter the MRN or patient name in the text box to locate the patient
2. Click any column heading to sort by that column



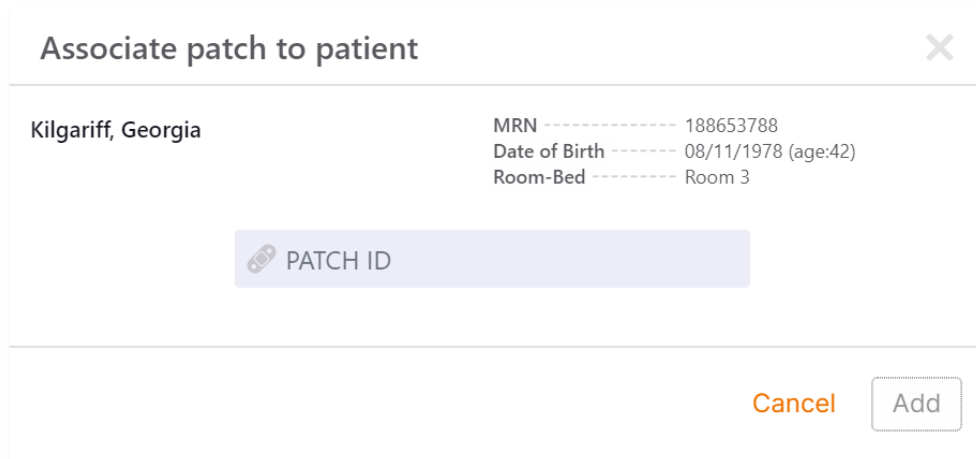
If the correct patient's information is not displayed in the Add Patient to Wireless Monitoring screen, click Cancel and select the correct patient.



Always verify the patient identity to ensure that the correct patient is being associated with the correct patch.

If the correct patient is not listed, it is possible that the patient was transferred to another ward/unit, or was recently transferred into your ward/unit and the Hospital Information System (HIS) has not yet been updated. Verify the status of the patient in the HIS. To manually add patients to the system, see section 2.3.1.

2. On the Associate patch to patient, do the following:



Associate patch to patient [X]

Kilgariff, Georgia

MRN ----- 188653788
Date of Birth ----- 08/11/1978 (age:42)
Room-Bed ----- Room 3

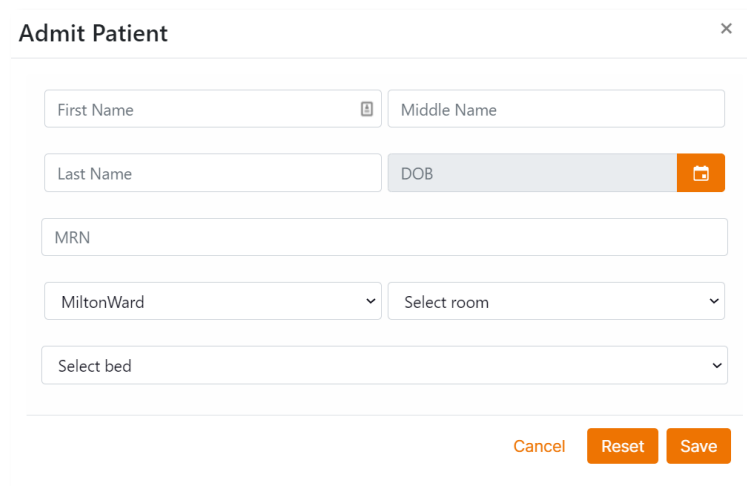
 PATCH ID

Cancel Add

- Enter the new patch ID number using one of the following methods:
 - Enter the serial number (SN) in the Patch ID text box.
 - Scan the barcode on the patch or pouch label (note each patch/pouch has a unique barcode and serial number).

2.3.1 Manually adding a patient to wireless monitoring

Admitting a patient using this method should only be used if the patient is not appearing on the 'Add Patient' list (see 2.3 'Adding patient to wireless monitoring' section) which is populated from the hospital Admission, Discharge and Transfer (ADT) feed.



Admit Patient [X]

First Name [icon] Middle Name

Last Name DOB [icon]

MRN

MiltonWard Select room

Select bed

Cancel Reset Save

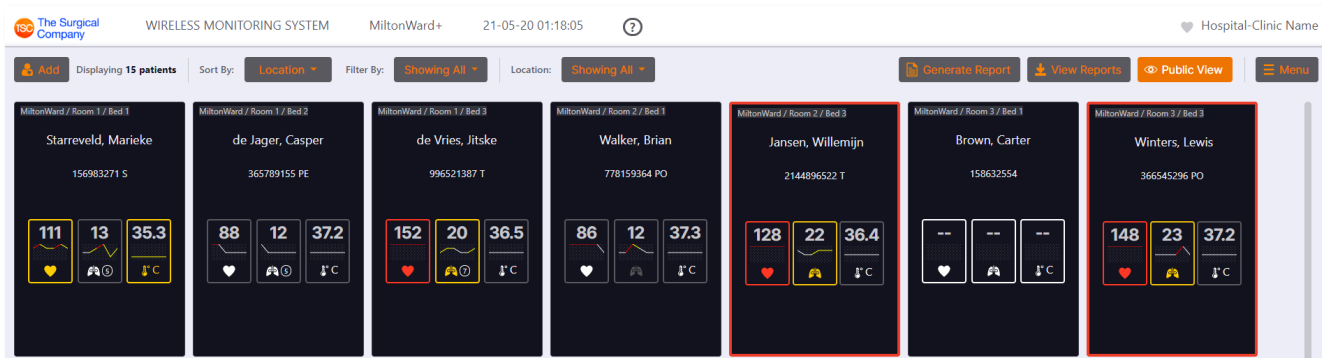
- To admit a patient, select 'Menu' on the top right and 'Manually admit patient'. Enter the relevant details including Name, Date of Birth, MRN, Ward, Room and Bed.
- Then click 'Save'. A pop-up window will confirm that the patient has been admitted.



The MRN must be correct to ensure that the records are merged with the hospital ADT when updated, if this is not done, a duplication in patient entry

may occur.

2.4 Main screen

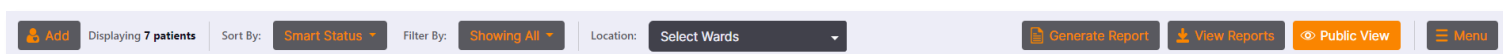


The main screen of the application shows all the patients in the selected locations/filters including their location, name, MRN, recent vital signs, mini trend graph and whether they are escalated. If the E-Obs functionality is activated, further information can be viewed on this screen as discussed in future chapters.

2.4.1 Header



Ward name (Unit name)	Displays the Ward/Unit for which the data is being displayed.
System time and date	Displays the current system time and date.
 About button	Displays Sensium® Wireless Patient Monitoring System information and provides a link to online help.
Hospital/Clinic name	Displays the hospital or clinic for which the data is being displayed



2.4.2 Control buttons

Controls to view and edit the patient details are presented as a series of buttons above the table (from left to right)

	Add Patient button - Allows you to add a patient to Sensium® Wireless Patient Monitoring System.
Sort By: 	Sort By button - Allows you to sort patients by location, name, EWS score (if applicable), or smart status. Smart status orders patients by indicated risk (highest risk, top left) considering factors such as if

	the patient is escalated, has open vital or system notifications, and if applicable, their Early Warning Score.
Filter By: Showing All ▼	Filter By button - Allows you to filter a specific group of patient e.g. escalated patients, patients with active notifications or overdue observations.
Location: Showing All ▼	Location filter button - Allows you to filter by specific locations to select the Ward/Room/Beds you want to view.
Generate Report	Generate report button - Allows you to generate a report based on a specific ward and/or patient(s).
View Reports	View Reports button – Shows the completed reports and progress of report creation.
Public View	Public View button – Enters a ‘public view’ removing the patients name from display.
Menu	Menu button – Allows you to admit, discharge and transfer patients manually, as well as logging out.

2.4.3 Data table

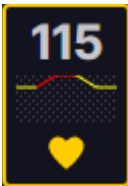
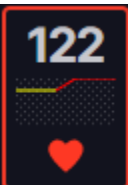
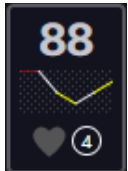
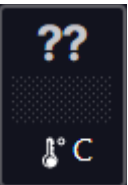
Patient data without E-Obs



Patient data with E-Obs



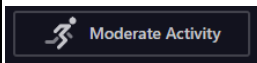
1.	Location - Indicates the patient's room and bed number
2.	Patient details – This will display the patient name and Hospital ID
3.	System notifications - Displays icons relating to patch status. If no icon is displayed, the patch is operating normally

4.	EWS banner – This banner is only visible when E-Obs functionality is enabled and displays the Early Warning Score (EWS) for that patient. The EWS gives an indication of the patient risk profile based on pre-defined hospital values.
5.	Vital signs columns - These columns display the current vital signs; heart rate, respiratory rate, and axillary temperature for each patient.  Vital signs within normal limits are displayed in grey on a black background. If a red or yellow flashing border surrounds the values, it indicates that there is an unacknowledged notification associated with the vital sign – see below.  Vital signs that exceed yellow pre-set limits are displayed with a yellow vital sign icon and yellow border. If the vital sign remains above the yellow limit for a sufficient period of time to generate a notification, this border will flash until the notification is acknowledged.  Vital signs that exceed red pre-set limits are displayed with a red vital sign icon and red border. If the vital sign remains above the red limit for a sufficient period of time to generate a notification, this border will flash until the notification is acknowledged.  If the system is unable to provide a valid reading, the previous reading will be held, and the age of the reading (in minutes) will be displayed in a circle.  If the system has been unable to provide valid readings for a pre-set period of time, question marks are displayed.  If the system has not received vital sign data for a configurable period of time, dashes are displayed. Dashes are displayed while a patch is being activated, or when the patch is roaming outside of RF connectivity. The mini-trend line graph in between the vital value and icon gives you a quick indication of recent vital trends. The line graph shows a snapshot of the average trend over the last 2 hours (this is done using a 20-min averaging window, across a



2-hour period). The vertical position of the trend and corresponding red/yellow colours indicates the trend warning level. For example, a flat white line in the middle indicates that over the last two hours, the vital values have (on average) remained within normal limits. A flat red line at the top of the window indicates that over the last two hours, the vital values have (on average) remained within high red limits. A trend line going up or down and showing different colours indicates that the average vital values over the last two hours have moved between warning limits. To see the patient's detailed vital trends over a selection of time periods, click on the patient.

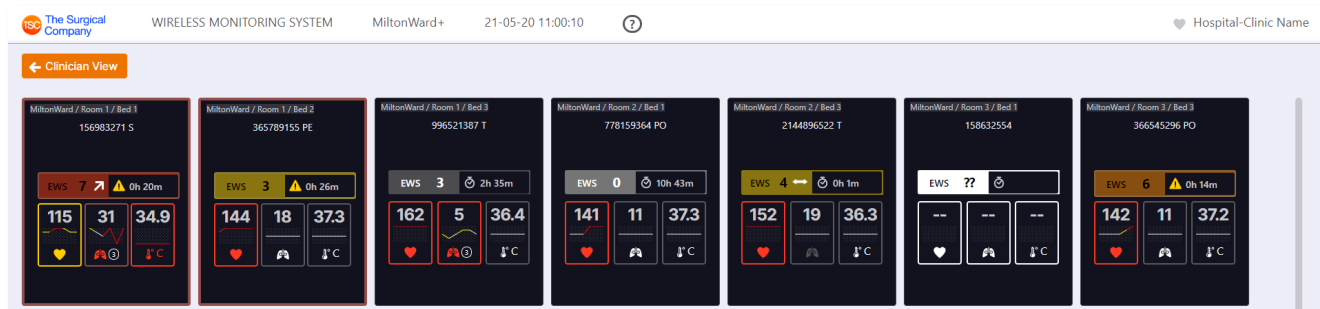
6. Activity posture



Activity posture displays the current activity posture of the patient (when enabled)

A warning symbol (▲) indicates that the activity posture is currently classed as "Invalid".

2.4.4 Public View



A 'Public View' of the main screen which shows the patients MRN and location but not their name, can be displayed in public areas of the hospital. This can be accessed from the 'Public View' button on the right-hand side of the screen at any time. Use the 'Clinician View' button on the top left to return to the normal main screen.

To use this screen permanently in a public area, the screen must be set-up by your IT department with a separate log-in. This screen will be fixed so other screens cannot be accessed from this view and so that the screen does not go to sleep. Contact your hospital IT to set-up this screen.

2.5 Patient Detail screen



Users should verify that the correct patient's information is displayed (see top row of patient information). If it is not the correct patient, go back to the summary screen via the home button in the far corner of the screen

1



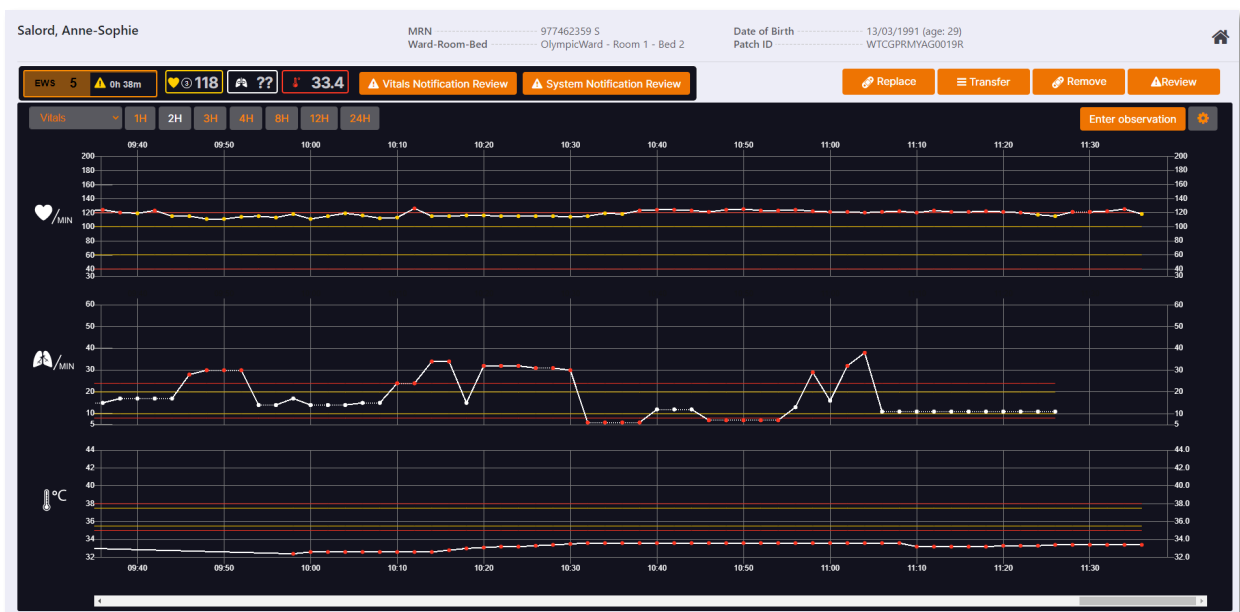
2

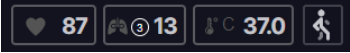


3



4



	Component (L)	Description	Component (R)	Description
1	Patient demographic data	Displays patient's name, ID, DoB and location	Home button	The home button – returns to the patient overview screen
2	Vitals and notifications	- Where enabled: EWS and EWS time (see EWS chapter) - Vitals (see overview chapter) - Vitals notification review – button to review vitals notifications - System notification review – button to review system notifications - Activity Posture –  Displays the current activity posture (if enabled)	Patch buttons & review	- Add/Replace – add a new patch for this patient - Transfer – transfer this patient to a new location - Remove – Remove this patient from patch monitoring - Escalate/Review – manually escalate this patient/review escalation notes and de-escalate (if permissions allow)
3	Time	- Option when EWS enabled: switch between Vitals, EWS and Obs graphs/tables - Choose the display time span for Vital or EWS graphs/tables; for example, data for the last four hours.	Observation & settings	- Where enabled: Enter observation – manual observations i.e. to complete EWS score can be added here - Settings – You can view and adjust vitals limits and EWS settings (where enabled). This depends on user privileges.

	Component (L)	Description	Component (R)	Description
4	Vital sign Trends	 /MIN Heart rate  /MIN Respiratory rate  °C Axillary Temperature Displays data over the selected time period. Data points within the set limits are displayed in white. Data points outside the yellow limits are displayed in yellow. Data points outside the red limits are displayed in red. If the data points are joined by dotted lines, it indicates that these data points are 'held' values from a previous reading. Hovering over the data points will display more details: 		

2.6 Notifications

Vital and system notifications are sent from the Monitoring Gateway Server to the Wireless Monitoring Application Server and, where applicable, mobile apps. A notification sound can be enabled through the admin user interface. Once enabled, this will sound on the MAS clinician user interface whenever a new notification is generated.

2.6.1 Receiving notifications

Notification types and descriptions.

Type	Description
Physiological	 Vitals Notification Review
Axillary Temperature 	Outside of yellow or red pre-set limits.

Type	Description
Heart Rate  /MIN	Outside of yellow or red pre-set limits.
Respiratory Rate  /MIN	Outside of yellow or red pre-set limits.
System	 System Notification Review
Leads Off 	Patch electrodes are not attached or electrodes are aged and should be replaced.
Replace Patch Soon 	Less than two (2) hours of use remaining.
Replace Patch Now 	Patch is no longer functional.
Communication Lost 	Patch is outside of wireless coverage area beyond a specified length of time. Caregiver is advised to check on the patient if it is unknown why the patient is no longer being monitored.
Reading Problem 	The system was unable to interpret vital sign data for several attempts in a row. This could be due to excessive patient motion This notification may also appear if the patch was incorrectly attached.

2.6.2 Acknowledging notifications

When a notification is received, it must be acknowledged in the Wireless Monitoring Application, on the Sensium apps or if configured via email.



The number of vital signs readings above or below a red or red limit to trigger a notification are user configurable in the admin application.

To acknowledge a notification from the wireless patient monitoring application

1. At the main screen, click on the patient to open the patient history screen

The 'Record of Action' window displays either vital or system notifications for that patient. Note that the acknowledge button will be greyed out until the action taken on notification has been selected.

Record of Action

Salord, Anne-Sophie

116

Ward
OlympicWard

Room-Bed
Room 1 - Bed 2

MRN
977462359 S

Date of Birth
13/03/1991

Age
29

Patch ID
WTCGPRMYAG0019R

Notification Time
21-05-2020 10:42:39

Vitals Alert!
0 Days 0 hours 57 minutes

No Action Taken

Observations Recorded

NEWS Pathway Followed

Escalated to Senior Clinician

Reapplied Electrodes

Close

Acknowledge

2. Select action taken.

In order to accurately record the action taken on receipt of a notification, the appropriate action must be selected from the dropdown list. Multiple actions may be selected from the list (apart from no action taken) for each notification. Once an action/action has/have been selected, the acknowledge button will be active.

Record of Action

Salord, Anne-Sophie

116

Ward
OlympicWard

Room-Bed
Room 1 - Bed 2

MRN
977462359 S

Date of Birth
13/03/1991

Age
29

Patch ID
WTCGPRMYAG0019R

Notification Time
21-05-2020 10:42:39

Vitals Alert!
0 Days 0 hours 57 minutes

No Action Taken

Observations Recorded

NEWS Pathway Followed

Escalated to Senior Clinician

Reapplied Electrodes

Close

Acknowledge

There are 5 pre-configured actions to choose from. Different actions can be configured on system installation. For notifications regarding the patch battery status i.e. "Replace Patch Now" and "Battery Low" and the action being to replace the patch please select "Reapplied electrodes" as the action from the drop-down list. Standard configured actions are:

- No action taken

- Observation recorded
- NEWS Pathway Followed
- Escalated to Senior Clinician
- Reapplied electrodes.

Once the acknowledge button has been selected a message confirms that notifications have been acknowledged.

3. Click OK to return to the patient's vitals history screen.

To acknowledge a notification via email.

Sensium can be configured to send notifications to an email account. If notifications have been configured to be sent this way, acknowledge the notification by replying to the email. You do not need to put any content in the reply, it can be blank, do not remove any content from the original notification email prior to replying.

If you want to track the action taken on the notification the action number from the action list (example below) must be added to the reply from the email. Multiple numbers of actions may be added for each notification and the "rules" for what can be selected together are the same as above.

Standard configured actions are the same as on the desktop and are as follows:

- No action taken
- Observation recorded
- NEWS Pathway Followed
- Escalated to Senior Clinician
- Reapplied electrodes.

When using a one-way pager or device where email reply is not a feature, the notification must be acknowledged from the Wireless Monitoring Application or Sensium apps.



Selecting an action from this list will not perform an action, it will just record your acknowledgement of performing an action.



If a notification is received for a patient that has been transferred from your care you must ensure that the clinician now responsible for that patient is informed as soon as practicable.



If the notification device is not working as expected contact IT to resolve & use the Wireless Monitoring Application to acknowledge notifications.



If replying to a notification from an email, do not remove any content from the notification email prior to replying. Deleting or editing the notification ID could cause a failure in the interpretation of the acknowledgement.

2.6.3 Reminder notifications

When a notification is not acknowledged within a specified period of time, a reminder notification may be sent. Reminder notifications contain the same information as the original notifications.

2.6.4 Escalation notifications

When a notification is not acknowledged within a specified time period, an escalation notification may be sent to another caregiver device, pre-determined in the system. Escalation notifications contain the same information as the original notifications.

Escalations can be reviewed by clicking on the review button. Clinicians can add notes before updating or de-escalating the patient.



2.7 Escalations

2.7.1 Escalating a patient

Patients can be escalated in several ways. Patients are automatically escalated when vital or system notifications are not acknowledged within a predetermined time period, as illustrated in previous text. Patients will also be automatically escalated if EWS observations go past the observation due time.

Patients can also be escalated manually, via the 'Escalate' button on the patient detail screen.



Notes can be added in the escalation screen, to complete the escalation, click confirm.

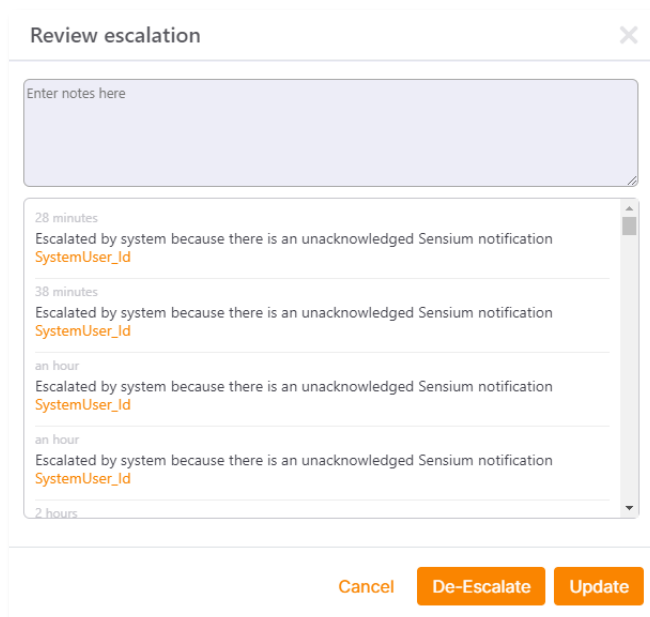


A dialog box titled "Escalate patient" with a close button (X) in the top right corner. It features a large text input area with the placeholder "Enter notes here". At the bottom right, there are two buttons: "Cancel" and "Confirm".

2.7.2 Reviewing/de-escalating a patient

Escalated patients can be identified on the main screen by a flashing red border.

To de-escalate a person (permission specific), open the patient's detail screen and click on the review button. Notes can be added in the review screen. The reviewer can choose to keep the escalation and click update, to add the notes to the system, or de-escalate by clicking on de-escalate

A dialog box titled "Review escalation" with a close button (X) in the top right corner. It features a large text input area with the placeholder "Enter notes here". Below the input area is a scrollable list of escalation events. Each event shows a time (e.g., "28 minutes"), a description ("Escalated by system because there is an unacknowledged Sensium notification"), and a link to "SystemUser_Id". At the bottom right, there are three buttons: "Cancel", "De-Escalate", and "Update".



If the escalation was due to unacknowledged notifications, the notifications should be reviewed and actioned.

2.8 Other functionalities and patient management

2.8.1 Generating and viewing a clinical data report

- 1) On the main screen, select Generate Report
- 2) The Clinical Data Report dialog box appears.



Generate clinical data report

From: 20-05-2020

To: 21-05-2020

☒ All patients
 ☐ Specific patient
 ☐ Discharged patients

MiltonWard ▾

Cancel

Generate Report

- 3) In the From and To boxes, enter the date range for the report.
Alternatively, click the calendar icons to select the date range from calendars.
- 4) Select All patients or Specific patient
 - a) Select 'Discharged Patients' to include only discharged patients in the report.
- 5) Select a ward
- 6) If selecting a specific patient, search for the patient using name or MRN and click on the selected patient
- 7) Click Generate Report.
- 8) The report PDF may take several minutes to generate depending on the number of patients and number of days monitored. A notification will appear when the report is ready. You can view and delete the reports on by going to the main screen and clicking

View Reports View Reports



You can print a clinical data report by clicking the print icon in the Adobe Acrobat Reader menu bar.



There is a risk to patient confidentiality if the reports generated in the Sensium system are downloaded and saved/printed.



Reports containing multiple patients are ordered by admission date

2.8.2 Change location on main screen

The location dropdown menu on the main screen can be used to select the location view. It can be filtered by ward, rooms and beds. Tick boxes indicate when locations are selected. When the top location is selected and no subcategories have been specifically selected (See image below, the Olympic ward), the whole ward/room is selected. Depending on user permissions you can view multiple wards.

2.8.3 Replacing a patch

- 1) Remove the patch, electrodes and temperature sensor from the patient.
- 2) Dispose of the patch in accordance with the hospital clinical waste procedure.
- 3) Apply a new patch to the patient as described in “Applying the patch” in section 2.2.2.
- 4) Update the patch information in the wireless patient monitoring application
 - a) On the patient summary screen, select the patient whose patch was replaced and

click Replace Patch.

Replace

- b) Enter the new patch ID number in the Patch ID box manually or by scanning the barcode on the patch or pouch.
- c) Click Replace.
A message confirms that the patch has been replaced.
- d) Click OK to return to the main screen.

2.8.4 Transferring a patient

There are two ways to transfer a patient's location on the system manually (if the patient can't be moved through the hospital ADT feed).

1. From the main screen select 'Transfer Patient' and choose the ward and patient name.
 - a. Then select the ward/unit, room and bed that you want to transfer that patient to from the drop-down menus and select 'Transfer'. A pop-up window will confirm that the patient has been transferred.

Transfer Patient

Search

OlympicWard

Location	Name	MRN	DOB
OlympicWard / Room 2 / Bed 3	Bernard, Hugo	558629456	28 Sep 1984
OlympicWard / Room 2 / Bed 1	Jacobs, Mae	962455832 T	06 Oct 1950
OlympicWard / Room 3 / Bed 2	Kilgariff, Georgia	188653788	08 Nov 1978
OlympicWard / Room 1 / Bed 1	Marchand, Camille	785442318	20 Aug 1984
OlympicWard / Room 1 / Bed 3	Miller, Charlie	178366951	30 Jun 1981
OlympicWard / Room 2 / Bed 2	Roberts, Sam	465517852 S	22 May 2003
OlympicWard / Room 1 / Bed 2	Salord, Anne-Sophie	977462359 S	13 Mar 1991
OlympicWard / Room 3 / Bed 1	Visser, Eefje	965337185	02 Sep 1998

Cancel Transfer

Transfer Patient

Search

OlympicWard

Location	Name	MRN	DOB
OlympicWard / Room 2 / Bed 3	Bernard, Hugo	558629456	28 Sep 1984
OlympicWard / Room 2 / Bed 1	Jacobs, Mae	962455832 T	06 Oct 1950
OlympicWard / Room 3 / Bed 2	Kilgariff, Georgia	188653788	08 Nov 1978
OlympicWard / Room 1 / Bed 1	Marchand, Camille	785442318	20 Aug 1984
OlympicWard / Room 1 / Bed 3	Miller, Charlie	178366951	30 Jun 1981
OlympicWard / Room 2 / Bed 2	Roberts, Sam	465517852 S	22 May 2003
OlympicWard / Room 1 / Bed 2	Salord, Anne-Sophie	977462359 S	13 Mar 1991
OlympicWard / Room 3 / Bed 1	Visser, Eefje	965337185	02 Sep 1998

Kilgariff, Georgia

MRN ----- 188653788
Date of Birth ----- 08/11/1978 (age:42)
Ward-Room-Bed ----- OlympicWard / Room 3 / Bed 2

Transfer patient to

OlympicWard Room 1 Bed 3

Cancel Transfer

A patient can also be transferred via the patient detail screen. Select the patient and select transfer.

Transfer Patient

Jacobs, Mae

MRN ----- 962455832 T
Date of Birth ----- 06/10/1950 (age:70)
Ward-Room-Bed ----- OlympicWard / Room 2 / Bed 1

Transfer patient to

Select Ward

Cancel Transfer

Transfer Patient

Jacobs, Mae

MRN ----- 962455832 T
Date of Birth ----- 06/10/1950 (age:70)
Ward-Room-Bed ----- OlympicWard / Room 2 / Bed 1

Transfer patient to

OlympicWard Room 1 Bed 2

Cancel Transfer

- b. In the screen, select the ward, room and bed that you want to transfer that patient to from the drop-down menus and select 'Transfer'. A pop-up window will confirm that the patient has been transferred.

2.8.5 Removing a patch from a patient

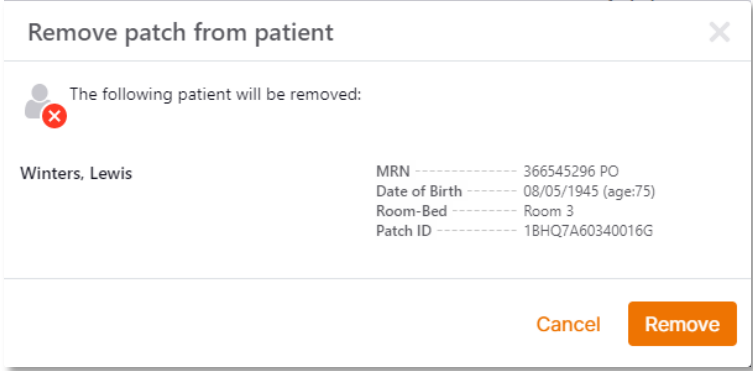


Removing a patch will remove patient from patch monitoring, the patch will be deactivated, their data will no longer be displayed, and no further notifications will be generated.



If E-Obs functionality is enabled, the patient will still be visible after the Patch has been removed and E-Obs functionality can still be used. The patient will only be removed from the application through an update to the hospital ADT feed or if manually discharged from the system (see below).

1. Remove the patch, electrodes, and temperature sensor from the patient.
2. Dispose of the patch in accordance with the hospital clinical waste procedure.
- a) On the main screen of the Wireless Patient Monitoring Application, select the patient to be removed from wireless monitoring – this will bring you to the patient summary screen, there click  Remove Patient.
- i) The Remove Patient from Wireless Monitoring screen appears.



Remove patch from patient	
The following patient will be removed:	
Winters, Lewis	MRN ----- 366545296 PO Date of Birth ----- 08/05/1945 (age:75) Room-Bed ----- Room 3 Patch ID ----- 1BHQ7A60340016G
Cancel Remove	

- ii) Click Remove - A message confirms that the patient was removed from monitoring.
- iii) Click OK - Return back to the main screen.

2.8.6 Manually discharging a patient

- b) On the main screen, go to menu and select Manually discharge patient

Discharge patients

Select a patient from below

Search

OlympicWard

Location	Name	MRN	DOB
OlympicWard / Room 2 / Bed 3	Bernard, Hugo	558629456	28 Sep 1984
OlympicWard / Room 2 / Bed 1	Jacobs, Mae	962455832 T	06 Oct 1950
OlympicWard / Room 3 / Bed 2	Kilgariff, Georgia	188653788	08 Nov 1978
OlympicWard / Room 1 / Bed 1	Marchand, Camille	785442318	20 Aug 1984
OlympicWard / Room 1 / Bed 3	Miller, Charlie	178366951	30 Jun 1981
OlympicWard / Room 2 / Bed 2	Roberts, Sam	465517852 S	22 May 2003
OlympicWard / Room 1 / Bed 2	Salord, Anne-Sophie	977462359 S	13 Mar 1991
OlympicWard / Room 3 / Bed 1	Visser, Eefje	965337185	02 Sep 1998

Cancel Discharge

- i) Select the ward the patient is in (where applicable), then select the patient from the list either by using the search bar or scrolling through the list.
- ii) After selecting the patient, check the patient information to ensure the right patient will be discharged.

Discharge patients

Select a patient from below

Search

OlympicWard

Location	Name	MRN	DOB
OlympicWard / Room 2 / Bed 3	Bernard, Hugo	558629456	28 Sep 1984
OlympicWard / Room 2 / Bed 1	Jacobs, Mae	962455832 T	06 Oct 1950
OlympicWard / Room 3 / Bed 2	Kilgariff, Georgia	188653788	08 Nov 1978
OlympicWard / Room 1 / Bed 1	Marchand, Camille	785442318	20 Aug 1984
OlympicWard / Room 1 / Bed 3	Miller, Charlie	178366951	30 Jun 1981
OlympicWard / Room 2 / Bed 2	Roberts, Sam	465517852 S	22 May 2003
OlympicWard / Room 1 / Bed 2	Salord, Anne-Sophie	977462359 S	13 Mar 1991
OlympicWard / Room 3 / Bed 1	Visser, Eefje	965337185	02 Sep 1998

MRN ----- 962455832 T
Date of Birth ----- 06/10/1950 (age:70)
Ward-Room-Bed ----- OlympicWard / Room 2 / Bed 1

Cancel Discharge

- iii) Click Discharge - A message confirms that the patient was removed from monitoring.
- iv) Click OK - Return back to the main screen.



‘Manually discharge patient’ should only be used when the patient has been discharged from the hospital and the hospital ADT feed has not removed them.

2.8.7 Editing Vital Range settings

Default vital range settings are set for the whole hospital/ward in the admin settings (for more information see the Admin user manual.)



Standard yellow and red vital sign limits (yellow and red limits) are defined and set by the hospital for all patients who are being monitored with the Sensium® Wireless Patient Monitoring System. Vital sign limits can be modified for a specific patient.

Vital range can be changed per patient, by going into the patient detail screen and clicking on the “settings” button



Vital range settings

Visser, Eefje

MRN

965337185

Date of Birth

02/09/1998 (age: 22)

Ward-Room-Bed

OlympicWard - Room 3 - Bed 1

Patch ID

8Z6NMZ44D8001H8

Documentation Interval:

1 Hour 0 Minutes

120

100

60

40

24

20

10

8

38.0

37.5

35.5

35.0

Cancel

Save

Where relevant, set a documentation interval for transferring the data into the patient’s electronic medical record:

Click the Documentation Interval drop-down list.

Select the new time interval.



The Documentation Interval controls how often the system copies data into the patient’s electronic medical record.

Set vital sign notification limits as follows:

Click the text box that displays the vital sign limit you wish to change.

Enter different upper and/or lower limits as needed.



Additional user privileges may be required to change some or all vital sign limits.

After completing the required changes, click Save.

Chapter 3 Using the Sensium® system with E-Obs functionality



Before starting observations for a patient who needs a customized observation frequency, change the observation frequency by going to the patient detail screen, click on the settings and adjusting the observation frequency

3.1 Entering a new observation set/calculating an Early warning Score (EWS)

To enter an observation into the system, click on the enter observation button. This will take you to the 'Enter Observations' screen

Enter observation

The system shows default observations, but observations can be configured hospital-wide to include different observations/different order through the admin application.

Enter Observations

Winters, Lewis

MRN 366545296 PO
Date of Birth 08/05/1945 (age: 75)
Ward-Room-Bed MiltonWard - Room 3 - Bed 3
Patch ID 1BHQ7A60340016G

	Previous	Current	
RR (Bpm)	11	17	✓
SPO2 S1 (percent)	99	98	✓
addO2	NO	NO	✓
Device	??	Select	—
SBP (mmHg)	120	132	✓
DBP (mmHg)	??		—
HR (Bpm)	87	145	✓
A/C/V/P/U	A	Select	✗
TEMP (Celsius)	37.3	37.3	✓
Pain	??		—
P BP	??	Select	—
Bowels	??	Select	—
22nd May, 2020 11:14			
Early warning score (EWS)	1		

Cancel
Confirm

The most recently recorded previous observation values are displayed on the left.

Observations can be entered into the system by adding the values and clicking confirm.

Patch values are pre-populated for patients wearing the Sensium patch but can be overwritten if required.



Check the pre-populated HR, RR and Temp values before calculating the EWS

Enter Observations [X]

Winters, Lewis MRN: 366545296 PO
Date of Birth: 08/05/1945 (age: 75)
Ward-Room-Bed: MiltonWard - Room 3 - Bed 3
Patch ID: 1BHQT60340016G

	Previous	Current	
RR (Bpm)	11	17	✓
SPO2 S1 (percent)	99	98	✓
addO2	NO	NO	✓
Device	??	Select	–
SBP (mmHg)	120	132	✓
DBP (mmHg)	??		–
HR (Bpm)	87	145	✓
A/C/V/P/U	A	A	✓
TEMP (Celsius)	37.3	37.3	✓
Pain	??		–
P BP	??	Select	–
Bowels	??	Select	–
22nd May, 2020 11:14			
Early warning score (EWS)	1	3	

Cancel Confirm

To calculate an EWS, all values with a red cross on the right should be populated – after which the populated values are indicated by a green tick. When all compulsory values are added, an EWS score will be calculated at the bottom.

You can confirm the observations and the EWS score by clicking confirm.

If you want to enter observations but not calculate an EWS, simply press 'confirm' once you have entered the required observations, the observations will be viewable in the Obs table (see next section).



If EWS calculation is required, check if all of the mandatory fields are completed before calculating EWS



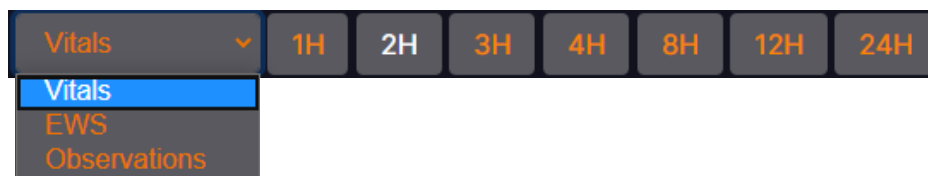
Check if the EWS displayed is commensurate with patient condition



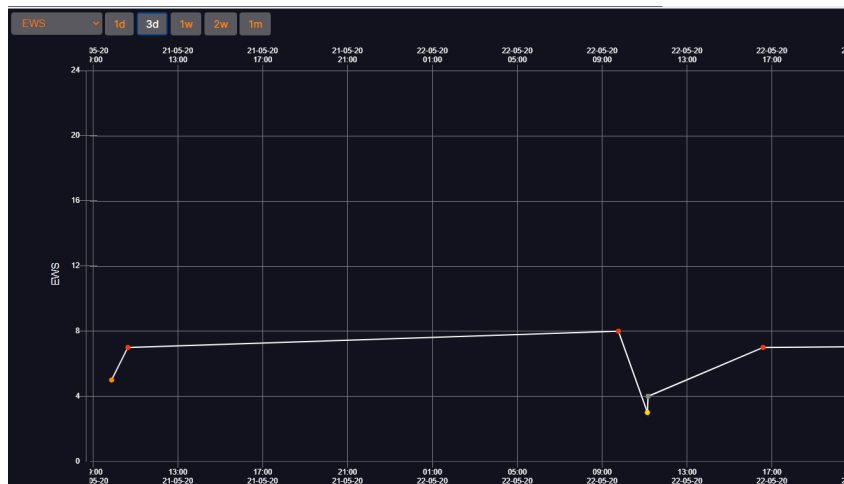
Clinical escalation should be commensurate to patient condition

3.2 Viewing EWS/Obs table

It is possible to view the EWS and Observation history per patient in the patient detail screen, by going into the dropdown menu in the left corner of the screen, usually preloaded on 'vitals'



The EWS window displays all calculated EWSs. As with the Vitals, the EWS window has pre-set time views. Selecting any of these pre-set views will show the data for that time period. It is possible to scroll back in time to see up to 24 hours of vitals and 1 month of EWS data at that pre-set window. To show exact observations, click and hold on the EWS point on the graph.



Under the ‘Observations’ view you can view all observations for this patient. The most recent observations show on the right-hand side. Scroll to the left to see prior observations. Where the observations entered do not meet the required parameters for an EWS, the EWS will display as “??”. Where observations have not been recorded, they will display as “??”.

Observations	21/05/2020 09:53	21/05/2020 10:39	22/05/2020 09:46	22/05/2020 11:08	22/05/2020 11:10	22/05/2020 16:35	26/05/2020 09:18	26/05/2020 09:23	27/05/2020 09:34	27/05/2020 09:34	28/05/2020 12:00	12/06/2020 14:36
EWS	5	7	8	3	4	7	8	0	2	2	2	4
RR	13	20	7	18	10	13	32	20	20	20	19	14
SPO2 S1	100	100	99	98	99	89	99	99	99	99	98	98
addO2	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Device	??	??	??	??	??	??	??	??	??	??	??	??
SBP	180	120	125	120	140	125	121	121	123	123	121	120
DBP	121	??	??	??	??	??	??	??	??	??	??	??
HR	124	115	125	80	115	135	115	80	123	123	120	108
A/C/V/P/U	A	A	A	A	A	A	A	A	A	A	A	A
TEMP	33.6	34.2	35.0	35.0	35.1	35.7	33.2	37.0	37.0	37.0	36.5	34.3
Pain	??	??	??	??	??	??	??	??	??	??	??	??
P BP	??	??	??	??	??	??	??	??	??	??	??	??
Bowels	??	??	??	??	??	??	??	??	??	??	??	??

3.3 Changing EWS Range settings

The EWS range settings are determined hospital-wide in admin settings but can be adjusted per patient. The ‘EWS range settings’ button will only be available for certain permissions.

Name	Low Limit	High Limit	Toggle
3_LOW	5	8	On
2_LOW			Off
1_LOW	9	11	On
0_NORMAL	12	20	On
1_HIGH			Off
2_HIGH	21	24	On
3_HIGH	25	60	On

Cancel Save

The EWS range settings allow EWS range settings to be edited on a per patient basis, by clicking on the pencil/pen button.



Toggle orange/white on the right to turn on/off score values. Select the value range which you would like to edit, for example respiratory rate 'RR' and change limits by scrolling up or down on the number. Editing one value e.g. 0_normal will influence values either side e.g. 1_High.

Click on 'Set Readings Frequency' to override the current observation frequency. Click on 'Reset' under the EWS Reading Frequency to reset the EWS reading frequency to the default value.

Click 'Reset All Ranges' under EWS range Settings to return all values to the default.



Editing these EWS range values will affect the Early Warning Score (EWS) generated and corresponding clinical response.

In the same window, the patient can also be moved from one SpO2 scale to another. Toggling between SpO2 scale 1 and SpO2 scale 2 will change the SpO2 scale in the EWS Entry Screen for that patient.

Chapter 4 Troubleshooting

4.1 Logging in and out

I am entering the correct username and password, but the system is not logging me in:

- Your computer's CAPS LOCK may be on. If so, turn it off and try again.
- If that doesn't work, double-check your username and password.
- If your username and password are correct and the system still will not log you in, contact your facility's IT department for assistance.

4.2 Adding a patient

Scanning the patient or patch barcode doesn't work:

If the barcode is damaged and scanners are having difficulty reading them, please enter the code manually.

If the problem persists with different barcodes, then you may have a faulty scanner. Contact your facility's IT department for assistance.

I need to add a patient to wireless monitoring, but the patient's name isn't in the list:

There are several reasons why a patient's name may not be in the 'Add patient to wireless monitoring list':

- The patient may have already been added to wireless monitoring. Check the main screen, then follow the procedures under '*The patient's name is not displayed on the main screen*' in the '4.3 Monitoring a patient' section of this chapter to see if the patient is already being monitored.
- The patient may have recently been admitted or transferred to your unit, and the system has not been updated yet.

If neither of the above applies, check with your facility's IT department for assistance.

I am unable to access the assign bed feature:

Additional user privileges are required to assign beds. Ask a designated user for assistance.

If you know that you should have access to this feature, but you do not, contact your facility's IT department for assistance.

I can't change the vital sign limits:

Additional user privileges may be required to change some or all vital sign limits. Ask a designated user for assistance.

If you know that you should have the ability to change vital sign limits, but you are not able to do so, contact your facility's IT department for assistance.

The patient's demographic information is incorrect:

Patient information is taken from the Hospital Information System (HIS). Check with the patient administrator to make sure that all information is correct and up to date.

4.3 Monitoring a patient

The patient's name is not displayed on the main screen:

- If the patient's name is not visible on the main screen, check the following:
- Check the Group drop-down list to make sure that the proper group is being shown or select All to display all patients being monitored.
- If there is a scroll bar to the right of the patient list, the list is too long to be displayed on one screen. Scroll down to see if the patient is farther down the list.
- It is possible that the patient was not added to wireless monitoring, even if a patch was applied and activated. Follow steps 1 and 2 of the procedure *2.3 Adding a patient to wireless monitoring* on page 23. If the patient's name is on the Patient List screen, follow the rest of the procedure in *2.3 Adding a patient to wireless monitoring*.
- It is also possible that the patient was transferred to another unit or was recently transferred into your unit and the Hospital Information System (HIS) has not yet been updated. Verify the status of the patient in the HIS.

If, after doing all the previous steps, the patient's name still is not displayed on the main screen, contact your facility's IT department for assistance.

There are dashes (- -) in all three columns of a patient's vital sign data:

If the system has not received vital sign data for a configurable period of time, dashes are displayed. Dashes are displayed while a patch is being activated, when the patch is roaming outside of RF connectivity or if the patch battery has expired. If you see dashes in all three vital signs columns, then check the following:



Immediate need to undertake below steps applies to use in hospital setting,

- Check the Patch column to see if the "Patch Activating" icon () is displayed. If so, wait a few minutes for it to disappear.



The patch can take up to 15 minutes to activate and display data on the main screen.

- Check the Patch column to see if the Out of Range/Signal Lost icon () is displayed. If so, see the icon in section 2.6.1.
- Check the Patch column to see if the "Replace Patch Now" icon () is displayed.
- If so, replace the patch following the instructions in 'Replacing a Patch' in section 2.8.3.
- Make sure that the activation tab has been removed.

- If you have checked all of these items, properly applied, and activated the patch, and the patient is not out of range, the patch may be faulty. Wait a few minutes for the next reading. If dashes (--) are still displayed, replace the patch following the instructions in the section 'Replacing a Patch' in section 2.8.3.

If, after doing all of the previous steps, the vital sign data columns still display dashes (--), contact your facility's IT department for assistance.

There are question marks (??) displayed on summary screen

If the system has been unable to provide valid readings for a pre-set period of time, question marks are displayed in the columns of a patient's vital signs. Question marks displayed would indicate that the patch is connected to the system but the vitals sign data being reported is considered to be invalid. There are situations where some or all a patient's vital signs might be displaying question marks, and these are described below.

There are question marks (??) in the Heart Rate and Respiratory Rate columns of a patient's vital sign data:

The Patch will automatically detect a 'Leads Off' condition if the Patch is removed from the patient or if the electrode application is poor. In this case the Heart Rate and Respiratory Rate readings are unreliable and will not be reported by the system, however a valid temperature may continue to be displayed. If you see question marks in the Heart Rate and Respiratory Rate vital signs columns, then check the following:



Immediate need to undertake below steps applies to use in hospital setting,

- Check the Notification column to see if a "Leads Off" notification has been generated for that patient. If a notification is present:
 - Ensure the patch is properly placed on the patient.
 - Ensure the electrodes are firmly attached to the patch and to the patient.
 - Replace the monitoring electrodes with fresh electrodes, if fresh electrodes are required ensure adequate skin preparation has been carried out.
- If, after following the previous steps, and waiting approx. four minutes, the heart rate and respiratory rate columns still displays question marks (??), contact your facility's IT department for assistance.

There are question marks (??) in the patient's Heart Rate column only:

This can be due to temporary electrical interference, the patient moving in certain ways, poor connection (for example; due to lack of skin preparation, hair, dry electrode gel, loose snap connectors, etc.) or something striking the patch. However, if the crosses persist, check the following:



Immediate need to undertake below steps applies to use in hospital setting,

- Ensure the patch is properly placed on the patient.

- Ensure the electrodes are firmly attached to the patch and to the patient.
- Replace the monitoring electrodes with fresh electrodes.
- If the problem persists, the system will send a 'Reading Problem' notification. In this event, replace the patch electrodes following the instructions in the section 'Replacing a Patch' in section 2.8.3.

If, after following the previous steps, the heart rate column still displays question marks (??), contact your facility's IT department for assistance.

There are question marks (??) in the patient's Respiratory Rate column only:

Due to the nature of impedance pneumography, it is possible that respiratory rate readings are disrupted, particularly when the patient is moving or talking, leading to (??) being displayed. It can take up to four minutes after the patient has stopped moving or talking for respiratory rate data to be displayed. However, if the patient is not moving or talking and question marks persist, do the following:



Immediate need to undertake below steps applies to use in hospital setting,

- Ensure the patch is properly placed on the patient and that the patient's skin was properly prepared before applying the patch.
- Ensure the electrodes are firmly attached to the patch and to the patient.
- Replace the monitoring electrodes with new electrodes.
- If the problem persists, the system will send a 'Reading Problem' notification. In this event, replace the patch electrodes following the instructions in the section 'Replacing a Patch' in section 2.8.3.

If, after following the previous steps, the respiratory rate column still displays question marks (??), contact your facility's IT department for assistance.

There are question marks (??) in the patient's Temperature column:

Temperature readings might become unavailable if the patient is moving their arm or if the patient's arm is not covering the temperature sensor completely. It can take several minutes after the patient's arm has returned to the proper position for temperature data to be displayed.

If question marks persist, check the following:



Immediate need to undertake below steps applies to use in hospital setting, otherwise refer to care-provider protocols.

- Ensure the temperature sensor is properly placed on the patient.
- If the problem persists, the system will send a 'Reading Problem' notification. In this event, replace the patch electrodes following the instructions in the section 'Replacing a Patch' in section 2.8.3.

If, after following previous steps, the temperature column still displays question marks (??),

contact your facility's IT department for assistance.

The patch status column displays the Out of Range/Signal Lost icon:

If the Out of Range/Signal Lost icon () is displayed in the Patch column, check the following:



Immediate need to undertake below steps applies to use in hospital setting, otherwise refer to care-provider protocols.

- The signal loss may be temporary. Wait a few minutes for the next patch reading. If the icon goes away, the signal has been restored.
- The Out of Range/Signal Loss icon can either flash or not flash, a flashing icon indicates that an unacknowledged notification has been sent
- If the Out of Range/Signal Loss icon remains, verify the location of the patient. The patient may have been temporarily moved to an area where there is no coverage.
- If the Out of Range/Signal Loss icon is still displayed, and the patient is in the assigned room, the patch may be faulty. Replace the patch following the instructions in the section 'Replacing a Patch' in section 2.8.3.

If, after following the previous steps, the Patch column still displays the Out of Range/Signal Lost icon, contact your facility's IT department for assistance.

A patient appears in my group list, but isn't under my care:

Check to ensure that bed assignments are up to date. A bed that another caregiver is responsible for may have been inadvertently assigned to you.

Also, your group could be the "default group" to which patients without room/bed information are assigned. The patient will be removed from your group when the room/bed information has been updated.

It may also be that the patient was recently transferred into your group in the system but has not yet been physically moved.

4.4 Patient history

Some data points in the patient history screen are yellow or red when they're within the vital sign limits:

A data point is marked red or red if it falls outside of the yellow or red vital sign limits at the time it was recorded. If the vital sign limits are later changed, yellow and red dots may fall within the new limits. Only the most recent yellow and red limits are displayed

Some data points in the patient history screen are blue when they're outside the vital sign limits:

A data point is marked blue if it falls within the vital sign limits at the time it was recorded. If the vital sign limits are later changed, blue dots may fall outside of the new limits.

4.5 Removing patients from wireless monitoring

A patient has been discharged, but the patient's name is still on the wireless monitoring list:

Even if a patient is discharged from a facility, the patient must be manually removed from wireless monitoring using the procedures in the section [Manually discharging a patient](#). This ensures that the local caregiver has the final say on when a patient is discharged from their care

4.6 E-Obs functionality

When entering an observation my value doesn't appear or reverts to the previous number

Check to ensure that value you are entering is within the observation range limits (see 3.2 EWS range settings).

My Early Warning Score is displaying EWS:??

Check to ensure that each vital sign is entered and has a green tick on the right (no vital sign has a red cross on the right) (see section 3.0).

When I go to confirm my Early Warning Score, I get an error message.

Check to ensure that you have a good network connection. If necessary, contact your IT team for support. Check if the EWS score has been registered by going to the Enter Observations screen and look at the previous observation or the Obs table. If the EWS score has not registered, then ensure that you have a better network connection, re-enter the data and select 'Confirm'.

4.7 General application questions

Online help doesn't work:

Contact your facility's IT department.

Clinical reporting doesn't work:

Contact your facility's IT department.

4.8 Notification questions

There is a notification on the main screen, but the notification was never sent to my local device:

Check to ensure that bed assignments are up to date. The bed you believe you are responsible for may have been inadvertently assigned to another caregiver.

If you are not receiving notifications for any patients, contact your facility's IT department to have your local notification device serviced or replaced.

I am receiving notifications for patients not under my care:

Check to ensure that bed assignments are up to date. A bed that another caregiver is responsible for may now be assigned to you.

Also, your group could be the "default group" to which patients without room/bed information are assigned. You will stop receiving notifications when the patient's room/bed information has been properly entered.

A patient's vital sign data is yellow or red, but I didn't receive a notification:

This may be normal depending on your system configuration. Vital sign notifications can be configured such that a notification is only sent after two or more consecutive yellow or red vital sign statuses are recorded.

It is also possible, depending on your system's configuration, that notifications are turned off for your system. Check with your facility's IT department to verify this.

If you are not receiving notifications for any patients, contact your facility's IT department to have your notification device serviced or replaced.

4.9 Error message questions

The message "Internet Explorer cannot display the webpage" displays when I try to open the main screen:

Try again. If the problem persists, contact your facility's IT department for assistance.

Appendix A Technical specifications

Specifications for Sensium Patch (SH202165 US & SH202166 EU), Sensium Hospital Bridge (SH202070 US & SH202071 EU) and Sensium Home Bridge (SH202220 US & SH202221 EU)

A.1 Patch performance

Item	Specification
Heart rate  /MIN	30 – 200 beats per minute (bpm) $\pm 10\%$ or ± 5 1/min
Respiratory rate  /MIN	5 – 60 breaths per minute (BrPM) $\pm 10\%$ or ± 5 1/min,
Minimum ECG signal level	500 μ V
Temperature sensor  °C	For axillary temperatures from 32° – 44°C (89.6° – 111.2°F) within ± 0.3 °C (± 0.5 °F)
Temperature sensor  °C	DIRECT MODE thermometer displaying the measured temperature of the axilla
Duration of Single Use (Service Life)	5 days
Dust/Water Resistance	IP54

A.2 Patch specifications

Item	Specification
Patch Weight	15 g
Patch Dimensions	155mm (360mm with temp sensor) x 58mm x 5mm
Operating Temperature Conditions	+5° – +40°C (+50° – +113°F) 15 % to 90% relative humidity 700 to 1060 hPa atmospheric pressure
Storage and transportation conditions	-25° – +70°C (-13° – +158°F) Up to 90% relative humidity
Classification (60601-1)	BF
Power	CR2032 3V Lithium Metal battery

A.3 Hospital Bridge specifications

Item	Specification
Weight	445g
Dimensions	195mm x 175mm x 40mm
Operating Conditions	+5° – +40°C 15 % to 90% relative humidity 700 to 1060 hPa atmospheric pressure
Storage and transportation Conditions	-25° – +70°C Up to 90% relative humidity
Power, PoE	PoE 44 V to 57 V
Power, AC Adaptor	12 V
Service Life	5 Years

A.4 Home Bridge specifications

Item	Specification
Weight	475g
Dimensions	195mm x 175mm x 80mm
Operating Conditions	+5° – +40°C 15 % to 90% relative humidity 700 to 1060 hPa atmospheric pressure
Storage and transportation Conditions	-25° – +70°C Up to 90% relative humidity
Power, AC Adaptor	12 V
Service Life	5 Years

Appendix B Compliance information

To avoid the risk of electric shock or fire hazard ensure that any external IEEE 802.3af PoE power source used with the SH20207x Hospital Bridge meets the requirements of IEC 60950-1 clause 2.1.1.5, Limited Energy and source must also meet the requirements of IEC 60950-1 clause 2.5, Limited Power Sources.

B.1 Electromagnetic compatibility

The Sensium system consists of both the Sensium Patch & Sensium Bridge.

The tables below refer to the complete system except for specific details of electromagnetic immunity where there are differences between the Bridge & Patch

Intentional Receiver and Transmitter

SH202165-US Patch

The Patch is an intentional receiver of RF electromagnetic energy for the purpose of its operation.

In the 902 MHz to 928 MHz (ISM) frequency band the receiver bandwidth is 140 kHz.

The Patch is an intentional transmitter of RF electromagnetic energy for the purpose of its operation.

In the 902 MHz to 928 MHz (ISM) frequency band the transmit bandwidth is 180 kHz, using Frequency Shift Keying (FSK) modulation at an effective radiated power (ERP) of 1 mW (0.001 W).

SH202066-EU Patch

The Patch is an intentional receiver of RF electromagnetic energy for the purpose of its operation.

In the 863 MHz to 870 MHz (SRD) frequency band the receiver bandwidth is 140 kHz.

The Patch is an intentional transmitter of RF electromagnetic energy for the purpose of its operation.

In the 863 MHz to 870 MHz (SRD) frequency band the transmit bandwidth is 180 kHz, using Frequency Shift Keying (FSK) modulation at an effective radiated power (ERP) of 1 mW (0.001 W).

SH202070-US Hospital Bridge

The Bridge is an intentional receiver of RF electromagnetic energy for the purpose of its operation.

In the 902 MHz to 928 MHz (ISM) frequency band the receiver bandwidth is 140 kHz.

The Bridge is an intentional transmitter of RF electromagnetic energy for the purpose of its operation.

In the 902 MHz to 928 MHz (ISM) frequency band the transmit bandwidth is 180 kHz, using

Frequency Shift Keying (FSK) modulation at an effective radiated power (ERP) of 1 mW (0.001 W).

SH202071-EU Hospital Bridge

The Bridge is an intentional receiver of RF electromagnetic energy for the purpose of its operation.

In the 863 MHz to 870 MHz (SRD) frequency band the receiver bandwidth is 140 kHz.

The Bridge is an intentional transmitter of RF electromagnetic energy for the purpose of its operation.

In the 863 MHz to 870 MHz (SRD) frequency band the transmit bandwidth is 180 kHz, using Frequency Shift Keying (FSK) modulation at an effective radiated power (ERP) of 1 mW (0.001 W).

SH202220-US Home Bridge

The Bridge is an intentional receiver of RF electromagnetic energy for the purpose of its operation.

In the 902 MHz to 928 MHz (ISM) frequency band the receiver bandwidth is 140 kHz.

In the supported cellular bands the receiver bandwidth is 1.4 to 20 MHz.

In the 902 MHz to 928 MHz (ISM) frequency band the transmit bandwidth is 180 kHz, using Frequency Shift Keying (FSK) modulation at an effective radiated power (ERP) of 1 mW (0.001 W).

In the supported cellular bands the transmit bandwidth is 1.4 to 20 MHz, using QPSK, 16QAM and 64QAM modulation at an effective radiated power (ERP) of up to 200 mW (0.2 W).

Supported US Cellular Bands

LTE Band	Transmit Band (Tx)		Receive Band (Rx)	
	Minimum	Maximum	Minimum	Maximum
B2	1850 MHz	1910 MHz	1930 MHz	1990 MHz
B4	1710 MHz	1755 MHz	2110 MHz	2155 MHz
B5	824 MHz	849 MHz	869 MHz	894 MHz
B12	699 MHz	716 MHz	729 MHz	746 MHz
B13	777 MHz	787 MHz	746 MHz	756 MHz
B14	788 MHz	798 MHz	758 MHz	768 MHz
B17	704 MHz	716 MHz	734 MHz	746 MHz
B25	1850 MHz	1915 MHz	1930 MHz	1995 MHz
B26	814 MHz	849 MHz	859 MHz	894 MHz
B66	1710 MHz	1780 MHz	2110 MHz	2200 MHz

SH202221-EU Home Bridge

The Bridge is an intentional receiver of RF electromagnetic energy for the purpose of its operation.

In the 863 MHz to 870 MHz (SRD) frequency band the receiver bandwidth is 140 kHz.

In the supported cellular bands the receiver bandwidth is 1.4 to 20 MHz.

In the 863 MHz to 870 MHz frequency band the transmit bandwidth is 180 kHz, using Frequency Shift Keying (FSK) modulation at an effective radiated power (ERP) of 1 mW (0.001 W).

In the supported cellular bands the transmit bandwidth is 1.4 to 20 MHz, using QPSK, 16QAM and 64QAM modulation at an effective radiated power (ERP) of up to 200 mW (0.2 W).

Supported EU Cellular Bands

LTE Band	Transmit Band (Tx)		Receive Band (Rx)	
	Minimum	Maximum	Minimum	Maximum
B3	1710 MHz	1785 MHz	1805 MHz	1880 MHz
B8	880 MHz	915 MHz	925 MHz	960 MHz
B20	832 MHz	862 MHz	791 MHz	821 MHz

Guidance and manufacturer's declaration – electromagnetic emissions

The Sensium system is intended for use in the electromagnetic environment specified below. The customer or the user of the Sensium system should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The System is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	The System is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Not applicable to Patch
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Sensium System guidance and manufacturer's declaration – electromagnetic immunity

Essential Performance

A temperature readout of the correct temperature, a notification of a temperature outside of the measurement range or a notification of a lack of communications is considered the Essential Performance of the System.

It is possible that the Heart Rate or Respiration Rate could show an incorrect value if degradation occurs due to Electromagnetic interference.

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the Bridge should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Complies.	Note that the Hospital Bridge and Patch could be damaged by – 15 kV air discharge. However the system remains safe to use and the clinician is informed.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for ac power supply lines	Complies	Not applicable to Patch.
	± 1 kV for input/output lines	Complies	Not applicable to Patch or Home Bridge.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line(s) to line(s)	Complies	AC Power Port. Not applicable to Patch.
	± 0.5 kV line(s) to earth	Complies	Ethernet Port. Not applicable to Patch or Home Bridge.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT for 0,5 cycle	Complies	Not applicable to Patch.
	0 % UT for 1 cycle		
	70 % UT for 25/30 cycles (0.5 seconds)		
	0 % UT for 5 s		
Conducted RF IEC 61000-4-6	3 V @ 150 kHz to 80 MHz	Complies	6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz. Not applicable to Patch.
Radiated RF IEC 61000-4-3	10 V/m @ 80 MHz to 2.7 GHz	Complies	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m @ 380 to 390 MHz	Complies	This applies for a 30 cm separation distance between the portable RF device and the Patch or Bridge. On some frequency bands there may be a temporary loss of
	28 V/m @ 430 to 470 MHz		
	9 V/m @ 704 to 787 MHz		
	28 V/m @ 800 to 960 MHz		

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
	28 V/m @ 1700 to 1990 MHz		communications of vitals which the clinician is notified about. Measurements made during this period are made available when the communications link is restored.
	28 V/m @ 2400 to 2570 MHz		
	9 V/m @ 5100 to 5800 MHz		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Complies	Not applicable to Patch.
Proximity magnetic Fields IEC 61000-4-39	8 A/m @ 30 kHz 65 A/m @ 134,2 kHz 7,5 A/m @ 13,56 MHz	Complies	Not applicable to Patch or Home Bridge.



UT is the a.c. mains voltage prior to application of the test level.

B.2 FCC compliance statement (United States)

SH202165-US Patch

FCC ID: AEJSH202165

SH202070-US Hospital Bridge contains the following module: -

FCC ID: AEJSH202075

SH202220-US Home Bridge contains the following modules: -

FCC ID: AEJSH202075

FCC ID: N7NHL78M

These devices comply with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.
2. These devices must accept any interference received, including interference that may cause undesired operation.



CAUTION: Changes or modifications to these units not expressly approved by the party responsible for compliance could void the user's authority to operate these units.

These units have been tested and found to comply with the limits for a Class A digital devices, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a non-residential installation. These units generate, use and can radiate radio frequency energy and, if not installed and used in accordance with the manufacturer's instructions, may cause interference harmful to radio communications.

FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. The bridge should be installed and operated with minimum distance 20 cm between the radiator and your body.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Appendix C Disposal of electronic devices

The Sensium Bridges are electronic devices and carry the symbol shown below. Bridges should be disposed of in accordance with the local electronic waste procedures.



WARNING - Used patches may be contaminated and should therefore be disposed of using local clinical waste procedures.

In compliance with the EU WEEE directive 2012-19-EU, the symbol shown below on the product and/or accompanying documents means that unused electrical and electronic products should not be mixed with general waste.



Appendix D Symbols on the product package

Symbol	Description
	Medical Device Class BF – Patient connection is isolated from any main supply
	See instructions for use
	Lot Number
	Use by Date
	Quantity in a package
	Symbol for Manufacturer
CE2797	CE (Conformity European) Mark with Notified Body designation.
	Devices should be disposed of in accordance with the local electronic waste procedures.
	For single use only. Do not reuse
	Serial Number for device
	Catalog Number
IP54	IP54 is the rating for the enclosure against water and dust protection.
	EU authorised representative
	Storage Temperature Limits
	Storage Humidity Limits