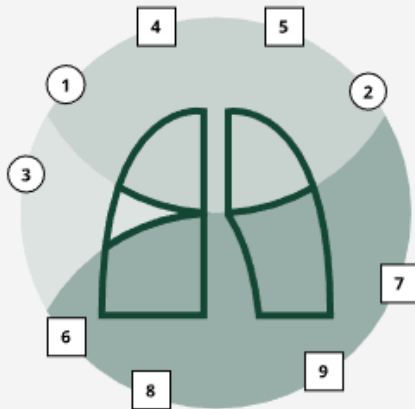




Senti Wear
Web Application

User Guide

Unique Version Identifier - 1.0
Issue Date 2022-12



senti

Senti Tech Ltd of 57 Jordan Street, Liverpool L1 0BW, UK.

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General Information

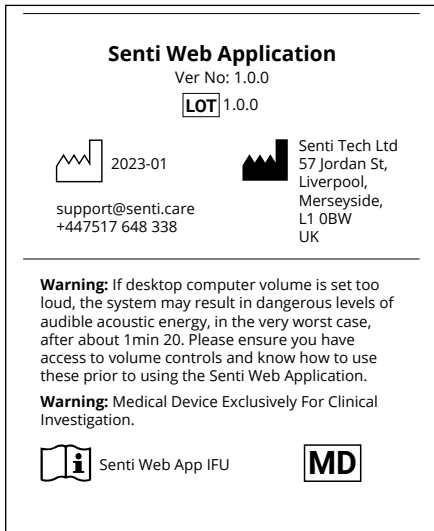
The Senti Wear Web Application is software which is intended for use by trained medical professionals who are competent in auscultation. It enables users to access and listen to breath and heart sounds of patients in their caseload and who have been issued with a Senti device. Users can listen to any of the available Records, which may be from a recent or historical recording session.

- **The software should not be used** by people who are not medically trained and competent in auscultation

The manufacturer of the Senti Wear Web Application is **Senti Tech Ltd of 57 Jordan Street, Liverpool L1 0BW, UK.**

The Senti support team can be contacted at support@senti.care or **+447517 648 338**.

Markings on Software



General Description

The Senti Wear Web Application should be used on a desktop computer using the latest version of the following browsers: Chrome or Microsoft Edge.

It is designed as a portrait-shaped panel so that users can use it alongside another window where, for example, they may refer to an electronic patient record. Only authorised users may attempt to access the system using their own username and password. Do not share your password with anyone else. Do not attempt to gain access to the system if you are not authorised.

High-quality headphones exhibiting a flat frequency response must be used when listening to audio records, such as:

- Audio-Technica M40x
- OneOdio DJ Headphones
- Beyerdynamic DT880 PRO

WARNING - If desktop computer volume is set too loud, the system may result in dangerous levels of audible acoustic energy, in the very worst case, after about 1min 20 seconds. Please ensure you have access to volume controls and know how to use these prior to using the Senti Web Application.

Report Serious Issues

If you or your patients experience any serious incident (for example, harm caused by the device, or wrong diagnosis or treatment) which you believe **may** have been caused by the device, report this to both the manufacturer (Senti Tech; support@senti.care or +447517 648 338) and to MHRA in the UK immediately.

Instructions for Use

Accessing the Web Application

Prior to using the Senti Wear web application (“web app”), the Senti support team will set each user and their caseload up on the system, by creating user accounts and allocating patient operators to these users.

Once a user has been set up to use the web app, they will receive a confirmatory email from the Senti support team, confirming the username (their email address) and the password that they should use to access the system.

To access the web app, the user should:

1. Go to <https://web.senti.care>
2. The Senti web app Login Page is displayed.
3. Enter the username and password given in the email from the Senti support team.
4. Click the “Sign in” button.
5. The Patient List will be displayed.

Please Note - If any difficulties are encountered logging into the system, the user should contact support@senti.care

Possible Errors

An error message will be displayed if login credentials are not recognised. There is no password reset feature in this version of the web app so, if this occurs, the user should contact support@senti.care

senti

Sign in

Email

Password

Sign in

Forgotten your password? Please contact support@senti.care for assistance

Senti Web Application
Ver No: 1.0.0
LOT 1.0.0

2023-01
support@senti.care
+447517 648 338

Senti Tech Ltd
57 Jordan St,
Liverpool,
Merseyside,
L1 0BW
UK

Warning: If desktop computer volume is set too loud, the system may result in dangerous levels of audible acoustic energy, in the very worst case, after about 1min 20. Please ensure you have access to volume controls and know how to use these prior to using the Senti Web Application.

Warning: Medical Device Exclusively For Clinical Investigation.

Senti Web App IFU MD

Login Page

Patient List

Default Patient List Display

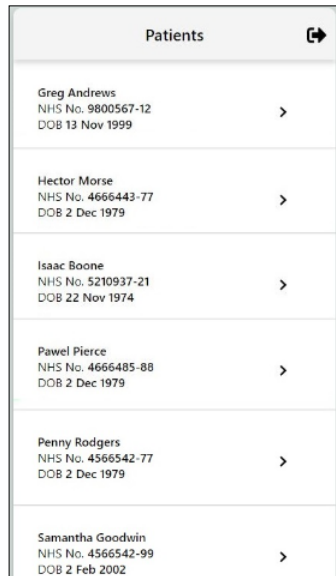
Once logged in, the Patient List is displayed, showing a list of all patients that have been allocated to the user.

On this page, the user can:

- Scroll up and down to view the full list of patients, as needed.
- Access the Records for a patient by clicking anywhere on their Patient Card.



Patient Card

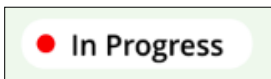


Patient List

Patient List Notifications

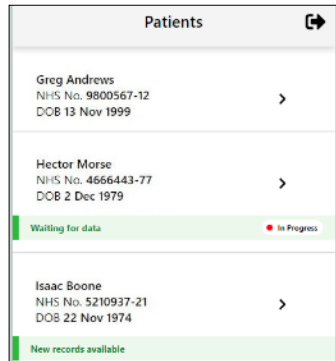
Notifications will be displayed on the Patient List in the following circumstances:

- If the patient operator is currently using their Senti device, an “In Progress” indicator is displayed in the Information Bar on their Patient Card.



The session “In Progress” indicator

- If any new Records are available for a Patient, an Information Bar is displayed on their Patient Card showing:
 - All Records are available, or
 - A counter of how many Records have been received so far (if the device is still in use)



Patient List with new data notifications



Patient Card with a counter of new Records displayed in the Information Bar

- If new Records are expected but are not available yet, a “Waiting for data” message is displayed.



Patient Card with the Information Bar showing the device is in use but no Records have been received so far

Issues with a Recording Session (Low Priority Technical Alarms)

If a problem has been identified with the latest recording session, information and notifications will be displayed on the Patient List, as follows:

- The Information Bar will show the current status of the device and whether any data has been received.
- A cyan alert is generated on failure to receive an expected message within 5 minutes of the last successful message during an active recording session. You do not need to act on cyan alerts.



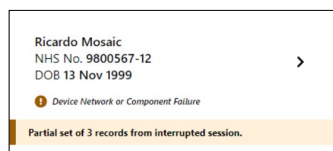
Example of when a patient is operating the device but the system has waited longer than five minutes for any data, so Information Bar shows it is still “Waiting for data”

- The “In Progress” indicator will display if the system is trying to recover and complete the recording session.
- If the system is not able to recover, the Information Bar will show how many (if any) Records are available and a message will be displayed summarising the error which has occurred.



Example of when there is an issue which the system is trying to recover from but some Records are available

- Amber warning messages are generated either within two minutes of the garment broadcasting an error state to the web application or within 15 minutes of an expected message failing to be received by the web application.

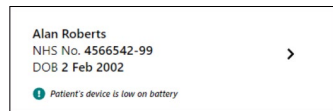


Example of when there was an irrecoverable error but some Records are available

- Amber warning messages may require action to resolve. In the first instance, the Senti support team will address these issues directly with the patient operating the device. However, **if you urgently need to assess the patient clinically, please contact the Senti support team on +447517 648 338.**

Device Low on Charge

If the system detects that a patient’s Senti device is running low on battery charge, a message will be displayed on the Patient List. The Senti team will contact the operator and support them in recharging the device. This is a low priority technical alarm.



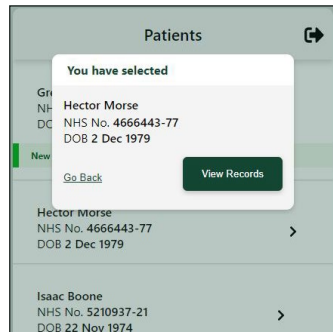
Low battery warning message

Confirming the User’s Choice of Patient Records to Access

When the user clicks a Patient Card, a dialog box is displayed, requiring the user to confirm their choice of patient prior to viewing the Records.

The user can:

- Click “View Records” to confirm the choice of Patient, or
- Click “Go Back” to return to the Patient List.



Dialog box to confirm Patient selection

Patient Home Page

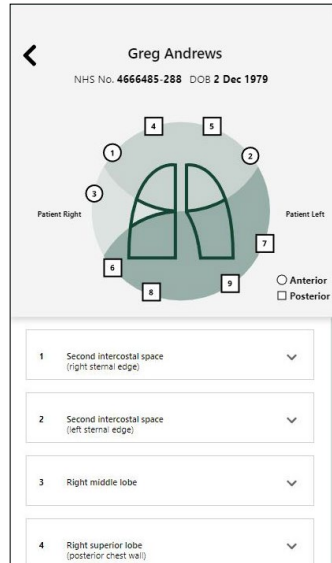
Default Patient Homepage

When the user has clicked “View Records” in the dialog box confirming their choice of patient, the Patient Home Page for that patient is displayed, containing:

- Patient details.
- Lung diagram, with numbers representing each of the nine auscultation points from which breath and heart sounds are recorded by the Senti device.
- Location List, consisting of a Location Card for each of these nine auscultation points.



Location Card for location 3, the Right Middle Lobe



Default Patient Home Page

On this page, the user can:

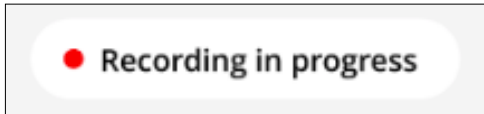
- Scroll down and up the Location List to view all the auscultation points as needed (the lung diagram remains in view at all times).
- Access the Records for an auscultation point by:
 - Clicking anywhere on that auscultation point’s Location Card,
 - or
 - Clicking the auscultation point number on the lung diagram.

This will expand the Location Card to display all Records for that auscultation point (see ‘Listening to Records’ section).

Patient Home Page Notifications

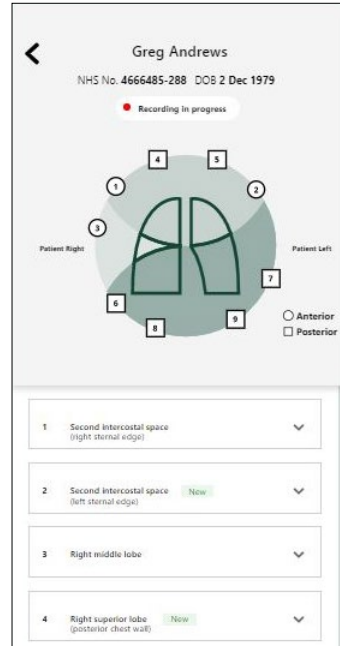
Notifications will be displayed on the Patient Home Page in the following circumstances:

- If the patient operator is currently using their Senti device, a “Recording in progress” indicator is displayed at the top of the page, below the patient details.



The “Recording in progress” indicator

- If new Records are available for an auscultation point, a “New” indicator is displayed on that Location Card (as shown for some of the Location Cards opposite).

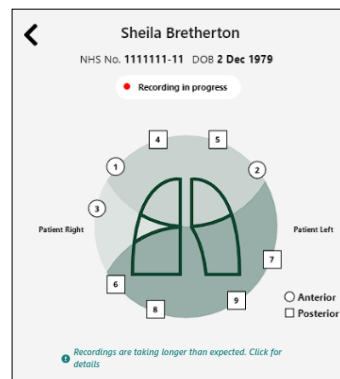


Patient Home Page with Notifications

Issues with a Recording Session (Low Priority Technical Alarms)

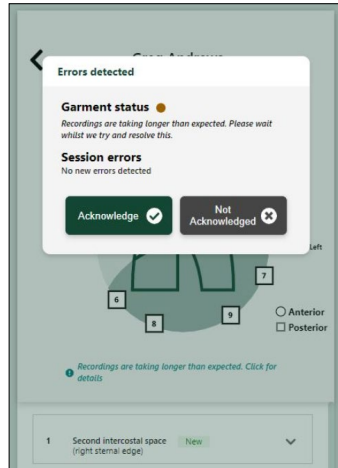
If a problem has been identified with the current or latest recording session, information and notifications will be displayed on the Patient Home Page, as follows:

- If there is a temporary fault from which the system is trying to recover, a cyan warning message is displayed. This cyan alert is generated on failure to receive an expected message within less than 5 minutes of the last successful message during an active recording session.



Cyan warning message about a temporary issue displayed on Patient Home Page

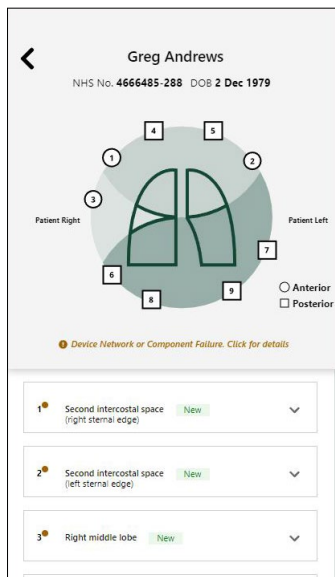
- If there is a fault from which the system is unable to recover:
 - When the user confirms their choice of patient, the Patient's Home Page is loaded but an error dialog box is also displayed, showing the current Device Status and any Session Errors that have occurred. The user should click "Acknowledge" or "Not Acknowledged" to view the page.
 - Clicking "Acknowledge" confirms you have reviewed these technical alerts, marks this error message as acknowledged, and prevents the error message dialog box from displaying the same errors again (unless these errors are actively ongoing).
 - Clicking "Not Acknowledged" will mean these technical alerts will reappear in the error message dialog box each time the patient page is accessed, until the technical alert is acknowledged.
 - On closing the error dialog box, the user can view the Patient Home page. The Device Status is displayed as an amber warning message below the lung diagram and the user can click this at any time to redisplay the error dialog box.
 - If this issue has prevented any Records being obtained during the latest recording session, an amber



Dialog box with a warning message and explanation of the issue that has occurred

notification circle is displayed on the Location Card for that auscultation point.

- Amber warning messages are generated either within two minutes of the garment broadcasting an error state to the web application or within 15 minutes of an expected message failing to be received by the web application.



Patient Home Page showing an amber warning message about the non-recoverable issue, and amber notification circles on Location Cards where Records are missing for this auscultation point

Listening to Records

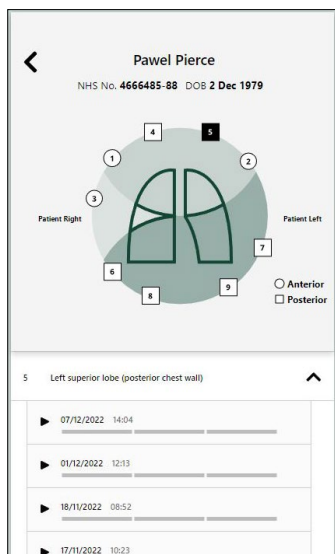
Displaying Records for a selected auscultation point

When the user has clicked on the number or Location Card for an auscultation point:

- The list of Location Cards moves up or down, so that this auscultation point's card is directly below the lung diagram.
- The Location Card's accordion expands to show a list of all Records for that auscultation point.
- Each Record consists of a playback line, the date and time of the recording, and a Play button (black triangle) to the left of the date and playback line.



Complete Record ready to play



Left superior lobe Location Card expanded, showing the Records available for this auscultation point

Listening to Records

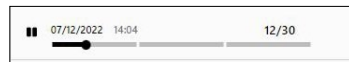
- All Records listed can be listened to, including those from previous recording sessions that have been listened to before.
- If a Record is new (i.e. it has not been listened to at all), a “New” indicator is displayed above the playback line.



New Record which has not been listened to yet

To listen to a Record, the user should click the Play button. When the user clicks Play:

- The Record will play such that the user can listen to it using high quality headphones (as described in General Description).
- The lung diagram is animated, representing when the patient is breathing in or out during the Record.
- A counter is displayed, showing where the user is up to in the Record.
- The Play button toggles to become a Pause button, which the user can click to pause the Record.
- Otherwise, the Record will play until the end and then stop.



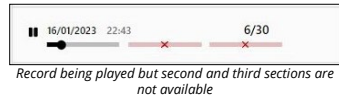
Record being played: most of the first section has been listened to so far

Please Note - Each Record is made up of three separate recordings, taken a short time apart.

Issues with Records; Alarms and Alerts Log

If there was an issue with a Record (in part or in full):

- Any section of a Record which is due to an unacknowledged error is shown in pink with a red cross.
- To see technical details of the fault, click on one of the bars marked with the red cross. This accesses the alarm system log and displays the dialog box with details of the issue - other sections can be played as normal.
- This alarm system log is maintained at all times, including when the alarm system is powered down.
- If our web application loses power, these logs will be recovered as part of our data restoration processes. If a device loses power, either during a recording session or over a 5-minute period 30 minutes after the device has last “checked in” with the web server, then this will generate a technical fault which will be recorded in this alarm log.
- If the alarm log reaches maximum capacity (~billions of entries), then new logs will replace the oldest logs.
- Once errors have been acknowledged, missing sections are shown with a red cross only (no pink background). If all sections of a Record are missing, no Play button is displayed.



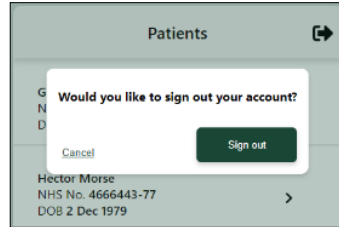
Signing Out of the Web Application

The user may sign out of the web application when viewing their Patient List, by clicking the Sign Out icon displayed in the top right corner and choosing “Sign out” in the drop down menu that appears.



Sign Out Icon

The user will be prompted to confirm their wish to sign out, and have the opportunity to Cancel at this point, or click the “Sign out” button to confirm.



Dialog box confirming that the user wishes to sign out

The user is automatically signed out of their account if they close the web application page.

Contact us

The **Senti support team** can be contacted via-

Email - support@senti.care

Phone - +447517 648 338

Website - www.senti.care

Post - Senti Care, 57 Jordan Street, Liverpool, L1 0BW, UK

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