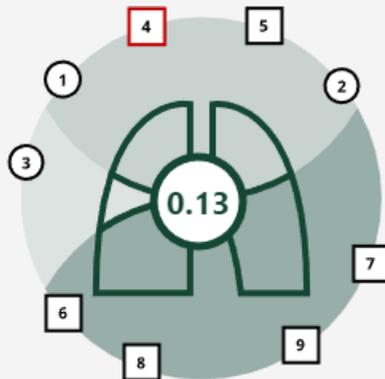# senti

Senti
AI Systems

User Guide

Unique Version Identifier - 1.0
Issue Date 2023-01

Table of Contents

General Information

The Senti-AI subsystem extends the Senti Wear Web Application. Please refer to the [Senti-Wear Web Application User Guide](#) in combination with this document.

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 Senti-AI subsystem is seamlessly integrated into Senti Wear and extends this functionality by autonomously reviewing all breath sound data collected by the Senti-Wear devices, and flagging for review those patients whom the AI system detects are moving away from their baseline.

• **The software should not be used** by people who are not medically trained and competent in auscultation
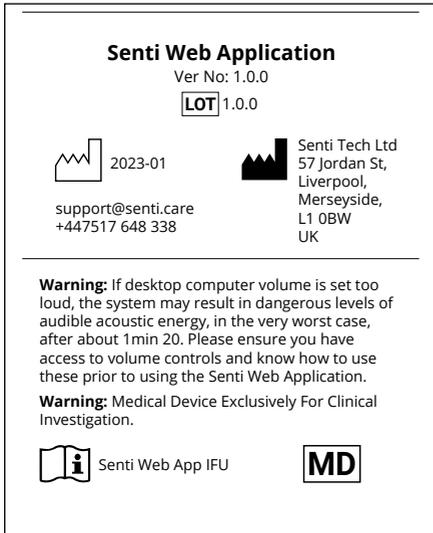
The manufacturer of the Senti-AI Web Application is **Senti Tech Ltd of 57 Jordan Street, Liverpool L1 0BW, UK.**

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

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.

Markings on Software

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**

General Description

The Senti-Wear Web Application and Senti-AI subsystem 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.

Patient Deterioration Detection System Overview

The Senti-AI system uses artificial intelligence to detect possible patient deterioration. It analyses the audio records from each auscultation point independently to produce an anomaly burden score for that location. A higher score indicates possible clinical deterioration. The algorithm will determine whether this score has changed from the patient's baseline and flags the patient for review if it has.

The algorithm also evaluates the nine auscultation points as a whole, to provide a global score, as an indicator of overall lung health. This may also flag the patient for review if deterioration is detected, which can occur either with or without a particular auscultation point(s) being flagged for review. The global score is only shown for the latest recording session.

Measuring Function

Patient Deterioration Score - The patient deterioration scores are currently undergoing clinical evaluation. No performance or accuracy claims are made for the system at this stage.

This device system is exclusively for investigational use.

Physiological Alarms

Detect Patient Deterioration and Flag for Review - The Detect Patient Deterioration and Flag for Review alarm is currently undergoing clinical evaluation. No performance or accuracy claims are made for the system at this stage.

This device system is exclusively for investigational use.

Instructions for Use

Accessing the Web Application

Prior to using the Senti-AI 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.

For instructions on how to log in, navigate the patient list, review a patient record, listen to audio recorded from our device, and log out, please refer to the Senti Wear Web App User Guide: https://senti.care/how-to-use-senti/

Patient Deterioration Detection System

**Flagging Patients for Review**

- When the Senti-AI system detects possible deterioration in a patient's global score or for one or more auscultation points, a "red flag" notification is displayed on the Patient List page alerting the user to review that patient's data.



Flagged Card on Patient List page

Global Score

- The patient's Global Anomaly Burden Score, indicating their current lung health, is displayed at the centre of the lung diagram. It ranges from 0 to 1, with a higher score indicating possible abnormal lung sounds.
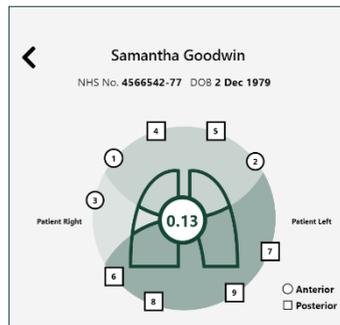
Global anomaly burden score

- If the algorithm detects deterioration when evaluating the auscultation records for the latest session as a whole (which can occur either with or without a particular auscultation point(s) being flagged), this Global Score is flagged for review.
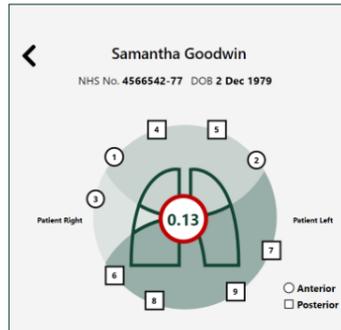
Global anomaly burden score - flagging a query patient deterioration
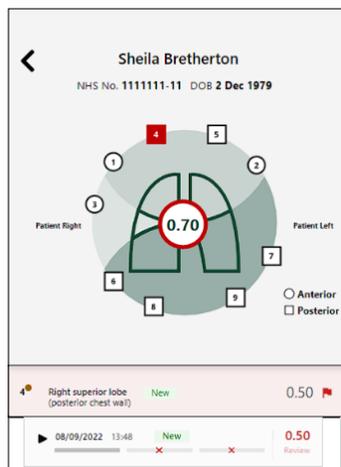
Anomaly Burden Score

- The Anomaly Burden Score for the most recent session for each auscultation point is displayed on the Location Card.

Location Card showing the latest anomaly burden score for the Second intercostal space auscultation point

- The Anomaly Burden Score, for each Record for each auscultation point, is displayed next to the playback line for that Record. It ranges from 0 to 1, with a higher score indicating abnormal lung sounds.

Record with an anomaly burden score of 0.04

- If the algorithm determines that this score has changed from the patient's baseline for this auscultation point, this Auscultation point and the Record are flagged for review.

Patient Home page showing the Global and Right superior lobe anomaly burden scores flagged for review

- Once the Record has been reviewed (this happens once the play button is clicked for that recording session), the red text and flag will change to black and the text for that Record will change to "Reviewed".

Reviewed Record with black text and Location flag

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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