

senti

Senti Wear Device

Instructions for Use

Unique Version Identifier - 2
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senti

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

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General Instructions

The Senti Wear device is intended for use by people with respiratory illnesses to capture their breath and heart sounds. The device has a single main function, which is to record these sounds when the device is being worn.

- **The device should not be used by** people with significant cognitive impairment or limiting physical disabilities (such that they must have assistance with personal care or getting dressed).
- **The device should not be used by** any persons known to have a sensitivity or allergy to any of the components of the device (silicone, cotton, elastase, micromodal fabrics).

The device cannot be serviced whilst in use. If the device requires servicing, then the device should be returned to the manufacturer.

Patients themselves are the intended operator of this medical device and can use all device functions safely, including charging the device battery. Cleaning and other maintenance will be undertaken by the manufacturer.

The manufacturer of the Senti Wear device is

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

Device Classifications

- Class ii medical electrical equipment
- Mains Powered device
- Applied parts are all type-b applied parts
- Suitable for operation up to 30 minutes, twice per day.

Seek Medical Attention

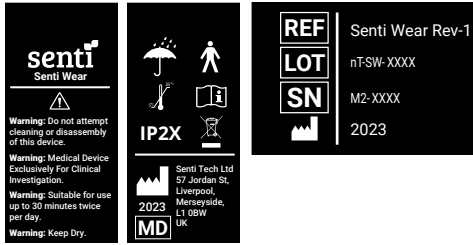
The garment does not offer any treatment directly; it is only there for diagnosis and monitoring purposes. If you start to feel increasingly ill, seek medical attention as usual.

Report Serious Issues

If you 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.

Device Markings

MARKINGS ON GARMENT



MARKINGS ON BATTERY CASE



MARKINGS ON BATTERY CHARGER



Device Symbol Explanation



Refer to instructions for use



Type-B Applied parts. These parts of the device are intended to come into contact with the patient and provide insulation from the device electronic components.



Device warning signs with information as stated next (or below) the symbol.



Keep Dry



Class ii ME equipment

IP2X

Protected against solid foreign objects 12.5mm or greater, not protected from ingress of water.

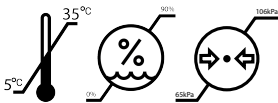


This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please return to Senti.



Indicates that the device is a Medical Device.

Environmental Conditions



LIMITS: When transporting, storing or using the device, do not exceed temperature of 35 degrees celsius or lower than 5 degrees celsius, 0% to 90% humidity, and 65 to 106 kPa, during normal operations.

Device is suitable for use in Pollution Degree 2 (or below) environments.

Warning and Safety Notices

WARNING:

This device has **two modes of operation**. These modes are **data capture** and **charging**. **Do NOT** attempt to charge the device whilst operating in data capture mode.

WARNING:

Dust and **Lint** may accumulate on the silicone sensor modules. This may degrade the contact between the sensor and the operator. The sensor modules should be cleaned at least every two weeks by wiping with alcohol-based or chlorhexidine-based wipes.

- WARNING:** Do NOT attempt to **hand-wash, machine wash, tumble-dry, or clean this device with water.** The charger, garment, and sensors may be cleaned with alcohol-based or chlorhexidine-based wipes. Other cleaning products **may** leave residue and cause skin irritation and allergic reaction. If the device requires further cleaning, please contact the manufacturer (see 'Contact Us' Section).
- WARNING:** Do NOT attempt to **remove any of the electronics (including the battery), open the silicone housing of the sensor modules or gain access to any electronic parts.** If device requires maintenance, contact the manufacturer.
- WARNING:** **KEEP DRY at all times.** Device **must NOT** be operated or charged **when wet.**
- WARNING:** The device is suitable for use only up to **30 minutes twice per day.** Over-use of the device may lead to pressure sores over the chest.
- WARNING:** Do NOT wear the device over breached or otherwise compromised skin.
- WARNING:** When charging the device, **Use ONLY** the wall socket and charging cables supplied with the device.
- WARNING:** **Modifying** the equipment may unacceptably affect the performance or safety of the device. **Do NOT** attempt to modify the device and use only as described in these instructions.
- WARNING:** The device uses hypo-allergenic materials and is not anticipated to cause skin irritation or an allergic reaction. However, if, after wearing the device, you notice areas of skin irritation (eg red or itchy areas of skin), please **STOP** using the device, contact your **GP**, and **inform the Senti support team** (see "Contact Us" section).

Electrical Power Source

During data capture mode, this device is internally powered by a battery. During charging mode, this device is class ii ME equipment and must be charged by an external power supply rated between 80-240V.

- WARNING:** Do NOT attempt to **access the electrical components of the device.** If the device loses power, please remove the garment and charge as per instruction below. Please contact the manufacturer if the device does not regain power.
- ONLY** use the power cord supplied with this device. **DO NOT** attempt charging the device using any other power cord.

Radiofrequency Communications

This Device uses the following radio frequencies for wireless communication (via "Wi-Fi"): 2.4GHz

- WARNING:** This device utilises radiofrequency communications ("Wi-Fi"). **The device system has been fully tested** to ensure Electromagnetic compatibility with other medical devices intended (and properly tested) for use in the home environment.
- Please ensure that any critical equipment** (eg. medical device equipment) used in the vicinity of this device **has been suitably tested and approved for use in the home environment** to avoid any compatibility issues.

Equipment Description

This device system comprises the Senti smart garment, command module, data-link, and data storage. The smart garment has a similar form to a T-Shirt, jacket or tabard, embedded with ten sensor modules encased in silicone. These sensor modules communicate with a command module which is also integrated into the garment. The command module manages the power and data transmission requirements of the device. The device is accompanied by cloud-based software to listen to both contemporary and historically recorded breath sounds for each Senti patient.

The garment itself is made from textile composite, including cotton, elastase, and bamboo. The garment also includes polyethylene foam (LD33) for comfort. All other components (including electronic and other plastic components) will be entirely encased in silicone.

The Senti Wear device will be labelled clearly to indicate the device (garment and electronics) version on the inside of the garment, and will be clearly labelled for Investigational Use Only, conforming to the Medical Device Regulation (MDR).

How the Device and Service Functions

The device will be supplied to you fully charged and clean. If you are dissatisfied with the device, please contact the support team using the details below (in section “Errors and Faults”). The device needs to be in contact with your skin in order to capture breath and heart sounds. Once wearing the device, tapping on the chest area of the device will change it from low powered mode into fully powered mode. In this mode the device will check if it can detect a heartbeat before any audio is collected. Occasionally the device may be accidentally tapped or moved in a way that activates it, however if no heartbeat is detected, it will go back into low power mode without recording any audio. The device has a blue light in the centre on the front of the device; this light should be off during low-power mode, should start blinking when listening for a heartbeat, and should become solid (unblinking) once a heartbeat is detected and you are in the correct position (see Operating Instructions from page 11).

The device will then transmit your breath and heart sounds to our secure servers, where an authorised clinician will listen to them (and any previously recorded breath and heart sounds) as part of the usual assessments and reviews that they would undertake with you.

We will notify you (via text message or a phone call) if the device needs to be charged; instructions for how to charge the device are included below. We monitor devices every half an hour to ensure they are functioning properly. If we detect a fault, we will notify you via text message or a phone call.

Physical and Performance Characteristics of the Device

The device contains nine acoustic sensors and a biokinetic sensor housed in silicone. These sensors align with the correct location on your chest, provided the garment fits comfortably and neither feels tight nor too baggy to you (the silicone modules must make good contact with your skin). The silicone modules must remain flush against your skin for the device to function. You must lie at least slightly reclined during recording, to ensure good contact (as per the Operating Instructions below).

If you are unable to tolerate using the device, for any reason, please contact the clinical team looking after you and let them know. Please also contact our support line (details in the section “Errors and Faults”) and let us know the issues you’ve experienced so we can take steps to address these.

The command module has a light to indicate whether the device is transmitting breath and heart sounds. The battery pocket has a light to indicate charging and indicate when the device is fully charged.

Service Life of the Device

The materials and electronics used in the garment (including the battery) may degrade after no less than 5 years. The device should take no more than 30 minutes to operate and is intended to be operated twice per day.

Instructions for Use

Installation

The device will arrive out-of-the-box ready, fully charged and clean. Either in advance or during installation, the device will be configured to connect to an existing wireless network, or a pre-configured standard commercial/residential router shall be provided. The device installer will discuss with you the best location for using the garment, depending on the router location. The device installer will ensure that the correct garment wings have been provided, ensuring a snug, but not tight, garment fit. The device installer will remove and take away the device's packaging (which is used for storage and transportation).

Operating Instructions

1. Before starting

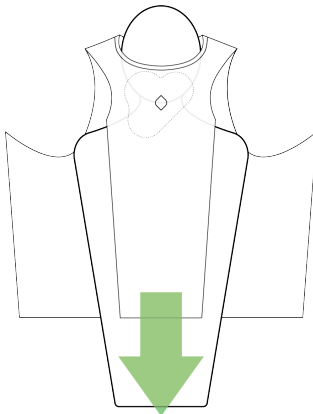
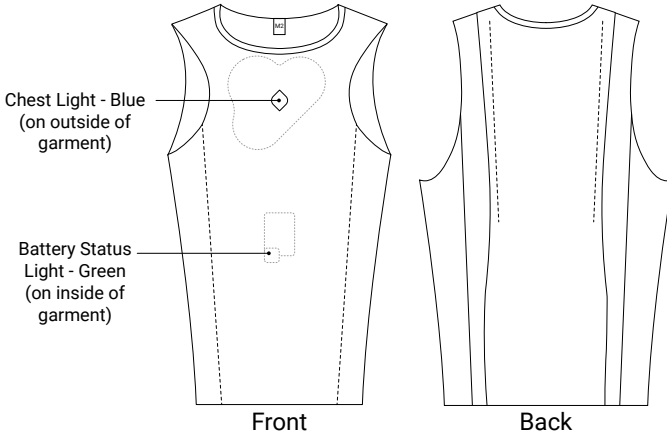
You will need to remove any clothing from around your chest in order for the device to be worn against the skin. No specific treatment or handling of the device is required before use.

Please Note - *If the device light shows a 'long blink' (5 seconds (5s) on and 5s off or 2s on and 18s off), it is currently communicating with the Senti servers and will only be usable once this has completed. This can occur every 30 minutes and typically takes between 3-5 minutes.*

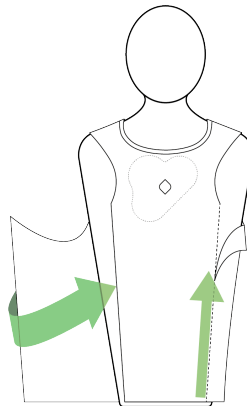
2. Putting the garment on

Pull the garment over your head and then zip the wings of the garment to the central chest piece. The garment should then sit as a T-Shirt/vest would sit. The garment should be worn so that the silicone modules are not visible on the outside of the device. When worn correctly, you should feel these modules in contact with your skin. The garment sizing label (eg M2, S3, L1 etc) is on the inside of the device and should align with the back of your neck.

Please Note - It is okay if you wish to wrap a blanket or loose clothing over the top of the garment whilst wearing it. This will not affect the quality of the recordings.



1. Pull the garment over your head.



2. Zip the wings of the garment to the central chest piece.

3. Check device is working

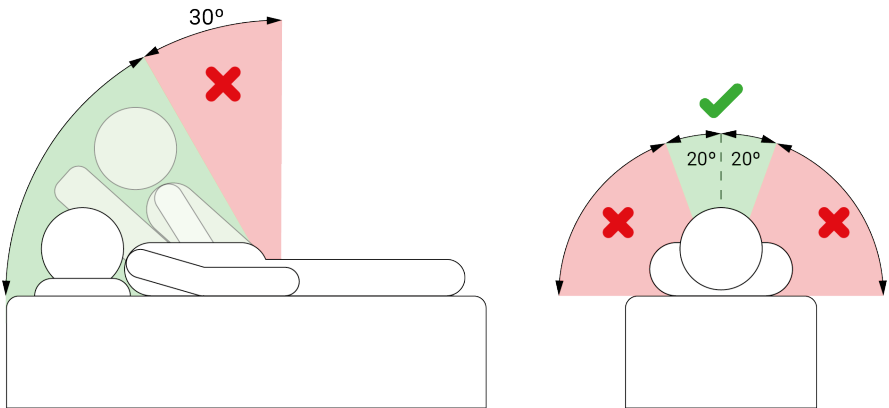
Once you are wearing the garment, gently tap the diamond shaped window on your chest. The light will begin to blink slowly, to indicate it is looking for your heartbeat. Once it detects this, the blink will change to mimic a heartbeat. This means the device is now active and waiting for you to get into the correct position (see below).

Please Note - Occasionally the device may begin flashing before it is tapped. This is due to the device sometimes registering movement as being similar to a tap and will therefore activate it.

4. Start a recording

Lie down on something flat and comfortable throughout the recording, ideally a sofa or bed. If lying down flat is not possible, recline in a comfortable position. See diagram below for reference.

The indicator light on the front of the garment should change to a solid blue once you are lying at the correct angle. This indicates that breath and heart sounds are being transmitted to our servers.



5. During a recording

Take deep breaths in through your nose and out through your mouth, at your own pace, stopping if you feel out of breath, light headed, or dizzy. The recording session should be complete in less than 10 minutes but may last up to 20 minutes. During a recording session, the light will remain a solid blue.

6. Shutdown Procedure

Once the recording session has completed successfully, the device will emit a high pitched tone for 10s after which the chest indicator light will turn off. Please wait until the tone has finished before removing the garment.

The chest light will then flash intermittently for 5 minutes to indicate it's sending data to the Senti servers. For this period of time it will not reactivate and should now be removed.

Store the device back on its hangar in a safe place to prevent any trip hazards. When not in use the device should always be stored upright.

Charging the Device

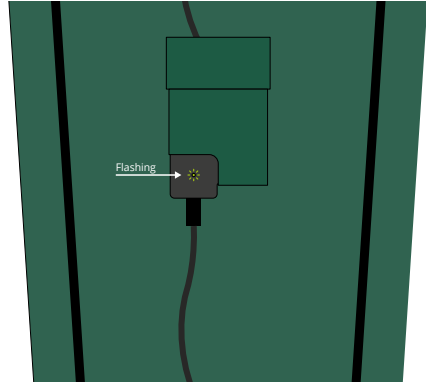
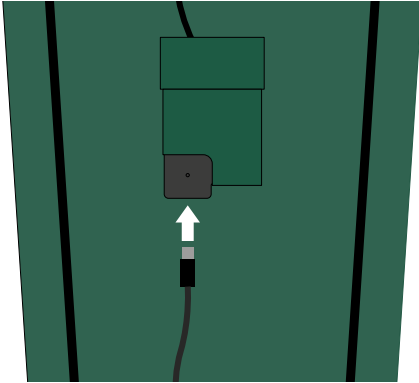
1. When to charge the device

We recommend charging the device overnight after each daily use.

DO NOT attempt to charge the device whilst wearing it.

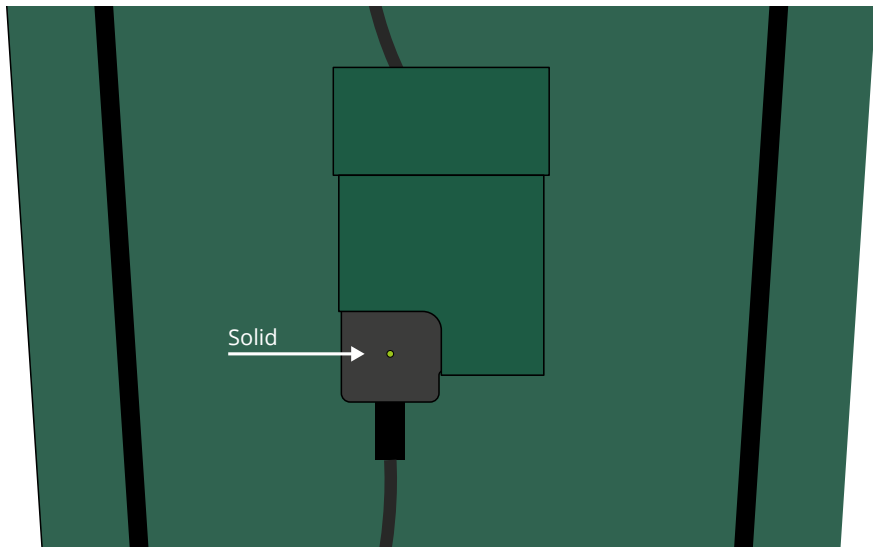
2. How to charge the device

When charging is required, locate the battery in its pocket on the inside front of the garment. Plug the charging connector into the battery (without removing the battery from the pocket) and switch the charger on at the mains. Use only the charging cable and wall plug supplied with the device. Once connected the light on the battery will flash green to indicate the battery is charging.



4. Charging complete

The charging indicator light on the battery will change to a solid green colour once charging is complete. Disconnect the device from the charging cable and continue to use as normal.



Errors and Faults

We will proactively contact you if we detect a problem with the device. All devices check in with us every half an hour, so we become aware of faults very quickly.

In the event of loss of power, including <30s, the device state, including indicator lights, will reset to their default values. The device will check that it is functioning within normal limits prior upon resumption of power (see “5sec On, 5sec Off” light pattern guide below). Recording sessions cannot be resumed in the event of any power failure and data collection mode must therefore be restarted. Note loss of power will only occur if the battery is fully discharged or is manually disconnected.

Please follow the steps outlined for the following specific scenarios:

Troubleshooting

LIGHT ON THE DEVICE DOES NOT TURN ON, DESPITE THE DEVICE BEING WORN

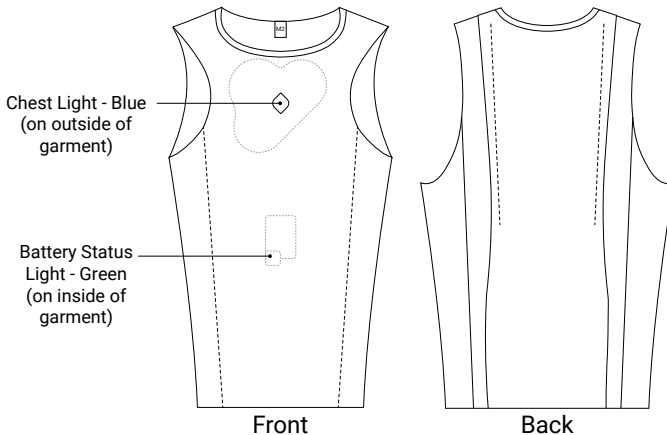
1. Remove the device
2. **Attempt to charge the device** as described in the ‘Charging the Device’ section.
3. **Battery indicator light** (visible from the inside of the garment, in front of battery pack) **should start to blink**
4. If the indicator light is blinking, **leave charging** until the light turns solid, then attempt data collection mode again. If this fails to resolve the issue, contact support using the details below.
5. If the indicator light does not turn on or start blinking, **contact support** using the details below.

LIGHT ON THE DEVICE STARTS BLINKING WHEN BEING WORN, BUT DOES NOT TURN SOLID.

1. **Check your internet connection** using another device connected to your Wi-Fi network.
2. Ensure sensors are making good contact with your skin (you should feel them distinctly making contact).
3. Ensure you are in the **correct position**, as per the diagrams above.
4. **Rest** in this position for **5 minutes**
5. If the light on the device fails to turn solid after this time, please **contact support** using the details below.

Indicator Light guide

The device has two indicator lights, the “Chest Light” which is blue, and the “Battery Status Light” which is green.



These lights are Information Signals, not alarms. Their purpose is to feedback on how the device is functioning to the device operator and improve device usability. The following guide describes the meaning of the indicator lights.

Light Pattern Guide - Chest Light

STATUS	DESCRIPTION
OFF	If the battery is connected and charged, the device is in sleep mode
5s ON, 5s OFF	The device is communicating with the Senti servers
1s ON, 1s OFF	The device is checking if it's being worn
DOUBLE BLINK	The device has detected a heartbeat and is now checking if the wearer is in the correct orientation.
SOLID ON	The device is listening to and recording sounds
RAPID BLINKS FOR 3S	The device's operating system has reset
RAPID BLINKS - MORE THAN 3S	The device has lost its connection to the WiFi router
Intermittent Flashes	If a recording session has just finished, the device is sending data to the Senti servers. <i>Or</i> - The device is updating its firmware.

Light Pattern Guide - Battery Status Light

OFF	The battery has not been connected to mains power
BLINKING	The battery is currently charging
SOLID	The battery has finished charging but is still connected to the mains power.

Additional Information

Messages

No messages are generated by the device. Error messages and states will be retrieved by service personnel during daily maintenance checks.

Cleaning, disinfection and sterilisation

This is not a sterile device. The device will be cleaned between operators/patients by a qualified Senti Tech technician. The operator may wipe down the charger, sensors, and garment with alcohol or chlorhexidine-based wipes. The device sensor modules should be cleaned in this way at least every two weeks. If further cleaning is required, please contact the support team using the details above.

Please do not use other cleaning products on the device, as this may leave residues that can cause skin irritation, sensitization and allergic reaction.

Maintenance

Service personnel will conduct an inspection of the device after each patient episode is concluded and conduct maintenance as needed.

The user/operator of the device will not conduct any maintenance.

Afterwards

Do NOT dispose or discard this device. Once the device is no longer required, please contact the Senti Support Team who will retrieve the device and arrange thorough cleaning and maintenance.

Accessories, supplementary equipment, used material

Only use the power supply & charging cable supplied with the device.

Environmental protection

At the end of this product's life, please return the device to the manufacturer, who will ensure any parts are recycled where appropriate or disposed of safely otherwise.

Reference to the technical description

The device technical description is found in the device service manual.

ME (Medical Electrical) equipment emitting radiation

This device does not emit radiation for medical purposes.

ME equipment and accessories supplied sterile

Neither the device nor any accessories supplied with the device are intended to be sterile.

Unique version identifier

This Instruction For Use unique version identifier can be found on the cover.

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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