SENS motion®
For Research

USER MANUAL

Discreet Body-worn Activity Sensor

The system requires minimal setup and is ideal for research use where physical activity is a parameter.

- The small SENS motion patch is worn discreetly on the thigh
- Data can be collected on many participants
- Delivers accurate measurements that can be extracted for research

Content

Indhold

Terms

*In this user manual, a distinction is made between **two different types of users**. The first type of user is the patient/citizen/other who utilizes the SENS motion sensor and thereby generates data. This user is referred to as the **participant** throughout this user manual.*

*The second type of user encompasses researchers/healthcare personnel/others who help the participant get started with SENS motion and supervise data collection and the use of data. This user is referred to as **research staff** throughout this user manual.*

What is SENS motion?

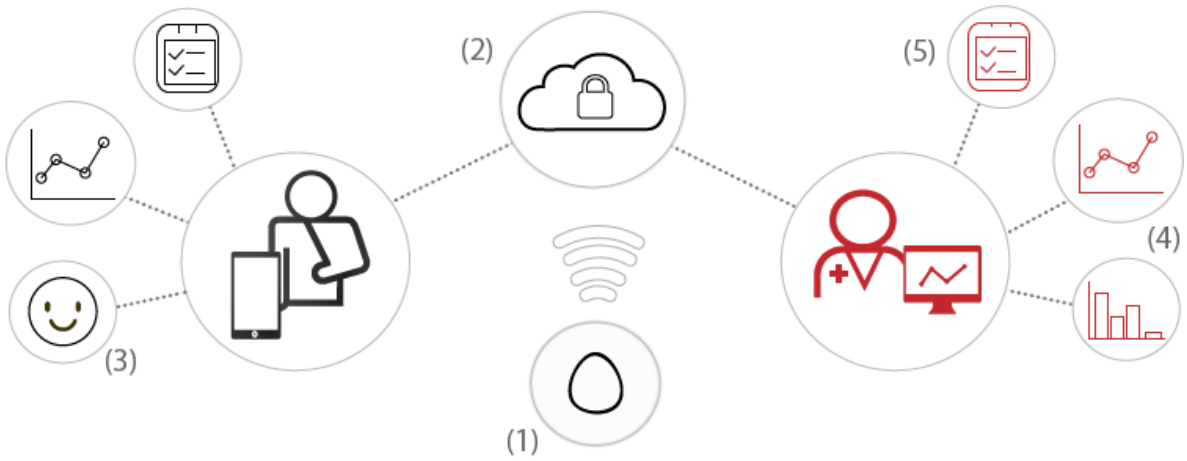
The SENS motion system measures the physical activity of participants. Data can be collected on many participants. Research staff can access the participants' activity profiles and extract data for analysis.

- Discreet sensor that monitors physical activity
- Skin-friendly patch for the sensors
- The sensor patch can be utilized by participants of all ages
- Quick and easy setup of the system
- 24 hours monitoring for up to 15 weeks
- Data is stored secure in a GDPR compliant database
- No recharging of the battery required
- Data is safely stored in the cloud
- Automatic and wireless transfer and processing of data

Material overview	
Product	Part number
Sensor – SENS motion PLUS	A01
Patch – SENS PATCH	A03
Tablet	A08
Alcohol wipes	A10

What does the SENS motion system consist of?

- The sensor (1) collects activity data and sends the encrypted data to the database server
- Server (2) where all the data is securely stored
- Tablet app (3), which enables the transfer of data from the sensor to the database server
- Generating an overview of activity profiles (4 and 5) is easily accessible for the research staff either via a PC or an overview screen



How to get started?

There are 3 simple elements you need to consider when getting started:

1. Assembling and installation of the sensor patch
2. Download and installing the SENS motion app for Smartphone
3. Using the online visualization tool

These elements are described in section 1,2 and 3.

1. Assembling and installation of the sensor patch

The patch is worn discreetly on the thigh **24 hours a day**. It is compact, waterproof, and flexible. As soon as the patch and sensor are placed and in use, the objective and precise activity measurements are displayed online where the health personnel can access the data. The measurement period depends on the purpose, ranging from hours to months. The sensor can measure continuously for up to 15 weeks and store up to 14 days of data in case it is not emptied. **The patch should be replaced after 14 days**. If redness or irritation occurs during use, remove the patch immediately according to the instructions (1.2).

Before assembling the sensor and patch (1.1.1) check that the sensor is active and associated with the desired patient. Note or remember the sensor name/number for the patient to be created.

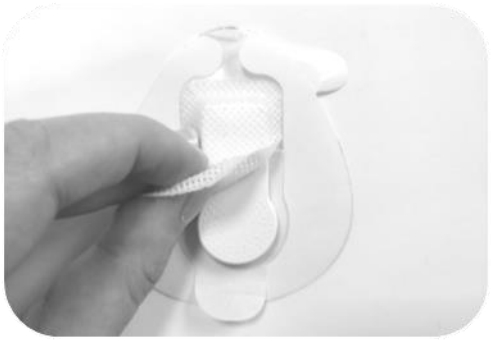
1.1 Attachment of sensor patch

First, the sensor and the patch are assembled (1.1.1), then it is placed on the patient's leg (1.1.2).

1.1.1 Assembling of the sensor and patch

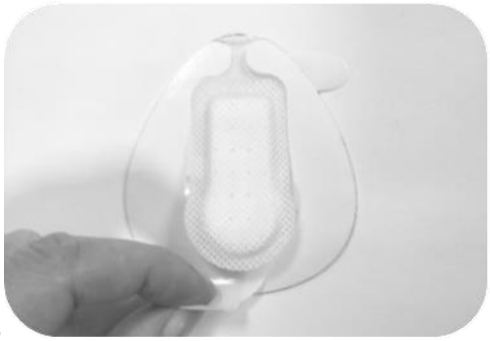
1

To be used:
A disinfection cloth, a sensor and a patch.



2

Place the sensor in the patch pocket with the SENS motion logo upward.



3

Pull down the bottom piece of foil/liner to allow the sensor and patch to be pressed together firmly.

4

Press the patch thoroughly around the edges of the sensor to glue the flanches.

1.1.2 Installation of the sensor patch on the patient's leg

It is important to place the patch correctly so that the sensor works properly. Read and follow the instructions below.

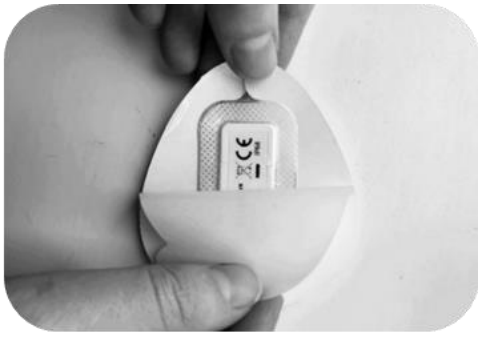
IMPORTANT:

The patch should be placed on the **OUTER SIDE** of the thigh above the patient's knee. The round part of the sensor should aim **DOWN** towards the knee and the upper part should have the direction **TOWARDS** the hip (see picture).

1

Clean the skin where the patch is meant to be placed.

2



Remove the back side.

3

Place the patch on the outer side of the thigh.

4

Remove the white edge.

1.2 Removal after use

When removing the patch, it is recommended to place one hand against the skin to provide support for the skin while the patch is gently pulled off along the leg. Do not pull away from the skin, but instead along the skin. To ease the removal, it is recommended to use a skin lotion to help loosen the adhesive. The patch typically begins to loosen itself after 10-14 days.

Video guide for patch removal: http://bit.ly/afmontering

Wear gloves when handling used sensors.

After use, patch material is removed from the sensor and the sensor is cleaned for reuse.

Note: Carefully remove patch material from sensor, especially around ID label. If necessary, keep a finger on the label while removing patch material. Should the label fall off, write down the ID and put the sensor with note aside.

Plastic material is not reusable and is disposed as normal waste.

1.3 Sensor

1.3.1 Reusing

The sensors are reusable. Simply clean the sensors before use with soap and water, 96% alcohol or a propyl alcohol solution.

Important: before a sensor can be used again, the previous measurement cycle must be over, i.e. the end date of the period must have passed (See section 3.4).

1.3.2 Data

All data is securely stored in the cloud. The data from the sensor is assigned to the specific subject registered to that sensor. Data assigned to specific participant is based on start and end date of measurement cycle. If the same sensor is used for a new patient, the two patients will not have access to each other's data (See section 3.5)

2. Downloading and installing the SENS motion app for Smartphone

The SENS motion app connects data from the sensor to the server. If continuities data is needed, it is necessary that a smartphone with internet and the app is located in a place where the participant moves daily. The app automatically transfers the data when it is close to a SENS motion sensor without any interaction between the participant and the smartphone.

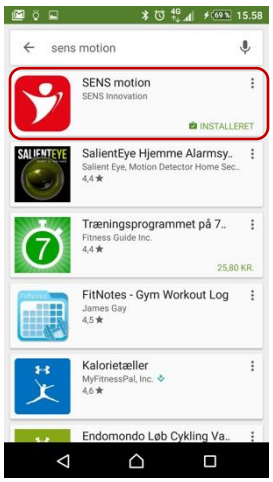
The sensor patch monitors and stores all data, even if the phone is not within close proximity, however, the data will only be accessible online once the two united are within close proximity, i.e. within 10-15 meters.

2.1 Get the SENS motion app

During the start-up of SENS motion, an app is required and needs to be downloaded. The app, which connects the data from the sensor patch to the database, can be downloaded for iOS and Android by searching for ‘SENS motion’ in App Store and Google Play shop, respectively. Or by scanning the QR code below:

(SENS motion app)

Note that ’Bluetooth’ must be switched on the first time the app is opened on the smartphone.



Download App

Start App

Ready to go!

On the main screen, any problems with data collection will appear. Also check that your sensor (s) are counting under nearby sensors. App design may vary on iOS devices.

Data is collected from sensors automatically as long as the app is kept open.

Pressing the 'ADVANCED' button will displays a list of nearby sensors. Here it is possible to select a favorite sensor whose status will always be displayed on the front page.

Collected data is available for viewing and interpretation on the SENS motion® online visualization tool. This is described in section 3.

3. Using the Online-visualization tool

SENS motion® online visualization tool is used when accessing the participants' data. This is done through a browser (e.g., Safari, Internet Explorer, Google Chrome).

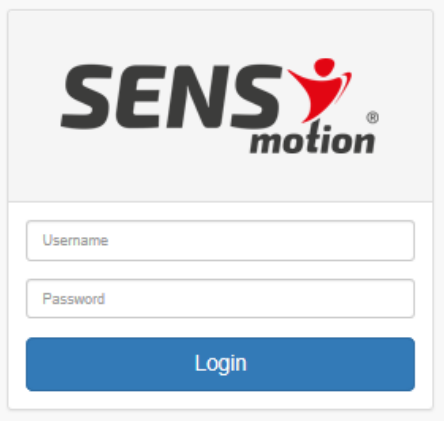
Address: https://app.sens.dk

This tool visualizes the data at both day level and down to minutes. In addition, the tool provides an overview of sensors and participants.

3.1 Login

A login and a password are required in order to use the SENS motion® app. These will be received when purchasing the product SENS motion®.

Type in the web address in the 'username' (e.g. erika@sens.dk) and then type in the password in 'password' (e.g. 1234567). Then click on 'Login'.

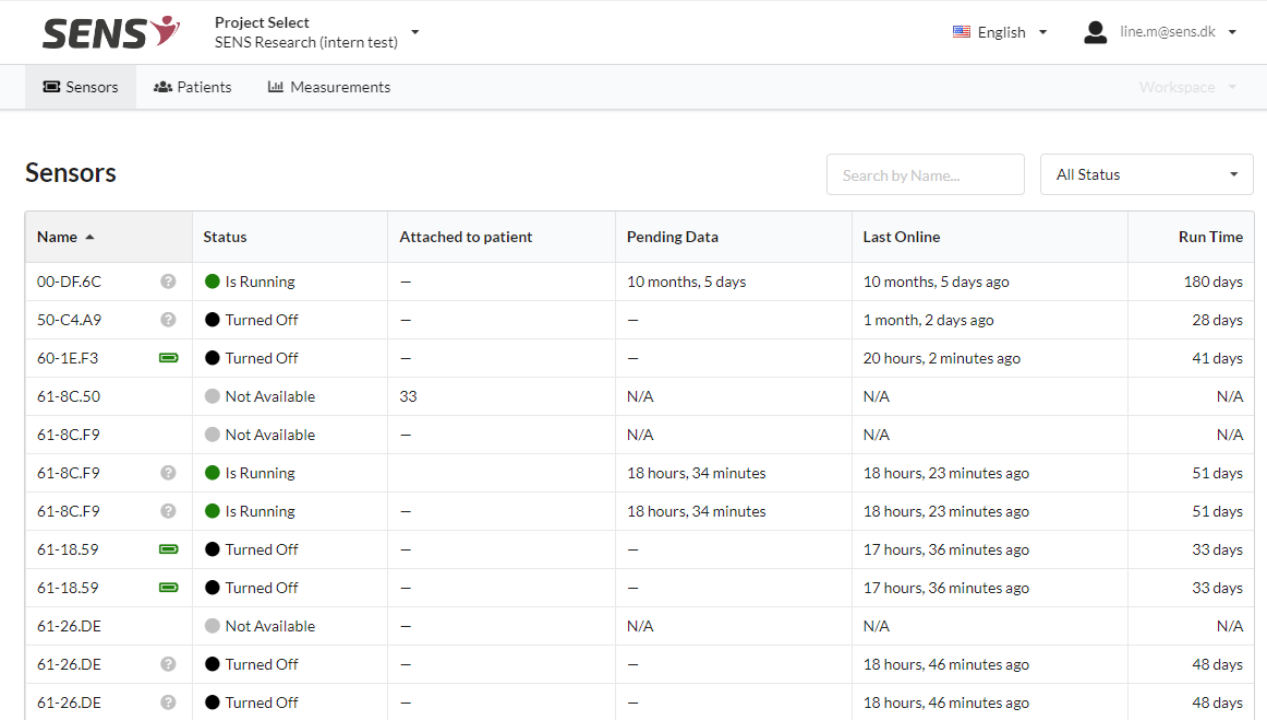


When logged in, the first thing you will see it the screenshot shown on the next page. This is the list of sensors.

3.2 Sensor overview

The overview of sensors is the home page when you log in.

For each sensor, information such as *Name*, *Status*, *Attached to Patient, Pending Data, Last Online, Run time* are shown. In the upper left corner are 3 options for different overviews. Here you can see an overview of sensors, participants (Patients) and measurements.



Name	Status	Attached to patient	Pending Data	Last Online	Run Time
00-DF.6C	Is Running	–	10 months, 5 days	10 months, 5 days ago	180 days
50-C4.A9	Turned Off	–	–	1 month, 2 days ago	28 days
60-1E.F3	Turned Off	–	–	20 hours, 2 minutes ago	41 days
61-8C.50	Not Available	33	N/A	N/A	N/A
61-8C.F9	Not Available	–	N/A	N/A	N/A
61-8C.F9	Is Running		18 hours, 34 minutes	18 hours, 23 minutes ago	51 days
61-8C.F9	Is Running	–	18 hours, 34 minutes	18 hours, 23 minutes ago	51 days
61-18.59	Turned Off	–	–	17 hours, 36 minutes ago	33 days
61-18.59	Turned Off	–	–	17 hours, 36 minutes ago	33 days
61-26.DE	Not Available	–	N/A	N/A	N/A
61-26.DE	Turned Off	–	–	18 hours, 46 minutes ago	48 days
61-26.DE	Turned Off	–	–	18 hours, 46 minutes ago	48 days

3.3 Manage sensors

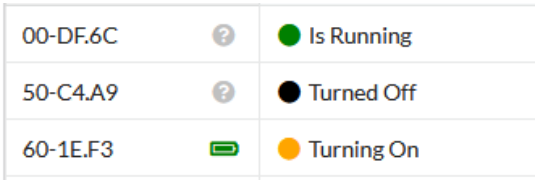
Each sensor can be in different types of ‘states’. In order for the sensor to measure a participant’s physical activity, the sensor must be ‘awake’. When the sensor is awake it has the status ‘OK’.

Under ‘Sensors’ is the overview of sensors. The sensor must have the status ‘OK’ to collect activity data.

A sensor must be ‘awakened’ (e.g., 21-2D.4D which is in hibernation) by clicking on the ‘Control Mode’ button in the lower right corner.

Click on ‘Wakeup’ or ‘Put to Sleep’ depending on whether you want to wake the sensor or put it to sleep.

By clicking on e.g., Wakeup , a round arrow appears. In order to wake up the sensor it is necessary to click on ‘Submit’ in the bottom right corner. You can ‘wake’ up several sensors at a time.

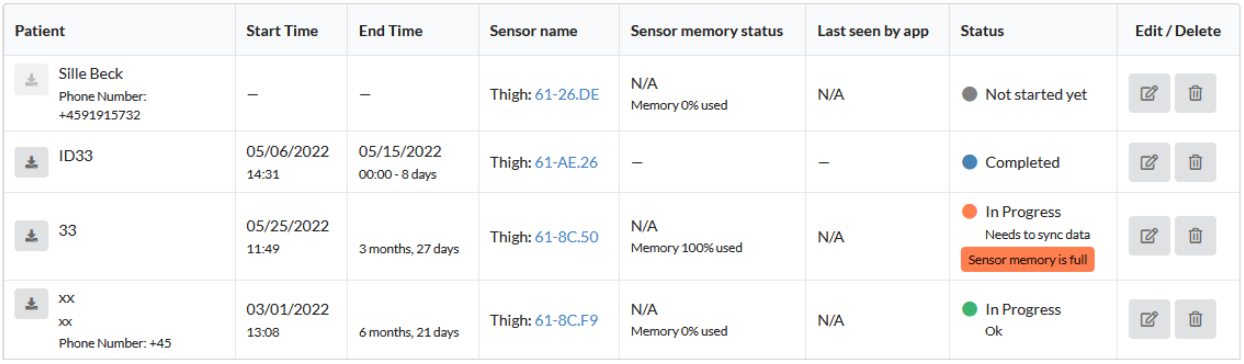


To wake up a sensor, it must be physically moved a few times until the status changes from ‘Waking up’ to ‘OK’. This may take a few minutes.

IMPORTANT: The SENS motion app must be activated and opened on a device near the sensors so that they can be started or put to sleep.

3.4 Participant overview

Clicking on ’Patients’ provides an overview of the participants.

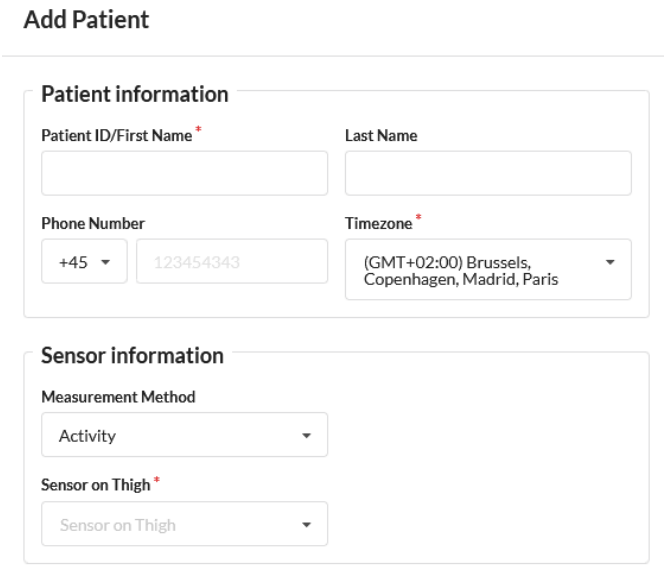


For each participant, information such as *Patient, Start Time, End Time, Sensor name, Sensor memory status, Last seen by app and Status* are shown.

3.5 Add patient

1. Start the specific sensor to use, see section “Manage sensor”

In tab “patients” press



Here must be entered Patient ID / First Name. The patient ID does not have to be personally identifiable, just as the last name and phone number are also optional to enter.

Under sensor information, choose which sensor is to be used for the patient who is being created.

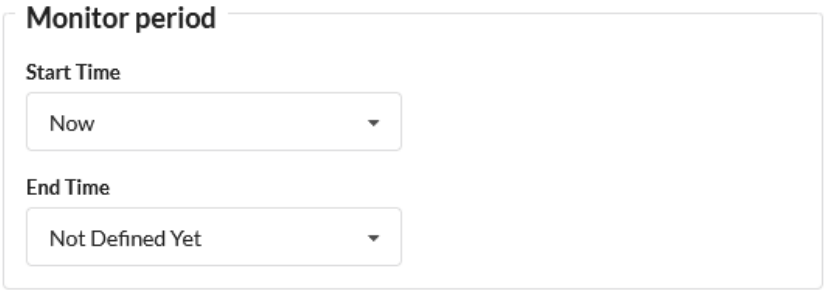
Under 'Measurement type', only 'Activity' can be selected. If the project wants to run with a 2-sensor solution, please contact SENS Innovation. Then this type of activity can be selected under 'Measurement type'.

Under sensor on thigh, select sensor. The sensor ID is on the sensor.

Important: Select only sensors that are ready to use and are not already associated with another patient. They are marked with a green dot in front of sensor ID in the menu and a gray man after sensor ID, see example:

NOTE: If the sensor is not turned on, the green dot will be replaced by a black one and if the sensor is associated with another patient, the gray man will be replaced by an orange one.

During the monitoring period, the start and end time of the period to be measured shall be chosen.



For start time, there are three options:

- *Now*: The measurement will therefore start as soon as 'Finish' is clicked
- *Specific time*: Enter a date and time (15-minute intervals) in which the measurement should start
- *Not defined yet:* No date to be added

For the end time, there are four options:

- *Now*: Refers to the measurement starting now. (This is most often used if a patient is created, and the measurement is initially set to an 'undefined end time' after which they go in and change the time to 'Now' when the measurement stops)
- *Specific time*: Enter a date and time (15-minute intervals) in which the measurement should end
- *Expected period*: Enter here the number of days the measurement is expected to last.
- *Not defined yet*: No date to be added

NOTE: An end time cannot be added if 'Not defined yet' is selected under start time.

If a sensor is turned on, it will collect data and store it, even if it is outside a period of time, given above. This means that you can always subsequently adjust the start and end day of a measurement.

A measurement will not be completed until a specific date has been set on it. This means that if 'not defined yet' is chosen, you must subsequently enter and end the measurement by specifying an end time.

1. Install sensor on participant. Be sure that the sensor is turned on beforehand. Note the time when needed.
2. Upon receipt of the sensor (The monitoring period is over), the sensor is placed close to the tablet (SENS motion app open). To make sure that all data has been transferred, it is recommended to turn off the sensor only after the sensor is emptied. However, a sensor cannot be turned off until all data is emptied. In the

period from when you turn off the sensor until it is turned off, it will appear as 'By turning off'.

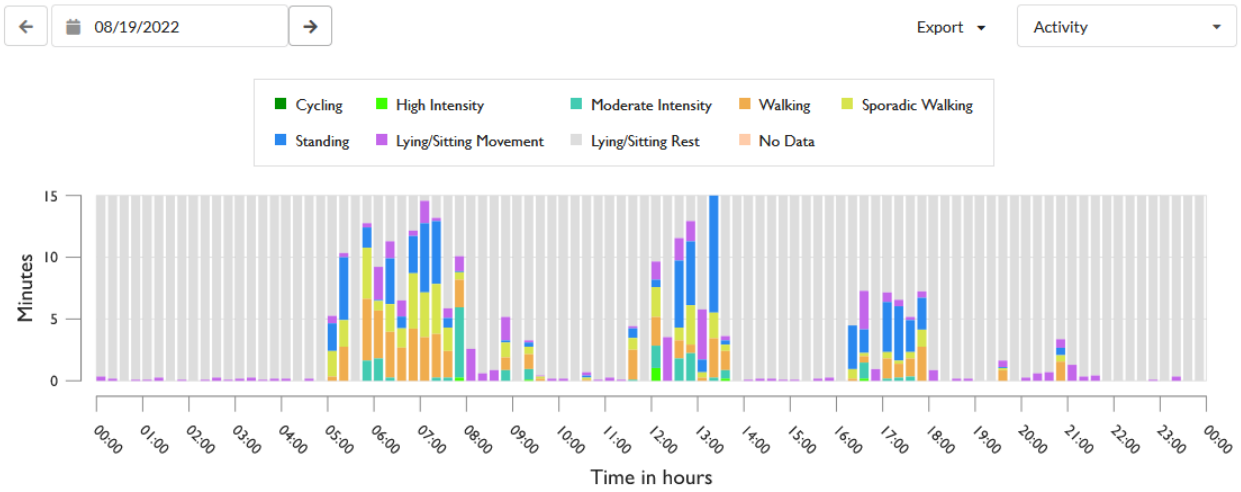
a. **NOTE:** When a sensor is turned on, it will always store new data, so it will never be 100% empty. By empty is meant that there are less than 1-2 hours of data and that this time does not go back further than the period for the current patient.

3.6 Details about the physical activity of participants

Detailed graphs about a participants' physical activity can be accessed in two different ways:

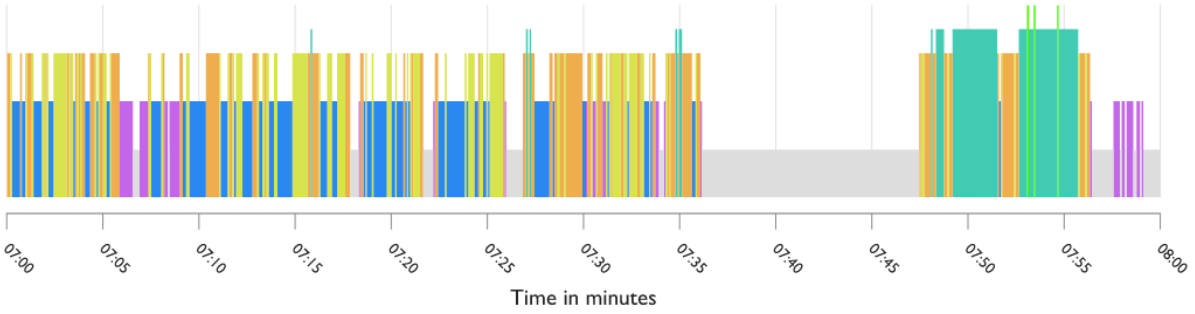
1. By clicking on a participant from the list of 'Sensors' or 'Measurements'
2. By clicking on the icon ⓘ on a participant from the list of 'Patients'.

By doing so, details are shown as demonstrated below.



The graph shows physical activity over a period of 24 hours. On the left side above the graph, it is possible to change the date to get the data that needs to be analyzed.

If you are interested in studying the data closely you can zoom in. This is done by clicking on an hourly interval in the graph whereby a new graph is displayed with detailed activity data for the selected hour.



If you are interested in even more details you can zoom in further. By clicking on the desired minute on the graph (as shown above), the graph shows activity data during the selected minute.

3.7 Types of activities

Data is analyzed in 5-second increments, and each interval is estimated to belong to a specific activity category. Different types of physical activity are distinguished, and these are displayed with different colors:

No data; No data collected.

Lying/sitting rest; The participant sits or lies down with little or no movement.

Lying/sitting movement; Movements of the participant in a lying or sitting state.

Standing; The participant stands upright.

Walking; The participant walks continuously.

Sporadic walking; The participant stands upright, but with a few movements. The activity relates to 'Standing' and 'Walking', but is a middle ground and irregular.

Cycling & similar; The participant cycles.

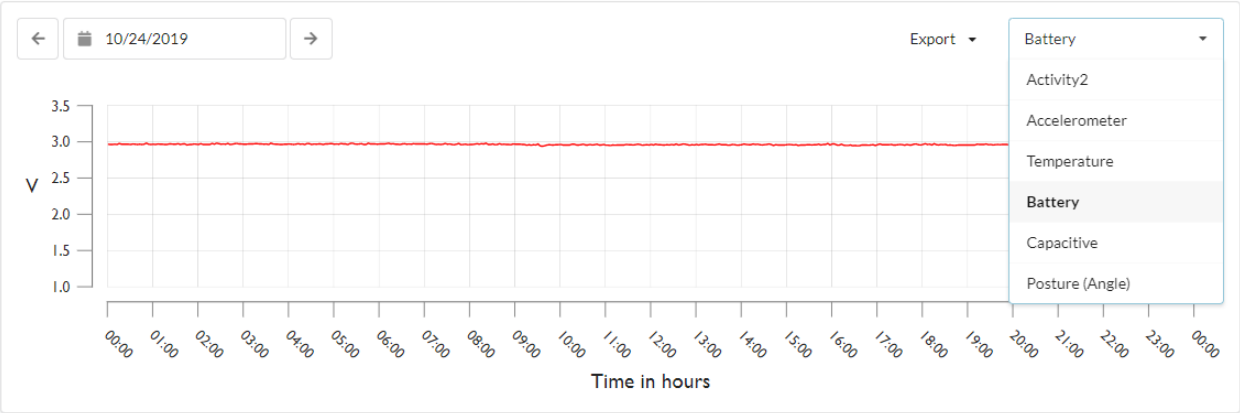
Moderate intensity; The participant is in a brisk walk, where the activity is higher than 'Walking', but lower than 'High intensity'.

High intensity; The participant runs.

Each hour in the graph is divided into four parts of 15 minutes. The physical activity measured in these intervals of 15 minutes is depicted in the graph vertically with colors depending on the type of activity.

3.8 Check the battery level on sensor

Click on the arrow in the ‘Activity’ field and select ‘Battery’.



It is recommended that the sensor has a minimum of 2,65 V remaining – this will provide approximately 14 days of battery time. The sensor shown in the picture above is almost new and is has close to 3 V.

Statements from health professionals and experts regarding SENS motion®

> *SENS motion® is an educational tool to motivate the citizen. The patch on Henrik (i)(citizen name changed)(/i) is a useful therapeutic tool to obtain factual knowledge about the physical activity profile of the citizen as well as provide the citizen with an understanding of the importance of exercise and everyday activities. Activities take place throughout the day and not only when the physiotherapist is present.*

LOUISE
Physiotherapist, Everyday Rehabilitation, 2016

> *We believe that the SENS motion® product could create significant benefits within the healthcare sector by enabling the measurement and online feedback of patient activity levels*

Henning Bliddal, MD, Professor,
Parker Institute At Bispebjerg And Frederiksberg Hospital, 2015

FAQ – user's questions

Here are a few questions from users of SENS motion®. If your question is not listed, then you are welcome to write or call us.

Questions about the sensor patch:

1. What do I do when the patch is falling off or getting loose at the edges?

   Answer: Switch the patch.

2. What if the sensor does not work even when the smartphone is connected?

   Answer: Restart the smartphone, plug it into the charger and then start up the app manually. If the problem continues, call SENS technical support and they will guide you and find a solution.

Questions about the smartphone:

1. Data will not be transferred even though the phone is within range of the sensor?

   Answer 1: There might be bad cellular coverage, move location of smartphone and wait.

   Answer 2: See "question about the sensor patch"

Questions about the online visualization tool:

1. What happens if the system breaks down?

Answer: The sensor will save all data, even if the system goes down, data will not be lost. Data will be retrieved when the system is up and running again.

Thank you for choosing SENS motion® For Research

Technical information

Sensor includes	Patch
Sensor for movement	Medical approved
Sensor for temperature	3M patch
Storage memory up to 14 days	DS/EN ISO 10993-10:2013
Battery life in use 15 weeks	Disposable plasters
Battery life in sleep mode 2 years (Within the application period)	Handle as normal waste

Dimensions	
Sensor	Patch incl. sensor
Length: 47 mm	Length: 80 mm
Width: 22 mm	Width: 60 mm
Thickness: 4.5 mm	Thickness: 5 mm
Weight: 7 grams	Weight: 10 grams

2.4GHz low energy transfer
Transfer time for 1 day's data – Approximately 5 minutes
Sampling frequency 12,5 Hz
3D Accelerometer -4G to 4G
IP68
Functional temperature 5° – 34°
Storage and transport temperaturen. -30° – 60° at 40-60% humiditet
Atmospheric pressure range from 700hPa (3000m) to 1060hPa
Technology: wireless transfer. Frequency band: 2400-2480MHz radiating effect max: 2.5mW (Class 2 transmitter). Can be used without any safety distance to user.

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General

This product is classified as medical equipment, class 1, in accordance with the directives 2002/96/EC (WEEE), 93/42/EEC, 2014/53/EU (RED), 2014/30/EU (EMC) and 2002/95/EC (ROHS). EN60601-1-Medical Device General Safety. The patch is tested for irritation and skin sensitization (DS/EN ISO 10993-5:2013).

Read the included instruction carefully before using SENS motion plus for the first time

The interchangeable patches can only be used once and should not be re-used. Batteries and other components within the sensor are NOT interchangeable.

Latex free

Compliant with IEC standards for “Type BF Applied Part”

Lead Free and RoHS Compliant.

WEEE – Sensor must be disposed as electronic waste

Keep away from sun

Storage: Keep the product away from heat – storage and transport at -30°C – +60°C.

Operating temperature: 0°C – 34°C.

IP68 Water resistant down to 1.5 meters and maximum 1 hour under water.

Data must not be used for potentially harmful medical decisions – consult with your doctor

SENS motion Plus must not be used in an MR-scanner.

Equipment with radio transmitters should not be used close to the SENS motion Plus product and should at least be 30cm away from the product.

If you experience discomfort in correlation with the use of SENS motion Plus, then the patch should be removed immediately.

Follow the instructions when removing the patch.

The surface temperature of the product can rise to 42°C in isolated cases even when the environmental temperature does not exceed the maximum of 34°C

Service and repair of the equipment is not possible and if problems are experienced or the equipment does not live up to the specification, please contact SENS Innovation ApS for a complaint.