



USER MANUAL

Discreet Body-worn Activity Sensor

Increases self-activation in hospitalized patients and supports the dialogue about physical activity

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

The small SENS motion[®] activity sensor is worn discreetly on the thigh

SENS motion[®] app motivates the patient by visualizing goals and expectations

Delivers accurate measurement and provides an overview to the healthcare personnel

Helps plan and target individual needs

Table of contents

What is SENS motion®?	3
What does the SENS motion® system consist of?	4
How to get started?	5
1. Sensor and patch	6
2. Using the motivational SENS motion® app	10
3. Overview screen	16
4. Using the Online-visualization tool	17
FAQ – user’s questions	21
General	23

Terminology

*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® activity sensor and thereby generates data. This user is referred to as the **patient** throughout this user manual.*

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

What is SENS motion[®]?

The SENS motion[®] system measures the physical activity of patients. Self-activation of patients is promoted by a motivational app on a tablet. The healthcare personnel can access the activity profiles of patients, which provides an overview of the activity level. SENS motion[®] includes the following:

- Discreet sensor that monitors physical activity
- Skin-friendly patch in which the sensor is placed
- The sensor patch can be utilized by patients of all ages
- Quick and easy setup of the system
- 24 hours monitoring for up to 15 weeks
- Data security approved.
- 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	A01
Patch	A03
Tablet	A08
Alcohol wipes	A10

What does the SENS motion® system consist of?

- Patch: Collects activity data and sends the encrypted data to the database server
- Server: Where all the data is securely stored
- Tablet app: Can provide motivational feedback to the patient
- Generating an overview of activity profiles: Easily accessible for the healthcare personnel either via a PC or an overview screen



How to get started?

There are 4 simple elements you need to consider getting started:

1. Assembling and installation of the sensor patch
2. Using the motivational SENS motion app
3. Overview screen
4. Using the online visualization tool

These elements are described in section 1,2, 3 and 4.

1. Sensor and patch

The patch is worn discreetly on the thigh **24 hours a day**. It is compact, waterproof and flexible. As soon as the patch with the sensor is 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 1.2 Removal of patch.

IMPORTANT! Important information's regards preparing and terms and condition

- Before assembling the sensor and patch see section *1.1.1 Assembling of the sensor and patch*.
- Check that the sensor is available in the lift of sensors and is listed as READY see section *2.2 Add patient*.
- The patient must have read and understood how data and personal information is handled and give consent to the responsible healthcare personnel.

1.1 Attachment of sensor patch

When patient is added with desired sensor see section 2.2 *add patient the sensor* and patch must be assembled see section 1.1.1 *Assembling of the sensor and patch*. The sensor must be mounted on the patient's leg see section 1.1.2 *Mounting of sensor patch*.

1.1.1 Assembling of the sensor and patch



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



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



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



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

1.1.2 Mounting of sensor patch

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

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 to the right.



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



Remove the back side.



Place the patch on the outer side of the thigh.



Remove the white edge.

1.2 Removal after use

When removing the patch, it is recommended to use one hand against the skin to support the skin where the patch is carefully being removed. Do not pull away from the skin but instead along the skin. To ease 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 see section *1.3.1 Reusing*.

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 propylalcohol solution.

Important: before a sensor can be used again, the previous patient must be disconnected from the sensor. This is done by discharging the patient via the app see section *2.4 Discharge patient*. Sensor do not get released by log out.

1.3.2 Data

All data is securely stored in the cloud. Data from the sensor is assigned to the specific patient who is registered that sensor. Data assigned to specific patient is based on start and discharged date. If the same sensor is used for a new patient, the two patients will not have access to each other's data.

2. Using the motivational SENS motion® app

The SENS motion® app connects data from the sensor patch to the server, and it is therefore necessary that a tablet with the app is located in a place where the patient moves daily and that this tablet has internet access. The app automatically transfers the data when it is close to a SENS motion® sensor without any interaction between the patient and the tablet.

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

SENS motion® can be used on patients with and without visual feedback to the patient.

With visual feedback: The tablet must be placed near a patient. The app must be logged in on patient feedback see section *2.3 Motivational patient feedback*.

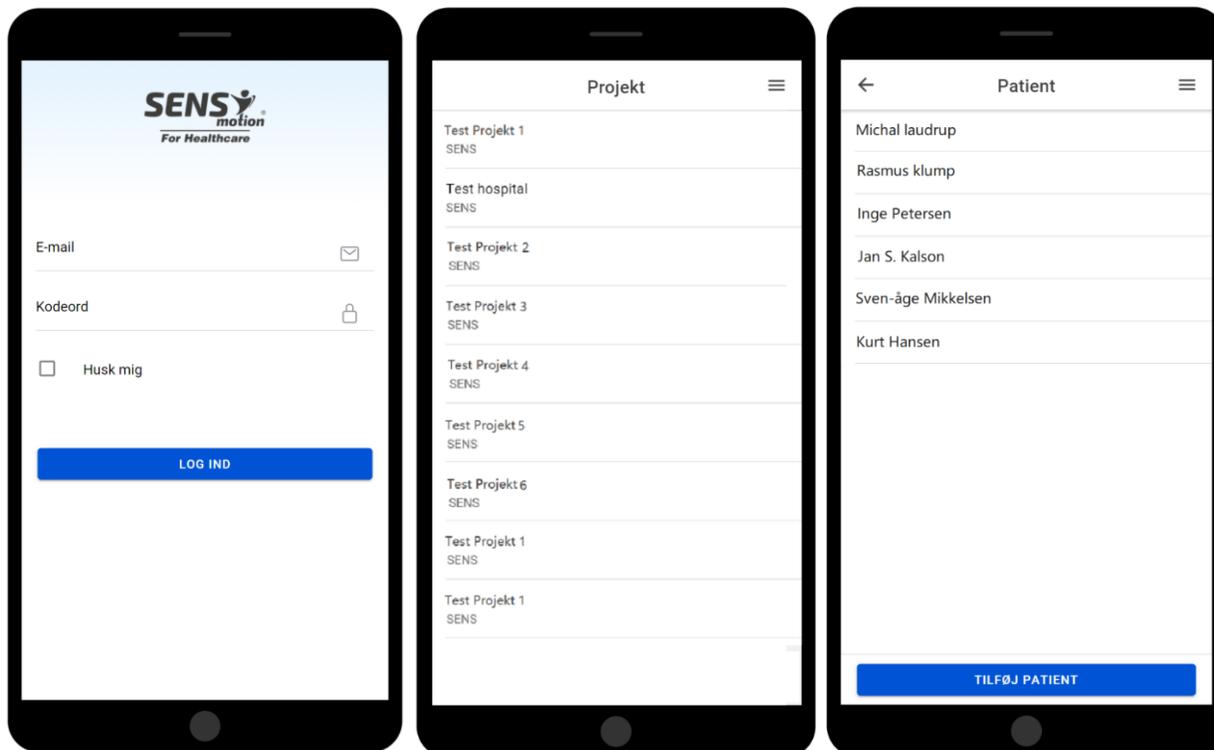
Without visual feedback: You have to log out of the app see section *2.5 Logout* before placing the tablet near the patient. The tablet will only function as a gateway for data upload.

IMPORTANT regards handling adding and preparing!

Login and adding of patients are done by the responsible healthcare personnel. Only when the app is configured and ready is it left to the patient.

2.1 Login and overview over projects and patients (healthcare personnel)

A login and password are required to use the SENS motion[®] app. This has been given when purchasing the product SENS motion[®] Check 'Remember me' if the E-mail address must be saved on the specific device and if a PIN code has to be created. The pin code applies to all devices, but before it can be used on a specific device, you must login with E-mail first.

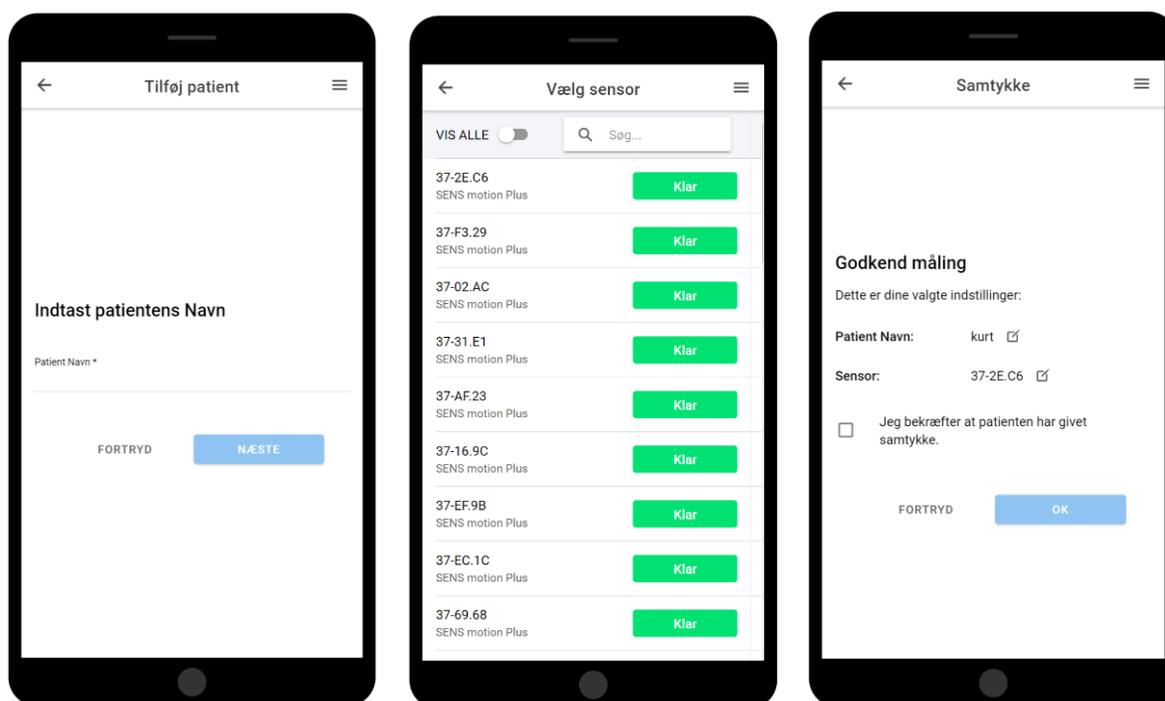


Once you have logged in, you will see an overview of the project and / or ward.

If you click on a ward / project, the list of patients who are associated will appear.

2.2 Add Patient

When adding a new patient in SENS motion® app, click on 'Create new patient'



A list of active sensors is then displayed. It is possible to view all sensors by selecting "Show all"

Select the sensor that the patient must wear. You find the sensor id on the sensor. The sensor must be set to 'Ready'

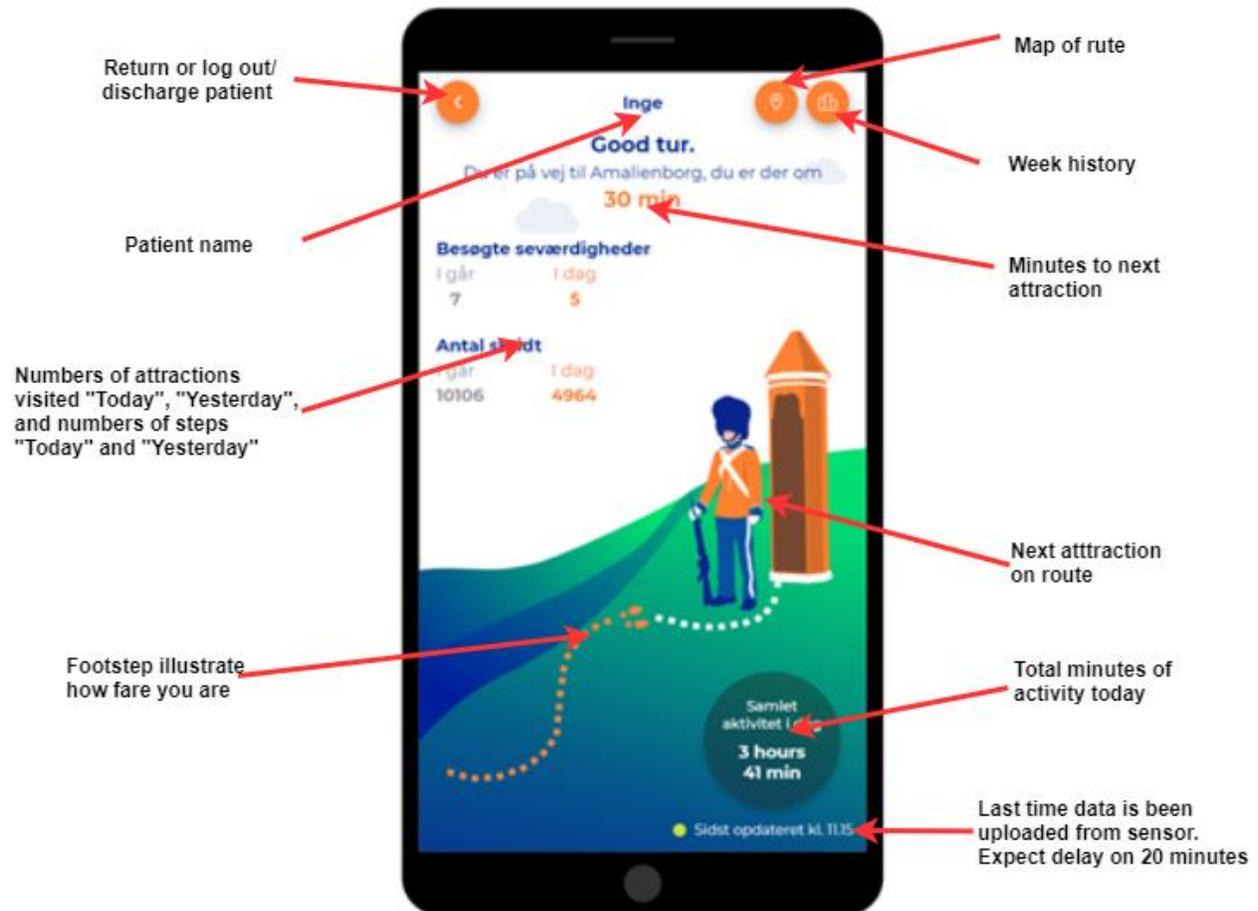
Once the sensor is selected, the healthcare personnel I must approve and confirm that the patient has given consent.

If the patient wishes to withdraw consent, the healthcare personnel will contact SENS Innovation. Contact information can be found on the last page.

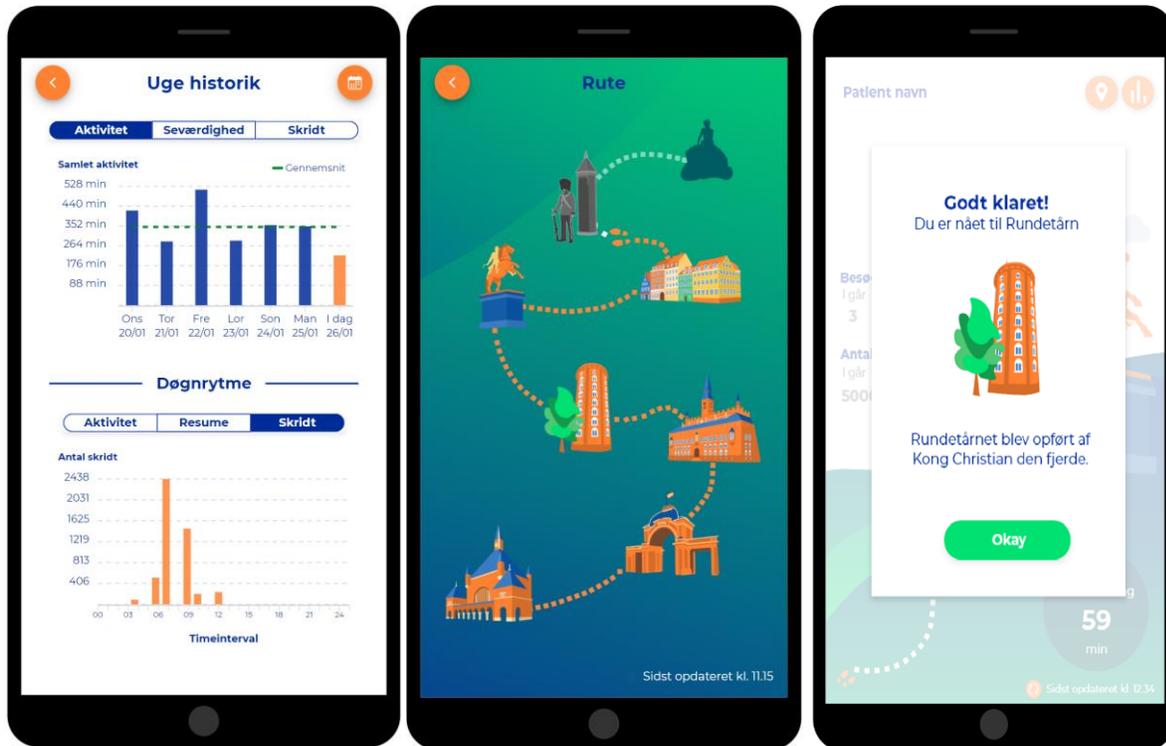
2.2.1 Select existing patient

If a patient already exists, it will be found in the list of patients. This can occur if logging out, see section 2.5 *Logout*. The reason could be that you have changed the tablet for various reasons collecting data without visual feedback, see *section 2*. Use of motivating SENS motion® app.

2.3 Motivational patient feedback



When the patient has reached one of the attractions, a box with a 'fun fact' about the attraction appears.



Top graph Week history 'Uge historik' shows patients

- Physical activity
- Visited attractions
- Steps

The orange bar indicates the day that is shown in detail in bottom graph circadian rhythm "Døgn rytme". If pressing another blue bar in top graph that day will be shown.

The green dotted line indicates the current average.

The blue toggle buttons in the top screen patients can change between data visualized in; activity(minutes), Attractions or numbers of steps.

Bottom graph circadian rhythm "Døgn rytme" shows patients activity in detail.

- Activity
- Resume
- Steps

Map view shows route between attractions. Attraction will be highlighted when visited. By pressing a highlighted attraction, a "fun fact" relative to attraction will show

2.4 Discharge patient

To discharge a patient the app screen must be on the frontpage. Push back button until there appears a dialog box.

In the dialog box you can choose between Logout and Discharge patient. If you discharge a patient, you will stop the measurement for this patient. The sensor will be free to be used on another patient.

IMPORTANT regard discharging!

Discharge in the app do not mean that a patient is discharged from hospital, this must be done separately.

2.5 Log out

To log out, the app must be on the front page. Press the back button until a dialog box appears on the app.

In the dialog you can choose whether you want to log out or discharge a patient. If you log out, you will either be able to log in to the same patient with the same tablet or with another tablet and continue the trip. Activity between the patient being logged out and the person being logged in again will not be lost.

As security, the button must be held down for 5 seconds until the process bar under the button is completely filled. This reduces logging out or discharging patients by mistake.

3. Overview screen

The overview screen is for the hospital staff, where they can get a quick overview of the hospitalized patients who are wearing SENS exercise® on a tablet/screen:

On the Overview screen you can see the following:

- NOTE: Status that tells whether the patient should be mobilized
 - o New: Refers to the fact that the patient has been hospitalized for less than three hours.
 - o Mobilize (Yellow): Refers to the fact that the patient has not been mobilized for 3 hours.
 - o Mobilize (Orange): Refers to the fact that the patient has not been mobilized for 24 hours.
 - o Offline: Refers to the fact that the sensor has not been near the tablet for 12 hours.
- Last Mobilized: Specifies a timestamp that tells when the patient was last mobilized.
- Days: Refers to the number of days hospitalized
- Total activity: Shows the total activity level 'yesterday' and 'today'
- Sensor ID: Unique sensor ID specified on each sensor
- Last updated: When the sensor was last near a tablet and transferred data

OUH - Ward-02

12:32 29-04-2021

Log out

Name ^	OBS	Last Time Mobilized	Days	Total Activity		Sensor	
				Today	Yesterday	ID	Last Update
Jørgen Jensen	Offline	16:01	10	01:08	21	15-EE.01	Never
Abellona Hansen	Mobilized	16:01	10	02:14	59	15-EE.02	Never
Anders Julia Ols...	Mobilized	16:01	10	02:25	21	15-EE.03	Never
Arvada Jørgensen	Offline	16:01	10	12	03:25	15-EE.03	Never
Balduin Olsen	New	16:01	10	02:36	26	15-EE.04	Never
Clemens Juliane	Mobilized	16:01	10	01:01	01:26	15-EE.03	Never

A patient is mobilized if there is 1 minute of activity in a 5 minute interval.

'Activity' is defined as all movement in which you stand upright. That is, even when they simply stand up and do not move, it measures as active time.

4. Using the Online-visualization tool

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

Address is: www.app.sens.dk

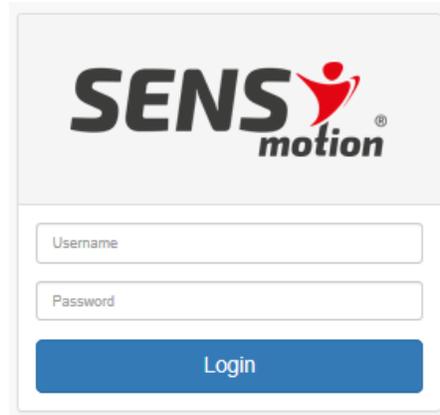
This tool visualizes the data at both day level and down to minutes.

In addition, the tool provides an overview of sensors, patients and measurements.

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'.



The screenshot shows the login interface for the SENS motion app. At the top, the SENS motion logo is displayed. Below the logo, there are two input fields: 'Username' and 'Password'. The 'Username' field contains the text 'erika@sens.dk'. Below the input fields is a blue button labeled 'Login'.

When logged in, the first thing you will see is the screenshot shown in section 3.2 *Sensor overview*, is the list of sensors.

3.2 Sensor overview

The overview of sensors is the home page when you login.

Sensors All Status ▾

Name ▲	Status	Attached to patient	Pending Data	Last Online	Run Time
00-DF.6C 	 Is Running	–	10 months, 18 days	10 months, 18 days ago	180 days
50-C4.A9 	 Turned Off	–	–	1 month, 15 days ago	28 days
60-1E.F3 	 Turning On	–	–	5 days, 23 hours ago	41 days

For each sensor, information such as *name*, *status*, *time run*, *etc.* are shown.

3.3 Patient overview

Clicking on 'Hospital Patients' provides an overview of the patients.

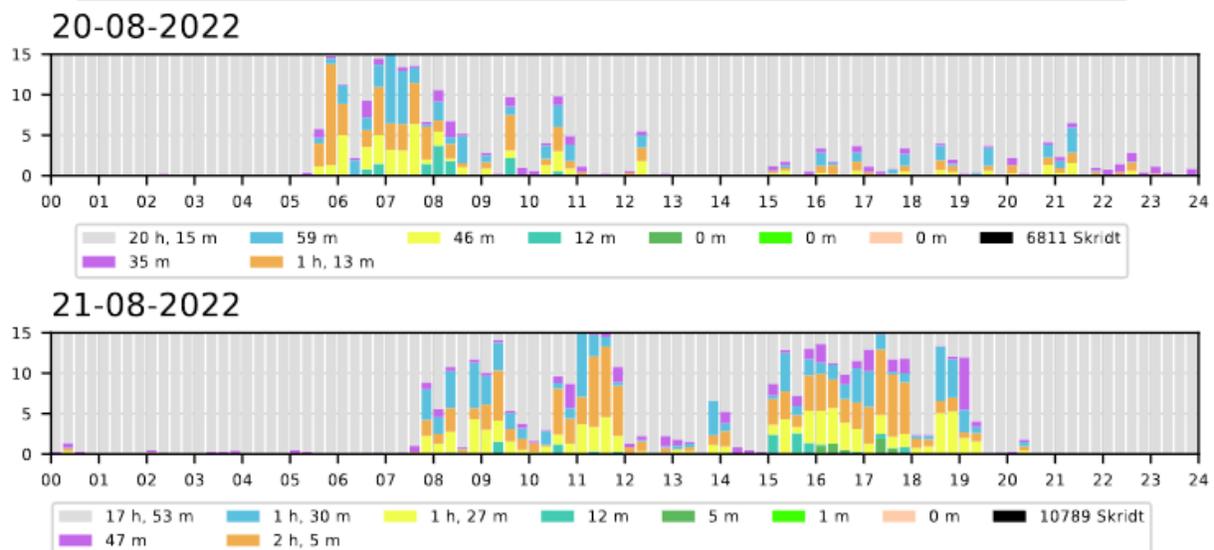
Project Select BB App Test English kasper.k@sens.dk
Sensors Hospital Patients Workspace

Hospital Patients

Name ^	Start	End	Sensor	Patient Status
2424	01/24/2021, 19:11	–	Name: 00-BE.F2 Last Seen: 3 years, 2 days ago	● Active
Chew	11/05/2020, 07:55	–	Name: 21-2D.4D Last Seen: 1 year, 6 months ago	● Active
Christian	05/22/2019, 14:07	–	Name: 27-72.E2 Last Seen: 3 months, 18 days ago	● Active
Christoffer	03/11/2021, 12:33	–	Name: 50-92.86 Last Seen: 4 months, 19 days ago	● Active
Emi	03/11/2021, 12:38	04/09/2021, 09:35	Name: 50-C4.A9 Last Seen: 13 days, 19 hours ago	● Discharged

For each patient, information such as; *name, start time for hospitalization and time for discharging, last seen and status on patient.*

By clicking on the pdf icon there will be generated a pdf print with visual representation of activity data.



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. The patch is detached or it is lose around the edges, what do I do?
Answer: You change the patch
2. It seems like the sensor and smartphone is not connected?
Answer: Restart the device, connect to charger. If the problem continue please call SENS technical support then we will assist you.
3. The sensor is not visible in list of sensors in app when adding new patient?
Answer: The administrator can check if sensor is awake. If sensor is not added to project, please contact SENS.

Questions about the tablet:

1. I have forgotten my pin code
Answer: Login with E-mail click remember me and change pin code
2. I have forgotten my password
Answer: Contact SENS.
3. Sensor is not uploading data even though sensor is next to tablet
Answer 1: There is bad mobile coverage move tablet to another place and wait.
Answer 2: See “Question about sensor patch” 2
Answer 3: See “Question about sensor patch” 3

Questions about the online visualization tool:

1. What happens if the system breaks down?

Answer: The patch will save all data, so 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 to use



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 temperatures. -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.



 SENS Innovation ApS
E-mail: contact@sens.dk
Tel: +45 26 23 82 34
Nannasgade 28
2200 København N



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.

PI-002-06-D01, Version 2.2