



USER MANUAL

Discreet Body-worn Activity Sensor

The system requires minimal setup and is ideal for research use where physical activity, sedentary behaviour, or sleep are parameters.

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

Contents

What is SENS motion?	3
How to get started	4
1. <i>Sensor and sensor patch</i>	5
2. <i>Downloading and installing the SENS motion app for Smartphone</i>	7
3. <i>Using the web app</i>	10
4. <i>Exporting data</i>	19
5. <i>Contact SENS Innovation</i>	21

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 the researcher/healthcare professional/other who helps the participant get started with SENS motion and supervises 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 from many participants simultaneously. Research staff can follow the participants' activity profiles and extract data for analysis.

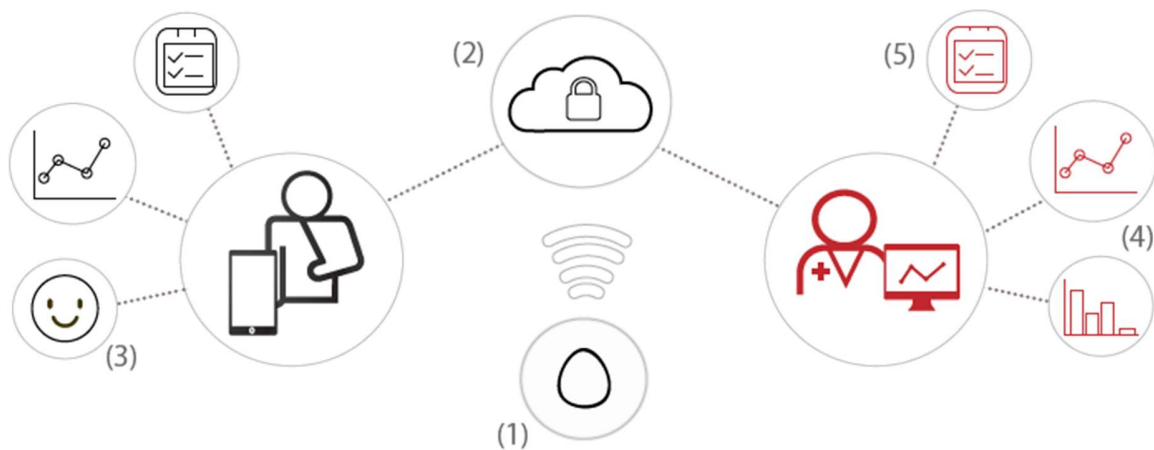
Key features of SENS motion

- 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 20 weeks
- Data is stored securely in a GDPR-compliant database
- No recharging of the battery required
- Data is safely stored in the cloud locally at the Amazon Web Services (AWS) data center in Frankfurt, Germany.
- Automatic and wireless transfer and processing of data

Material overview	
Product	Part number / model
Sensor – SENS motion PLUS	A016
Patch – SENS PATCH	A03
Tablet	A08
Alcohol wipes	A10

What does the SENS motion system consist of?

- The sensor (1) collects activity data by recording acceleration and sends the encrypted data to the database server.
- Server (2) where all the data is securely stored.
- Mobile application (3) which enables the transfer of data from the sensor to the database server.
- Research staff can easily access an overview of activity profiles (4 and 5) through a web browser.



How to get started

Three elements require your attention when getting started:

1. Assemble and position the sensor patch.
2. Download and install the SENS motion app for smartphone.
3. Using the web application.

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

1. Sensor and 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 activated, the objective and precise activity measurements are displayed online where the research staff can access the data. The measurement period depends on the purpose, ranging from hours to months. The sensor can measure continuously for up to 20 weeks and locally store up to 10 days of data in case the sensor has not been synchronized with a mobile application and transferred data to the cloud.

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 check that the sensor is active and associated with the desired participant. Note or remember the sensor ID for the participant to be created.

1.1 Assembly and positioning of sensor patch

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

1.1.1 Assembly of the sensor and patch



Required materials:

A disinfection cloth, a sensor and a patch.¹



Pull down the bottom piece (marked no. 1) of foil/liner to allow the sensor and patch to be pressed together firmly. Do not forget to press the patch thoroughly around the edges of the sensor to secure it.

¹ Patch type B. If you have patch type C, you can follow the manual till step 3 on the next page, and skip step 4.

1.1.2 Securing the sensor patch on the patient's leg

It is important to place the patch correctly for the sensor to work properly. Read and follow the instructions below.

IMPORTANT:

Place the patch on the **OUTER SIDE** of the thigh above the knee. The sensor can be placed on either the right or left leg. The **round part** of the sensor should point **towards the knee**. See pictures below.



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



Remove the back side (marked no. 2)



Gently adhere the patch on the outer side of the thigh. Press firmly to ensure it adheres evenly



Only for patch type B: Remove the white edge (marked no. 3)

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. Pull along the skin, not away from it. To ease the removal, it is recommended to use skin lotion to loosen the adhesive. The patch typically begins to loosen itself after 10-14 days.

Wear gloves when handling used sensors.

After use, patch material is removed from the sensor. The patch is not reusable and is disposed as normal waste. The sensor can be 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 aside with a note of the sensor ID.

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 reused, the previous measurement cycle must be over, i.e., the end date of the period must have passed.

1.3.2 Data

All data is securely stored in the cloud. To transfer data from sensor to the cloud, see section 2.2. The data from the sensor is assigned to the participant registered to that sensor. Data assigned to a participant is based on start and end date of a measurement cycle. If the same sensor is used for a new participant, the two participants will not have access to each other's data.

2. Downloading and installing the SENS motion app for Smartphone

The SENS motion app facilitates the connection between the sensor and the cloud server.

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:



Google Play Store



SENS motion
Health & Fitness

SENS motion app in App Store



App Store

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

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.

Collected data is available for visualization and interpretation on the SENS motion® web app. This is described in section 3.

2.2 Transferring data

To transfer data from the sensor to the server, simply open the SENS motion app within 10-15 m of the sensor. The app must be open to transfer data. Data is ready for transfer when the top "Gateway Status" is green as seen below. If the status is yellow or red when opening the app, please restart your phone and ensure that Bluetooth is turned on.

Save a favorite sensor by clicking the blue 'ADVANCED' button. Select the desired sensor and "Set Favourite". The sensor's status will now be displayed on the front page.



Data automatically transfers when the app is open. All data is transferred when there are 0 "busy" and 0 "pending" sensors nearby.

Data transfer may take a few minutes. The data will be available in the web app shortly after data transfer is completed.

NOTE: The sensor can store up to 10 days of data. To prevent the sensor's memory from becoming full, we recommend transferring data at least once a week.

All data must be transferred before turning the sensor off (section 3.3).

3. Using the web app

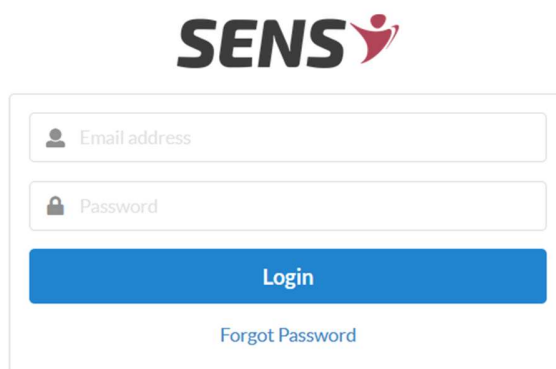
SENS motion[®] web app is an online visualization tool for accessing the participants' data. This is done through an internet browser.

Link: app.sens.dk

This tool visualizes the activity data and is the gateway of data export. In addition, the tool provides an overview of sensors and participants.

3.1 Login

A login and a password are required to use the SENS motion[®] app. These will be received when purchasing the product SENS motion[®]. If you have lost or forgotten your login, please [contact SENS Innovation](#). The login page is the first page of the web application.



The login form features the SENS motion logo at the top. Below the logo, there are two input fields: the first is labeled 'Email address' with a person icon, and the second is labeled 'Password' with a lock icon. A blue 'Login' button is positioned below these fields. At the bottom of the form, there is a link that says 'Forgot Password'.

3.2 Sensor overview

The overview of sensors is the home page when you log in. It displays information such as *Status* and *Last Online*.

Project Select
Simple Project Test

Need help
English

Files

Sensors
Patients

Sensors

Search by Name...
All Available

Name	Status	Attached to patient	Pending Data	Last Online	Run Time
00-18.24	Turning Off	—	1 year, 7 months	1 year, 7 months ago	311 days
00-26.4F	Turned Off	—	—	2 years, 22 days ago	346 days
00-28.73	Turning Off	—	1 year, 9 months	1 year, 9 months ago	285 days
00-41.0F	Is Running	—	2 years, 18 days	2 years, 18 days ago	241 days
00-46.0F	Is Running	—	2 months, 18 days	2 months, 18 days ago	150 days
00-68.FA	Turned Off	—	—	5 months, 15 days ago	146 days
00-B1.1D	Turning Off	—	5 years, 28 days	5 years, 23 days ago	15 hours
00-B1.1D	Turning Off	—	5 years, 28 days	5 years, 23 days ago	15 hours

3.3 Manage sensors – turn sensor on/off

A sensor can have different “statuses”.

Follow these steps to turn on a sensor and prepare it for measuring activity:

- 1) Select the sensor to turn on in the “Sensors” menu.
- 2) Enter the “Turn On/Off” modal. Click ‘Turn on Sensor’.

Sensor Details

Name: I-297.43D - Status: Turned Off

Details
Turn On/Off

This sensor is turned off and is not collecting data. Do you want to turn it on?

Turn on Sensor

- 3) The sensor status will now change to “Turning On”. Open the SENS motion app on a smartphone.
- 4) Shake the sensor a few times to activate it. A connection between the sensor and the server will now be established.

- 5) Check on the web app that the sensor status has been changed to “Is running” with a bright green dot:  **Is Running**

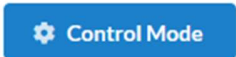
IMPORTANT: A sensor’s status MUST be “Is running” with a bright green dot to store measurements. If the sensor has any other status, it is NOT measuring!

The above also applies to turning the sensor off. Follow steps 1, 2 and 4 to turn off a sensor. When a sensor is turned off, it has the status “Turned Off” with a black dot:

 **Turned Off** . Remember to complete data transfer as per section 2 before turning off a sensor.

If your sensor status does not change to “Is Running” or “Turned Off”, restart your smartphone and repeat the instructions above.

3.3.1 Turn several sensors on/off

To turn on/off several sensors at a time, scroll down to the bottom of the page and select ‘Control Mode’ 

By clicking  a round arrow appears. This means the sensor has been selected. Select the sensors to turn on/off and click ‘Submit’ at the bottom of the page. The SENS motion app must then be opened and connected to the sensors as per steps 2-4 in section 3.3.

NOTE: The sensor is only “ON” if the status has changed from “Turning on” to “Is running”.

3.4 Participant overview

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

Patients

Sort by: Create Date ASC Filter status Search by Name... Bulk export

Patient	Start Time	End Time	Sensor name	Sensor memory status	Last seen by app	Status
Patient 1	—	—	Thigh: 13-2B.01	Turned off Memory 0% used	2 years, 11 months ago	 Not started yet
Patient 2	—	—	Thigh: 00-BE.F2	5 years, 1 month Memory 100% used	5 years, 1 month ago	 Not started yet

For each participant, information such as *Patient*, *Start Time*, and *End Time* are shown.

3.5 Add patient

Turn on the sensor that will be used, see section 3.3.

In the “Patients” tab press  to add a new participant

Add Patient

Patient information

Patient ID/First Name *

Last Name

Phone Number

+45 ▾

123454343

Timezone *

(GMT+02:00) Brussels, Copenhagen, Madrid, Paris ▾

Sensor information

Measurement Method

Activity (v5.4) ▾

Sensor on Thigh *

Sensor on Thigh ▾

Monitor period

Start Time

Now ▾

End Time

Not Defined Yet ▾

Cancel

Submit

Please enter the Patient ID or First Name.

NOTE: The patient ID does not have to contain personally identifiable information, and entering the last name and phone number is optional.

Under 'Measurement method' a default algorithm is pre-selected. For 2-sensor solutions, please [contact SENS Innovation](#).

Under “Sensor on Thigh”, select sensor. The sensor ID is on the sensor label. Select only sensors that are ready to use and are not already associated with another patient.

NOTE: If the sensor is ‘on’ there is a green dot in front of sensor ID. If the sensor is off, the dot turns black. If the sensor is linked to another patient, the gray ‘person’ icon changes to orange.

Under ‘Monitor period’ define the start and end time of the period to be measured.

Monitor period

Start Time

Now

End Time

Not Defined Yet

For start/end time, there are three options; “Now”, “Specific time” and “Not defined yet”. For the end time you can select “Expected period” in addition to the former three.

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

You can always subsequently adjust the start and end time of the monitor period. Data will be stored on the sensor as long as it is running and adjusting the monitor period will not impact the stored data.

3.6 Editing or deleting participants

To edit participant information such as name, phone number, sensor information or monitor period, click the three dots on the right of the patient and select ‘Edit Patient’. To delete a participant, select “Delete Patient”.

Patients

Sort by: Create Date
ASC
Filter status
Search by Name...
Bulk export

Patient	Start Time	End Time	Sensor name	Sensor memory status	Last seen by app	Status
Patient 1	—	—	Thigh: 13-2B.01	Turned off Memory 0% used	2 years, 11 months ago	● Not started yet
Patient 2	—	—	Thigh: 00-BE.F2	5 years, 1 month Memory 100% used	5 years, 1 month ago	● Not started yet
Patient 3	07/30/2021 07:53	08/05/2021 00:00 - 5 days	Thigh: 00-B1.1D	5 years, 0 months Memory 100% used	5 years, 23 days ago	● Completed Needs to sync data

Export Data
Edit Patient
Delete Patient

3.7 Details about the physical activity of participants

Detailed graphs of a subject's physical activity can be accessed in two different ways:

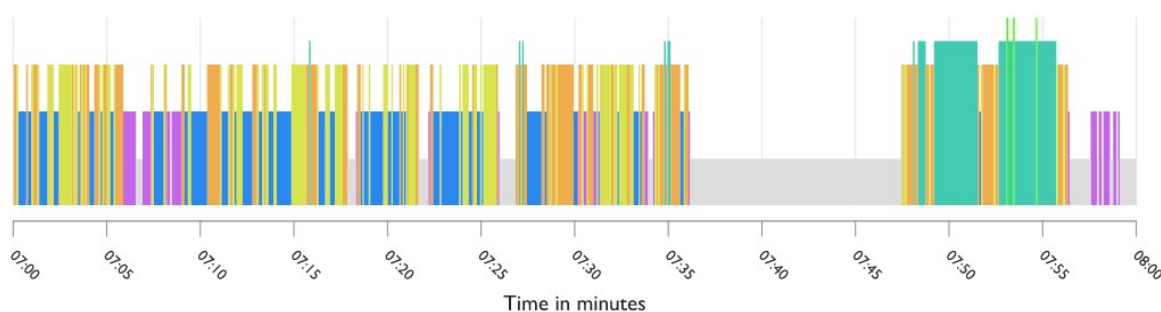
1. By clicking on the sensor's 'Sensor name' under 'Patients'.
2. By clicking on a sensor under 'Sensors'.

By doing so, details are shown as demonstrated below.



The graph shows physical activity over a period of 24 hours.

You can zoom in to study a specific hour by clicking on an hourly interval in the graph. This opens a zoomed in view of the selected hour as seen below.



To study a specific minute, please click on a minute interval after you have clicked an hour.

3.8 Types of activities

Data is analyzed in 5-second increments, and each interval is estimated to belong to a specific activity category. Various activity levels are denoted by distinct colors:

No data; No data collected.

Lying/sitting rest; Lying down or sitting with little or no movement.

Lying/sitting movement; Lying down or sitting with movement.

Standing; Standing upright.

Walking; Continuous walking.

Sporadic walking; Standing upright, but with few movements. The activity relates to 'Standing' and 'Walking' but is in between and irregular.

Cycling & similar; Cycling.

Moderate intensity; Brisk walking where the activity is higher than 'Walking' and lower than 'High intensity'.

High intensity; Running or other rapid, continuous movements.

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.

3.9 Battery of sensor

During its period of use, the battery can last at least 120 days when running or up to 2 years when off. The sensor's battery level updates when it connects to the app. Please note that the sensor's battery is not rechargeable. When it's depleted, the sensor should be returned to SENS Innovation.

3.9.1 How to check the battery level

To check the battery level, click on "Sensors " and click on the corresponding sensor.

Sensors Search by Name... All Status

Name	Status	Attached to patient	Pending Data	Last Online	Run Time
00-DF.6C	● Turning Off	—	10 months, 25 days	10 months, 25 days ago	180 days
50-C4.A9	3008 mV • 13 days ago	—	—	1 month, 22 days ago	28 days
60-1E.F3	● Turning On	—	—	13 days, 14 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	● Not Available	xx.xx	N/A	N/A	N/A
61-8C.F9	● Not Available	—	N/A	N/A	N/A

It is recommended that the sensor has a minimum of 2.70 V (2700 mV) left.

3.9.2 Color codes

The battery level can be read via the color codes on the overview page of the sensors. By hovering over the battery icon, it is also possible to get information about the exact voltage level of the battery.

	Battery level is completely fresh
	The battery can last for at least 4 weeks and has less than 2800 mV
	The battery can last for about 14 days and has less than 2700 mV
	The battery is empty, so data must be transferred as soon as possible, and the sensor must be switched off and put aside. Battery has less than 2550 mV.
	Battery status not updated for at least 3 months. Please open the SENS motion app to update the battery status.

It is recommended that the sensor's battery level is updated at least two days before the sensor is attached to a participant. This ensures that there is enough battery for the sensor to measure the desired period.

4. Exporting data

4.1 Exporting data for a single participant

Exporting data is done within the 'Patients' menu. Data for a single sensor or participant can be exported by clicking the 3 dots next to the participant and then clicking 'Export data'.

Patient 0	07/30/2021 07:53	08/05/2021 00:00 - 5 days	Thigh: 00-B1.1D	5 years, 0 months Memory 100% used	5 years, 23 days ago	Needs to sync data	⋮
Patient 1	—	—	Thigh: 13-2B.01	Turned off Memory 0% used	2 years, 11 months ago	● Not started yet	Export Data
Patient 2	—	—	Thigh: 00-BE.F2	5 years, 1 month Memory 100% used	5 years, 1 month ago	● Not started yet	Edit Patient
							Delete Patient

Following options for exporting data are available:

Export Data

Patient 0

Data files:

Summarized for every 1 hour: [1 hour \(CSV\)](#)

Summarized for every 15 min: [15 min \(CSV\)](#)

Not summarized: [Detailed \(CSV\)](#)

Accelerometer Data: [BIN](#)

PDF reports:

Summary Report: [PDF](#)

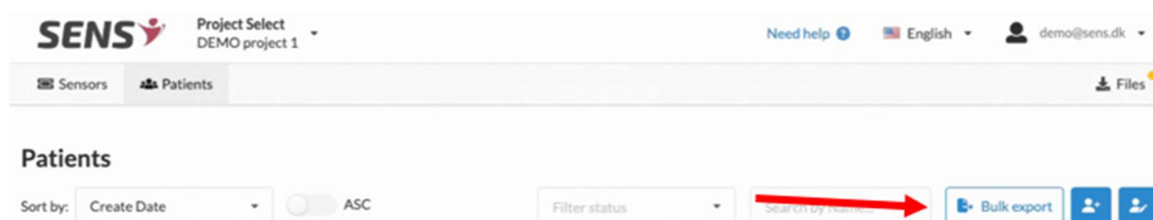
Details for all days: [PDF](#)

Combined Report: [PDF](#)

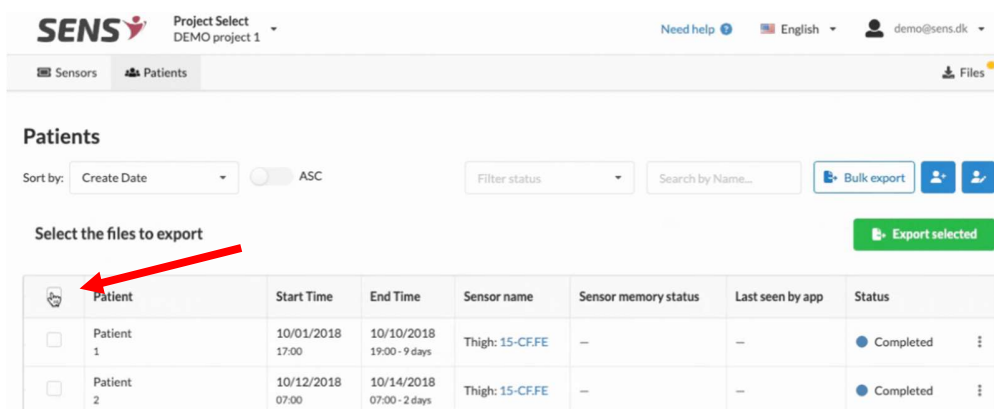
After selecting a file format, the 'Files' modal will open. Here you can view all queued downloads. Click [Download File](#) to download the file to your device.

4.2 Bulk export – exporting data for several participants

It is possible to export data for several participants simultaneously. Click 'Bulk export' to select the participants you wish to export data for.



Select the participants by ticking the checkbox on the left side of the participant's name. Select all participants in a project by ticking the top checkbox.



When the participants have been selected, click . The 'Files' modal will pop up, where the queued downloads are placed. Click  to download a file to your device.

4.2 File formats

SENS motion currently supports 3 different file formats of data: CSV (Comma-separated values), PDF-files and raw accelerometer data. Select the file format that is best suited your project. For details about the different file formats, please refer to this article: [Data export](#).

5. Contact SENS Innovation

If you have any questions, please refer to our support page: support.sens.dk

Here you will find detailed information on different aspects of using SENS. If the support page does not answer your questions or you need further information/assistance, please get in touch with us by sending an e-mail to support@sens.dk

We are more than happy to help!

Thank you for choosing



Technical information

Sensor includes	Patch
Sensor for movement	Medical approved
Sensor for temperature	3M patch
Storage memory up to 10 days	DS/EN ISO 10993-10:2013
Battery life in use 20 weeks	Disposable plasters
Battery life in sleep mode 2 years (within the application period)	Handle as normal waste
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.	
Versions Web app v.3.7.x SENS motion app v.3.0.x	

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



SENS
motion[®]



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IC
CE
FCC

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).



FCC ID: 2BFOF-A016 IC: 32412-A016

This device meets FCC and ISED **radio frequency (RF) exposure requirements** for body-worn operation. It is safe to wear directly on the body with no minimum distance required.



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.

Service and repair of the equipment is not possible. If issues occur or the equipment does not live up to the specification, please contact SENS Innovation ApS for complaint procedures.

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.

FCC Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

FCC Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules.

This equipment generates, uses, and can radiate radio frequency energy, and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. There is no guarantee that interference will not occur. If this equipment does cause harmful interference to radio or television reception, the user is encouraged to try to correct the interference by one or more of the following measures:

- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/TV technician for help.

Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

RF Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. The device is intended to be worn directly on the body and meets the FCC portable exposure requirements with a minimum separation distance of 0 mm.

FCC ID: 2BFOF-A016**ISED Canada Compliance Statement / Déclaration de conformité**

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference; and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage, et
2. L'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

RF Exposure Statement / Déclaration d'exposition aux RF

This equipment complies with ISED RF exposure limits set forth for an uncontrolled environment. The device is intended to be worn directly on the body and meets the portable RF exposure requirements with a minimum separation distance of 0 mm.

Cet équipement est conforme aux limites d'exposition aux radiofréquences établies par ISED pour un environnement non contrôlé. L'appareil est conçu pour être porté directement sur le corps et satisfait aux exigences d'exposition RF pour dispositifs portatifs avec une distance de séparation minimale de 0 mm.

IC: 32412-A016