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, 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

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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.

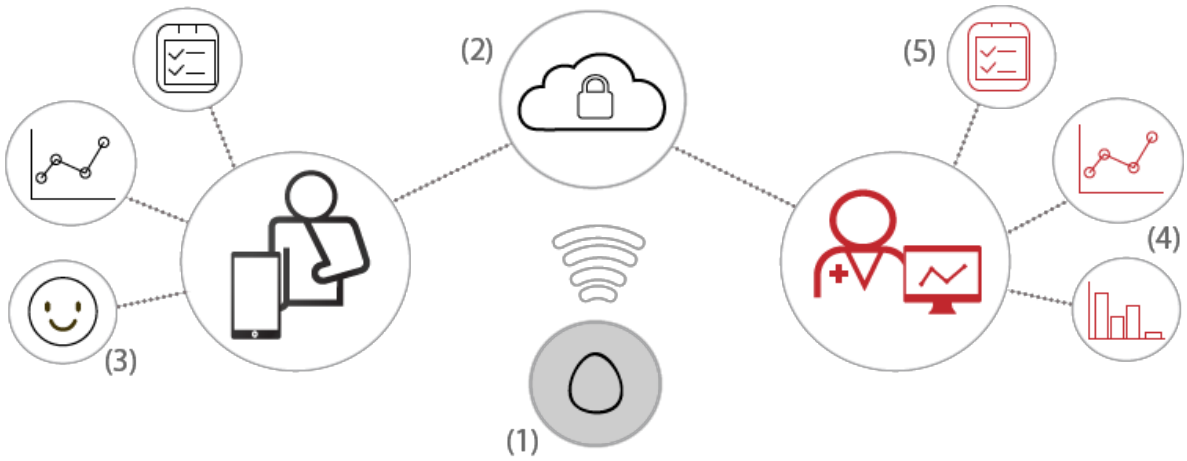
Key features of SENS motion

- Discreet sensor that monitors physical activity
- Skin-friendly patch for the sensors
- The sensor patch can be used by participants aged 3 years and older
- Quick and easy setup of the system
- 24 hours monitoring for 17 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 number	Product	Part number / model
6	Sensor – SENS motion PLUS	A06.1
3	Patches – SENS PATCH B	136-100 B
4	Patches – SENS PATCH C	136-100 C
7	Tablet	A08
113	Alcohol wipes	A10.2

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 via the SENS motion app.
- Server (2) where all the data is securely stored.
- Mobile app (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 and patch.
2. Download and install the SENS motion app on your smartphone.
3. Use the web app.

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 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 120 days, but must synchronize with the SENS motion app at least every 7 days to transfer data to the cloud. The sensor can store data for 7-10 days.

The patch should be changed as needed. Depending on which type of patch you use, the maximum is 10 (B) or 14 (C) days. Sometimes it needs to be changed more often, depending on how active the participants are. 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 turned on 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 and patch

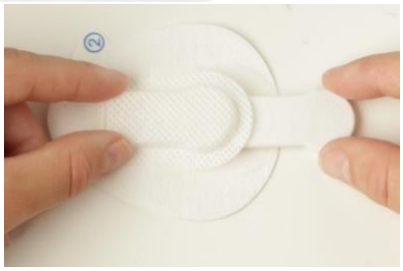
First, the sensor and the patch are assembled (1.1.1), then it is placed on the participant's leg (1.1.2).

1.1.1 Assembly of the sensor and patch



Required materials:
A disinfection cloth, a sensor and a patch.[1]

1





Place the sensor inside the patch pocket. 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 until step 3 on the next page and skip step 4.

1.1.2 Securing the patch on the participant'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.

1



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

2



Remove the back side (marked no. 2).

3



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

4



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

1.1.3 Factors Affecting Patch Adhesion and Durability

- **Correct Application**
  The patch and sensor must be applied correctly according to the official SENS guide. Incorrect application may reduce adhesion and increase the risk of the patch detaching prematurely.
- **Choice of Patch Type**
  The two patch types have different adhesion properties. Patch Type C (2-step patch) is generally recommended for children and active individuals, as it typically provides better adhesion. Patch Type B (3-step patch) is recommended for less active or bedridden individuals.
- **Drying Time After Application**
  After application, it is recommended to wait at least 24 hours before activities such as swimming, bathing, or intense physical activity, as moisture may weaken the adhesive during the initial period.
- **Water, Sweat, and Activity Level**
  Frequent exposure to water, e.g. swimming several times per week, high sweat production, and high levels of physical activity may affect the durability of the patch and increase the risk of premature detachment.
- **Need for Additional Patches**
  During periods of high activity or repeated water exposure, it may be necessary to replace or supplement with additional patches during the measurement period.

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. If the patch is hard to remove, applying skin lotion can help 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 of as normal waste. The sensor can be cleaned for reuse.

Note: Carefully remove patch material from the sensor, especially around the 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 period must be over, i.e., the end date registered in the web app for the period must have passed.

1.3.2 Data

All data is securely stored in the cloud on the server in the EU. To transfer data from the 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 the start and end date of the measurement period. 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.

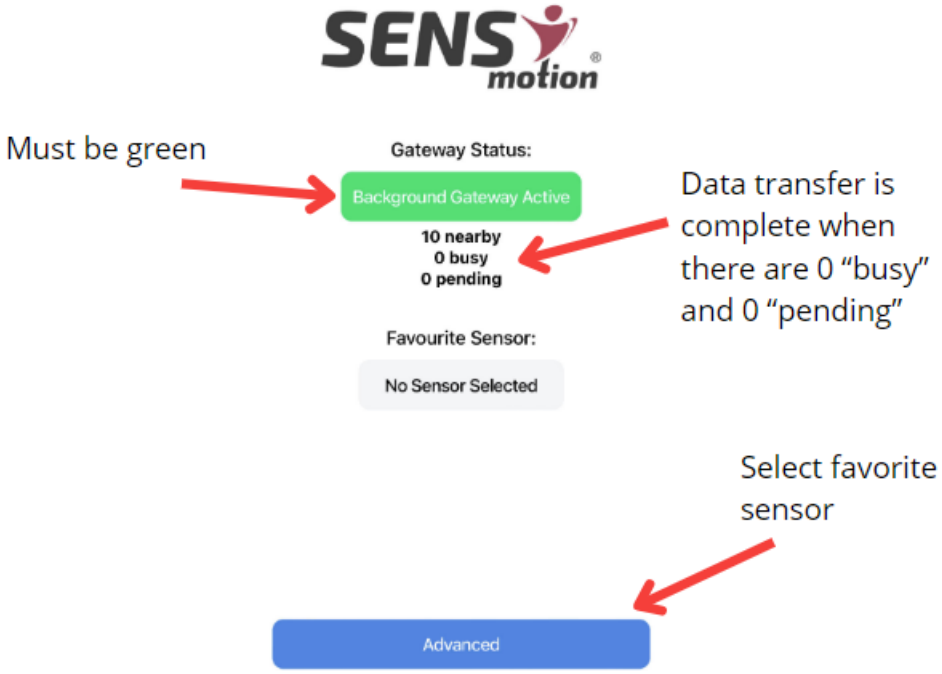
On the main screen, any problems with data collection will appear. Also check that your sensor(s) are counting under 'nearby sensors'. App design may vary on iOS devices.

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 3.5).

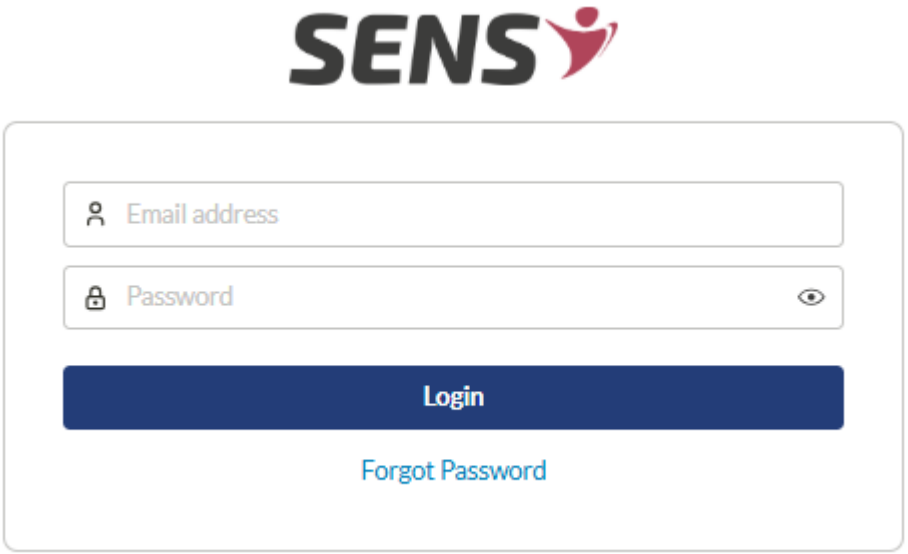
3. Using the web app

SENS motion® web app is an online visualization tool for accessing the participants' data. This is done through an internet browser using this link: app.sens.dk

This tool visualizes the activity data and is where you export data. 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® web 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 app.



3.2 Tabs overview

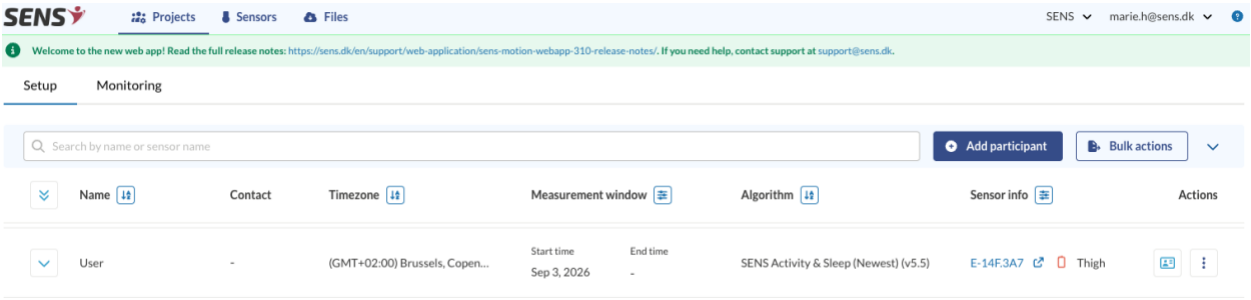
After you have logged in, you will see three tabs: ‘Projects’, ‘Sensors’ and ‘Files’.



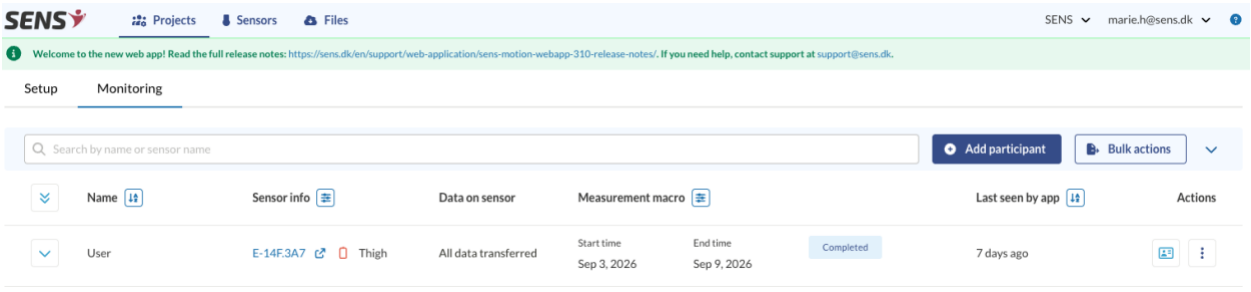
3.3 Participant overview – Projects

Click ‘Projects’ in the top bar to get an overview of the projects connected to the organization. Once you choose a project, this tab gives an overview of the participants in the project. The participant overview has two views: ‘Setup’ and ‘Monitoring’. In both views you have access to the same functions – both those for a single participant under ‘Actions’ and those for several participants at once under ‘Bulk actions’. The difference is which columns are shown.

In the ‘Setup’ view you can, for every participant, see *Name, Contact, Timezone, Measurement window, Algorithm, Sensor info* and *Actions*:

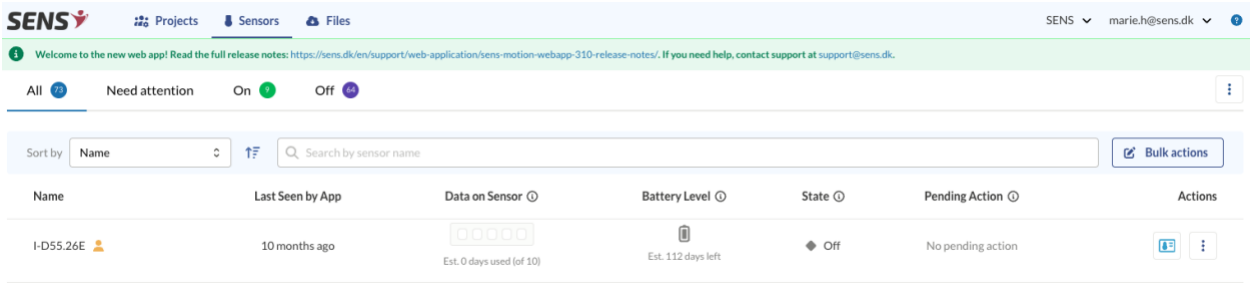


In the ‘Monitoring’ view you can, for every participant, see *Name, Sensor info, Data on sensor, Measurement macro, Last seen by app and Actions*:



3.4 Sensor overview – Sensors

Click ‘Sensors’ in the top bar to get an overview of all the sensors in the organization. Here you can, for every sensor, see *Name, Last Seen by App, Data on Sensor, Battery Level, State, Pending Action* and *Actions*:



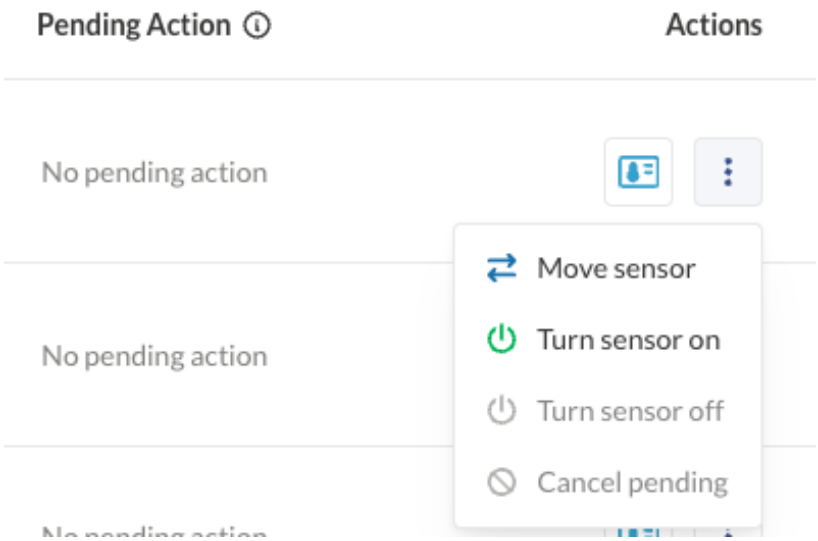
3.5 Turn sensor on/off

You can turn the sensor on/off from both the ‘Sensors’ tab and the ‘Projects’ tab.

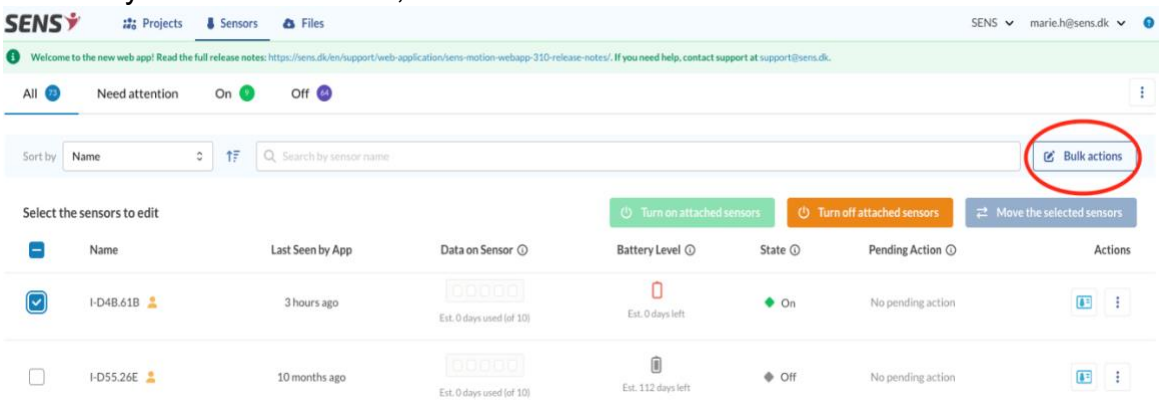
3.5.1 Turn sensor on/off from the ‘Sensors’ tab

A sensor’s “State” indicates the status of the sensor. A sensor is powered on and ready to measure when its state is “On”. Follow the steps below to turn a sensor on. A sensor is turned off the same way – simply choose off instead of on, and the state must end up as “Off”:

1. Click the three dots on the far right next to the sensor you want to turn on, and choose:
   “Turn sensor on”



2. Or, if you want to turn on multiple sensors at once, select ‘Bulk actions’, tick the sensors you want to turn on, and then click “Turn on selected sensors”.



3. The sensor’s “Pending action” will now change to: Turn on
4. Open the SENS motion app on a smartphone (accept Bluetooth and location services the first time the app is opened).
5. Shake the sensor a few times to activate it. A connection between the sensor and the server will now be established.
6. Check in the web app that the sensor’s state is “On” and displayed in a clear green colour: On

The sensor is turned off the same way. When it is turned off, it has the state “Off” with a grey colour: Off

IMPORTANT: Wait until the pending action has gone through

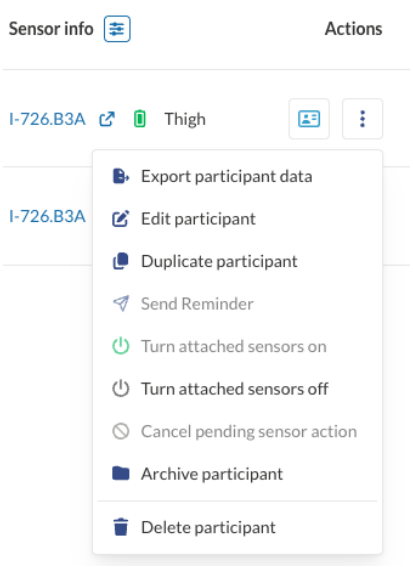
The sensor is only turned on or off once the pending action (e.g. Turn off) has disappeared. Until then, it is waiting for a connection to the SENS motion app and the final data transfer. Keep the SENS motion app open – this can take several minutes.

The sensor only stores measurements when its state is “On” with a clear green colour.

If the state does not change to “On” or “Off”, restart your smartphone and repeat the steps above.

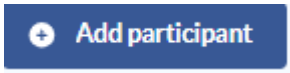
3.5.2 Turn sensor on/off from the ‘Projects’ tab

1. Select the participant whose sensor(s) you want to turn on or off by clicking the three dots on the far right and choose:
   “Turn attached sensors off”



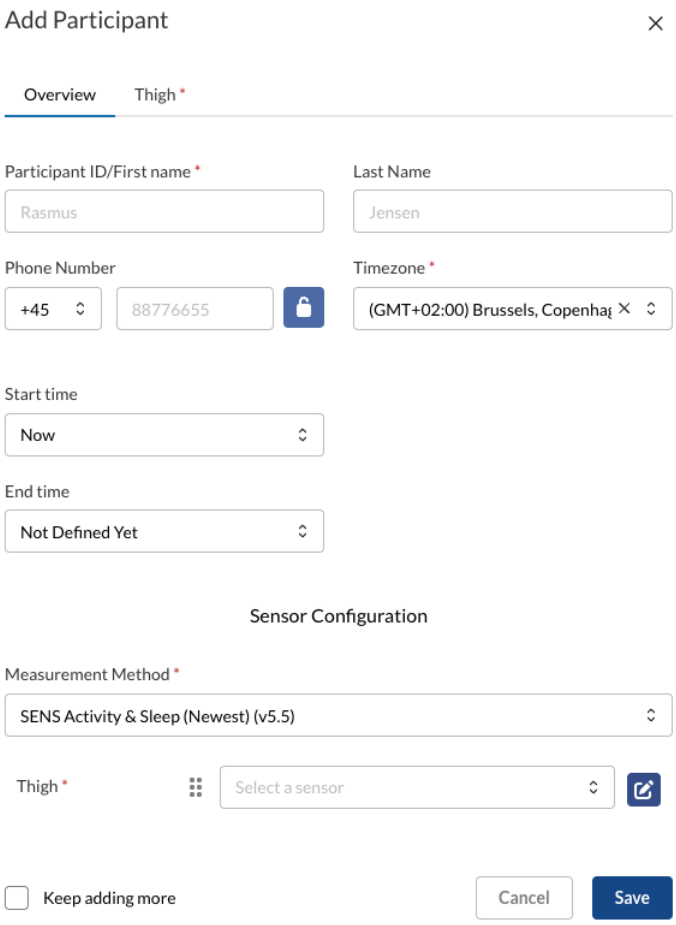
2. Do steps 4-6 from 3.5.1 Turn sensor on/off from the ‘Sensors’ tab

3.6 Add participant

In the ‘Projects’ tab, click 

to add a new participant.

Enter the Participant ID or First Name:



NOTE: The participant ID can be an anonymous ID, and entering the last name and phone number is optional.

Under ‘Measurement method’ a default algorithm is pre-selected. For other solutions, please contact SENS Innovation.

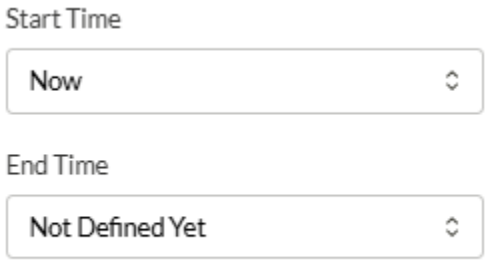
Under “Thigh*”, select the sensor. The sensor ID is on the sensor label. Both the ‘Thigh*’ tab and the “Thigh*” dropdown menu at the bottom of the page can be used, but the tab also lets you use the action “Turn sensor on” if needed. Select only sensors that are ready to use and are not already associated with another participant.

NOTE:

If the sensor is on, there is a green mark next to the sensor ID: 

If the sensor is off, the mark is grey: 

Define the start and end time of the period to be measured:

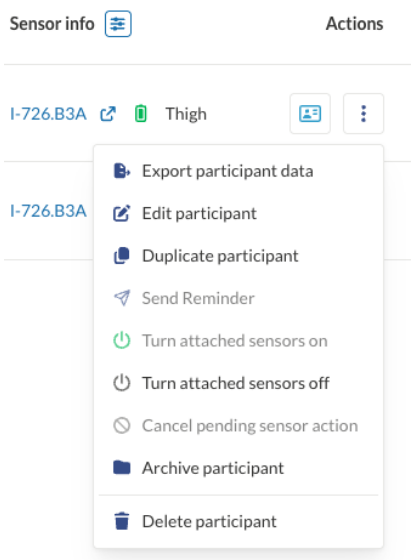


For the start time, you can choose between “Now”, “Specific time” and “Not defined yet”. For the end time, you can choose between “Now”, “Specific time”, “Specify Duration” and “Not defined yet”.

You can always adjust the start and end time of the measurement period afterwards. The sensor’s data is stored if it is on, and adjusting the measurement period will not affect the stored data.

3.7 Editing or deleting participants

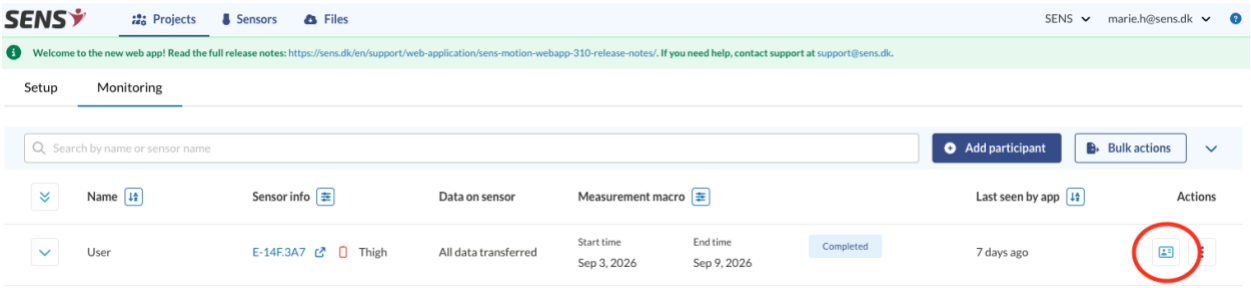
To edit participant information such as name, sensor or measurement window, click the three dots on the right of the participant and select ‘Edit participant’. To delete a participant, select “Delete participant”:



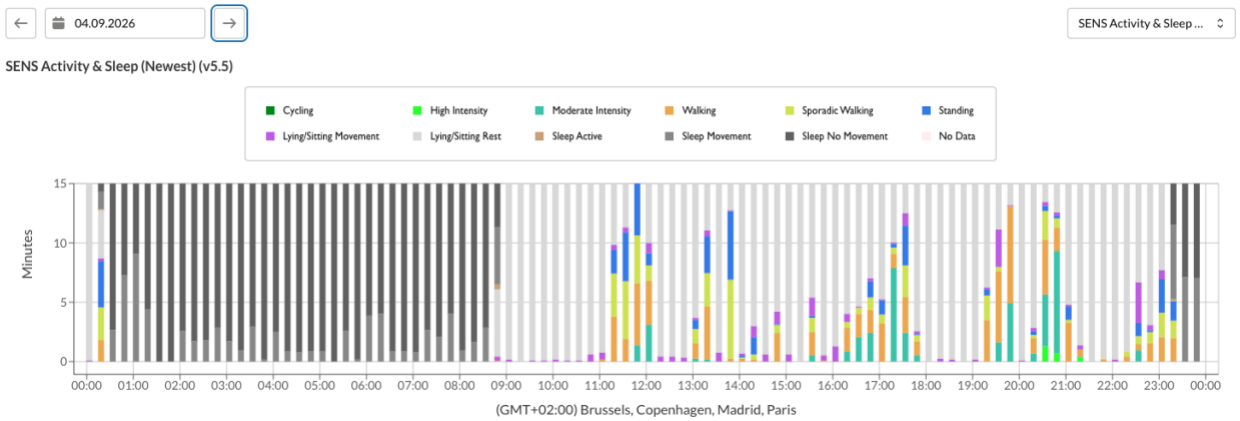
Editing can also be done for several participants at once with the ‘Edit selected’ function under ‘Bulk actions’.

3.8 Details about the physical activity of participants

Detailed graphs of a participant’s physical activity can be accessed by clicking the small square icon on the right, under “Actions” in the ‘Projects’ tab:

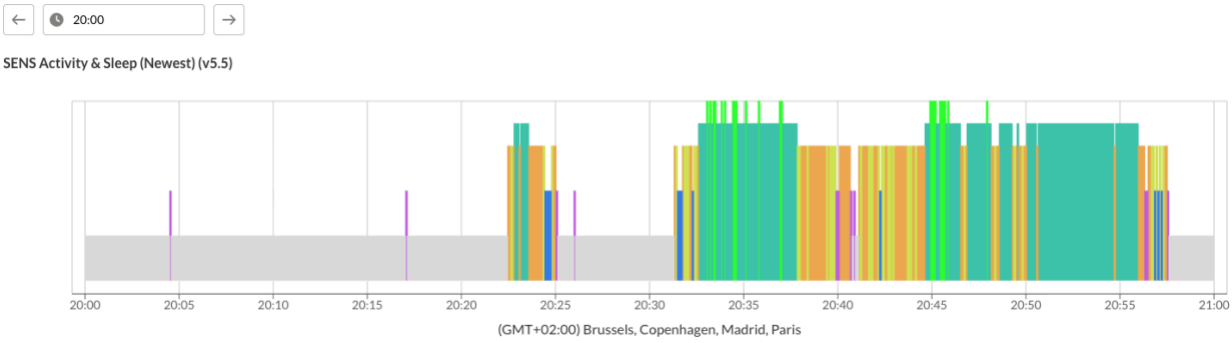


By doing so, details are shown as demonstrated below:



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

You can zoom in on a specific hour by clicking on an hourly interval in the graph. This opens a new graph with detailed activity data for the selected hour, as seen below.



To see the details of a specific minute, click on a minute interval after you have selected an hour.

3.9 Types of activities

Data is analyzed in 5-second increments, and each interval is estimated to belong to a specific activity category. The different activity levels are shown with 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 throughout this user manual.

Standing: Standing upright.

Walking: Continuous walking.

Sporadic walking: Standing upright, but with few movements. The activity lies between 'Standing' and 'Walking' but is 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.

Sleep active: The participant is active (up and walking) during the sleep period.

Sleep movement: The participant is lying down and sleeping, but moving.

Sleep no movement: The participant is lying down, sleeping and *not* moving.

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

3.10 Battery of sensor

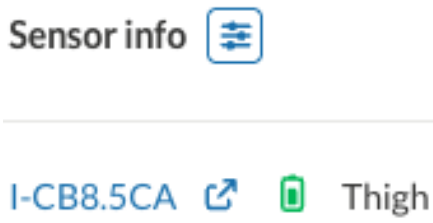
During its period of use, the battery can last 120 days when on and up to 2 years when off. The sensor's battery level updates when it connects to the app.

Note that the sensor's battery is not rechargeable. When it is empty, the sensor must be returned to SENS Innovation for recycling or collected as electronic waste.

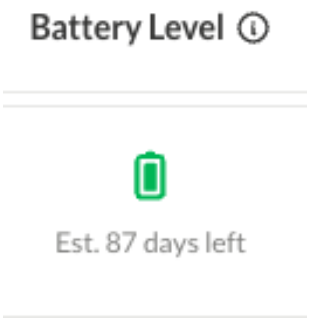
3.10.1 How to check the battery level

You can check a sensor's battery level in two places in the web app.

In the participant overview
Open the project under 'Projects'. In the participant overview, the 'Sensor info' column shows a battery icon next to each participant's sensor:



In the sensor overview
Go to 'Sensors' in the top menu and find the sensor. Under 'Battery Level' you can see the battery icon and an estimate of how many days of battery life remain, e.g. "Est. 87 days left".



What the battery icons mean
The colour of the battery icon gives a rough estimate of the battery status:

Green – high battery level

Yellow – medium battery level

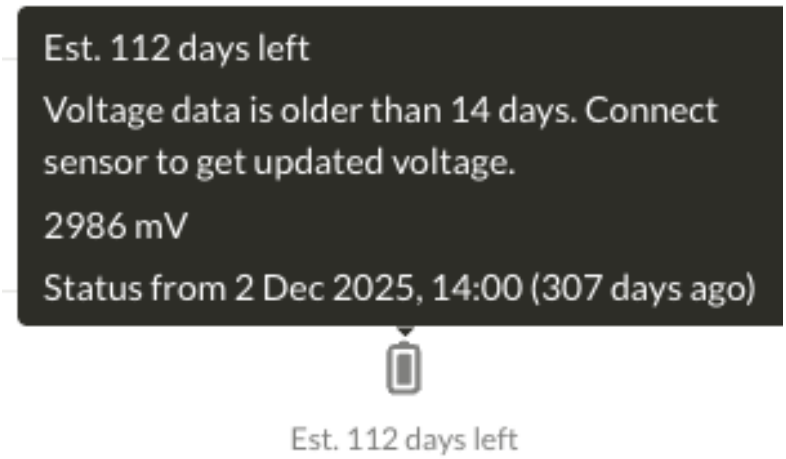
Red – low battery level

Grey – the battery status has not been updated for more than 14 days, so the level shown may no longer be accurate. Connect to the SENS motion app to update it.

Crossed out – the sensor connected to the participant has been recycled

More battery information
Wherever you see a battery icon, you can hold the mouse over it to see more information:

- The estimated number of days of battery life left
- The battery voltage (in mV)
- When and how many days ago the battery status was last registered, and the total number of days the sensor has been running

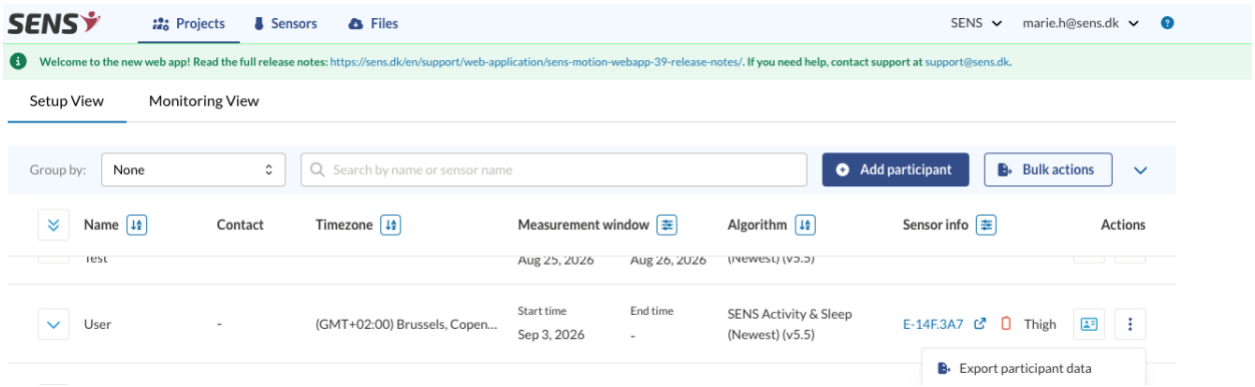


Before a measurement
Update the sensor's battery level before you attach it to a participant by syncing the sensor with the app. This makes sure there is enough battery for the whole measurement period.

4. Exporting data

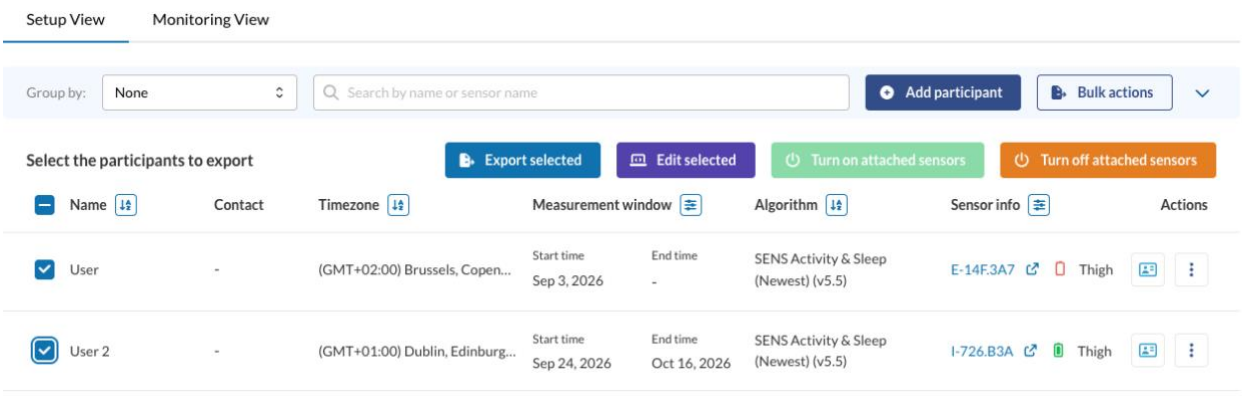
4.1 Exporting data for a single participant

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



4.2 Exporting data for several participants at once

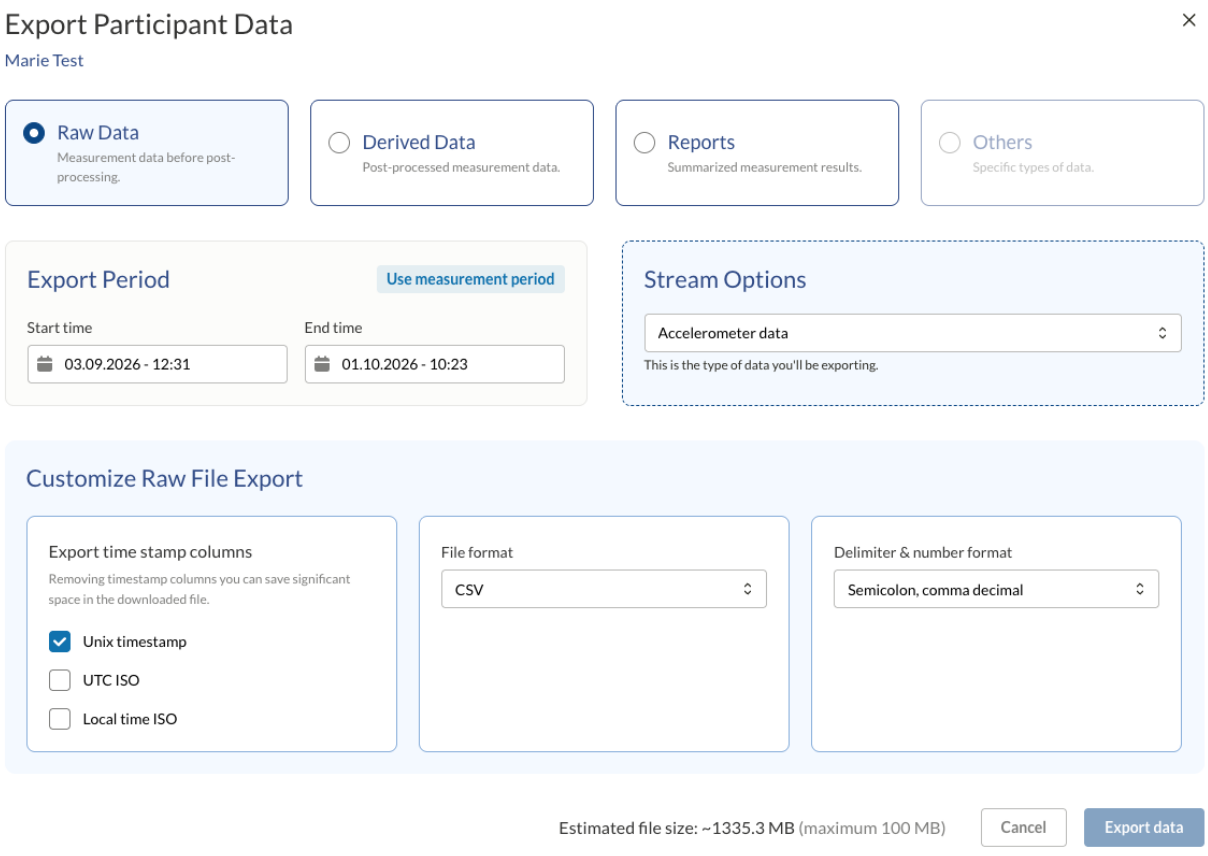
It is possible to export data for several participants simultaneously. Click ‘Bulk actions’, select the participants you wish to export data for, and click ‘Export selected’.



4.3 The Export window

The same window opens whether you export data for several participants at once or for a single participant. First choose a data type: Raw Data, Derived Data or Reports. Then set the Export Period, or click ‘Use measurement period’. The other settings change with the data type. If the estimated file size is above the maximum, shorten the period or reduce the file size. Once you are happy with your settings, click ‘Export data’.

You can find your exported file in the ‘Files’ tab, where you can download it. For details about the different export options, please refer to the “Data export” support article: https://sens.dk/en/support/web-application/data-export/



5. Contact SENS Innovation

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

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 SENS motion For Research

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 17 weeks / 120 days	Disposable patches
Battery life in sleep mode 2 years (within the application period)	Handle as normal waste

Dimensions	
Sensor	Patch incl. sensor
Length: 43 mm	Length: 80 mm
Width: 22 mm	Width: 60 mm
Thickness: 5 mm	Thickness: 5 mm
Weight: 7 grams	Weight: 1 gram

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
Waterproof: IP68
Functional temperature 5° – 34°
Storage and transport temperature -30° to +60° at 40-60% humidity
Atmospheric pressure range from 700 hPa (3000 m) to 1060 hPa
Technology: wireless transfer. Frequency band: 2400-2480MHz. Radiating effect max: 2.5 mW (Class 2 transmitter). Can be used without any safety distance to the user.
Versions Web app v.3.10.x



SENS Innovation ApS
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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 10993-10:2013).

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 instructions 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 – The sensor must be disposed of as electronic waste

Keep away from sunlight

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

Operating temperature: 5°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 closer than 30 cm to the SENS motion Plus product.

If you experience discomfort in connection with the use of SENS motion Plus, 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 ambient 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