Instruction Manual Sensor Insole

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Approval

Record

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1.3	DRAFT	RV	Include FCC Part 15.19 and 15.21 statements	DRAFT
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1.0	07.11.2016	RV	Initial version	07.11.2016

MOTICON SCIENCE

Sensing Foot Dynamics

No Wires. No Limits.

Instruction Manual

Model: SENSORINSOLE2

1 Warning Symbols and Location of Labels

The following signs and symbols are used in these instuctions for use, the sensor insole labeling, and the packaging labeling:

Safety critical warning

Safety critical warning, prohibited action

Safety critical warning, mandatory action

Indicates that the instuctions for use must be consulted

Caution sign

Do not dispose of in your houshold waste (EU WEEE Directive 2012/19/EU)

Identification of manufacturer and date of production (year/month)

SN Device serial number

Product is a Type BF Applied Part

IPX1 International Protection (IP) Marking

Temperature range for operation/storage

Humidity range for operation/storage

Handle package with care

On the sensor insole, the labeling is located in the heel area of the lower surface, and on the battery lid. On the packaging, handling instructions are given on the outer surface of the packaging.

2 Product Description

Note: In the following, the term "sensor insole" refers to an individual left/right sensor insole, as well as to a pair of sensor insoles.

Intended Use

Measurements may be incorrect when the product is used outside of the defined intended use.

The sensor insole is intended to be used inside a shoe for measuring the plantar pressure at the sole of foot, and the acceleration of the foot in three axes.
The use of the product is not specific to certain diseases or symptoms. It is the responsibility of the user to interpret the measurement data obtained from the product, and no diagnosis or treatment decision shall be carried out solely on the basis of the data.

Contraindications

The following conditions are absolute contraindications for using the product:

- open wounds of the foot, irritated or otherwise unhealthy foot skin
- orthopedic or other reasons depending on the health status of the patient, which do not allow for wearing the sensor insoles
- severe gait impairments where the sensor insole might increase the risk of fall
- inability of the patient to wear closed shoes for wearing the sensor insoles

When applying the sensor insole to a patient for more than one day, the user applying the product to the patient must ensure that the patient will not encounter negative orthopedic long-term effects from wearing the product, and must instruct the patient to report discomfort and pain due to wearing the device, and to stop wearing the device in such cases.

Device User Group

The device user group applying the product to the patient are health professionals familiar with the provision of insoles or foot orthotics, such as clinical doctors, physicians, orthopedic specialists, physiotherapists or nurses.

The user must be able to correctly apply sensor insoles to patients, including proper size selection/fitting and identification of contraindications.

Product Types

SCIENCE sensor insoles provide the standard functions. SCIENCE Pro+ sensor insoles provide further optional functions, which are in the following indicated by "only SCIENCE Pro+".

Product Functions

The sensor insole is controlled wirelessly via ANT from a PC or smartphone ("controlling device"), and supports different operation modes.

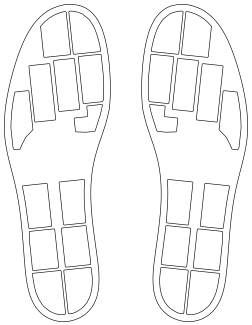
Live: Wireless data streaming to the controlling device
Recording: Measurement function which stores the data directly on the sensor insole memory
Smart recording: Recording function with automatic start/pause function triggered by motion pattern detection and longterm time sync exchange between left and right insole (only SCIENCE Pro+)
Smart monitoring: Extended recording time through memory saving with total force and center of pressure (COP) computation directly on the sensor insole (instead of storing individual sensor values) (only SCIENCE Pro+)

In the operation modes live, recording and smart monitoring the sensor insole measures the plantar pressure and the acceleration of the foot.

Further functions:

- Automatic shutdown for saving energy
- Zeroing of pressure sensors, initiated from controlling device
- Wireless ANT download of recorded measurement data
- USB download of recorded measurement data (only SCIENCE Pro+)
- Pairing mode for pairing the sensor insole with the controlling device

The pressure sensor layout is as follows (not to scale):



3 Application Procedure

This section describes the general application procedure. See Sec. 4 for details about how to operate the sensor insole.

Safety warnings for application:

The sensor insole is not an orthotic. In case an orthotic is used by the patient, the attending doctor must be consulted about whether it can be replaced by the sensor insole.

The sensor insoles must be worn only pairwise (both left and right) in order to avoid asymmetric gait.

Only sensor insoles with appropriate size may be worn. Incorrect sizes (too small, too big, or improper fit) are potentially dangerous, may be damaged during walking, and cause erroneous measurement values. Check the proper fit of the sensor insole after insertion into the shoe.

The sensor insole may only be worn in closed footwear.

The battery compartment must face down towards the floor when inserting the sensor insole into a shoe.

Immediately stop wearing sensor insoles in case of pain or skin irritation.

The weight of the patient wearing the sensor insole may not exceed 120 kg.

Remove the battery from both insoles after finishing a measurement, or when the battery is not used for some time. Store the sensor insole only without battery.

In case of an internal fault, surface temperatures of 41 °C to 43 °C may occur, constituting a possible temperature hazard.

The sensor insole may not be worn with open wounds or ulcers.

The sensor insole must be worn with socks in order to avoid direct skin contact.

See the detailed product information and tutorial videos on www.moticon.com/support

Safety warnings against misuse:

Do not attempt to modify the size or shape of a sensor insole. Do not cut the sensor insoles! This is dangerous and will damage the sensors.

Do not bend or twist the sensor insole, to prevent damage of electronics. The sensor insole is designed to be used inside a shoe, atypical bending or torsion will destroy it.

Do not sting or prick the sensor insoles. Sharp elements can cause dangers and severe damage. Remove any sharp or spiky objects from the footwear when wearing sensor insoles. Do not use sensor insoles when damaged.

Do not use sensor insoles for measurements outside of footwear.

Do not wear sensor insoles when driving a car or climbing a ladder.

Do not use the sensor insole in wet or humid conditions, e.g. rain or strong foot sweat.

Application steps:

1. Select an appropriate sensor insole size
2. Insert the batteries into the sensor insoles
   → *Refer to Sec. 4, Battery Handling*
3. Insert the sensor insoles into the patient's shoes
   → *Refer to Sec. 4, Sensor Insole Handling*
4. Let the patient put on the shoes
5. Let the patient walk 20–30 steps
6. Check the walking comfort of the patient
7. Connect the sensor insoles using a controlling device/software
   → *Refer to Sec. 4, Sensor Insole Handling*
8. Carry out the sensor zeroing
   → *Refer to Sec. 4, Sensor Insole Handling*
9. Start the measurement
10. . . . Patient wears the sensor insole. . .
11. Stop the measurement
12. Remove the sensor insoles from the patient's shoes
13. Remove the batteries from the sensor insoles
    → *Refer to Sec. 4, Battery Handling*

4 Using the Sensor Insoles

Battery Handling

Never use batteries other than batteries provided by Moticon for your sensor insoles. They are labelled as follows: **Route JD Inc Li-ion Rechargeable 3.7V**

Do not use the sensor insole in case of a damaged, demolished or shifted battery contact.

Do not use the sensor insole with open battery compartment.

Do not remove the battery during a measurement. For longer measurements, instruct the patient to not remove the battery and to not remove the battery lid.

Do not use sharp objects for removing the battery. Only use the tip of the finger.

Only insert fully charged batteries into sensor insoles, otherwise the battery level indicator in the software of the controlling device will display wrong values.

How to insert the battery into the sensor insole:

1. Make sure that positive (+) pole of the coin cell battery points towards you. With this orientation, slide the coin cell battery under the contact flap.
2. Sink the battery into the battery case by gently pushing it downwards.
3. Place the lid loosly on the top of the groove that runs around the battery case. The prominent flap on one side of the battery lid must rest above the corresponding gap in the sensor insole.
4. Snap in the battery lid into the circular groove by pushing in the center of the lid. Only when you noticed the snap, the lid rests in the groove correctly

How to remove the battery from the sensor insole:

1. Pull on the flap of the battery lid to remove the battery lid from the sensor insole
2. If the battery does not readily slide out of the battery case, use your fingertip to gently remove it
3. **Warning:** Never pull on the battery flap, and do not bend the battery flap away from the sensor insole. For removing the battery, it is sufficient to only slightly elevate the battery flap.

Sensor Insole Handling

Do not bend or twist the middle part of the sensor insole when putting it into or taking it out from a shoe.

Wireless connections are potentially unstable. When starting a recording, check in the software of the controlling device that the recording has started properly before letting the patient walk.

Do not disconnect the sensor insole from the USB download cable or the USB download cable from the PC during data transfer. The data transfer will not resume after reconnecting the cable.

The sensor insole does not have any switch. In order to turn the sensor insole on, it is sufficient to moderately shake the sensor insole. The sensor insole will enter a power-safe mode after 30 s time of inactivity, so it does not have to be turned off. However, the battery must be removed before storing the sensor insole.

Before connecting the sensor insole with a controlling device, the sensor insole must be paired. To bring the sensor insole into pairing mode, shake it to turn it on, put it **upside down** on a flat surface, and leave it in this position while carrying out the pairing. Please refer to the software manual about how to carry out the pairing.

How to put the sensor insole into a shoe:

1. If the shoe has a removable inner sole or liner, remove it before inserting the sensor insole.
2. Place the sensor insole into the shoe, with the top layer pointing towards you, and the battery compartment pointing towards the bottom of the shoe. **Note:** The lower sides of the sensor insoles are marked with "left" and "right", indicating the respective foot side.
3. When sliding the sensor insole all the way into the shoe, pay particular attention to not bend the sensor insole in the mid foot area, since this will damage the sensor insole.
4. Gently push the heel area all the way into the shoe.
5. Check that the sensor insoles fits neatly into the shoe, otherwise use an appropriate sensor insole size.

How to remove the sensor insole from the shoe:

1. Slightly lift the sensor insole in the medial midfoot area.
2. Gently pull on the heel area of the sensor insole to pull it out of the shoe, while paying particular attention to not bend the sensor insole in the mid foot area.

Accessories

Only use USB download cables provided by Moticon.

Only use accessories supplied by Moticon. Using unauthorized is potentially dangerous and may damage the product.

The USB download cable (optional) is used to download recorded data from the sensor insole. For using the USB download cable:

1. Remove the battery lid from the sensor insole while leaving the battery in the sensor insole.
   Caution: The data download via USB requires an inserted battery in the sensor insole.
2. Plug in one of the two sensor insole connectors of the USB download cable into the sensor insole. The connector has the same shape as the battery lid. Please refer to the above explanation of how to insert the battery lid.
3. Plug in the standard USB plug into a compatible connector of the controlling device (PC).
4. Refer to the software manual about how to start the data transmission via USB.

5 Reprocessing

The sensor insole is not a sterile product.

Do not spray the disinfection spray on skin or feet. Pay attention to the safety instructions provided by the disinfection spray manufacturer.

Only use disinfection spray based on the active ingredients didecyldimethylammonium chloride and ethanol.

If worn by different patients, the sensor insole must be reprocessed before it can be reused.

Cleaning and disinfection procedure:

1. Remove the battery, and properly insert the battery lid.
2. Clean the upper and lower side of the sensor insole with a damp soft wipe, then dry with a clean soft wipe.

3. Spray disinfection spray on the upper and lower side of the sensor insole. Only use disinfection spray based on the active ingredients didecyldimethylammonium chloride and ethanol.
4. Let the disinfection spray work for 1 minute, then let dry.

If necessary, repeat the cleaning and disinfection procedure with the top layer being taken off. The top layer is cloth which sticks to the top of the sensor insole. It can be removed and re-attached by hand. Do not attempt to open the seam on the edge of the sensor insole!

The top layer can be replaced, as required. Please contact Moticon or your local distributor for replacement top layers.

6 Technical Data

General information:

- Power supply: PD2032 3.7 V Li-ion rechargeable coin cell battery (supplied by Moticon)
- 16 MB flash memory
- Recording duration (at different sampling rates): 48 h (5 Hz), 29 h (10 Hz), 11 h 36 m (25 Hz), 5 h 48 m (50/100 Hz). With smart monitoring up to 58 h (5 Hz) (only SCIENCE Pro+).
- 9 available size from 32/33 to 48/49 (EU)
- Selftest function: The sensor insole continuously carries out a monitoring self-test. In the case of a sensor defect, the sensor insole will not allow any further measurements to be started.

Environment:

- Operation temperature range: 20 °C to 30 °C
- Storage temperature range: -10 °C to +50 °C
- Storage humidity range: 5% to 95%
- Air pressure range for storage and operation: 690 hPa to 1070 hPa (≡ max. 3000 m altitude)
- The sensor insole operates in the 2.4 GHz ISM band. Disadvantageous radio performance may occur if used in an environment with other devices operating at 2.4 GHz (e.g. WLAN, Bluetooth). In this case, stop using the sensor insole in this environment.
- The sensor insole must not be used in environments where radio emissions at 2.4 GHz are potentially harmful or forbidden by law.

7 Specifications

The sensor insole outputs binary data, which is represented by the controlling device in the following output format:

- Pressure in N/cm^2
- Total force in N
- Acceleration in g
- Center of pressure (COP) in mm

Pressure sensors:

- 13 capacitive pressure sensors per sensor insole
- Pressure range: 0...40 N/cm^2
- Pressure resolution 1.0 N/cm^2
- Accuracy of pressure at 10 N/cm^2: ±25%
- Accuracy of peak total force in walking: ±25%
- Accuracy of COP in x/y direction: ±20 mm

Acceleration sensor:

- 3D acceleration sensor (MEMS)
- Acceleration range per axis: ±8 g
- Resolution of acceleration: 0.0625 g
- Zero-g offset: ±0.1 g

Sampling rates and timing:

- Sampling rates: 5, 10, 25, 50, 100 Hz (8 sensors)
- Relative timing accuracy: $2/f_S$ (f_S = sensor sampling frequency)
- Absolute timing accuracy: $0.01 \cdot T_M$ (T_M = measurement duration)

Product Life Expectancy:

- Durability: 100 km walking distance
- 250 reprocessing cyles

8 Waste of Electrical and Electronic Equipment (WEEE)

According to the WEEE Directive 2012/19/EC, electrical and electronic equipment (EEE) covered by this directive should be disposed of and collected separately and use the best available treatment, recovery and recycling techniques.

It is important to collect WEEE separately from other wastes, since it contains hazardous substances to the human health and environment, and is also a valuable resource of raw materials.

Moticon products are subject to the Directive. We therefore urge you to not dispose the equipment as normal household waste. Instead, please send all products back to Moticon. We will take care of proper disposal of these products.

9 Product Compliance

Standards compliance:

- IEC 60601-1
- IEC 60601-1-2 (for EMC)

Notified body:

TÜV SÜD Product Service GmbH
Ridlerstr. 65, 80339 München, Germany

CE
0123

Equipment classifications:

- Internally powered Medical Electrical Equipment
- Type BF Applied Part
- Medical device class Im
- Mode of operation: Continuous Operation
- IP classification: IPX1

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). In addition, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3rd edition of IEC 60601-1). Anybody connecting additional equipment to medical electrical equipment configures a medical system, and is therefore responsible that the system complies with the requirements for medical electrical systems. Note that local laws take priority over the above mentioned requirements. If in doubt, consult your local distributor or the Moticon support.

FCC Part 15.19 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 Part 15.21 Statement:
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Imprint

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