.MOVESENSE

MOVESENSE MD
User Guide

OP174

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CONTENTS

1   INTENDED USE

Movesense MD sensor is a wearable and portable medical device and is intended for measuring single channel ambulatory ECG for the investigation of the human heart, and to provide precise quantitative measurement of human movement, enabling tracking of the effects of body condition, disease or injury through their influence on the movement system.

Movesense MD provides an optional ECG R-peak detection and physiological parameter analysis of ECG data, such as HRV (Heart Rate Variability) and HR (Heart Rate).

Device ECG functionality is intended to be used by home and professional users for patients with bodyweight of 10 kg or more, whereas the movement measurement functionality has no limitations.

Device allows third party[1] manufacturers to access and further process the measured data and data analyses via third party developed custom software, according to their intended purpose.

1.1   Intended Users and Use Environments

Movesense MD is designed to be handled and operated by users with adequate motoric and cognitive skills. The users may be end-users / consumers or medical professionals, i.e., nurses, doctors, physical therapists, emergency response personnel. The end-user / consumer may also present any other occupational group than medical professionals.

Target users: Medical professionals and consumers. The device may be operated by the patient.

Movesense MD is designed to work in multiple different environments, in home environment and in healthcare facilities, both indoor and outdoor.

As an output of the Movesense MD sensor, the measured signals are sent by a wireless Bluetooth connection to a host device for further processing, analyzing, and storing, as needed by the end application.

Since the host device is developed and designed by a 3rd party Medical Device Manufacturer, the Medical Device Manufacturer is obligated to determine the user profile and use environment for their end-product.

Movesense MD sensor has a limited internal recording capability for storing raw recorded signal data or processed derivatives of the data. This memory can be utilized

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[1] 3rd parties who use Movesense MD sensor are referred later in this document as Medical Device Manufacturers or OEM integrators. OEM stands for Original Equipment Manufacturer.

by implementing a custom firmware and allows Movesense MD to operate without a continuous connection to the host device.

Movesense MD operating conditions: -20°C to +60°C/-5°F to +140°F, 0-99% Relative Humidity, Pressure: 300hPa to 3000hPa

Movesense MD may be operated in an oxygen rich environment, when the partial pressure of oxygen is maintained at or below 85kPa (pO2 < 85kPa), equal to an air atmosphere under a 300kPa overpressure.

1.2 Contraindications

Movesense MD shall not be used as a primary monitoring device for vital physiological parameters (such as ECG, heart rate, respiratory rate) in clinical situations where the patient is in an immediate danger, such as during intensive care.

Movesense MD shall not be used as a life sustaining or life supporting device.

Movesense MD may not be used to measure ECG from infants weighing less than 10kg. There is no weight limit for the patients whose motion is measured.

1.3 Device description

Product: Movesense MD sensor

Device description: Movesense MD is a medical device, which measures ECG, HR, HRV and motion, and which is used in connection with host medical device systems. Movesense MD sensor records signals for further analyses, which are provided by the medical device manufacturer. Movesense MD sensor has also a non-medical temperature measurement capability, which shall not be used for medical purposes.

Movesense MD sensor uses wireless BLE (Bluetooth Low Energy) connection to send data to a host device for further processing, analyzing, and storing, as needed. Suitable host devices include mobile phones, tablet computers, personal computers, and other devices compliant with the Bluetooth v4.0 (or above) specification and running a suitable host application capable of processing the measured signals.

For plain heart rate monitoring, utilizing the Bluetooth LE Heart Rate Service, capable of providing heart rate and R-R intervals, as specified by the Bluetooth SIG[2], a suitable sports watch or mobile application can be used. Please note: if Movesense MD sensor is connected with a non-medical host device or a non-medical system, e.g., a sports watch, the sensor-system combination is no longer classified as a medical device.

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[2] For details see www.bluetooth.org

1.4 Safety classification

- Movesense MD is a Class IIa medical device
- Movesense MD is INTERNALLY POWERED EQUIPMENT
- Movesense MD is TYPE BF APPLIED PART, fulfilling the requirements of the IEC 60601-1 standard
- Movesense MD is a CONTINUOUS OPERATION device
- Movesense MD may be used both in PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT and in HOME HEALTHCARE ENVIRONMENT
- Movesense MD may be used to measure motion, heart rate and R-R intervals from infants weighing less than 10kg.
- The upper limit of the Movesense MD ECG measurement bandwidth is 40Hz, hence the sensor may not be used to measure ECG from infants weighing less than 10kg (as defined in IEC 60601-2-47:2012)
- Movesense MD is suitable for operation in an OXYGEN RICH ENVIRONMENT.

1.5 Device lifetime

The maximum expected life of the Movesense MD sensor in normal home use is 5 years. Replace the sensor after this or earlier, if

1) otherwise instructed; or

2) harsher than normal operating conditions have caused deterioration of the essential features; or

3) if any damage to the device is observed.

See the section 5.6 for recycling guidance. If any cracks or structural damage is observed, cease the use and replace the sensor immediately.

NOTE: the battery must be replaced when the sensor does not start or if the red indicator led does not light up during power-up, when instructed by the accompanying host application or otherwise when needed. The O-ring and the sealing surfaces must be visually inspected and cleaned every time the battery cover is opened, according to the section 4.3.
The maximum expected battery life in the plain heart rate monitoring use case is 400 hours. The maximum expected battery life in the continuous ECG monitoring use case is 7 days. The maximum expected storage life of the battery before the first use is 1 year. Always use a fresh battery when a long duration continuous measurement is anticipated.

The maximum expected service life for the textile heart rate monitor strap is 100 hours of use.

The maximum expected service life for the battery cap O-ring is 10 battery replacement cycles.

2   SAFETY

2.1   Explanation of the markings used on the device and in the documentation

Symbol	Explanation
	Manufacturer
	Date of manufacture
	CE marking and the notified body identity number
	WEEE Directive logo. Do not throw in the garbage.
L	Left side electrode connection
R	Right side electrode connection
	See user guide for important information
	Type BF applied part
	Bluetooth logo. The sensor utilizes a Bluetooth LE radio for wireless communications.
	Fragile, handle carefully.
	Keep away from sunlight
	Operating temperature range
	Operating humidity range
	Operating pressure range

HRM strap specific symbols

	Machine wash 30°C / 86°F
	Do not tumble dry
	Do not iron
	Do not bleach
	Do not use fabric softeners

2.2   Types of safety precautions

WARNING: is used in connection with a procedure or situation that may result in serious injury or death

CAUTION: is used in connection with a procedure or situation that will result in damage to the device, affect the measurement results or pose a risk to the safety of the patient/user or the operator.

NOTE: is used to emphasize important information, which the user and the operator must be aware of to guarantee safe and practical use.

TIP: is used for extra tips on how to utilize the features and functions of the device.

2.3   Safety precautions

WARNING: Only for intended use.

WARNING: The Movesense MD sensor must not be used for purposes other than what it is intended for.

⚠ **WARNING:** Stop the usage immediately if the sensor is damaged or if a change in the performance is observed.

⚠ **WARNING:** Stop the usage immediately if an allergic reaction is observed.

⚠ **WARNING:** Do not modify the equipment without prior written authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

⚠ **WARNING:** Always consult your doctor if you have a medical condition and before beginning an exercise program. Overexertion may cause serious injury.

⚠ **WARNING:** Always consult your doctor before using the sensor if you have a pacemaker or other implanted device. Although several implanted pacemaker manufacturers state the risk assiated with the simultaneous use is low, it is essential to consult a doctor who knows the exact type and model of the implanted device in question before using the sensor. In any case keep the sensor at least 15cm/6" away from the implanted device.

⚠ **WARNING:** Do not use the sensor during magnetic resonance imaging (MRI), unless specifically approved by the personnel operating the MRI equipment. The coin cell battery inside the device is magnetic.

⚠ **WARNING:** Not to be worn by multiple users if consequences from possible cross contamination may be severe. Careful cleaning and disinfection is recommended to prevent cross infection if worn by multiple users.

⚠ **WARNING:** The conductive parts of the sensor and/or electrode connections must not be allowed to contact any conductive parts, including protective earth connection.

⚠ **WARNING:** Keep the sensor and any accessories away from the reach of children, pets or pests when not in use.

⚠ **WARNING:** The battery used must be compliant with the requirements of the IEC 60086-4 lithium battery safety standard.

⚠ **WARNING: KEEP THE BATTERY OUT OF REACH OF CHILDREN.**
EVERY EFFORT MUST BE TAKEN TO PREVENT ACCIDENTAL SWALLOWING OF THE BATTERY OR OTHER PARTS. IF ACCIDENTAL SWALLOWING IS SUSPECTED, SEE DOCTOR IMMEDIATELY. THE BATTERY TYPE IS LITHIUM / MANGANESE DIOXIDE (Li/MnO2).

⚠️ **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Movesense MD, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠️ **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠️ **WARNING:** Do not use the sensor with accessories or parts not meant for it or interconnect with other equipment that are not intended to be interconnected with it, as the result may be unsafe and may negatively affect the electromagnetic compatibility.

⚠️ **CAUTION:** Do not apply solvent of any kind to the product, as it may damage the surface.

⚠️ **CAUTION:** Do not use the sensor on patient skin during defibrillation.

⚠️ **CAUTION:** Do not use on patient skin simultanously with HF surgical operation.

⚠️ **CAUTION:** Do not apply insect repellent on the product, as it may damage the surface.

⚠️ **CAUTION:** Do not knock or drop the product, as it may get damaged.

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⚠️ **CAUTION:** Do not modify the device. Any modifications are potentially unsafe.

📝 **NOTE:** If the storage temperature is below -20°C /-5°F, allow the device's internal temperature to stabilize for 10min at room temperature before use.

📝 **NOTE: T**he sensor is immediately usable when brought to room temperature from a storage temperature of -20°C to +60°C/-5°F to +140°F

+60°C

-20°C

99% RH

0% RH

3000hPa

300hPa
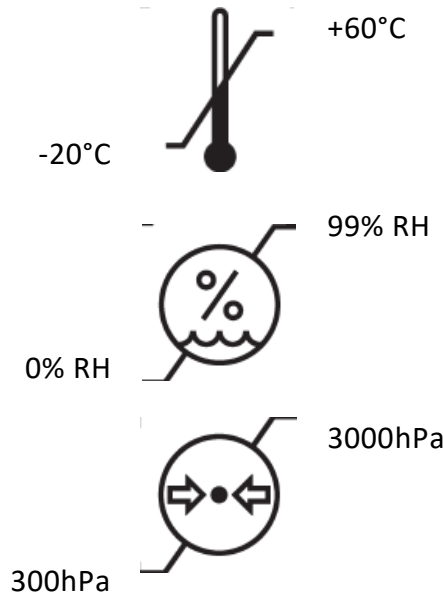
📝 **NOTE:** If the Movesense MD sensor is used for heart rate measurement, the standard Heart Rate Service may be used, as specified by the Bluetooth SIG[3], in connection with a compatible general purpose host application or device. If extended functionalities like ECG or motion measurement are used, a dedicated host application is required, capable of receiving the custom data. Please note: if Movesense MD sensor is connected with a non-medical host device or a system, e.g. a sports watch, the sensor-system combination is not classified as a medical device as a whole.

📝 **NOTE:** Use at least 30cm/12" away from the sources of power line frequency magnetic fields, radio frequency communcations equipment and other sources of radio frequency signals (such as radars or microwave ovens).

If the measurement results are fluctuated by a strong nearby radio frequency disturbance source, move further away from the source of the disturbances.

To avoid any degrading effects of the external electromagnetic disturbances, the sensor should be used in connection with equipment fulfilling the IEC60950 and/or EN60601-1 standards. Avoid using the sensor in the proximity of electrostatic disturbance sources.

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[3] For details see www.bluetooth.org. The Bluetooth LE radio technology used in the Movesense MD is specified in the Bluetooth v4.0 specification. Suitable host devices include mobile phones, tablet computers and other devices compliant with the Bluetooth v4.0 (or above) specification and running a suitable host application capable of processing the measured signals. For plain heart rate monitoring, utilizing the Bluetooth LE Heart Rate Service, capable of providing heart rate and R-R intervals, as specified by the Bluetooth SIG, a suitable sports watch or mobile application can be used. Please note: if Movesense MD sensor is connected with a non-medical host device or a system, e.g. a sports watch, the sensor-system combination is not classified as a medical device as a whole.

Do not use close to a 2.4GHz signal source, as strong signal may negatively affect the performance of the Bluetooth radio link.

 NOTE: The Movesense MD sensor is waterproof and can be used in wet environments. The IP68 ingress protection rating means that the sensor withstands submerging to a depth of 1m/3.3ft underwater for a duration of one hour.

It must be taken into account that the Bluetooth connection will be interrupted if a large enough RF energy absorbing body of water is inserted between the Movesense MD sensor and the respective host device.

 NOTE: When the sensor is not in use, do not allow the two metal studs to simultaneously contact an electrically conductive medium. If the studs are connected, for example via a metal surface or a moist fabric, the sensor will remain powered on and this will unnecessarily consume the battery.

2.4 Serious incidents

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state of the European Union in which the user and/or patient is established.

'Serious Incident' means any incident that directly or indirectly led, might have led or might lead to any of the following;

- the death of a patient, user or other person
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- a serious public health threat.

Manufacturer's contact information can be found in chapter 5.2.

3 MEASURING HEART RATE / ECG

3.1 Getting started

To start using the Movesense MD sensor with a heart rate belt[4], pair the sensor with a compatible receiving device as instructed in 3.2. Then follow steps 1-4:
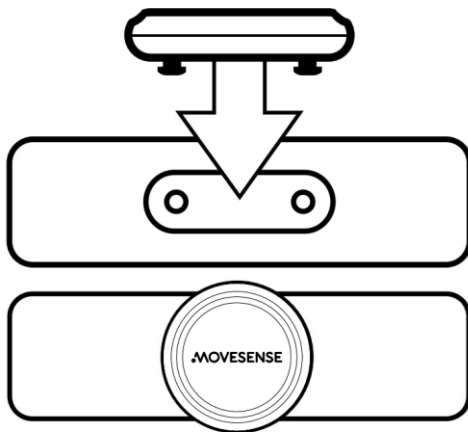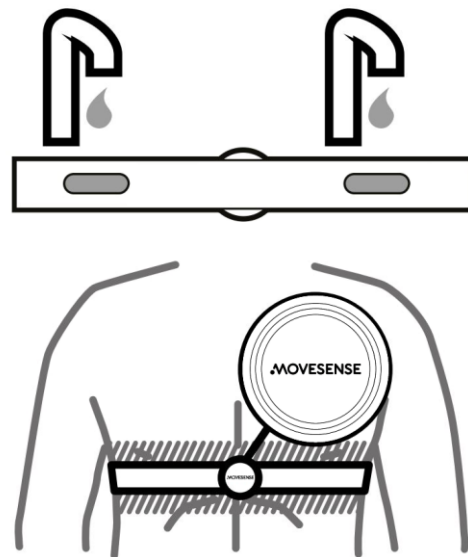
1. Snap the sensor firmly into the belt connector. Make sure that the electrode connection marked with "L" is on the left side of the patient and the electrode marked with "R" is on the right side of the patient and the sensor is properly attached to the belt before measuring ECG or heart rate.
2. Adjust the belt length as needed.
3. Moisten the belt electrode areas with water or electrode gel.
4. Put the belt on so that it fits snugly and the logo on the front face of the sensor is facing up. The sensor turns automatically on upon detecting electrical signal.

The sensor turns on automatically when it detects a heartbeat.

TIP: Wear the belt against your bare skin for best results.

NOTE: The Movesense MD sensor measures the electrical signal of the heart at the location where it is in contact with the skin. Depending on the placement of the skin contacts, the signal will be different and may or may not represent any of the standard leads of a 12-lead ECG measurement.

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[4] Compatible heart rate belts are available separately. See Chapter 5.4. for a list of accessories.

⚠ **CAUTION:** If the sensor is worn upside down and if recording ECG, the measured raw ECG signal is inverted.

⚠ **CAUTION:** If the electrical connection to the user's body is poor, the measured ECG signal will be attenuated.

⚠ **CAUTION:** If the electrode connectors of the sensor are not properly snapped to the belt connector, the measured ECG signal will be erroneous.

⚠ **WARNING:** The Movesense MD sensor contains an additional internal functionality to speed up the recovery from an excessively high ECG input overvoltage, such as a static discharge. In case there is an excessively large amplitude input, larger than 100 times a typical QRS complex, the ECG channel is briefly disconnected from the patient and the sensor runs through a dedicated reset procedure to keep the AC-coupled ECG signal within its measurement range. After the automatic reset process is completed, the ECG signal path is connected to the patient again, and the ECG measurement continues normally. This ECG input reset process may take up to 1.5 secods to complete, during which time the patient ECG channel shows the reset pulse instead of the patient ECG.

⚠ **WARNING:** Be careful to keep the heart rate monitor strap from getting snagged into external objects, as a choking hazard could develop.

3.2 Pairing

You need to connect (pair) your Movesense MD sensor with a compatible Bluetooth$^®$ Low Energy (BLE) device to view the measurement data. These devices can be, for example mobile devices running respective host applications for data visualization. Pairing procedures may vary, so refer to the instructions of your mobile application for guidance.

You can pair the sensor with multiple host devices, but only one connection can be active at a time.

Follow the usage guidance provided by the host application.

The sensor turns automatically off, if no electrical signal is detected within a predetermined time and the sensor is not connected to a Bluetooth host device.

The maximum continuous ECG recording time with 256Hz sampling rate and a fresh battery is 7 days.

The heart rate is calculated using the R-R intervals: HR [BPM] = 60000/R-R [ms]

4   CARE AND SUPPORT

4.1   Handling guidelines

Movesense MD sensor module should be rinsed clean with fresh water after each use. If more thorough cleaning is needed, the sensor may be quickly wiped with a soft cloth moistened with <u>ethanol</u> based disinfectant[5]. No immersion in chemicals other than water is allowed.

⚠️ **CAUTION:** Do not pull the sensor module straight off the connector. This may damage the belt connectors. Unsnap one side at a time.

The belt should be machine washed in 30° C, preferably using a wash bag, after every 2-3 uses. See the belt tag for further washing instructions. Replace the belt every 100 hours, or sooner, if deterioration in performance or physical properties is observed.

Cleaning and disinfection of the sensor as well as washing the strap can be performed by the device operator or the patient/user.

⚠️ **CAUTION:** Do not machine wash the sensor module. Machine washing damages the module.

⚠️ **WARNING:** Careful cleaning and disinfection by the operator is recommended between uses to prevent cross infection if worn by multiple users or patients. Disinfect before and after each use. Allow disinfectant to dry before taking into use. Not to be worn by multiple users if consequences of cross contamination may be severe.

📝 **NOTE:** Repetitive disinfection with ethanol based disinfectant may in the long run cause aging and discoloration of the plastics used. Discoloration does not affect the safe use. If any cracks or structural damage is observed, replace the sensor.

⚠️ **CAUTION:** Long term continuous usage of the belt may cause skin irritation. Cleaning and disinfection is recommended to prevent long term irritation and infection. Be extra cautious in high temperature and/or humidity.

⚠️ **CAUTION:** The maximum allowable continuous skin contact time in >43°C/109°F ambient temperature is 1 hour. Exercise caution when touching or using the Movesense MD sensor in skin contact in elevated ambient temperatures. In case the Movesense sensor is placed on the body in elevated ambient temperature, it is recommended to equalize the surface temperature of the Movesense MD sensor with that of the user's body by briefly holding the sensor in a closed palm, before placing it on other more

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[5] Minimum ethanol content: 70 w-%. Berner A12T equivalent recommended.

sensitive parts of the body.

📝 **NOTE:** Store in a dry cool place and away from the sunlight between uses.

📝 **NOTE:** Contact the manufacturer in case assistance in needed in setting up, using or maintaining the device or to report unexpected operation or events.
If the sensor is an OEM variant, please contact the OEM that supplied the sensor, according to the separate instructions provided by the OEM in question.

4.2 Software updates

The Movesense MD sensor firmware can be updated over Bluetooth. Please refer to the instructions of your host application for guidance.

4.3 Battery

The Movesense MD sensor uses a 3-Volt lithium coin cell battery (CR 2025).

To replace the battery:
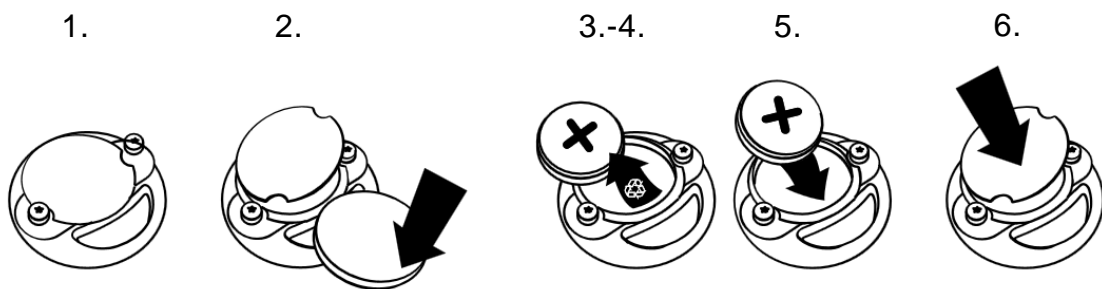
1. Remove the sensor from the Movesense connector.
2. Open the battery cover using a coin as a tool. Remove the old battery.
3. Visually inspect the battery contacts, O-ring, and the sealing surfaces for contamination. Remove any contamination and clean with a dry soft non-clogging cloth. Replace the O-ring if damaged[6]. Replace the sensor if sealing surfaces are damaged.

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[6] O-ring size: 20.3mm x 0.9mm, Silicone, shore A 70

4. Make sure that the O-ring is in correct position in the groove on the battery cover before closing the battery cover.
5. Replace the battery by inserting the replacement battery first into the battery cover, **positive side up**, and then pressing the sensor body on the battery cover.
6. Firmly close the battery cover. Make sure that the O-ring is not visible after closing the battery cover.
7. Please dispose of the old battery according to the local rules and legislation, treating it as battery waste. Do not throw it in the garbage.

NOTE: Inspect battery compartment carefully for any leakage or residue from the old battery. If residue exists, replace the sensor. The battery must be removed prior to long term storage.

NOTE: The battery is to be replaced if the accompanying host application instructs to do so, if the sensor does not power up or if the red indicator led does not light at power up normally.

NOTE: Make sure that the plastic insulator under the battery is intact and in place when replacing the battery.

4.4 Troubleshooting

Observation	Possible cause	Action to take
The device does not turn on automatically upon becoming in contact with the patient	Battery empty	Replace the battery according to the instructions
ECG signal level is low, or the signal quality is low	Patient connection is dry, strap is contaminated dirty, sensor is not properly connected to the strap	Moisten the contacts, ensure that the sensor is correctly connected to the strap, wash the strap, replace the strap
Sensor or strap is damaged	Mechanical damage	Replace the sensor or strap
No connection to the host application or device	No mobile application installed, or Bluetooth not enabled on the host device	Consult the application specific user guide for the application installation and usage. Turn on the Bluetooth radio in the host device.
Signal lost when the sensor is too far away from the host device	Signal attenuated	Bring the host device closer to the terminal
Signal is inverted	Sensor attached upside down	Re-attach the sensor observing the correct orientation
Sensor cannot be connected to a host device	Sensor already connected to another host device Non-compatible host device	Use the sensor with one device at a time only Use a host device complying with Bluetooth 4.0 or above

4.5   Indicator LED

Movesense MD houses a red color indicator led on the top edge of the sensor housing, visible through the plastic casing. The functionality of the indicator led is as follows:

Indicator LED state	Meaning	Action to be taken
On for 2s when the device turns on	The device turns on and the LED functionality is tested. Normal operation	None
Off during the normal use	Normal operation	None
2-7 brief flashes	Normal operation; battery level measurement is underway	None
Continuous rapid flashing	The battery is empty	Stop the usage and replace the battery.
LED constantly on	The sensor is in firmware update mode	Follow the firmware updating instructions on the accompanying application
LED does not turn on when the sensor is started	The battery is empty	Replace the battery

NOTE: the OEM integrator may modify the functionality of the indicator LED to suit the application specific needs. Therefore, the OEM application specific user guide must be consulted for possible additional information.

5   REFERENCE

5.1   Technical specifications

General

- Device name and type identifier: Movesense MD sensor module, OP174
- UDI-DI: 6429810883001
- Weight: 9.4g/0.33oz (battery included)
- Diameter: 36.6mm/1.44in
- Thickness: 7.8mm/0.31in (10.6mm / 0.42in with connector studs)
- Operating conditions: -20°C to +60°C/-5°F to +140°F, 0-99% Relative Humidity, Pressure: 300hPa to 3000hPa
- Storage and transportation conditions: -30°C to +60°C/-22°F to +140°F, 0-90% Relative Humidity, non-condensing, Pressure: 700hPa to 1060 hPa
- Water resistance: 30m/100ft (tested according to ISO 6425 standard), IP classification: IP68 (1m/1h)
- The Movesense MD fulfills the requirements set for the operation in oxygen rich environment, as specified in IEC 60601-1:2005, 11.2.2.1 b) 1. Movesense MD may be operated in an oxygen rich environment, when the partial pressure of oxygen is maintained at or below 85kPa (pO_2 < 85kPa), equal to an air atmosphere under a 300kPa overpressure (400kPa absolute pressure)
- Battery type: Maxell CR2025 Lithium / Manganese Dioxide (Li/MnO2)
  - o The battery used must fulfill the requirements of the IEC60086-4 safety standard
- Radio technology: Bluetooth Low Energy (BLE)
- Transmission frequency: 2.400GHz - 2.4835GHz, Modulation: GFSK, Channel bandwidth: 1MHz, Pmax = 0dBm, ERP = -4.85dBm
- GMDN number: 12391 Wearable multiple physiological parameter recorder

Signal measurements

- Single channel ECG waveform
  - o Sampling frequency: 125/128/200/250/256/500/512Hz
  - o Measurement bandwidth: 0.5Hz-40Hz as defined in IEC 60601-2-47
  - o Dynamic range 60mV$_{p-p}$, max offset: 500mV, resolution: 15 bits[7]
  - o Heart rate: 20BPM-240BPM, resolution: 1BPM, accuracy: ±1BPM
  - o R-R intervals: 250ms-3000ms, resolution: 1ms[8], timing accuracy: ±1ms

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[7] The default ECG output values are unitless signed integers. The conversion factor for converting instantaneous ECG values to voltage is $V(ECG) = ECG * 0.05V/2^{17}$, i.e., 1 count = 0.381µV.
[8] 1ms R-R resolution is only available simultaneously with 125Hz ECG sampling rate. With other ECG sampling rates, R-R resolution is 8ms.

- Modified Pan-Tompkins algorithm used for R-peak detection
- Motion (16-bit output resolution)
  - Acceleration
    - ±2/±4/±8/±16g, output unit: m/s^2, accuracy: ±2%
    - 12.5/26/52/104/208Hz sampling frequency
  - Angular velocity
    - ±125/±245/±500/±1000/±2000°/s, output unit: °/s, accuracy: ±2%
    - 12.5/26/52/104/208Hz sampling frequency
  - Magnetic field[9]
    - ±49 gauss, 1.5±10% mgauss /LSB, output unit: mgauss

- Additionally, a non-medical temperature measurement capability, which shall not be used for medical purposes
  - Device's internal temperature
    - 0 to +65°C, accuracy better than ±0.5°C

5.2 Manufacturer

Movesense Ltd
Tammiston kauppatie 7 A
FI-01510 Vantaa FINLAND

www.movesense.com

The time of manufacturing is included in the device's serial number, in the form of manufacturing year and week.

Example: serial number **2310**12356789: Manufactured during week 10 of year 20**23**

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[9] Due to the inherent nature and behavior of the magnetometer measurement circuitry in the vicinity of local ferromagnetic objects (i.e., the battery), the magnetometer output signal is not linear. The magnetometer is mainly meant to be used for gyroscope drift compensation in inertial measurement (IMU) application. If the use case requires absolute magnetic field strength value measurements, an application specific calibration procedure must be implemented, to the extent considered necessary, in the client application.

5.3   Requirements for the connected device

5.3.1   Mechanical interface

The electromechanical interface of the Movesense Medical sensor consists of two stainless steel studs, protruding from the bottom surface of the sensor module. The studs are used for both mechanical connection and to feed the electrical ECG signal to the sensor.

The center-to-center separation of the Movesense studs is 27.0mm. The stud head major diameter is 4.25mm and the stud neck diameter is 3.6mm. Typically the counterpart connecting to the studs is a pair of female snap connectors.

5.3.2   Wireless Bluetooth interface

Movesense Medical communicates wirelessly with a Bluetooth Low Energy (BLE) radio. Typical devices with which the Movesense Medical sensor exchanges information or sends data to, are BLE equipped smart phones, tablet computers, personal computers, wrist devices (i.e. watches), Bluetooth capable hubs, or similar. A device/system utilizing the measurement information provided by the Movesense Medical sensor must always contain software functionality for controlling, processing, and analyzing the said information and data.

Movesense Medical sensor is not compatible with radio technologies other than Bluetooth Low Energy.

5.4   Compatible accessories

Movesense Ltd provides a range of accessories for wearing the Movesense Medical sensor. The accessories are not certified as medical devices. These accessories include

- Movesense chest strap, for heart rate and ECG measurement. Order codes MS060212000 (size M), MS060213000 (size L), MS060211000 (size S)
- ECG glue-on patch electrode kit. Order code SS050133000 (2-pack)
- Movesense Strap Mount, for attaching the sensor to a wrist band or any other strap. Order code SS050204000 (10-pack)
- Movesense Clothing Clip. Order code SS050205000 (10-pack)
- Movesense Surface Mount, for attaching the sensor to flat solid surface. Order code SS050203000 (10-pack)

The collection of accessories is subject to change. A comprehensive list of available accessories can be found at www.movesense.com/shop/.

5.5   Compliance

5.5.1   Medical Device standards

Electromagnetic compatibility, electrical safety, product safety and performance standards fulfilled by the Movesense MD sensor include the following:

- IEC60601-1:2005 + A1:2012 Medical electrical equipment - part 1: General requirements for basic safety and essential performance
- IEC60601-1-2:2014 Medical electrical equipment - part 1-2: General requirements for basic safety and essential performance. Collateral standard: electromagnetic disturbances. requirements and tests
    - CISPR 11:2009 +A1:2010 Radiated emissions Class B, group 1
    - IEC 61000-4-2:2008 ESD immunity, ±8kV contact, ±2, ±4, ±8, ±15kV air
    - IEC 61000-4-3:2006 +A1:2007 +A2:2010 Radiated field immunity 80 MHz-2.7 GHz, 10 V/m
    - IEC 60601-1-2:2014 Table 9 IMMUNITY to proximity fields from RF wireless communications equipment. See chapter 5.8 for details.
    - IEC 61000-4-8:2009, Power frequency magnetic field immunity: 30 A/m, 50 and 60 Hz
- IEC 60601-1-11:2015 Medical Electrical Equipment - part 1-11: General requirements for basic safety and essential performance. Collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC60601-2-47:2012 Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems; taking into account the intended use and limited analysis functionality of the Movesense MD device
- IEC 62479:2010 Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

Note: During Radiation Measurements, Radiated RF EM Fields tests and Proximity fields From RF wireless communications equipment patient connection according to IEC 60601-2-47:2012, Figure 202.101 was used. EUT was connected to metal plate with load simulating the PATIENT (51kΩ in parallel with 47nF).

5.3.2 Other standards

- FCC 47 CFR Part 2.1093
- ISED RSS -102 Issue 5:2015 FCC Rules and Regulations CFR 47, Part 15, Subpart C (10-1-15 Edition) & ICES-003 ISSUE 6 (2016)
- USA FCC Part 15.247, 15.209
- CANADA RSS-247, RSS-Gen Radio Frequency Devices. Operation within the bands 902 - 928 MHz, 2400 - 2483.5 MHz, and 5725 - 5850 MHz. Digital Transmission Systems (DTSs), Frequency Hopping Systems (FHSs) and License-Exempt Local Area Network (LE-LAN) Devices. General Requirements and Information for the Certification of Radio Apparatus.
- IEC 60601-1-6:2010 + A1:2013
- EN ISO 15223-1:2006
- EN ISO 10993-1:2009 + AC:2010
- IEC 62366-1:2015
- ISO 20417:2021
- EN 62304:2006 + A1:2015

5.5.2 EU Radio Directive

Hereby, Movesense Ltd, declares that the radio equipment type OP174 is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.movesense.com/conformity.

5.5.3 United States FCC

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

Class B device notice

NOTE: 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. These limits are designed to provide reasonable protection against harmful interference in a residential installation. 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. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

— Reorient or relocate the receiving antenna.
— Increase the separation between the equipment and receiver.
— Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
— Consult the dealer or an experienced radio/TV technician for help.

RF exposure safety

Product OP174 is a radio transmitter and receiver.

It is designed not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

5.5.4 Canada ISED

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Les changements ou modifications non expressément approuvés par la partie responsable de la conformité pourraient annuler l'autorisation de l'utilisateur d'utiliser l'équipement.

This device complies with Industry Canada's license-exempt RSSs. 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'Industrie 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 safety

The model is a radio transmitter and receiver.

It is designed not to exceed the emission limits for exposure to radio frequency (RF) energy set by the ISED.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Le modèle est un émetteur et un récepteur radio.

Il est conçu pour ne pas dépasser les limites d'émission pour l'exposition à l'énergie radiofréquence (RF) établie par l'ISDE.

L'émetteur ne doit pas être colocalisé ni fonctionner conjointement avec à autre antenneou autre émetteur.

CAN ICES-3 (B)/NMB-3(B)

This Class B digital apparatus complies with Canadian ICES-003

Cet appareil numérique de classe B est conforme à la norme Canadienne ICES-003.

5.6 Patent notice

This product is protected by granted patents, pending patent applications and their corresponding national rights.

5.7   Trademark

Movesense, its logos, and other Movesense brand trademarks and made names are registered or unregistered trademarks of Movesense Ltd. All rights are reserved.

5.8   Disposal of device

Please dispose of the device in an appropriate way, treating it as electronic waste. Do not throw it in the garbage. If you wish, you may return the device to your nearest Suunto representative.

5.9   Copyright

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5.10 Immunity test signals

Test signals used in the RF wireless communications equipment proximity field immunity tests, as defined in IEC 60601-1-2:2014, Table 9:

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	Tetra 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430-470	DMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5500						
5785						