Seismofit®
Instructions for use

Version 4.1

Disclaimer
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Any such relationship must be considered as an interpretation that VentriJect® cannot be responsible for. The information is only intended for achieving a secure and exact use of the Seismofit®.

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Changes
The Instruction for Use may be updated without warning. The user may find the Instruction for Use for any version of the Seismofit® at the VentriJect® website from where it may be downloaded.

The illustrations may deviate from the actual equipment which reflects the constant work for improving the product.

Brand name
VentriJect® and Seismofit® are registered trade names owned by the company.

VentriJect ApS
Ryvangs Alle 81-83
2900 Hellerup
Denmark
www.ventriject.com

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Introduction

Instructions for Use (IFU)

This instruction for use is intended as a reference guide for the safe and correct use of Seismofit®.

The IFU contains both general and specific instructions for use including the seismocardiographic recording, maintenance, and information on specific components.

To ensure optimal use of the Seismofit® it is important to read the IFU carefully and understand the use of the product before starting.

Seismofit® and the environment.

Seismofit® is designed and sized to minimize the impact on the environment.

The sensor is small with wireless communication, the adhesive patch is similarly of minimal size, and the outer packaging is made from cardboard that may be discarded as ordinary paper waste.

Seismofit® contains microelectronic components and must not be discarded as ordinary waste but be delivered for recycling.

Product Description

The Seismofit® Sensor is an equipment for recording vibrations of the chest of a person.

Seismofit® records the vibrations arising from the heart on the person's chest and transmits the recording to the VentriJect App.

The Seismofit® System consists of two parts: a Seismofit® Sensor and a Seismofit® Patch and is operated with the VentriJect Clinical

App. The patch is for adhering the sensor to the chest when positioned at the sternum.

The Seismofit® Sensor is shown in the picture below.

Intended use

The Intended use of Seismofit® is to determine a VO_2max-score equivalent based on seismocardiography to assess subject health and vitality status.

Use of the recording

The recording will be transmitted to a smartphone for further examination.

The smartphone will communicate with a cloud server that will analyze the recording and calculate an equivalent to the CRF-score (estimated VO_2max) which will be displayed in the Clinical App.

Risks

By use of Seismofit®, a VO_2max-score equivalent will be created. If using this for strategies concerning health issues it should

be done together with a professional like medical doctors, physiologists, therapists, or technicians.
Using the Seismofit® outside of its intended use or not following the guidelines for correct recording, described in this document, can result in estimations of unintended higher or lower VO_2max-score for the subject.

The Seismofit® will not be able to cause any hazards. The battery is low power, the Bluetooth® connection is low power and any emission will be much weaker than emissions from a smartphone.
The patch is made of skin-friendly and non-sensitizing adhesive.

Intended user profile
Seismofit® is intended for use with health care professionals like medical doctors, nurses, technicians, therapists, and coaches after having read the IFU or being instructed in the system but not limited thereto.

Intended test persons
Seismofit® is intended to be used for adult persons of both genders above 18 years of age and without electronic implants.

Use conditions
Seismofit® is intended to be used in medical clinics or equivalent at room temperatures and atmospheric pressure range of 700 hPa to 1060 hPa.

Do not sterilize, autoclave, or wash the Seismofit® Sensor.
Do not record in a noisy environment where vibrations could be expected or with strong electromagnetic fields or radio frequency from machines or equipment.

Warning: Use of the Seismofit® Sensor adjacent to or stacked with other equipment should be avoided because it may result in improper operation. If such use is necessary, the Seismofit® and the other equipment should be observed to verify that they are operating normally.

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 Seismofit®. Otherwise, degradation of the performance of this equipment could result.

Remove hair before recording if disturbing the fixation.

Only use tissue moistened with water or an ethanol wiper for cleaning.

Symbols

Symbol	Explanation
	Medical device
	Series number
	Warning and precautions *Notice the description below*
	Guidance for help in the Instruction for Use
	Label for compliance with relevant EU-directives.
	Batch code
	Producer

	The Seismofit® Sensor must at discarding be delivered for recycling according to national law. (Directive 2012/19/EU, (WEEE)
	Limit for temperature
	Limit for humidity
	Limit for atmospheric pressure
	Use before

	Type BF applied part
	Do not reuse

Definitions:
The Instruction for Use contains symbols and user information that are important and must be read carefully before the recording is started.

Symbols and warnings will also be found on the packaging for the Seismofit® Sensor and the Seismofit® Patches.

Symbols of products and in the Instructions for Use.
Warnings: describe situations where the VO_2max-score may be disturbed.

Precautions: describe situations where the functionality of the Seismofit® Sensor may interfere.

Warnings
Deviation of procedures from the IFU or use of the Seismofit® outside the intended field of use may result in errors and misinterpretations for the patient.

Do not use the Seismofit® on patients with implanted electronic equipment like pacemakers or equivalent as scores may be incorrect.

Do not use Seismofit® on very hairy skin, scars after surgery, or abnormal body shapes that lead to poor fixation of the product as this may lead to wrong scores.

Do not use the Seismofit® Sensor without the original Seismofit® Patch as this may lead to misleading scores.

Do not apply liquids (water, oils, solvents, surfactants, or the like) to the Seismofit® Sensor as it may cause functional errors.

Do not use the device if the outer plastic shell is damaged or broken, exposing the internal components of the device.

Do not modify the device in any way.

Precautions

Avoid dropping or violent handling of the Seismofit® Sensor as this may cause damage to the microelectronic part including the accelerometer and Bluetooth® transmission.

Apply correct cleansing of the Seismofit® Sensor.

Store and apply the Seismofit® Sensor and Patch according to claims in the Instruction for Use concerning temperature and humidity.

Seismofit® Sensor

The Seismofit® Sensor records the vibrations of the chest originating from the heart and recorded at the sternum. The recorded signal will be transmitted to a smartphone. The sensor has direct physical contact with the skin via an adhesive patch.

The test person must rest on the back (supine position) and the sternum **(lower third of chest bony prominence)** must be localized. The Seismofit® Sensor must be used together with the Seismofit® Patch for firm contact with the chest ensuring the best recording. If a patch is placed wrongly, a new one shall be used. The patch is for single use only.

The test person must not have an elevated pulse. If blood pressure is determined, it will be optimal to make the VO_2max estimation afterward.

First recording
A prerequisite for the first recording is installing the VentriJect App on your smartphone according to purchase instructions.

Before starting the first recording, the battery tray shall be opened and the battery co-packed with the Seismofit® Sensor shall be placed in the tray **(orientation of the positive battery terminal is marked in the tray)**. Close the battery tray.

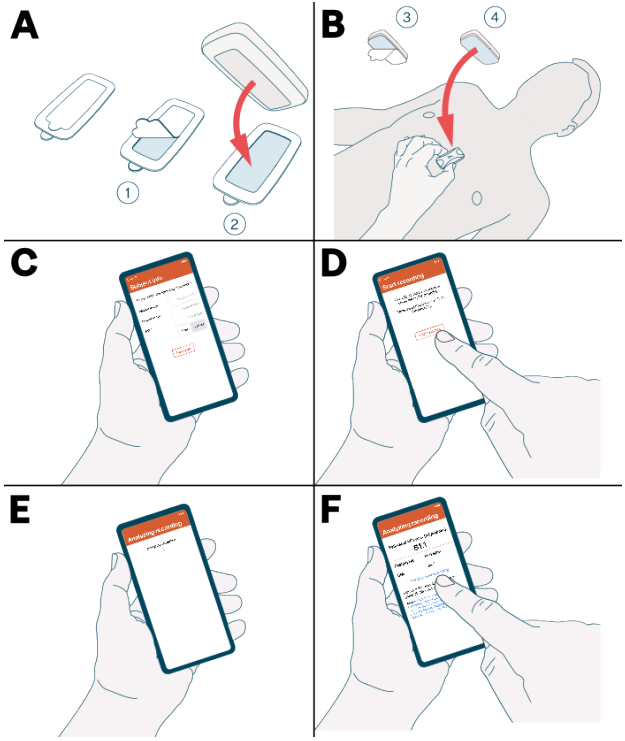
Now the sensor is active (photo: open tray).

Start Recording
The overall investigation time will be a few minutes. The following guide describes the major steps when using the Seismofit® Sensor and VentriJect Clinical App to perform a recording.

The VentriJect Clinical App can be downloaded via www.ventriject.com/app

The steps are

A. Mounting the adhesive patch
B. Position of the sensor at the distal (lowest) third part of the sternum with <u>head drawing towards the head</u> of the test person
C. Input weight, height, age, and sex
D. Start of recording
E. Analyzing step
F. Read out of result



Seismofit® Patch
The Seismofit® Patch is supplied in boxes containing 20 pieces. The patches are disposable and can be discarded together with ordinary plastic or laminated packaging.

The patch has a liner with adhesive on both sides as a core with silicone release papers on top. In use, the patch shall first have removed the small release paper (no print) and be applied to the sensor's bottom surface. Next, the first part followed by the second part of the second release paper is removed and the combined sensor and patch are applied to the skin of the lower third part of the chest with the correct orientation towards the head of the test person.

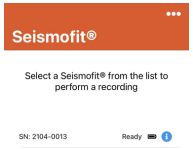
Preparing a test person
To ensure a high quality of the recorded signal, the presence of hair must be removed from the skin at the sternum, if it is considered to interfere with the proper contact between the sensor and the skin.

An ordinary electric razor machine is recommended.

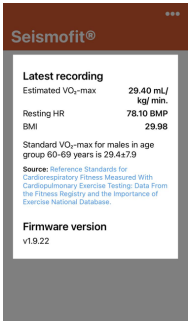
A patch shall never be applied to broken skin.

Performing a recording

After opening the VentriJect Clinical App, the following steps are presented

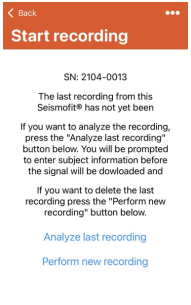


Screen 1

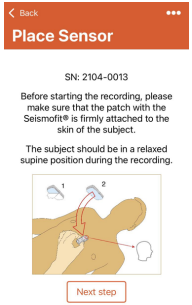


Screen 2

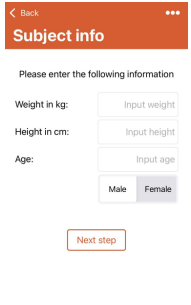
Screen 1: select and choose the Seismofit® Sensor by its ID. Screen 2: recall the latest test result, by clicking on the blue information icon.



Screen 3



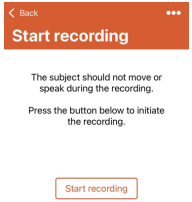
Screen 4



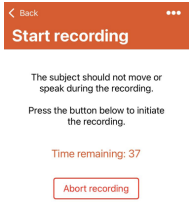
Screen 5

Screen 3-5 Approving device (in case more devices are contactable), positioning at chest, and entering of information.

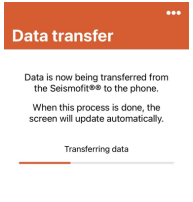
Screen 3 allows for analysis of a recording stored on the device. This is only pertinent if the App has been disconnected from the Seismofit® Sensor during a previously ongoing recording.



Screen 6

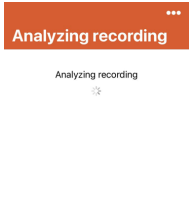


Screen 7

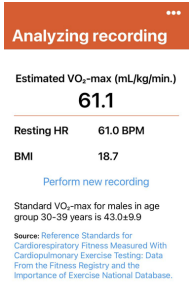


Screen 8

Screen 6-8 Initiation of recording and transferring of the data from the Seismofit® Sensor to the smartphone.



Screen 9



Screen 10

Screen 9-10 Analyzing and showing final VO_2max

After the recording
Remove and discard the Seismofit® Patch and cleanse the Seismofit® Sensor with a 70% ethanol cleaning tissue.

Never use running tap water for the cleansing of the Seismofit® Sensor.

If the Seismofit® Sensor by accident becomes wet, let it dry for 24 hours at ambient temperature in low to medium humidity air. Never use an electric oven or hairdryer.

Lost Connection to Seismofit®
In the case of a lost connection to the Seismofit® that does not automatically reconnect to the app, close the App completely on the smartphone and open it again.

Error Messages
In case an error occurs during the analysis of the recording, an error message is displayed in the VentriJect Clinical App. The possible error messages are:

- *Heart rate out of bounds*: If the heart rate is below 30 BPM or above 100 BPM.

- *Internal algorithm error*: Errors in the algorithm not described by the other error messages in this list.

- *No heartbeat signal detected*: A signal of sufficient quality for analysis could not be detected. This error can also be caused by the recording being too short.

- *No heart rate detected*: It was not possible to detect a stable heart rate in the recording.

- *Signal too noisy*: The signal is too noisy to analyse, e.g. due to movements or poor contact between the patch and the skin.

- *Subject not in supine position*: The subject was not resting on the back (supine position) during the recording.

In case any of these error messages occurs, the VO_2max could not be estimated and it is therefore recommended to perform a new recording.

Maintenance

Seismofit® Sensor does not hold any parts that require service.

If expired, the battery must be changed.

The Seismofit® Sensor requires no calibration.

Discarding

Patch
The Seismofit® Patch may be discarded as ordinary trash.

Sensor
When the Seismofit® Sensor is worn out, the discarding must be done by the recycling station according to national regulations.

Seismofit® and the distributors of Seismofit® Sensor and Patches must respect the EU Directive 2012/19/EU regarding the discarding of electronic equipment (WEEE).

Seismofit® Sensor requirements

Functionality:
Temperature 10-40°C.
Relative humidity 20-80% without condensate

Storage
Temperature 10-40°C.
Relative humidity 20-80% without condensate

Recording conditions
Pulse < 100 bpm

Power supply
Battery 3V like Maxell CR2032

System specifications
Apple iOS 13.3 or newer.
Android 10 or newer.

Warranty

The Seismofit® Sensor is covered by a one-year warranty from the date of purchase.

The Seismofit® Patch has an expiration period of 2 years from the manufacturing date.

The warranty is not valid in case of misuse or if Seismofit® Sensor housing parts have been taken apart.
The warranty does not cover the interpretation of results outside of indicated use.

Approvals

IEC 60601	Compliance to IEC 60601-1
CE-mark	Compliance to Medical Device Directive 93/42/EEC
EMC-emission	Compliance to the requirements in EMC emission Class B devices in EN 60601-1-2
EMC-immunity	Compliance to immunity requirements of EN60601-1-2:

Acronyms & Definitions in text

Akronyms	Definitions
Seismocardiography	Recording and interpretations of vibrations originating from the beating heart
Seismofit® System	Sensor and Patch.
Seismofit®	Sensor that records vibrations from the heart
Seismofit® Patch	Adhesive patch for fixation of sensor to the skin at the chest
VO_2max-score / Seismofit® Score	Cardiorespiratory fitness score – a measure of health
Recording	Obtaining a seismogram from the heart

EMC Information

Electromagnetic Emission

Technology: Wireless Bluetooth Low Energy (BLE)
Modulation type: Gaussian frequency shift keying (GFSK) modulation
Frequency area: 2400 -2480 MHz
Radiated effect maximum: 2.5 mW (Class 2 transmitter)
The radio equipment can be used without safety distance to the user.

Emission Test
RF Emission CISPR 11
Compliance
Group 1 Class B
Guidance
Device uses Radio Frequency energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Elektromagnetic Immunity

The Seismofit® can be used in electromagnetic environments as described in the table below:

Immunity Test
Electrostatic Discharge (IEC 61000-4-2)
Compliance
Contact Discharge: ±8 kV Air Discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV
Guidance
Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity Test
Radiated RF EM filed (IEC 61000-4-3)
Compliance
80-2700 MHz; 1kHz AM 80 %; 3 V/m
Guidance
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2,7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Immunity Test
Proximity fields form RF wireless communications equipment (IEC 61000-4-3)
Compliance
- 385 MHz; Pulse Modulation: 18 Hz; 27 V/m - 450 MHz, FM $\pm$ 5 Hz deviation: 1 kHz sine; 28 V/m - 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m - 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m - 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m - 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; - 5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m
Guidance
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 30 cm.

Immunity Test
Rated power frequency magnetic fields (IEC 61000-4-8)
Compliance
30 A/m, 50 Hz: 217 Hz; 9 V/m
Guidance
Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.