VentriJect

Seismofit®System Instructions for use

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ventriject.com

General information

Disclaimer

The information in the instructions for use addresses an international market for health services and is based on text, illustrations, and symbols.

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®,Seismofit®Sensor, Seismofit®Patch and VentriJect®App, also referred to as the Seismofit®system.

Reporting obligation

For complaints, please contact your supplier directly. However, in the event of a serious incident that could lead to serious health deterioration or death, you must contact both the manufacturer and the competent authority of your Member State.
A “serious incident” is defined in Article 2(65) of the Medical Device Regulation 2017/745 (EU-MDR).

Copyright

The content of the instruction for use must not be reproduced for third parties without written consent from VentriJect®.

Changes

The Instructions for use may be updated.
The user may find the instruction for use for any version of the Seismofit®, Seismofit®Sensor, Seismofit®Patch and VentriJect®App at the VentriJect®website from where it may be downloaded.

The illustrations may deviate from the actual equipment, reflecting the constant work to improve the device.

Brand name

VentriJect®and Seismofit®are registered trade names owned by VentriJect ApS.

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Introduction

Instructions for Use (IFU)

This IFU is intended as a reference guide for the safe and correct use of the Seismofit®,Seismofit®Sensor, Seismofit®Patch and VentriJect®App, also referred to as the Seismofit®System.

For a physical copy of the IFU, please contact VentriJect. See contact information on Page 2.

Product Description

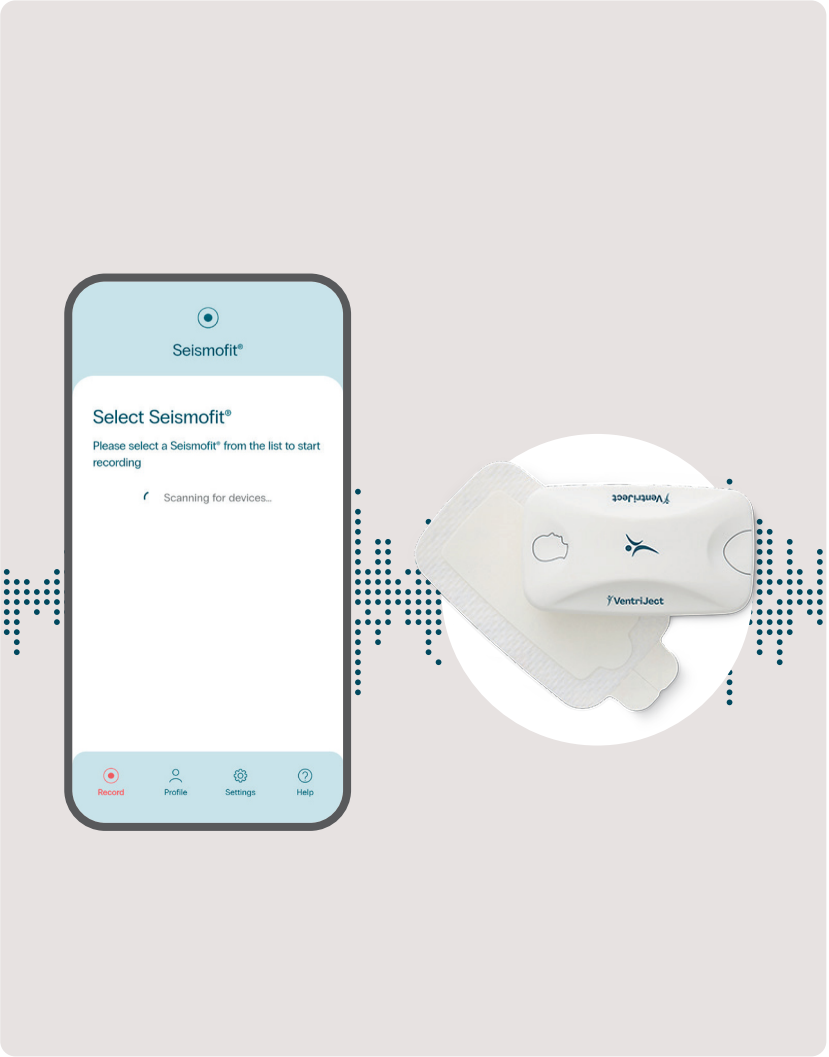
The IFU covers the following products:

- The Seismofit®: A medical device software consisting of an online algorithm that can estimate a VO_2max score equivalent based on seismocardiography and demographic data

- The Seismofit®Sensor: A medical device accessory to Seismofit®used for recording vibrations. The Seismofit®sensor is applied to the lower part of the sternum, using the Seismofit®Patch

- The Seismofit®Patch: A medical device accessory to Seismofit®that utilises doubled adhesive tape to ensure proper contact between the subjects skin and the Seismofit®Sensor

- The VentriJect App: A medical device software accessory that can be installed on a smartphone. The app is used to interact with the Seismofit®Sensor and to transfer the vibration signal along with demographic data to the Seismofit®for signal analysis



Intended use

The Seismofit®

The Intended use of Seismofit®is to determine a VO_2max score equivalent based on Seismocardiography to assess adult person health and vitality status.

The Seismofit®Sensor

To record vibrations from a patient's chest.

The Seismofit®Patch

To securely attach the sensor to a patient's chest for optimal data collection. The Seismofit®Patch is single use.

The VentriJect App

To guide users on sensor placement, collect and transmit sensor and demographic data for analysis, and display the results in an understandable format.

Intended user

- Healthcare Professionals
- Wellness Professionals and Health Educators
- Patients when instructed by one of the above

Patient target group

Patients above 18 years of age.

Safety and performance

Standard Error of Estimate (SEE)< 7.2 mL/min/ kg.
Within-subject's standard variation less than 2 mL/ kg/min in day-to-day variation in VO_2max estimate.
Bias < 2 mL/min/ kg.

Publications concerning the performance of the Seismofit®are available via ventriject.com/publications

Clinical benefit

Measure of cardiac health/fitness: By providing an accurate VO_2max score, Seismofit can help assess cardiovascular health.

Track changes in VO_2max: The ability to monitor changes in VO_2max over time allows healthcare professionals to track the progression of certain conditions, assess the effectiveness of interventions (e.g.,medication, lifestyle changes, cardiac rehabilitation), and make more informed treatment decisions.

Warnings

If the estimated VO_2max differs markedly from what is expected, a VO_2max ergometer test must be conducted.

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®Sensor and the other equipment should be observed to verify that they are operating normally.

Do not touch or press down on the Seismofit®Sensor while a signal acquisition is ongoing as this may impact the estimated VO_2max value.

Do not place the Seismofit®Sensor underneath a bra strap or other tight fitting clothes as this may impact the estimated VO_2max value.

Do not use the Seismofit®Sensor without the original Seismofit®Patch as this may lead to misleading estimates of VO_2max.

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 Seismofit®Sensor if the outer plastic shell is damaged or broken, exposing the internal components of the device.

Do not modify the devices in any way.

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

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 before using the device.

Store and apply the Seismofit®Sensor and Patch according to claims in the Instruction for Use concerning temperature and humidity. See page 15.

Do not apply the Seismofit®Patch on broken, damaged, inflamed, or irritated skin.

Precaution

Using the device(s) in the following conditions should be done with precaution:

Seismofit®

- Known ischemic heart disease
- Known uncontrolled heart failure
- Beta-blockers
- BMI > 50
- Active Cancer
- Chronic Kidney Disease (CKD)
- Chronic Obstructive Pulmonary Disease (COPD)
- Lower-Limb Neuromuscular Impairment
- Significant Aortic/ Mitral Valve Disease & Congenital Heart Disease
- Recent Sternotomy (<3-4 months) & Unstable Thorax:
- Chronic Diseases

The result of the VO_2max estimation should be reviewed by a Healthcare Professional if used for the prevention and monitoring of disease.

Seismofit®Sensor

See pages 19-20 about EMC immunity requirements.

Contraindications for the Seismofit®

- Ongoing cardiac arrhythmia including atrial fibrillation
- Artificial mechanical heart valves
- Biventricular pacemakers
- Tachycardia (resting heart rate > 100 BPM)

Contraindications for the Seismofit®Sensor and Seismofit®Patch

- Hair on the chest that hinders the Seismofit®Patch for adhering to the chest

For the following conditions, there is a lack of data to support the proper functioning of the device.

- Pregnancy
- Recent (3-4 months) cardiac surgery with sternum split
- Significant aortic or mitral valve stenosis or insufficiency
- Unstable thorax

Operational Safety Notifications:

- Patient Identity Verification: Operator must verify patient data in the app prior to starting recording.
- Professional Review: Results must be reviewed by an HCP before making clinical decisions.
- RF Separation Distance: Keep active RF equipment (phones, Wi-Fi routers) at least 30 cm away from the sensor during acquisition.
- The Seismofit®Patch is single-use only. Reusing patches causes cross-contamination and loss of mechanical adhesion.

Note: Not approved in the USA by the FDA as a medical device

Using the system

Overall steps

The following six steps describe how to use the system. In the following sections, more details are provided about each of the six steps.

→ 1)Download the VentriJect App

→ 2) Login with user credentials provided by VentriJect (see page 9 for account creation)

→ 3) Select the Seismofit®Sensor from the list of available sensors

→ 4) Attach the Seismofit®Sensor to the subjects sternum using the Seismofit®Patch

→ 5) Enter demographic subject information and initiate the data acquisition. Wait for the signal processing to be completed

→ 6) Check the result

Download the VentriJect App

The VentriJect App is installed via an App Store. The VentriJect App can only be installed on compatible devices. If the app cannot be installed (or found), your device is not compatible with the system or hardware requirements of the app.

Download on the App Store

GET IT ON Google Play

Due to variations in how manufacturers implement Android systems, some Android devices may experience reduced connectivity with the Seismofit®Sensor. For best performance, we recommend checking your device compatibility before use (See Requirements box).

Instruction for installation via Apple iOS Store and Google Play Store

→ 1)Open the App Store application on the phone and select the search function

→ 2) Enter "VentriJect" in the search field and press Search

→ 3) Find the VentriJect App and press on the Install button

→ 4) The App will now be installed on your device. Once installed, open the app

The VentriJect App will ask for acceptance of permissions the first time the app is opened. This must be accepted to use the App.

Requirements

VentriJect App
Apple iOS 18or newer
Android 10or newer

The smartphone must have a Bluetooth Low Energy (BLE) module installed to connect to the Seismofit®Sensor.

The smartphone must have access to Wi-Fi or a cellular mobile internet connection to function.

A user account must be created prior to using the VentriJect App (see page 9).

Seismofit®Sensor
Battery type CR2032 3V of high quality.

Login

Login with user credentials provided by VentriJect

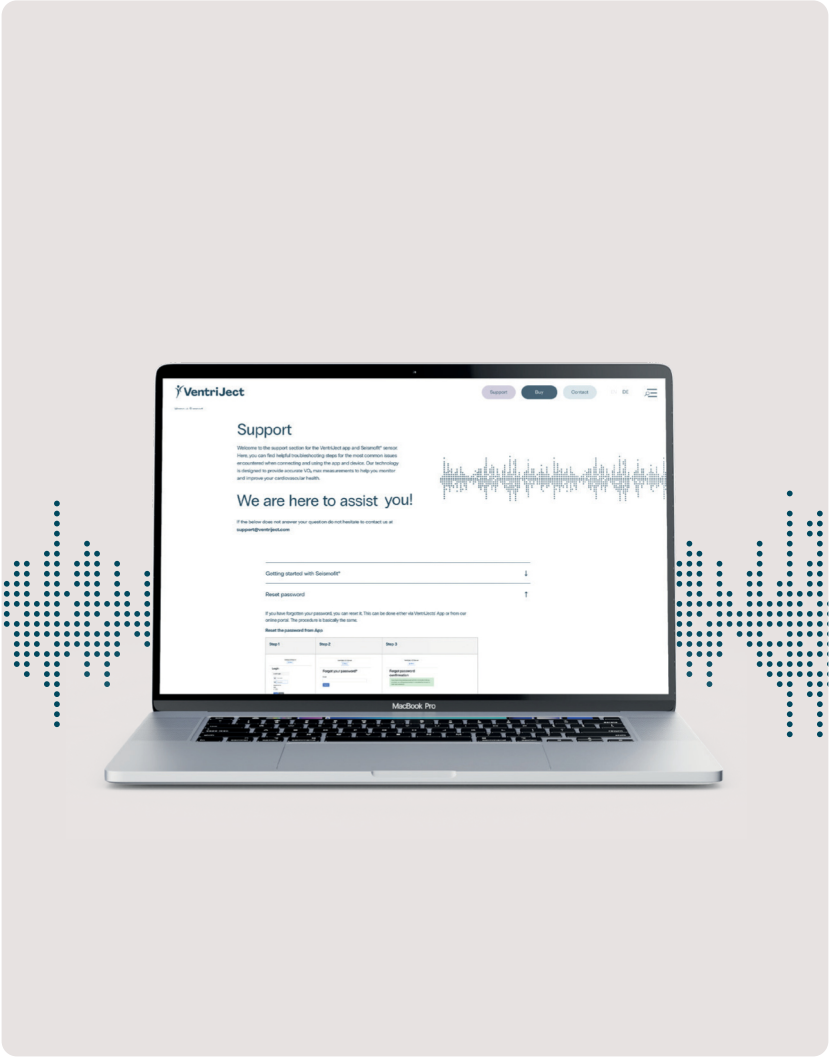
When you sign a contract with VentriJect you automatically receive an email with instructions about how to set your password.

With this password, and your email address, you are able to sign into the VentriJect App.

If you are missing your password, please go to www.ventriject.com/password-reset to request a password reset.
When you request a password reset, you will receive a link that allows you to update your password.

Please note: the link you receive for resetting your password is valid for 24 hours. If you have not registered a new password within that time frame, please request a new password.

If you need more users on your company account, please go to www.ventriject.com/request-user-login to request more users.



Select Seismofit®Sensor

Select the Seismofit®Sensor from the list of available sensors

When you have signed into the VentriJect App a list of available Seismofit®Sensors will appear.
Identify the Seismofit®Sensor you want to use by comparing the serial number (SN) on the bottom of the Seismofit®Sensor to the serial number displayed in the App.

Pair the Seismofit®Sensor in the app by verifying the Serial Number (SN) BEFORE peeling or applying the patch to the Seismofit Sensor.

Click on the serial number of the Seismofit®Sensor you want to use to establish the Bluetooth connection.

If a Seismofit®Sensor does not show up in the app

Check the battery orientation

- The battery must be positioned correctly in the battery drawer of the Seismofit®Sensor.
- The positive (+) pole should point towards the Serial Number label on the bottom of the Seismofit®Sensor.

Check the battery voltage

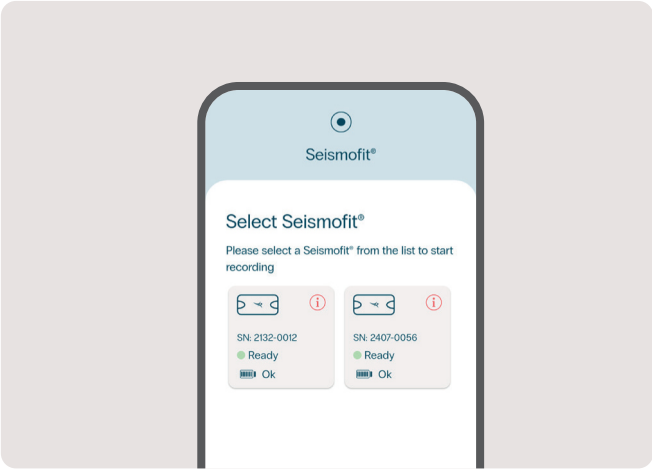
- Sufficient voltage must be available for the Seismofit®Sensor to work.
- Try to insert a new battery into the Seismofit®Sensor. A 3V button cell battery of type CR2032 must be used.
- VentriJect recommends to use batteries of high quality, for the Seismofit®Sensor.

Check the Bluetooth and localisation permissions on your phone

- The VentriJect App needs permission to use Bluetooth®Low Energy.
- For Some Android Operating Systems, the user must also grant access to “Nearby Devices” and “Location” to work correctly.
- These settings can be found in the Settings App on the phone, in “Security and Privacy” -> “Privacy” -> “Permissions Manager”.
- From here, make sure that the VentriJect App is allowed to use Bluetooth®, scan for Nearby Device and use location.

Please note: the VentriJect App does not use your location. The Android Operating system requires this, when giving permission to use Bluetooth

If a Seismofit®Sensor shows up as ”Unregistered”
In this case, please contact the VentriJect support team via support@ventriject.com with information about the Serial Number of the affected Seismofit®Sensor.
The support team will be able to resolve this issue remotely.



Attach the Seismofit®Sensor

The Seismofit®Patch has a front side and a backside. The backside is the one with the VentriJect brand name printed. The frontside has a white protective plastic liner.

1.Take a Seismofit®Patch from the blister box.

2. Peel off the white plastic liner from the Seismofit® Patch. Underneath the liner is an adhesive area that f its the bottom of the Seismofit®Sensor.

3. Place the Seismofit®Sensor onto the adhesive area.

4. Turn over the Seismofit®Sensor and Patch and peel off the backside plastic liner.
   Note, that this liner is split into two parts.

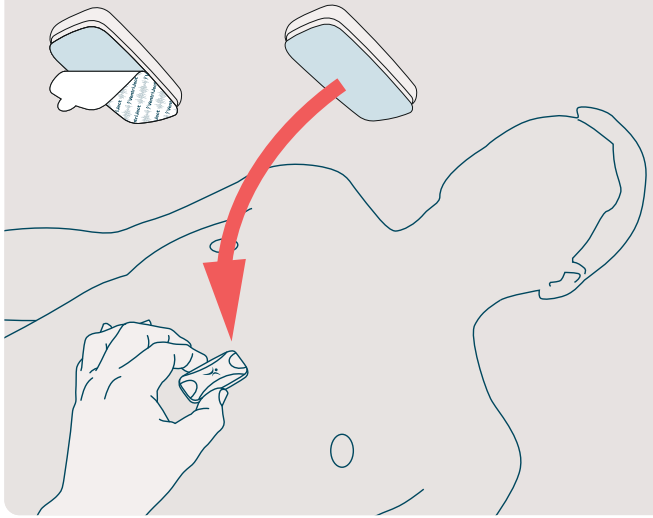
The Seismofit®Sensor should be oriented with the picture of the head, pointing towards the head of the subject. Attaching the Seismofit®Sensor should be done with the subject in supine (resting on the back) and resting position.

5. Attach the Seismofit®Sensor to the lower part of the subjects sternum (breast bone) using the Seismofit® Patch. See figure (Apply the Seismofit®Patch).

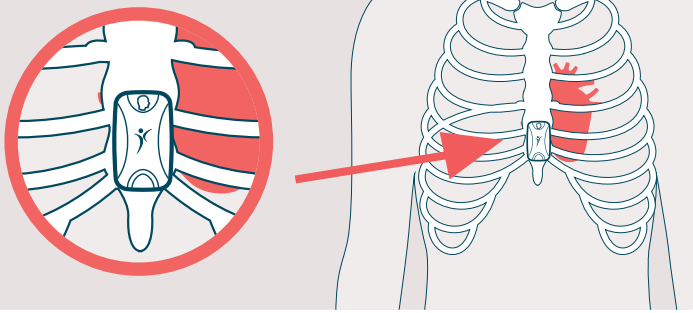
6. The subject should be relaxed to ensure resting heart rate.

Note: If hair is hindering a firm attachment of the Seismofit® Sensor to the chest, the hair must be removed.

Apply the Seismofit®Patch



Physiological placement



Perform a recording

Subject information

Using the app, please enter demographic information about the subject's weight, height, age and sex.

Make sure that the values are correct, before proceeding to the next step.

Start data acquisition

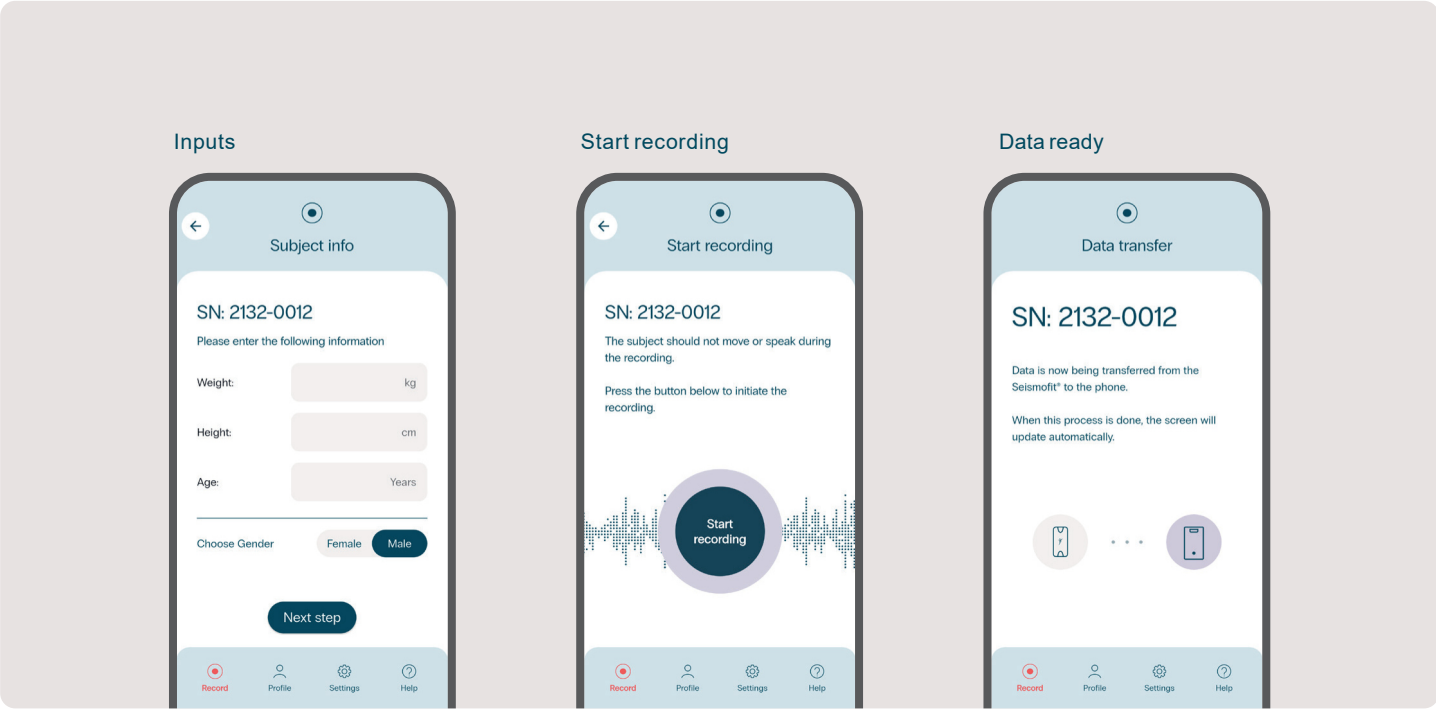
- Make sure that the subject is in the supine position and relaxed.
- Initiate the data acquisition from the app.
- The recording will take 40 seconds to complete.
- Instruct the patient to remain completely still, quiet, and in a supine position during the 40-second recording. Keep the patient motionless until the App explicitly displays the screen "Data Transfer- When the recording is completed, the App will automatically update".
- The signal from the Seismofit®Sensor will be transferred to the phone and then to our cloud solution for signal processing.

Note: If the VentriJect App closes unexpectedly during signal acquisition, the Seismofit®Sensor will still continue to record, until the 40 seconds have passed.

When the recording is completed, the status indication next to the Seismofit®Sensor will be "Data ready".

Click on the Seismofit®Sensor, enter the demographic data, and the stored signal will be transferred and analyzed.

The Seismofit®Sensor will store the recorded signal for 5 minutes, before it is automatically deleted.



VO_2max result

Check the result

When the signal processing is completed, the estimated VO_2max score will be displayed in the app. Below the result, a text will show the average VO_2max scores for the corresponding age and sex, as the subject.

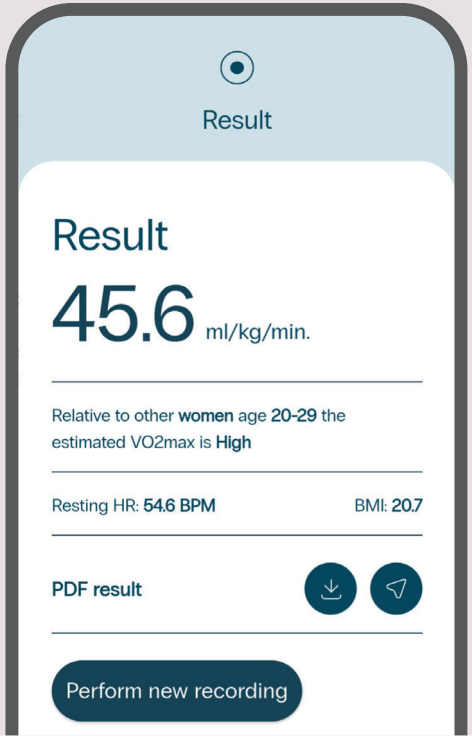
This information is based on the scientific paper "Reference Standards for Cardiorespiratory Fitness Measured With Cardiopulmonary Exercise Testing: Data From the Fitness Registry and the Importance of Exercise National Database" by Leonard A Kaminsky, Ross Arena, Jonathan Myers, published in Mayo Clin Proc. 2015 Oct 5;90(11):1515–1523

You are able to request a PDF with the result of the VO_2max estimation from the result screen. The PDF will be sent directly to the email address of the user signed into the VentriJect App.

From the result screen, you are able to navigate to the list of Seismofit®Sensors and perform a new recording.

NB: Before performing a new recording, remove the old Seismofit®Patch from the Seismofit®Sensor.
Clean the Seismofit®Sensor after each analysis.

Result



Recording erros

Errors during signal analysis

When the Seismofit® analyses the seismocardiogram, errors can occur.

- The list below describes the errors that can occur when the Seismofit® is analysing the seismocardiogram.

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

No heartbeat signal detected:
- A signal of sufficient quality for analysis could not be detected.

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 Seismofit® Patch and the skin.

Subject not in supine position:
- The subject was not resting in supine position during the recording.

Internal algorithm error:
- Errors in the algorithm not described by the other error messages in this list.
- Try to redo the signal acquisition in order to re-do the analysis.

If an error, not described above occurs, please contact the VentriJect Support team with an description of the error message.

- 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.
- If the error persists after retrying, please contact the VentriJect support team at support@ventriject.com

Maintenance / Discarding

Maintenance

Seismofit®Sensor does not consist of parts that require service. The Seismofit®Sensor requires no calibration. If expired, the battery must be changed. Do not sterilize, autoclave, or wash the Seismofit®Sensor. The Seismofit®Sensor can be cleaned with a 70%isopropyl or similar alcohol-based wipe. If the Seismofit®Sensor shows signs of material degradation the device must be replaced.

The VentriJect App will be updated. Updates are provided via the official App Stores. When an update is available, users are advised to update the app, if this is not done automatically.

Discarding

Seismofit®Sensor

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

Seismofit®Patch

The Seismofit®Patch may be discarded as ordinary waste.

Storage and Usage

Seismofit®Sensor

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

Seismofit®Patch

Temperature 10-27°C.Relative humidity 40-60%without condensate.

Symbols

Symbols explanation

MD	→	Medical device
SN	→	Serial number
⚠	→	Caution
📖	→	Consult instructions for use or consult electronic instructions for use
CE	→	Conformité européenne
LOT	→	Batch code
🏭	→	Manufacturer
🗑	→	The Seismofit®Sensor must at discarding be delivered for recycling according to national law. (Directive 2012/ 19/EU, (WEEE)

🌡	→	Temperature limit
%	→	Humidity limitation
⇔	→	Atmospheric pressure limitation
⌛	→	Use-by
🚶	→	Type Body Floating (BF) applied part
⊘	→	Do not reuse
22 PAP	→	The Resin Identification Code is a system of symbols that identify the type of material used in a product, to facilitate proper sorting for recycling.
UDI	→	Unique device identifier

Definitions, abbreviations and acronyms

Xiphoid process
The xiphoid process is the small, bony projection at the bottom of the sternum (breastbone). It is usually located where the lower ribs meet the sternum, right above the diaphragm.

Seismocardiogram
The vibrations that occur on the chest, as a result of the heart beating.

Warning
Provides instructions on how to avoid or mitigate the hazard or risk.

Contraindication
A specific condition or circumstance under which the use of a medical device is not advised.

Precaution
A specific condition or circumstance under which the results from using the medical device must be used with caution.

EMC
Electromagnetic Compatibility

BPM
Beats Per Minute

Approvals

IEC 60601-1
Compliance to IEC 60601-1

CE-mark
The Seismofit®Sensor, Patch and the VentriJect App are in compliance with Medical Device Regulation 2017/745

The Seismofit®is compliant with 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

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

Emission Test
RF Emission CISPR 11
Compliance
Group 1Class 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 (IEC61000-4-2)
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 (IEC61000-4-3)
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 (IEC61000-4-3)
Compliance
- 385 MHz; Pulse Modulation: 18 Hz; 27 V/m - 450 MHz, FM + 5 Hz deviation: 1kHz sine; 28 V/m - 710,745, 780 MHz; Pulse Modulation: 217Hz; 9 V/m - 810,870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m - 1720,1845, 1970MHz; Pulse Modulation: 217Hz; 28 V/m - 2450 MHz; Pulse Modulation: 217Hz; 28 V/m; - 5240, 5500, 5785 MHz; Pulse Modulation: 217Hz; 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 (IEC61000-4-8)
Compliance
30 A/m, 50 Hz: 217Hz; 9 V/m
Guidance
Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.