VentriJect

Instructions for the VentriJect application

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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

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.

Manufacturer:
VentriJect ApS
Ryvangs Alle 81
2900 Hellerup
Denmark
www.ventriject.com

Contact us:
contact@ventriject.com

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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

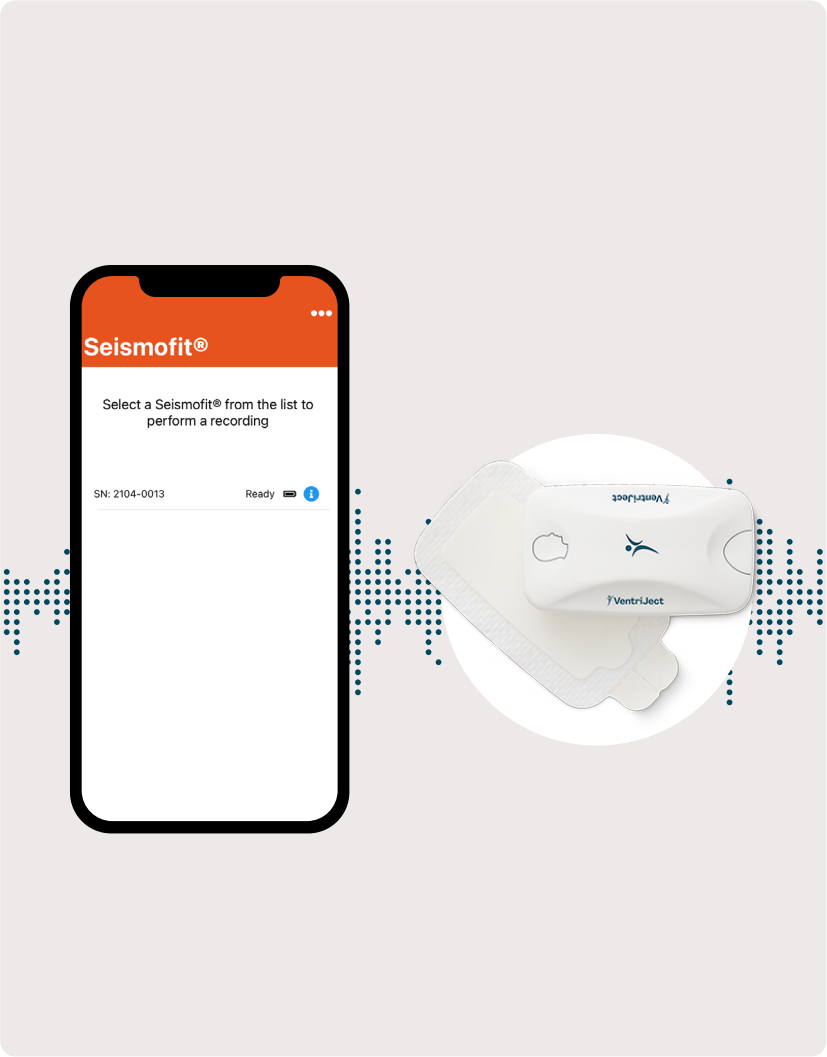
The IFU covers the following products:

- The Seismofit®: A medical device software consisting of an online algorithm that can estimate a VO_2-max score equivalent based on seismocardiography and demographic data

- The Seismofit® Sensor: A medical device accessory to the 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 the Seismofit® Sensor 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®
To determine a VO_2-max score equivalent based on seismocardiography data.

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_2-max estimate.
Bias < 2 mL/min/kg.
Publications concerning the performance of the Seismofit® are available via ventriject.com/publications

Clinical Benifits
Measure of cardiac health/fitness: By providing an accurate VO2max score, Seismofit can help assess cardiovascular health.

Track changes in VO2max: The ability to monitor changes in VO2max 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.

Chronic disease management: Monitoring patients with heart failure, pulmonary disease, or other conditions where VO2max is a relevant clinical indicator.

Warnings

The result of the VO_2-max estimation should be reviewed by a Healthcare Professional if used for the prevention and monitoring of disease.

If the estimated VO_2-max differs markedly from what is expected, a VO_2-max 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 aquisition is ongoing as this may impact the estimated VO_2-max value.

Do not place the Seismofit® Sensor underneath a bra strap or orther tight fitting clothes as this may impact the estimated VO_2-max value.

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

Do not use the Seismofit® Sensor without the original Seismofit® Patch as this may lead to misleading estimates of VO_2-max.

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 device in any way.

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.

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 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
- Known active cancer
- BMI > 50

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

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

Requirements

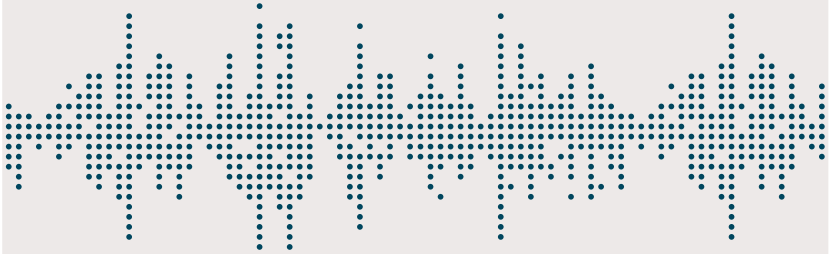
VentriJect App
Apple iOS 18 or newer
Android 10 or newer

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.



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

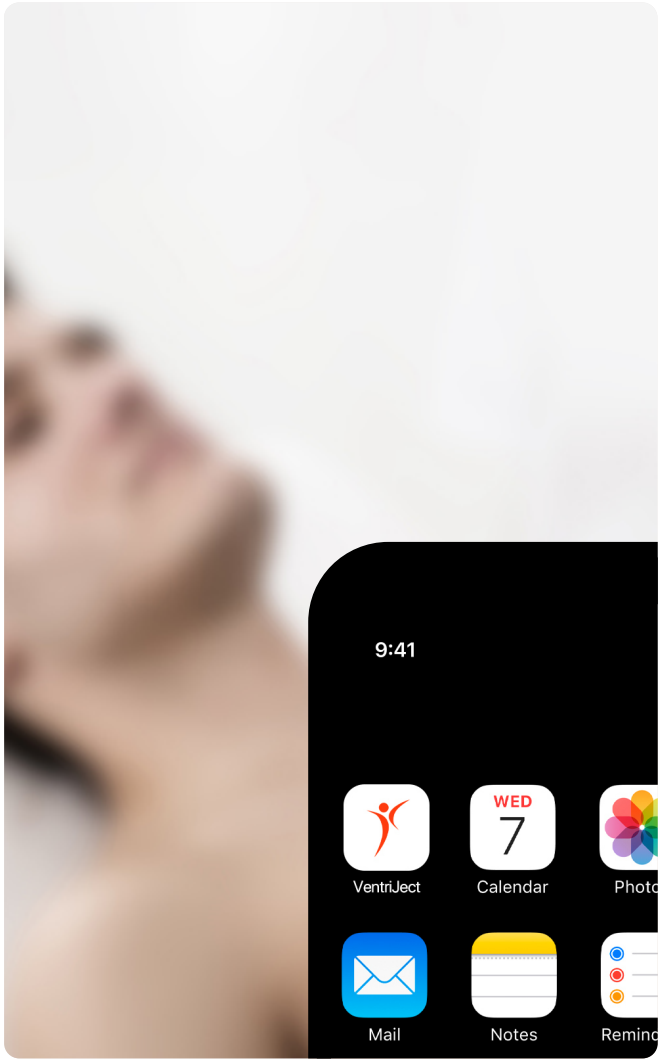
→ 6) Check the result

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 page 7).

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.

Login

Login with user credentials provided by VentriJect

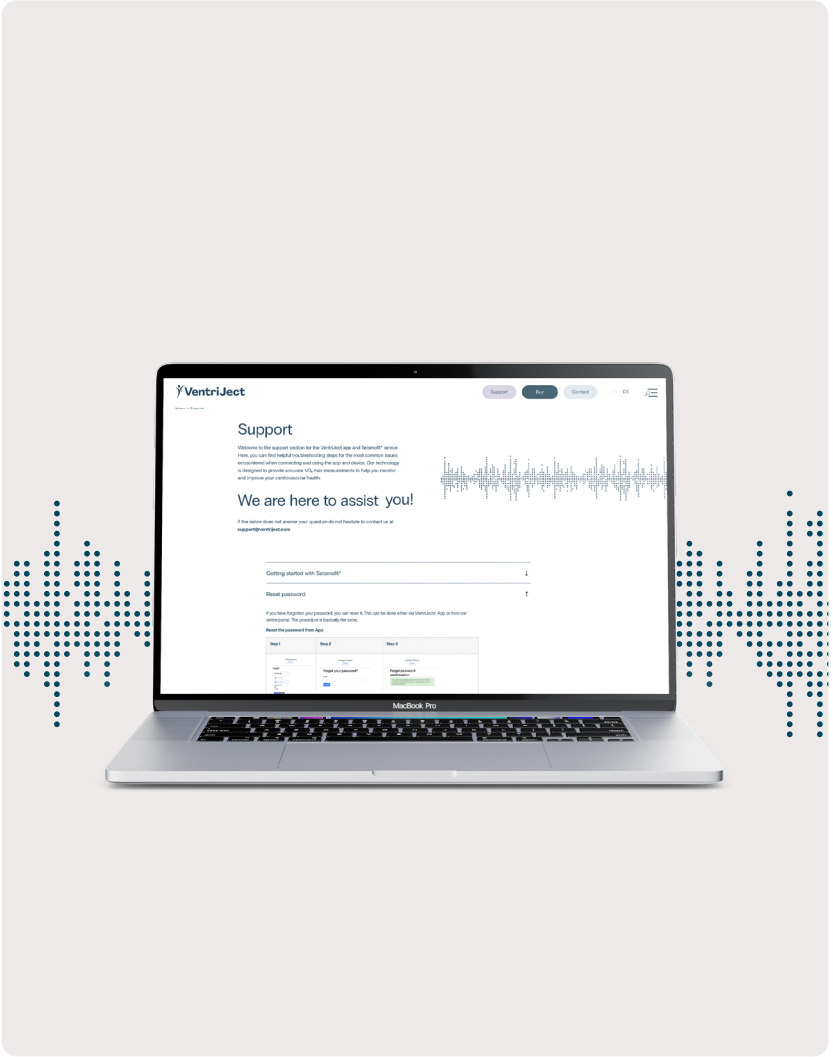
When you sign a contract with VentriJect you automatically receive an email with instructions about how to set your password.

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

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 a battery of high quality, for the Seismofit® Sensor

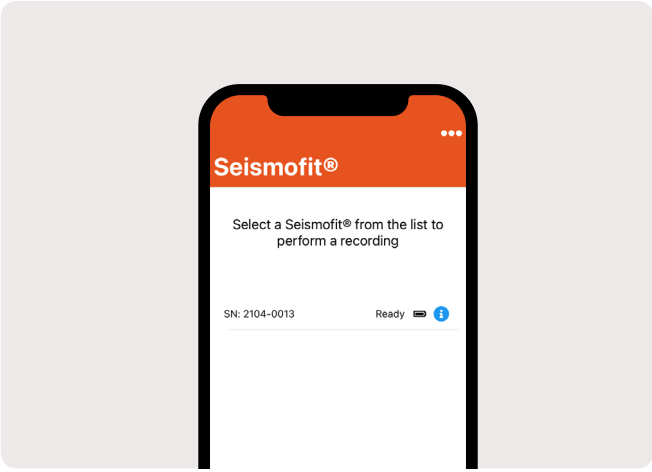
Check the Bluetooth and localisation permissions on your phone

- 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.

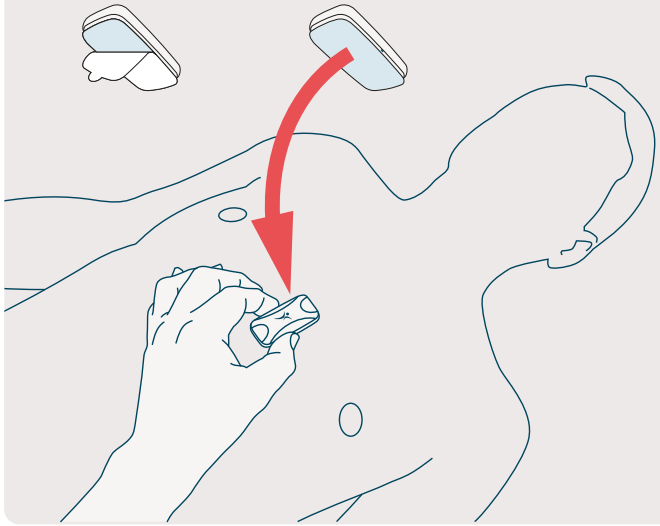
The Seismofit® Sensor should be oriented with the picture of the head, pointing towards the head of the subject. Attaching the Seismofit® Sensor should be done with the subject in supine (resting on the back) and resting position.

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



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

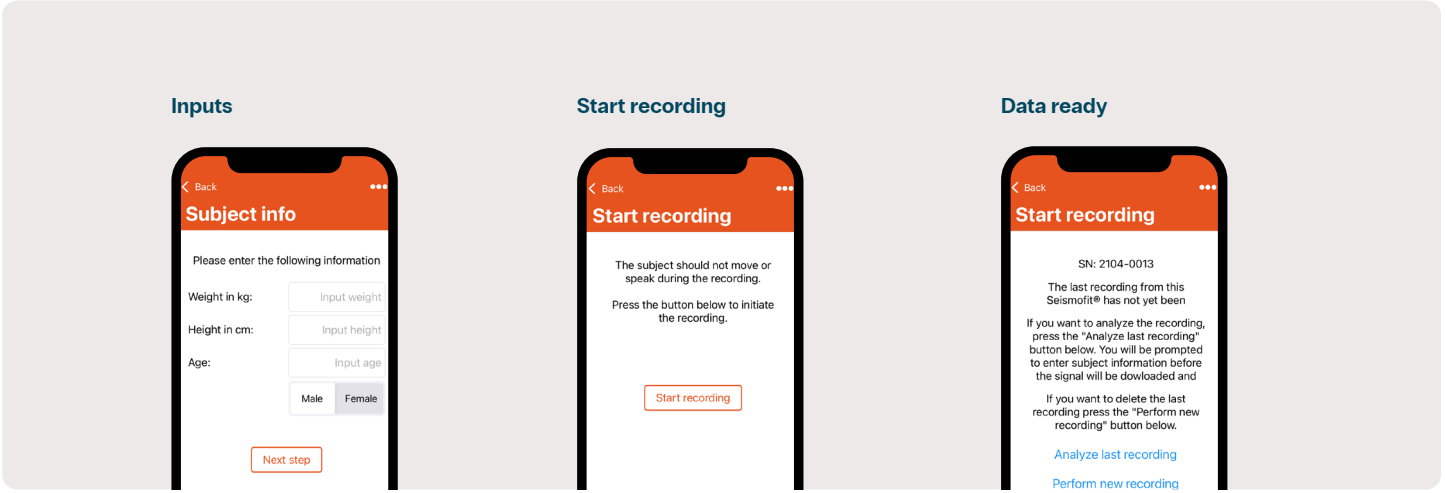
- Make sure that the subject is in the supine position and relaxed.
- Initiate the data acquisition from the app.
- The recording will take 40 seconds to complete.
- During the recording, the subjects must not speak or move as this can impact the signal quality.
- When the recording is completed, the 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 con tinue 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_2-max result

Check the result

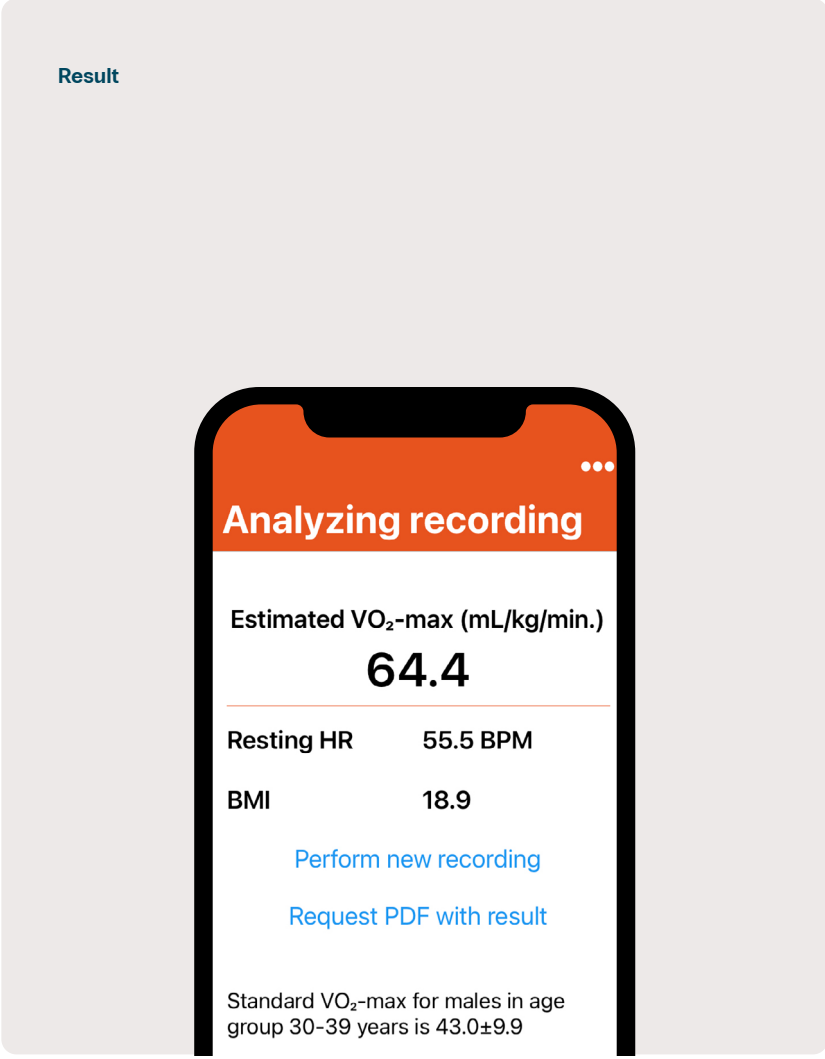
When the signal processing is completed, the estimated VO_2-max score will be displayed in the app. Below the result, a text will show the average VO_2-max scores for the corresponding age and sex, as the subject.

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_2-max 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.



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.
- In case any of these error messages occurs, the VO_2-max 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

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

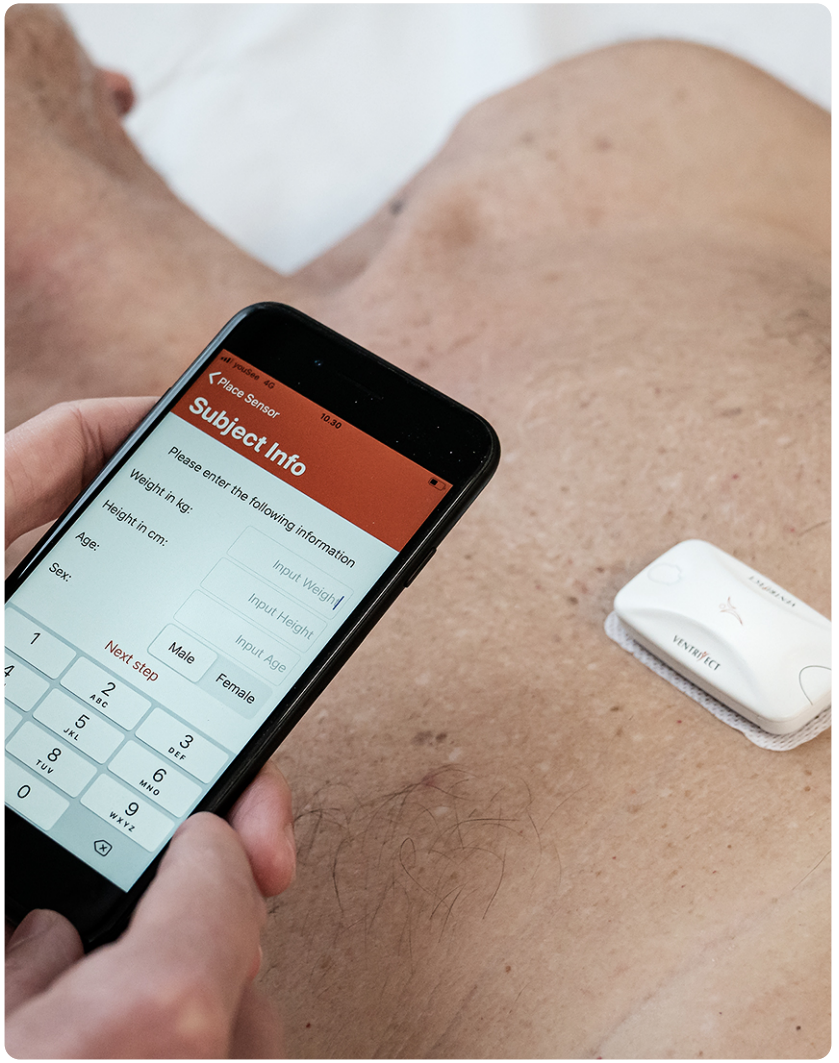
No heart rate detected:
- It was not possible to detect a stable heart rate in the recording

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



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 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 + 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.