



Semi-couch-ergometer SanaCouch 1000 and Stress-Echo Semi-couch-ergometer SanaCardio 1000

User Guide



* The picture may slight differ from the original product

CE Conformity Declaration

Ergosana GmbH herein declare that the ergometers SanaCouch 1000 and SanaCardio 1000 (medical device class IIa) comply with the relevant requirements of EC medical devices directive 93/42/EEC Annex I.

In the manufacture of the product, only components are used that are compliant with EC Directive 2011/65/EU (RoHS 2) and EC Regulation 1907/2006 (REACH).

This declaration loses its validity if the above devices are modified without ergosana's consent.

ergosana GmbH's quality management system and medical devices have been certified by the notified body, TÜV SÜD Product Service, and bear the marking



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IMPORTANT NOTE:

The ergometer may not be opened by an unauthorized person nor may modifications be made to it which have not been discussed with the manufacturer.

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1 General

The semi-couch ergometers SanaCouch 1000 and SanaCardio 1000 are high-performance ergometers designed for use as remote devices (training program input by PC, ECG device, etc.). If no master device is available for remote operation, there are the possibilities of a manual operation, in which the load is set manually in 5 watt steps by the operator via the display, or the automatic mode, in which the load is increased according to a step profile set by the user.

If desired, the current ergometry data can be displayed on the user's tablet PC (doctor, therapist, ...). To do this, the "ErgoSmart" app from the Google Play Store must be installed on your device (Android operating system) and connected to the ergometer.

Alternatively, the load specification of the ergometer can be done in stand-alone mode without a master device (PC, EKG, ...) via the user's tablet or smartphone. For this purpose, a license key for the above listed App "ErgoSmart" can be purchased, which gives the user up to 5 freely parameterizable ergometry programs (step or ramp profiles) as well as rehabilitation training programs, such as Pulse steady state, various interval profiles or freely definable load programs are available (note: single-channel chest strap ECG SanaBlue or pulse transmitter POLAR H10 required).

In addition, the ergometer can be equipped with the following optional functions on request.

- 1st Blood pressure measurement with QRS-Trigger
- 2nd SpO₂- Measurement
- 3rd Bluetooth- or WLAN- interface (to Master device)
- 4th Pulse detection (with Chest strap ECG or Pulse transmitter e.g. Polar H10)
- 5th Supply voltage 115 V or 230 V

Regardless of their features, the devices meet the highest quality standards for accurate physical exertion tests to conduct measurements in cardiovascular and pulmonary function diagnostics.

The following characteristics make the unit exceptional:

- Attractive design
- Comfortable mounting and dismounting thanks to a footrest and handlebar
- Stable steel construction, compact drive unit
- Level adjustment for stable stand
- Levelling mechanism for a stable position of the ergometer
- Comfortable, stable couch enabling the patient to lie still
- Safe position of the patient in case resuscitation should be necessary
- Easy electrical adjustment of couch, saddle and headrest
- High-performance control electronics
- Touch display showing the most important ergometry data
- Impact- and scratch-resistant casing, easy to clean
- Easy operation
- Remote operation
- Absolute disturbance-free blood pressure measurement - possibility of ECG triggering (option: blood pressure measurement)
- Load range from 1 to 999 watts
- Guaranteed accuracy (DIN VDE 0750-238)
- Almost noiseless drive mechanism
- Pleasant pedaling sensation due to large gyrating mass
- Galvanically isolated RS232 interface for secure data transfer (optional Bluetooth™ or WLAN)

1.1 Intended use

The ergometers SanaCouch 1000 and SanaCardio 1000 which belongs to the product family of semi-couch-ergometers. Due to the stable and semi-recumbent upper body position, during the precise physical exertion of patients, they are suitable for exercise ECG examinations and pulmonary function diagnostics, as well as the SanaCardio 1000 by their additional left sideways tilt especially for right heart catheter and ultrasound examinations of the heart under load, which causes an optimal echo position (sound window).

Moreover, they are intended to build up the circulation of older or handicapped patients who have suffered a cardiac infarction and are in rehabilitation phase III.

The devices are used in practices, clinics, therapy and rehabilitation as well as sports trainings centers and are operated by physicians or medical professionals after a detailed briefing by an authorized person.

1.2 Indications

Possible indications for exercise ECGs:

- Diagnostic clarification of chest pain (angina pectoris including vasospastic angina) for myocardial ischemia (insufficient blood supply) or for coronary heart disease (coronary artery disease)
- For patients with cardiac risk factors such as suspected coronary artery disease and arterial hypertension (high blood pressure)
- Following a myocardial infarction, for the assessment of prognosis, physical activity, medication and cardiac rehabilitation
- Before and after a revascularization (restoration of the blood supply) using interventional techniques or aortocoronary bypass surgery, to assess any remaining ischemia
- Assessing the physical exercise capacity, e.g. for expert reports
- Examination of asymptomatic men >40 years of age, or women >50 years of age, respectively, before physical exercise
- For occupations where a medical condition influences public safety (e.g. for bus drivers, pilots, ...)
- For patients with cardiac arrhythmia that only manifests itself during exercise (e.g. ventricular tachycardia in the case of arrhythmogenic right-ventricular disease, coronary artery disease)
- Exercise trials for patients with frequency-adaptive pacemaker systems to define the ideal intervention frequency
- Proof of undesirable pro-arrhythmic effects – amplification of arrhythmia during anti-arrhythmic therapy
- Measuring the physical exercise capacity of high-performance athletes/competitive athletes

Indications for cardiac rehabilitation:

- Post cardiac infarction
- Stable angina pectoris
- Coronary artery bypass surgery
- Cardiomyopathy
- PCI (percutaneous coronary intervention)
- Compensated cardiac insufficiency

1.3 Contra indications

There is always a certain risk when performing exercise examinations. Therefore, contra indications for ergometry apply.

In the event of the following contra indications, **NO** exercise test must be performed:

Absolute Contra indications:

- Existing acute cardiac infarction (myocardial infarction)
- Unstable angina pectoris
- Symptomatic serious aortic stenosis
- Serious hypertonia at rest
- Carditis
- Insufficiency of the heart
- Serious cardiac arrhythmia at rest and/or restricted hemodynamics
- Aorta aneurysm
- Acute aortic dissection (dissection of the layers of the aorta walls)
- Acute pulmonary embolism
- Acute myocarditis (inflammation of the heart muscle)
- Acute pericarditis (inflammation of the pericardium)

Relative contra indications:

- Serious valvular heart defect
- Manifest cardiovascular diseases
- Left main stenosis
- Known electrolyte imbalance
- Arterial hypertonia (RR >200 mmHg syst. / >110 mmHg diast.)
- Tachyarrhythmia or bradyarrhythmia
- Hypertrophic cardiomyopathy and other obstructions of the outflow tract
- Higher degree AV block
- Physical or mental impairment

Contra indications for cardiac rehabilitation:

- Unstable angina pectoris
- Blood pressure at rest >200/110 mmHg
- Critical aortic stenosis

1.4 Abort criteria

When any of the following symptoms occur, the exercise needs to be aborted:

Absolute abort criteria:












- Moderate to serious angina pectoris (painful chest tightness), dyspnea (shortness of breath), cyanosis (blue coloration of the skin or mucous membrane), dizziness, cold sweat, ataxia or exhaustion
- ST depression ≥ 3 mm or ST elevation ≥ 1 mm
- Persistent ventricular tachycardia (>30 s)
- Fall in blood pressure >10 mmHg with signs of myocardial ischemia (angina pectoris, ST elevation >0.1 mV, horizontal ST depression >0.2 mV), or lacking systolic increase in blood pressure, respectively
- Blood pressure >240 mmHg (systolic) and >115mmHg (diastolic)
- No increase of heart rate
- Reaching the max. heart rate (= 220 - age in years ± 10 beats)
- Technical problems (e.g. failure of the ECG device)

Relative abort criteria:

- Hypertensive dysregulation
- Fall in blood pressure >10 mmHg without signs of myocardial ischemia (angina pectoris, ST elevation >0.1 mV, horizontal ST depression >0.2 mV)
- Polymorphous supraventricular extrasystoles (SVES), couples, runs, atrial fibrillation/flutter
- Supraventricular tachycardia (VT)
- Bradyarrhythmia or disturbance of conduction (higher degree AV block, new left bundle branch block)
- Minor angina pectoris

1.5 Signs and symbols

In this section, the signs and symbols used in connection with this device are explained (acc. DIN EN 60601-1):

	Supply voltage 230 V 50 Hz / 115 V 60Hz (refer power plug module)		Maximum Patients weight
	Safety class I		Warning! Follow the instructions in the documentation
	Fuses within power plug module (refer chapter 3.1)		Conformity with 93/42/EEC Notified Body 0123 TÜV SÜD
	BF-classified applied part		Manufacturer
IPX0	Protection class of the casing: IPX0		Date of production
	Potential equalization connection (earth)		Article No. / Device type
		S/N	Serial number of the device

1.6 Technical specifications

Drive mechanism	Almost noiseless and maintenance-free, with Poly-V belt (no chain)
Device class	S = Professional/commercial use under the supervision of an operator A = Accuracy class A
Braking principle	Computer-controlled brakes with permanent measurement of torque. Braking performance is independent of revolutions per minute.
Performance/ load range	- 1 to 20 watts (revolutions per minute dependent load rang) - 20 to 999 watts (revolutions per minute independent load rang)
Load precision	DIN VDE 0750-238
Long-term accuracy	Continuous torque control and equalization according to weight
Control range (independent of revolutions per minute)	30 to 130 rev/min
Load parameters	- External by Master unit (PC, ECG, ...) with a resolution of 1 watt - Automatically by ergometer in steps of 5 watts (step profile with load steps of 5-100 watts with a step duration of 1-10 minutes) - Manually by the operator on the ergometer control unit (in individual steps of 5 watts)
Display	Touch display (57x43 mm)
Supply voltage	230 VAC with 50 Hz, or 115 VAC with 60 Hz The unit is suitable for use in electric networks according to CISPR 11, group 1, class B
Electric inputs/outputs	- RS232 (galvanically isolated) - USB-charging socket (5 VDC)
Length of pedal crank	172,5 mm (double length of pedal crank: 345 mm)
Base dimensions	160 x 70 cm
Weight	117 kg (SanaCouch 1000) 125 kg (SanaCardio 1000)
Max. power consumption	28 Watt
Admissible patient data	Patients with - a max. weight of 160 kg - a height between 135 and 210 cm
Pulse measurement	- ECG (Master device) - Blood pressure measurement unit (if applicable) - Chest strap ECG / Pulse transmitter POLAR H10 (with App „ErgoSmart“)
Blood pressure measurement (Option: blood pressure measurement)	Indirectly, with a specific, modified measuring system based on R-R, and computer analysis including maximal suppression of artefacts during ergometry. Automatic pressure release by 3 mmHg/pulse; quick pressure release at the average of high amplitudes. Measuring range 40–300 mmHg.
SpO₂- measurement (Option: SpO ₂ - measurement)	- Finger sensor (standard configuration) - Ear sensor (on customer request)

1.7 Maintenance

This is a low-maintenance device. You will find detailed maintenance instructions in chapters 7 and 8.

1.8 Transport and storage

- The ergometer shall not be stacked, nor the package may be loaded from above.
- The ergometer shall not be storage/transported within a humid or wet environment (<60 % RH).
- The ergometer shall be transported within normal environmental conditions/temperatures.
- The ergometer shall not be exposed to direct sunlight or heat for extended period of time.

2 Safety information


2.1 Precautions during operation/use

- Before using the unit, make sure that the medical product consultant has conducted an introduction with regard to function and safety precautions.
- The unit must not be used if there are any doubts as to it being isolated from earth or the suitability of the mains cable.
- The unit must only be used with a mains cable that complies with the regulations for use in medical technology.
- The unit is not intended for use in wet rooms, outdoors or in areas where there is danger of explosion.
- Before using the ergometer, all wheels need to be locked by pressing down the brake levers.
- It must be ensured that the device is set up on a level floor or aligned without play with the level adjustment screw to ensure absolute stability.
- Position the ergometer to ensure that when the couch is horizontal and the head rest maximally extended, there is enough space for unrestricted operation.
- The holding straps on the pedals must fit perfectly across the upper side of the shoe and be fastened with a Velcro strap.
- The therapist or physician must take care that the patient do not stuck within the pedals during climbing up or down of the ergometer.

Remark:

→ The seating aid serves exclusively to adjust the distance between the patient's upper body and the pedals. Do never use the saddle to move the patient upwards by means of the motor when the couch is inclined.

2.2 Safety precautions when operating with other devices

- When several devices are coupled, there is a risk that the leakage currents may add up.
- The RS232 interface, which can be used for communication with other devices, is isolated to ensure the patient's safety.
- External devices may only be connected with the interface cables supplied by the supplier.
- Portable communication devices, HF radios and devices labelled with the symbol  (non-ionic electromagnetic radiation) can affect the operation of this device (see section 8.5).

2.3 Precautions during maintenance

- The device must be turned off and power plug disconnected before cleaning with liquid cleaning agents.
- Only use standard cleaning agents for plastic and imitation leather surfaces.
- The unit may **only** be opened, repaired and serviced by **authorized and trained personnel**. If the unit is opened inadmissibly, the warranty becomes void.

2.4 Interference

The unit meets EMC regulations for medical products to ensure protection against emission and radiation. Special caution needs to be taken when using this unit in combination with high-frequency devices (see chapter 8.5).

2.5 Instruction

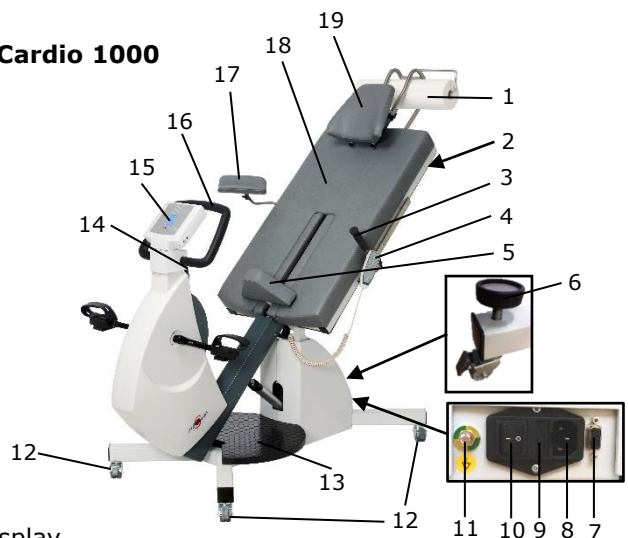
- The ergometer shall be operated only by trained/instructed persons.
- Before initial operation, carefully read through this user guide, paying special attention to the warnings and safety instructions.

3 Device components and accessories

3.1 Device components

3.1.1 Device components SanaCouch 1000 and SanaCardio 1000

1. Paper roll
2. Connector for blood pressure cuff (at the back of the lying surface)
3. Grab handle
4. Remote control
5. Electrically adjustable seating aid
6. Levelling mechanism (back right foot)
7. RS232 interface
8. Power supply socket
9. Fuse box
10. Master switch of ergometer
11. Potential equalization socket
12. Wheels with lockable heavy-duty rollers
13. Footboard
14. Clamp lever for handlebar adjustment
15. 180° turnable control unit with touch display, RPM-display and USB- charging socket (see chapter 3.4)
16. Handlebar (as ascent assistance)
17. Adjustable arm rest for blood pressure measurement
18. Electrically tiltable lying surface
19. Electrically adjustable head rest with paper roll holder



* The pictures may slight differ from the original product

3.1.2 Additional components SanaCardio 1000

20. Adjustable arm rest and shoulder support
21. Foldable opening
22. Adjustable hip support (optional: belt)
23. Extendable foot
24. Enlarged pedals
25. Electrically inclinable couch



3.2 Accessories and optional functions

Standard accessories: (part of each device)

- Mains cable
- User guide
- Paper roll
- Inspection report

Optional accessories: (depending on the device equipment)

- Blood pressure cuff (Medium size) / Size Large on customer request (if option blood pressure measurement is available)
- Arm rest (if blood pressure measurement option is available)
- SpO₂ finger sensor / on customer request ear sensor (if option SpO₂ measurement is available)
- Chest strap ECG
- Pulse transmitter POLAR H10
- Tablet PC
- Tablet holder

Optional device functions:

- Blood pressure measurement
- SpO₂- Measurement
- Bluetooth interface (to Master device)
- Stand-Alone-Function (Ergometry- and Reha-Training function with App „ErgoSmart“)

3.3 Potential equalization

A standard potential equalization stud is located on the rear panel, next to the power connection unit. It is marked with a green/yellow information sign. Using an earthing cable, the ergometer can be connected to the potential equalization of the examining room, which serves as a common earthing point for all other mains-operated devices in the room to ensure that all devices have the same earthing potential.

Note:

→ In electricity grids that are built and safeguarded according to European regulations, the earth wire (green/yellow) integrated in the mains cable is used for potential equalization. **No additional** earth cable should be connected in this case.

3.4 Control unit (Measuring Head)

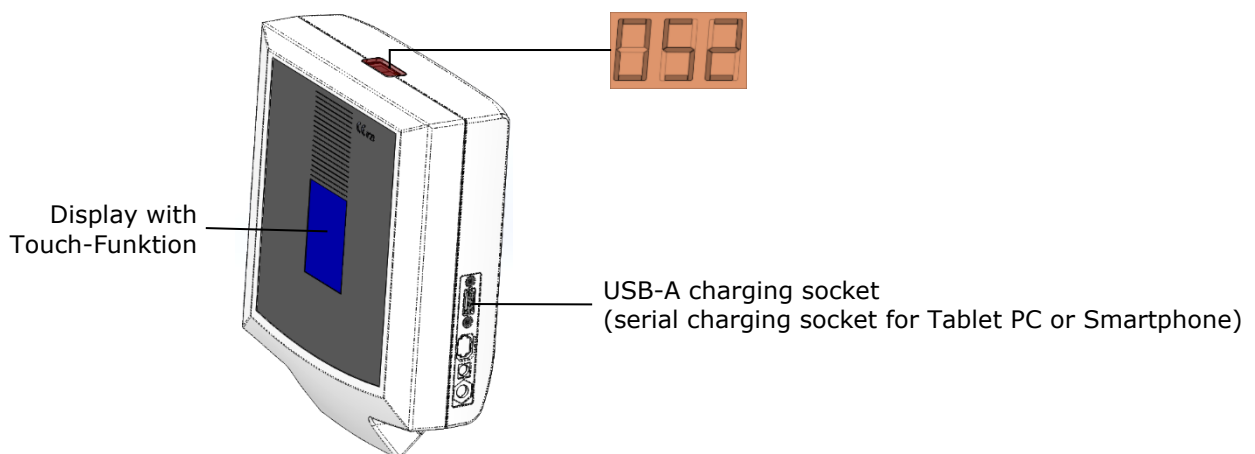
The control unit located on top of the handlebar includes a 57x43 mm color touch display for displaying the current ergometric parameters and for operating the ergometer. In normal operation it faces the doctor or therapist, but for special applications such as patient training, etc., it can also simply be rotated by 180° so that the patient can see the display clearly and can easily reach the controls.

Note:

→ For a functional description see chapter 6 Operation and operation modes of the ergometer.

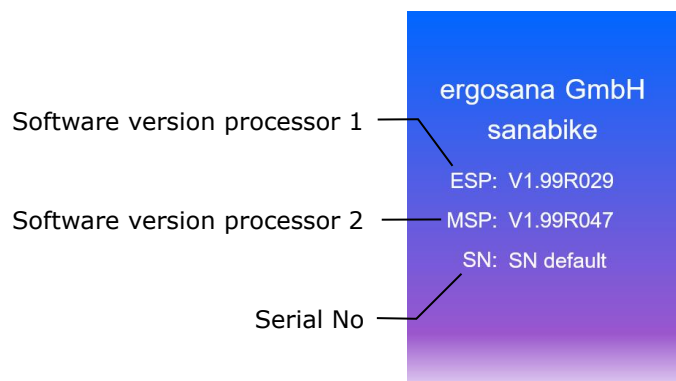
At the top of the console, a 7-segment display shows the current revolutions per minute of the pedals.

At the right side of the control unit there is a USB charging socket (5,0 VDC).



3.5 Device information

After switching on, the currently installed software versions and the serial number of the ergometer appear on the display.



3.6 Remote control for adjustment of seat- and couch

The quick and easy adjustment of the couch, the seat cushion and the headrest is done via a remote control, which allows independent motorized adjustment of the components by touch of a button. This makes the correct placement of the subject on the lounger very easy.

Button pair 1 to adjust the couch's slope.

- Left button: Couch twists backwards
- Right button: Couch twists frontwards

Button pair 2 for adjustment of the headrest.

- Left button: Headrest moves upwards
- Right button: Headrest moves downwards

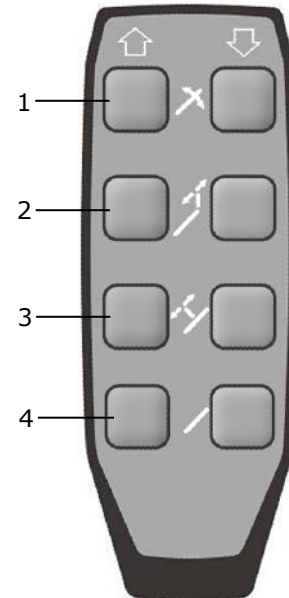
Button pair 3 for adjustment of the seat cushion.

- Left button: Seat cushion moves upwards
- Right button: Seat cushion moves downwards

Only at SanaCardio 1000

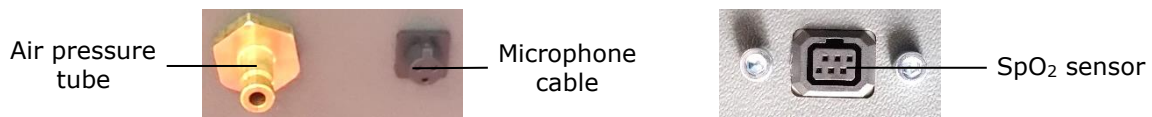
Button pair 4 to swivel the couch.

- Left button: Couch swivels to the side
- Right button: Couch swivels to the horizontal position



3.7 Connector sockets for blood pressure cuff and SpO₂ sensor

The blood pressure cuff and the SpO₂ sensor are connected at the back (upper end) of the lying surface by attaching the air pressure hose and microphone cable or the SpO₂ sensor onto the specific connector socket. The air pressure hose can be unlocked later by pulling back the outer sleeve on the plug and disconnect.



3.8 The blood pressure measuring unit

In order to conduct exercise testing correctly, it is of utmost importance to record physical performance data and ECG data as well as simultaneously measuring and recording blood pressure data to determine the reaction of the circulatory system to increased exertion.

For this purpose, ergosana has developed a highly accurate blood pressure measuring system that is not susceptible to interferences. It has been integrated into this ergometer and uses a so-called indirect method of blood pressure measurement. The Korotkoff sound, which is created by the air being forced out of the cuff as blood flows through the area of compression, is recorded along with several other important parameters of critical importance to attain accurate measurement. These measurements are evaluated in milliseconds by an internal digital evaluation system and shown on the ergometer's display as systole and diastole. The pulse rate is also determined during measurement and shown on the display. At the same time as they are shown on the display, the measurements can also be transferred via RS232 interface to a peripheral device such as an ECG or pulmonary function unit for evaluation and recording.

3.8.1 Blood pressure cuff

The blood pressure cuff is the measurement sensor for blood pressure. Despite the perfectly functioning measuring system, it remains critically important that the cuff is placed on the arm correctly and carefully (see chapter 6.3.1).

The standard blood pressure cuff of size medium (Order No. 24-20-111-GR) is designed as a Velcro cuff. It can be used for an arm circumference of 25-40 cm. If this arm circumference is exceeded, a large blood pressure cuff (order no. 24-20-131-GR) should be used. It can be used for an arm circumference of 35-50 cm.

A microphone is installed in a microphone pocket on the inside of the cuff. It serves the transmission of the blood pressure sound.

The connection cable with an air and a microphone connection is 110 cm long, which is sufficient for normal use. This length was chosen to prevent the cable from dashing against the ergometer when the patient is pedaling because this can cause unnecessary artefacts that can affect the blood pressure measurement. For special examinations, longer cables (200 cm) are available; however, it is imperative to prevent artefacts as described above.

Note:

→ For information on cleaning the cuff, see chapter 7.3.

3.9 SpO₂ Measuring unit

The measurement of the SpO₂ value takes place as a non-invasive measurement of the oxygen saturation of the blood and is one of the five vital signs. It takes place via an optical sensor which, depending on the model, is attached to the finger or attached to the ear and is used for rapid assessment and monitoring of the patient's breathing function.

3.9.1 SpO₂-Sensor

Devices with the option SpO₂ measurement are generally equipped with a finger sensor, which can be substituted by an ear sensor on customer request. The finger sensor should be put on a finger of the right hand (preferably forefinger) or the ear sensor hooked on the ear.

4 Installation and commissioning

4.1 Location

- Install the device in a suitable position (refer to safety instructions in section 5).
- The unit must not be stored or operated in wet, moist or dusty surroundings.
- The unit must not be exposed to direct sunlight or other sources of heat.
- The unit must not come into contact with acidic vapors or fluids.
- The unit should not be placed near X-ray units, large transformers or electrical motors.
- There must be a distance of at least one meter between the unit and the mains network.
- Position the couch so that you can easily reach the patient from each side.
- The entry area to the ergometer must be $\geq 0,6$ m.

4.2 Assembly instructions

4.2.1 Unpacking and assembling

After unpacking the couch ergometer and unscrewing it from the transport container (4 screws M10x50 mm) turn the frame on the container so that the enclosed heavy-duty rollers can be mounted (use M10 x 20 mm screws on the levelling mechanism).

Note: (only at SanaCardio 1000)

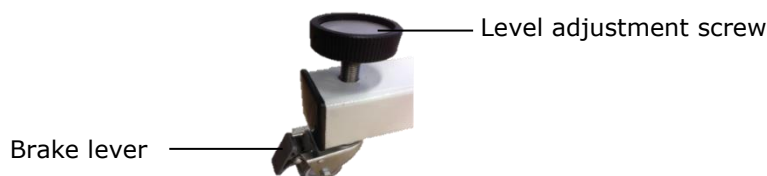
→ The SanaCardio 1000 ergometer has a separate extension of the rear left stand, which is mounted to the base frame with 4 screws (M8 x 16 mm)

After the ergometer is at its place of use

- lock all transport rollers with the brake levers and
- adjust the device with the help of the level adjustment screw at the rear right stand in such a way that there is no more play in relation to the floor and the ergometer is completely stable, for which a non-slip surface must be chosen.

Note:

→ If the couch is still unstable due to an uneven floor, all wheels can be replaced by base adjustors.



Adjust the clamp lever downwards after fixing the handle bar in place. In order to be able to adjust the handle position without loosening the clamping, the handle must be unlocked by pulling it back out of its lock. Afterwards, the handle can be turned to the desired position and simply released, whereby it locks itself automatically.



4.2.2 Mounting of arm rest and handlebar

Mounting the arm rest and handlebar to the semi-couch ergometer SanaCouch 1000:

- Mount the arm rest for blood pressure measuring on the left guide rail. For measurements on the right arm, the arm rest has to be mounted on the right guide rail.
- Mount handlebar onto the left guide rail.

Mounting the arm rest and handlebar to the stress-echo semi-couch ergometer SanaCardio 1000:

- Mount the arm rest for blood pressure measuring on the right guide rail.
- Mount handlebar onto the right guide rail.
- If applicable, route the hip belt around the right guide rail (optional accessory).

4.2.3 Connecting

Plug the supplied power cord into a grounded socket. If there is no earthed socket, equipotential bonding must be established (see chapter 3.3). The device is factory-set to the local mains voltage (see chapter 8.3) and can be switched on with the main switch on the rear.

The bike ergometer is now ready for use and can be connected to the master device (ECG, PC or similar) via the RS232, WLAN or Bluetooth interface.

Note:

→ Installation and basic configuration of the ergometer and connection to a master device must be performed by an instructed service technician.

4.2.4 Connecting the blood pressure cuff

As regards ergometers with the optional feature blood pressure measurement, the interfaces for the air tube and the microphone are located on the rear of the lying surface (see chapter 3.7). The air tube is connected via a special plug coupling; to connect the tube to the console, press the plug coupling in (connector needs to click into place), to disconnect, pull the outer sleeve back. The microphone is connected to the other socket; use the guiding slot for correct positioning.

4.2.5 Connecting the SpO₂ sensor

As regards ergometers with the optional feature SpO₂ measurement, the interface for the sensor is located on the rear of the lying surface (see chapter 3.7). The orientation of the SpO₂ finger sensor (or ear sensor on customer request) is defined by a guiding slot.

5 Settings

After preparing the ergometer as described in chapter 4, the device is ready for use and can be individually adapted to patients with a height between 135 cm and 210 cm and / or the application.

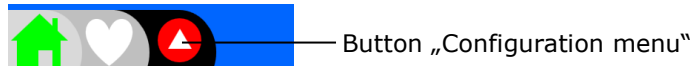
5.1 Language selection

The ergometer is set to the desired language upon delivery. However, it can easily be changed at any time via the configuration menu, whereby the following languages are available.

- German
- English
- French
- Italian
- Spanish

5.1.1 Language setting

The language will be changed within the configuration menu. To open the configuration menu, the device must be restarted, whereupon the button for starting the configuration menu appears in the menu bar of the display for 5 seconds.

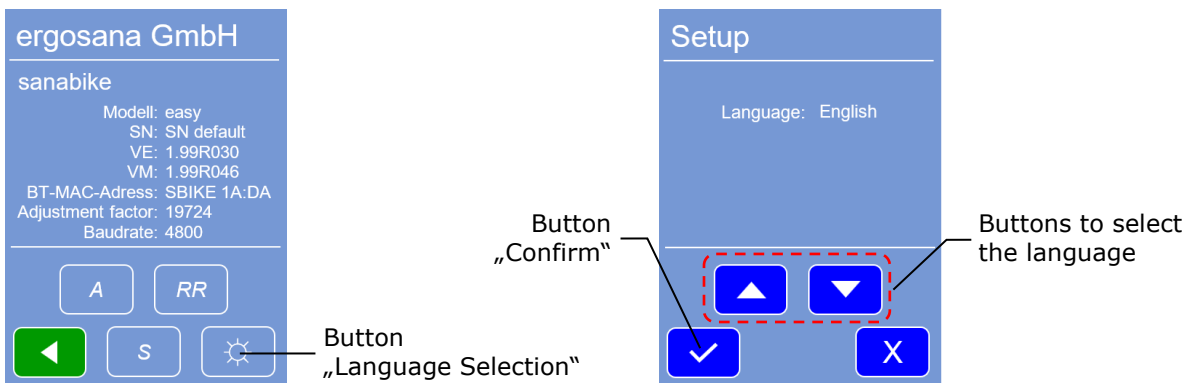


Note:

→ When changing the language by the user, make sure that only the language selection menu will be opened.

⚠ Changes to other device settings may only be carried out by qualified service staff!

To select the language, press the button „*Language Selection*“. The desired language can then be selected using the buttons for language selection and accepted with the button „*Confirm*“.



5.2 General patient specific adjustments

The advantage of recumbent ergometry is the ideal placement of the patient on the ergometer, whereby in completely relaxed position of the patient the same performance is guaranteed as on a seat ergometer. As a result, the measurement results of the blood pressure measurement and the ECG are artifact-free and thus better valued. Additionally, older and sick patients find the recumbent position safe and comfortable.

Note:

→ The horizontal position should only be used for resuscitation or cardiac catheterization to avoid pulmonary edema.

5.2.1 Seat aid

The seating aid serves exclusively to adjust the distance between the patient's upper body and the pedals. It can be continuously electrically adjusted with the remote control.

To adjust the correct seat distance, the **heel** should touch the pedal that is in the furthest position with the leg straightened.

Note:

→ To avoid possible crushing and to relieve the drive motor, the patient should not sit on the sitting aid during the adjustment process, but should support himself with his feet on the pedals.

5.2.2 Headrest

The headrest is adjusted so that the head rests comfortably and does not press on the patient's back. It can be continuously electrically adjusted with the remote control and provides the paper for covering the lying surface and for sweat absorption during ergometry.

5.2.3 Pedals and pedal straps

For the couch ergometer SanaCouch 1000, the feet need to be positioned with the ball of the foot on the pedals and they need to be secured with the straps.

The stress echo couch SanaCardio 1000 is supplied with pedal shoes; for the SanaCouch 1000, these can be ordered optionally.

5.2.4 Grab handle

This arm rest is set to support the patient's right arm and shoulder in a comfortable position.

5.3 Specific adjustment SanaCardio 1000

In contrast to an ordinary couch ergometer, the couch of the stress echo ergometer can be swiveled infinitely up to 30 degrees to the left; in doing so, the heart is brought into a suitable position for ultrasound examinations during exercise. In this position, clearer and sharper ultrasound images of the heart are achieved. The tilting is controlled via the remote control which is described in chapter 3.6.

The following supports ensure the patient's safety in any tilt position and give him a secure feeling.

5.3.1 Hip support

The hip support is adjustable lengthwise (up and down). It needs to be positioned level with the hip so that the patient is secured in the middle of the lying surface and so that pedaling is not hindered.

Note:

→ Alternatively, a hip belt can be used (optional accessory).

→ If the unit is only used for ergometry, the hip support can be replaced with the arm rest for blood pressure measurement.

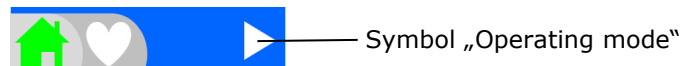
5.3.2 Arm support

Together with the hip support, the shoulder support ensures that the patient is held securely when the lying surface is swiveled to the side. It is adjusted so that the patient is centered on the lying surface and can support himself with his armpit on the round armpit pad. The handle is extended so that the patient's arm does not interfere with the examination area. The swivel range of the shoulder joint must be observed.

6 Operation and operation modes of the ergometer

The ergometer has 3 operating modes: remote operation, manual operation and automatic operation. If the ergometer is connected to an operational master device (PC, ECG, ...) via one of the interfaces, it is automatically in remote operation after the switch-on process (see chapter 6.2.1). In this operating mode, the ergometer executes the control commands of the master device and transmits the current ergometric data (load, speed, ...) for evaluation to the master device, where they are displayed on a larger screen together with the patient's vital values.

If no master device is available or an examination method requires independent control of the ergometer, the operating modes manual operation (chapter 6.2.2) or automatic mode (chapter 6.2.3) can be selected. For this, communication with the master device must be interrupted, whereupon a white triangle symbol appears in the menu bar.



Note:

→ As long as **no** triangle symbol is visible in the menu bar, the device is in remote mode.

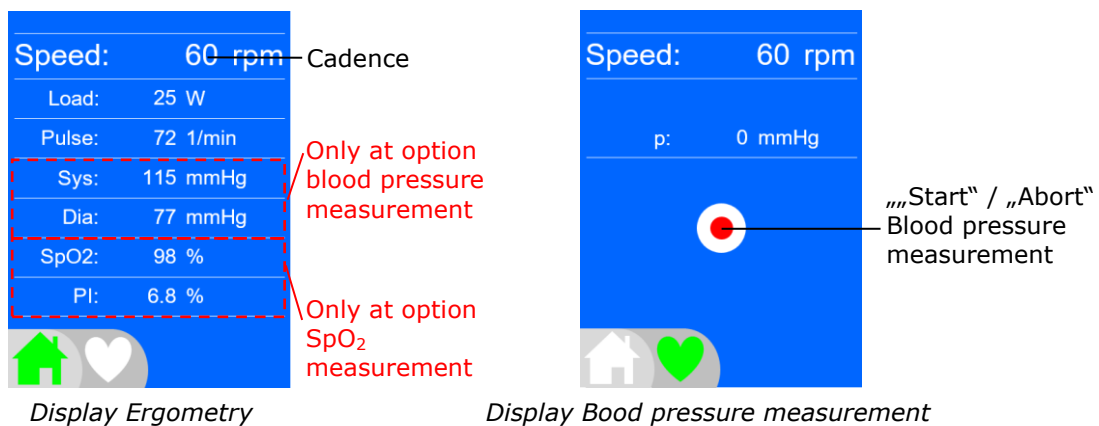
6.1 Displays and operation

The ergometer is primarily operated using the buttons in the menu bar at the bottom of the display. The number and display of the buttons varies depending on the operating mode and the equipment of the ergometer. This gives the user a clear overview of the functions available in the current operating mode, which makes the operation of the ergometer very clear.

A fully equipped ergometer has the following displays in remote operation:

- "Ergometry" display shows the most important ergometry data of the patient
- "Blood pressure" display to start and stop a blood pressure measurement manually (only if option blood pressure measurement is available)

Use the buttons at the bottom of the display to switch between the modes.



For self-control of the cadence, the speed value is shown in the display in different colors. This indicates to the user the ideal speed range depending on the current load in order to guarantee the desired physical load (load diagram see chapter 9).

- Speed value **white** = Cadence in order (ideal range)
- Speed value **red** = Cadence to high
- Speed value **green** = Cadence to low

Note:

→ The load control of the ergometer takes place over the entire speed range from 30 to 130 revolutions independent of the speed.

6.2 Operation modes

6.2.1 Remote operation

In remote operation, the ergometer is controlled by the ergometry / exercise program of an external master device such as a PC, EKG, or similar. This operating mode can be recognized by the fact that **no** triangle symbol (white or red) is shown in the menu bar next to the selection fields.

Requirements for remote operation:

For running an ergometry program which is controlled by an external training program, the following applies

- the ergometer needs to be individually adjusted to the patient, as described in chapter 5.2.
- the ergometer needs to be connected to the master device via an interface (RS232, Bluetooth, WLAN).
Note: For patient safety, the RS232 interface is galvanically isolated
- the transmission rate (Baud rate) needs to be set correctly.
- the data protocol type P10 needs to be selected (ergometer and master device).

6.2.2 Manual operation

In addition to the standard remote operation, the load can also be defined manually by the user in steps of 5 watt on the ergometer.

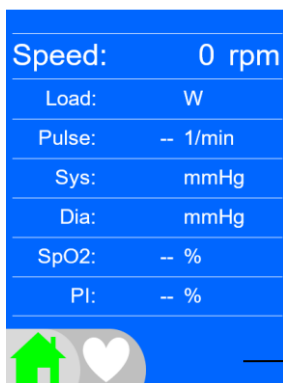
Requirements for Manual mode and Automatic mode:

For running an ergometry program or an external training program, the following applies

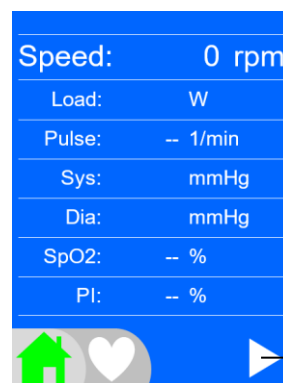
- the ergometer needs to be individually adjusted to the patient, as described in chapter 5.2.
- the ergometer must not be coupled to a master device in order not to receive remote commands via the interface.

Note:

→ As soon as the ergometer receives a remote command, manual operation is ended automatically.



Remote operation active



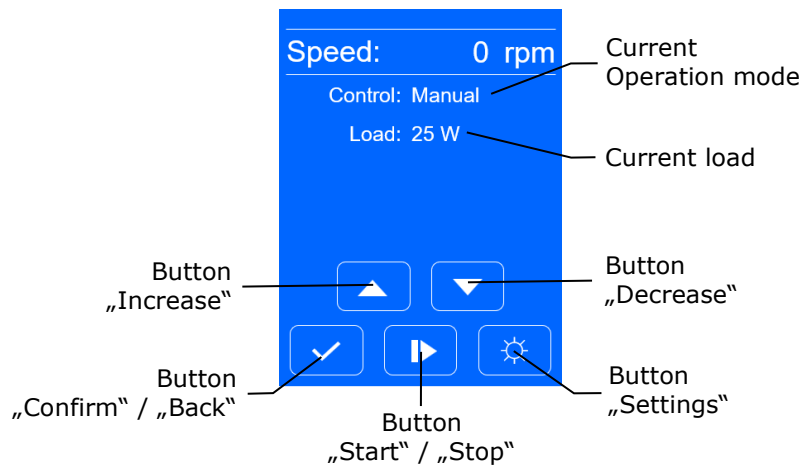
Manual-/Automatic operation available (not active)

Start of Manual operation and Load adjustment:

Manual mode is available as long as the ergometer is not in remote mode. This can be recognized by the fact that **no** triangle symbol is shown in the menu bar.

If manual mode is available, the selection menu can be viewed by pressing the triangle symbol in the menu bar.

The currently selected operating mode and the set load are shown in the selection menu.



If the load setting and the operating mode are OK, the training can be started directly via the button "Start", whereupon the current duration of the training is displayed.

Here you have the option of switching to the ergometry display by pressing the button "Back" in order to take a look at the current ergometry parameters or to carry out a blood pressure measurement. In this case, the active manual operating mode can be seen from the red triangle symbol in the menu bar at the bottom right.

If an adjustment of the load level is desired, this can be done by the user in 5 watt steps using the buttons „▲“ (Increase) and „▼“ (Decrease) in the manual mode display, for which the triangle symbol in the menu may be used must be pressed in the ergometry display.

6.2.3 Automatic operation

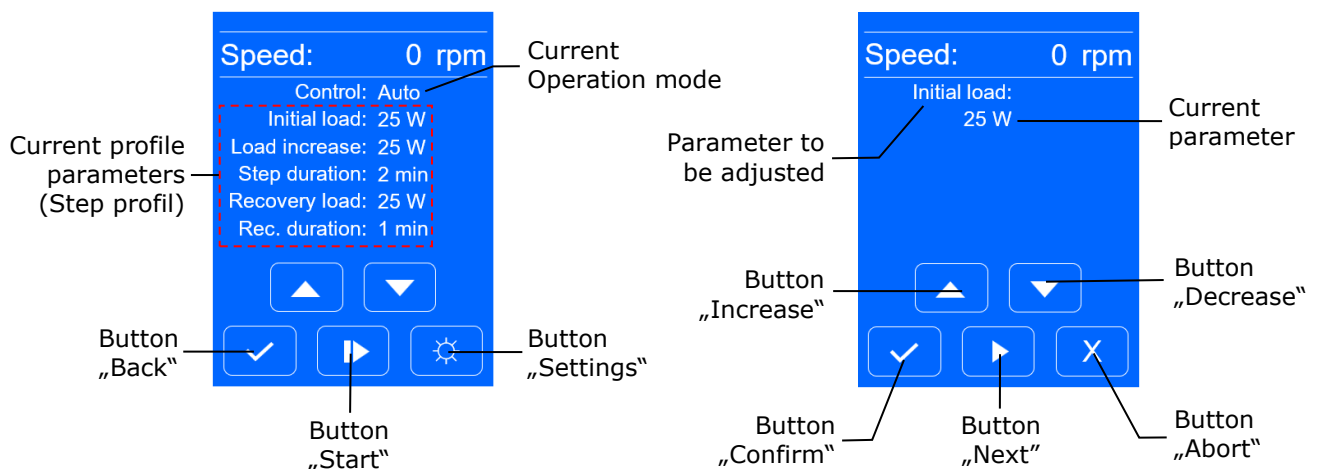
This operating mode enables the load to be increased by the ergometer in constant steps (step height 5-100 watts), on demand of the operator.

Requirements for Automatic Operation

See Chapter 6.2.2 Manual operation.

Definition of a Load program

In order to adjust the parameters of the step program, the white triangle symbol must be pressed in the home display, which takes the user to the selection display for manual / automatic mode. The "Settings" button must be pressed in this display, after which the first profile parameter appears.

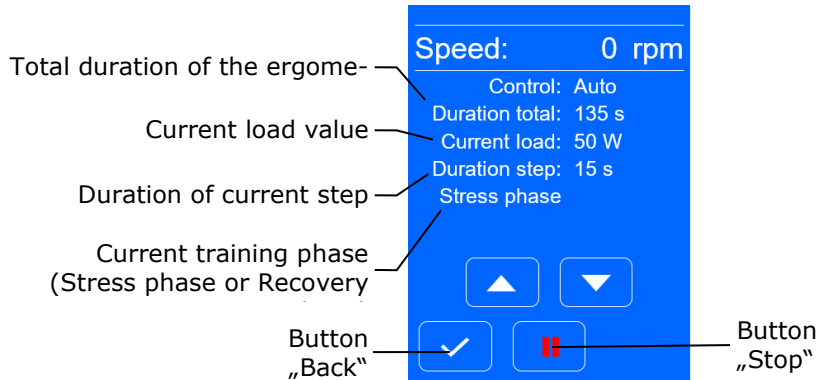


These parameters can be adjusted using the buttons „▲“ (Increase) and „▼“ (Decrease). You can then switch to the next parameter using the button "Next" until all parameters have been run through and the values are accepted by pressing the button "Confirm" or the setting process will be terminated by pressing the button "Abort".

Usage of Automatic operation:

To carry out an ergometry in automatic operation mode, the control mode "Auto" must first be selected. If the profile parameters shown in the display are OK, the button "Start" can be pressed.

After the start of the automatic load program, the display appears with the current load / training parameters and the "Stop" button appears as a red symbol, as a sign that automatic operation is active and the patient can start pedaling.



It is also possible to view the patient's current vital parameters via the home display, for which the button "Back" must be pressed without terminating the ergometry. In this case, the active automatic operating mode is indicated by a red or green triangle symbol ("Operating mode" button) in the menu bar at the bottom right. This symbol can then be used to call up the load control display again.

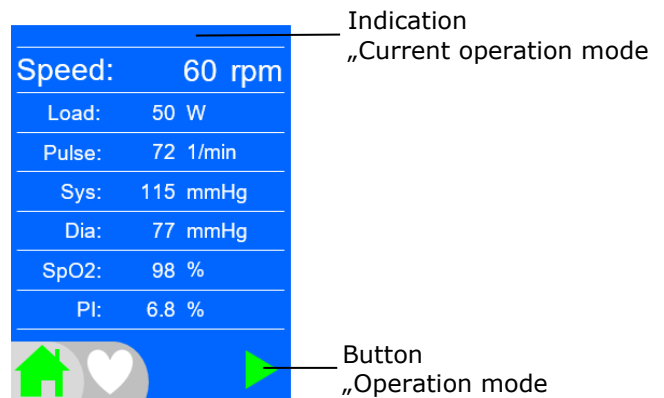
If the ergometer has the additional functions blood pressure measurement or electrical saddle height adjustment, you can switch from the home display to the blood pressure measurement display or the saddle height adjustment display, from where the respective actions can be carried out.

In automatic mode, the load increase takes place continuously with the defined load increase. This can be ended by pressing the button "Stop", whereupon the control changes to the recovery phase in which the load set for this is present.

Note:

→ The last active parameters (load values from previous operation) are retained after the end of the program and may have to be manually reset to the desired value by the user before the next usage.

- Red triangle = Stress phase
- Green triangle = Recovery phase



6.3 Blood pressure measurements during stress tests

According to international agreement, the blood pressure should be measured on the left arm, which is near the heart, as the flow impedance level is lowest there. An exception to this rule is formed by approx. 1 to 2 per cent of test persons on whom the Korotkoff sound cannot be measured due to vascular phenomena. The cuff is placed on the right arm of such patients.

An arm rest is attached to the ergometer for the arm on which the blood pressure is measured. The armrest provides a stable position for the arm to prevent distortion of the result caused by artefacts. Position the arm rest to support the arm in a slightly angled position. It can be mounted on the right or left-hand side of the ergometer.

⚠ Warning!

Please note that the cuff's air tube must be fixed in a way that prevents it from dashing against the ergometer. This is to prevent unnecessary artefacts that might affect the measurement's accuracy.

The ergosana blood pressure measuring unit is equipped with a QRS trigger input for blood pressure measurements during exercise tests.

6.3.1 Applying the cuff

The microphone is indicated in red on the cuff and needs to be positioned so that it lies on the brachial artery, the largest arm artery.

The ideal location for the microphone is approx. 2 cm above the elbow joint on the inside of the arm, below the biceps. The cuff must be put on so it is tight and cannot shift out of position during the movement created during the stress test.

The cuff is inflated rapidly at the start of the measurement. The blood pressure and pulse rate are already roughly measured during pumping and the inflation pressure is determined.

After the systolic pressure value has been reached, the air is released from the cuff at a rate of 3 mmHg per heartbeat.

This procedure guarantees approximately equal measuring times despite the rising pulse rate during exertion.

The blood pressure measurement should not exceed a maximum total length of 45 seconds. A measurement interval of 2 or 3 minutes is preferable in most cases; however, an interval of 1 minute is also available.

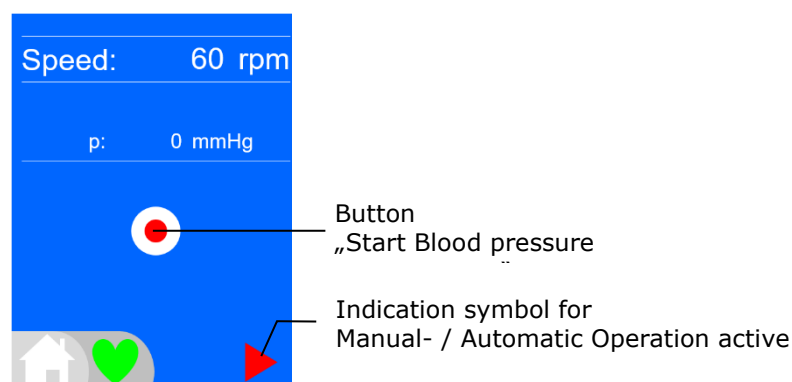
The blood pressure measurements are shown in the "Ergometry" display, together with the load and pulse value.

Note:

→ The air tube needs to be routed over the lower handlebar in a way that prevents it from being touched by the patient while pedalling. Otherwise, artefacts may distort the measurement.

6.3.2 Perform blood pressure measurement manually

In remote operation, the blood pressure measurements are generally controlled by the master device, but they can be triggered by the user in this mode as well as in manual or automatic mode. To do this, switch to the blood pressure measurement display and press the "Start blood pressure measurement" button.



Display Blood pressure measurement

7 Cleaning

7.1 Cleaning the device

The surface of the casing can be cleaned with a soft cloth that is dry or moist. Commercially available cleaning agents for household appliances can be used.

Afterwards all surfaces have to be wiped dry with a dry soft cloth.

- When cleaning the device, it is important to ensure that no water / liquid enters into the device.
- The ergometer shall **never be cleaned** with petrol, nitro cleaner or acetone.

7.2 Disinfection of device

The saddle and the handlebar can be treated with the disinfectant *Incidin Plus fluid* as needed.

For disinfection, the affected parts of the device have to be sprayed with a spray bottle and wiped dry with a soft cloth after a reaction time of approx. 5 minutes.

- When disinfecting the device, it is important to ensure that no liquid enters the device.

7.2.1 Disinfection interval

It is recommended to perform a disinfection in the following situations:

- Daily commissioning
- After use with transpiring, contagious or vomiting patients

7.3 Cleaning of blood pressure cuff

The blood pressure cuff should be cleaned within a certain space of time. It consists of a polyamide textile (blue) or waterproof plastic foil (gray), which can be cleaned with soapy water and a cloth. The water temperature must not exceed 30 °C.

Note:

→ The cuff should only be washed off with soapy water and then dried again immediately. It is not advisable to soak the cuff in soapy water and then wash it, as this can matt the fleece and Velcro straps.

If it should nevertheless be required to wash the cuff in water, the microphone must first be removed, and the air admission pipe must be closed. After washing, the cuff must be dried, and the microphone put back in the pocket.

Important!

- **The microphone shall never come into contact with moisture.**
- **When assembling the cuff, make sure that the smooth side of the microphone is on the side facing the arm.**

Remark:

When using the blood pressure cuff during an exercise the cuff may be soaked by heavy sweat secretion. In order to prevent this, before putting on the cuff in this area, a piece of "fine mesh hose assembly" (Lohmann & Rauscher, Hartmann, ...) can be put over the arm. Which greatly reduces this unpleasant effect.

8 Maintenance and trouble shooting

The ergometer contains a little number of wear parts and can be operated nearby maintenance-free. Therefore, it is sufficient to check the mechanical condition within the scope of the metrological control to be performed regularly. Whether of this, special-duty components in daily operation and safety-relevant components must be observed separately and immediately replaced if damaged, so that a safe operation can be guaranteed. These are for example the pedal loops (Velcro straps) on the pedals, which are to be replaced in case of loss of holding power in order to avoid possible injuries.

8.1 Metrological Check (MTC) and Safety Check (STC)

The unit's measuring technology should be checked every 24 months. The following verification must be performed:

1. Check of the overall mechanical condition of the ergometer
2. Check of correct ergometer rotational speed display and performance range
3. Check of mechanical power loss of the ergometer's drive system
4. Electrical safety check
5. Check of the blood pressure recorder's pressure measuring unit
6. Check for tightness of the pneumatic system
7. Check of the safety symbols and markings on the casing
8. Writing of an inspection report

Warning

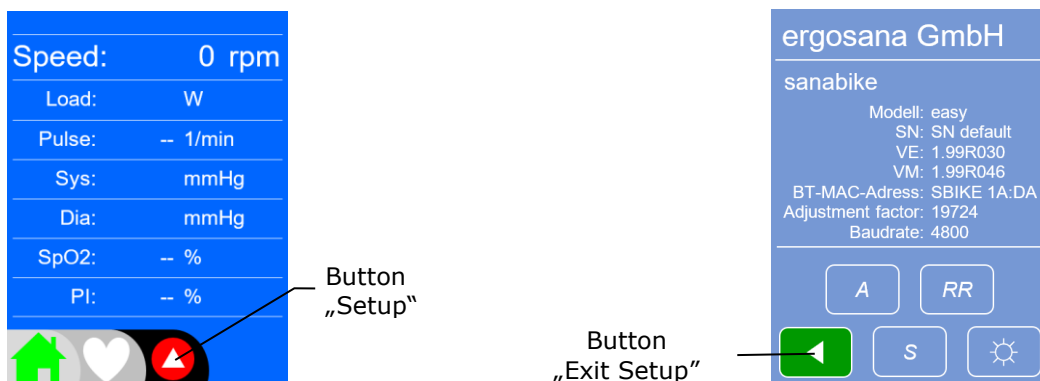
Metrological Checks and Safety Checks as well as any recalibrating work necessary must only be performed by authorized and trained personnel with the special tools required for this purpose.

8.2 Configuration

Deviations of the load control, blood pressure measurement or electrical saddle height adjustment detected during maintenance or MTC and STC can be readjusted in the configuration menu. To do this, the button "Setup" must be pressed, which will be visible for a period of 5 seconds in the menu line at the bottom right.

Warning!

The settings may only be carried out by trained service staff, which is why these activities are not described further in this user guide. Contact the specialist dealer in your area for this.



8.3 Checking and setting the supply voltage

On delivery, the unit is set for the local supply voltage (115 VAC or 230 VAC). The current voltage setting is recorded on the mains module.

 **Warning!**

- **To change the supply voltage, the device must first be disconnected from the supply voltage.**
- **Voltage conversion must only be performed by trained electricians.**

After the device is disconnected from the power supply, open the power supply cover on the bottom of the unit.

The voltage can then be changed on the power supply board with a special voltage selector switch.

8.4 Changing a mains fuse

 **Warning!**

- **To change fuses, the device must first be disconnected from the power supply voltage.**
- **Fuses must only be replaced by trained electricians.**

The fuse switch is located in the center of the mains module. The lid can be prized out of its lock-in position with the help of a small screwdriver. It can then be pulled out of the fuse compartment. Two fuses are located in the fuse switch. After a continuity check, change the fuses if necessary. Return the fuse switch to the well and press it into the lock-in position.

Replace fuses only with other fuses of the same type with the same specifications.
(2x 2,5 AT for 230 V and 2x 3,25 AT for 115 V)

8.5 Eliminating electromagnetic interferences

The unit is only designed for operation in the following electromagnetic environment:


Radio frequency emission according to CISPR 11, group 1, class B.

Group 1 means that the ergometer uses HF energy exclusively for its internal function. Therefore, HF emissions are very low and interferences with electronic devices nearby are unlikely.

Class B means that the ergometer is suitable for use in any facilities including residential areas, even if it is directly connected to the public mains that also supplies residential buildings.

The unit is resistant to jamming in an electromagnetic environment if the following prerequisites are met:

- The voltage corresponds to the typical business or hospital environment in which the humidity should be at least 30%, especially if the floors are synthetic.

If any disorders should occur nevertheless, especially in the vicinity of devices labelled with the symbol  "non-ionic electromagnetic radiation", check the recommended minimal distance according to the following table. More information is given in the service manual.

Recommended safety distances between portable and mobile HF telecommunication devices and the ergometer.

The ergometer is designed for operation in an electromagnetic environment with controlled HF disturbance. The customer or user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the ergometer, depending on the output performance of the communication device as indicated below.

Recommended minimal distance between the telecommunication devices and the ergometer.

Device/HF-Source	Standard	Rate [MHz]	Rated power Transmitter [W]	Distance [m]
Baby phone		27-41	0.1	0.37
Walkie-talkie (rescue service, police, fire brigade, service)		81-470	5	2.6
Mobile radio system (rescue services, police, fire brigade)		81-470	100	11.7
Walkie-talkie	GMRS 460, FRS 460	430-470	2	0.3
Mobile phone	LTE Band 13, 17	704-787	0.2	0.3
Mobile phone	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	800-960	2	0.3
Cordless DECT telephone, WLAN, UMTS phone	GSM 1800, CDMA 1900 GSM 1900 DECT; LTE Band 1,3,4,25 UMTS	1700-1990	2	0.3
Bluetooth, WLAN systems (wireless mouse, wireless keyboard, handsfree set)	802.11 b/g/n, RFID 2450, LTE Band 7	2400-2570	2	0.3
WLAN systems	802.11 a/n	5100-5800	0.2	0.3

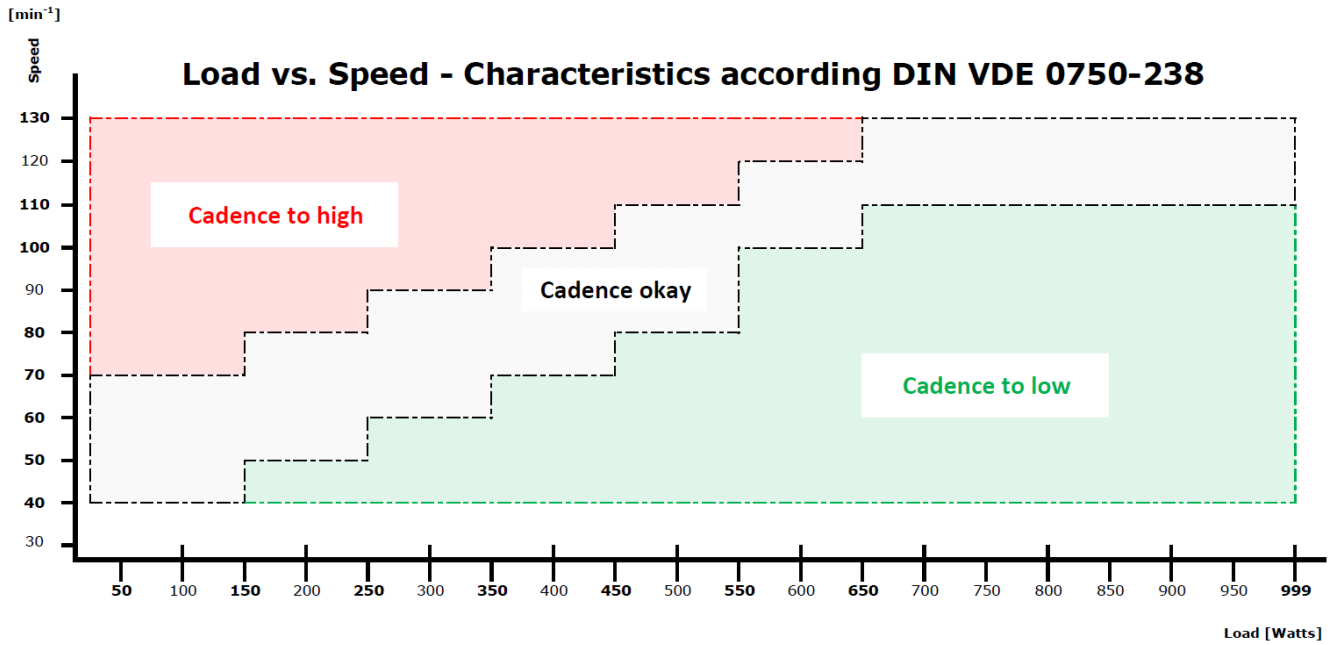
8.6 Disposal

Devices that are no longer usable can be returned to ergosana for disposal. Alternatively, the device can be taken to an approved disposal location.



There is a backup battery in the control unit, which must be disposed of separately.

9 Characteristics for the braking moment control



10 Technical Customer Service

The products are sold by authorized agents (Schiller). The agents are trained in the service of the devices. Please contact one of the local agents if your device requires servicing.

If this is not possible, please contact the manufacturers service department.

Service department ergosana

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