Bike ergometer SanaBike 1000

User guide

* The picture may differ slightly from the original product

CE Conformity Declaration

Ergosana GmbH herein declare that the ergometer SanaBike 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

CE 0123

Manufactured by:

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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 SanaBike 1000 bicycle ergometer is a high-performance ergometer that is intended to be used for remote operation (training program provided by PC, ECG unit or similar). If no master device is available for remote operation, there are options for manual operation, in which the operator sets the load manually in 5 watt steps via the display, or automatic operation in which the load increase is based on a User-specified step profile runs.

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 Electrical Seat height adjustment
3rd SpO_2-Measurement
4th Bluetooth- or WLAN-interface (to Master device)
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
- Stable steel construction, compact drive unit
- Stable position thanks to a larger base (optionally, additional tilting protection is available)
- Stable clamps on saddle and handlebars
- Infinitely variable height adjustment of handlebar and handlebar pipe
- Infinitely variable saddle height adjustment (optionally: electrical adjustment)
- Standardised saddle pipe (change of saddle possible at any time)
- Impact- and scratch-resistant casing, easy to clean
- High-performance control electronics
- Touch display showing the current ergometry data
- 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 pedalling sensation due to large gyrating mass
- Galvanically isolated RS232 interface for secure data transfer (optional Bluetooth™)

1.1 Intended use

The SanaBike 1000, which belongs to the product family of bicycle ergometers, is intended for accurate physical exertion tests to conduct measurements in cardiovascular and pulmonary function diagnostics. Moreover, they are intended to build up the circulation of patients who have suffered a cardiac infarction and are in rehabilitation phase III.

The devices are used in medical practices, clinics, therapy and rehabilitation as well as sports performance centres, where they are to be operated by doctors, 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 ischaemia (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 hypertonia (high blood pressure)
- Following a myocardial infarction, for the assessment of prognosis, physical activity, medication and cardiac rehabilitation
- Before and after a revascularisation (restoration of the blood supply) using interventional techniques or aortocoronary bypass surgery, to assess any remaining ischaemia
- 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 tachy-cardia 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
- roof of undesirable pro-arrhythmic effects – amplification of arrhythmia during anti-arrhythmic therapy
- Measuring the physical exercise capacity of high-performance athletes/competitive athletes

1.2.1 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 haemodynamics
- 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

1.3.1 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:

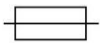
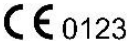
- moderate to serious angina pectoris (painful chest tightness), dyspnoea (shortness of breath), cyanosis (blue coloration of the skin or mucous membrane), dizziness, cold sweat, ataxia or exhaustion
- ST depression ≥3 mm or ST elevation ≥1 mm
- persistent ventricular tachycardia (>30 sec.)
- fall in blood pressure >10 mmHg with signs of myocardial ischaemia (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 ischaemia (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 (DIN EN ISO 60601-1):

	Supply voltage 230 V 50 Hz / 115 V 60Hz (refer power plug module) Safety class I		Maximum Patients weight
	Fuses within power plug module (refer chapter 3)		Warning! Follow the instructions in the documentation
	BF-classified applied part		CE-marking acc. 93/42 EEC of notified body TÜV Süd Product Service
IPX1	Protection class of casing against water		Manufacturer
	Potential equalisation connection (earth)		Date of production
REF	Article-No. / Device type	S/N	Serial-No. of 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 supervision of the operator A = Accuracy class A
Braking principle	Computer-controlled brakes with permanent measurement of torque and braking performance which is independent of revolutions per minute
Performance/ load range	- 1 to 20 watts (range is dependent of revolutions per minute) - 20 to 999 watts (range is independent of revolutions per minute)
Load precision	DIN VDE 0750-238
Long-term accuracy	Continuous torque control and equalisation according to weight
Control range (independent of revolutions per minute)	30 to 130 rev/min
Load parameters	- Externally by a master device (PC, ECG, …), in steps 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	45 x 83 cm
Weight	54 kg
Max. power consumption	28 watts
Admissible patient data	Patients with - a max. weight of 160 kg (200 kg with additional tilting protection) - a height between 120 and 210 cm (optional: electrical saddle height adjustment)
Pulse measurement	1. Via blood pressure measurement unit, or optionally via pulse monitoring system (for ex. Polar) 2. ECG (master device 3. Chest belt ECG (SanaBlue) / 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.
SpO_2- 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 (-10°C–+50°C).
- The ergometer shall not be exposed to direct sunlight or hear for extended period of time.

2 Safety notes

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 initial operation, the device must be adjusted using the base adjustors at the back to grant absolute stability.
- When the saddle is exchanged, make sure that the screws at the saddle are tightened hard enough so that the saddle cannot be moved on the saddle pipe.
- To move the handlebars and saddle, loosen the clamps and retighten them well afterwards. It is recommended to position the clamps with the levers positioned downwards. Secure clamping is ensured when the clamps are again turned to this position after every adjustment.
- When the patients mounts/dismounts, the therapist/physician needs to make sure that the patient's feet do not get trapped in the pedal straps.
- The holding straps on the pedals must fit perfectly across the upper side of the shoe and be fastened with a Velcro strap.
- For patients who weigh more than 140 kg or are taller than 190 cm, the separately available tilting protection is recommended.
- For patients weighing more than 160 kg, the additional tilting protection is mandatory.

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 galvanically isolated to ensure the patient’s safety.
- External devices must only be connected using an interface cable supplied by the manufacturer.
- 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 the power plug disconnected before cleaning with liquid cleaning agents.
- Only use standard cleaning agents for plastic surfaces.
- The unit may only be opened, repaired and serviced by authorised and trained personnel. If the unit is opened inadmissibly, the warranty becomes void.

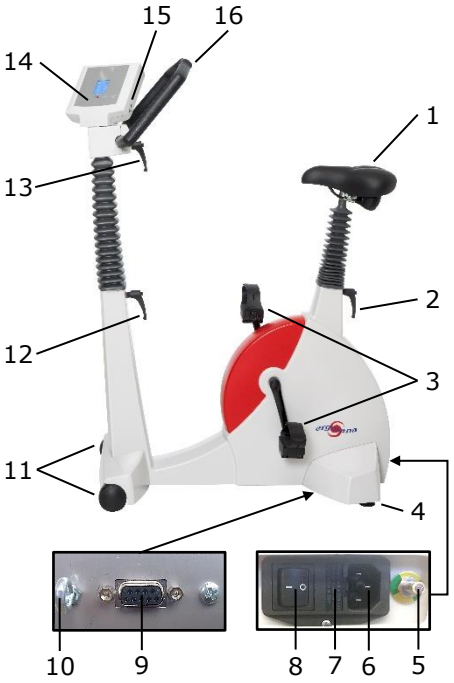
2.4 Interference

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



1. Saddle
2. Clamp for saddle height adjustment
   (only at manual saddle height adjustment)
3. Pedal cranks with pedals and safety straps
4. Base adjuster for adjustment of the device
5. Potential equalization socket
6. Power supply socket
7. Fuse box
8. Master switch of ergometer
9. RS232-interface (underneath left-hand side cover)
10. Cable relief RS232-Cable
11. Running gear
12. Clamp for handlebar pipe adjustment
13. Clamp for handlebar adjustment
14. 180° rotatable console with touchscreen display and rpm display
15. Connectors for blood pressure cuff / SpO_2 sensor,
    USB-charging socket (see chapter 3.3)
16. Handlebar

3.1 Accessories and optional functions

Standard accessories: (part of each device)

- Mains cable
- User guide
- 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)
- SpO_2 finger sensor / on customer request ear sensor (if option SpO_2 measurement is available)
- Chest strap ECG
- Pulse transmitter POLAR H10
- Tilt protection
- Tablet PC
- Tablet holder

Optional device functions:

- Blood pressure measurement
- SpO_2-Measurement
- Electrical seat height adjustment
  Bluetooth interface (to Master device)
- Stand-Alone-Function (Ergometry- and Reha-Training function with App „ErgoSmart")

3.2 Potential equalisation

A standard potential equalisation 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 equalisation 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 equalisation. **No additional** earth cable should be connected in this case.

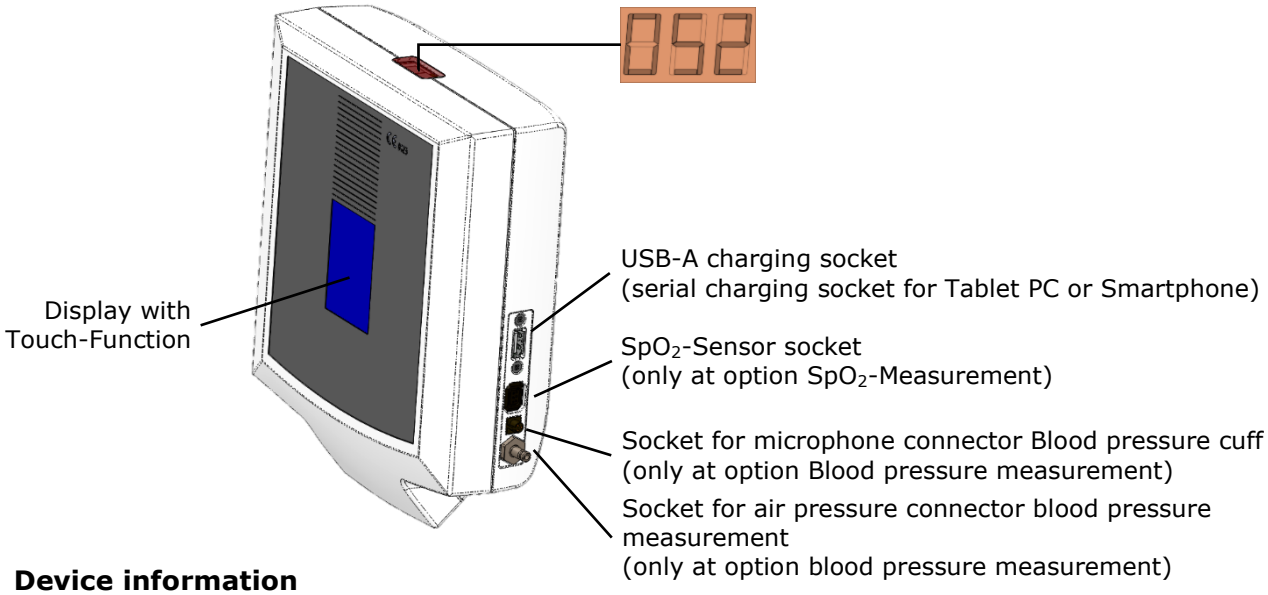
3.3 Control unit (Measuring Head)

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.

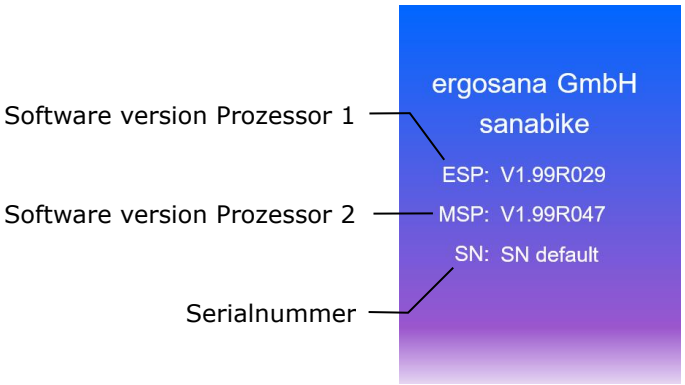
At the top of the console, a 7-segment display shows the current revolutions per minute of the pedals.

At the right side of the control unit there is a USB charging socket (5.0 VDC) and, depending on the equipment of the ergometer, connections sockets for a blood pressure cuff and an SpO_2 sensor.



3.4 Device information

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



3.5 Blood pressure measurement 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 socalled 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.

3.5.1 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.

3.6 SpO_2 Measuring unit

The measurement of the SpO_2 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.

3.6.1 SpO_2 Sensor

Devices with the option SpO_2 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 2).
- 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 vapours 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.

4.2 Assembly instructions

4.2.1 Unpacking and assembling

Pull the saddle and handlebar column to normal height, adjust the clamp lever downwards after fixing the saddle and handlebar pipe in place. To do so, pull the clamp outwards, position and then release.

With the help of the base adjustors on the lower rear side of the ergometer, adjust the device so that there is no gap between the ergometer and the floor, and the ergometer is stable. Ensure the ergometer is placed on a non-slip surface.

4.2.2 Connecting

Plug the supplied power cord into a grounded socket. If there is no earthed socket, equipotential bonding must be established (see chapter 3.2). 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.

4.2.3 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 right-hand side of the console (see chapter 3.3). 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 micro-phone is connected to the other socket; use the guiding slot for correct positioning.

4.2.4 Connecting the SpO_2 sensor

As regards ergometers with the optional feature SpO_2 measurement, the interface for the sensor is located on the right-hand side of the console (see chapter 3.3). The orientation of the SpO_2 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 120 cm and 210 cm and / or the application.

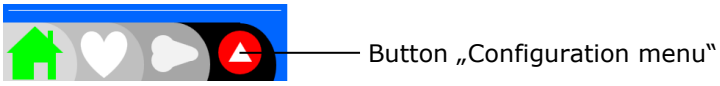
5.1 Language selection

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.

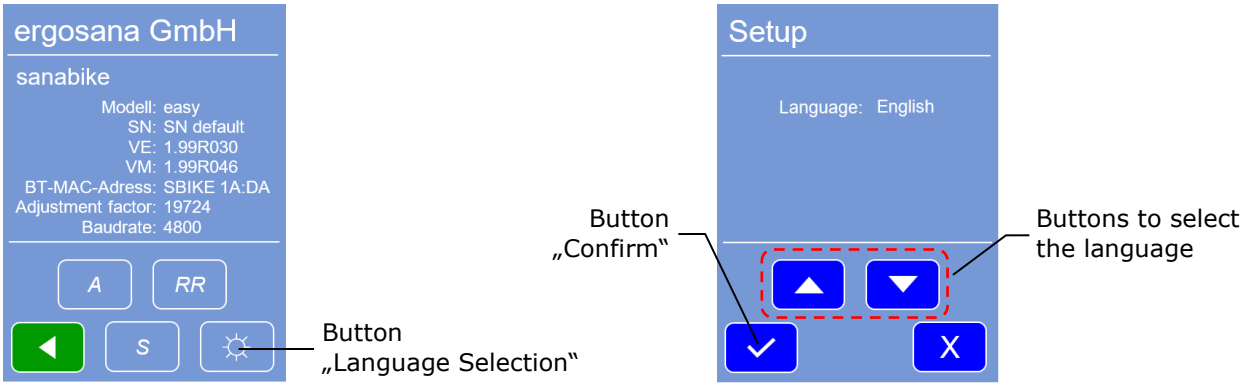


Note:

➜ 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 language selection buttons and accepted with the Confirm button.



5.2 Adjustment of saddle and handlebar height

Before the start of each training session, the sitting position needs to be individually adjusted to the patient. To do so, the saddle height and handlebar position can be continuously adjusted, whereby the following points must be observed.

Adjusting of saddle position

- The saddle needs to be in a horizontal position
- To set the correct saddle height, the patient needs to be sitting on the saddle and touching the pedal with their **heel** when the leg is fully stretched and the pedal in the lowest position

Adjusting the handlebar position

- To set the correct handlebar position, the patient needs to grab the handlebar with arms stretched while the upper body is slightly tilted forward (angle of approx. 10°)

Ergometer adjustment with patient

Pedal in the lowest position

5.2.1 Manual Saddle height adjustment

To adjust the saddle height, the clamping of the seat post must be loosened with the clamping handle on the back of the ergometer. The seat post can then be moved continuously into the required position (see chapter 5.2) and the clamping handle tightened again.

The saddle clamp is designed for patients weighing up to 200 kg. To attain optimal clamping action, only moderate strength is needed to tighten the clamps. It is recommended to adjust the clamp handle in clamped position, with the handle positioned vertically downward. Use this position of the clamp for further reference to ensure secure clamping.

Note:

➜ In order to be able to adjust the grip position without releasing the clamp, the grip must be unlocked by pulling it back from its locking mechanism. The handle can then be turned to the desired position and simply released, after which it will lock itself again automatically.

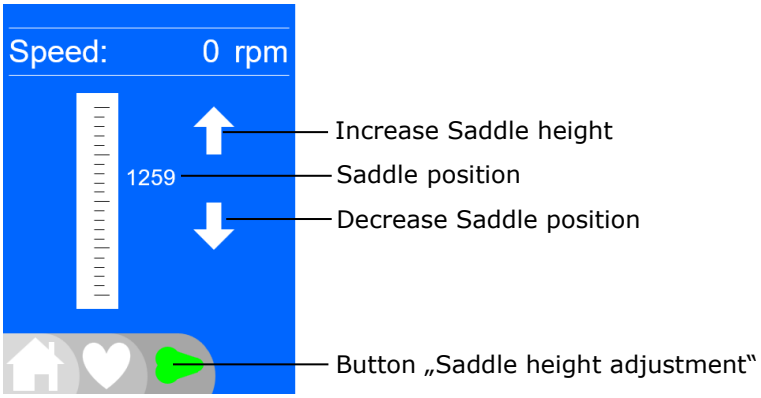
5.2.2 Motorized saddle height adjustment

If the device is equipped with the optionally available saddle height adjustment, the saddle height can be easily adjusted via the touch display.

To do this, call up the operating display for the saddle height adjustment on the touch display by pressing the button "*Saddle height adjustment*" in the menu bar at the bottom of the screen. On the right side of this display there are two arrow buttons that can be used to adjust the saddle height.

Note:

➜ When adjusting the saddle to a higher position, it is recommended to relieve the hoist motor by shifting the body weight onto the pedals.



Saddle height adjustment screen

5.2.3 Manual handlebar adjustment

The handlebar position can be adjusted in two places by moving the handlebars and turning the handlebar grip in order to achieve the patient's position described in Chapter 5.2.

To adjust the handlebars, loosen the clamp with the clamp grip underneath the bellows and retighten it after positioning.

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To attain optimal clamping action, only moderate strength is needed to tighten the clamps. It is recommended to adjust the clamp handle in clamped position, with the handle positioned vertically downward. Use this position of the clamp for further reference to ensure secure clamping.

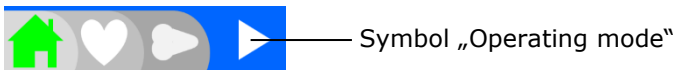
Note:

➜ In order to be able to adjust the grip position without releasing the clamp, the grip must be unlocked by pulling it back from its locking mechanism. The handle can then be turned to the desired position and simply released, after which it will lock itself again automatically.

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, EKG, ...) 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.

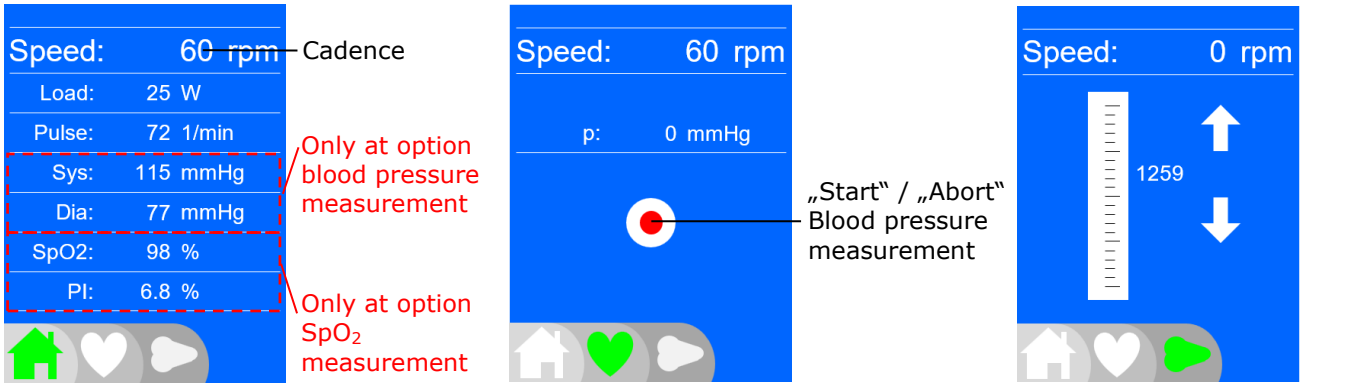
6.1 Displays and operation

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)
- "*Saddle height adjustment*" display to adjust the saddle height electrically (only if option electrical saddle height adjustment is available)

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



Display Ergometry *Display Bood pressure measurement* *Display Saddel height adjustment*

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

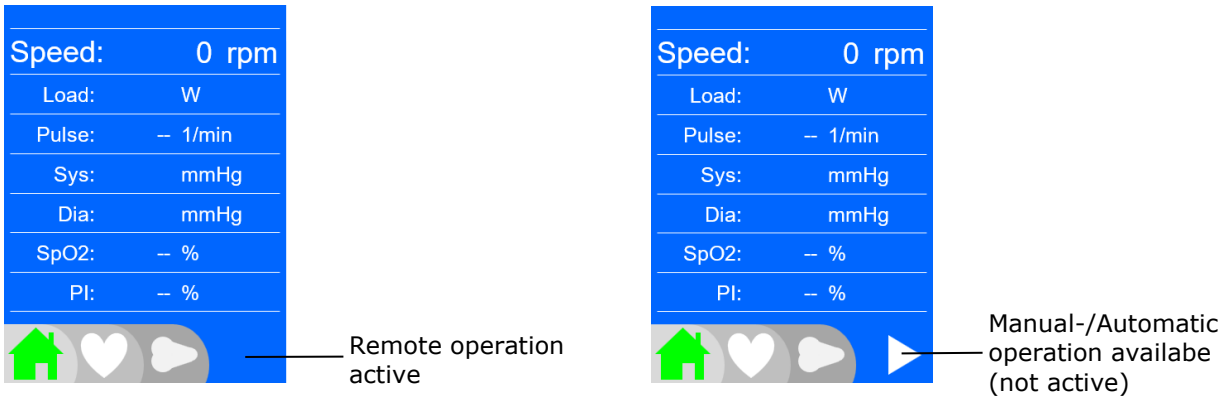
In addition to the standard remote operation, the load can also be defined manually by the user in steps of 5 watt on the ergometer.

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.

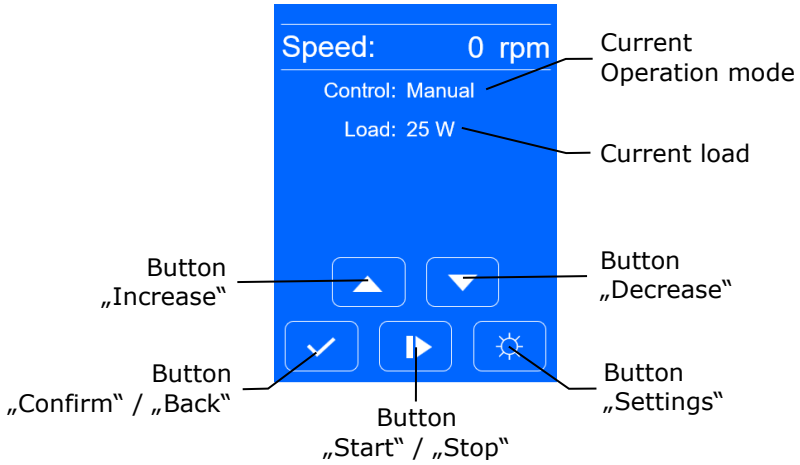


Start of Manual operation and Load adjustment:

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

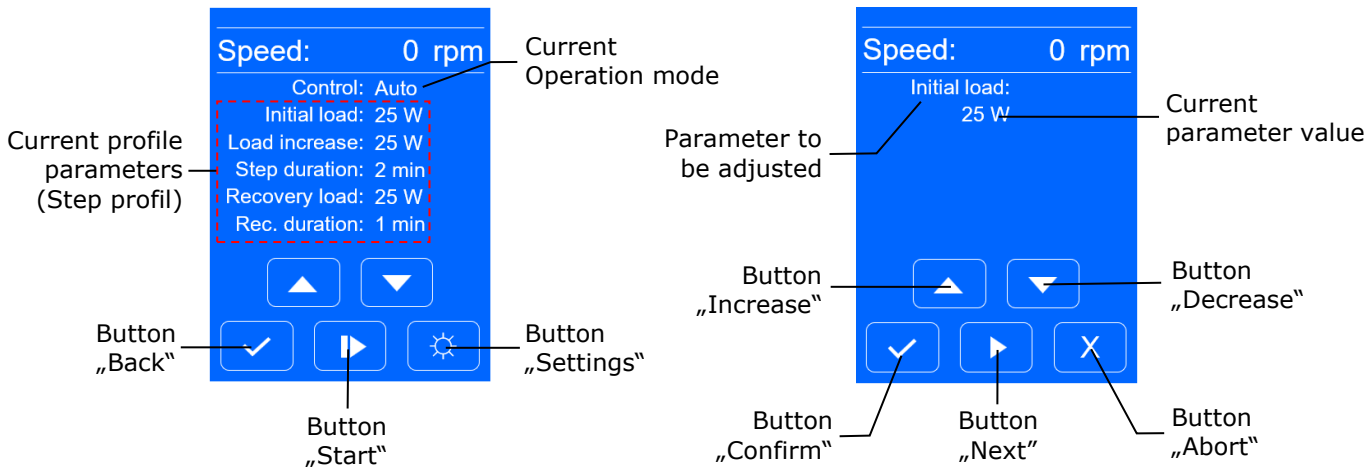
This operating mode enables the load to be increased by the ergometer in constant steps (step height 5-100 watts), on demand of the operator.

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.

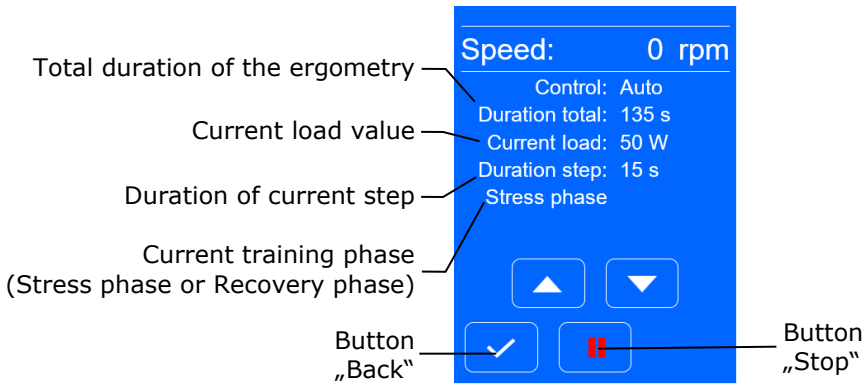


These parameters can be adjusted using the buttons „▲“ (*Increase*) and „▼“ (*Decrease*). You can then switch to the next parameter using the button “*Next*” until all parameters have been run through and the values are accepted by pressing the button “*Confirm*” or the setting process will be terminated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

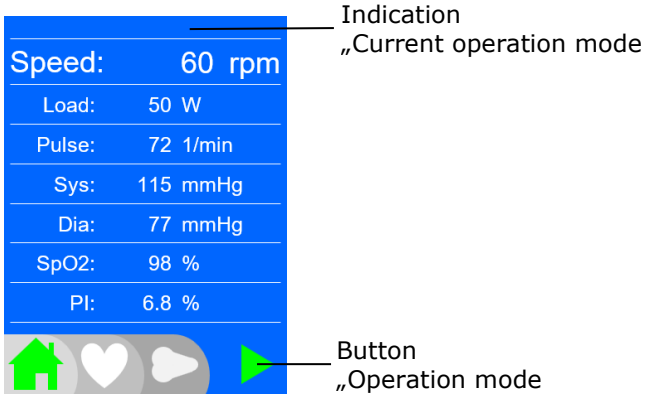
If the ergometer has the additional functions blood pressure measurement or electrical saddle height adjustment, you can switch from the home display to the blood pressure measurement display or the saddle height adjustment display, from where the respective actions can be carried out.

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 ap-prox. 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.

⚠ **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 al-ready 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.

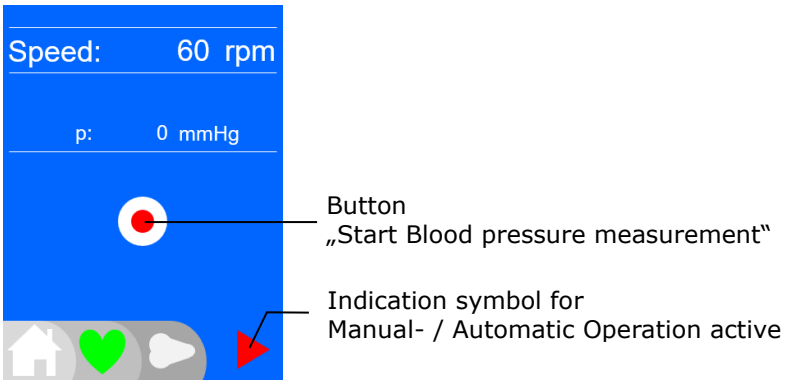
The blood pressure measurement should not exceed a maximum total length of 45 seconds. A measurement interval of 2 or 3 minutes is preferable in most cases; however, an interval of 1 minute is also available.

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 Bood 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 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 tex-tile (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

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. Display check (contrast, lighting, etc.)
3. Check of correct ergometer rotational speed display and performance range
4. Check of mechanical power loss of the ergometer's drive system
5. Electrical safety check
6. Check of the blood pressure recorder's pressure measuring unit
7. Check for tightness of the pneumatic system
8. Check of the safety symbols and markings on the casing
9. Writing of an inspection report

⚠ **Warning!**

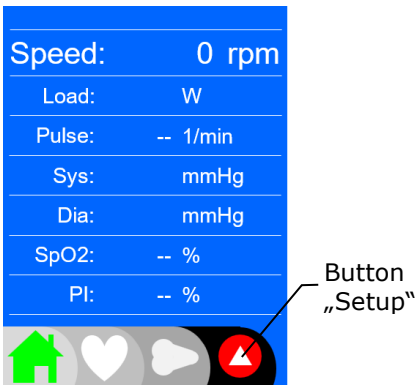
Metrological Checks and Safety Checks as well as any recalibrating work necessary must only be performed by authorised and trained personnel with the special tools required for this purpose.

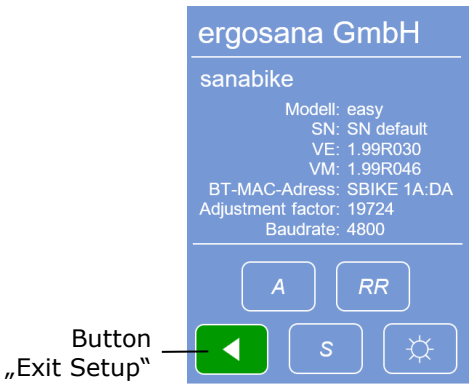
8.2 Configuration

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 centre of the mains module. The lid can be prised out of its lock-in posi-tion with the help of a small screwdriver. It can then be pulled out of the fuse compartment. Two fuses are locat-ed 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 1,25 AT für 230 V und 2x 2,5 AT für 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 emis-sions 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.

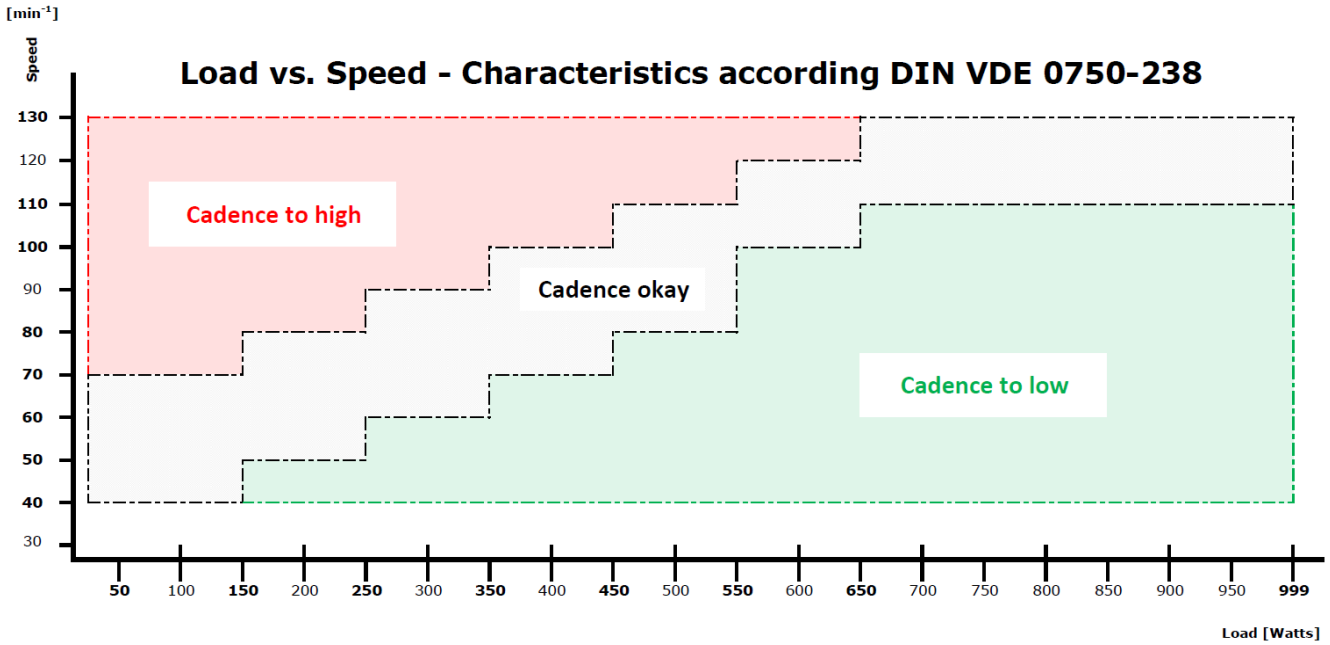
Device/HF-Source	Standard	Rate [MHz]	Rated power Transmitter [W]	Distance [m]
Baby phone		27-41	0.1	0.37
Walkie-talkie (rescue service, police, fire brigade, service)		81-470	5	2.6
Mobile radio system (rescue services, police, fire brigade)		81-470	100	11.7
Walkie-talkie	GMRS 460, FRS 460	430-470	2	0.3
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

Ergosana products are also sold by authorised agents with their own brand name. The agents are trained in the service of our devices. Please contact one of these specialist dealers if your device requires servicing.

If this is not possible, please contact the company's central service department:

Ergosana service department

ergosana GmbH
- Service -
Truchtelfinger Str. 17
D-72475 Bitz

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