



Bike ergometer SanaBike 500 - easy

User guide



CE Conformity Declaration

ergosana GmbH herein declare that the medical products (Class IIa) of the ergometer system SanaBike 500 "easy" comply with the relevant requirements of the EC medical devices directive 93/42/EEC, Annex I.

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, DEKRA, and bear the marking



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A handwritten signature in blue ink, appearing to be "D. Beck".

Dieter Beck
Managing director, ergosana GmbH

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1 Allgemeines

The bike ergometer SanaBike 500 „easy“ is a modern high-performance ergometer and is intended to be used for remote operation (training programs provided by PC, ECG unit or similar). Alternatively, it may also be operated in manual mode, in which the load can be changed by the user in steps of 5 Watt on the display.

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 handle bars
- Infinitely variable height adjustment of handle bar and handle bar 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)
- Performance 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 RS-232 interface for secure data transfer

1.1 Intended use

Medical ergometers like the bike ergometer SanaBike 500 are 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 practices, clinics, therapy and rehabilitation as well as sports trainings centres 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 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 hypertension (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 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

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 hypertension 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 s)
- 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 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.

1.6 Maintenance

This is a low-maintenance device. You will find detailed maintenance instructions in chapters **Fehler! Verweisquelle konnte nicht gefunden werden.** and 0.

2 Product description

The ergometer SanaBike 500 easy is intended for remote operation together with a master device (PC, ECG unit or similar). It may also be operated in manual mode, where the load can be defined in steps of 5 watts by the user.

The colour touchscreen in the console shows the current measurement results as well as the manual load control.

2.1 Device components

1. Handle bar
2. Saddle
3. Clamp for saddle height adjustment
4. Main switch ergometer, mains connection, potential equalisation and RS-232 interface (accessible from the back)
5. Base adjuster for height adjustment
6. Pedal cranks with pedals and safety straps
7. Running gear
8. Clamp for handle bar adjustment
9. 180° rotatable console with touchscreen display and rpm display



2.2 Accessories

Every device comes with:

- Mains cable
- User manual
- Inspection report

2.3 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.

2.4 Technical specifications

Drive mechanism	Almost noiseless and maintenance-free, with Poly-V belt (no chain)
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 500 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 - Manually on the ergometer, in steps of 5 watts
Display	Touch display (57x43 mm)
Power supply	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	RS-232 (galvanically isolated)
Length of pedal crank	172.5 mm (double length of pedal crank: 345 mm)
Base dimensions	45 x 83 cm
Weight	46 kg
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	1. ECG (master device) 2. via Polar pulse monitoring

2.5 Signs and symbols

In this section, the signs and symbols used in connection with this device are explained:



Mains operated, alternating current



Potential equalisation connection (earth)



BF-classified applied part



Warning! Follow the instructions in the documentation.



CE-marking acc 93/42 EEC
of notified body DEKRA

IPX0

Protection class of the casing: IPX0

3 Installation

3.1 Location

- Install the device in a suitable position (refer to safety instructions in section 0).
- 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.

3.2 Assembly instructions

3.2.1 Unpacking and assembling

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



With the help of the base adjusters 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.

3.2.2 Connecting

Establish potential equalization (refer to section 2.3) and plug the supplied mains cable into an earthed socket. As the device is preset to the local mains voltage (refer to section I 9.2), you can switch it on using the main switch on the rear side.

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

Note:

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

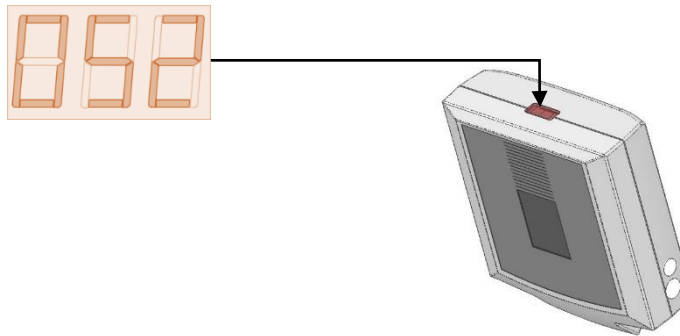


4 Unit components

The console mounted on the handle bar is rotatable by 180°. Depending on the application, it can be facing either the examiner or the user.

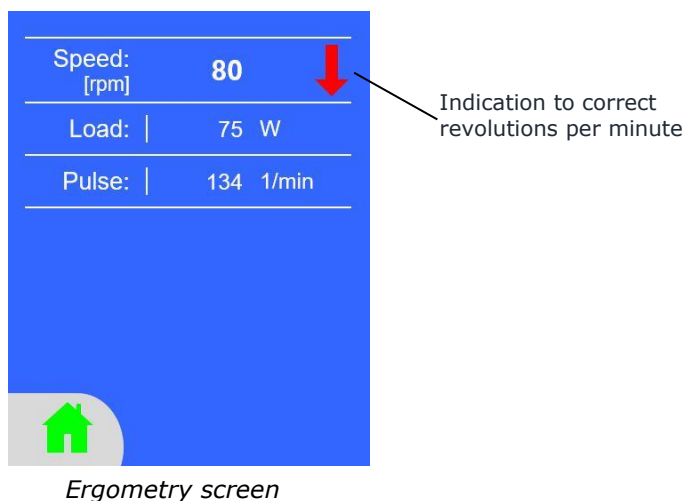
At the front, a high-resolution touchscreen provides all important information at a glance as well as all elements to control and program the ergometer.

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



4.1 Displayscreens

A foil-covered touchscreen (57 x 43 mm) is located at the front of the console. Depending of the range of functions of the ergometer, the display shows on to three different screens, which shows all important ergometry data and allows to the control the functions of the ergometer. Moreover, when performance is 30 watt or higher, a red arrow indicates if the correct range of revolutions is exceeded.



4.2 Setting the language

The device is delivered with the selected language; however, the language can be changed by a service technician at any time. The following languages are available.

- German
- English
- French
- Italian
- Spanish

4.3 Adjusting the saddle height and handle bars

The saddle can be adjusted upwards or downwards for optimal exercise position. It can be adjusted for heights between 120 and 210 cm.

T-handles that protrude from under both the handlebar and saddle pipe are used for adjustment (for manual saddle height adjustment). After loosening the respective T-handle, the saddle rod can be moved up or down to the desired height. When the adjustment is finished, the clamp needs to be 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 T-handles in clamped position, with the handle positioned vertically downward. The clamp can be unlocked by pulling back the handle from its lock. Once the clamp is unlocked, it can be turned to the desired position and simply released, after which it will lock itself again automatically. Use this position of the clamp for further reference to ensure secure clamping.

In the same way, use the clamp to optimally position the ergonomic handle bar.




5 Safety notes

5.1 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 adjusters 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 handle bars 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.

5.2 Safety precautions when operating with other devices

- When several devices are coupled, there is a risk that the leakage currents may add up.
- The RS-232 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 0).

5.3 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.

5.4 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 section 0).

6 Initial operation

Once the ergometer has been prepared as detailed in chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**, it can be connected to a master device (ECG, PC or similar).

6.1 Ergometer adjustment

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 adjusted (see chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**); the following needs to be observed.

Adjusting the 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

7 Operation modes

7.1 Remote operation

When the load is automatically controlled by an exercise/training program, this is done by the ergometry control program of an external master device such as PC, ECG unit or similar, depending on the application.

7.1.1 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 **Fehler! Verweisquelle konnte nicht gefunden werden.**
- the ergometer needs to be connected to the master device via an interface (RS232, WLAN, Bluetooth). (Note: For patient safety, the RS-232 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).

7.2 Manual operation

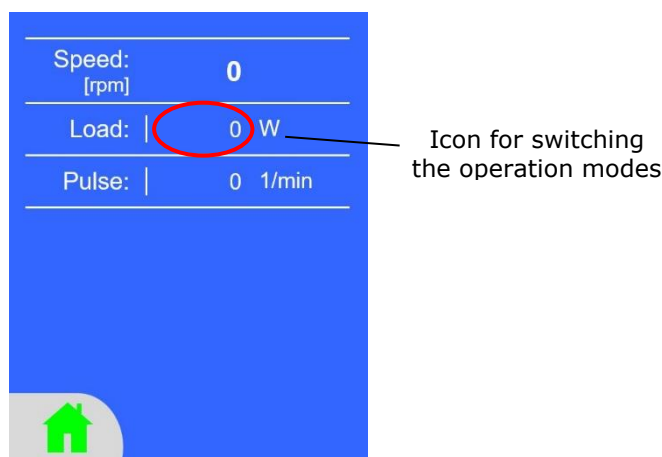
In addition to the standard remote operation, the load can also be defined manually by the user in steps of 5 watt on the ergometer, which is described in this chapter.

7.2.1 Requirements for manual operation

For performing an ergometry manual, the ergometer should be justified individually to the patient acc. section **Fehler! Verweisquelle konnte nicht gefunden werden.**

7.2.2 Change into manual operation mode

Switching to manual operation mode and back to remote operation is done via the standard display „ergometry screen“. By pressing the display in the range of the current load value, the „Manual Operation“ screen will be displayed to start and manually adjust the load.

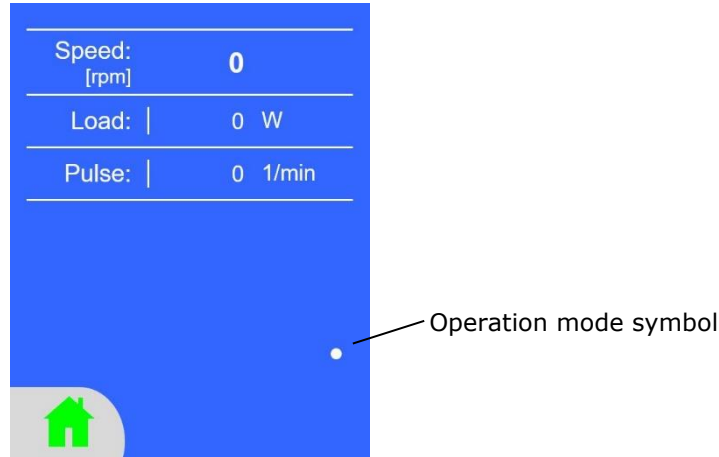


Standard display „ergometry screen – remote operation“

When pressed, the screen changes to manual mode to manually control the load with the default start value of 25 watts or the last defined load value. This value can be changed by the user by means of the two arrow symbol buttons "down" and "up" in increments of 5 watts.

Which operating mode is currently activated will be shown by a circle symbol on the right side of the display below the ergometry data.

- No or red dot = Load will be defined by master device (Remote operation)
- White dot = Load will be defined by the user (Manual operation)



Standard display „ergometry screen – manual operation“

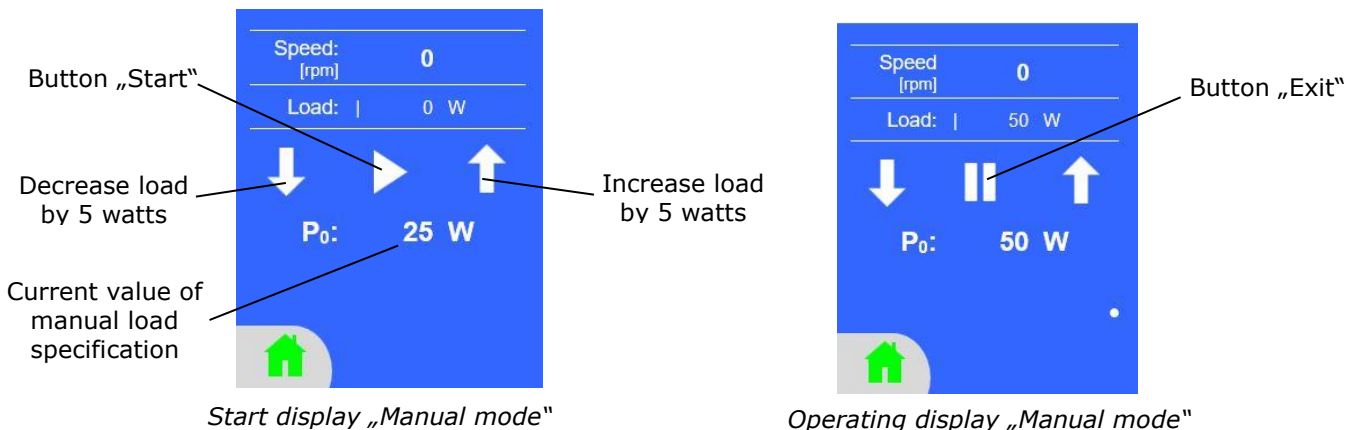
Note:

While manual operation is active, the automatic control by the master device is deactivated. Here, the current ergometry data will be transmitted from the ergometer to the master device but commands of the master device will be not accepted.

7.2.3 Starting, adjusting and terminating manual operation mode

The manual load definition will be started by activating the button „Start“ in the middle of the display, whereupon the manual defined load will be activated. A white dot at the lower right side signalize the activation of the manual operation mode. This dot is shown during the manual mode is active. If there is no dot or a red dot visible, the ergometer is in remote operation wherein the load control will be performed by a master device.

The manual mode can be terminated by pressing the „Exit“ button the touch display.



Start display „Manual mode“

Operating display „Manual mode“

8 Cleaning

8.1 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.

8.2 Disinfection

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

8.2.1 Disinfection interval

It is recommended to perform a disinfection in the following situations

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

8.2.2 Procedure

Wipe the saddle and/or handle bar thoroughly with Incidin plus and let it work in for 5 minutes. Then rub dry with a soft cloth.

- Make sure that no liquid penetrates the device.
- The device should never be cleaned with petrol, nitro cleaner or acetone.

9 Maintenance and trouble shooting

9.1 Messtechnische Kontrollen (MTK) und Sicherheitstechnische Kontrollen (STK)

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!

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

9.2 Checking and setting the supply voltage

On delivery, the unit is set for the local supply voltage (110 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.

9.3 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 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 1,25 AT for 230 V and 2x 2,5 AT for 110 V)

9.4 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 SanaBike 500 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 SanaBike 500 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 SanaBike 500.				
The ergometer SanaBike 500 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 (senders) and the ergometer SanaBike 500, 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

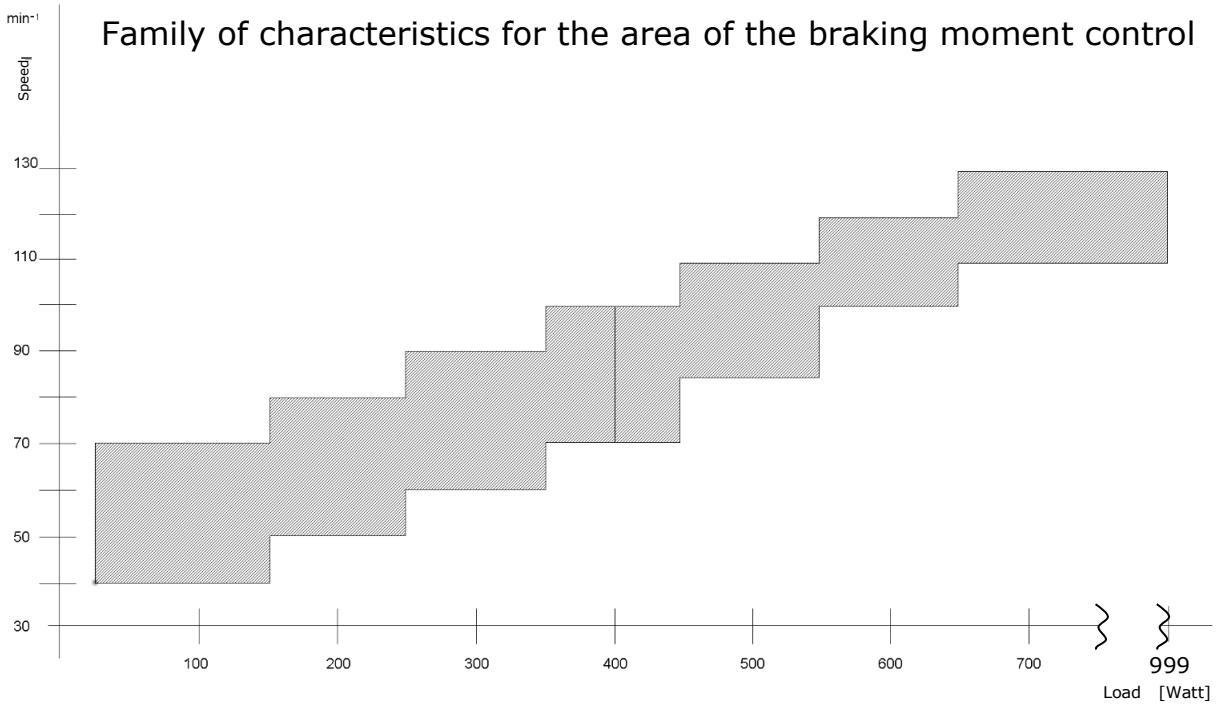
9.5 Disposal

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



- The control unit of the device contains a buffer battery, which must be disposed of separately.

10 Characteristics for the braking moment control



11 Technical Customer Service and Sales Locations

ergosana products are also sold by exclusively authorised Schiller agents with SCHILLER 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
Truchtelfinger Str. 17
D-72475 Bitz

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