



*The picture may differ from the original product

CE Conformity Declaration

ergosana GmbH herein declare that the medical products (Class IIa) of the ergometer system ERG 911 plus comply with the relevant requirements of the EC medical devices directive 93/42/EEC, Annex II.

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 read 'Dieter Beck'.

Dieter Beck
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Managing director

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1 General

The bike ergometer ERG 911 plus 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, the ergometer is available in a "smart" version; this version can be used for remote operation as well as stand-alone device without training programs provided by an external device.

In addition, both device versions can be equipped with various optional features.

Optional features:

- 1st Blood pressure measurement using QRS trigger
- 2nd Electrical saddle height adjustment
- 3rd SpO₂ measurement
- 4th Bluetooth
- 5th WLAN interface (to remote device)
- 6th ECG amplifier module
- 7th Pulse detection (Polar chest belt)
- 8th Operating voltage 115V or 230V

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 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 ERG 911 plus are intended for defined and accurate physical exercise during a patient's ergometry examination and therapy. They are used in practices, clinics, therapy and rehabilitation centres and are operated by physicians and medical personnel.

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

1.3 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
- 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 hypertension (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

1.4 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 or exhaustion
- ST depression ≥ 3 mm or ST elevation ≥ 1 mm
- persistent ventricular tachycardia (>30 s)
- drop in blood pressure >10 mmHg, with signs of myocardial ischaemia (angina pectoris, ST depression)
- no increase of heart rate

Relative abort criteria:

- hypertensive dysregulation
- drop in blood pressure >10 mmHg, without signs of myocardial ischaemia (angina pectoris, ST depression)
- polymorphic ventricular extrasystoles, couplets, VES run
- supraventricular tachycardia
- bradyarrhythmia or disturbance of conduction (higher degree AV block, bundle branch block)
- minor angina pectoris

1.5 Instruction

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 section 8 and 9.

2 Product description

The ergometer ERG 911 plus is intended for remote operation together with a master device (PC, ECG unit or similar).

The colour touchscreen in the console shows the current measurement results.

Moreover, optional blood pressure measurement and electrical saddle height adjustment can be controlled via the touchscreen.

2.1 Device components

1. Handle bar
2. Saddle
3. Clamp for saddle height adjustment (if clamped mechanically)
4. Mains connector, potential equalisation (accessible from the back)
5. Base adjuster for height adjustment
6. RS-232 interface (underneath the cover, right hand side)
7. Running gear with lockable heavy rollers
8. Clamp for handle bar pipe adjustment
9. Clamp for handle bar adjustment
10. Connector for blood pressure cuff (option: BP measurement)
11. Console with display and rpm display, rotatable by 180° (touchscreen)



2.2 Accessories

Every device comes with:

- Mains cable
- Blood pressure cuff (if blood pressure measurement option is available)
- User guide
- 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. Braking performance is independent of revolutions per minute.
Performance range	1 to 999 watts
Load range	- 1 to 20 watts (range is dependent of revolutions per minute) - 20 to 999 watts (range is independent of revolutions per minute)
Range of revolutions	30 to 130 /min
Load precision	DIN VDE 0750-238
Load parameters	Parameters from external master unit via interface (smallest resolution 1 watt)
Time intervals	1 min to 99 min
Display	Touch display (57 x 43 mm)
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.
Pulse measurement	Priority principle 1st ECG 2nd via blood pressure measurement unit, or optionally via Polar pulse monitoring system
Admissible patient data	Patients with - a max. weight of 160 kg - a height between 120 and 210 cm (optional: electrical saddle height adjustment)
Long-term accuracy	Continuous torque control and equalisation according to weight
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)
Base dimensions	45 x 83 cm
Weight	54 kg

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.



93/42/EEC for medical products 0124
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 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 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 and handle bar column to normal height, adjust the clamp lever downwards after fixing the saddle and handle bar pipe 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 the blood pressure cuff

The interfaces for the air tube and the microphone are located at the side of the control panel. 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.

3.2.3 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 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).

4 Unit components

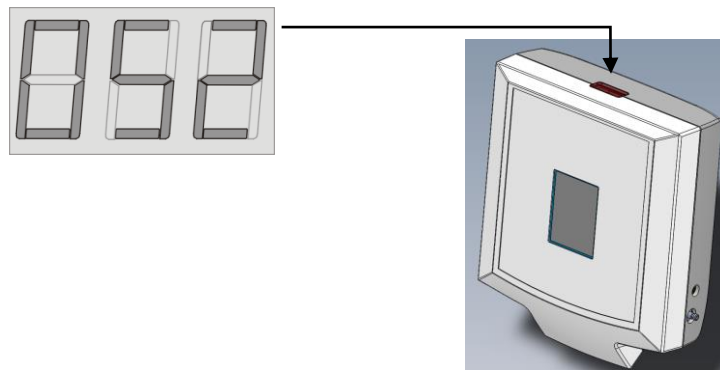
4.1 Displays

The console mounted on the handle bar is rotatable by 180°. During normal operation, it should be facing the examiner. However, for special purposes such as patient training etc., it can be rotated to face the patient so that he can see and use the display.

At the front, a touchscreen provides all important information at a glance as well as all control elements.

4.1.1 Rpm display on the console

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



4.1.2 Operation and display

A foil-covered touchscreen (57 x 43 mm) is located at the front of the console. On the display, the user can see all data that is important to monitor the ergometry.

- "Ergometry" mode featuring the patient's most important ergometry data
- "Blood pressure" mode to manually start and stop a blood pressure measurement (only if option blood pressure measurement is available)
- "Saddle height adjustment" mode to electrically adjust the saddle height (only if option electrical saddle height adjustment is available)

Moreover, when performance is 30 watt or higher, a red arrow indicates if the correct range of revolutions is exceeded.



Ergometry display

Indication revolutions per minute



BP measurement display

Start/stop BP measurement



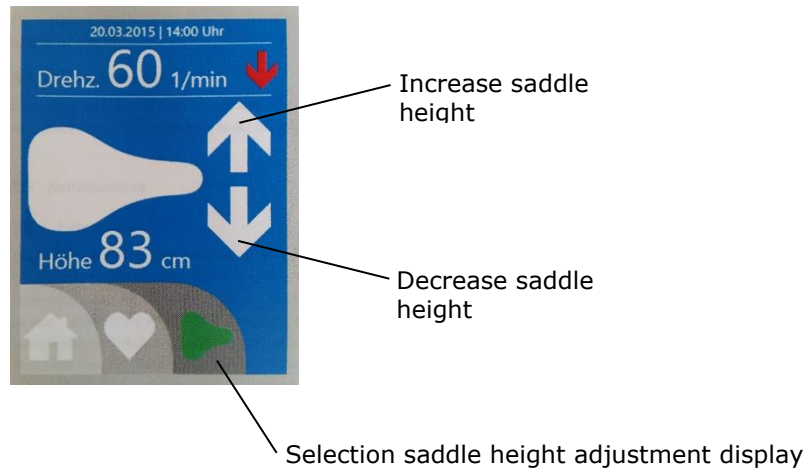
Saddle height adjustment display

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

4.1.3 Motorised saddle height adjustment

The device is available with an optional motorised saddle height adjustment. The saddle height can be adjusted infinitely via the touchscreen, the max. upper and lower saddle position is fixed. The adjustment range covers heights between 120 and 210 cm and weights up to 160 kg.

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



4.1.4 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
- Chinese

4.2 Adjusting the saddle and handle bars

Both the saddle and handle bars can be infinitely moved upward or downward for optimum exercise position. They can be adjusted for heights between 120 and 210 cm.

T-handles that protrude from under both the handle support and saddle pipe are used for adjustment. After loosening the respective T-handle, the handle bars and saddle rod can be moved up or down to the desired height. When the adjustment is finished, the clamp needs to be tightened again.

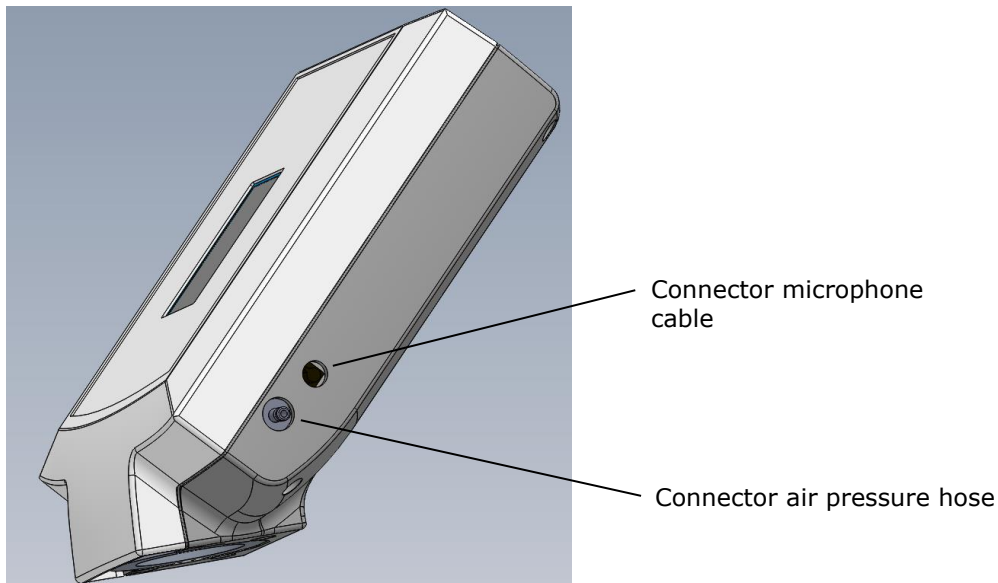
The saddle clamp is designed for patients weighing up to 160 kg. To attain optimal clamping action, only moderate strength is needed to tighten the clamps. It is recommendable to adjust the T-handles in clamped position with their underside positioned vertically downward. To do so, pull the clamp outwards and turn to position as required. 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.



4.3 Connectors for blood pressure measurement

The blood pressure cuff connectors are located on the right hand side of the console.



4.4 Blood pressure cuff

The standard blood pressure cuff (order no. 24-10-301) has Velcro fixing. It can be used for arms up to 40 cm in diameter. A larger cuff (order no. 24-10-321) is available for larger arm diameters.

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 pedalling 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.

Cleaning the blood pressure cuff:


The cuff should only be washed with soapy water and immediately dried off again. The surface of the microphone pocket is waterproof. Make sure that no moisture penetrates the opening of the microphone pocket as this might lead to damages to the microphone.

5 Safety notes

5.1 Precautions during operation

- 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.
- The holding straps on the pedals must fit perfectly across the upper side of the shoe and be fastened with a Velcro strap.

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 9.4).

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.

6 Initial operation

6.1 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 RS-232 interface to a peripheral device such as an ECG or pulmonary function unit for evaluation and recording.

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.

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.

⚠ 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.

6.1.1 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.

7 Ergometry

7.1 Load parameters

Depending on the application, exercise programs are provided by an external master device such as PC, ECG unit or similar.

7.2 Prerequisites

The device needs to be connected to the master unit using the RS-232 interface or WLAN.

Note:

For patient safety, the RS-232 interface is galvanically isolated.

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. The saddle and the handlebar should be cleaned with a leatherette cleaner.

- Only use soapy water to clean the saddle, do not use disinfectants.
- It is imperative to make sure that no water penetrates the device.
- Do not use petroleum spirit, nitro cleaner or acetone to clean the foil covering the console.

8.2 Cleaning the blood pressure cuff

The blood pressure cuff consists of a waterproof plastic foil. It can be cleaned with soapy water and a cloth. The water temperature must not exceed 30 °C.

Note:

The cuff should not be plunged into suds to clean, as the Velcro straps might mat. 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.

9 Maintenance and trouble shooting

9.1 Measurement checks (MTK) and safety checks (STK)

The unit's measuring technology should be checked every 24 months. The following checks need to be performed in the process:

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 (110/115 VAC or 230/240 AC). The current voltage setting is recorded on the mains module. The power unit covering lid on the bottom of the unit must be opened to convert the voltage. The voltage can then be changed on the power unit on-board with a special voltage selector switch.

Warning!

Voltage conversion must only be performed by trained electricians.

9.3 Changing a mains fuse

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

Warning!

Fuses must only be replaced by trained electricians.

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 ERG 911 plus uses HF energy exclusively for its internal function. This makes its HF emission very low and unlikely to disturb electronic devices in the vicinity.

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 ERG 911 plus.			
The ergometer ERG 911 plus 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 ERG 911 plus, depending on the output performance of the communication device as indicated below.			
Recommended minimal distance between the telecommunication devices and the ergometer.			
HF source	Rate [MHz]	Rated power of the sender [W]	Distance [m]
Radio telephone (microcellular) CT1+, CT2, CT3	885–887 MHz	0,01	0,23
Baby phone	27–41 MHz	0.1	0.37
Bluetooth systems (wireless mouse, wireless keyboard, handsfree set)	2400-2500	0.0025	0.38
Cordless DECT telephone, WLAN devices, UMTS phone	1880-2500	0.25	1.17
Mobile phone, USA	850/1900	1,2	1.8
Mobile phone, GSM850, NMT900, DCS 1800	850/900/1800	1	2.3
Mobile phone, GSM 900	900	2	3.3
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

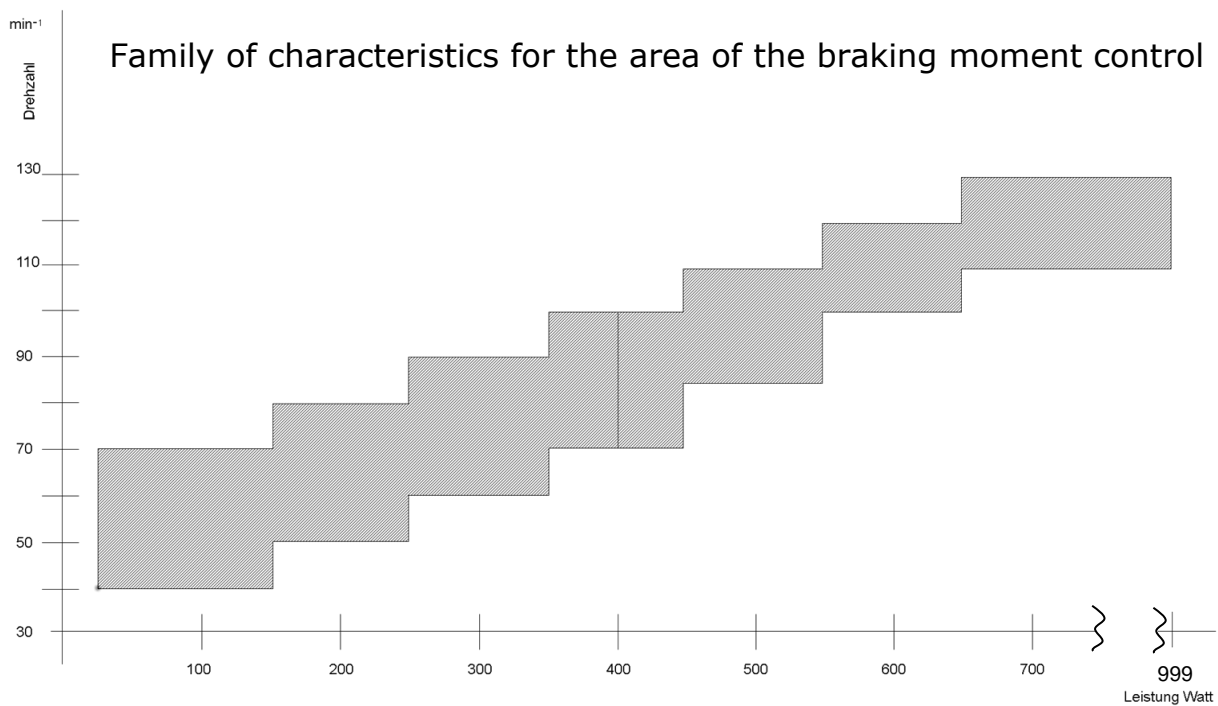
9.5 Disposal information

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 console 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

In Germany, products manufactured by ergosana are also sold by authorised SCHILLER agents as OEM products with the SCHILLER logo. The agents are trained in the service of our devices and are happy to help you if you need service support. Please contact one of these specialist dealers near you.

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

Service department Schiller Deutschland

Rudolf Diesel Strasse 14
D-85521 Ottobrunn

Phone: +49 (0)89 62 99 810

Fax: +49 (0)89 60 95 090

E-mail: info@schiller.de

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