SanaComfort 1000

Seat Ergometer

User Guide

Doc.-No.: 88-14-101 Rev.01

Sales and Service Information

ergosana has a worldwide sales and service centre network. Contact your nearest ergosana subsidiary to obtain the address of your local distributor. A complete list of all distributors and subsidiaries is provided on our Internet site:

www.ergosana.de

Sales information can also be obtained from:
sales@ergosana.de

Manufacturer

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If any serious incident occurs in relation to the seat ergometer, such incident needs to be reported without delay to GANSHORN and to the competent national authority of the country in which the user and/or patient is established.

The seat ergometer is also marketed under different names:

Type ergosana	Equivalent type
SanaComfort 1000	ERG 911 Comfort

CE 0123

The seat ergometer bears the CE-0123 mark (Notified Body: TÜV-SÜD Produkte Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), indicating its compliance with the essential requirements of Annex I of the Regulation (EU) 2017/745 (MDR) regarding safety, functionality, and labelling. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.

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1 Safety Notes

▲ Read and follow these safety notes and the intended purpose to prevent any injuries or damages.

1.1 Intended Purpose

The seat ergometer is a device for quantitative measurement of the speed at which a muscle or group of muscles performs work (energy) under controlled conditions. It is intended for a person using their legs, usually, the patient undergoing an examination, treatment, or training, and measures the associated muscle activity during specific workloads.

During an exercise test, the ergometer can be used with an exercise electrocardiograph and/or exercise echocardiograph.

1.1.1 Indications and contraindications

The seat ergometer may only be used for exercise tests of cardiac and cardiovascular patients in combination with the exercise electrocardiograph and exercise echocardiograph. The indications and contraindications of exercise electrocardiography equipment must be observed.

1.1.2 User profile

Healthcare professionals who have been thoroughly instructed based on the user guide.

Patients of the intended target patient group who have been thoroughly instructed by trained professionals.

1.1.3 Patient target group

The intended target patient group includes:

- Patients who qualify for a exercise test based on their height and age. For different ergonomic reasons it is not possible to indicate exactly the height and age.
- Patients with a maximum body weight of 200 kg
- Patients whose health status has been checked by a physician and who deems them suitable for the exercise test such as:
  - Patients with cardiovascular diseases
  - Patients with lung diseases

1.2 Responsibility of the user

- The numerical and graphical results and any interpretation given must be examined with respect to the overall clinical condition of the patient and the quality of the displayed data.
- The user is responsible for compliance with all applicable accident prevention regulations and safety regulations.
- All persons working with the system must read this user guide and the operating instructions of any ancillary equipment. In particular the safety instructions of the system must be read and understood.
- Operating the ergometer with a defective casing or defective cables constitutes a danger to the patient or the user. Immediately replace defective cables and connections.
- Immediately report any changes that impair safety (including operating behaviour) to the person responsible.
- The safety, reliability and performance of the device can only be guaranteed when the maintenance intervals as stated in the maintenance section are observed (see paragraph 6.3, p. 44)
- Equipment damage due to spilled liquid:
  - Do not place any liquids on the device.
  - If liquid is spilled on the device, immediately disconnect the device from the power supply and wipe it. Before using the device again, have it tested and repaired, if necessary.
- During the exercise test, monitor the patient and keep a defibrillator at hand.
- During operation, the temperature of the unit housing may exceed 41 °C. Instruct the patient to avoid any contact with the housing.

1.2.1 Abort criteria during exercise

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

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1.3 Organisational Measures

- ▲ Before putting the device into operation, have the features and necessary safety measures explained by a medical product representative.
- ▲ This user guide, and especially these safety notes, must be read and observed.
- ▲ These operating instructions do not override any statutory or local regulations for the prevention of accidents and environmental protection.
- ▲ Ensure this operating instruction manual is always complete, legible and available at the point of use of the ergometer.

Environmental

- ▲ The ambient conditions for storage and operation must be observed (see paragraph 6.3, p. 44).
- ▲ This device is not intended for use in potentially explosive areas. An explosion hazard may occur from the use of flammable anaesthetic agents, skin cleansing agents and disinfectants.

Packaging

- ▲ If the packaging is damaged, check the device for external damage and contact the manufacturer`s customer service if necessary.
- ▲ Do not use the device if the packaging is exposed to environmental conditions outside of those specified (see paragraph 9, p. 51). Contact the manufacturer`s customer service if necessary.

1.4 Maintenance

- ▲ The ergometer is only allowed to be installed, put into service and maintained in accordance with the valid regulations and standards. Installation, initial operation, modifications and repairs, and technical safety inspections may only be performed by the manufacturer or by partners authorised by the manufacturer.
- ▲ Do not open the ergometer. There are no serviceable parts inside.
- ▲ Service and maintenance service must not be performed when the device is used on the patient.
- ▲ Changing any parts of the system can result in augmented electromagnetic disturbance emissions or reduced electromagnetic RF immunity of the device.
- ▲ Inspection and calibration must be carried out on a regular basis (see paragraph 6.3, p. 44).

1.5 Operation with other devices

- If the ergometer is combined into a system by the ergosana partner or the operator, the ergosana partner or operator becomes the producer of the system and is therefore responsible for safety and compliance with all applicable standards.

Accessories connected to the ergometer need to be certified according to the respective IEC standards (e. g. IEC 60950 for data processing equipment, IEC 62368-1 for audio/video, information and communication technology equipment, or IEC 60601-1 for medical electrical equipment). In addition, any configurations need to fulfil standard IEC 60601-1. Everyone who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible that the system complies with the requirements of the valid version of IEC/EN 60601-1. If in doubt, contact an authorised ergosana partner.

- Injuries, incorrect information and/or damage to the device:
  - Only use accessories supplied or recommended by the manufacturer.
  - Using hardware that is not approved by the manufacturer is at the user's own risk. and the warranty might become void, see paragraph 1.9, p. 13.
  - Do not modify this device without the manufacturer's permission.
- Any other equipment used with the patient must use the same potential equalisation as the Seat Ergometer SanaComfort 1000.
- Portable communication devices, HF radios and devices labelled with the  symbol (non-ionic electromagnetic radiation) can affect the operation of this device (see paragraph 7.5, p. 48).

1.6 Cleaning / Disinfecting

- For cleaning and disinfection, observe the legal requirements applicable.
- Only use detergents and disinfectants recommended by the manufacturer. Unsuitable agents can damage the device. Clean and disinfect the device in accordance with the instructions given in this user guide (see paragraph 6, p. 38)
- Do not use solvent or abrasive cleaners on either the device or cable assemblies.
- Do not under any circumstances, immerse the unit, cable assemblies, or transducers in liquid.
- Do not use high-temperature sterilization processes (such as autoclaving). Do not use E-beam or gamma radiation sterilization.

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1.7 Safe use of electrical devices

- ▲ Danger of injury for the patient or user when using the device with defective cables or incorrect fuses:
  - Do not use the device if the protective earth is suspect or if the mains lead, power supply unit or device is damaged or suspected of being damaged.
  - Only connect to a power supply with protective earth connection.
  - Immediately replace damaged cable connections and connectors.
  - Do not modify electrical safety devices, such as fuses.
- ▲ Danger of injury to the patient or user due to an electrical shock:
  - Do not touch the power source during a thunderstorm
  - Do not touch the plug when your hands are moist/wet
- ▲ Fuses must only be replaced with the same type and rating as the original.
- ▲ Damage to the cable due to mechanical stress:
  - When disconnecting a cable, pull the plug and not the cable
  - Route the cable so as to help prevent people from tripping.

1.8 Implied Authorisation

Possession or purchase does not convey any express or implied license to use the device with replacement parts which would alone, or in combination with this device, fall within the scope of one or more patents relating to this device.

1.9 Safety symbols and signs

1.9.1 Symbols used in this document

The safety and warning messages are designed and phrased according to the applicable standards.

⚠ DANGER

▲ For a direct danger which could lead to severe personal injury or to death.

⚠ WARNING

▲ For a possibly dangerous situation which could lead to severe personal injury or to death.

▲ Embedded warning messages of this level are indicated with the signal word **WARNING**.

⚠ CAUTION

▲ For a possibly dangerous situation that could lead to personal injury.

▲ Embedded warning messages of this level are indicated with the signal word **CAUTION**.

NOTICE

- Warning concerning equipment damage or system failure.
- Embedded warning messages of this level are indicated with the signal word **NOTICE**.

▲ For general or supplementary safety notes as listed in this section.

▲ For electrical hazards or precautionary measures when dealing with electricity.

▲ For interferences caused by non-ionising electromagnetic radiation.

Especially important or helpful information

Reference to other documents

Required tools/equipment

1.9.2 Safety symbols on the device

Reading the user guide before using the device is compulsory

Attention: Observe the warning and safety notes given in the user guide

Non-ionic electromagnetic environment. The device may cause or be susceptible to electromagnetic disturbances.

The device contains an HF transmitter (WiFi).

Symbol for the recognition of electrical and electronic equipment.

Equipment, components and accessories no longer used must be disposed of in a municipally approved collection point or recycling centre. Alternatively, you can return the device to your supplier or the manufacturer for disposal. Improper disposal can harm the environment and human health.

IPX0

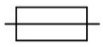
Protection class: IPX0. According DIN EN 60529. Not protected against ingress of water, may only be used indoors.

X = not tested against ingress of foreign bodies

Potential equalisation stud (see paragraph 3.3.1, p. 21)

Type B applied part

Supply voltage
230V 50Hz / 115V 60Hz



Fuses in the mains plug module
(Fine fuse 5x20 mm 1,25 A slow blow)

Maximum patient weight 200 kg

For additional symbols: see paragraph 11, p. 63.

2 Introduction

The seat ergometer is a device for quantitative measurement of the speed at which a muscle or group of muscles performs work (energy) under controlled conditions.

The seat ergometer can be operated in three different modes. With the optional device functions, blood pressure and oxygen saturation can be measured.

Remote Operation

Training programs provided by PC or ECG unit.

Manual operation

The load is adjusted manually by the operator in increments of 5 watts using the display.

Automatic operation

The load is automatically adjusted according to the increments settings defined by the operator.

Optional device features

In order to determine the reaction of the circulatory system to the increasing exertion, in addition to the physical performance data and the ECG data the following vital signs can also be measured:

- Systolic and diastolic blood pressure data with pulse rate
- Oxygen uptake SpO2

The measurements can be transferred via the RS232 interface to a peripheral device (e.g. ECG device or pulmonary function unit) for evaluation and recording.

2.1 Accessories

Every device comes with:

- Mains leads
- User manual (printed short instruction + CD)
- Inspection Report Protocol

2.1.1 Optional device features

- Blood pressure measurement
- SpO_2 measurement
- Continuous Electric Seat Position Adjustment

2.1.2 Optional Accessories

- Blood pressure cuff
- SpO2 finger sensor; ear sensor (on customer request)

2.2 Device components

(1) Handlebar and clamp for handlebar adjustment
(2) Console with touchscreen (rotatable by 180°) with option to adjust the sitting position and speed indication (rpm)
(3) Power button, mains connector, potential equilisation, RS-232 interface
(4) Running gear with lockable heavy-duty wheels
(5) Pedal cranks with pedals and safety straps
(6) Locking lever for adjusting the backrest
(7) Seat handlebar
(8) Base adjuster for height adjustment
(9) Connectors for blood pressure and SpO_2 measurements (optional)
(10) Seat with adjustable backrest

2.2.1 Applied parts

Applied parts include all device components that may have direct or indirect physical contact with the patient or user.

- Seat and backrest
- Handlebar and clamp for handlebar adjustment
- Seat handlebar
- Pedal cranks with pedals and safety straps
- Console with touchscreen for manual operation

2.2.2 Optional applied parts

- Blood pressure cuff
- SpO2 sensor

2.2.3 Mains, potential equalisation and RS-232 connectors

⚠ CAUTION

▲ Danger to the patient due to modifications of the electrical system:
- Only connect accessories approved by the manufacturer to the device.

NOTICE

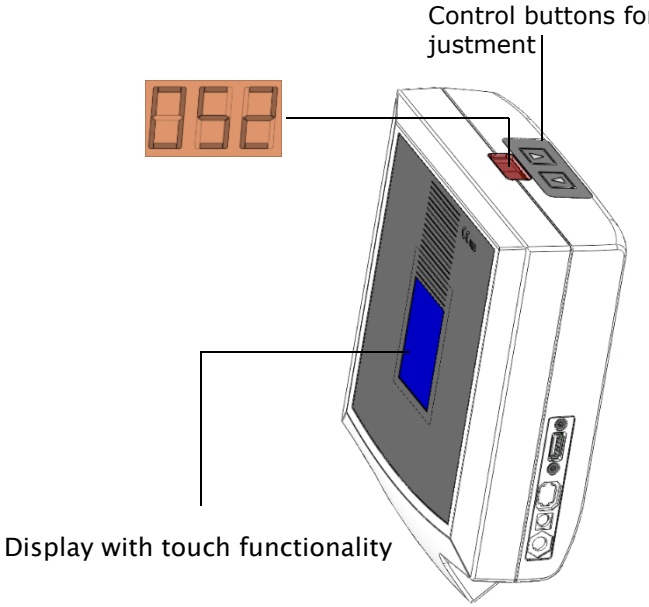
• Equipment damage due to not approved external hardware:
- Only connect external hardware approved by the manufacturer.
- Connecting not approved hardware is done at the user's own risk and may render the warranty invalid.

(11)RS-232 connector
(12)ON/OFF Switch
(13)Fuse
(14)Mains connector
(15)Potential equalisation connector

2.3 Console (probe)

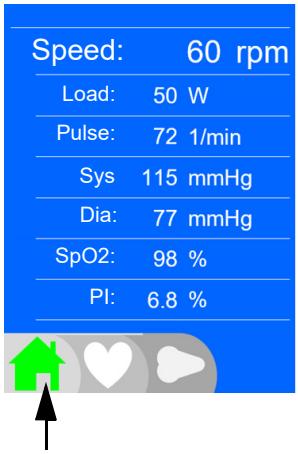
During normal operation, the console is turned towards the physician/therapist. For special purposes such as individual patient training, however, the unit can be rotated by 180 degrees, so that the patient can easily see the display and reach the control elements.

The two arrow keys can be used to adjust the sitting position according to the patient's height.



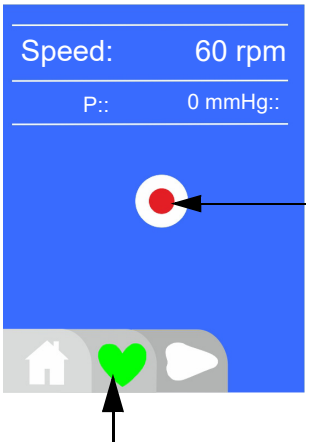
2.3.1 Touchscreen

In remote mode, a fully equipped ergometer has the following displays and functions:



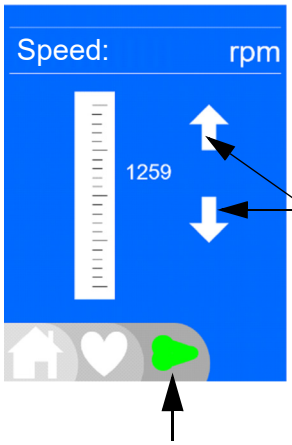
Ergometry featuring the patient's most important ergometry data

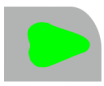
- Speed/Cadence (If the speed exceeds the defined range, the number is displayed in red.)
- Load indication
- Pulse (If no SpO2 sensor is connected, the pulse is derived from the NIBP measurement.)
- Systolic/diastolic blood pressure value (optional)
- SpO2 and PI (Perfusions Index) (optional)



Blood pressure to manually start and stop a blood pressure measurement (only if option blood pressure measurement is available)

Start / stop blood pressure measurement





Motorised adjustment of saddle height (optional) with saddle height indication

Arrow keys for saddle adjustment (saddle up/down)

Manual and automatic mode available. The load can be set using the display (manual mode) or it is automatically defined by the predefined load program.

3 Start-up and initial preparation

▲ Serious injury caused by an electrical shock:
- Do not use the device if the protective earth is suspect or if the mains lead/power supply unit is damaged or suspected of being damaged.
- This device may only be connected to a mains supply with protective earth.
- Prior to initial operation and daily use, the device has to be inspected for external damage.

3.1 Location

NOTICE

- Position the device on a horizontal and even surface.
- Do not store or operate the device in a wet, humid, or dusty environment.
- Do not expose the device to direct sunlight or heat from other sources.
- Check the device`s supply voltage against the mains voltage (115/240 V).
- Equipment overheating:
  - Operate the device at a 300-watt load setting for a maximum of 20 minutes with a 10-minute break between each use.
- Device malfunction
  Do not position the device in close proximity to the following equipment:
  - X-ray equipment
  - Diathermy units
  - Large transformers
  - Electric motors
  - High-frequency devices

3.2 Unpacking and assembling

NOTICE

- Unpacking and setup should only be performed by an authorised service technician.

- Combination spanner 17

The device is securely fastened to the pallet with two screws and should only be lifted from the pallet by two people.

1. Loosen the two hex screws under the pallet and have two people lift the device from the pallet.
2. The device can now be transported to its designated location on the wheels if the floor is horizontal and level.
3. Adjust the base leveler for leveling.

CAUTION: risk of tipping

4. The device must not wobble under any circumstances.

3.3 Connecting cables/accessories

(see paragraph 2.2.3, p. 17).

- Mains cable
- Potential equalisation cable
- Interface cable
- Accessories

1. Check the device's power supply voltage (see nameplate 115/240) against the mains voltage.
2. Connect the device to the power supply using the power cord.
3. Connect the device to the building's potential equalisation by means of the potential equalisation cable.
4. To connect the communication cable, carefully lay the device on its side and attach the RS-232 cable, securing it with strain relief (cable tie), (see paragraph 2.2.3, p. 17).

▲ **CAUTION: risk of tripping**

5. Position the cable in a way that prevents users/patients/third parties from tripping over it (see image).
6. Connect the necessary accessories (see paragraph 2.3, p. 18):
   - Blood pressure cuff
   - SpO_2 sensor

NOTICE

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

3.3.1 Potential equalisation

⚠ WARNING

▲ Danger of ventricular fibrillation triggered by equalising currents between different device potentials. This may be the case if the device is used together with medical devices for direct cardiac application:
- Connect both devices to the building's joint potential equalisation.

Potential equalisation cable (optional).

3.4 Power supply

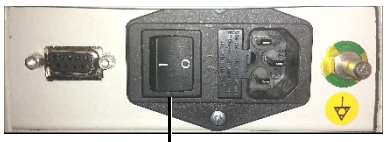
3.4.1 Isolating from the mains supply

NOTICE

- Cable damage:
  - Unplug the cable by pulling the plug, not the cord.

Position the device so that it can quickly and easily be isolated from the power supply.

3.5 Switching ON and OFF



Press the On/off key (1), to switch the device on or off

- If the device cannot be switched on:
  - see paragraph 7.4, p. 47

3.5.1 Device information

After switching on the device, the display will show the currently installed software versions as well as the serial number of the ergometer.

3.6 Changing the device location

The device can be easily moved using the two front wheels.

NOTICE

- Device damage: Turn off the device and disconnect all cables before moving the device.

3.7 Language selection

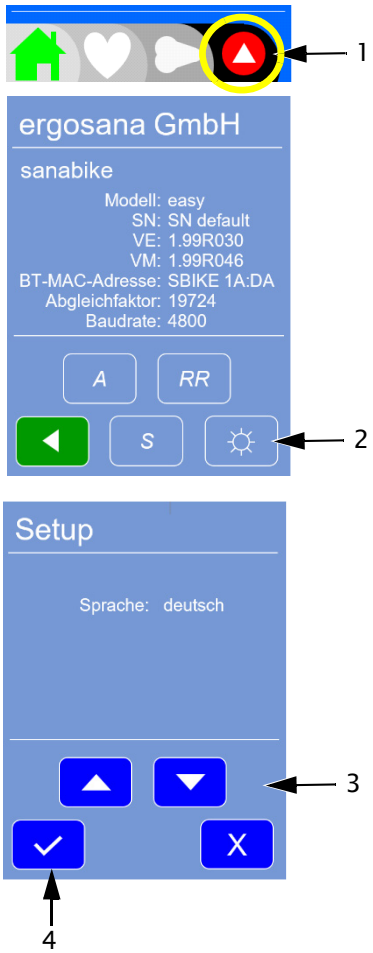
The ergometer is set to the desired language upon delivery. However, you can easily change it at any time via the configuration menu, with the following languages available for selection:

- German
- English
- French
- Italian
- Spanish

3.7.1 Changing the language

When the user is changing the language, it should be ensured that only the language selection menu is opened.

Modifications to other device settings should only be carried out by qualified service personnel.



1. Switch on the device. The configuration menu (1) appears for 5 seconds.
2. Press the configuration menu button (1).
3. Press the language selection button (2).
4. Select a language using the arrow keys (3).
5. Confirm selected language by pressing the button (4).

4 Operation

Before the start of each training session, the sitting position must be individually adjusted to the patient.

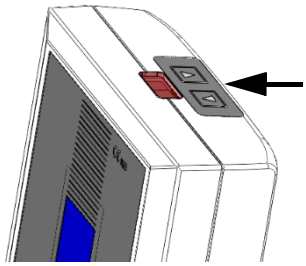
The saddle height and handlebar position can be adjusted.

4.1 Adjusting seat, backrest, and handlebar

⚠ CAUTION

▲ Before the patient takes a seat on the ergometer, check if the handlebar and backrest are properly secured.

4.1.1 Adjusting the seat distance



1. Ask the patient to sit on the ergometer and place their heel on the pedal that is in the frontmost position.
2. Adjust the motorised seat using the arrow keys so that the heel (1) touches the pedal with the leg fully extended.

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

4.1.2 Adjusting the backrest

The backrest can be mechanically adjusted in 3 positions.

1. Ask the patient to relieve the backrest. Use the front handlebars for support.
2. Push the lever **(1)** beneath the seat inward to release the lock.
3. Adjust the backrest to the required position. Ensure that the patient's belly does not come into contact with their thighs.
4. Push the lever outward to lock the backrest in position again.
5. CAUTION: Double-check that the backrest lock is securely engaged before the patient leans against it.

4.1.3 Adjusting Handlebar

left = release

right = tighten

The handlebar can be adjusted using the clamp.

Note:

The clamp can be brought to the desired position by pulling it out to facilitate the loosening/tightening of the clamping.

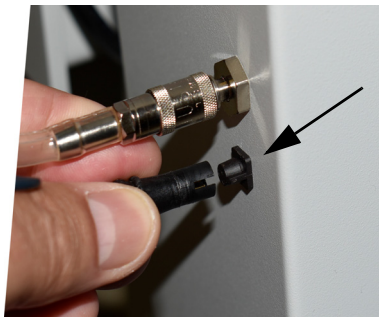
- When the clamp is horizontal and on the left side, push it downward to release the clamp.
- When the clamp is horizontal and on the right side, push it downward to tighten it.

  ➜ Tighten the clamp with moderate force.

  ➜ Position the clamp vertically in the clamped position.

4.1.4 Connector for blood pressure cuff (optional)

- The air pressure hose is equipped with a bayonet lock that engages as soon as you push the tube onto the connection.
- The microphone plug has a guiding slot that must face upwards (see arrow).



Connecting

➜ Slide the air pressure hose onto the connection until the bayonet lock snaps into place.

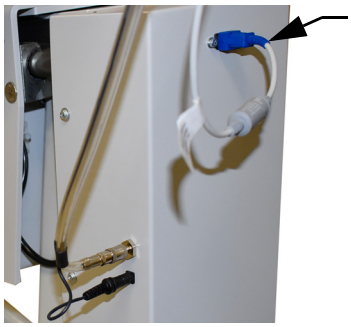
➜ Align the microphone plug with the guiding slot facing to the right and insert it.

Disconnecting

➜ Pull back the outer ring of the air pressure hose to release the bayonet lock.

➜ Pull the microphone plug from the connector housing (not the cable).

4.1.5 Connecting SpO_2 sensor (optional)



➜ Insert the SpO_2 SpO2 finger sensor (or ear sensor as per customer preference) into the SpO2 connector.

4.2 Performing an exercise test with the patient

4.2.1 Safety Notes

⚠ CAUTION

- ▲ An exercise test may only be initiated, if the patient has been informed about the test procedure and the associated risks.
- ▲ **Risk of falling**: The health staff must ensure that the patient does not trip when getting on or off the ergometer.
- ▲ If possible, check whether the resting ECG is normal and if the patient is physically fit for an exercise test.
- ▲ **Risk of infection**: Examine the patient for injuries on their hands.
- ▲ Monitor the patient during the exercise test. Terminate the test if any of the abort criteria are met see paragraph 1.2.1, p. 9.

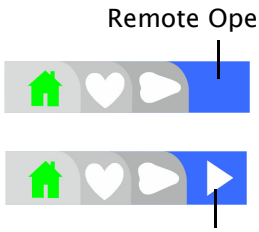
4.2.2 Patient Information

- The patient should wear appropriate sportswear to avoid additional strain on the circulatory system.
- During long exercise tests, the temperature of the unit housing may exceed 41 °C. There is no risk of burns with brief contact; nevertheless, the patient should be informed and should avoid contact.
- After completing the test, the patient should not dismount from the ergometer without being accompanied by the medical staff (risk of falling).
- Patient should use the handlebars when getting on the ergometer.
- The patient should immediately inform the medical staff if they feel unwell during the exercise test.
- For information on display during the training, refer to see paragraph 5.3, p. 31.

4.2.3 Adjusting the seat and backrest

➜ see paragraph 4.1, p. 24.

5 Modes of operation



In remote mode, the ergometer is controlled by the ergometry/exercise program of an external system such as a PC or EKG device.

Operation mode detection:

Remote mode = **no** triangle symbol

Manual/automatic mode = white, red, or green triangle symbol

- white = operation not active
- red = operation active, exercise phase
- greem = operation active, recovery phase

5.1 Remote operation requirements

To run an externally controlled exercise/training program, the following must be observed:

- The connection to the external system through an interface (RS232 or Bluetooth) must be established.
- The transmission rate (Baud rate) needs to be set correctly.
- The data protocol type P10 needs to be selected.

  ➜ Once remote operation is active, all settings are controlled through the external system.

  ➜ Blood pressure measurement can be manually initiated on the device at any time see paragraph 5.4.2, p. 35.

5.2 Requirements for manual/automatic operation

- The ergometer is not paired with the master device to prevent receiving remote commands through the interface.

  ➜ To do this, simply turn off the PC or the EKG device.

Note:

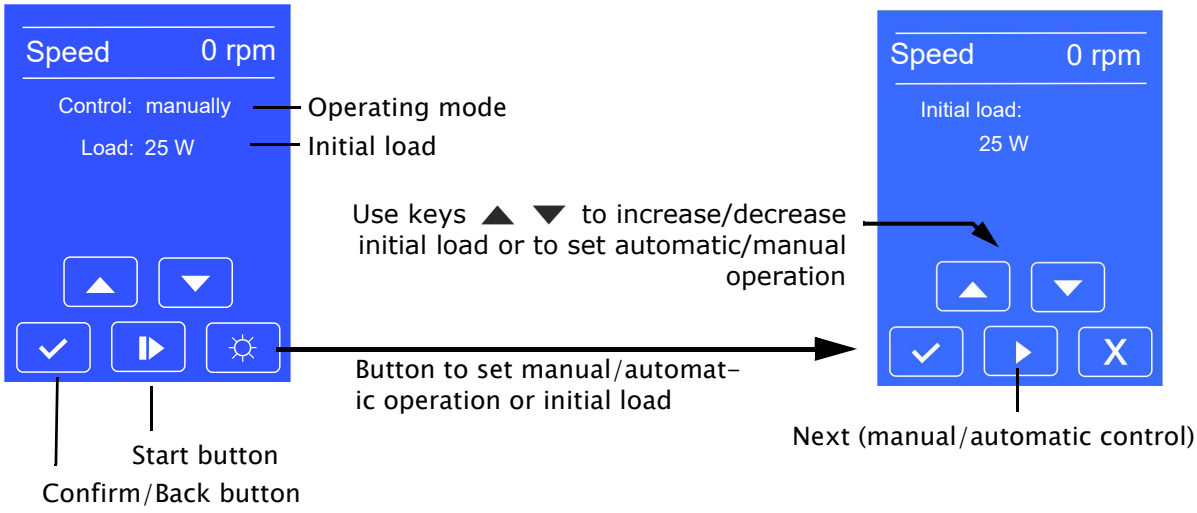
As soon as the PC or the EKG device is switched on, manual/automatic operation is terminated.

5.2.1 Manual operation and performance adjustment

This mode enables gradual load increment (in 5-watt steps) by the user.

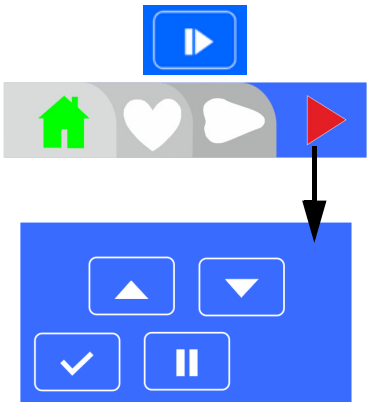
➜ Open the settings menu by clicking on the triangle symbol in the menu bar.

Menu for setting the manual load control



Set load and start training

1. Press button ☼ and use ▶ to select operation mode/initial load.
2. Use button ▲ ▼ to set the manual mode and to define the initial load in 5-watt increments.
3. Confirm the settings with ✓ .



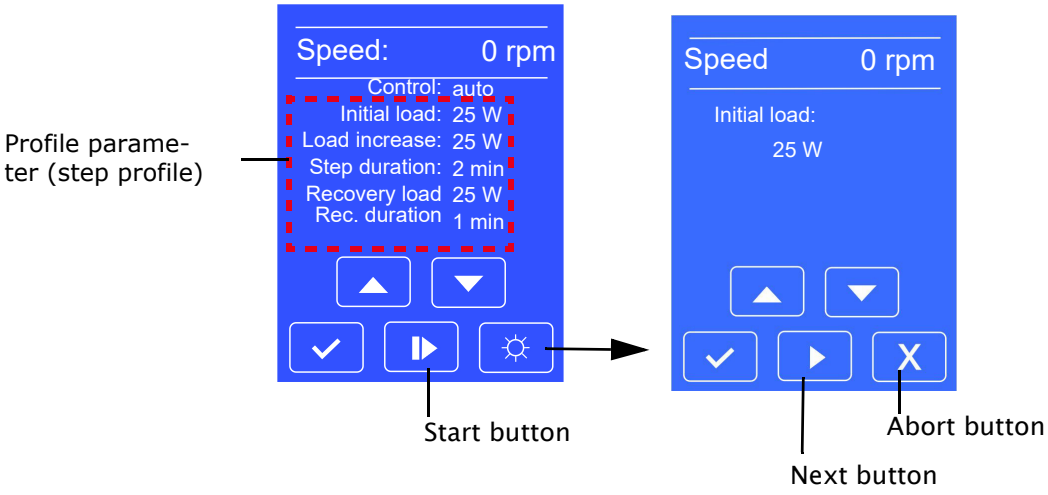
4. Start the training with ▶❚ . The program switches to the ergometry display to show the current ergometry parameters or to perform a blood pressure measurement. In this case, the active manual operating mode is designated by the red triangle symbol in the bottom right corner of the menu bar.
5. Press ▶ to return to the manual load setting. The following parameters are displayed:
   - Current running period
   - Currently applied load
6. Using the button ▲ ▼, set the load to the desired value in 5-watt increments.
7. With button ✓ , switch to the ergonometry display or stop the training with ❚❚ .

5.2.2 Setting and starting the automatic mode

- This mode enables stepwise load increment by the ergometer as specified by the operator.
- In automatic mode, load is incremented continuously at the defined rate. The load increment can be stopped at any time, causing the program to switch to the recovery phase.

➜ Open the settings menu by clicking on the triangle symbol in the menu bar.

Menu for setting the load increment program in automatic mode



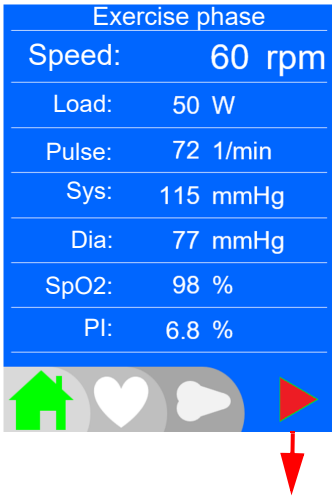
Setting profile parameters and start training

1. Press ☼ and use Next button ▶ to select operation mode/initial load.
2. Use button ▲ ▼ to set the automatic mode and to define the initial load in 5-watt increments.
3. Press the button ▶ to switch to the following parameters:
   - Stepwise load increment (5 to 100 W)
   - Step duration (1 to 10 minutes)
   - Recovery load (5 to 50 Watt)
   - Recovery duration (1 to 10 minutes)

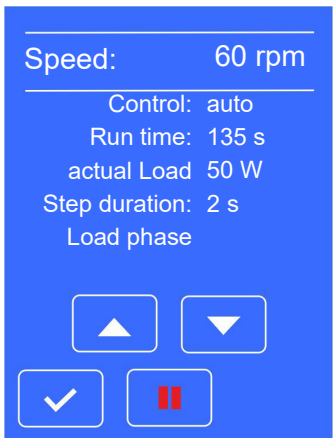
   and adjusting values using the buttons ▲ ▼.

4. Confirm the settings with ✓ .

Ergometry display



Load setting/Stop Training



5. Start the training with ▶ . The program switches to the ergometry display to show the current ergometry parameters or to perform a blood pressure measurement. In this case, the active manual operating mode is designated by the red triangle symbol in the bottom right corner of the menu bar.

6. Press ▶ to return to the current load setting. The following parameters are displayed:
   - Current running period
   - Currently applied load
   - Stage time (current elapsed time in the stage)
7. With button ✓ , switch to the ergometry display or stop the automatic load increment by pressing the red button ❚❚ (stop training). The program switches to the recovery phase for the defined time (recovery time) with a defined load (recovery load). The program ends when the time expires.
   ➜ The recovery phase can be stopped during this time by pressing the green button ❚❚ .

Note:

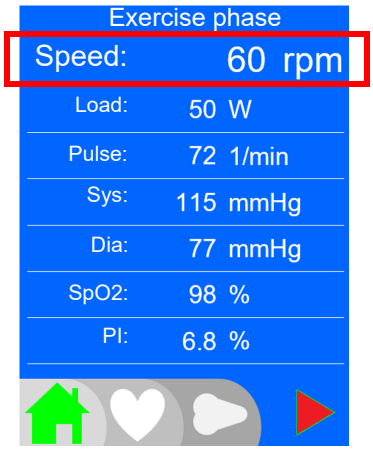
The last active load value is retained after the program ends and needs to be manually reset to the desired initial value by the user before the next use.

5.3 During the training

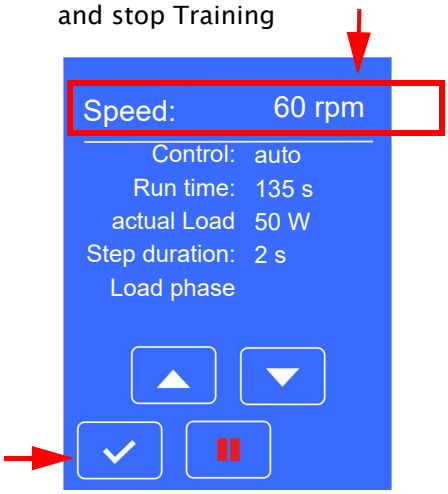
For self-monitoring of the pedaling cadence, the speed value is displayed in different colours to provide the user the following information:

- White speed value = cadence is ok (ideal range)
- Red speed value = cadence too high
- Red speed value= cadence too low

Ergometry display



Load Setting in manual Mode and stop Training



5.3.1 Braking moment control

The ergometer applies load independently of the speed between 30 and 130 RPM (revolutions per minute).

Performance range during ergometric exercise:

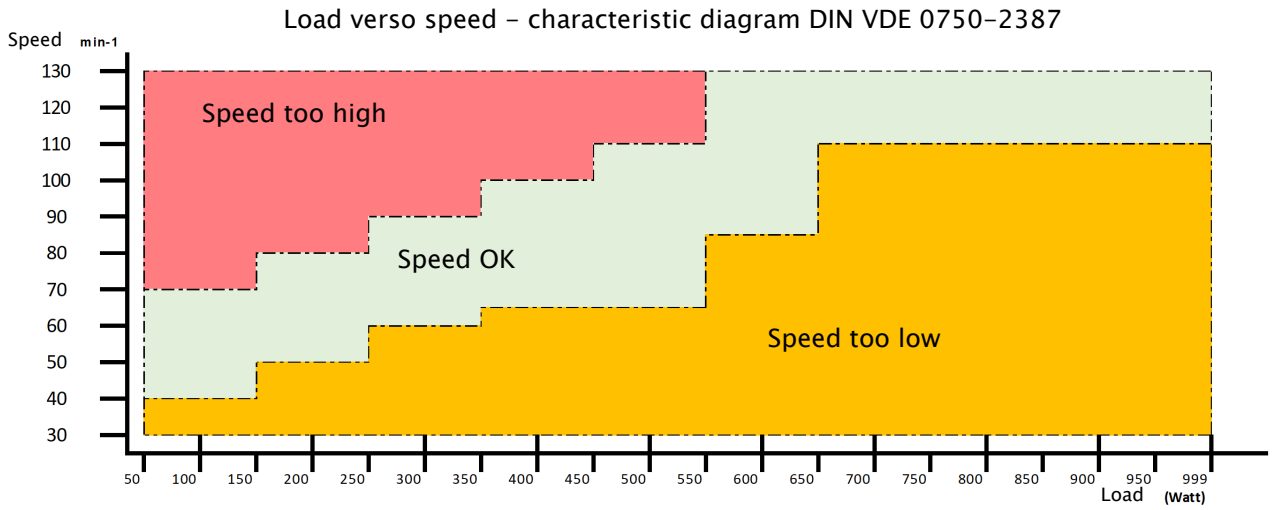
At around 30 years of age, the peak performance of a man is, on average, approximately 3.2 watts per kilogram of body weight. Trained high-performance athletes can achieve higher performance levels.

In women, performance levels are approximately 20 to 25 % lower than in male subjects. With age, a person's performance levels decrease (approximately 10 % per decade).

As a consequence, the primarily used working range of an average ergometer falls between 100 Watts and 300 Watts.

Higher performance levels are only achieved for short periods by high-performance athletes and for specific mechanical tests.

Characteristics for the braking moment control



5.4 Blood pressure measurement (optional)

⚠ WARNING

- ▲ It must be certain that, according to the patient's health, the device will not damage blood circulation in the arm.
- ▲ To prevent extensive pressure on the extremity, it is very important to:
  - Choose the correct cuff size.
  - Check the initial pressure in the NIBP menu. The correct initial pressure for adults is 160 mmHg
- ▲ The cuff must not be attached to a limb that is already used for interventions such as:
  - infusions or
  - SpO2 measurement (loss of data can occur during cuff inflation) or
  - if an arterio-venous shunt is present.
- ▲ To prevent extensive pressure on the extremity and incorrect measurement results make sure that the tube is not kinked or compressed.
- ▲ If a too short measurement interval is defined for recordings, bruising can occur on the arm, or it may result in poor blood circulation in the arm. Only carry out recordings with 5 minute measurement intervals under constant medical supervision.
- ▲ To achieve correct arterial pressure measurement, the cuff must always be installed on the level of the right atrium.

⚠ CAUTION

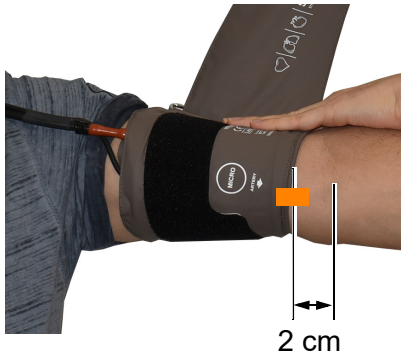
- ▲ The cuff must not be placed over or near a wound that could cause further injury.
- ▲ As with occasional blood pressure meas-urement, petechial bleeding can occur in patients with coagulation disorders or having anticoagulant treatment even with the correct cuff size.
- ▲ In patients that have had a single mastectomy the cuff can be placed on the opposite arm.
- ▲ A cuff that is applied to a patient in the recumbent or sitting position is normally located at the same level as the heart. If the cuff is positioned above heart level, this can lead to lower blood pressure readings (reduction approximately 7.5 mmHg per 10 cm difference in height).

Cuffs

Arm size: circumference at midpoint of arm [cm]	Cuff Designation
18 – 26	S (Adult)
25 – 35	M (Adult)
35 – 45	L –XL (Large Adult)
Note: A cuff that is too small for the patient may give over measurements. Similarly, a cuff that is too large for the patient may give under measurements.	

Cuffs see paragraph 8.3, p. 50

5.4.1 Cuff application

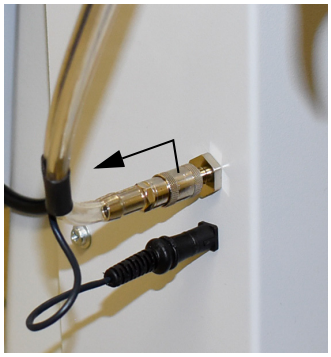


1. Instruct the patient to remove upper clothing.
2. Select the appropriate cuff size according to the patient's upper arm.
3. Uncover the **left** upper arm of the patient. (The cuff is designed to fit the left upper arm, but can be placed on the right arm if required.)
4. Locate the brachial artery above the elbow bend inside the upper arm.
5. Position the cuff so that the microphone (indicated by an orange fabric flag on the cuff) is located over the brachial artery.
6. Wrap the cuff around the upper arm in such a way that the patient can still bend arm (the bottom edge of the cuff should be 2 cm away from the elbow bend).
7. Tighten the cuff and secure with the velcro strip. The cuff must be tightened to such an extent that it fits properly on the upper arm and is prevented from moving.
8. To avoid a venous congestion don't tighten the cuff too firmly.

9. Connect the pressure hose and microphone cable (if not already connected) to the recorder

Note:

- The air pressure hose is equipped with a bayonet lock that engages as soon as you push the tube onto the connection.
- The microphone plug has a guiding slot that must face upwards (see arrow).
- To remove the air pressure hose, pull back the outer ring to release the bayonet lock.



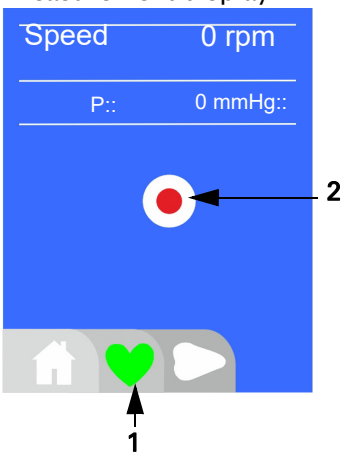
NOTICE

- Please note that the cuff's air pressure hose 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 air pressure hose needs to be routed over the lower handlebar in a way that prevents it from being touched by the patient while pedalling. Otherwise, interferences may occur, which can distort the measurement.
- To prevent the blood pressure cuff from becoming sweaty, a piece of a fine mesh tubular bandage (from companies like Lohmann & Rauscher, Hartmann) can be slipped over the arm within the cuff area, significantly reducing this unpleasant effect.

5.4.2 Performing manual blood pressure measurement

The blood pressure measurement can be initiated by the user in all operating modes.

BP measurement display



1. If a different menu is shown, press the Confirm/Back button to switch back to the ergometry display.
2. Press the heart button (1).
3. Press button (2) to start blood pressure measurement.

5.5 SpO2

5.5.1 Safety Notes

⚠ WARNING

- ▲ Before using the sensor, carefully read the sensor directions for use.
- ▲ The ear sensor is designed for use with adults and children over 30 kg and should not be used with neonates.
- ▲ The information in this manual does not overrule any instructions given in the sensor user guide, which must be consulted for full instructions.
- ▲ An incorrect application or sensor usage can cause tissue damage. Inspect the sensor application location as described in the sensor directions to ensure skin integrity and correct positioning and adhesion of the sensor.
- ▲ Do not use damaged sensors.
- ▲ Substances causing disturbances: Carboxyhaemoglobin can lead to falsely high measurement readings. The degree of the deviation approximately corresponds to the quantity of carboxyhaemoglobin. Colours or substances containing colours that influence the natural blood pigments can also lead to incorrect measurement readings.
- ▲ Exposure to excessive illumination, such as surgical lamps (especially those with xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps or direct sunlight can affect the performance of an SpO2 sensor. To prevent exposure to excessive illumination, ensure that the sensor is correctly applied and that it is covered with an opaque material, if required. If these measures are neglected, excessive illumination can lead to incorrect measurements.
- ▲ Fuctional tests cannot be used to assess the accuracy nor to calibrate an oximeter sensor or an oximeter monitor.

⚠ CAUTION

Alarms

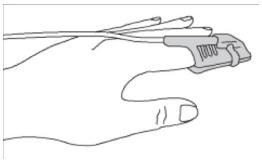
- ▲ If the connection between the sensor and the SpO2 module is interrupted or if the module fails, no alarm will be issued.
- ▲ No alarm settings can be made for the SpO_2 value. Therefore,it cannot be used for vital data monitoring.

5.5.2 Applying Sensor

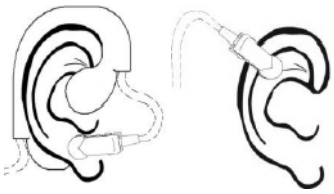
For pulse oximetry, a reusable ear-clip sensor or finger sensor is used.

Ear-clip sensor

If the measurement is performed during an exercise ECG, loop the cable and secure it to the patient's clothing with a crocodile clip or medical tape (strain relief).



➜ Apply the SpO_2 finger sensor to the patient. Use the index finger. Depending on finger size, other fingers can also be used.



➜ Apply the SpO_2 ear sensor to the patient. The preferred part for the application is the earlobe. Alternatively, the sensor can be attached to the ear helix.

For more information on usage, consult the user manual of the SpO2 sensor.

6 Cleaning and disinfecting

⚠ WARNING

- ▲ Danger of electric shock due to ingress of liquid:
  - Switch the device off before cleaning and disconnect the plug
  - Do not immerse the device or accessories in liquid
  - Do not spray detergent/disinfectant onto the device or accessories
  - Moisten the cloth with detergent/disinfectant (do not let it soak up too much liquid)
- ▲ Do not sterilise the device or accessories
- ▲ Do not autoclave the device or accessories
- ▲ Only use the detergents/disinfectants listed below
- ▲ Observe the manufacturer's instructions on using the detergent/disinfectant
- ▲ The device and accessories may become less resistant if an alkaline detergent or a detergent with a high alcohol concentration is left for a long time, or if a warm detergent/disinfectant is used:
  - Only use the detergents/disinfectants listed below at room temperature
  - Observe the manufacturer's instructions on using the detergent/disinfectant

6.1 Procedure overview

Detergents and/or disinfectants (see following)

Soft cloth

Inspect the device, accessories and cable before cleaning/disinfection:

- Device and accessories: no damages, keys and connectors are mechanically working fine
- Cable: no damages, wear, exposed wires or bent plugs
- All plugs engage securely

General procedure:

1. Wipe the device, accessories and cables on the surface with a slightly moistened (not wet) cloth. The saddle and handlebars can, as an exception, be sprayed with a spray bottle and wiped dry with a soft cloth after an exposure time of approximately 5 minutes.
2. Carefully wipe off excessive detergent/disinfectant.
3. Remove any grease marks and fingerprints with a mild detergent or a 50 % alcohol solution.
4. Make sure that no liquid runs into sockets, switches or gaps.

6.1.1 Cleaning

Interval

Before each use.

Approved Cleaning Solutions

- 50 % Isopropyl alcohol
- Neutral, mild detergent solution
- All products designed for cleaning plastic

Cleaning Materials that must not be used

Do not use detergents containing the following:

- Ethyl alcohol
- Acetone
- Hexane
- Abrasive cleaning powder
- Plastic-dissolving products

6.1.2 Disinfection

▲ Always clean the equipment before disinfection.

Interval

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

- Initial operation
- After use with transpiring, contagious or vomiting patients

Approved Disinfectants

- Isopropyl alcohol (50 %)
- Propanol (35%)
- Aldehyde (2-4%)
- Ethanol (50%)
- all products that are suitable for sensitive surfaces, such as:
  - Bacillol® 30 foam/ Bacillol® 30 Tissues
  - Mikrozid® AF
  - Incidin plus

6.2 Cleaning the blood pressure cuff

The blood pressure cuff should be cleaned regularly. It is made of a polyamide fabric (blue) or a plastic film (gray), which can be washed with soapy water and a cleaning cloth at a temperature of up to 40 °C.

Note:

- The cuff should only be washed with soapy water and immediately dried off again.
- If it should nevertheless be required to wash the cuff in water, the microphone and the bladder must first be removed. After washing, the cuff must be dried, and the microphone and bladder (airbag) inserted.

Important!

- The microphone must not come into contact with moisture under any circumstances.
- When assembling the cuff, ensure that the smooth side of the microphone is positioned on the side facing the arm.

- Do not use bleach
- Do not iron
- Do not tumble dry
- Do not spin dry

- Observe the following when washing:
  - Program setting of 40°C (104°F)
  - Select gentle or delicate cycle.
  - Use a mild washing powder. Do not use biological powder because of possible allergic reactions.
  - Do not use fabric softeners, disinfectant rinses, textile deodorants or any other additives – these solutions may leave residues and damage the material.
- Leave to dry naturally.

The cuff must be washed or disinfected on a regular basis using any of the following methods:

In a Standard Washing Machine

- Prepare Cuff (see next page).
- Fold the cuff and secure the cuff with the velcro strip.
- Place the cuff in a cleaning bag.

Dry Clean

- Prepare the cuff in the same way as for washing.

Disinfection

- Disinfect by gently wiping the cuff with an approved hospital grade disinfectant (see paragraph 6.1.2, p. 39).

6.2.1 Cuff preparation

Two types of cuff are available: Cuff type with a D-ring and cuff type without a D-ring. Both are available in various sizes. The cuff preparation procedure for cleaning is the same for both type and all sizes.

Disconnecting the Pressure Hose and Removing the Microphone and Bladder

Before cleaning, the microphone and the bladder must be removed from the cuff and the pressure hose disconnected.

1. Disconnect the pressure hose from the cuff inflation bladder connector by twisting the connector a quarter turn.
2. Gently remove the microphone from the microphone pouch by pushing on the outside of the cuff to move the microphone along the pouch channel until it can be removed from the cuff.

NOTICE

Do not pull on the microphone lead when removing the microphone as this can cause damage to the connections.

3. Remove the bladder from the cuff.
4. Fold the cuff and secure the cuff with the velcro strip.
5. Place the cuff in a cleaning bag and wash.

Re-inserting the Microphone and the Bladder and Connecting the Pressure Hose

1. Gently slide the microphone in the microphone pouch and push fully home from the outside of the cuff. Ensure the microphone is fully home and occupies the area indicated by the micro designation printed on the cuff.
   - The metallic (yellow) side of the microphone must be facing upwards when inserting in the cuff (the metallic side faces the patient).
   - Ensure that the microphone is correctly inserted in the cuff. It must fully reach the bottom of the pouch.
2. Replace the bladder in the cuff – ensure that the bladder is flat and not twisted in the cuff.
3. Connect and secure the pressure hose to the cuff bladder connector with a quarter turn.

   ➜ If the bladder tube and microphone connector outlet should be directed downward, follow the images on the page after the next.

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Bladder tube and microphone connector – upward outlet

Gently push the microphone out of the cuff and disconnect the pressure hose from the bladder (connector quarter twist).

Remove the bladder from the cuff.

After washing re-insert the bladder in the cuff.

Push the microphone until home in the micro pouch.

Reconnect the pressure hose to the cuff bladder.

Bladder tube and microphone connector – downward outlet

6.3 Cleaning the SpO2 sensor

➜ Disconnect the sensor from the monitor before cleaning or disinfection.

For cleaning and disinfection information, consult the user manual of the SpO2 sensor.

7 Maintenance

⚠ CAUTION

- ▲ 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.
- ▲ The settings should only be carried out by trained service personnel. Therefore, these measures are not further described in this manual. Please contact the local specialist dealer.

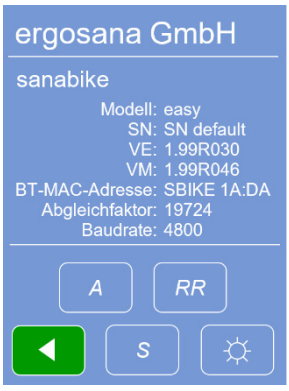
7.1 Measurement and Safety Checks

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

- Check of the ergometer's overall mechanical condition
- Check of correct ergometer rotational speed display and performance range
- Check of mechanical power loss of the ergometer's drive system
- Electrical safety check
- Check of the blood pressure recorder's pressure measuring unit
- Check for tightness of the pneumatic system
- Check of the safety symbols and markings on the casing
- Writing of an inspection report

7.2 Configuration

Deviations in load control, blood pressure measurement, or electric saddle height adjustment identified during maintenance or measurement and safety checks can be readjusted in the configuration menu.



1. Switch on the device. The configuration menu (1) appears for 5 seconds.
2. Press the configuration menu button (1).

Attention

- ▲ The settings should only be carried out by trained service personnel. Therefore, these measures are not further described in this manual. Please contact the local specialist dealer.

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7.3 Checking and setting the supply voltage

⚠ WARNING

▲ The device may only be opened by the manufacturer's customer service. If any ambiguities should arise, promptly contact the manufacturer's customer service.

On delivery, the unit is set for the local supply voltage (115 VAC or 230 VAC).

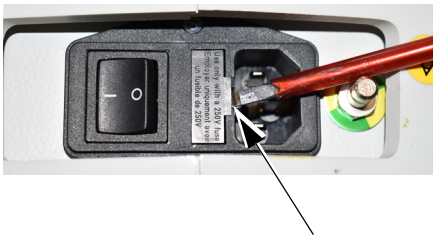
➜ See name plate

7.3.1 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.
▲ Only replace with fuses with the same electrical specifications (250 V T 1.25 A)

1. Disconnect the device from the mains.
2. Pry out the fuse holder with a screwdriver, and then pull out the fuse holder.



3. Replace both fuses. Push the fuse holder back in until it clicks into place.

7.4 Trouble Shooting

Fault	Cause/note	Remedies
Unit does not switch on, blank screen	No power supply	1. Power cord plugged in? 2. Mains switch ON? (see paragraph 3.5, p. 22) 3. Checking the Device`s Fuses (see paragraph 7.3, p. 46)
Touch screen does not react when tapped	Software error	1. Switch off the device 2. Wait a couple of seconds, then switch the device on again • If the error persists: – Call ergosana`s service partner.
No transmission possible via RS-232	Communication cable incorrectly connected	Check that the communication cable is correctly connected
	Incorrect settings	Check the settings and edit, if necessary (see paragraph 5.1, p. 27)

7.5 Preventing electromagnetic interferences

⚠ CAUTION

▲ Interference caused by radiated high-frequency electromagnetic energy:
- Use the device in accordance with the user guide
- Use portable high-frequency telecommunication devices in a distance of at least 0.3 meters to the ergometer including cables
- Do not place the ergometer near electrical/electronic devices.

The distance depends on the output performance of the communication device:

High-frequency source/telecommunication device	Transmitted frequency [MHz]	Testing frequency [MHz]	max. power P [W]	Distance d [m]
Various radio services (TETRA 400)	380-390	385	1,8	0,3
Walkie-talkie (FRS) Rescue, police, fire brigade, maintenance (GMRS)	430-470	450	2	0,3
LTE band 13/17	704-787	710/745/780	0,2	0,3
GSM800/900 LTE band 5 Radio telephone (microcellular) CT1+, CT2, CT3	800-960	810/870/930	2	0,3
GSM1800/1900 DECT (radio telephone) LTE band 1/3/4/25 UMTS	1700-1990	1720/1845/1970	2	0,3
Bluetooth, WLAN 802.11b/g/n LTE band 7 RFID 2450 (active and passive transponders and reading devices)	2400-2570	2450	2	0,3
WLAN 802.11a/n	5100-5800	5240/5500/5785	0,2	0,3

For permanent high-frequency telecommunication devices (e. g. radio and TV), the minimum distance can be calculated as follows:

$d = 0.6 \times \sqrt{P}$

where:

d = minimum distance in meters

P = transmitted power in Watts

For detailed information, see ergometer service manual.

Measures to prevent interferences

- Switch off the device
- Stop data transmission
- Increase distance to the source of interference (see above)
- Turn the device to change the angle of radiation
- Connect the device to a different mains connector
- Connect the potential equalisation cable
- Only use original accessories
- Immediately replace defective cables
- Connect the patient cable correctly
- Observe the maintenance intervals as stated in section 7.1.

7.6 Disposal

⚠ WARNING

▲ Danger to the environment due to improper disposal:
– Dispose of packaging material, device and accessories according to the country's regulations in which the device is used

Device and accessories no longer used must be disposed of in a municipally approved collection point or recycling centre for electronic devices.

Alternatively: return the device including battery and accessories to the manufacturer (see page 2).

Dispose of packaging materials in a municipally approved collection point or recycling centre.

8 Accessories and Disposables

⚠ WARNING

▲ Danger to the patient as well as risk of the warranty becoming invalid if accessories or disposables are used that are not approved:
- Only use accessories and disposables approved by the manufacturer.

Accessories and disposables area available from the local ergosana representative or directly from ergosana (see page 2).

8.1 Mains lead/power supply unit

Part No.	Description
69-01-004	Mains cable Schuko Europe, angled, 2.0 m
69-01-118	Mains cable UK, angled, 2.0 m
69-01-106	Mains cable USA, straight, 2.0 m
69-01-104	Mains cable China, angled, 2.5 m

8.2 Blood Pressure

Part No.	Description
2.120080	BP cuff D-Ring size S (18-26 cm)
2.120081	BP cuff D-Ring size M (25-35 cm)
2.120082	BP cuff D-Ring size L (35-45 cm)

8.3 SpO2

Part No.	Description
90-30-001	SpO2 finger sensor, SoftCap SC7500 Smart SB3 bluepoint
90-30-001	SpO2 ear-clip sensor, EP7500 Smartsat SB3 bluepoint

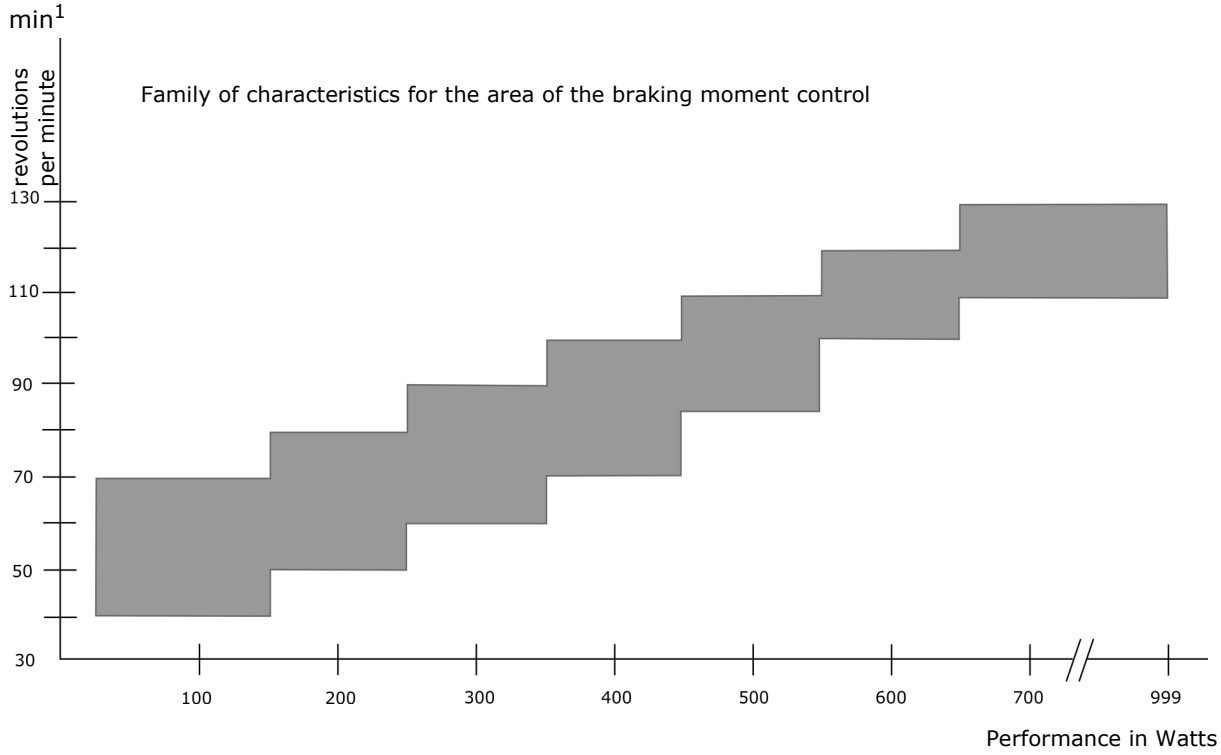
9 Technical Data

9.1 Device

Feature	Value/description
Base dimensions	40 x 130 cm
Weight	75 kg
Allowed patient weight	200 kg
Screen	LCD Touch display (57x43 mm)
Power supply device	230 VAC with 50 Hz, or 115 VAC with 60 Hz
Power Consumption	max. 28 Watt
Electrical protection class	Class I
Load precision	DIN VDE 0750-238
Control range (independent of revolutions per minute) Control range	30 to 130 rev/min
Device class	S = Professional/Commercial Use Under Operator Supervision A = Accuracy class A
EMC	The unit is suitable for use in electric networks according to CISPR 11, group 1, class B
Interfaces	• Data interface (RS-232) • Potential equalisation connector • Air pressure port (NIBP) • Microphone port (NIBP) • Connection of the SpO2 sensor
Operating conditions	• Temperature: +10 to +35 °C • Relative humidity: 15 to 95 % (non-condensing) • Atmospheric pressure: 700 to 1060 hPa (max. 3000 m above sea level)
Storage conditions	• Temperature: +5 to +50 °C • Relative humidity: 10 to 95 % (non-condensing) • Atmospheric pressure 500 to 1060 hPa
Transport conditions	• Temperature: −10 to +50 °C • Relative humidity: 10 to 95 % (non-condensing) • Atmospheric pressure 500 to 1060 hPa

9.1.1 Drive mechanism

Feature	Value/description
Length of pedal crank	172.5 mm (double length of pedal crank: 345 mm)
Drive	With Poly-V belt
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)
Continuous operation	up to 100 watts
Limited operation	Maximum 20 minutes at 300 watts, with a 10-minute break for preparation for the next patient Maximum 16 tests per day
Characteristics for the braking moment control	



Family of characteristics for the area of the braking moment control

9.1.2 Setting Load Parameters

Feature	Value/description
Externally via ergo system PC, ECG	Load in 1-watt increments Stage duration: set in ergo system
Automatic operation of console	5-watt increments (stage profile with load increments of 5-100 Watt); stage duration 1-10 minutes
Manual operation	Manual adjustment by the operator on the ergometer's console (in single increments of 5 watts)

9.2 Blood pressure module

Feature	Value/description
Methods of measurement	Auscultatoric (Korotkoff/Riva-Rocci) with or without QRS trigger

Feature	Value/description	
Measurement Range		
Systolic	50 ...270 mmHg	(± 3mmHg)
Diastolic	20 ...150 mmHg	(± 3mmHg)
Pulse	40 ...250 bpm	(40 ...100 bpm < ± 2%)
		(100 ...200 bpm < ± 4%)
		(200 ...250 bpm < ± 5%)
Deflation rate	3 mmHg/beat automatically	
Measurement intervals	On demand from host. Manual measurement interruption Manual or automatic	
QRS trigger	From external ECG source (host system)	

9.3 SpO2 module

Feature[1]	Value/description
Module	SMART Sat® bluepoint MEDICAL
Sensor	Finger SC7500 / Ear EP7500
Protection class of housing	IP 33
LED wavelength/output power	Red: 660nm/ < 5mW Infrared: 905nm/ < 5mW
Accuracy	
SpO_2	• Adults 70 to 100% ± 2 digits
PP	• 30 ... 300/min ± 2 digits
Stabilisation time after storage	Up to 20 minutes

1.Consult the sensor's user manual for further technical details.

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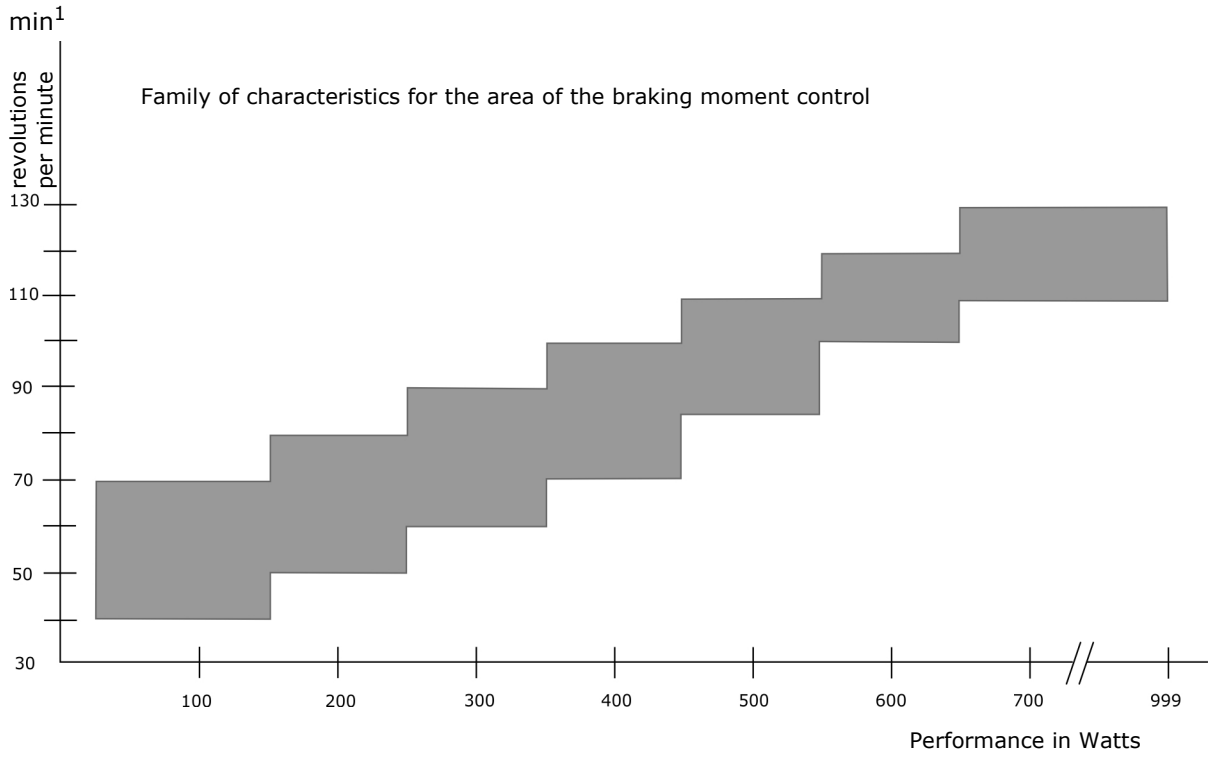
9.4 Wi-Fi connection box

Feature	Value/description
Modules	ESP-WROOM-32
FCC ID	2AC7Z- ESPWROOM32
Transmission standards	IEEE 802.11 b,g,n
Security/encryption	WPA™ Enterprise, Personal, WPA2™ Enterprise, Personal with security EAP-TLS, EAP-TTLS, MSCHAPv2, PEAPv0/EAP-MSCHAPv2
Frequency range	Dual-band 2.4 GHz and 5 GHz
Max. power output 2.402 -2.480 GHz	4 mW
Max. power output 2.412 -2.462 GHz	46 mW

9.5 Characteristics for the braking moment control



Family of characteristics for the area of the braking moment control

9.6 Manufacturer's Declaration EMC

9.6.1 Electromagnetic emissions

The device is intended for use in an electromagnetic environment as described below. The customer or user of the device should ensure that the device is used in such an environment.

Emission measurement	Compliance Level	Electromagnetic environment – guidance
RF emissions acc. to CISPR 11	Group 1	The device uses RF energy only for its internal function. Thus its RF emission is very low and it is unlikely that nearby electronic devices would be disturbed.
RF emissions acc. to CISPR 11 Emission of overtones acc. to IEC 61000-3-2 Emission of voltage fluctuations/flicker acc. to IEC 61000-3-3	Class B Class B Fulfilled	The device is a professional medical device that is intended for use by healthcare professionals. It is not intended for home use or to be used in a domestic environment

9.6.2 Electromagnetic immunity

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic environment - guidance
ESD IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV for power supply lines ±1kV I/O lines	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	± 1 kV ± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	<5% U_T (95% dip in U_T) for 0,5 cycles[1] <5% U_T (60% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	<5% U_T (95% dip in U_T) for 0,5 cycles[1] <5% U_T (60% dip in U_T) for 1 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. The unit shutoff during the >95% for 5 second disturbance. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterrupted power supply or battery.
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

1. At an angle of 0, 45, 90, 135, 180, 225, 270, and 315 degrees..

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic environment - guidance
			Portable and mobile communications equipment should be used no closer to any part of this device, including cable, than the recommended separation distance (d) calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V_{rms} outside ISM band 6 V_{rms} in the ISM & amateur radio band 150 kHz to 80 MHz	$[V_1]$ = 3 Vrms $[V_1]$ = 6 Vrms 150 kHz to 80 MHz	$d = \frac{3.5}{V_1} \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2700 MHz	$[E_1]$ = 3 V/m 80 MHz to 2700 MHz	$d = \frac{6}{E_1} \times \sqrt{P}$ for 80 MHz to 2700 MHz
Proximity fields from RF wireless communications IEC 61000-4-3	9.6.3 Immunity to proximity fields from RF wireless communications equipment, page 57	9.6.3 Immunity to proximity fields from RF wireless communications equipment, page 57	$d = \frac{6}{E_1} \times \sqrt{P}$ for tested frequencies Tested Frequency see 9.6.3 Immunity to proximity fields from RF wireless communications equipment, page 57
			Where P is the maximum power in watts and d is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site[a] survey, should be less than the compliance[b] levels (V_1 and E_1). Interference may occur in the vicinity of equipment marked with following Symbol:  "non ionizing radiation"
Note 1 Note 2	At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast ant TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If an abnormal behaviour is detected, additional measures need to be taken, e.g. reorientation or change of location of the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.

9.6.3 Immunity to proximity fields from RF wireless communications equipment

Test frequency [MHz]	Area[1] [MHz]	Service	Modulation	Max. power P [W]	Distance d [m]	Immunity level [V/m]
385	380–390	Various radio services (TETRA 400)	Pulse modulation[2] 18 Hz	1.8	0.3	27
450	430–470	– Walkie-talkie (FRS) – Rescue, police, fire brigade, maintenance (GMRS)	FM [3] ±5 KHz ±1 KHz sine	2	0.3	28
710 745 780	704–787	LTE band 13/17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800–960	– GSM800/900 – LTE band 5 – Radio telephone (microcellular) CT1+, CT2, CT3	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700–1990	– GSM1800/1900 – DECT (radio telephone) – LTE Band 1/3/4/25 – UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400–2570	– Bluetooth, WLAN 802.11b/g/n – LTE Band 7 – RFID 2450 (active and passive transponders and reading devices)	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100–5800	WLAN 802.11a/n	Pulse modulation 217 Hz	0.2	0.3	9

1. For some services, only the uplink frequencies are included.
2. The carrier shall be modulated using a 50%duty cycle square wave signal.
3. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

9.6.4 Recommended minimum distances

For fixed installed HF-Transmitters (z.B Radio und TV transmitters) the following minimum distance to the transmitter can be calculated as follows:

Maximum Power Output [watts]	Separation distance according frequency of the transmitter [m]	
	150 kHz to 80 MHz $d = \frac{3.5}{V_1} \times \sqrt{P}$	**80 MHz to 2700 GHz** $d = \frac{6}{E_1} \times \sqrt{P}$
0.01	0.04	0.06
0.1	0.11	0.19
1	0.35	0.6
10	1.1	1.9
100	3.5	6

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

Note 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9.7 Revision History

Rev. 01	2023-09-25	Initial version

10 Index

11 Appendix - Symbols

This appendix lists all general symbols that may be present on the device, label and accessories. Not all of those symbols are necessarily present on your device.

	Identification of the manufacturer
	Identification of the manufacturing date
	Identification of the distributor
	Identification of the importer
MD	Medical device
SN	Serial number
REF	Reference number
LOT	Batch code
GTIN	Global trade item number
CAT	Catalogue number
QTY	Quantity
UDI	UDI: unique device identification as QR code machine readable and human readable as number, e.g. (01) 0 7613365 00210 2 (21)xxxx.xxxxxx
	Number of pieces in the packaging
EC REP	EU-Bevollmächtigter
CE XXXX	Notified body, e.g. CE 0123 marking notified body TÜV SÜD
CE	CE marking affirms its conformity with European Standards

	UK Conformity Assessed
	The regulatory compliance mark for the Australian Standards
	The device is recyclable
	The symbol for the recognition of electrical and electronic equipment. The device must not be disposed of in the household waste.
	The symbol for the recognition of a battery. The battery must not be disposed of in the household waste.
	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Non-ionising electromagnetic radiation. To indicate that the device contains a Radio Frequency (RF) transmitter to transmit data. e.g. Bluetooth or Wi-Fi
	The device contains a Bluetooth module
	Do not reuse
	Temperature range for the storage or transport, respectively
	The pressure range for the storage or transport, respectively
	Humidity range for the storage or transport, respectively
	Consult the Instruction for Use (indicates the need for the user to consult the Instruction for Use)
	Keep the device dry (store the device in a dry location)
	Keep the device away from sunlight (protect the device from direct sunlight)
	Fragile device, handle the device with care

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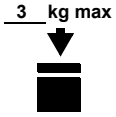
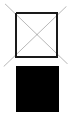
	Transport the device upwards (this way up)
	Do not use hooks
	Maximum stack load weight
	Do not stack
	EIP = electronic information product (does not contain any toxic and hazardous substances or elements above the maximum concentration values (the product can be recycled and re-used).

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