ergoline

MOVING TO HEALTH

ergoselect 1

Bicycle Ergometer

Operator's Manual

201000551000 • Version 2023-09-18 / Rev 06 • English

Manual

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Bicycle Ergometer

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This manual was written with the utmost care. Should you still find details that do not correspond with the system, please let us know and we will correct the issue as soon as possible.

We reserve the right to modify the design and technical features and are not bound by the information and illustrations provided in this manual.

This manual will not be automatically updated. Please contact the manufacturer for the latest document revision.

This manual also describes optional components that are not included in the standard scope of delivery of this product.

The document "Cleaning, and Disinfecting ergoline Medical Devices" (Part No. 201000641000) in its most recent version is also part of this manual. This document is exclusively made available for download from the ergoline website www.ergoline.com.

ergoline GmbH
Lindenstrasse 5
72475 Bitz
Germany

Tel.: **+49-(0)-7431 - 9894 - 0**
Fax: **+49-(0)-7431 - 9894 - 128**
e-mail: **info@ergoline.com**
http: **www.ergoline.com**

CE 0123

Contents

1 General Information

- The medical device bears the CE marking CE-0123 (notified body: TÜV SÜD Product Service GmbH), indicating its compliance with the provisions of the Medical Device Regulation (EU) 2017/745 and meets the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745.
  The CE marking covers only the accessories listed in chapter 7.1 *Accessories Overview*.
  The device is a class Im product (m: with a measuring function) pursuant to Annex VIII of the Regulation (EU) 2017/745.

- The product fulfills the requirements of standard EN 60601-1 "Medical Electrical Equipment, Part 1: General Requirements for Safety" as well as the electromagnetic immunity requirements of standard EN 60601-1-2 "Electromagnetic Compatibility – Medical Electrical Devices".
  The radio-interference emitted by this device is within the limits specified in EN 55011, class B.

- This manual is an integral part of the device. It should be available to the device operator at all times. Close observance of the information given in the manual is a prerequisite for proper device performance and correct operation and ensures patient and operator safety. Please note that information pertinent to several chapters is given only once. Therefore, carefully read the manual once in its entirety.

- Observance of the safety information protects from injuries and prevents inappropriate use of the device. All device users and persons responsible for assembly, maintenance, inspection, and repair of the device must read and understand the content of this manual, before using the device or working with it. Paragraphs with special symbols are of particular importance.

- If unauthorized individuals open the control terminal, damaging the calibration sticker, any warranty claim shall become void.

- This manual reflects the device specifications and applicable safety standards valid at the time of printing.

- On request ergoline will provide a Field Service Manual.

- The ergoline quality management system complies with the standard EN ISO 13485: 2016.

- The safety information given in this manual is classified as follows:

Danger

indicates an imminent hazard. If not avoided, the hazard will result in death or serious injury.

Warning

indicates a hazard. If not avoided, the hazard may result in minor injury and/or product/property damage.

Caution

indicates a potential hazard. If not avoided, the hazard may result in minor injury and/or product/property damage.

- To ensure patient safety, the specified measuring accuracy, and interference-free operation, we recommend using only original ergoline accessories. The user is responsible if accessories from other manufacturers are used.

- ergoline is responsible for the effects on safety, reliability, and performance of the device, only if
  – modifications and repair are carried out by ergoline GmbH or by an organization expressly authorized by ergoline GmbH to carry out these tasks
  – the device is used in accordance with the instructions given in this operator manual.

- Before use, adjust the saddle height to fit the patient size. An incorrect saddle height will cause the patient to adopt an ergonomically incorrect posture, which leads to transient pain.

- Before use, adjust the handlebar to the patient. An incorrect handlebar setting will cause the patient to adopt an ergonomically incorrect posture, which leads to transient pain.

- Before starting a test, check that the settings are correct for the patient.

- All reportable incidents involving the ergometer shall be reported to the manufacturer and the competent authority of the country where the user resides.

Warning

- *This device should not be used adjacent to or stacked with other devices as this could result in incorrect operation. If adjacent or stacked use is necessary, this device and the other devices should be observed to verify normal operation.*
- *The use of accessories, transducers, and cables other than those specified or provided by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity and incorrect operation.*
- *Portable RF communications equipment (including accessories such as antenna cables or external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME device or ME system], including cables, specified by the manufacturer. Otherwise, degradation of the performance of the device could result.*

2 Safety Information

Danger

Explosion Hazard

The device is not designed for use in areas where an explosion hazard may occur.

Explosion hazards may result from the use of flammable anesthetics, skin cleansing agents, or disinfectants.

Warning

Patient Hazard, Equipment Damage

Do not expose the medical device to direct sunlight to prevent system components from reaching inadmissible high temperatures.

Do NOT use the medical device outdoors. Furthermore, the device has no additional protection against the ingress of humidity. Humidity inside the device may cause equipment malfunctions and increases the risk of an electric shock.

Additionally, the device should not be operated in the vicinity of power systems, because they may impair equipment functions.

The medical device may only be used in combination with accessories approved by ergoline GmbH.

Personal Injury

Before using the ergometer, the user must ascertain that it is in correct working order and operating condition. The cables and connectors, in particular, must be checked for signs of damage. Damaged parts must be replaced immediately.

Equipment Malfunction

Only the special shielded cables supplied by ergoline may be used to connect the device to other pieces of equipment.

Equipment Malfunction

Cellular telephones may not be used in the immediate vicinity of the ergometer, because they might interfere with the proper functioning of the ergometer.
Electromagnetic interference most probably exists when the watt reading is unstable. If the displayed value changes frequently even though the speed is above 30 RPM, this may be due to electromagnetic interference.

Note

Only the removal of the power cord will result in an all-pole disconnection of the device from the power line.

Warning

Shock Hazard

- *When the device is connected to other equipment or if a medical system is created, it must be ensured that the added leakage currents do not present a hazard. In case of questions, please contact your ergoline dealer or the ergoline GmbH Service Department.*

- *For use, the ergometer must always be connected to electrical installations that fulfill the local requirements.*

- *To prevent the risk of electric shock, connect the device only to a power line with protective conductor.*

Patient Hazard

- *To prevent personal injury by an electric shock or due to a defective medical device, do not place objects containing liquids on top of the medical device.*

- *In case of liquid ingress into the device, immediately disconnect it from the power line and inform your dealer or contact the ergoline GmbH Service Department.*

- *If*
  - *faults*
  - *defects*
  - *illegible warnings*

  are identified and/or suspected, immediately put the medical device out of operation for reasons of safety.
  In this situation, the medical device needs to be clearly labeled to prevent it from use. Immediately inform your dealer or the ergoline GmbH Service Department in writing.

- *As a general rule, modifications to the medical device are not allowed, unless*
  - *the modifications are carried out by ergoline GmbH, authorized specialists, or*
  - *ergoline GmbH has reviewed and approved the modification.*

- *To prevent personal injury, please observe the following points:*
  - *Do not transport the ergometer during use.*
  - *Do not transport the ergometer while someone is sitting on it.*
  - *Before transporting the ergometer, observe its own weight (see type plate).*

- *At the maximum load level of the ergometer, the temperature at the saddle may reach 41.5 °C.*

- *The ergometer may only be used on a dressed and fully conscious patient.*

Warning

Patient Hazard

The German Medical Device Operator Ordinance (MPBetreibV, § 4) demands that users

- *must be trained in the use of the medical device*
- *must be familiar with the routines for handling and assembly*
- *must be familiar with and observe the safety rules and regulations for operation of this type of equipment*
- *must be informed about any other pertinent rules and regulations (e.g., safety features)*
- *must be informed about the potential hazards arising from the use of this type of equipment*
- *must make sure that no unauthorized changes are carried out.*

Patient Hazard

The medical device is only intended for use by trained and appropriately qualified staff.

Caution

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g., EN 60950 for data processing equipment).

Furthermore, all configurations must meet the requirements of the applicable medical systems standards (see 3rd edition of EN 60601-1).

Anyone connecting additional devices to medical electrical equipment is a system configurator and as such responsible for compliance of the system with the applicable system standards. Please note that local laws take precedence over the standards mentioned above.

In case of questions, please contact your local dealer or ergoline GmbH.

Note

Applied Parts

Applied parts are components that come into physical contact with the human body (e.g., sphygmomanometers).

Note

Stability

Ensure the stability of the ergometer. If the maximum permitted patient weight is exceeded, the stability of the ergometer can no longer be guaranteed. The device may become unstable as a result.

2.1 Indications, Contra-indications, and Exclusion, Criteria for Termination

Indications

- Asymptomatic subjects
  - diagnosis of latent disease and of possible risks in sport
  - assessment of physical performance ability and counseling before the start of training; monitoring and guidance of training
  - assessment of performance capacity and physical performance ability in occupational medicine

- Patients with ...
  - diagnosis of cardiovascular and pulmonary disease
  - evaluation of symptoms: dyspnea, chest pain, palpitations, dizziness (syncope)

- Follow-up assessment during training (for patients as well):
  - recommendations on the extent and intensity of training
  - in accordance with the above, the diagnostic objectives are the assessment of performance, development, suitability, and structure; stress is measured by external parameters and effort by "internal" ones as a response of the subject's organs to the task.

Contra-indications and exclusions

- Absolute
  - any acute or severe chronic cardiorespiratory disease causing marked functional impairment (e.g., severe congestive heart failure, high-grade congenital heart defects, cardiomyopathy, severe arrhythmias, thromboses, malignant hypertension, or pulmonary hypertension)
  - any acute or severe disease of other organ systems, e.g., nephritis, poorly controlled diabetes mellitus, or electrolyte disturbances
  - febrile infections
  - musculoskeletal and neuromuscular disorders that preclude safe and adequate test performance

- Relative
  - known obstructice left main coronary artery stenosis
  - moderate to severe aortic stenosis with uncertain relation to symptoms
  - tachyarrhythmia or bradyarrhythmia with uncontrolled ventricular rate
  - moderate to severe valvular heart disease
  - acquired advanced or complete heart block
  - hypertrophic obstructive cardiomyopathy with severe resting gradient
  - recent stroke or transient ischemic attack

- age or mental impairment leading to inability to cooperate
- resting hypertension with systolic or diastolic blood pressures > 200/110 mmHg
- uncorrected medical conditions, such as significant anemia, important electrolyte imbalance, and hyperthyroidism
- ventricular aneurysm

Criteria for termination

- Subjective symptoms
  - dizziness
  - incoordination
  - progressive chest pain
  - shortness of breath
  - pain in the legs or disability to perform the test

- Objective signs
  - ECG changes
    progressively severe arrhythmias
    progressive intracardiac conduction disturbance
    progressive repolarization disorder
  - hemodynamic changes
    progressive drop in blood pressure
    insufficient rise in blood pressure
    excessive rise in blood pressure
  - abnormal findings during auscultation of the lungs (e.g., breath sounds such as cawing, wheezing)

Complications secondary to exercise testing

- Cardiac
  - Bradyarrhythmias
  - Tachyarrhythmias
  - Acute coronary syndromes
  - Heart failure
  - Hypotension, syncope, and shock
  - Death (rare; frequency estimated at 1 per 10 000 tests, perhaps less)

- Non-cardiac
  - Musculoskeletal trauma
  - Soft-tissue injury

- Miscellaneous
  - Severe fatigue (malaise), sometimes persisting for days
  - Dizziness
  - Body aches
  - Delayed feelings of illness

2.2 Intended Use

The medical device is an ergometer used to apply stress to a patient's cardiovascular and musculoskeletal systems and for exercise training.

2.3 Clinical Benefit

In cardiac rehabilitation and secondary prevention programs with the medical device, patients benefit from training by improving their physical capacity and, at the same time, by reducing the probability of recurrence of medical conditions such as cardiovascular diseases, metabolic disorders, cancers, pulmonary diseases or diseases resulting from a sedentiary lifestyle. Furthermore, the medical device can be used as a diagnostic device in stress ergometry and exercise testing.

2.4 Intended User/Operator

Only the intended users are allowed to use the ergometer.

Intended users/operators are, among others, healthcare professionals thoroughly instructed on the basis of the operator manual, such as

- physicians
- healthcare providers
- therapists

The group of intended users does not include persons whose mental and physical capabilities and skills have an adverse effect on their ability to use the medical device in accordance with its intended purpose.

2.5 Intended Patient Group

The intended patient group includes all persons
- with a maximum weight of 160 kg
- whose body height and age makes them eligible for exercising on the ergometer. Due to various ergonomic aspects, it is not possible to provide exact data for body height and age.
- whose medical condition has been checked by a medical specialist who judged them to be suitable for the application described in the intended use.

2.6 Biocompatibility

The parts of the product described in this manual, including all accessories that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards if used as intended.

If you have questions in this matter, please contact ergoline GmbH or an ergoline representative.

2.7 Applicable Laws, Regulations, and Directives

If you have questions regarding laws, regulations or directives related to the product, please contact ergoline GmbH.

3 Symbols

Type B applied part.

Observe the information given in the operator manual.

Protection class II equipment.

This symbol indicates that the waste of electrical and electronic equipment must not be disposed of as unsorted municipal waste but must be collected separately.
Consult Operator's Manual!

REF Order number.

SN Serial number.

Scheduled date of the next inspection (e.g., March 2024).

Toggle switch ON (voltage).

Toggle switch OFF (voltage).

IP21 Devices rated IP21 are protected against insertion of fingers and solid objects with a diameter greater than 12 mm. They are also protected against the harmful ingress of dripping water (vertically falling drops).

CE 0123 CE mark per the Medical Device Regulation (EU) 2017/745.
Notified body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany.

Nationally Recognized Testing Laboratory
NRTL label for the USA and Canada.

Do not lean against device: tipping hazard.

MD This symbol indicates that the equipment is a medical device.

This symbol indicates the overall weight of the medical device.

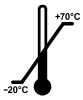
Manufacturer's identification.

Date of manufacture.
The number found under this symbol is the date of manufacture in the YYYY-MM-DD format.

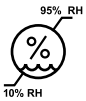
Transport and storage label:
top.

Transport and storage label:
keep dry.

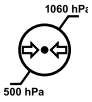
Transport and storage label:
fragile.



Transport and storage label:
approved temperature range.



Transport and storage label:
approved humidity, non-condensing.



Transport and storage label:
approved pressure range.

Transport and storage label:
do not stack.

4 Setup and Mains Connection

4.1 Controls and Indicators

1. Control terminal*
2. Speed display (RPM) for the patient
3. Handgrip*
4. Clamping lever* (adjustment of handlebar angle)
5. Saddle*
6. Clamping lever* (saddle height adjustment)
7. Power switch (toggle switch [I / 0])
8. Leveling feet to adjust the ergometer to uneven floors
9. Connectors for power cord and connection cables (underside of the ergometer)
10. Pedal*
11. Castors

* = applied parts as defined in IEC 60601-1

To safely terminate operation of the ergometer after use, turn it off with the power switch.

Figure 4 – 1: ergoselect 1 components and controls

4.2 Mounting the Control Terminal

The control terminal can be installed with the display facing either the patient or the operator.

It is recommended to install the terminal with the display and control keys towards the operator and the speed read-out towards the patient.

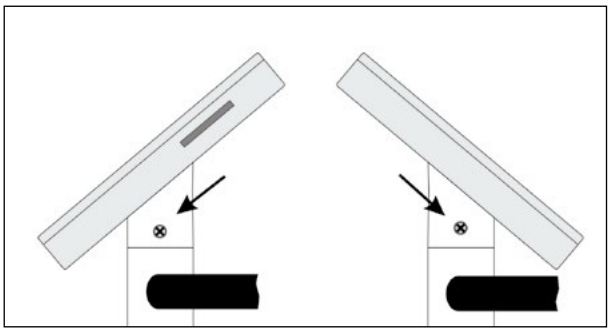


Figure 4 – 2: Different orientations of the control terminal

4.3 Transport

For short distances, the ergoselect 1 can be lifted at the saddle and rolled away on its castors.

To cover greater distances with the ergoselect 1, however, we recommend the following method:

- Disconnect the power cord from the wall outlet.
- Rotate the handlebar of the ergoselect 1 towards the front.
  Tighten the clamping lever.
- Stand in front of the ergoselect 1, grasp the handlebar and tilt the ergometer towards you until it is standing on the castors only and is balanced.
- It is now possible to transport the ergoselect 1.
- When you have reached the new location, lower the ergoselect 1 very carefully to avoid damage.

Caution

Equipment Damage

Avoid strong vibrations of the medical device during transport.

Figure 4 – 3: Transporting the ergoselect 1

4.4 Setup

Place the ergoselect 1 on a level floor.

The ergoselect 1 must be set up in a secure and stable position; the two leveling feet at the back make for easy adjustment to uneven floors. Extend the foot concerned until the ergoselect 1 no longer wobbles.

In case of delicate flooring, it is recommended to place a mat under the ergometer to protect the flooring from damage by the feet.

The ergoselect 1 has 2 castors at the front for transport.

Figure 4 – 4: Leveling feet of the ergoselect 1 ergometer

4.5 Connecting the Power Cord

- Rotate the handlebar of the ergometer towards the front.
- Tilt the ergometer carefully towards the front until it rests on the handlebar.

Figure 4 – 5: Assembly position of the ergoselect 1 ergometer

- Connect the power cord on the underside of the ergoselect 1.
- Insert the power cord into the strain relief and screw the strain relief to the frame. Make sure that the plastic pin engages in the corresponding hole.
- Return the ergometer carefully to its upright position and adjust the handlebar.
- Plug the power cord into a wall outlet.

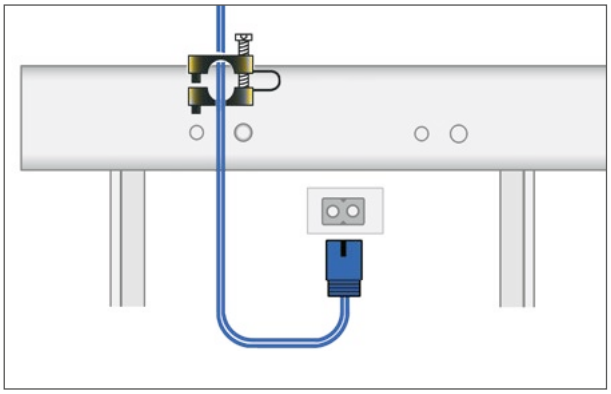


Figure 4 – 6: Power cord in strain relief mounted to frame

Warning

- *Arrange the power cord properly.*
- *Lay the power cord flat on the floor.*
- *Keep the power cord away from the pedals.*

Caution

Equipment Damage

Before connecting the ergometer to the power line, check that the line voltage corresponds to the ratings on the type plate.

The type plate is located on the back of the device, at the bottom.

Note

Disconnection from Power Supply

Only the removal of the power cord will result in an all-pole disconnection of the device from the power line.

Ensure that the power plug is readily accessible at all times.

4.6 Connecting the ECG Cable

The ergoselect 1 ergometers can be connected to electrocardiographs and PC-based ECG systems of most manufacturers.

The ergoselect 1 ergometers are equipped with a digital interface.

The connection cable is plugged into the 9-pole socket of the connection panel (Port 1) or the USB port and secured at the metal frame with an additional strain relief.

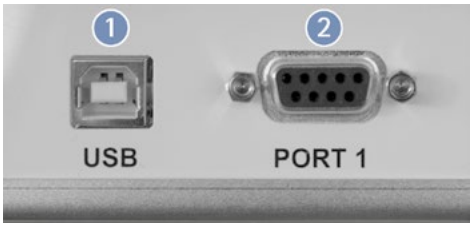


Figure 4 – 7: Connection for ECG recorder / PC ECG system
1 *USB: PC connection via USB (virtual COM)*
2 *PORT 1: Digital connection (remote control from PC or ECG recorder)*

Note

Connection Cables

Use only connection cables approved by ergoline.

A special PC driver software, which can be obtained from ergoline, is required for operation via the USB port. You can download the driver at https://www.ergoline.com/en/software.html section DRIVERS (EN) or use the QR code.

4.7 Integration in an IT Network

The medical device has an interface that enables it to be combined with
- other medical devices or
- other products

for assistance, diagnosis or assessment in a manner that is compatible with the intended purpose of the medical device or other products and within the limits of use specified by their manufacturers.

In this configuration, the ergometer is controlled and used as an aid to apply physical stress to the patient.

IT Network Specifications

Specification	Description
Interface	RS232
Connector	1 x D-Sub socket, 9-pole 1 x USB port (B)
Connection cables	Null modem cable USB cable A/B
Protocol	Please contact ergoline GmbH.
Compatible devices	Please contact ergoline GmbH.

Warning

Caution!

Only devices, software, and connection cables which ergoline or the manufacturer of the host device has declared as compatible may be connected to the ergometer.

Unsuitable configurations of the ergometer with
- other medical devices or
- other products

in a manner that is compatible with the intended purpose of the medical device or other products and within the limits of use specified by their manufacturers as well as
- the use of unsuitable connection cables may cause ergometer malfunctions which lead to serious, previously unknown, hazards for the patient, the operator, and third parties.

These are the obligations of the responsible organization regarding previously unknown risks that occur after integration of the ergometer in the IT network or after subsequent modification to the IT network:
- determine
- analyze
- evaluate, and
- control the new risks

Modifications to the IT network include:
- modification of the IT network configuration
- connection of additional elements/more medical devices from other manufacturers to the IT network
- removal of IT elements from the IT network
- "update" or "upgrade" of hardware connected to the IT network (e.g., router, printer, data monitor, patient monitor, medical device)
- "update" or "upgrade" of software used in the IT network (e.g., operating system, anti-virus software).

5 Preparing the Patient

5.1 Handlebar Adjustment

To adjust the handlebar angle, open the clamping lever 1 by turning it counter-clockwise.

Choose a handlebar angle that allows the patient to sit up straight and comfortably. Tighten clamping lever 1 hand tight by turning it clockwise. Then tighten the clamping lever another 1/4 turn clockwise so that the clamping is secure.

Caution

Before use, adjust the handlebar to the patient. An incorrect handlebar setting will cause the patient to adopt an ergonomically incorrect posture, which leads to transient pain.

Figure 5 – 1: Handlebar adjustment
1 Clamping lever

Figure 5 – 2: Secure the clamping lever

Before allowing the patient to lean on the handlebar, check the clamp as follows:

Danger

- *With the ergometer standing firmly, check that the handlebar is tight by trying to push the handlebar downwards from above. Adjust the clamping force of the clamping lever if necessary.*

The handlebar is not designed to support the full body weight! Risk of falling!

5.2 Saddle Adjustment

The saddle height of the ergoselect 1 is adjusted manually with a clamping lever.

When the pedal is in its lower position, there should be a 10° angle between the axis formed by the upper body and the thigh.

If necessary, adjust the handlebar to a position where it is comfortable to reach for the patient while sitting upright.

Caution

Before use, adjust the saddle height to fit the patient size. An incorrect saddle height will cause the patient to adopt an ergonomically incorrect posture, which leads to transient pain.

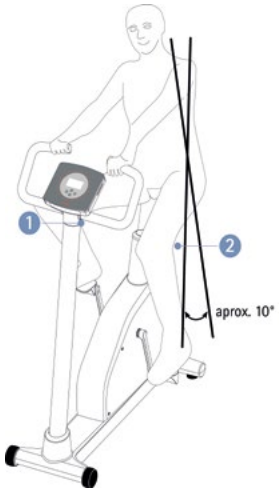


Figure 5 – 3: Adjusting saddle and handlebar
1 Adjusting the handlebar angle
2 Adjusting the height of the saddle

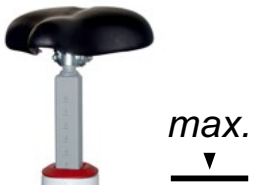
To adjust the saddle height, open the clamping lever 2 by turning it counter-clockwise.

Adjust the appropriate saddle height. Ask the patient to stand next to the saddle. Position the saddle at the level of the patient's hip. Tighten clamping lever 2 hand tight by turning it clockwise. Then tighten the clamping lever another 1/4 turn clockwise so that the clamping is secure.

Figure 5 – 4: Tightening the clamping lever

Warning

- *Do not choose saddle height settings above the "max." mark.*
- *Do not exceed the maximum height marked on the scale to avoid any risk of falling!*
- *At the maximum load level of the ergometer, the temperature at the saddle may reach 41.5°C.*
- *The ergometer may only be used on a dressed and fully conscious patient.*



Before allowing the patient to sit down on the saddle, check the secure fixation of the saddle as follows:

Danger

With the ergometer standing firmly, check that the saddle is securely clamped by trying to push it downwards from above. Adjust the clamping force of the clamping lever if necessary.

6 Operation

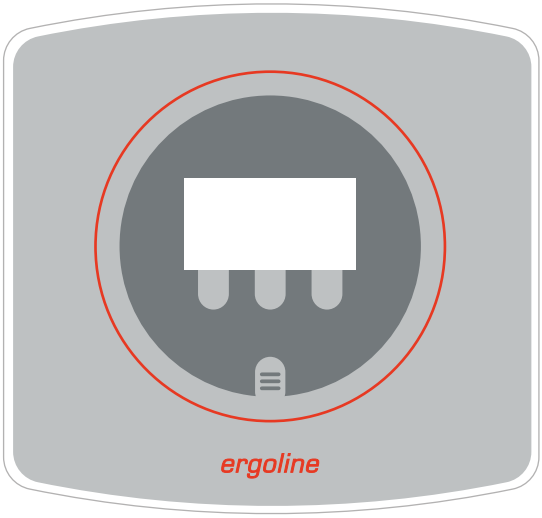


Figure 6 – 1: Control terminal of ergoselect 1

6.1 Turning the System On

You turn on the ergometer by pressing the power switch.

The ergometer runs a self-test. Subsequently, the main menu displays.

Figure 6 – 2: Self-test screen

Note

- *Instruct the patient not to pedal while the ergometer is being turned on and during the self-test.*
- *The device can be configured to default to one of the operating modes.*

If this option is selected, the start screen of the selected operating mode (e.g., Ergometry) will be displayed instead of the main menu.

With the key, you can display the main menu.

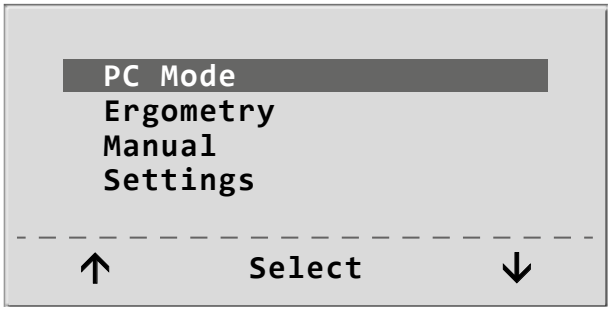


Figure 6 – 3: Main menu

The ergometer software is controlled with 4 keys:

With this key you display the main menu or return to the previous menu level.

The functions of these 3 softkeys change with the displayed menu – the key label describing the function is shown on the display.

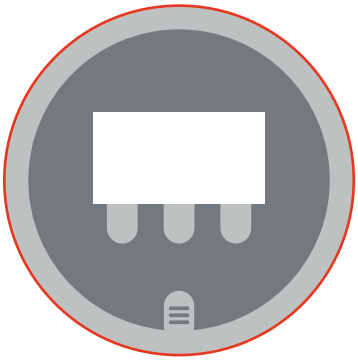


Figure 6 – 4: ergoselect 1 – keypad and display

6.2 Operating Modes

The ergoselect 1 ergometer supports the following operating modes:

PC Mode
An external device (e.g., an ECG recorder, a PC-based ECG system) controls the ergometer – no intervention at all is required at the ergometer.

Ergometry
The ergometer runs an automatic exercise test – some of the corresponding test protocols are user programmable and stored in the system.
(see chapter 11.2 *Exercise Test Protocols* on page 36)

Manual
The ergometer is controlled manually, i.e., the user performs all load changes via the keypad.

Settings
Used to configure the ergometer.

6.3 Speed Readout

A speed readout as well as five LEDs at the top of the control terminal inform the patient of the speed: too slow, too fast, or correct.

The ranges for the respective speed ratings depend on the selected load (see "Note" on page 27).

Note

If, during an exercise test, the speed drops below 30 RPM, the load readout starts blinking on the display.

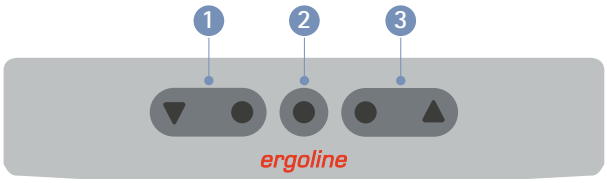


Figure 6 – 5: Speed readout
1. *speed low (patient should pedal faster)*
2. *correct speed*
3. *speed high (patient should pedal slower)*

6.4 PC Mode

Use the softkeys on the right and left (↑ ↓) to position the bar cursor on **PC Mode** and confirm the selection with **Select**.

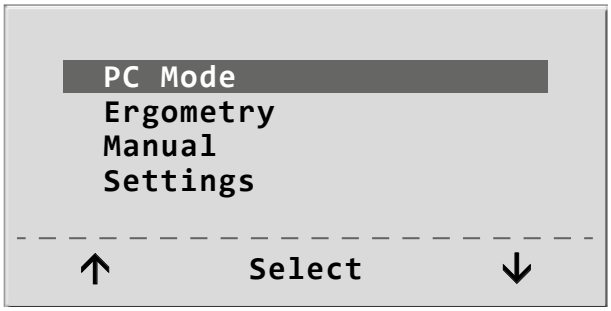


Figure 6 – 6: Main menu

The display changes – the ergometer is waiting for commands from the external ECG unit.

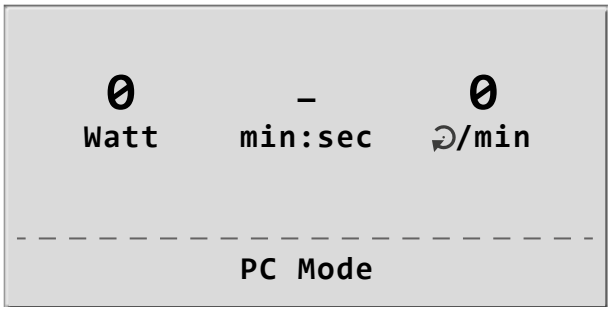


Figure 6 – 7: Start screen

As soon as the ergometer receives commands from the controlling ECG unit or PC, the exercise test will start and the corresponding values will be displayed.

The exercise test can only be terminated with the corresponding command from the controlling ECG unit.

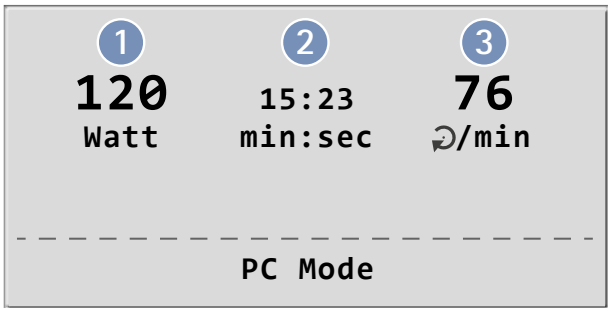


Figure 6 – 8: Exercise test screen
1. *current load (watts)*
2. *duration of exercise test (min)*
3. *pedal speed (RPM)*

6.5 Ergometry

Use the softkeys on the right and left (↑ ↓) to position the bar cursor on **Ergometry** and confirm the selection with **Select**.

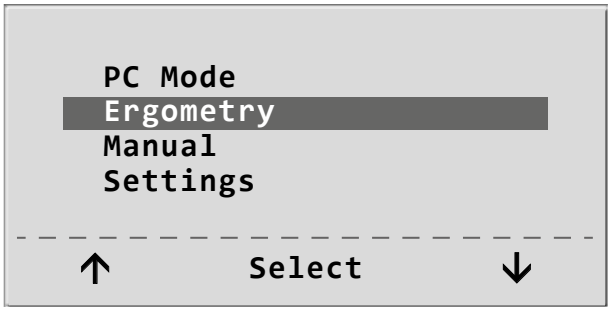


Figure 6 – 9: Main menu

The stored test protocols available for selection will be displayed. There are five fixed protocols (protocols 1 to 5) (see chapter 11.2 *Exercise Test Protocols* on page 36), whereas protocols 6 to 15 are user programmable.
The protocol menu provides an overview of the test phases.
Example: **50 W / 2 min / 25 W**
indicates: Basic load of 50 W
Stage time of 2 min
Load stage of 25 W

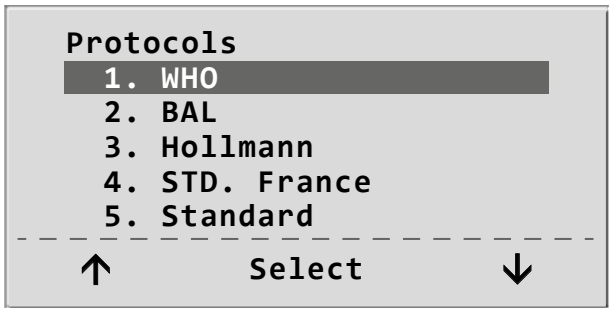


Figure 6 – 10: Selecting an exercise test protocol

Use the softkeys on the right and left (↑ ↓) to position the bar cursor on one of the protocols and confirm the selection with **Select**.

The exercise test is started with the **Start** key.

When the basic load appears on the display (after approx. 15 seconds) and the patient's RPM indicator blinks, the patient should start pedalling.

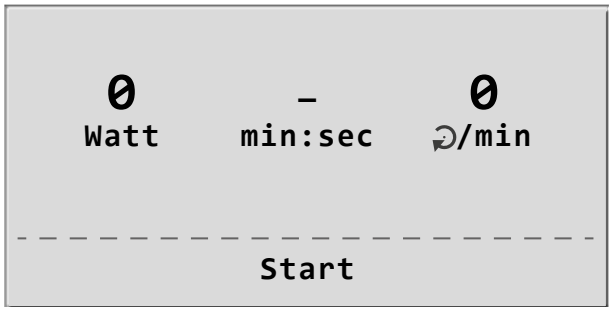


Figure 6 – 11: Starting the exercise test

The internal protocol will now control the entire exercise test – the display always indicates the current values.

With the +10 W and –10 W keys, the current load can be changed any time (in increments of +/–1 W, +/–5 W, +/–10 W, or +/–25 W, as configured).

Figure 6 – 12: Display during the exercise test

6.6 Terminating an Exercise Test

The exercise phase can be terminated manually at any time with the **Recovery** key.

The load will immediately be reduced to 25 watts, but a higher or lower value can be selected manually.

It is recommended that the patient continue to pedal in the recovery phase.

The **End** key in the middle will terminate the test.

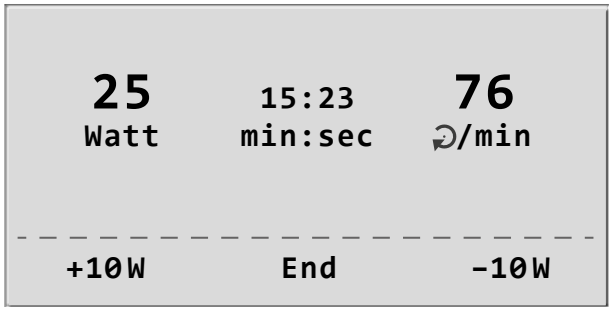


Figure 6 – 13: Recovery phase

6.7 Manual

Use the softkeys on the right and left (↑ ↓) to position the bar cursor on **Manual** and confirm the selection with **Select**.

In this operating mode the user controls the entire exercise test by selecting the load levels.

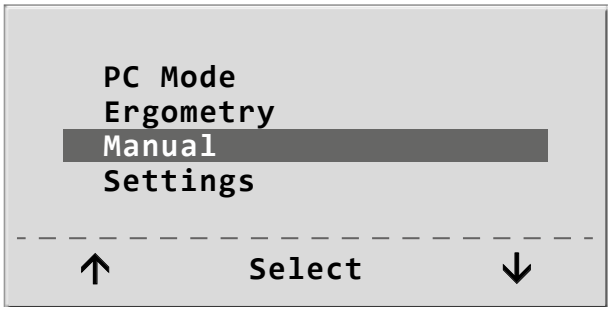


Figure 6 – 14: Main menu

The exercise test is started with the **Start** key, afterwards the load can be set and changed with the +10 W and –10 W keys (in increments of +/–1 W, +/–5 W, +/–10 W, or +/–25 W, as configured).

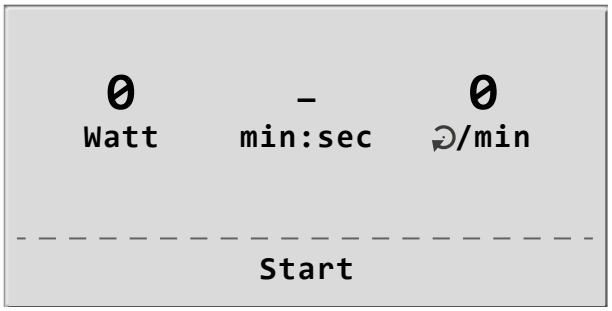


Figure 6 – 15: Initial screen of a manual exercise test

6.8 Terminating an Exercise Test

The exercise test can be terminated manually at any time with the **End** key located in the middle.

The load will immediately drop to 0 watt.

There is no recovery phase in the manual mode.

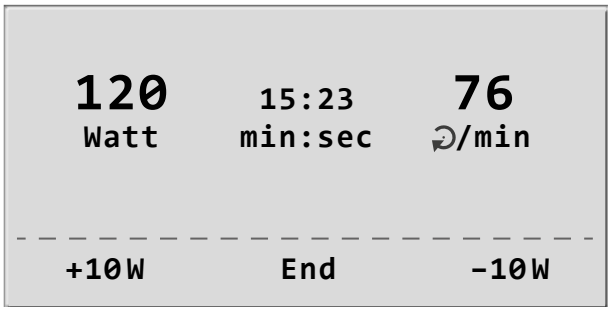


Figure 6 – 16: Display during the exercise test

6.9 Settings

Some of the device settings are programmable to meet specific requirements. The settings will be saved and remain stored even when the ergometer is switched off.

Use the softkeys on the right and left (↑ ↓) to position the bar cursor on **Settings** and confirm the selection with **Select**. The configuration menu displays.

When all changes have been made, you can exit the configuration menu with the ☰ key.

Use the softkeys on the right and left (↑ ↓) to position the bar cursor on the parameter to change and confirm the selection with **Select**.

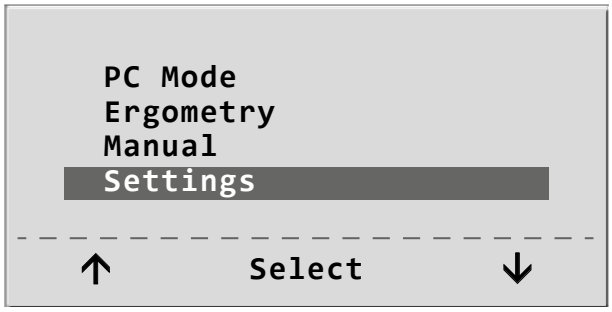


Figure 6 – 17: Main menu

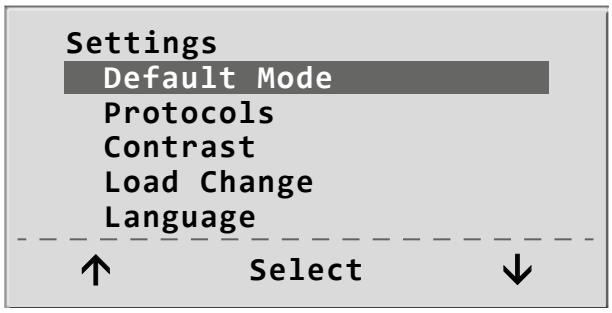


Figure 6 – 18: Settings menu

6.9.1 Default Mode

In this menu you choose the default mode activated when the ergometer is turned on. When first turned on after delivery, the ergometer will display this menu.

Use the softkeys on the right and left (↑ ↓) to position the bar cursor on your preferred default mode and save the selection with **Select**.

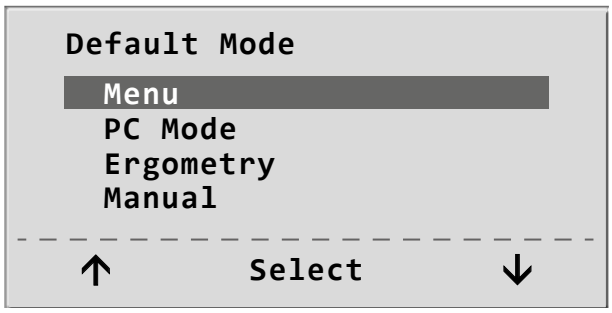


Figure 6 – 19: Selecting the default mode

6.9.2 Protocols

Protocols 6 to 15 are user-programmable (protocols 1 to 5 are fixed, see Appendix for protocol parameter details). Default values can be entered for the following parameters:

- Basic Load
- Stage Time
- Load Stage (load increase with each stage)

Use the softkeys on the right and left (↑ ↓) to position the bar cursor on the protocol to change (No. 6 to 15) and confirm the selection with **Select**.

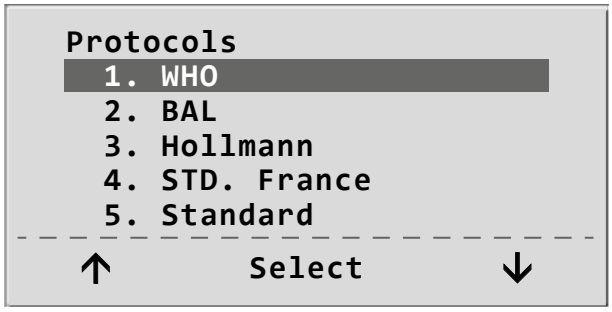


Figure 6 – 20: Selecting the exercise test protocol to edit

Use the right and left softkeys (↑ ↓) to select the parameter to edit.

The protocols can be configured with steps (increments) or ramp (gradual changes).

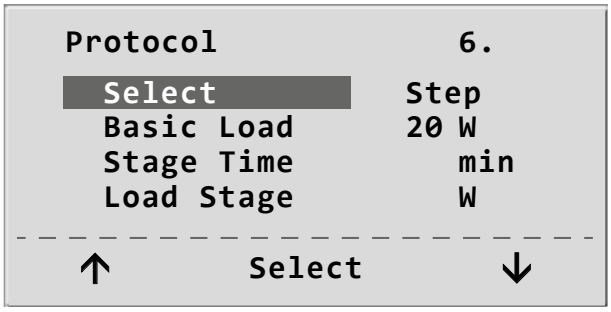


Figure 6 – 21: Selecting the parameter to edit

After confirming with **Select**, the corresponding value is highlighted and can be adapted with the keys (↑ ↓).

Pressing **Select** will save the new value.

The other parameters are edited in the same way.

You exit the configuration with .

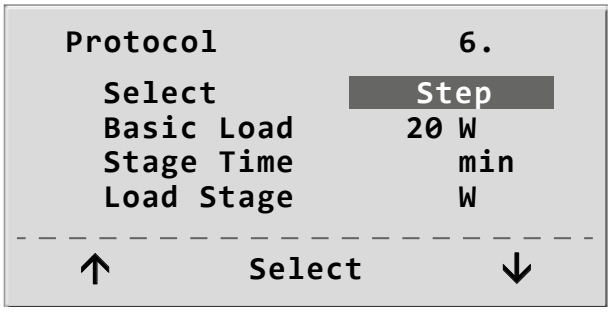


Figure 6 – 22: Editing the parameter value

6.9.3 Contrast

The display contrast is adjustable in the range from 0 to 100%.

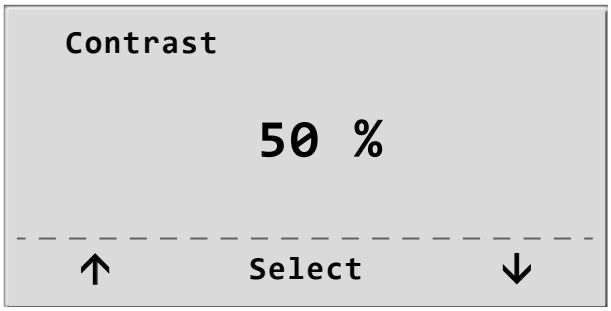


Figure 6 – 23: Adjusting the display contrast

6.9.4 Load Change

Here you determine the increments for each load change. Depending on your choice, each key press will change the load by +/–1, 5, 10, or 25 watts.

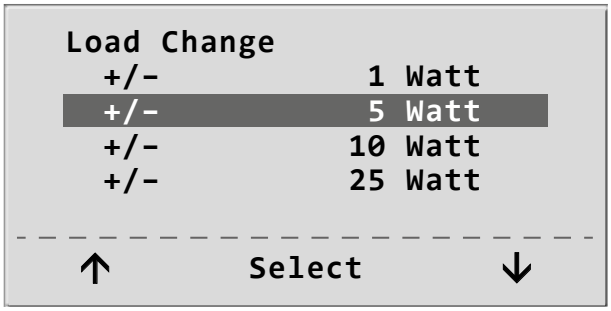


Figure 6 – 24: Selecting the increment for manual load changes

6.9.5 Language

The texts can be displayed in different languages.

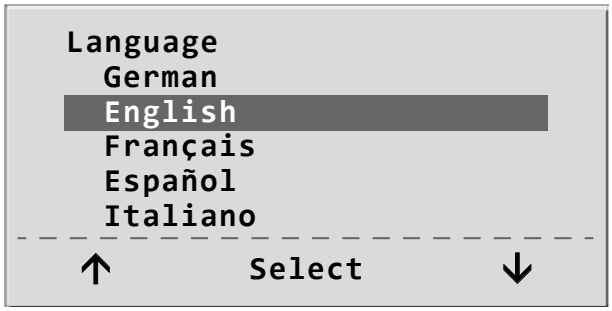


Figure 6 – 25: Language menu

6.9.6 Software Version

Select this option to view the installed software version.

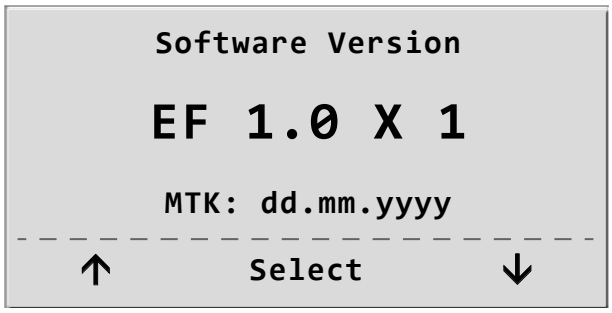


Figure 6 – 26: Display of the installed software version

6.9.7 ECG Type

The selected ECG Type determines the communication method with the ECG recorder, PC-based ECG system, etc.

To prevent an accidental change of this setting, the menu is protected with a password.
Enter the service code "003" and confirm with **Select**.

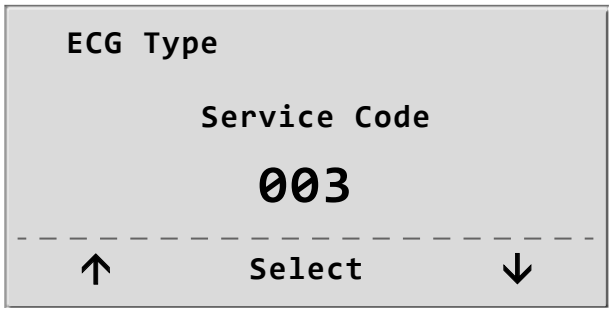


Figure 6 – 27: Entering the ECG Type password

The ergometer supports the following communication mode:

- **Digital**
  There is only one option: "Digital". This option is set by default. The communication with the ergometer is entirely controlled with digital commands.

The communication mode is selected and confirmed with **Select**.

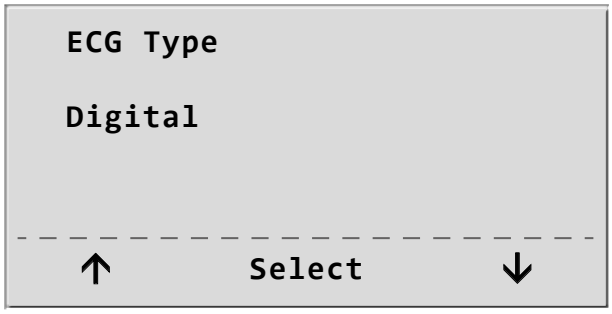


Figure 6 – 28: Selecting the ergometer communication mode

Note

- *The ECG Type needs to be selected only when the ergometer is connected to an ECG unit. This configuration setting is part of the installation procedure.*

6.9.8 RPM

Here you determine the RPM limits. When these limits are exceeded, the LEDs for high or low speed (RPM) will illuminate.

Select the value to change (Min. or Max.) and confirm with **Select**.

Using the arrow keys, change the value and save the new value with **Select**.

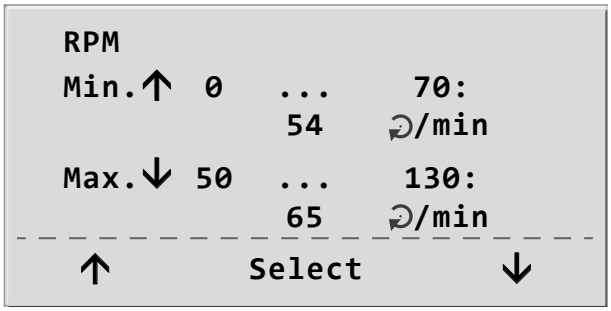


Figure 6 – 29: Setting the RPM limit values

Note

The limits selected in this menu only apply to the load range between 6 and 150 watts. At higher loads the RPM limits automatically adapt to the respective load ranges:

Load (watts)	Green RPM range (1/min)
6 – 150	*54 – 64 (adjustable)*
151 – 250	*61 – 62*
251 – 350	*71 – 72*
351 – 450	*81 – 82*
451 – 550	*91 – 92*
551 – 650	*101 – 102*
651 – 750	*111 – 112*
751 – 850	*121 – 122*
851 – 950	*> 130*
951 – 999	*> 135*

6.9.9 HR Belt Number

If the test subject wears a chest strap to measure the heart rate during the training, the corresponding chest strap number must be entered here. You will find the number on the back of the chest strap housing. It is the unique identifier for this particular strap.

With keys ↑ ↓, you toggle between the menu screens.

Figure 6 – 30: Setting the HR belt no. – screen 1

When the HR belt option has been selected (see figure 6 – 30), you can set the first digit of the number of up to 8 digits by pressing key ↓. The desired digit is selected with the arrow keys and the selected digit is saved with the **Select** key. Repeat these steps for each digit until the complete number has been entered.

Figure 6 – 31: Setting the HR belt no. – screen 2

7 Accessories / Compatible Devices

7.1 Accessories Overview

Part no.	Designation	Application	Information
707259	Horizontal seat adjustment	Ergonomics	optional
705308	Quick release adapter (w/o saddle)	Comfort	optional
705905	Pedal cranks, adjustable	Ergonomics	optional
705942	Pedal cranks, adjustable w/o tools	Ergonomics	optional
705944	Comfort pedal strap with ratchet	Pedal	optional
705786	Pedal, extra wide, with Comfort pedal strap	Pedal	optional
707001	Storage basket with holder	Comfort	optional
471107	Racing saddle with standard receptacle	Sports	optional
707300	Anti-tipping device, white stabilizer plate	Stability	optional

7.2 Compatible Devices

A large number of ECG and ergospirometry devices as well as PC software programs are compatible with ergoline ergometers via the ergoline interface protocol P10Vnnn.

Please contact *service@ergoline.com* for more information.

8 Cleaning, Disinfection and General Hygiene Measures

The document "Cleaning, and Disinfecting ergoline Medical Devices" (Part No. 201000641000) in its most recent version is also part of this manual. This document is exclusively made available for download from the ergoline website www.ergoline.com.

9 Maintenance

Only qualified technicians authorized by ergoline are allowed to carry out maintenance, servicing, technical inspections of the measuring system, and technical safety inspections. These interventions may only be carried out when the ergometer is not in use.

On request, ergoline GmbH will provide circuit diagrams, component lists, descriptions, calibration instructions, and other information that support the maintenance personnel when they repair those parts of the medical device which the manufacturer identified as repairable by maintenance personnel.

The parts of the medical device which the manufacturer identified as repairable by maintenance personnel are listed in the Field Service Manual.

9.1 Checks Before Each Use

Before each use, visually inspect the device for signs of mechanical damage. If you detect damage or impaired functions which may result in a hazard to the patient or the operator, the device must be repaired before it can be used again.

9.2 Technical Safety Inspections, Inspections of the Measuring System

The inspection of the measuring system and the technical safety inspection must be completed every two years according to the rules of the art by a Service Engineer authorized by ergoline GmbH.

The date of the next inspection is indicated on the inspection sticker attached next to the type plate on the ergometer.

9.3 Disposal

The device described in this operator manual must not be disposed of as unsorted municipal waste but must be collected separately.

Please contact your authorized manufacturer ergoline GmbH for information concerning the disposal of your device. There is no proof of disposal. Proper disposal is documented by ergoline GmbH.

Consult Operator's Manual!

10 System, Error and Failure Messages

Displayed error	Error description	Troubleshooting
Device cannot be switched on.	Device cannot be switched on with the power switch.	• Check that the power cord is properly plugged into the power outlet. • Check that the power cord is properly plugged into the device. • Check that voltage is applied to the power outlet (connect another functioning device). If the error persists, please contact the ergoline GmbH Service Department or a service partner authorized by ergoline.
Wrong SW config.	The software configuration of some of the PC boards is not compatible with the configuration of the overall software.	Switch the device off and on again. If the error persists, please contact the ergoline GmbH Service Department or a service partner authorized by ergoline.
To high rotation	The pedal speed of 130 revolutions/min was exceeded.	The error message disappears after 5 seconds. If the error message does not disappear after 5 seconds, switch the device off and on again. If the error persists, please contact the ergoline GmbH Service Department or a service partner authorized by ergoline.
Load out of limit	The load is outside the tolerance limits.	Switch the device off and on again. If the error persists, please contact the ergoline GmbH Service Department or a service partner authorized by ergoline.
DMS Offs. invalid	The offset value of the torque sensor is outside the tolerance limits.	Switch the device off and on again. If the error persists, please contact the ergoline GmbH Service Department or a service partner authorized by ergoline.
DMS Gain invalid	The gain of the torque sensor is outside the tolerance limits.	Switch the device off and on again. If the error persists, please contact the ergoline GmbH Service Department or a service partner authorized by ergoline.
+24V out of range	The 24 V DC voltage supply is outside the tolerance range.	Switch the device off and on again. If the error persists, please contact the ergoline GmbH Service Department or a service partner authorized by ergoline.
Brake not releas.	The torque sensor is not recognized.	Switch the device off and on again. If the error persists, please contact the ergoline GmbH Service Department or a service partner authorized by ergoline.
Safety state mode	Safety circuit violated.	Switch the device off and on again. If the error persists, please contact the ergoline GmbH Service Department or a service partner authorized by ergoline.

Displayed error	Error description	Troubleshooting
Setup not ready	Setup aborted	Switch the device off and on again. If the error persists, please contact the ergoline GmbH Service Department or a service partner authorized by ergoline.
CAN zykl. Timeout	CAN bus fault	Switch the device off and on again. If the error persists, please contact the ergoline GmbH Service Department or a service partner authorized by ergoline.

11 Technical Specifications

11.1 Ergometer

Version

modular ergometer system
model ergoselect 1

Operating mode

Load	Speed	1st interval in minutes*	followed by	OFF time in minutes	ON time in minutes
450 watts	85 rpm	25		26	4
400 watts	85 rpm	30		25	5
350 watts	80 rpm	35		24	6
300 watts	75 rpm	40		23	7
250 watts	70 rpm	50		20	10
200 watts	65 rpm	70		18	12
150 watts	60 rpm	100		15	15
100 watts	55 rpm	∞		–	–

Power supply

~ 100 – 240 V AC / 50 – 60 Hz / 100 VA max.

specifications of the US power cord:
SJT 2x18AWG 125 V AC / 7 A
"hospital" or "hospital grade"

Braking principle

computer-controlled eddy current brake

Load range

6 – 450 W, speed-independent

Speed range

30 – 130 rpm

Crank length

172 mm (adjustable length cranks available as optional accessories)

Moment of inertia of the crank

14 kg · m^2

Load accuracy

Deviation of measured load:
≤ 5 % or 3 W, whichever is greater
(DIN VDE 0750-238:2002-10)

Deviation of measured speed:
≤ 2 rpm (DIN VDE 0750-238:2002-10)

Load increments

user programmable

Internal protocols

Control Terminal C:
- 5 predefined incremental protocols (WHO, Hollmann, etc.)
- 10 user-programmable exercise test protocols

Permitted patient weight

160 kg max.

Permitted patient height

- approx. 120 – 210 cm
- children if their height and weight is within the defined limits

Handlebar adjustment

- for body heights from 120 cm to 210 cm
- continuous handlebar adjustment over 360°

Saddle adjustment	mechanical, continuous
Display	**liquid crystal display (LCD):** 68 x 34 mm / 128 x 64 pixels LED as speed readout
Interfaces	**PORT 1 (DSUB-9-pol.):** remote control from PC or ECG recorder **USB:** remote control from PC (driver required) **optional:** Bluetooth, WiFi
Dimensions, weight	**length:** 1000 mm **width:** 440 mm (width of handlebar approx. 535 mm) **height:** 1280 mm **weight:** approx. 55 kg
Safety standards	DIN EN 60601-1, DIN EN 60601-1-2, DIN VDE 0750-238
Protection class	II 
Applied part	type B (ergometer)
Classification	class Im (m: with a measuring function) according to Annex VIII of the Medical Device Regulation (EU) 2017/745
RF emission	class B to DIN EN 55011 / 5.0 DIN EN 60601-1-2
Environment	**operation:** temperature: +5 °C to +40 °C rel. humidity: 15 to 90 %, no condensation atmospheric pressure: 700 to 1060 hPa (3000 m) **transport and storage:** • no relative humidity check required at temperatures of –25 °C and above • +5 °C to +35 °C at a relative humidity of up to 90 %, no condensation • > 35 °C to 70 °C at a water vapor pressure up to 50 hPa
Type of protection	IP21
Expected lifetime	5 years

11.2 Exercise Test Protocols

Protocol	Basic Load [W]	Stage Time [min]	Load Stage [W]	Recovery Load [W]	Recovery Time [min]
1. WHO	25	2	25	25	99
2. BAL	50	3	50	25	99
3. Hollmann	30	3	40	25	99
4. STD France	30	3	30	25	99
5. Standard	20	1	25	25	99
6. – 15. (user programmable)	25	2	25	25	99
Adjustment Range	20 – 100	1 – 30	1 – 400	20 – 100 (*)	1 – 99

(*) The recovery load is fixed at 25 W.

11.3 Family of Characteristics of the Braking Torque Control Range

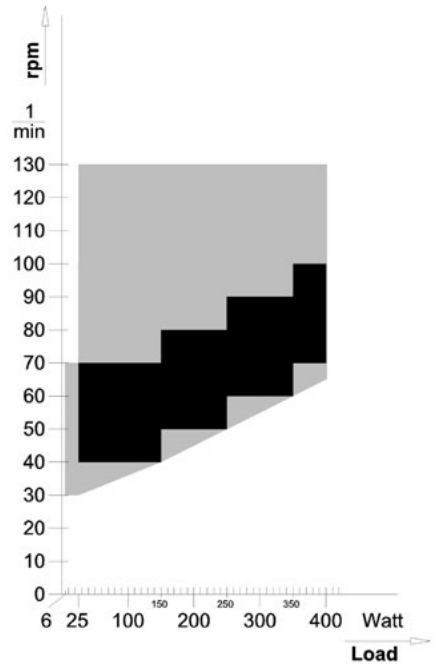


Figure 11 – 1: black: *speed-independent range to DIN VDE 0750-0238*
black + grey: *speed-independent range of the ergoselect 1 ergometer*

11.4 Family of Characteristics of the Load Periods according to IEC 60601-1

Load	Speed	1st interval in minutes*		OFF time in minutes	ON time in minutes
450 watts	85 rpm	25	followed by	26	4
400 watts	85 rpm	30		25	5
350 watts	80 rpm	35		24	6
300 watts	75 rpm	40		23	7
250 watts	70 rpm	50		20	10
200 watts	65 rpm	70		18	12
150 watts	60 rpm	100		15	15
100 watts	55 rpm	∞		–	–

* The times refer to a cold start of the ergometer at a maximum ambient temperature of 40 °C. This means that the temperature of the ergometer may not exceed the maximum allowed room temperature when starting the first interval. If operation of the ergometer continues after the indicated time interval, it is mandatory to observe the OFF and ON times.

12 Electromagnetic Compatibility EN 60601-1-2

Changes or modifications to this system not expressly approved by ergoline GmbH could cause EMC issues with this or other equipment.

This system is designed to comply with applicable regulations regarding EMC.

Its compliance with these requirements has been verified. It needs to be installed and put into service according to the EMC information stated as follows.

Warning

RF Interference

Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

Caution

Equipment Malfunction

The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The ergoselect 1 ergometer is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the ergoselect 1 ergometer is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions to EN 55011	Group 1	The ergoselect 1 ergometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions to EN 55011	Class B	The ergoselect 1 ergometer is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions to EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions to EN 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ergoselect 1 ergometer is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the ergoselect 1 ergometer is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) to EN 61000-4-2	± 8 kV contact ± 16 kV air	± 8 kV ± 16 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst to EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input and output lines	± 2 kV passed	Mains power quality should be that of a typical commercial or hospital environment.
Surge to EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV N. A.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines to EN 61000-4-11	to EN 61000-4-11	passed	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ergoselect 1 ergometer requires continued operation during power mains interruptions, it is recommended that the ergoselect 1 ergometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field to EN 61000-4-8	30 A/m 50 Hz	passed	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. The ergoselect 1 ergometer has no components susceptible to magnetic fields.
Note: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ergoselect 1 ergometer is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the ergoselect 1 ergometer is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF to EN 61000-4-6 Radiated RF to EN 61000-4-3	3 V / 6 V^{ISM} 150 kHz to 80 MHz 10 V/m 80 MHz to 2.5 GHz	3 V / 6 V^{ISM} 10 V/m	Portable and mobile RF communications equipment should be used no closer to the ergoselect 1 ergometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d = 1.2 √P d = 1.2 √P for 80 MHz to 800 MHz d = 2.3 √P for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: 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 radio, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess 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 ergoselect 1 ergometer is used exceeds the applicable RF compliance level above, the ergoselect 1 ergometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ergoselect 1 ergometer.
b) Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ergoselect 1 ergometer

The ergoselect 1 ergometer is intended for use in an electromagnetic environment, as specified below, in which radiated RF disturbances are controlled. The customer or the user of the ergoselect 1 ergometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ergoselect 1 ergometer as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter [W]	**Separation Distance according to Frequency of Transmitter [m]**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3

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: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

ergoline

MOVING TO HEALTH

ergoline GmbH
Lindenstraße 5
72475 Bitz
Germany

Tel.: +49-(0) 7431 98 94 - 0
Fax: +49-(0) 7431 98 94 - 128
e-mail: info@ergoline.com
http: www.ergoline.com