ergoline

MOVING TO HEALTH

ergoselect 1

Bicycle Ergometer

Operator's Manual

201000551000 • Version 2021-05-12 / Rev 02 • English

Manual

ergoselect 1

Bicycle Ergometer

Operator's Manual

201000551000 • Version 2021-05-12 / Rev 02 • English

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 product ergoselect bears the CE marking CE-0123 (Notified Body: TÜV), indicating its compliance with the provisions of the Council Directive 93/42/EEC about medical devices and fulfills the essential requirements of Annex I of this directive.
  The CE marking covers only the accessories listed in the Order Information chapter.
  The device is an MDD class IIa product.

- The device fulfills the requirements of the standard EN 60601-1 "Medical electrical equipment, Part 1: General Requirements for Safety" as well as the interference protection 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.

- The symbol  means: protection class II.

- 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, read the manual once in its entirety.

- The symbol  means: Follow the instructions in the documentation.
  It indicates points that are of particular importance in the operation of the device.

- 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.
  All rights are reserved for devices, circuits, techniques, software programs, and names appearing in this manual.

- 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 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
  - the device is used in accordance with the instructions given in this operator manual.

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 ergoselect to direct sunlight to prevent system components from reaching inadmissible high temperatures.

Do NOT use the ergoselect outdoors (medical device). 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 ergoselect 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 electric installations that fulfill the local requirements.

Patient Hazard

The German Medical Device Operator Ordinance (MPBetreibV, § 5) demands that users

- *must be trained in the use of the ergometer*
- *must be familiar with the routines for handling and assembly of the ergometer*
- *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 instructions)*
- *must be informed about the potential hazards arising from the use of this type of equipment*
- *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., IEC 60950 for data processing equipment).
Furthermore, all configurations must meet the requirements of the applicable medical systems standards (see 3rd edition of IEC 60601-1).

Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible for the system's compliance with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements.

If in doubt, please consult your local dealer or ergoline GmbH.

Note

Applied Parts

Applied parts are components that are in direct 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. It may become unstable as a result.

2.1 Contraindications

- The general, absolute contraindications to cardiac stress testing apply.
- Patients with physical, psychological, or mental afflictions who cannot be mobilized and are therefore not capable of using rehabilitation facilities.

The following patient categories are excluded from using the device:
- dizziness, nausea, or pain
- patients under the influence of substances that may impair vigilance (alcohol, drugs, medication).

Contraindications in exercise testing carried out with ergometers

(source: Banerjee A et al., 2012)

Contraindications in exercise testing:
- acute myocardial infarction in the previous 4 to 6 days
- unstable angina with rest pain in the previous 48 hours
- uncontrolled heart failure
- acute myocarditis or pericarditis
- acute systemic infection
- deep vein thrombosis as it is likely to shift and cause pulmonary embolism
- uncontrolled hypertension with systolic blood pressure > 220 mmHg or diastolic blood pressure > 120 mmHg
- severe aortic stenosis
- severe hypertrophic obstructive cardiomyopathy
- untreated life-threatening arrhythmia
- dissecting aneurysm
- recent aortic surgery
- abnormalities during testing include:
  - abnormal ST-segment response (horizontal, planar, or down-sloping depression of > 1 mm).
  - T-wave elevation of > 1 mm in non-Q-wave leads.
  - T-wave changes such as inversion and pseudo-normalization when an inverted T-wave becomes upright are non-specific changes.

Criteria for stopping bicycle-based exercise testing

(source: Banerjee A et al., 2012).

Criteria for stopping bicycle based exercise testing include:

ECG criteria
- severe ST depression of > 3 mm
- ST elevation > 1 mm in non-Q-wave lead
- frequent ventricular extra systoles
- onset of ventricular tachycardia
- new atrial fibrillation or supraventricular tachycardia
- development of new bundle branch block
- progression of heart block to second or third degree
- cardiac arrest

Clinical criteria
- excessive fatigue
- severe chest pain, dyspnoea, or dizziness
- > 20 mmHg reduction in systolic blood pressure
- rise in blood pressure

2.2 Intended Use

The medical device is a stationary ergometer used for reproducible, controlled stress testing of the cardiovascular system.

It is employed as a training device in the field of orthopedics, in rehabilitation and secondary prevention for the treatment of decreased physical fitness resulting from the following conditions:
- cardiovascular diseases
- metabolic disorders
- cancers
- pulmonary diseases
- sedentary lifestyle

Furthermore, it is a diagnostic tool in performing exercise stress tests.

2.3 Intended User

Only the intended users are allowed to use the ergometer.

The group of intended users includes:
- healthcare professionals thoroughly instructed on the basis of the operator manual
- patients of the intended patient group who have been thoroughly instructed by trained specialists

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.

2.4 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 exercise testing. 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.

2.5 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 applied as intended.

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

2.6 Applicable Laws, Regulations and Directives

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

3 Symbols

Symbol 'type B applied part'.
Type B applied parts have no direct contact with patients and offer the lowest protection against electric shock.

Note: Consult accompanying documents.

Protection class II equipment.

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

Order number.

Serial number.

Scheduled date of the next inspection (e.g., March 2020).

Toggle switch ON (voltage).

Toggle switch OFF (voltage).

CE mark per the Medical Device Directive 93/42/EEC of the European Union.
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.

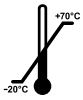
Manufacturer's identification.

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.

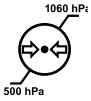
Transport and storage label:
keep dry.

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 Preparing the Patient

4.1 Handlebar Adjustment

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

Choose a handlebar angle that allows the patient to sit up straight and comfortably. Then tighten the rotary lever 1 hand tight by turning it clockwise.

Before allowing the patient to rest the full body weight on the handlebar, check the clamping as follows:

Figure 4 – 1: Handlebar adjustment
1 Rotary lever

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 rotary lever if necessary.*

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

4.2 Saddle adjustment

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

Set the handlebar to a position where it is comfortable to reach for the patient while sitting upright (see section 4.1 *Handlebar Adjustment* on page 10).

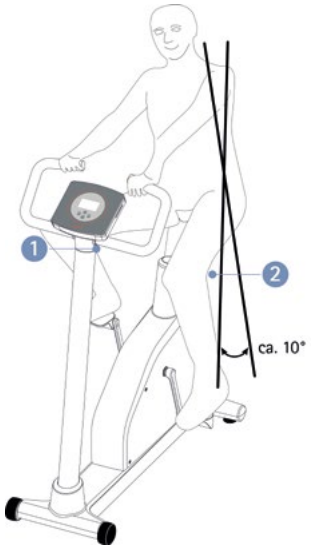


Figure 4 – 2: Adjusting Saddle and Handlebar
1 Adjusting the handlebar angle
2 Adjusting the height of the saddle

To adjust the saddle height, open the rotary lever (1) by turning it counter-clockwise.

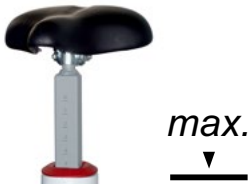
Adjust the appropriate saddle height. Ask the patient to stand next to the saddle. Position the saddle at the level of the patient's hip. Then tighten the rotary lever (1) hand tight by turning it clockwise.

Figure 4 – 3: Tightening the rotary 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!



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 rotary lever if necessary.

5 Setup and Mains Connection

5.1 Controls and Indicators

1. Control terminal
2. Speed indication for the patient
3. Adjustment of handlebar angle
4. Castors
5. Adjustment of saddle height
6. Power switch (toggle switch [I/0])
7. Leveling feet to adjust the ergometer to uneven floors
8. Sockets for power cord and connection cables (underside of ergometer)

Figure 5 – 1: Operating controls of the ergoselect 1

5.2 Mounting the Control Terminal

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

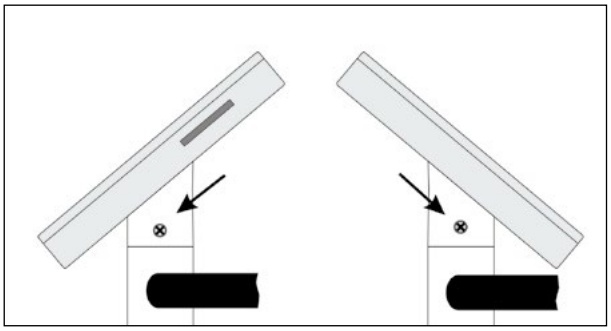


Figure 5 – 2: Different orientations of the control terminal

5.3 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 and 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 protect it from considerable damage.

Caution

Equipment Damage

Avoid strong vibrations of the ergoselect 1 during transport.

Figure 5 – 3: Transporting the ergoselect 1

5.4 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 5 – 4: Leveling foot of the ergoselect 1 ergometer

5.5 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 5 – 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.

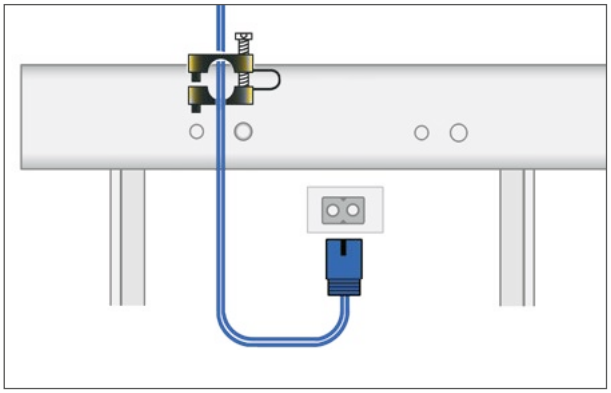


Figure 5 – 6: Power cord in strain relief mounted to frame

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

Pressing the power switch or removing the power cord disconnects the device from the power supply.

Removing the power cord results in a complete disconnection of the device from the power supply (all poles).

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

5.6 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.

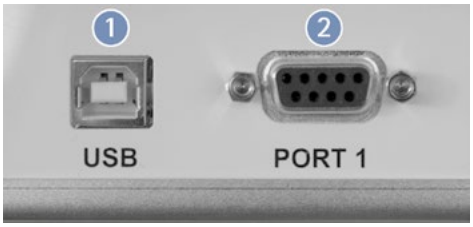


Figure 5 – 7: Connection for ECG recorder / PC ECG system
1 *USB: PC connection via USB (virtual COM)*
2 *PORT 1: Digital connection (remote control from PC or ECG recorder)*

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.

6 Operation

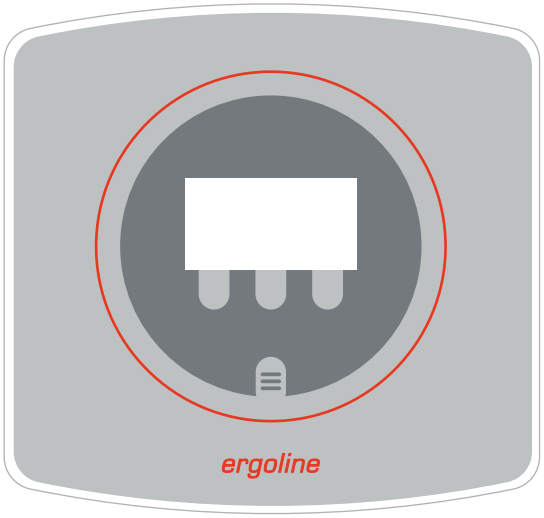


Figure 6 – 1: Control terminal of ergoselect 1

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.

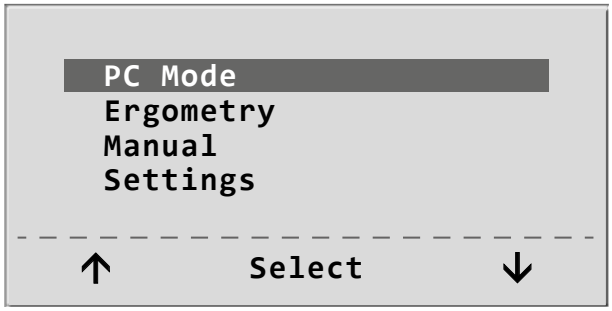


Figure 6 – 3: Main menu

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.

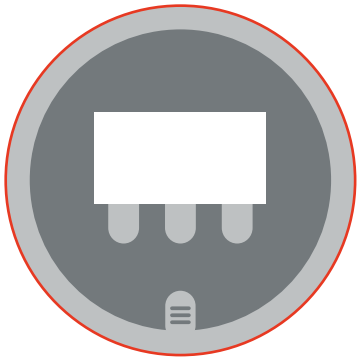


Figure 6 – 4: ergoselect 1 – keypad and display

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-configurable and stored in the system.
(see chapter 10.2 *Exercise Test Protocols* on page 29)

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 24).

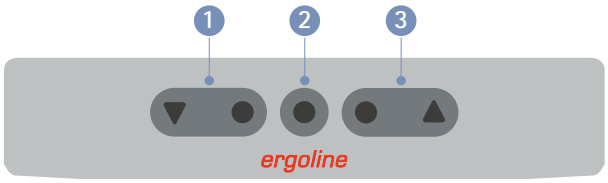


Figure 6 – 5: Speed readout
1. *speed low (patient should pedal faster)*
2. *correct speed*
3. *speed high (= patient should pedal slower)*

Note

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

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**.

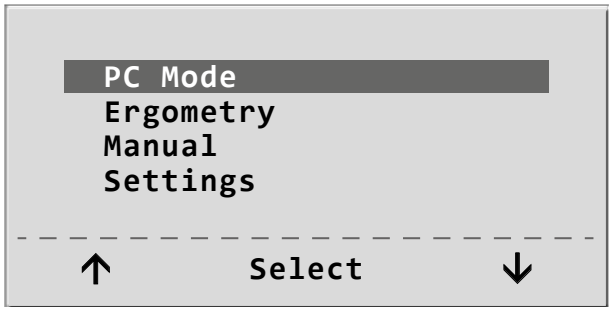


Figure 6 – 6: Main menu

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

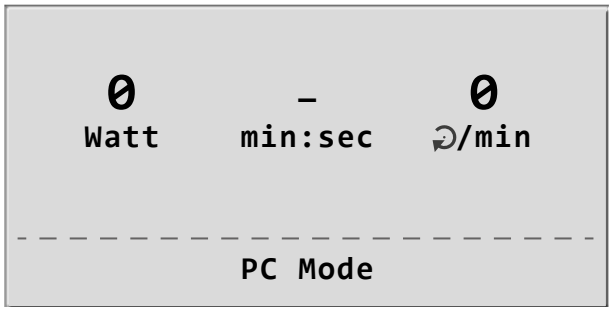


Figure 6 – 7: Start screen

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.

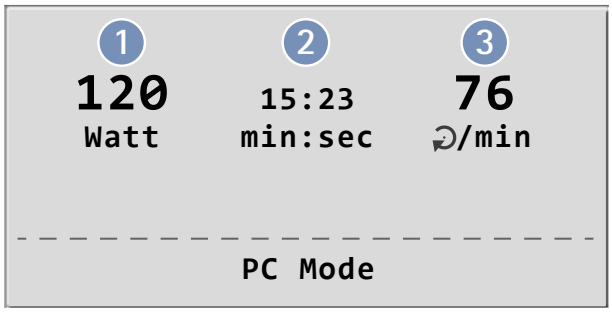


Figure 6 – 8: Exercise test screen
1. *current load (watts)*
2. *duration of exercise test (min)*
3. *pedal speed (RPM)*

6.5 Ergometry

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

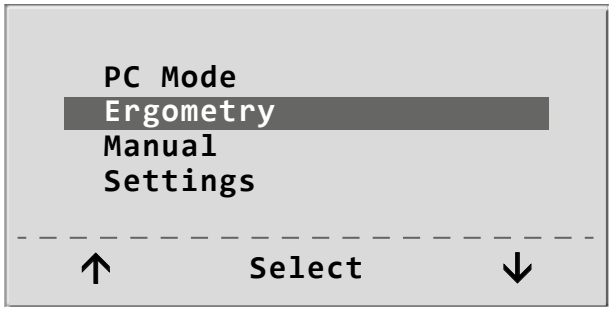


Figure 6 – 9: Main menu

The stored test protocols available for selection will be displayed. There are five fixed protocols (protocols 1 to 5) (see chapter 10.2 *Exercise Test Protocols* on page 29), whereas protocols 6 to 15 are user-configurable.
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

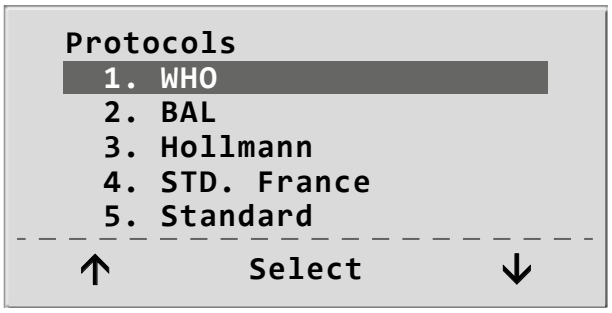


Figure 6 – 10: Selecting an exercise test protocol

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.

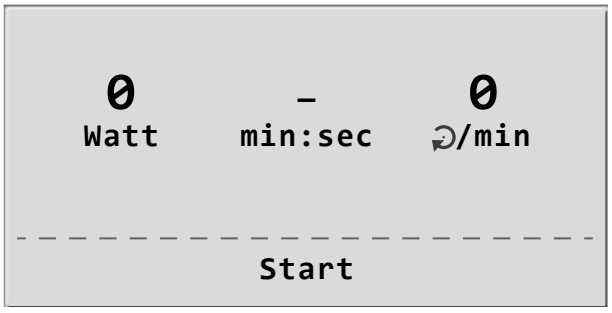


Figure 6 – 11: Starting the exercise test

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.

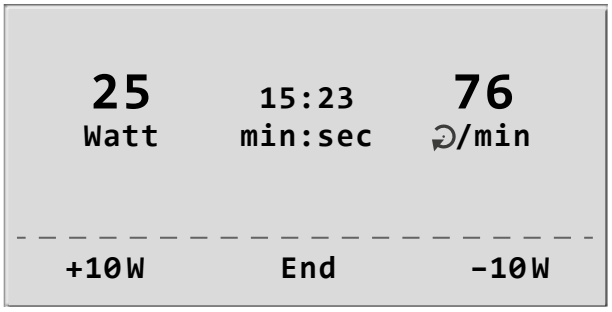


Figure 6 – 13: Recovery phase

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.

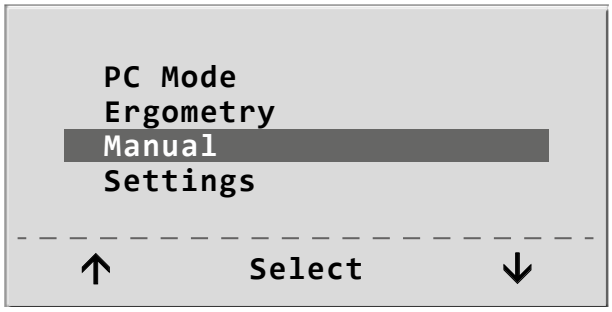


Figure 6 – 14: Main menu

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).

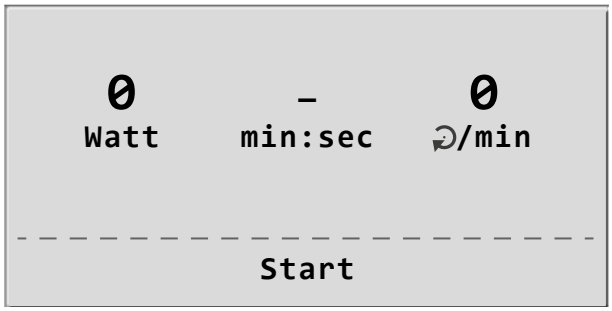


Figure 6 – 15: Initial screen of a manual exercise test

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.

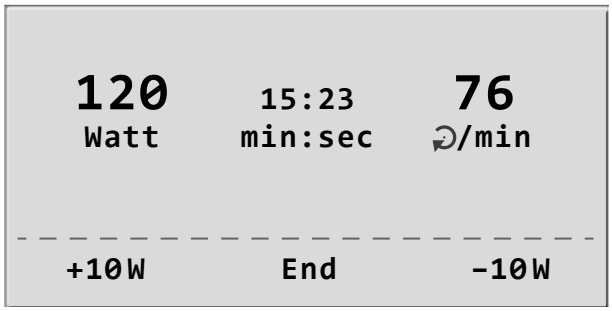


Figure 6 – 16: Display during the exercise test

6.9 Settings

Some of the device settings are configurable 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**.

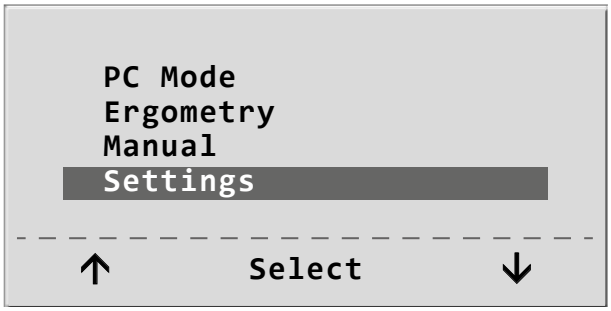


Figure 6 – 17: Main menu

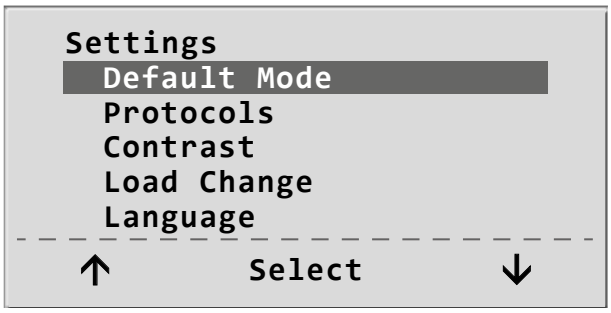


Figure 6 – 18: Settings menu

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**.

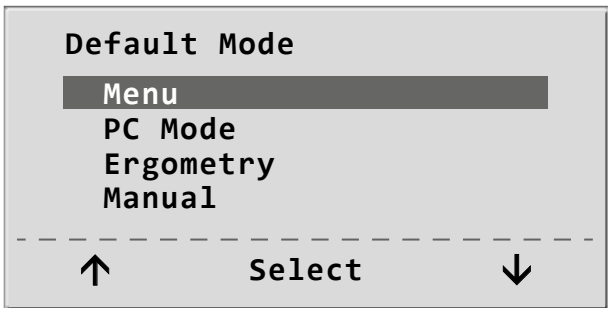


Figure 6 – 19: Selecting the default mode

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**.

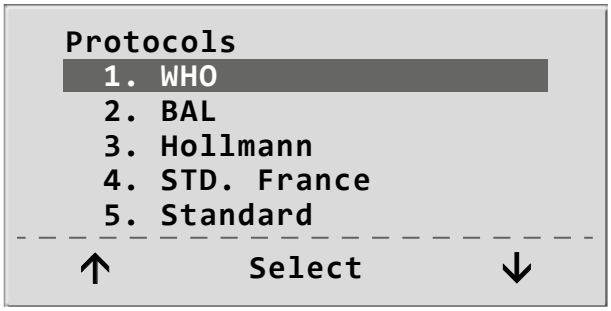


Figure 6 – 20: Selecting the exercise test protocol to edit

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

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

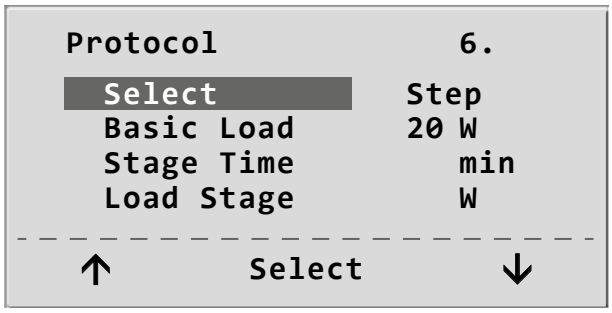


Figure 6 – 21: Selecting the parameter to edit

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 .

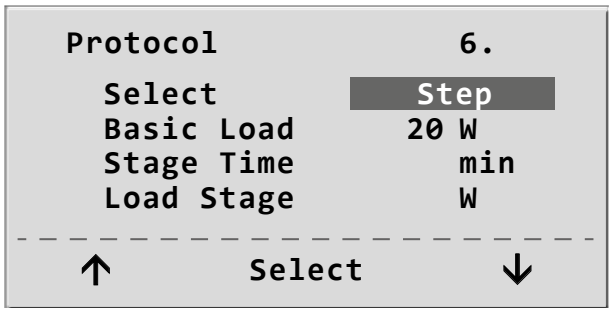


Figure 6 – 22: Editing the parameter value

6.9.3 Contrast

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

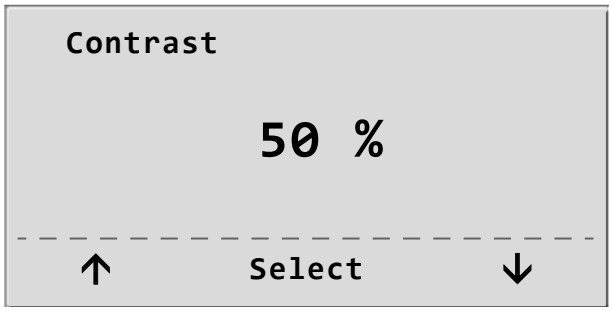


Figure 6 – 23: Adjusting the display contrast

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.

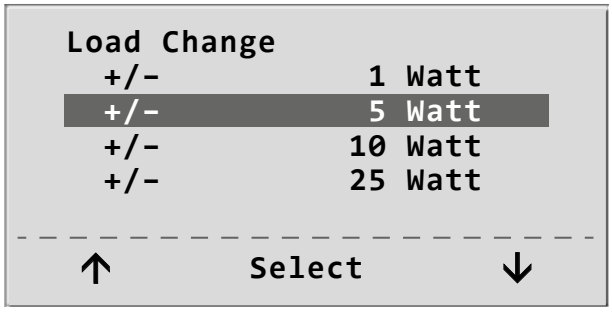


Figure 6 – 24: Selecting the increment for manual load changes

6.9.5 Language

The texts can be displayed in different languages.

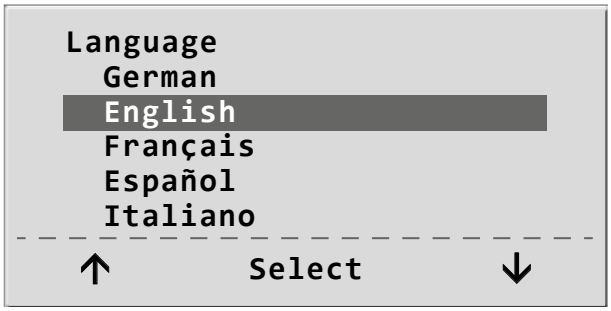


Figure 6 – 25: Language menu

6.9.6 Software Version

Select this option to view the installed software version.

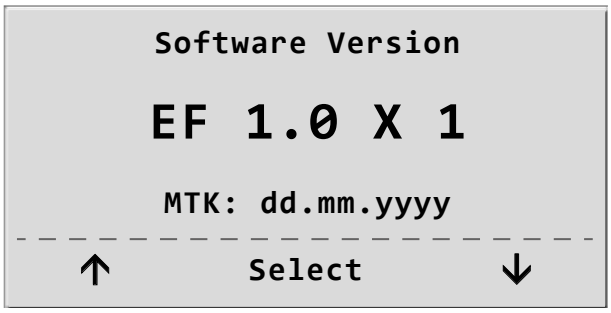


Figure 6 – 26: Display of the installed software version

6.9.7 EKG Type

The selected EKG 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**.

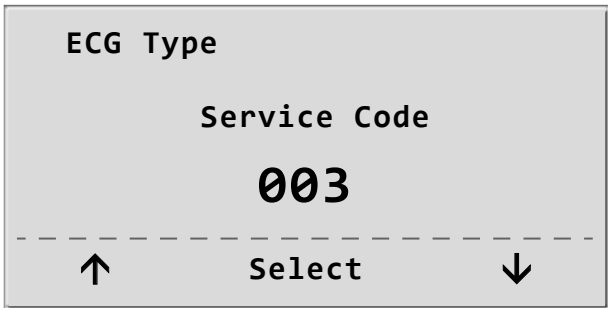


Figure 6 – 27: Entering the EKG Type password

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**.

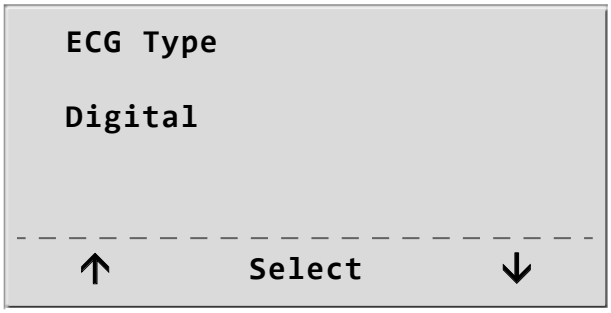


Figure 6 – 28: Selecting the ergometer communication mode

Note

- *The EKG 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**.

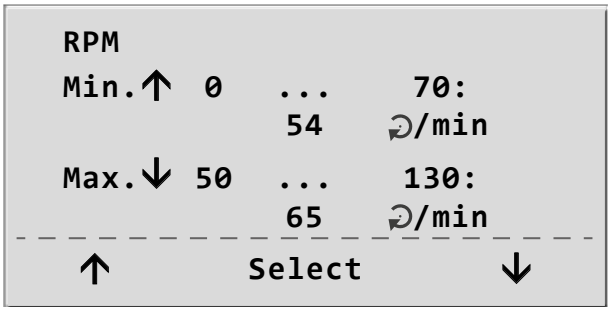


Figure 6 – 29: Setting the RPM limit values

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 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 numeral is selected with the arrow keys and the selected numeral is saved with the **Select** key. Repeat these steps for each numeral until the complete number has been entered.

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

7 Accessory/Compatible Devices

7.1 Accessories Overview

Part no.	Description	Application	Information
erg705.944	Comfort pedal straps, with ratchet (set)	Comfort	optional
erg705.084	Horizontal seat adjustment	Ergonomics	optional
erg705.308	Quick release adapter (w/o saddle)	Comfort	optional
erg705.905	Pedal cranks, adjustable	Ergonomics	optional
erg705.942	Pedal cranks, adjustable w/o tools	Ergonomics	optional
erg705.786	Pedal, extra wide, with Comfort pedal straps (set)	Pedal	optional
erg705.300	Tilt protection	Stability	optional
erg705.838	POAG connection kit (potential equalization/functional ground)	Connection	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

9.1 Checks Before Each Use

Before each use, visually inspect the device for signs of 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.

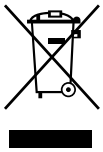
9.2 Technical Safety Inspections, Inspections of the Measuring System

The technical safety inspections and the inspections of the measuring system 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 product described in this operator manual must not be disposed as unsorted municipal waste; it must be collected separately.



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

Consult Operator's Manual!

10 Technical Specifications

10.1 Ergometer

Version	modular ergometer system model ergoselect 1
Operating mode	continuous operation
Power supply	100 – 240 V / 50 – 60 Hz / 60 VA max. **specifications of the US power cord:** SPT 2x18AWG 125 V / 10 A "hospital" or "hospital grade"
Braking principle	computer-controlled eddy current brake
Load range	6 – 450 W, speed-independent
Speed range	30 – 130 rpm
Load accuracy	to DIN VDE 0750-238
Load increments	user programmable
Internal protocols	**Control Terminal P:** • 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 (from 6 to 12 years of age) if their height and weight is within the defined limits.
Handlebar adjustment	• for body heights between 120 cm 210 cm • continuous handlebar adjustment over 350°
Saddle adjustment	infinitely, mechanical
Crank length	170 mm (adjustable length cranks available as optional accessories)
Display	**LCD:** 68 x 34 mm / 128 x 64 pixels LED as speed readout
Interfaces	**PORT 1 (DSUB-9-pole):** remote control from PC or ECG recorder **USB:** remote control from PC (driver required) **option:** Bluetooth, WLAN

Dimensions, weight	**length:** 1000 mm **width:** 440 mm (width of handlebar approx. 535 mm) **height:** 1280 mm **weight:** approx. 55 kg
Safety standards	DIN IEC 60601-1, DIN EN 60601-1-2, DIN VDE 0750-238
Protection class/degree of protection	II ⧈ / B (ergometer)
MDD classification	class IIa to 93/42 EEC
RF emission	class B to DIN EN 55011/5.0 DIN EN 60601-1-2
Environment	**operation:** temperature: +10 to +40 °C rel. humidity: 30 to 75%, no condensation atmospheric pressure: 800 to 1060 hPa **transport and storage:** temperature: –20 to +70 °C rel. humidity: 10 to 95%, no condensation atmospheric pressure: 500 to 1060 hPa

10.2 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.

10.3 Family of characteristics of the braking torque control range

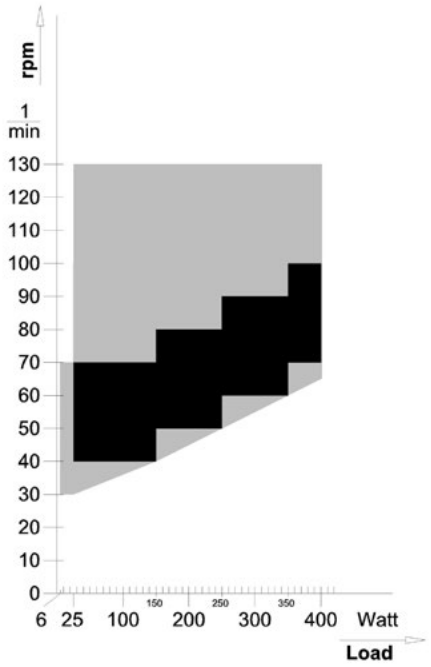


Figure 10 – 1: **black:** *speed-independent range to DIN VDE 0750-0238*
black + gray: *speed-independent range of the ergoselect 1 ergometer*

10.4 Family of characteristics of the load periods according to IEC 60601-1

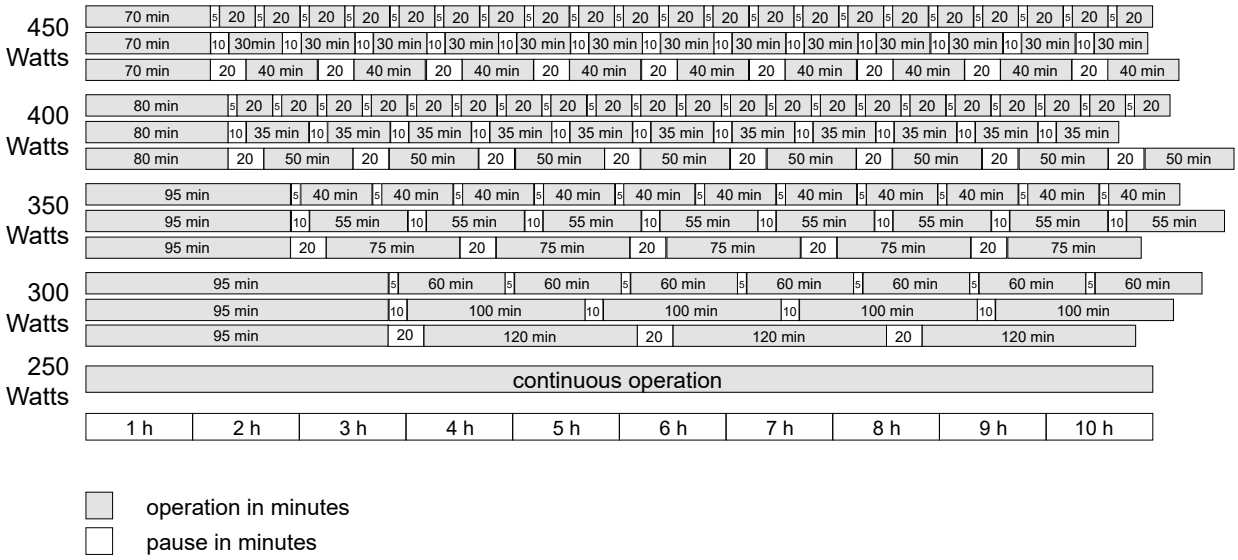


Figure 10 – 2: In continuous operation, the illustrated load periods and pauses shall be observed.

11 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 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 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 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 any part of 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:** $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 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, 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 √P	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.5 GHz d = 2.3 √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