ergoline

MOVING TO HEALTH

ergoselect 1

Bicycle Ergometer

Operator's Manual

201000551000 • Version 2020-01-14 / Rev 01 • English

Manual

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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 1 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 product 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 symbols  mean:

  Consult accompanying documents.
  They indicate 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 1 to direct sunlight to prevent system components from reaching inadmissible high temperatures.

Do NOT use the ergoselect 1 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 1 may only be used in combination with accessories approved by ergoline GmbH.

• Risk to Persons •

Before using the ergometer, the operator 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.

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 device*
- *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 •

- *Only properly trained and appropriately qualified personnel is allowed to operate and work with the medical device.*

Note

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

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 shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3rd Ed. of IEC 60601-1, respectively).

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 directly in contact with the human body (e.g., blood pressure measuring devices).*

Note – Stability

- *Ensure the stability of the ergometer. If the maximum permitted patient weight is exceeded by +10 %, the stability of the ergometer can no longer be guaranteed. It may become unstable as a result.*

2.1 Contraindications

The following patient categories are excluded from using the device:

- patients feeling discomfort or suffering from 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 leads without Q-waves.
  - 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, dyspnea, or dizziness
- > 20 mmHg reduction in systolic blood pressure
- rise in blood pressure

2.2 Intended Use

The ergoselect 1 is a computer-controlled medical ergometer, which operates at pedal speeds between 30 and 130 RPM and loads between 6 and 450 W.
The speed-independent range is shown in the Appendix (Technical Specifications).

The ergoselect 1 ergometers may only be used in exercise testing and for rehabilitation of cardiac and cardiovascular patients according to the instructions given in this manual. If the ergometer is used for other purposes, the manufacturer cannot be held liable for personal injuries or property damage resulting from the unintended use of the equipment.

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 instructions for use
- patients of the intended patient group who have been thoroughly instructed by trained specialists

The group of intended users does not include persons with special needs, such as:

- impaired mental and physical abilities;
- impaired motor skills

which have an influence on the intended use of the medical device.

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.

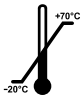
Manufacturer's identification.

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.

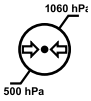
Transport and storage label:
keep dry.

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 Adjusting Saddle and Handlebar

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.

Set the handlebar to a position where it is comfortable to reach while sitting upright.

For this adjustment, open the clamping lever 1 and adjust the appropriate angle.

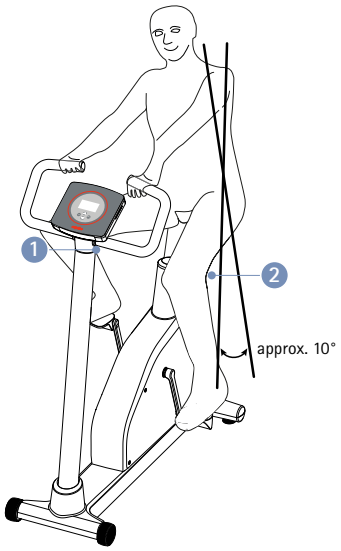


Figure 4 – 1: Adjusting saddle and handlebar
1 Adjusting the handlebar angle
2 Adjusting the height of the saddle

Open the clamping lever 2 by turning it counter-clockwise. Then you are able to adjust the saddle height. Adjust the appropriate saddle height. Fix the saddle height by turning the clamping lever clockwise until a resistance is felt.

Then tighten the clamping lever by turning it a quarter revolution (approx. 15 Nm) clockwise.

Figure 4 – 2: Tightening the clamping lever

Note

- *Tighten the clamping levers only as tight as necessary, NOT with maximum force.*
- *Lubricate the threads of the clamping levers every three months at minimum with a suitable lubricant (e.g., OKS470).*

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: Controls 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.

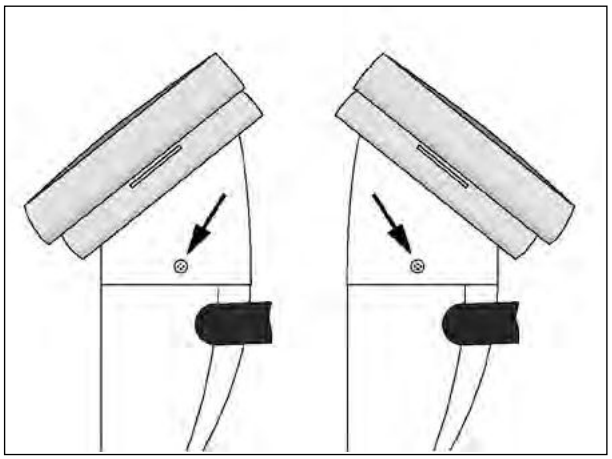


Figure 5 – 2: Different orientations of the control terminal

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.

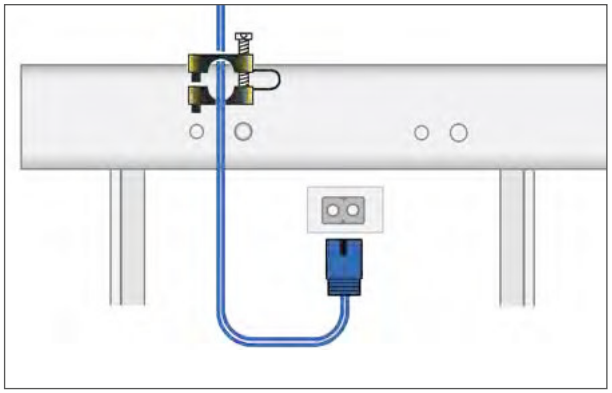


Figure 5 – 6: Power cord in strain relief mounted to frame

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.

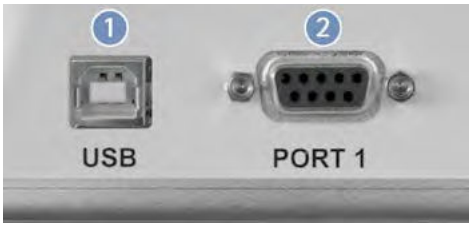


Figure 5 – 7: Connection for ECG recorder / PC ECG system
1 *USB: PC connection via USB (virtual COM)*
2 *PORT 1: Digital connection (remote control from PC or ECG recorder)*

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: ergoselect 1 control terminal

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.

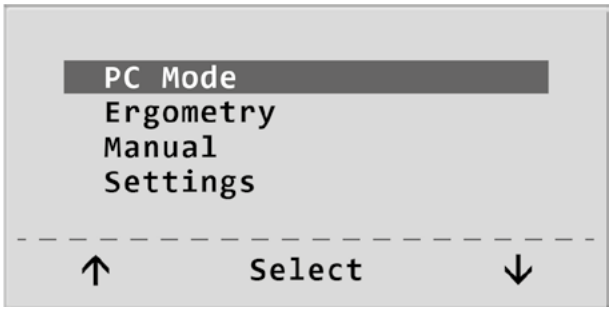


Figure 6 – 3: Main menu

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 three softkeys change with the displayed menu – the key label describing the function is shown on the display.

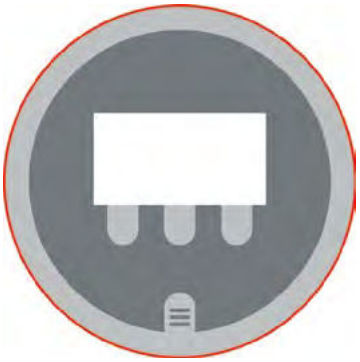


Figure 6 – 4: ergoselect 1 – keypad and display

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 8.2 *Exercise Test Protocols* on page 27)

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 limit values for the respective speed ratings depend on the selected load (see "Note" on page 21).

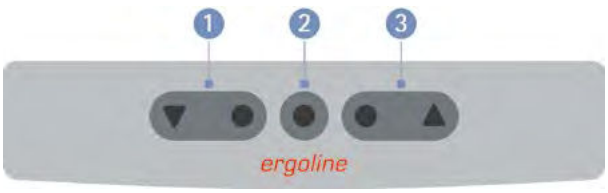


Figure 6 – 5: Speed readout
1. *speed low (= patient should pedal faster)*
2. *correct speed*
3. *speed high (= patient should pedal slower)*

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**.

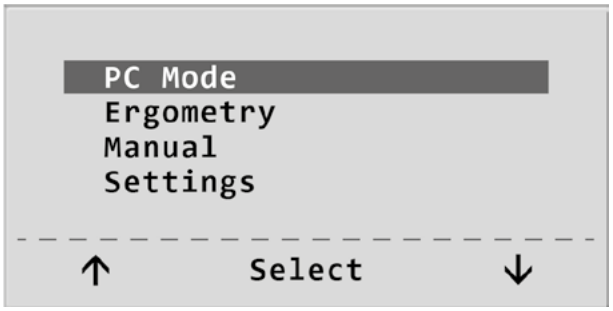


Figure 6 – 6: Main menu

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

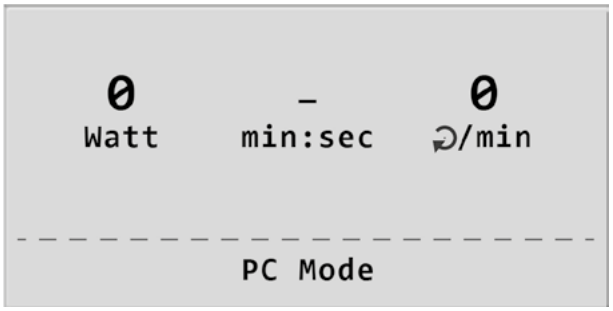


Figure 6 – 7: Start screen

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 (Watt)*
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**.

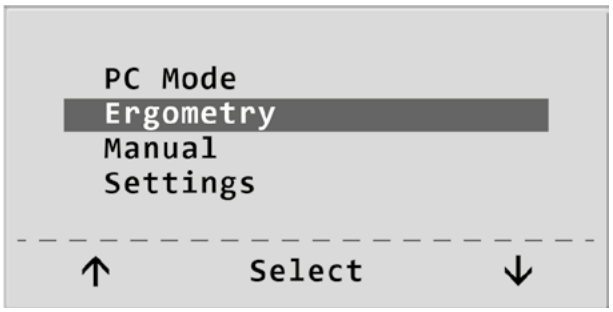


Figure 6 – 9: Main menu

The stored test protocols available for selection will be displayed. There are five fixed protocols (protocols 1 to 5) (see chapter 8.2 *Exercise Test Protocols* on page 27), 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

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

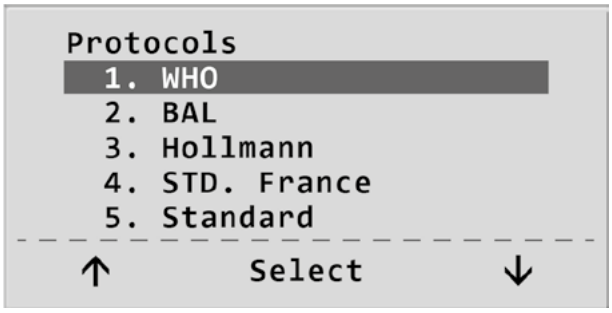


Figure 6 – 10: Selecting an exercise test protocol

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.

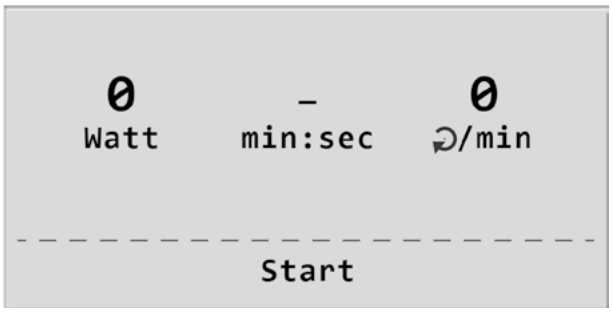


Figure 6 – 11: Starting the exercise test

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.

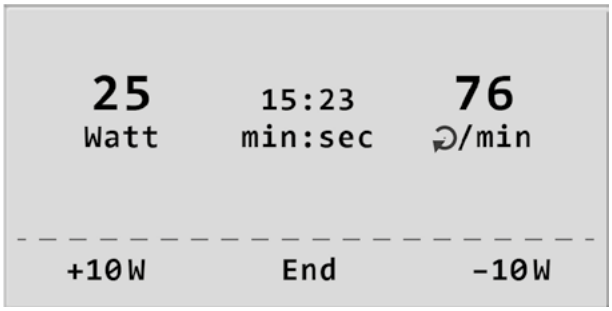


Figure 6 – 13: Recovery phase

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.

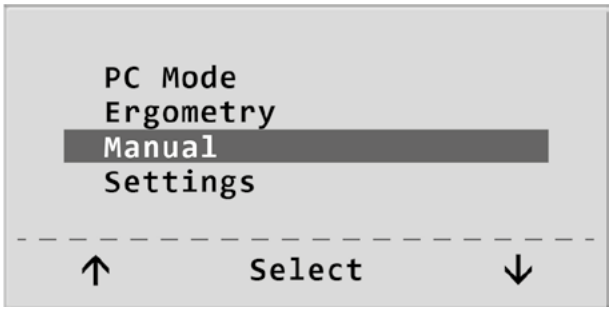


Figure 6 – 14: Main menu

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).

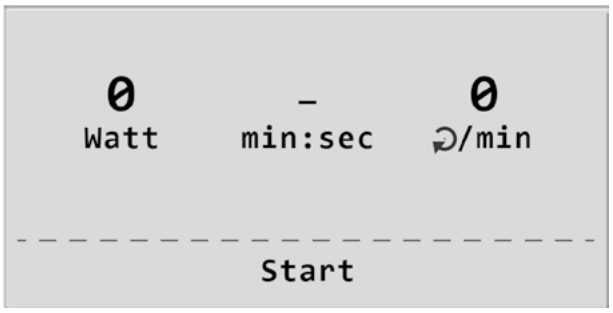


Figure 6 – 15: Initial screen of a manual exercise test

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.

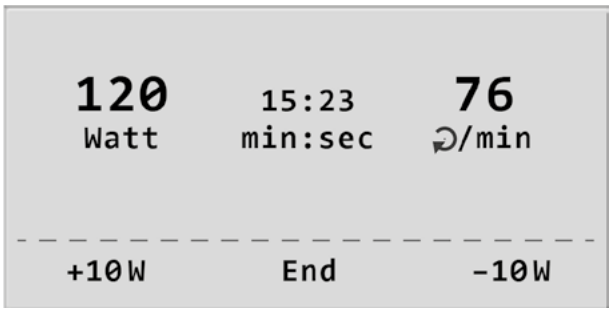


Figure 6 – 16: Display during the exercise test

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**.

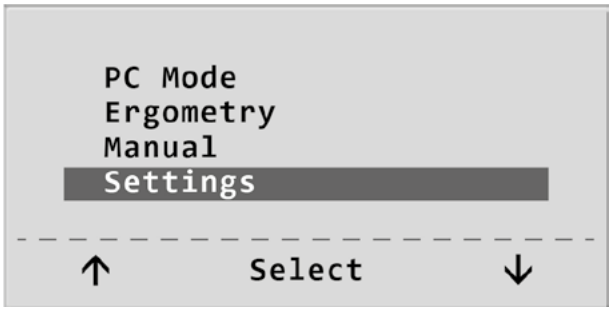


Figure 6 – 17: Main menu

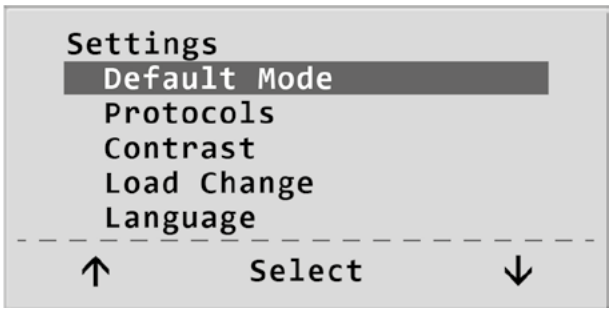


Figure 6 – 18: Settings menu

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**.

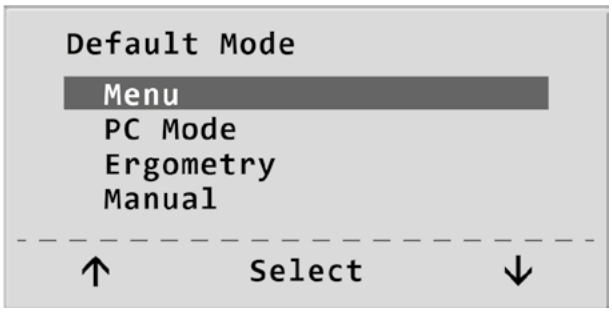


Figure 6 – 19: Selecting the default mode

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**.

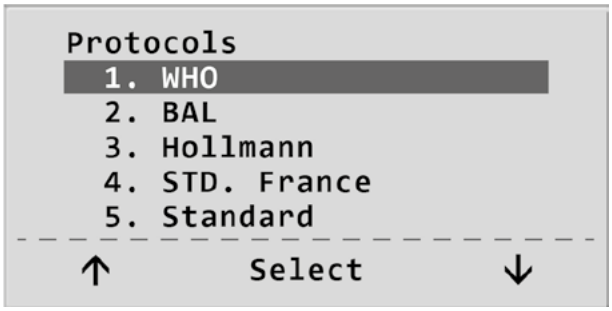


Figure 6 – 20: Selecting the exercise test protocol to edit

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

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

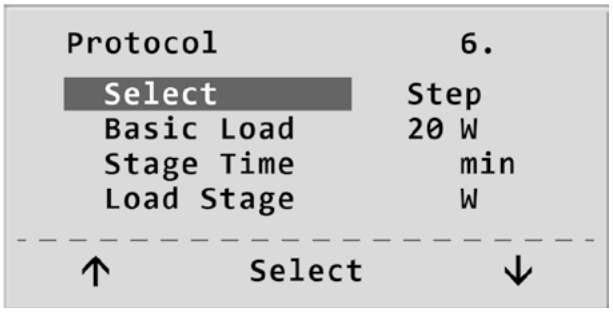


Figure 6 – 21: Selecting the parameter to edit

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 ☰.

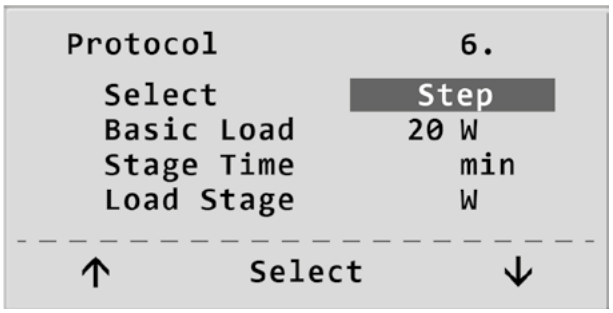


Figure 6 – 22: Editing the parameter value

6.9.3 Contrast

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

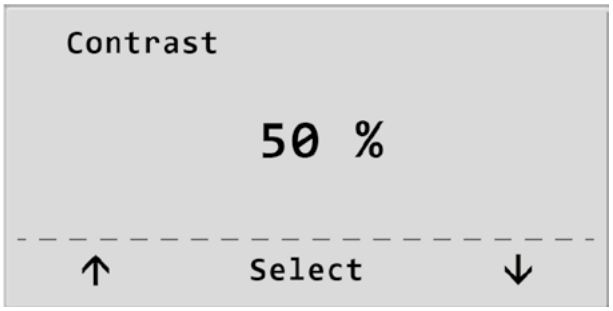


Figure 6 – 23: Adjusting the display contrast

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.

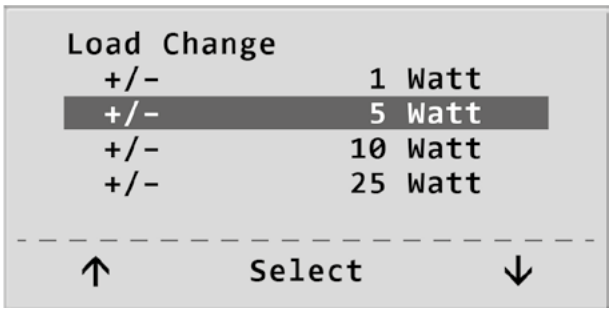


Figure 6 – 24: Selecting the increment for manual load changes

6.9.5 Language

The texts can be displayed in different languages.

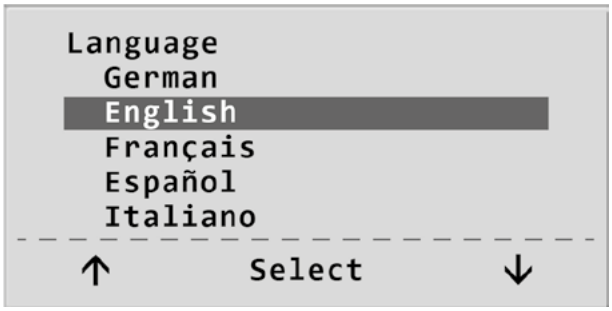


Figure 6 – 25: Language menu

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 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**.

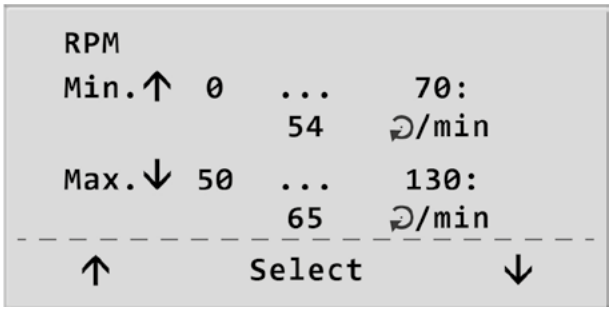


Figure 6 – 27: Setting the RPM limit values

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 loads:

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*

6.9.8 Pulse Display

The pulse readout on the display can be turned off.

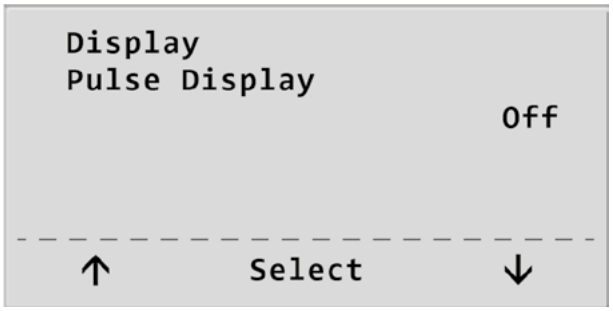


Figure 6 – 28: Enable/disable the pulse readout

7 Cleaning, Maintenance, Disposal

7.1 General Cleaning

Wipe the device surface down with a cloth moistened with soap water or a disinfectant.
The cloth should not be dripping wet; do not allow liquids to enter the device.

Warning

• Shock Hazard •

- *Disconnect the device from the power line before cleaning.*

• Equipment Damage •

- *Do not allow liquids to enter the device.*
  Devices into which liquids have entered must be immediately cleaned and checked by a service technician, before they can be reused.
- *Do not use acids, alkaline solutions (household cleaners) or caustic disinfectants.*

7.2 Cleaning the Handlebar

After each training session, the handlebar should be disinfected with one of the disinfectants listed below.

7.3 Cleaning the Saddle

Clean the saddle with a soft and dry or moist cloth.
Disinfectants used should not contain alcohol.

7.4 Disinfection

The following disinfectants are approved for disinfection:

Schülke & Mayr GmbH:
- Antifect® AF, FF, FD 10
- Terralin® (0.5 %)
- Quartamon Med®

B. Braun Melsungen AG:
- Hexaquart plus® (0.5 % / 5.0 %)
- Hexaquart S® (1.5 % / 5.0 %)
- Meliseptol®
- Melsept SF® (0.5 % / 5.0 %)

ECOLAB:
- Incidin Foam®

Note

- *Strictly observe the manufacturer's instructions for use.*

7.5 Maintenance

7.5.1 Checks Before Each Use

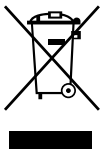
Before each use, visually inspect the device for signs of damage. If you detect damage or impaired functions which may result in a hazard to the patient or the operator, the device must be repaired before it can be used again.

7.5.2 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.

7.5.3 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!

8 Technical Specifications

8.1 Ergometer

Model	modular ergometer system model ergoselect 1
Operating mode	continuous operation
Power supply	100 – 240 V / 50 – 60 Hz / 100 VA max.
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 2 to 12 years of age) if their height and weight is within the limits defined
Saddle adjustment	infinitely, mechanical
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)
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

8.2 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.

8.3 Family of characteristics of the braking torque control range

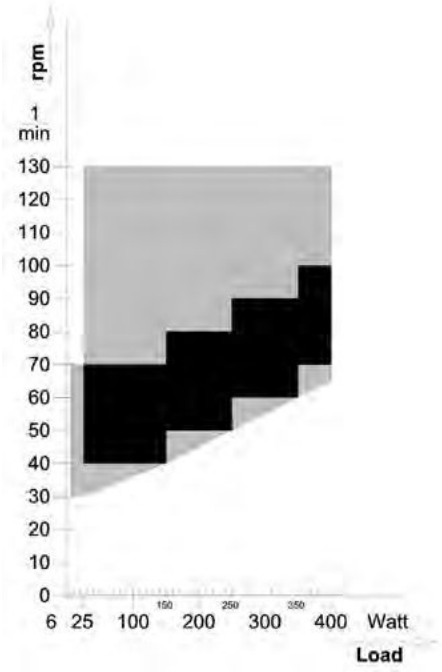


Figure 8 – 1: black: *speed-independent range to DIN VDE 0750-0238*
black + gray: *speed-independent range of the ergoselect 1 ergometer*

9 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