

ergoselect 50

Bicycle Ergometer

Operator's Manual

201000147000 • Version 2018-01-18/Rev 03 • English



Manual

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 of the device and are not bound by the information and illustrations provided in this manual.

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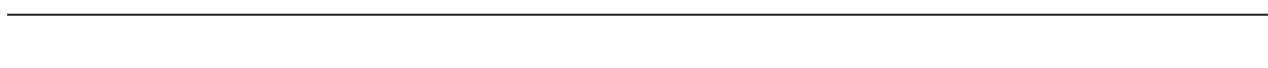
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This manual is not subject to any change order service. Please contact the manufacturer for the latest document revision.

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Printed in Germany



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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 ergometer is an MDD class IIa product.
- The device fulfills the requirements of 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 equipment. It should be available to the equipment 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 carefully in its entirety.
- The symbols   mean:
Consult accompanying documents.
It indicates points which 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 equipment users and persons responsible for assembly, maintenance, inspection and repair of the device must read and understand the content of this manual, before using or work on 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 equipment 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 Service Manual.
- The ERGOLINE quality management system complies with the standards ISO 9001: 2008 and EN ISO 13485: 2003-AC2007.
- 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 non-ERGOLINE accessories are used.
- ERGOLINE is responsible for the safety, reliability, and performance of the equipment, only if
 - modifications and repair are carried out by ergoline GmbH or by an organization expressly authorized by ergoline GmbH
 - the equipment is used in accordance with the instructions given in this operator's manual.

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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 anaesthetics, 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 electric power plants, because they may impair equipment functions.

The ergoselect ergometer 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, before use.

- 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 ergometer 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 features)
- must be informed about the potential hazards arising from the use of this type of equipment.
- make sure that no unauthorised changes are carried out.

Hint

Removing the power cord results in complete disconnection from mains (all poles).

Danger

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 3Ed. of IEC 60601-1, respectively).

Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies 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, consult your local representative or the technical service department.

- IEC 60601-1+A1+A2:1995: 6.8.2.c, 19.2.b, 19.2.c,
- IEC 60601-1:2005: 7.9.2.5, 8.1, 16.2.d,
- MDD 93142IEEC: Annex I clause 13.6.c

Note application parts

- *Application components are components that are directly in contact with the human body (eg, 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.*

SYMBOLS

	<p>Symbol 'type B applied part'. Type B applied parts have no direct contact with patients and offer the lowest protection against electric shock.</p>		<p>Manufacturer's identification.</p>
	<p>Symbol 'type BF applied part'. Type BF applied parts are connected to the body of the patient and provide a higher degree of protection against electric shock. The applied parts are isolated.</p>		<p>Date of manufacture. The number found under this symbol is the date of manufacture in the YYYY-MM-DD format.</p>
	<p>Caution, consult accompanying documents.</p>		<p>PVC-free.</p>
	<p>Protection class II equipment.</p>		<p>Latex-free.</p>
	<p>This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Consult operating instructions.</p>		<p>Suitable for indicated arm circumference.</p>
	<p>Catalog number.</p>		<p>Small size.</p>
	<p>Serial number.</p>		<p>Standard size.</p>
	<p>Scheduled date of the next inspection (e.g., March 2017).</p>		<p>Large size.</p>
	<p>On/off switch for pressure actuation.</p>		<p>Transport and storage label: top.</p>
	<p>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.</p>		<p>Transport and storage label: keep dry.</p>
	<p>Ergometer weight.</p>		<p>Transport and storage label: fragile.</p>
	<p>Nationally Recognized Testing Laboratory NRTL label for the USA and Canada.</p>		<p>Transport and storage label: approved temperature range.</p>
	<p>Do not lean against the ergometer: there is a risk of the ergometer tipping over.</p>		<p>Transport and storage label: approved humidity, non-condensing.</p>
			<p>Transport and storage label: approved pressure range.</p>
			<p>Transport and storage label: do not stack.</p>

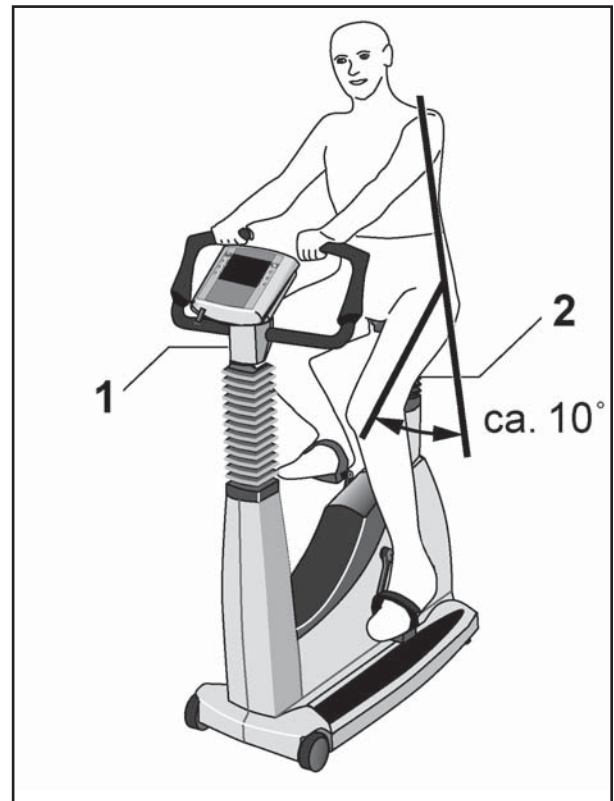
PREPARING THE PATIENT

ADJUSTING THE SADDLE AND THE HANDLEBAR

On the ergoselect 50, you adjust the saddle height manually with a clamping lever.

With the pedal in the bottom position, the angle between the axis formed by the upper body and the thigh should be approximately 10°.

Set the handlebar to a position where the patient sitting upright on the saddle can reach it easily. To do so, open clamping lever 1 and set the handlebar to a suitable angle.



ADJUSTING SADDLE AND HANDLEBAR

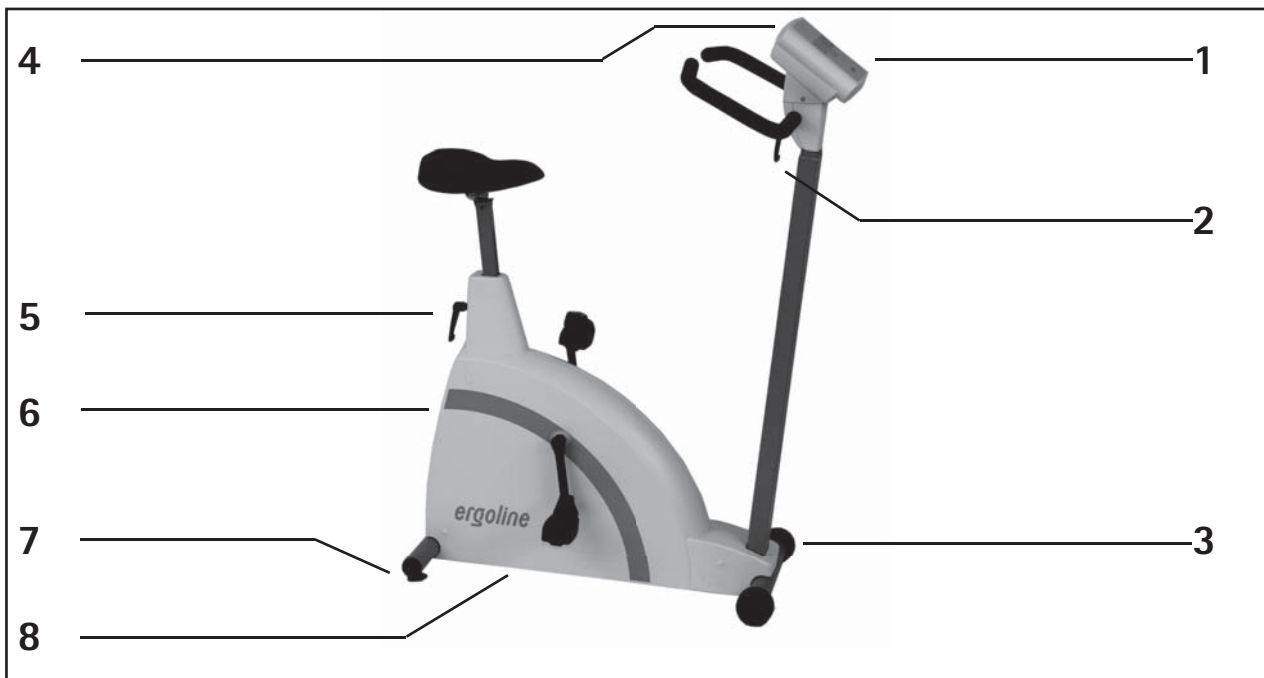
- 1 Adjustment of the handlebar angle
- 2 Adjustment of the saddle height

Note

- Tighten the clamping levers only as far as necessary, *NOT* with maximum force.
- Lubricate the clamping lever threads quarterly at minimum, using a suitable lubricant (e.g. OKS470).

SETUP AND MAINS CONNECTION

CONTROLS AND INDICATORS



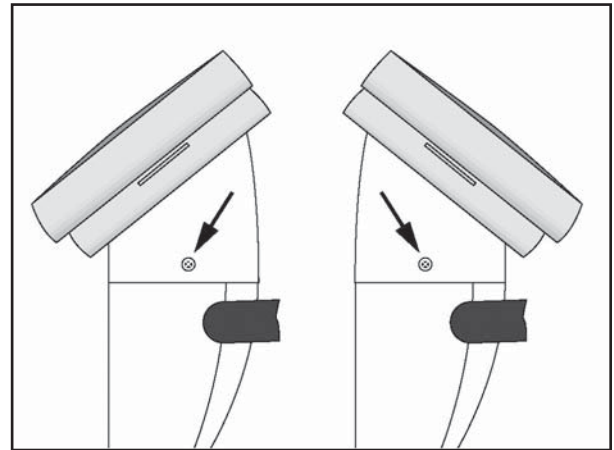
ERGOSELECT 50 – CONTROLS, CONNECTIONS AND INDICATORS

- 1 Control terminal model P
- 2 Adjustment of the handlebar angle
- 3 Castors
- 4 Speed display (RPM) for patient
- 5 Adjustment of the saddle height
- 6 Power switch (green button)
- 7 Levelling devices to adjust the ergometer to uneven floors
- 8 Sockets for power cord and connection cables (underside of ergometer)

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 display towards the patient.



MOUNTING OPTIONS FOR CONTROL TERMINAL

TRANSPORT

For short distances, the ergoselect 50 can be lifted at the saddle and rolled away on its castors.

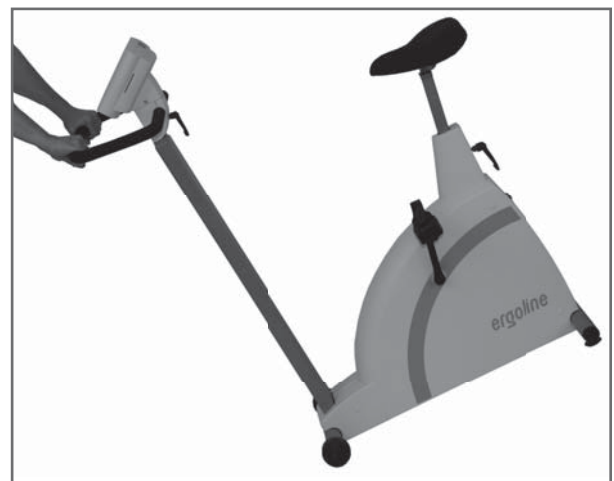
To cover greater distances, however, we recommend the following method:

- Disconnect the power cord from the wall outlet.
- Rotate the handlebar towards the front. Tighten the clamping lever.
- Stand in front of the ergoselect 50, grasp the handlebar and tilt the ergoselect 50 towards you until it is standing on the castors only and is balanced.
- It is now possible to transport the ergoselect 50.
- When you have reached the new location, lower the ergoselect 50 very carefully to avoid damage.

Caution

- Equipment Damage •

Avoid strong vibrations of the ergoselect 50 during transport.



TRANSPORTING THE ERGOSELECT 50

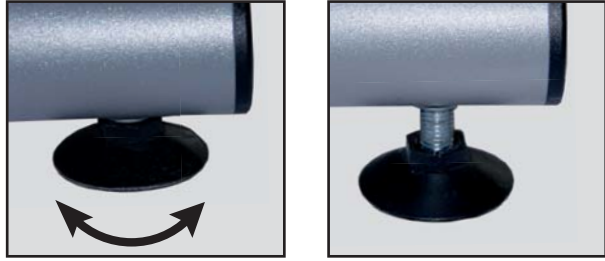
SETUP

Place the ergoselect 50 on a level floor.

The ergoselect 50 must be set up in a secure and stable position - the two levelling feet at the back make for easy adjustment to uneven floor surfaces. Extend the foot concerned until the ergoselect 50 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.

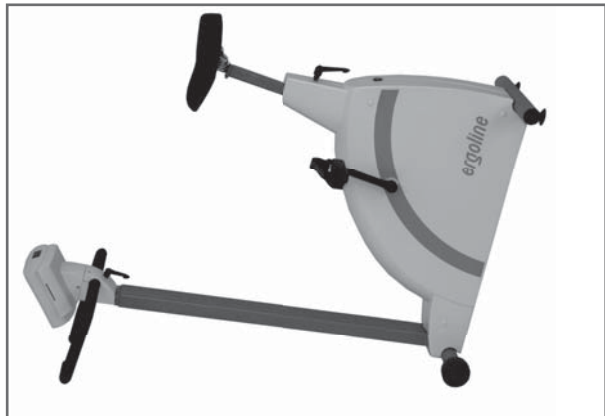
The ergometer can be transported by means of the 2 front castors.



LEVELLING FEET OF THE ERGOSELECT 50 ERGOMETER

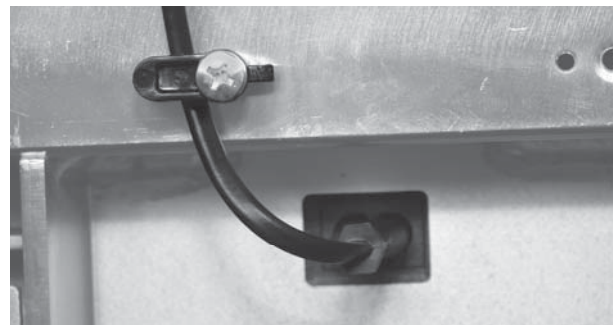
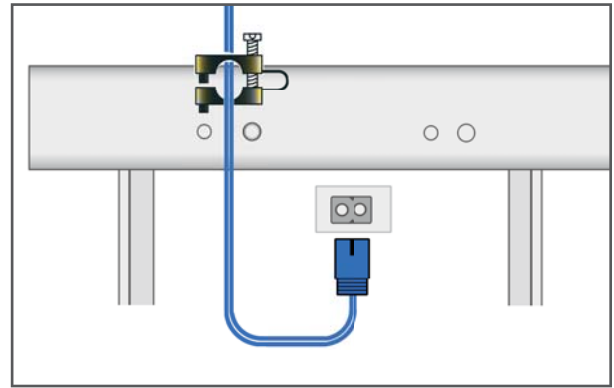
CONNECTING THE POWER CORD

- Rotate the handlebar towards the front.
- Tilt the ergometer carefully towards you all the way until it rests on the handlebar.



ASSEMBLY POSITION OF THE ERGOSELECT 50 ERGOMETER

- Plug in the power cord on the underside of the ergometer.
- Guide the power cord under the strain relief and screw the strain relief to the frame: the plastic pin must lock into place in the boring provided.
- Put the ergometer back on its feet and set the handlebar to the correct position.
- Connect the power cord to a wall outlet.



POWER CORD WITH INSTALLED STRAIN RELIEF

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 ergometer, at the bottom.

Caution

- 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 from the power supply (all poles).

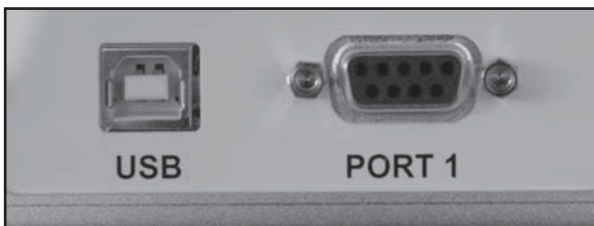
Ensure that the power plug is readily accessible at all times.

CONNECTING THE ECG CABLE

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

Different connection cables are available to support different communication modes (digital, analog, remote start, etc.).

The appropriate cable is plugged into the corresponding socket on the connection panel (Port 1, Port 3 or Analog) and secured with the strain relief.



ECG / PC-ECG CONNECTION

USB	PC connection via USB (virtual COMx)
PORT 1	Digital interface connector (remote control through PC or ECG)

Hint

- connecting cables •

Only the use of ergoline-approved connection cables is permitted.

A special PC driver software, which can be obtained from ergoline, is required for operation via the USB port.

OPERATION CONTROL TERMINAL P



Control terminal P


TURNING THE SYSTEM ON

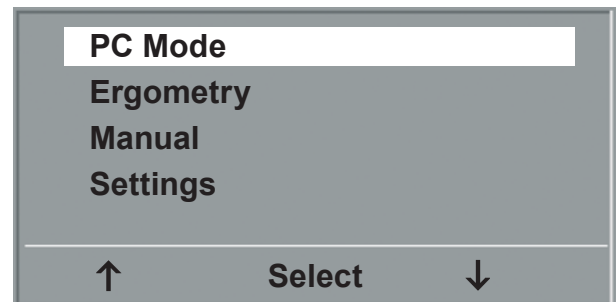
You turn the ergometer on by pressing the power switch - the green indicator in the switch lights up. The ergometer runs a self-test. Subsequently, the main menu displays.



SELF-TEST SCREEN


Note


- *Instruct the patient not to pedal while the ergometer is being turned on and during the self-test.*
- *Apply the blood pressure cuff to the patient AFTER the ergometer has been turned on and the self-test completed.*
- *The device can be configured to default to one of the operating modes. If this option is selected, the initial 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.*




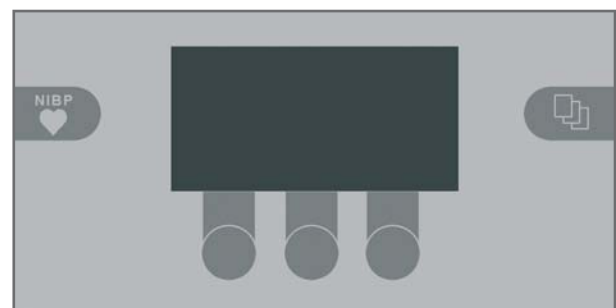
MAIN MENU

The ergometer software is controlled with 5 keys:

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

 With this key you initiate a blood pressure measurement. A measurement in progress can be aborted with the same key.

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



KEYPAD P

OPERATING MODES WITH CONTROL TERMINAL P

An ergoselect ergometer with a control terminal P supports the following operating modes:

PC MODE

An external device (e.g. stand-alone electrocardiograph, 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 "Settings").

MANUAL

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

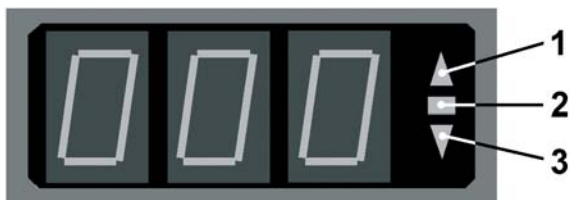
SETTINGS

Used to configure the ergometer.

SPEED READOUT

At the top of the control terminal, there is a speed readout for the patient as well as three LEDs that 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 "Technical Specifications").



SPEED READOUT

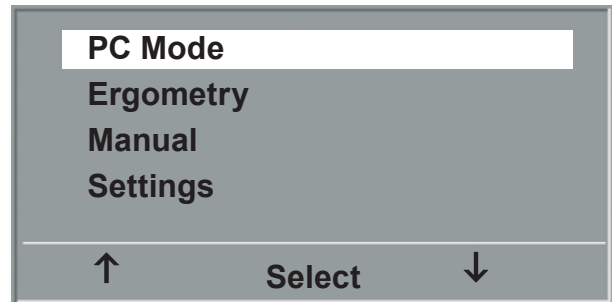
- 1 speed low (patient should pedal faster)
- 2 correct speed
- 3 speed high (= patient should pedal slower)

Note

- If, during an exercise test, the speed drops below 30 RPM, the load readout starts blinking on the display.
- To reactivate the saddle height adjustment function, press  and the arrow keys will again be displayed.
- Additional blood pressure measurements can be initiated with .

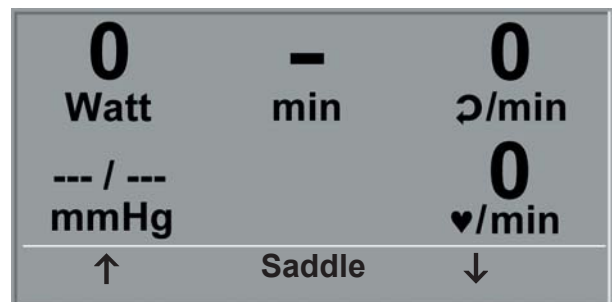
PC Mode

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



MAIN MENU

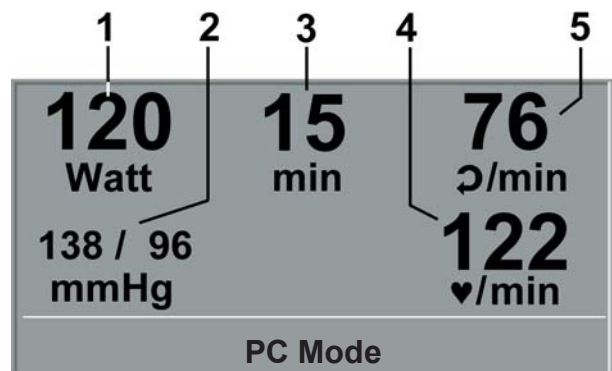
The display changes - the ergometer is waiting for commands from the external ECG unit.



INITIAL SCREEN

With the arrow keys, the saddle height can be electrically adjusted on the ergoselect 200 (on the ergoselect 400, these keys adjust the height of the drive unit).

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.

DISPLAY DURING EXERCISE TEST

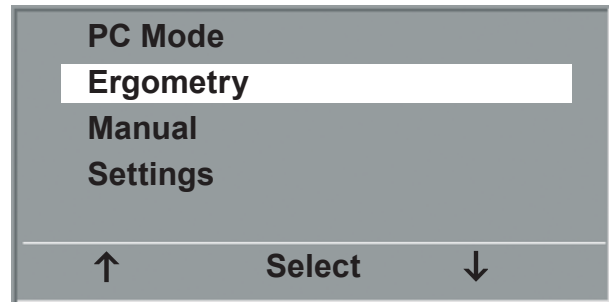
- 1 current load in watts
- 2 most recent BP value (systolic/diastolic values) or cuff pressure during inflation
- 3 duration of exercise test (min)
- 4 heart rate at the time of the BP measurement (BPM)
- 5 pedal speed (RPM)

Note

- All functions are locked while the ergometer is operating in PC mode, except for the saddle height adjustment and the blood pressure key.
- To reactivate the saddle height adjustment function, press  and the arrow keys will again be displayed.
- Additional blood pressure measurements can be initiated with .

ERGOMETRY

Use the softkeys on the right and left (↑ ↓) to position the bar cursor on ERGOMETRY and confirm the selection with SELECT.

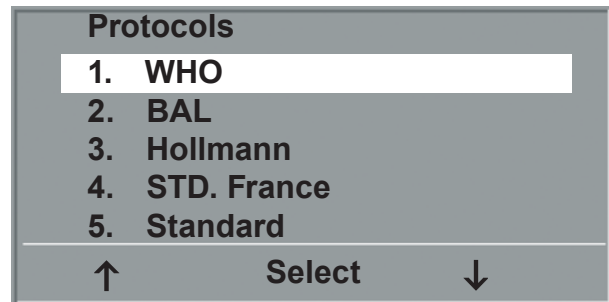


MAIN MENU

The stored test protocols available for selection will be displayed. There are five fixed protocols (protocols 1 to 5, see Appendix), whereas protocols 6 to 15 are user-programmable.

The protocol menu provides an overview of the test phases:

e.g.: **50 W / 2 min / 25 W**
 means: initial (basic) load 50 watts
 stage time 2 minutes
 load increment 25 watts



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, a blood pressure measurement at rest may precede the test (see "Settings").

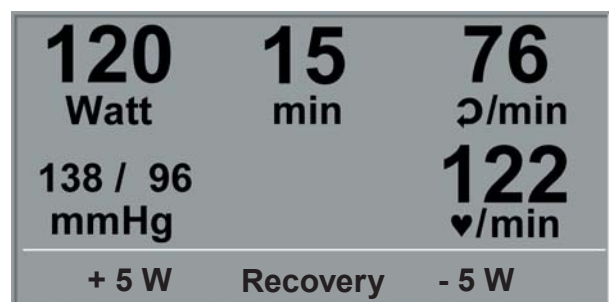
When the basic load appears on the display (after approx. 15 seconds or upon termination of the blood pressure measurement) and the patient's RPM indicator blinks, the patient should start pedalling.



INITIAL EXERCISE TEST SCREEN



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

With the +5 W and -5 W keys, the current load can be changed at any time (in increments of +/-1 W up to +/-25 W, as configured).



SCREEN DISPLAY DURING THE TEST

Note

- The saddle height (ergoselect 200) can be changed during an exercise test.
- To reactivate the saddle height adjustment function, press  and the arrow keys will again be displayed.
- Additional blood pressure measurements can be initiated with .

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 continues to pedal in the recovery phase.

The END key in the middle will terminate the test.

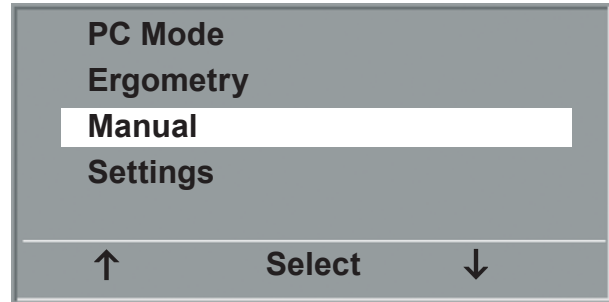
120 Watt	15 min	76 r/min
138 / 96 mmHg		122 r/min
+ 5 W	End	- 5 W

RECOVERY PHASE

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 loads, stage times and by initiating blood pressure measurements.



MAIN MENU

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

Blood pressure measurements can be initiated with .



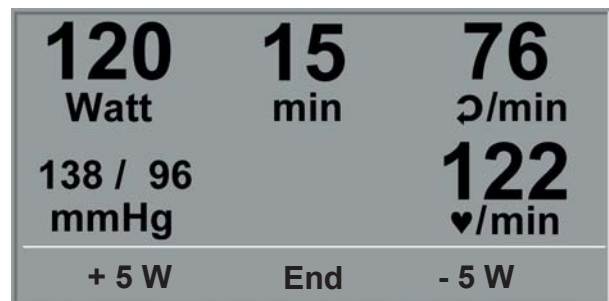
INITIAL SCREEN OF A MANUAL EXERCISE TEST

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.



SCREEN DISPLAY DURING THE TEST

SETTINGS WITH CONTROL TERMINAL P

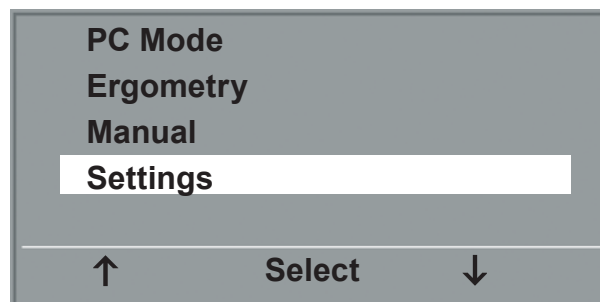
Some of the device settings are configurable to meet specific requirements. The settings will be saved and remain stored even when the ergometer is switched off.

Use the softkeys on the right and left (↑ ↓) to position the bar cursor on SETTINGS and confirm the selection with SELECT.

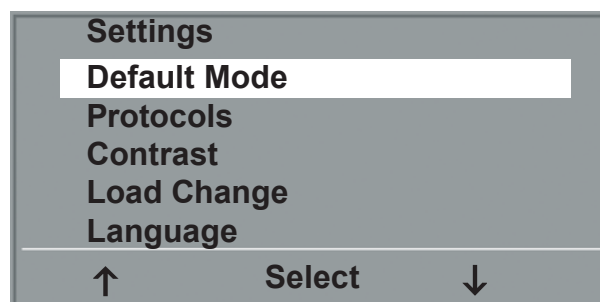
The configuration menu displays.

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.



MAIN MENU

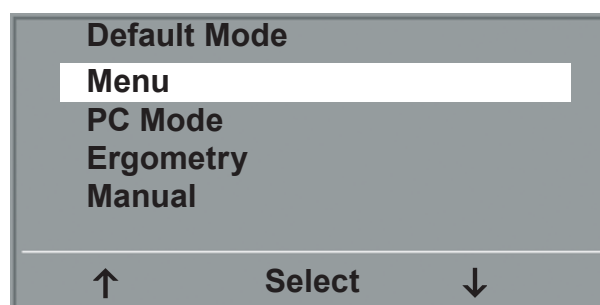


CONFIGURATION MENU

DEFAULT MODE

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



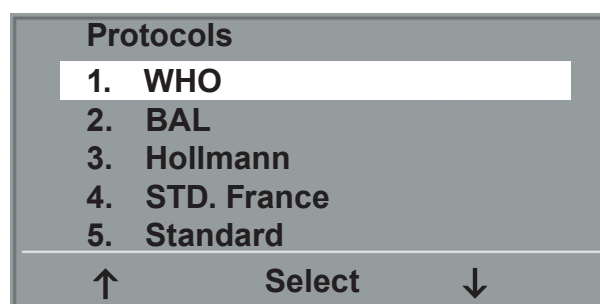
SELECTING THE DEFAULT MODE

PROTOCOLS

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

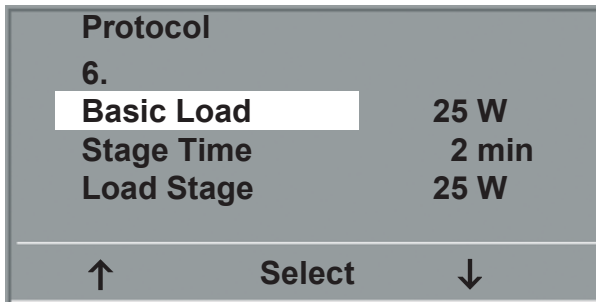
- initial load
- stage time
- load increment (load increase with each stage)

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



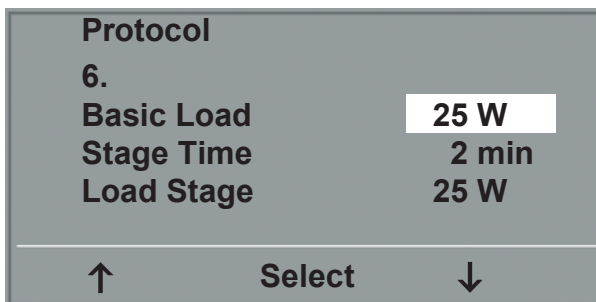
SELECTING THE EXERCISE TEST PROTOCOL TO EDIT

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




SELECTING THE PARAMETER TO EDIT

When confirmed with SELECT, the corresponding value appears in reverse video and can be changed with the arrow keys ↑ ↓.



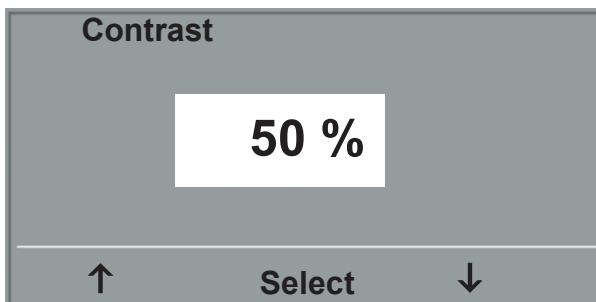
EDITING THE PARAMETER VALUE

Pressing SELECT will save the new value.

All other parameters are edited in the same way. You exit the configuration with .

CONTRAST

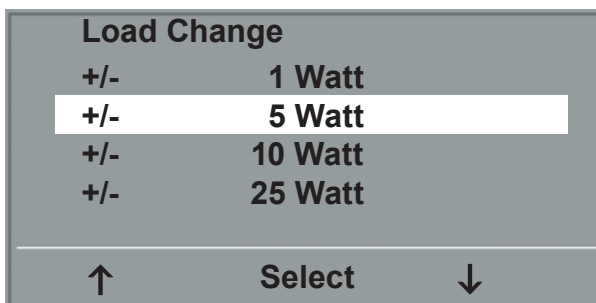
The display contrast is adjustable in the range from 0 to 100%.



ADJUSTING THE DISPLAY CONTRAST

LOAD CHANGE

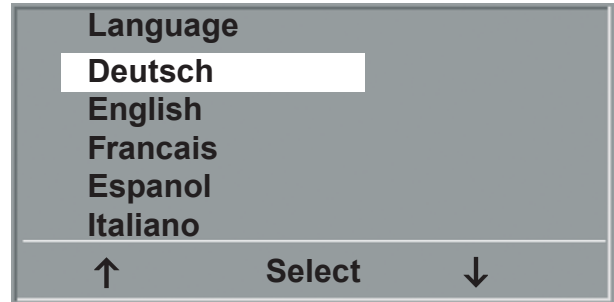
Here you determine the increments for each load change. Depending on your choice, each key press will change the load by +/- 1, 5, 10 und 25 Watts.



SELECTING THE INCREMENT FOR MANUAL LOAD CHANGES

LANGUAGE

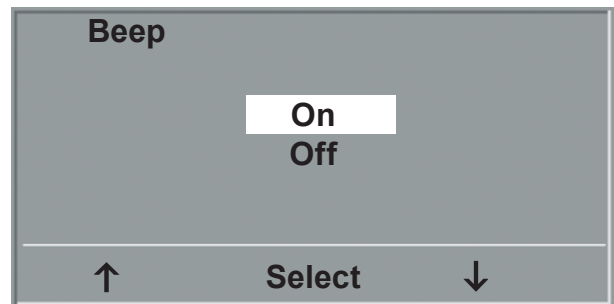
The texts can be displayed in different languages.



LANGUAGE MENU

BEEP

The audio signal emitted during blood pressure measurements can be turned on and off.




BEEP DURING BP MEASUREMENTS

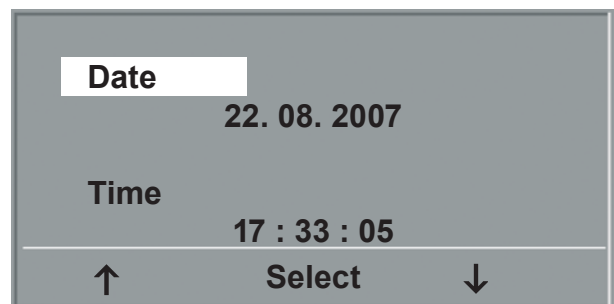
SOFTWARE VERSION

Select this option to view the installed software version.

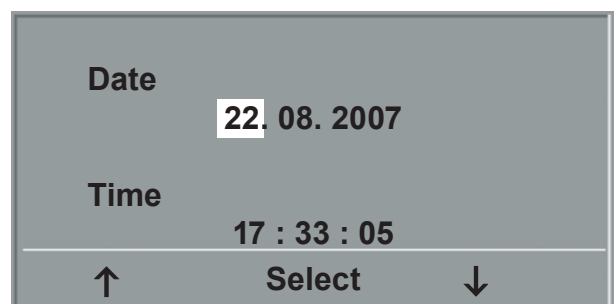
DATE/TIME

To begin with, you select DATE or TIME and confirm the selection. Then the value displayed in reverse video can be edited with the $\uparrow \downarrow$ keys and saved with SELECT.

The time is adjusted in the same way. You exit the configuration with .



SETTING THE DATE



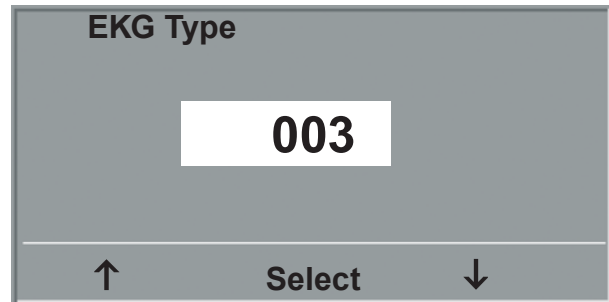
SETTING THE DAY

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.

Using the arrow keys, enter 003 and confirm the entry with SELECT.

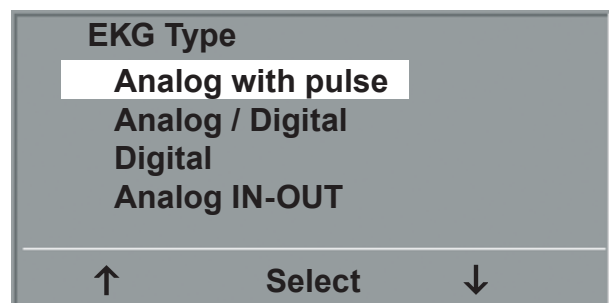


ENTERING THE EKG TYPE PASSWORD

All ergoselect ergometers support the following communication modes:

- **Analog with pulse**
Remote start mode; prior to each load change, the ergometer generates a control pulse and sends the corresponding data via the interface.
- **Analog / Digital**
An analog voltage controls the load - blood pressure measurements can be initiated with digital commands.
- **Digital (default)**
The communication with the ergometer is entirely controlled with digital commands.
- **Analog IN-OUT**
The entire communication (load control and BP measurements) is controlled with analog signals. No digital data will be sent.

Select the communication mode and confirm with SELECT.



SELECTING THE ERGOMETER COMMUNICATION MODE

Note

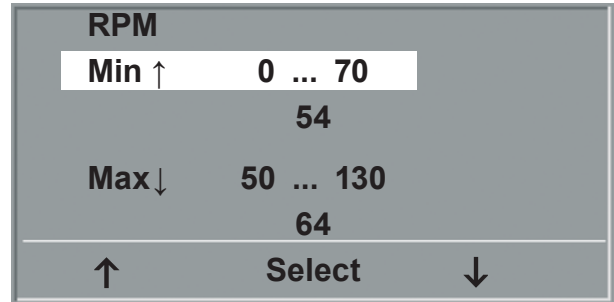
- *The EKG Type needs to be selected only when the ergometer is connected to an ECG unit. The selection is part of the installation procedure.*
- *The "Analog/Digital" and "Digital" communication is only possible when PC Mode is selected from the main menu or when this is the default mode.*

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.



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	58 - 65
251 - 350	68 - 75
351 - 450	78 - 85
451 - 550	88 - 95
551 - 650	98 - 105
651 - 750	108 - 115
751 - 850	118 - 125
851 - 950	> 125
951 - 999	> 130

PULSE DISPLAY

The pulse readout on the display can be turned off.

CLEANING, MAINTENANCE, DISPOSAL

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.

CLEANING THE SADDLE

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

CLEANING THE UPHOLSTERY (E.G. COUCH ERGOMETER)

Wipe the upholstery down with a soft cloth moistened with soap water. The cloth should only be moist and not dripping wet. If the cleaning agents and disinfectants used are caustic or contain alcohol, they may damage and/or discolor the upholstery.

DISINFECTION

Only 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®

Warning

- Shock Hazard •
- *Disconnect the device from the power line before cleaning.*
- Equipment Damage •
- *Do not allow liquids to enter the equipment. 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.*

Note

- *The use of cleaning agents and disinfectants containing alcohol is not permitted!*

Hint

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

MAINTENANCE

CHECKS BEFORE EACH USE

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

If you detect damages 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.

TECHNICAL SAFETY INSPECTIONS AND TECHNICAL 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.

Similarly, the automatic sphygmomanometer in the control terminal must be checked and calibrated by an authorized specialist every two years to fulfill legal requirements.

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

DISPOSAL

Do not dispose the product described in this Operator Manual as unsorted municipal waste. It must be collected separately.



Please contact the authorized manufacturer ergoline GmbH to obtain information concerning the decommissioning of your equipment. There is no proper waste management, proper disposal is documented by ergoline GmbH. Consult operating instructions.

TECHNICAL SPECIFICATIONS

ERGOMETER

Model	ergometer system ergoselect 50
Operating Mode	continuous operation
Power	100 – 240 V / 50 – 60 Hz (100 VA max.) specification power cord US: SPT 2x18AWG 125 V / 10 A "hospital" or "hospital grade" specification internal backup battery: IEC: CR 2032 / 3V 230 mAh
Braking Principle	computer-controlled eddy current brake with torque measurement; speed independent to DIN VDE 0750-0238
Load Range	6 – 450 watts, speed independent (see diagrams)
Speed Range	30 to 130 RPM
Deviation of Measured Load	to DIN VDE 0750-0238
Load Increments	user programmable
Internal Protocols	Control Terminal P: <ul style="list-style-type: none">• 5 fixed incremental exercise test protocols (e.g. WHO)• 10 user-programmable protocols• manual load control
Permitted Patient Weight	160 kg
Saddle Height Adjustment	continuous, for patients between 120 cm and 210 cm manual adjustment of saddle height
Handlebar Adjustment	for patient heights between 120 cm and 210 cm continuous handlebar adjustment over 360°
Crank Length	170 mm (cranks with adjustable length are optional accessories)
Displays	LCD: 68 x 34 mm, 128 x 64 pixels additional LED display for speed (RPM)
Interfaces	PORT 1 (DSUB-9-pole): digital remote control by PC or ECG recorder, remote start of ECG recorder (optional) USB: digital remote control by PC (driver required)


Dimensions, Weight

length: 820 mm
width: 420 mm
(width of handlebar: approx. 535 mm)
height: 900 mm to 1350 mm
weight: approx. 49 kg

Safety Standards

DIN EN 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 (50 to 104 °F)
rel. humidity: 30 to 75%, no condensation
atmospheric pressure: 800 to 1060 hPa

transport and storage:

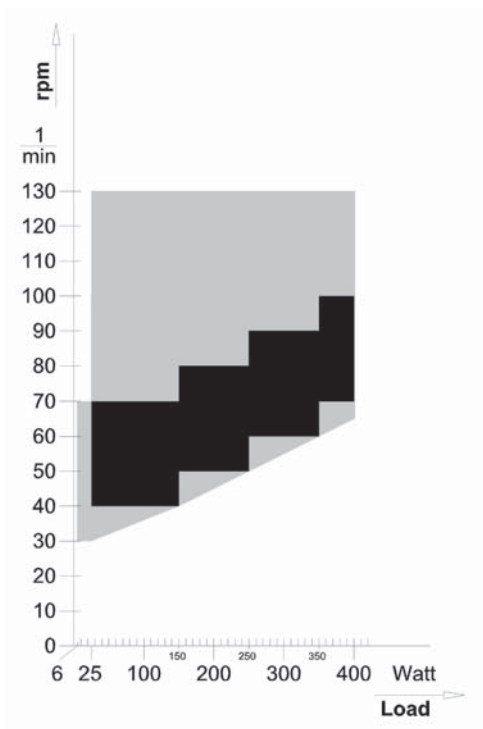
temperature: -20 to + 70 °C (-4 to +158 °F)
rel. humidity: 10 to 95%, no condensation
atmospheric pressure: 500 to 1060 hPa

EXERCISE TEST PROTOCOLS

Protocol	initial load [W]	time in stage [min]	load increment [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	-- (*)	1 - 99

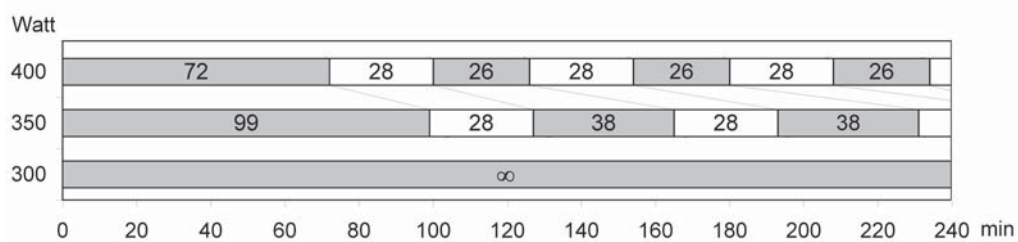
(*) With Control Terminal P, the recovery load is fixed at 25 W.

FAMILY OF CHARACTERISTICS OF THE BRAKING TORQUE CONTROL RANGE



black: speed-independent range to DIN VDE 0750-0238
black + grey: speed-independent range of the ergoselect ergometer

FAMILY OF CHARACTERISTICS OF THE LOAD PERIODS ACCORDING TO IEC 60601-1



Under permanent load, the load periods and pauses (white) shall be observed.

ELECTROMAGNETIC COMPATIBILITY

EN 60601-1-2

Changes or modifications to this system not expressly approved by ergoline 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 telephones 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 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 ergometer is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions to EN 55011	Group 1	The ergoselect 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 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 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 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	± 6 kV contact ± 8 kV air	± 6 kV ± 8 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	< 5 % UT (> 95 % dip in UT) for 0.5 cycles 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	< 5 % UT 40 % UT 70 % UT < 5 % UT	Mains power should be that of a typical commercial or hospital environment. If the user of the ergoselect ergometer requires continued operation during power mains interruptions, it is recommended that the ergoselect ergometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field to EN 61000-4-8	3 A/m	passed	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. The ergoselect 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 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 ergometer is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
<p>Conducted RF to EN 61000-4-6</p> <p>Radiated RF to EN 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the ergoselect ergometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>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</p> <p>where P is the rated output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>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).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol</p> <div style="text-align: center;">  </div>

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 ergometer is used exceeds the applicable RF compliance level above, the ergoselect 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 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 ERGOMETER**

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

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

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

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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