

ergoselect 10

Couch Ergometer

Operator's Manual

201000546000 • Version 2022-11-16 / Rev 03 • English



Manual

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

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

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

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

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

ergoline GmbH
Lindenstrasse 5
72475 Bitz
Germany

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





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1 General Information

Danger

In the case of failures, visible wear or defect:

- Ensure that the device is de-energized.
- Ensure that the device cannot be switched on by other persons.
- Contact your service partner or the ergoline GmbH Service Department immediately.

- 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 device fulfills the requirements of the standard EN 60601-1 "Medical electrical equipment, Part 1: General Requirements for Safety" as well as the electromagnetic immunity requirements of standard EN 60601-1-2 "Electromagnetic Compatibility – Medical Electrical Devices".
The radio-interference emitted by this device is within the limits specified in EN 55011, class A.
- 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 carefully in its entirety.
- Observance of the safety information protects from injuries and prevents inappropriate use of the device. All device users and persons responsible for assembly, maintenance, inspection, and repair of the device must read and understand the content of this manual, before using the device or working with it. Paragraphs with special symbols are of particular importance.
- By opening the control terminal, you will damage the calibration sticker. This will automatically void the warranty.
- 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 GmbH will provide a Field Service Manual.
- The implemented quality management system covers all aspects of the ergoline GmbH operations as per 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 GmbH accessories. The user is responsible if accessories from other manufacturers are used.
- ergoline GmbH 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 to carry out these tasks
 - the device is used in accordance with the instructions given in this operator manual.

2 Safety Information

Warning

- Patient Hazard •

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

- Risk to Persons •

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

Danger

- Explosion Hazard •

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

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

Warning

- Patient Hazard, Equipment Damage •

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

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

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

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

- Equipment Malfunction •

Only the special shielded cables supplied by ergoline GmbH 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 rotational speed is above 30 RPM, this may be due to electromagnetic interference.

Note

The device characteristics determined by emissions allow the device to be used in industrial environments and in hospitals (CISPR 11, class A). When used in domestic surroundings (which normally requires compliance with CISPR 11 class B), the device may not offer adequate protection for radio services. If required, the user may have to take remedial action by relocating or re-orienting the device.

Warning

- Shock Hazard •

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

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

- 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 •

- The medical device is only intended for use by trained and appropriately qualified staff.
- To prevent personal injury and product/property damage, the hand grip must not be used by patients as an aid to standing up.
The sole function of the hand grip is to allow patients to hold on to it during the intended application.

Note

- Disconnection from Power Supply •

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

- Stability •

Ensure the stability of the ergometer. If the maximum permitted weight load on the ergometer is exceeded by +10%, its stability can no longer be guaranteed. The device may become unstable as a result.

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 edition 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. Please note that local laws take precedence over the standards mentioned above.

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

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 impair vigilance (alcohol, drugs, medication).

Contraindications in exercise testing carried out with ergometers

(source: Banerjee A et al., 2012)

Contraindications in exercise testing:

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

Criteria for stopping bicycle-based exercise testing

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

Criteria for stopping bicycle based exercise testing include:

ECG criteria

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

Clinical criteria

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

2.2 Intended Use

The medical device ergoselect 10 is a reclining ergometer used on the intended patient population for the following purposes:

- ECG recording during exercise stress tests;
- diagnosis or monitoring of vital physiological processes.

Furthermore, the reclining ergometer can be used

- in rehabilitation programs or
- as treatment table.

The medical device is intended to impose exercise workloads on the intended patient population. During the test, the patient is pedaling while lying on the ergometer. While the patient is pedaling, the pedals are braked by an eddy-current brake to control the workload, which can be done manually or via a PC software program.

The patient position can be adjusted both before and during the test.

2.3 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.

2.4 Applicable Laws, Regulations and Directives

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

3 Symbols



Type B applied part



Type BF applied part



Note: Observe the information given in the operator manual!



Protective ground



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 2024).



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 push!



This symbol indicates the overall weight of the medical device.



Manufacturer's identification.



Date of manufacture

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



PVC-free.



Latex-free.



Suitable for the indicated arm circumference.



Small size.



Standard size.



Large size.



Transport and storage label: top.



Transport and storage label: keep dry.



Transport and storage label: fragile.



Transport and storage label: approved temperature range.



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



Transport and storage label: approved pressure range.



Transport and storage label: do not stack.

4 Setup and Mains Connection

Note

- Check the device for damage before each use.
- If you detect signs of damage or identify malfunctions, switch the device off.
- Contact your service partner or the ergoline GmbH Service Department immediately.

4.1 Description of the Medical Device

- 1 Speed readout for the patient*
- 2 Armrest*
- 3 Saddle*
- 4 Pedal unit*
- 5 Release lever for pedal unit*
- 6 Type plate (on the back of the table column)
- 7 Connections for power cord and connection cables (under the cover panel)
- 8 Couch surface*
- 9 Exam table paper roll
- 10 Headrest*
- 11 Knob for adjustment of the headrest*
- 12 Remote control*
- 13 ON/OFF switch* (toggle switch)

* = applied parts as defined in IEC 60601-1

The ON/OFF switch* (toggle switch) is located on the right side of the housing, below the couch surface.

"|" activated on toggle switch = ON (voltage)

"O" activated on toggle switch = OFF (no voltage)

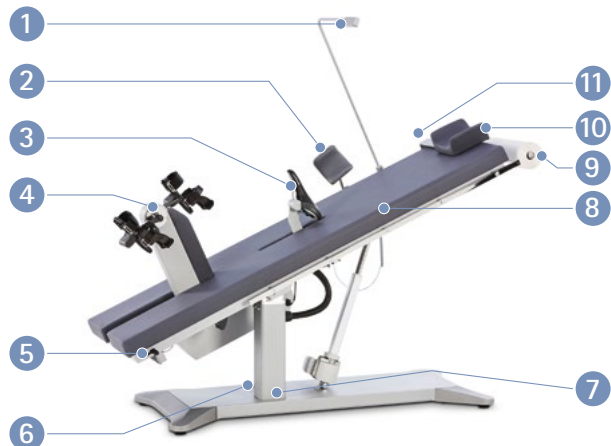


Figure 4-1: Controls ergoselect 10



Figure 4-2: Remote control



Figure 4-3: Location of the ON/OFF switch (toggle switch)

4.2 Transport

The ergoselect 10 is quite large and heavy. Therefore, the reclining ergometer will be shipped to you and set up by a qualified carrier.

Reclining ergometers with wheels can be transported (within a room or between rooms) by the user or third parties.

To prevent personal injury and product/property damage during transport, it is mandatory to observe the following points:

- The reclining ergometer may be transported only when the couch surface is in a horizontal position.
- Nobody is allowed to lie on the couch during transport of the reclining ergometer.
- It is not permitted to transport the reclining ergometer while it is used as intended.

4.3 Setup

Several persons should be present to set up the ergoselect 10.

The ergoselect 10 must be set up on a horizontal level floor.

The reclining ergometer must be set up in a secure and stable position! The leveling feet make for easy adjustment to uneven floors.

During setup, the six leveling feet need to be screwed into the baseplate. To do this, place the reclining ergometer carefully on one side, screw the leveling feet into the corresponding borings (see figure 4-4) and align.

Screw in the feet so the reclining ergometer is standing securely; tighten the counter nut with an open-end wrench (see figure 4-5).

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 reclining ergometer can be equipped with optional wheels. These wheels are screwed into the baseplate in the same positions as the leveling feet.

Caution

- **Equipment Damage** •

Avoid strong vibrations of the reclining ergometer during transport.

Warning

- *To prevent personal injury and product/property damage, set the couch to the horizontal position before transport.*
- *To prevent personal injury, ensure that nobody is lying on the couch during transport.*

Caution

- **Patient Hazard/Equipment Damage** •

During assembly, the ergometer must be disconnected from the power line.

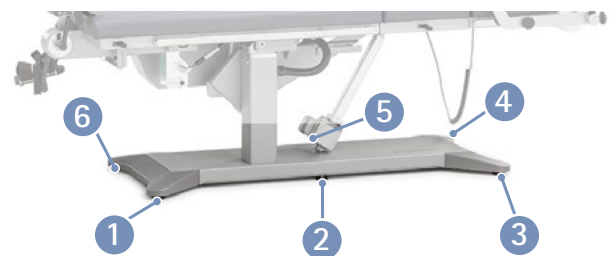


Figure 4-4: Location of the wheels/leveling feet



Figure 4-5: Aligning the wheels/leveling feet

Caution

To prevent injuries, check that the brakes on all wheels are locked before use.

4.4 Mounting attachment parts

Retaining screws ① on the right and left of the standard rail are provided to prevent attachment parts from sliding off the rail.



Figure 4-6: Retaining screws in the standard rail

- Loosen and remove the retaining screws ② with an Allen key (M5x10, 8.8) before sliding the attachment parts onto the rail.

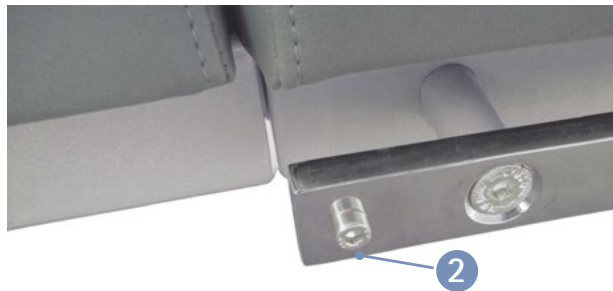


Figure 4-7: Loosen and remove retaining screws

Note

There are two types of attachment parts:

- Attachment parts that you slide onto the standard rails and secure.
- Attachment parts that are secured on perforated rails. When mounting attachment parts with perforated rails, make sure that the bolts of the set screw engage properly in the rails before tightening the set screws by turning them clockwise.

Secure all attachment parts by turning the set screw clockwise.

- Slide the attachment parts onto the standard rails on the sides ① and secure.
- Loosen the set screw ② of the attachment part before placing it on the standard rail.
- Always position and move the attachment parts carefully on the standard rail ③. Do not force the attachment parts onto the standard rail!
- Slide the attachment part to the appropriate position ④ and secure by tightening the set screw ②.
- Use an Allen key (M5x10, 8.8) to tighten the retaining screws (see figure 4-6) at the ends of the standard rail.

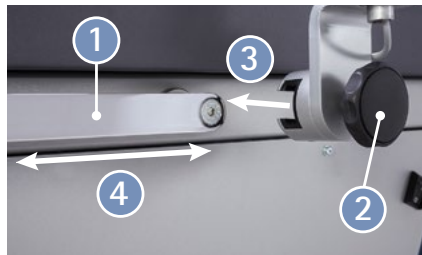


Figure 4-8: Mounting attachment parts

Attachment Part	Description	Mounting Method	Safety Information/Warnings
Headrest ① * The numbers refer to figure 4-10, page 14	Helps the patient remain in position, especially when lying on an inclined surface.	Standard rail	<ul style="list-style-type: none"> Do not hold on to the guide rail when adjusting the headrest!
External RPM indicator ②	Shows the patient the rotational speed of the pedal unit during the exercise test.	Standard rail	<ul style="list-style-type: none"> When standing up from the couch, the patient must not hold on to the external RPM indicator for assistance! The external RPM indicator must not be used as a grab handle! Do not hold on to the guide rail when adjusting the external RPM indicator!
Armrest ③	Supports the arm when the blood pressure is measured during the exercise test.	Standard rail	<ul style="list-style-type: none"> To prevent injuries, do not hold on to the guide rail when adjusting the position of the armrest!
Saddle ④	Provides support and security during the exercise test, especially when the patient is lying on an inclined surface.	Inserted in the saddle guide rail.	<ul style="list-style-type: none"> To prevent injuries, check that the saddle is firmly locked in the guide rail!
Pedal straps ⑤	For secure fixing of the feet during the exercise test.	Permanently fitted.	<ul style="list-style-type: none"> Pull the pedal straps tight to keep the patient's feet securely on the pedals!
Pedal unit ⑥	Retractable pedal unit for exercise tests.	Permanently fitted.	<ul style="list-style-type: none"> To prevent injuries due to the pedal unit falling down, hold the pedal unit with one hand after releasing the locking lever when you extend or retract the pedal unit!

4 Setup and Mains Connection

- Mount the holder for the exam table paper roll by means of two countersunk screws M6x20 **1** which are screwed into the frame.

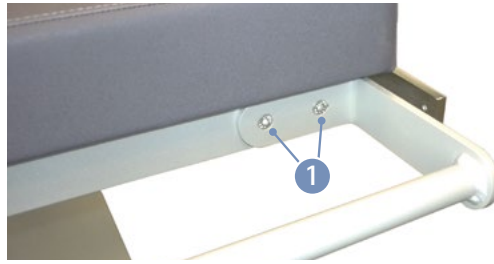


Figure 4–9: Mounting the holder for the exam table paper roll

Caution

- **Equipment Damage** •

Use only white exam table paper.
Colored paper may leave stains on the padded surface.

- Install, position, and secure the headrest **1**.
- Install, position, and secure the RPM readout for the patient **2**.
- Install, position, and secure the bracket for the armrest **3** on the right or left standard rail (only on devices with blood pressure module).
- Introduce the saddle post **4** in the saddle guide rail (see figure 4–11).
- Attach the exam table paper roll to the holder **7**.

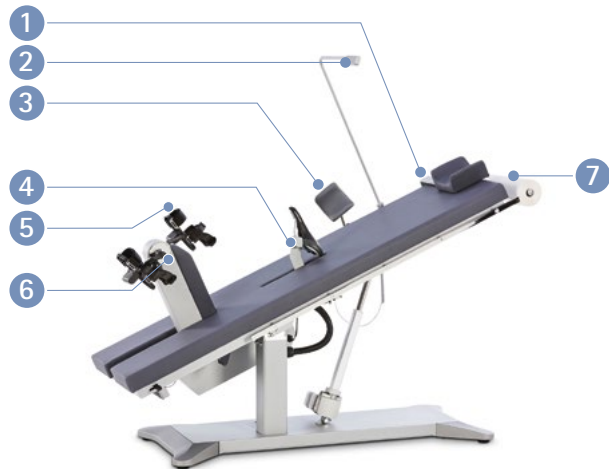


Figure 4–10: Mounting attachment parts

Note

- Tighten the set screw only as much as necessary, **NOT** with maximum force.
- Grease the threads of the set screws every 3 months at minimum, using a suitable grease, such as OKS470.

- Introduce the saddle post into the saddle guide rail **1** and press down lightly until the post locks into place.

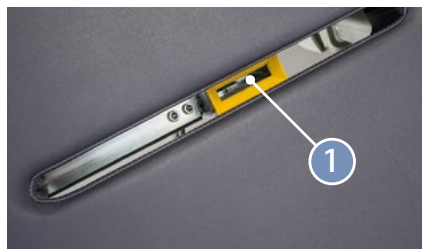


Figure 4–11: Introducing the saddle post into the guide rail

4.5 Connecting the Power Cord

The connection panel is located in the baseplate under the cover panel.

- Plug the power cord into the socket.
- Secure the power cord with a strain relief.

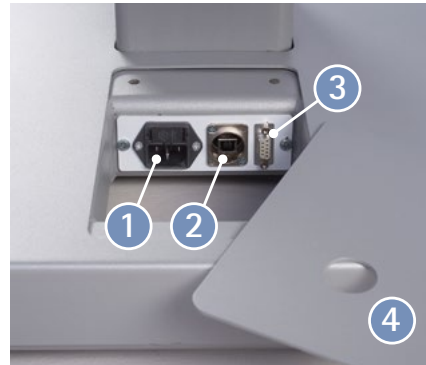


Figure 4-12: Connection panel in the baseplate

- ① Socket for power plug
- ② USB PC connection via USB (virtual COM)
- ③ Port 1 Digital connection (remote control from PC or ECG recorder), connection for cable adapter (analog interface + remote start)
- ④ Cover

Warning

- Equipment Damage •

For operation, the ergometer must be connected to a properly installed, grounded power socket.

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 at the bottom of the table column.

4.6 Interface

The 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.).

All ergoselect ergometers are equipped with a digital interface.

(Special adapters are needed for analog control or the remote start capability. Please contact ergoline GmbH for these adapters.)

The connection cable is plugged into the USB port **1** or the 9-pole socket of the connection panel (Port 1) **2** and secured at the metal frame with an additional strain relief.

Note

- Disconnection from 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.



Figure 4–13: 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), connection for cable adapter (analog interface + remote start)

Note

- Connection Cables •

Use only connection cables approved by ergoline GmbH.

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

4.7 Start-up and preparation

- 1** MCU (Motor Control Unit) power supply
24 VDC
- 2** P2: Patch cable for control terminal (types M, P, T)
- 3** P3: Patch cable for external RPM indicator
- 4** H: Sensor for pedal unit
- 5** R1: Remote control cable or receiver for remote control by radio signal
- 6** R2: free (not assigned)



Figure 4–14: Connections

Concerning its functionality, the control terminal on the underside of the reclining ergometer is equivalent to control terminal M (see chapter 7.1 *Control Terminal D/M* on page 21).

For putting the unit into service, remove the control terminal from below the couch surface. Use a 4-mm Allen key to loosen the two screws ①.

The control terminal allows you to adjust a number of parameters (such as the baud rate, ECG type) before use, or to initiate a manual blood pressure measurement.

These adjustments should be referred to a qualified Service Engineer.



Figure 4-15: Control terminal under the couch surface

5 Operation

5.1 Adjusting the Couch

The saddle and the couch position are adjusted with the remote control (see figure 5– 1):

Keys 1: saddle adjustment

Keys 2: incline adjustment (0 to 38°)

The yellow indicator 4 is illuminated while any of the adjustment keys is pressed.

All movements stop automatically when the end position is reached. Movements also stop when two adjustment keys for a motor are pressed at the same time.

The battery indicator 3 indicates the charge level of the battery in the remote control:

Battery OK LED off

Battery low: LED on

The batteries used must meet the following technical specifications:

Power supply: 3 V DC (batteries 2 x 1.5 V AA IEC LR6, alkaline manganese)



Figure 5– 1: Remote control

Caution

• Patient Hazard •

The armrest (for blood pressure measurements) is not designed to support the full body weight and it must not be used as a support when getting on and off the couch.

Note

• Motor •

The motor is not suitable for continuous operation. The duty cycle of 10% (1 min ON / 9 min OFF) must be observed. This means that 1 minute of continuous operation of the control terminal must be followed by a pause of 9 minutes.

Caution

- Do not place any metal objects in the battery compartment. If short-circuiting of the batteries occurs, they may become very hot and cause burn injuries.
- The remote control will not work when the battery polarity is not observed. The remote control may heat up, the batteries may leak and destroy the remote control.
- Never use old and new batteries together or mix batteries of different brands as this may cause the device to malfunction.
- Use only high-quality, leak-proof batteries.

5.2 Extending/Retracting the Pedal Unit

To extend and retract the pedal unit, unlock the locking lever ① and raise or lower the pedal unit, holding it with one hand.

When extending the pedal unit, raise it until you hear it click into place. The pedal unit is secured against dropping inadvertently only when it is properly locked in place.

When retracting the pedal unit, lower it carefully with your hand and don't let it drop.



Figure 5-2: Extending and retracting the pedal unit

6 Preparing the Patient

6.1 Preparing the Couch with the Patient

Before the patient can lie down on the couch, the ergometer must be prepared as follows:

- Lower the saddle to the bottom position.
- Remove the saddle.
- Adjust the couch surface to the horizontal position so that the patient can get easily on the couch.
- Lower the pedal unit.
- Ask the patient to lie down on the couch.
- Reinstall the saddle.
- Raise the pedal unit.
- Close the straps at both pedals and secure the feet in the pedal shoes by means of the hook and loop fasteners of the straps.

There should be a 10° angle between the axis formed by the upper body and the thigh when the pedal is in the lower position:

- Adjust the saddle until this angle is achieved.
- Adjust the headrest until in contact with the shoulder, when the head is placed on the headrest.
- Choose a position for the RPM indicator where the patient can easily read the displayed values.

Now you can adjust the incline of the couch.

Note

• Patient Safety •

Always secure attachment parts by turning the set screw clockwise.

When mounting attachment parts with perforated rails, make sure that the bolts of the knobs engage properly in the rails before tightening the knobs by turning them clockwise.

Note

• Motor •

The motor is not suitable for continuous operation. The duty cycle of 10% (1 min ON/9 min OFF) must be observed. This means that 1 minute of continuous operation of the control terminal must be followed by a pause of 9 minutes.

7 Control Terminals

The control terminals can be installed on a table stand or on a high floor stand (accessories).

Warning

To prevent injuries, the cable connecting the couch and the control terminal needs to be routed properly. Ensure that the connection cable never presents a trip hazard.



Figure 7-1: Control terminals on separate stands (left: table stand, right: floor stand)

Warning

To prevent injuries, please do not lean on the control terminal on the high floor stand. There is a risk of tipping over.

7.1 Control Terminal D/M



Figure 7-2: Control terminal D (Service)
(installed under the couch surface – standard)



Figure 7-3: Control terminal M (remote control)
(separate terminal – option)

The two terminals are identical in operating routines and functionality.

7.1.1 Turning the System On

You turn on the ergometer by pressing the power switch. The ergometer runs a self-test. Subsequently, the start screen displays.

Control terminal D/M is entirely operated by remote control (e.g., from an ECG recorder or a PC).



Figure 7-4: Start screen

Note

- Instruct the patient not to pedal while the ergometer is being turned on and during the self-test.

7.1.2 Operating Mode with Control Terminal D/M

Ergometers with control terminal D/M support the following operating mode:

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.

When the ergometer is switched on, the display shows the start screen – the ergometer is waiting for commands from the external ECG unit.



Figure 7-5: 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 appropriate command from the controlling ECG unit.

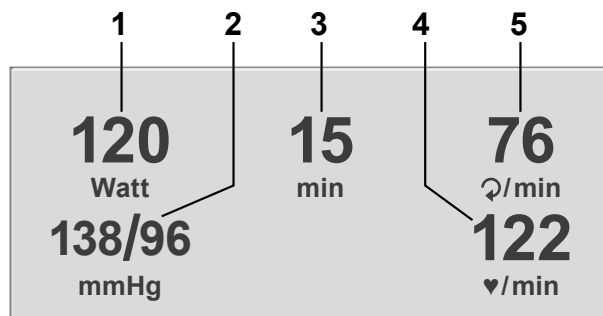


Figure 7-6: Exercise test screen 1

- 1 current load (watts)
- 2 most recent BP value (systolic/diastolic) or cuff pressure during inflation and bar graph indicating microphone signal strength (see below)
- 3 duration of exercise test (min)
- 4 heart rate at the time of the BP measurement (BPM)
- 5 pedal speed (RPM)



Figure 7-7: Exercise test screen 2

7.2 Control Terminal P

7.2.1 Turning the System On

You turn on the ergometer by pressing the power switch (toggle switch [I/O]).

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

Note

- The control terminal is equipped with a backup battery. Type: CR 2032 / 3 V 230 mAh. Only authorized qualified staff is allowed to replace the battery.

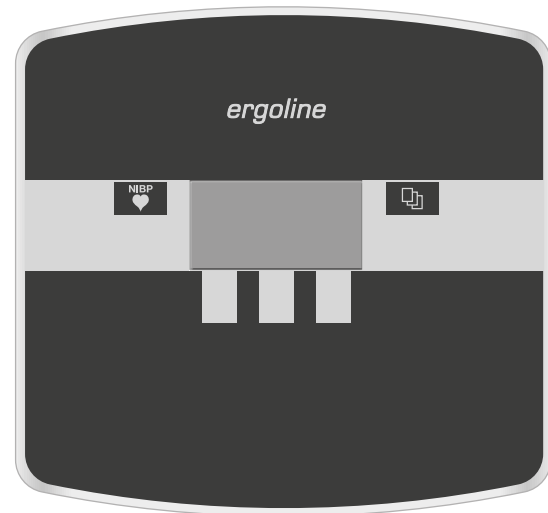



Figure 7-8: Control terminal P

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.

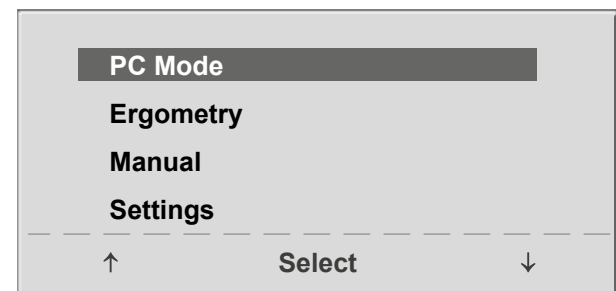



Figure 7-9: Main menu

The ergometer software is controlled with 5 keys:

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


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



Figure 7-10: Keypad P

7.2.2 Operating Modes

Ergometers with control terminal P support 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 7.2.2.4 *Settings with Control Terminal P* on page 28).

Manual

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

Settings

Used to configure the ergometer.

7.2.2.1 PC Mode

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

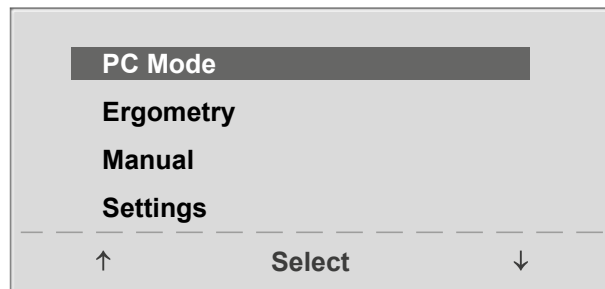


Figure 7–11: Main menu

The start screen will be displayed – the ergometer is waiting for commands from the external ECG unit.

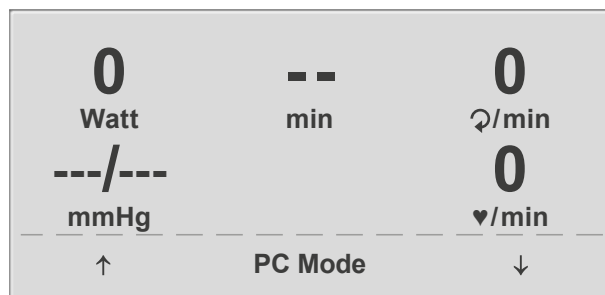


Figure 7–12: Start screen

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 appropriate command from the controlling ECG unit.

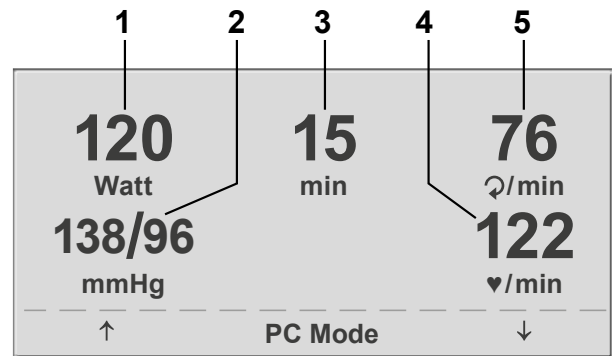



Figure 7-13: Exercise test screen 1

- 1 current load (watts)
- 2 most recent BP value (systolic/diastolic) or cuff pressure during inflation and bar graph indicating microphone signal strength (see below)
- 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.

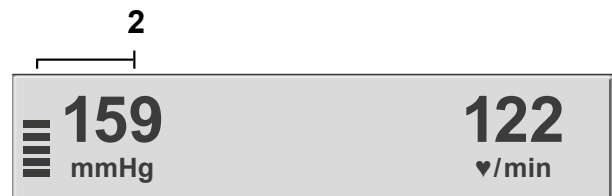


Figure 7-14: Exercise test screen 2

7.2.2.2 Ergometry

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

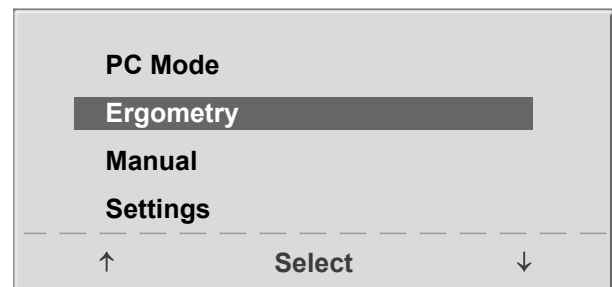


Figure 7-15: Main menu

7 Control Terminals

The stored test protocols available for selection will be displayed. There are five fixed protocols (protocols 1 to 5, (see chapter 11.2 *Exercise Test Protocols* on page 53)), whereas protocols 6 to 15 are user-configurable.

The protocol menu provides an overview of the test phases.

Example: **50 W/2 min/25 W**
indicates: Basic load of 50 W
Stage time of 2 min
Load stage of 25 W

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 (depending on the selected exercise test protocol).

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 pedaling.

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 any time (in increments of +/-1 W up to +/-25 W, as configured).

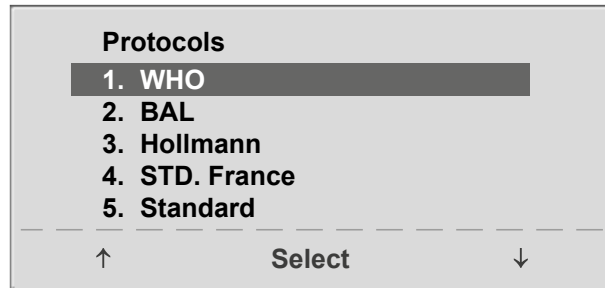


Figure 7–16: Selecting an exercise test protocol

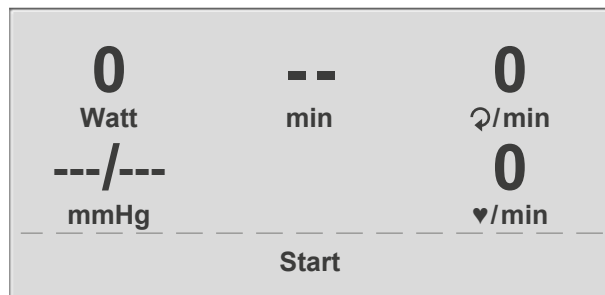


Figure 7–17: Initial exercise test screen

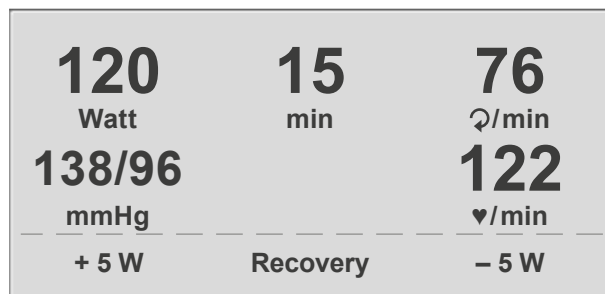



Figure 7–18: Display during the exercise test

Note

- The saddle height can be adjusted during an exercise test.
- To activate the saddle height adjustment, press : the arrow keys will be displayed then.

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.

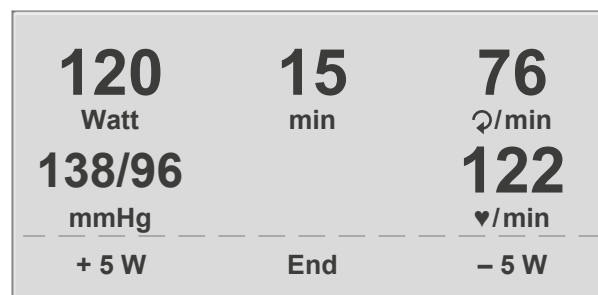


Figure 7-19: Recovery phase

7.2.2.3 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.

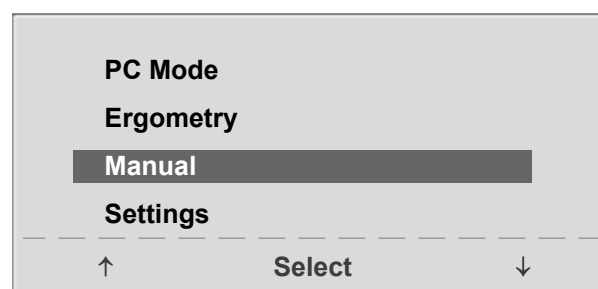


Figure 7-20: Main menu

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).



Figure 7-21: 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.

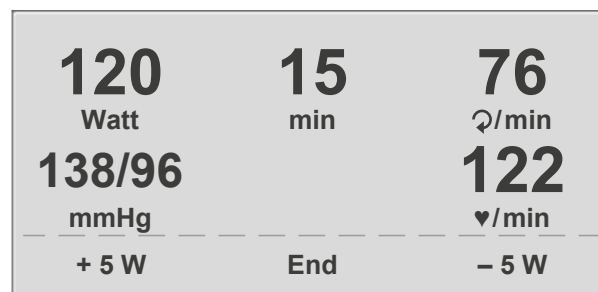



Figure 7-22: Display during the exercise test

7.2.2.4 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**.

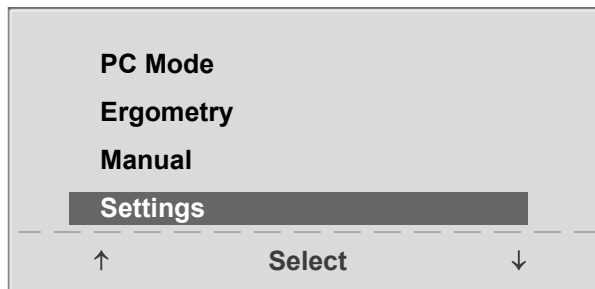


Figure 7–23: Main menu

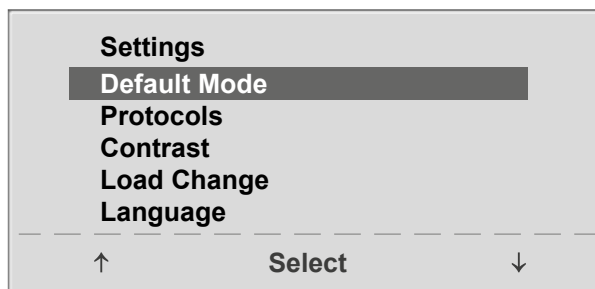


Figure 7–24: Settings menu

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**.

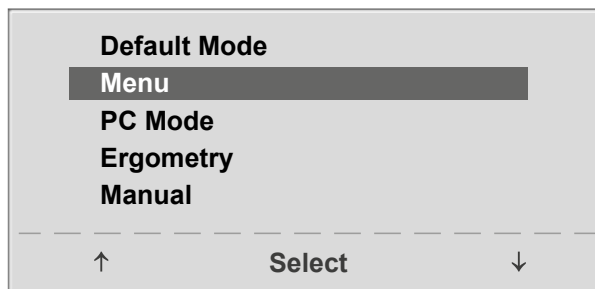


Figure 7–25: Selecting the default mode

Protocols

Protocols 6 to 15 are user-configurable (protocols 1 to 5 are fixed, see chapter 11.2 *Exercise Test Protocols* on page 53 for protocol parameter details). Default values can be entered for the following parameters:

- protocol type (Step/Ramp)
- 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**.

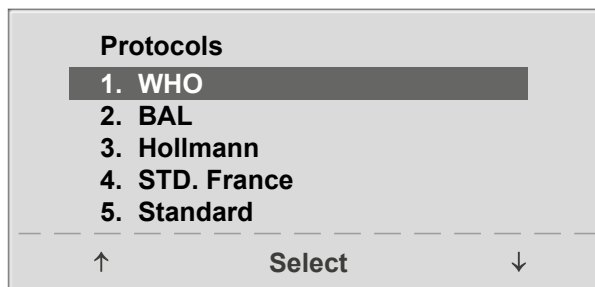



Figure 7–26: Selecting the exercise test protocol to configure

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

At **Select**, for example, you can choose the protocol type:

- Step (load increase in steps) or
- Ramp (continuous load increase).


Press **Select** to save the selected protocol type.

To cancel the selection, press the  key.

All other parameters are edited in the same way.

Using the arrow keys (↑ ↓), highlight a parameter and confirm the selection with **Select**: the corresponding value appears in reverse video and can be changed with the arrow keys (↑ ↓).

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

You exit the configuration with .

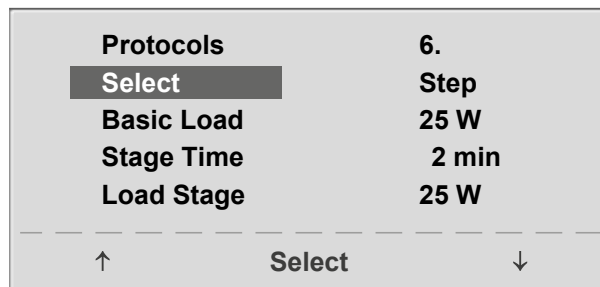


Figure 7-27: Selecting the parameter to edit

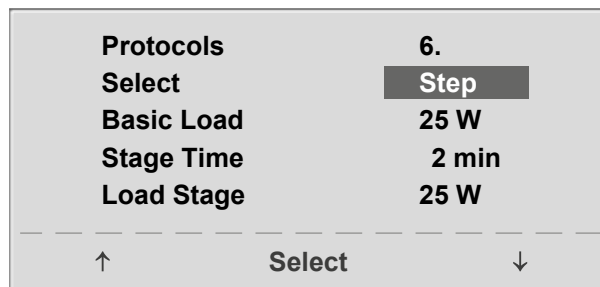


Figure 7-28: Editing the parameter value

Contrast

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

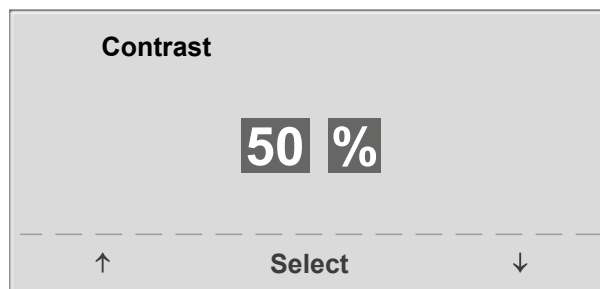


Figure 7-29: Adjusting the display contrast

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 or 25 watts.

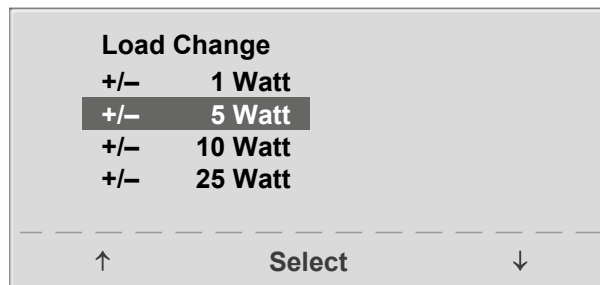


Figure 7-30: Selecting the increment for manual load changes

Language

The texts can be displayed in different languages.

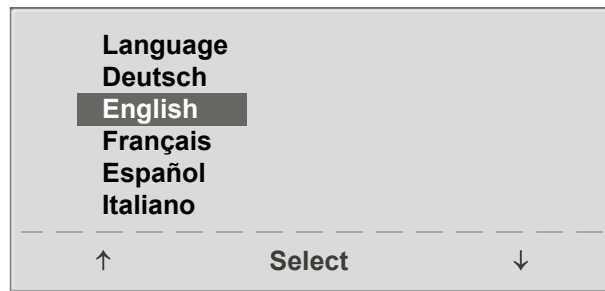


Figure 7–31: Language menu

Beep

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

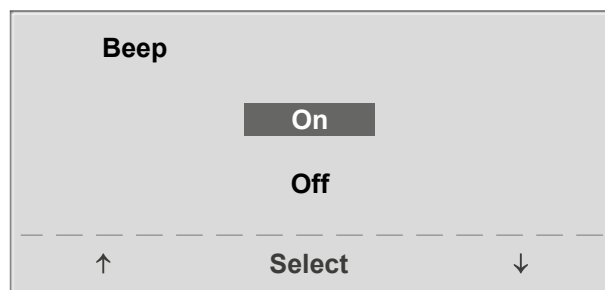



Figure 7–32: Beep during BP measurements

Software Version

Select this option to view the installed software version.

Date/Time

To begin with, you select **Date** and confirm the selection. Then the value displayed in reverse video can be edited with the ↑ ↓ keys and saved with **Select**.

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

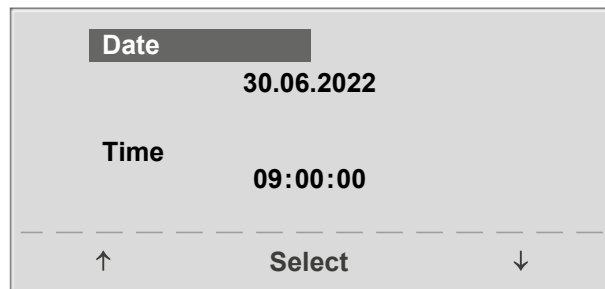


Figure 7–33: Setting the date

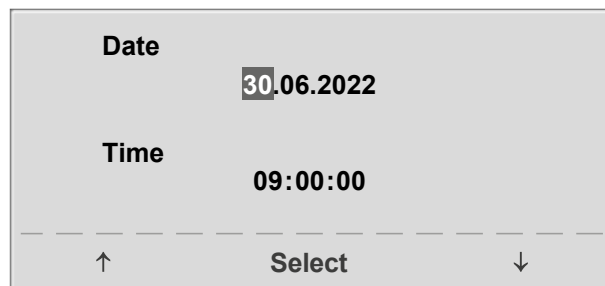


Figure 7–34: Setting the day

ECG Type

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

To prevent an accidental change of this setting, the menu is protected with a password.

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

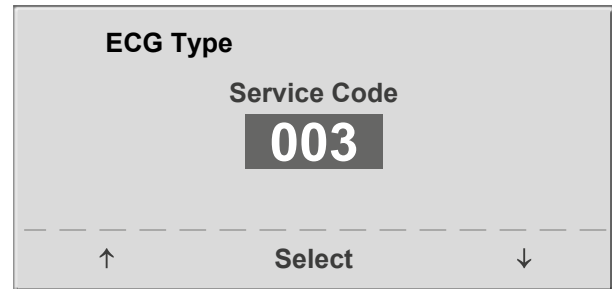


Figure 7–35: Entering the ECG Type password

All ergometers support the following communication modes:

- **Analog with pulse**
Remote start mode; before advancing to the next load level, 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.

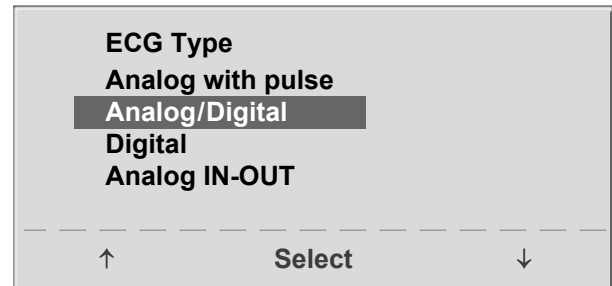


Figure 7–36: Selecting the ergometer communication mode

Select the communication mode and confirm with **Select**.

Note

- *The ECG 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 rotational 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**.

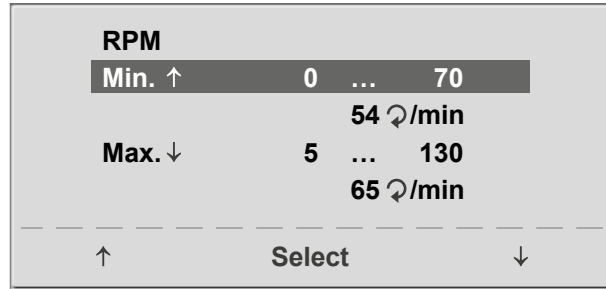


Figure 7–37: Setting the RPM limit values

Note

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

Load (watts)	Green RPM range (1/min)
6 – 150	54 – 64 (adjustable)
151 – 250	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.

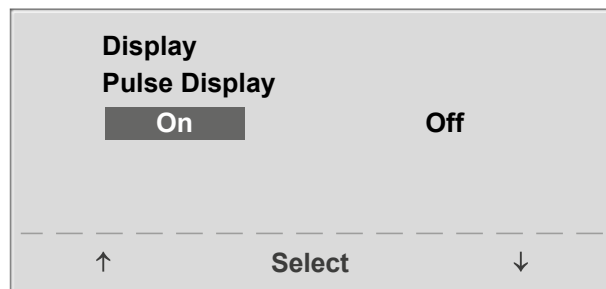


Figure 7–38: Setting the pulse readout

7.3 Control Terminal T

7.3.1 Turning the System On

You turn on the reclining ergometer by pressing the power switch (toggle switch [I/O]).

Note

- The control terminal is equipped with a backup battery. Type: CR 2032/3 V 230 mAh. Only authorized qualified staff is allowed to replace the battery.

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.

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

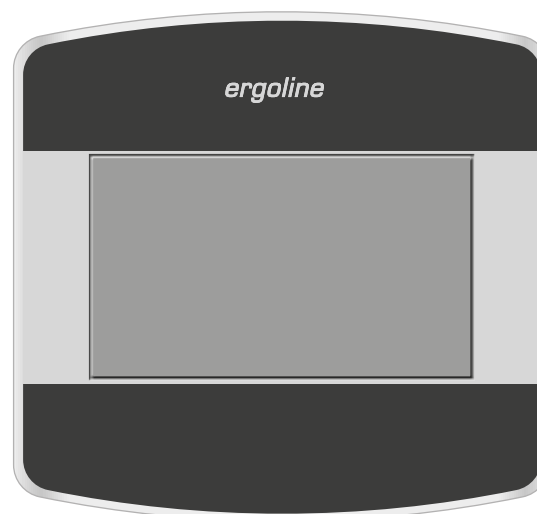


Figure 7-39: Control terminal T

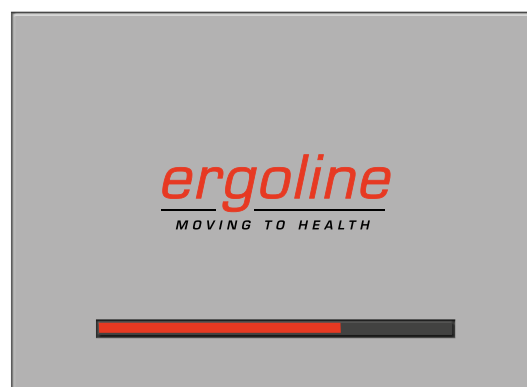


Figure 7-40: Self-test screen

The ergometer software is controlled from the touch panel.

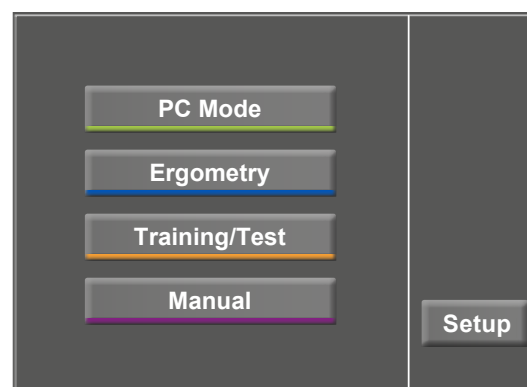


Figure 7-41: Main menu

7.3.2 Operating Modes with Control Terminal T

Reclining ergometers with control terminal T support the following operating modes:

PC Mode

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

Ergometry

The reclining ergometer runs an automatic exercise test – the available protocols (5 preconfigured, editable protocols and 5 user-configurable protocols) are saved in the ergometer (see chapter 7.3.2.2 *Ergometry*, section *Settings* on page 36).

Training/Test

Ten user-configurable training/test protocols are available (see chapter 7.3.2.3 *Training/Test* on page 38).

A POLAR receiver is integrated in the reclining ergometer and provides the relevant data for heart-rate controlled training sessions. The test subject's performance can be assessed on the basis of these protocols.

Manual

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

Setup

Used to configure the reclining ergometer.

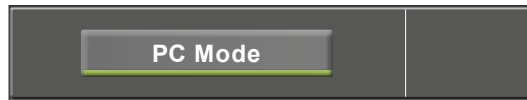


Figure 7-42: PC mode

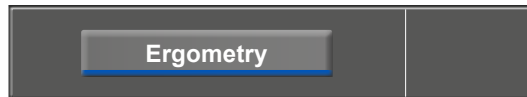


Figure 7-43: Ergometry mode

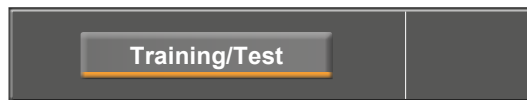


Figure 7-44: Training/Test mode

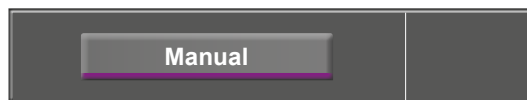


Figure 7-45: Manual mode



Figure 7-46: Setup mode

7.3.2.1 PC Mode

When the [PC Mode] key has been pressed, the screen appears as shown at right. The reclining ergometer is waiting for commands from the external ECG 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 display shows heart rate (1/min), blood pressure (mmHg), oxygen saturation in percent (%), duration of the exercise test (min:ss), pedal speed (1/min) and current load (W).

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

A blood pressure measurement can be initiated with the [RR] key. Pressing the [RR] key a second time during a measurement will stop the measurement.

When you press the [ECG] key, the display will change. The acquired, electrical signals will be displayed. The amplitude (gain) can be adjusted with the arrow keys [▲] and [▼].

The pump for the suction electrode system can be switched on and off with the [I/O] key.

You can change the vacuum intensity between low, medium and high by touching the [I/O] key.

To switch off the pump, press the appropriate key [low], [middle], [high] for about 3 seconds.

Confirm all inputs with the [✓] key.

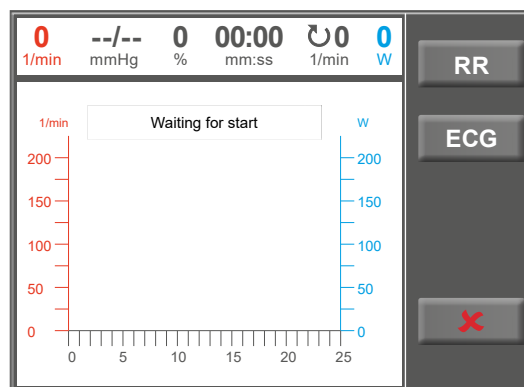


Figure 7-47: PC mode screen

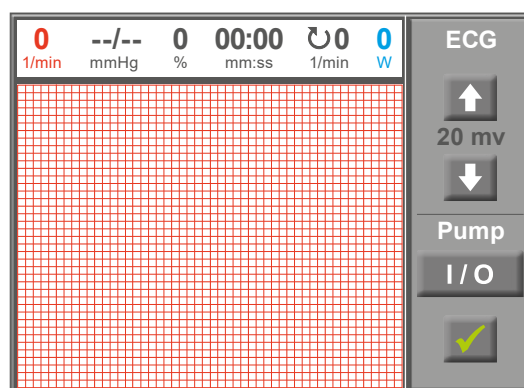


Figure 7-48: ECG screen

7.3.2.2 Ergometry

Pressing the [Ergometry] key in the main menu activates the ergometry mode.

The different exercise test protocols will be displayed (5 preconfigured, editable and 5 user-configurable protocols).

All exercise test protocols (including the 5 preconfigured protocols) are editable.

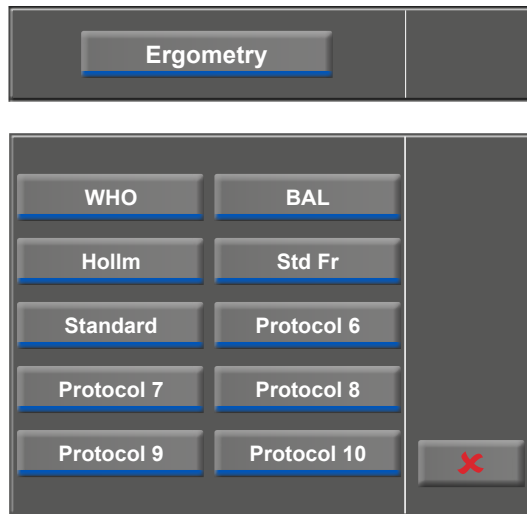


Figure 7 – 49: Ergometry menu

Settings

When you touch a protocol, the available parameters will be displayed.

With the [Edit] key, you can modify each protocol parameter. The new inputs overwrite the existing values.

All protocols can be edited during operation (except for the PC mode).

User-configured, custom protocols must be saved via [Setup] in the main menu (see chapter 7.3.2.5 *Setup*, section *Protocols* on page 41).

In the configuration menu, the following parameters can be edited:

- the basic load (from 6 to 100 W),
- the stage time (from 1 to 30 min),
- the stage rate (increment, from 1 to 400 W).



Figure 7 – 50: Exercise test protocol – screen 1

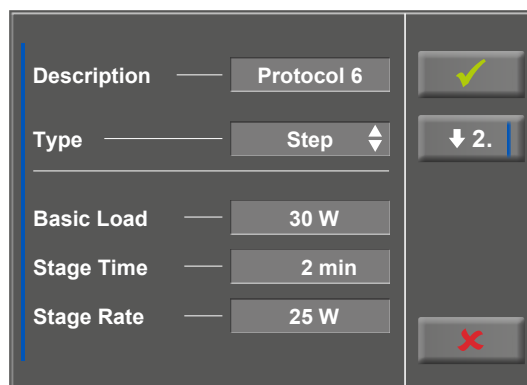


Figure 7 – 51: Exercise test protocol – screen 2

With the [\blacktriangledown 2.] key, you proceed to the next menu level where you can edit these parameters:

- the recovery load (from 6 to 100 W) and
- the recovery time (from 1 to 30 min).

With the [\blacktriangle 1.] key, you return to the previous screen.

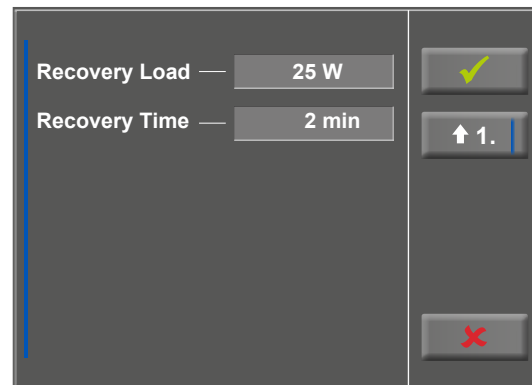


Figure 7-52: Exercise test protocol – screen 3

Touch a light gray field, e.g., at Basic Load: a submenu with input field and numeric keypad opens. You can enter values directly via the numeric keypad.

Confirm your inputs with the [\checkmark] key. To cancel the input, press the [\times] key.

The other parameters can be edited in the same way, they will overwrite the current values.

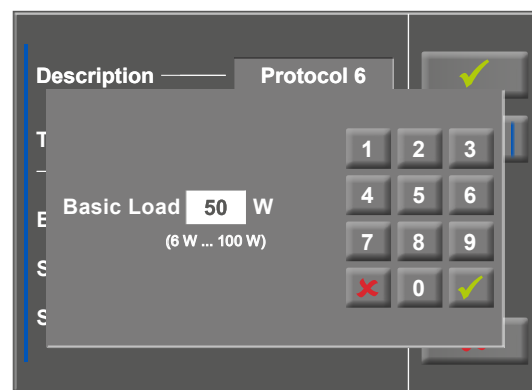


Figure 7-53: Exercise test protocol, basic load

When you touch the [\checkmark] key again after confirming, the display will change. Touching the [Start] key on the display will initiate the training session. The session is entirely controlled by the protocol. The display indicates the current values.

When you press the [const.] key, the current load will be maintained for the rest of the session.

You change the load with the [+5 W] and [-5 W] keys. The actual load change can be set in the configuration menu between +/-1 W and +/-25 W (see chapter 7.3.2.5 Setup, section Load Change on page 43).

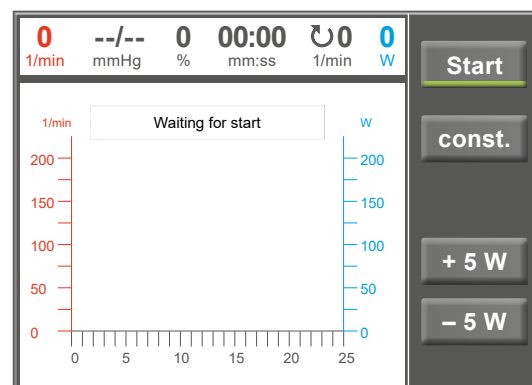


Figure 7-54: Starting an exercise test

Terminating the Protocol

Once the full protocol has been completed, it terminates automatically.

The protocol can be terminated manually at any time with [Stop]. First, you enter the recovery phase.

When you touch [Stop] again, the training will be terminated.

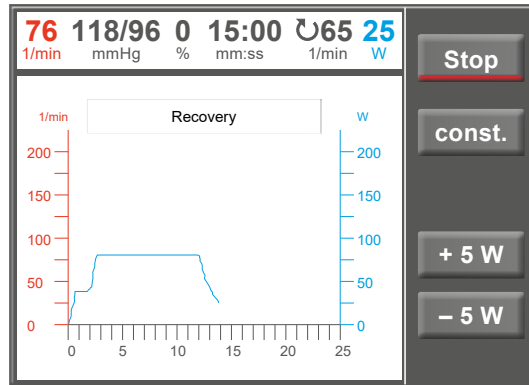


Figure 7-55: Terminating an exercise – screen 1

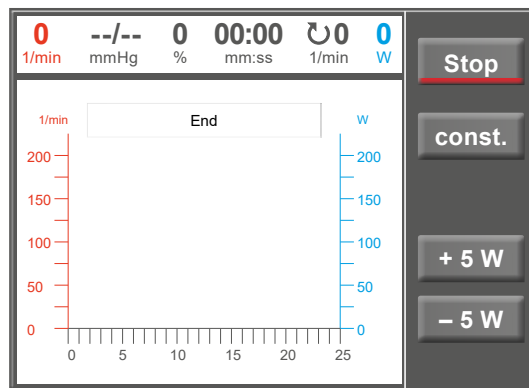


Figure 7-56: Terminating an exercise – screen 2

7.3.2.3 Training/Test

Ten different protocols are available in the Training/Test menu.

To edit the protocol parameters, first touch the Training/Test protocol you want to edit.

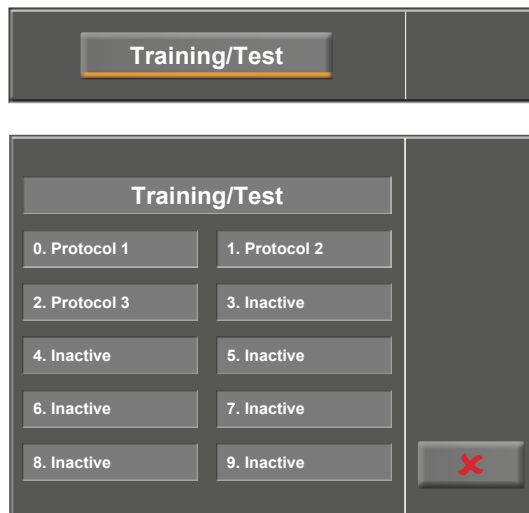


Figure 7-57: Selecting the training /test protocol

Then press the [Edit] key.

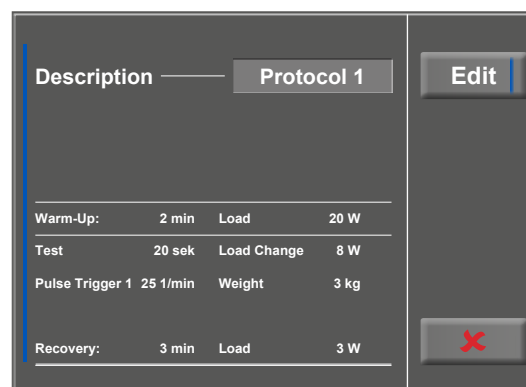


Figure 7-58: Editing the training/test protocol

The individual parameters (light gray fields) can now be edited by touching the display or by repeatedly tapping [↕]. If you need to input characters (numbers or letters), a numeric keypad or a keyboard will be displayed.

The options for Type are [Pulse ↕], [Constant ↕], [Interval ↕], [Ramp Test ↕], [PWC Test 1 ↕], [PWC Test 2 ↕], [PWC Test 3 ↕] and [Inactive ↕]. You scroll through the Type options by tapping the [↕] key. Configure the parameters as required by the selected type.

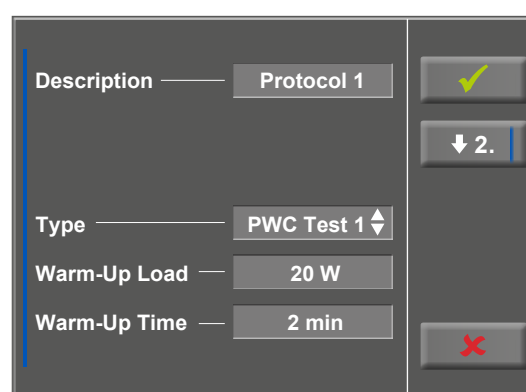


Figure 7-59: Editing parameters – screen 1

With the [↘] key (arrow down, [↘2.] or [↘3.]), you advance to the next menu level where more parameters can be configured. With the [↗] key (arrow up, [↗1.] or [↗2.]), you return to the previous screen of the menu.

Inputs are confirmed with the [✓] key.

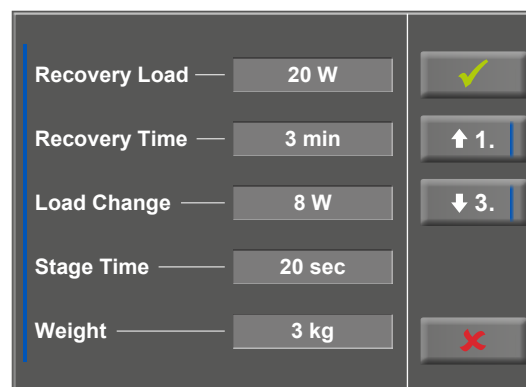


Figure 7-60: Editing parameters – screen 2

7.3.2.4 Manual

In this operating mode the user has complete control over the reclining ergometer and initiates blood pressure measurements.

Pressing the [Start] key initiates the exercise test, the [+5 W] and [-5 W] keys are used to control the load. The actual load change can be set in the configuration menu between +/-1 W and +/-25 W (see chapter 7.3.2.5 Setup, section Load Change on page 43).

A blood pressure measurement is initiated with the [RR] key.

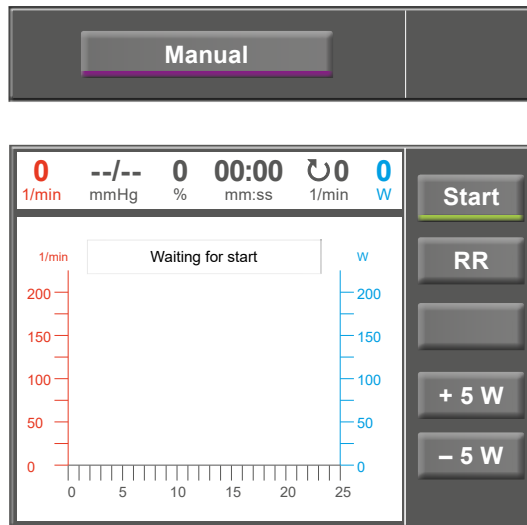


Figure 7 – 61: Starting a manual test

Terminating an Exercise Test

The exercise test can be terminated manually at any time with the [Stop] key.

The load will immediately drop to 0 watt.

There is no recovery phase in the manual mode.

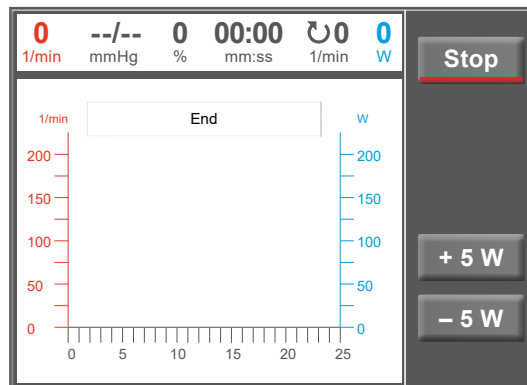


Figure 7 – 62: Terminating a manual test

7.3.2.5 Setup

The [Setup] key opens the configuration menu where various program functions can be defined.

To edit a setting, touch the corresponding menu item on the display.

Confirm inputs with the [✓] key and exit menus with the [✕] key.

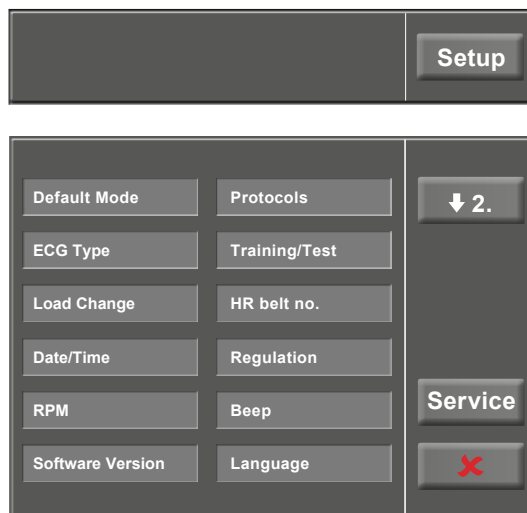


Figure 7 – 63: Setup menu

Default Mode

Select the operating mode to be activated when the reclining ergometer is turned on:

- PC Mode
- Ergometry
- Training/Test
- Manual

and confirm the selection with the [✓] key.

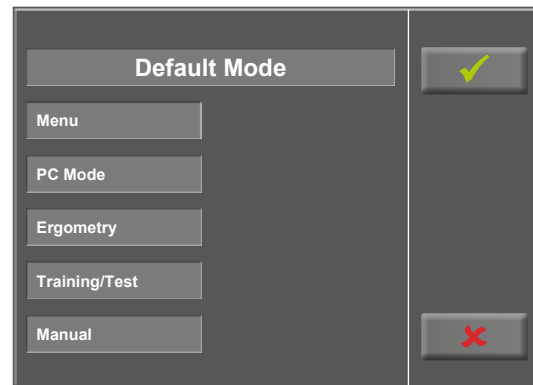


Figure 7–64: Setup – default mode

Protocols

The first 5 exercise test protocols (WHO, BAL, Hollm, Std Fr and Standard) are preconfigured, but all protocols in the list are editable.



Figure 7–65: Setup – protocols, screen 1

To reach the level for editing of the individual protocol parameters, first touch the protocol that you want to modify (e.g., [5. Protocol 6]), and then touch the [Edit] key.

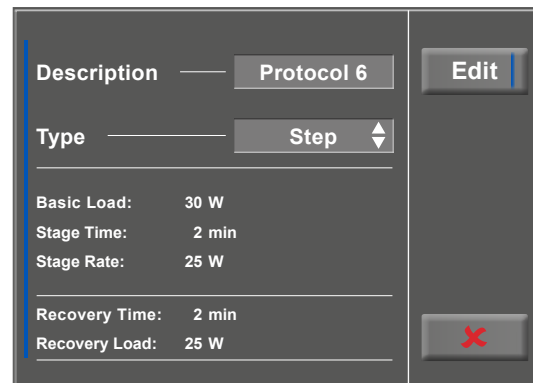


Figure 7–66: Setup – protocols, screen 2

To change the name of a protocol, touch the protocol name and enter the new name from the keypad. Confirm your inputs with the [✓] key.

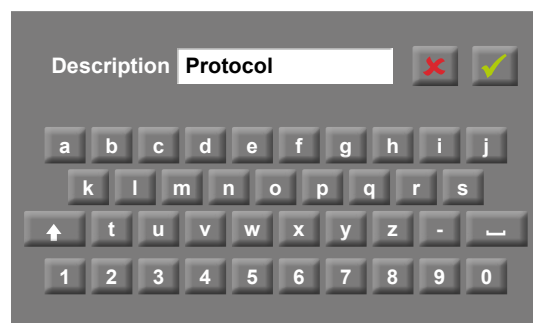


Figure 7–67: Setup – protocols, screen 3

7 Control Terminals

At Type, you can choose [Step ↕], [Ramp ↕] or [Inactive ↕]. You scroll through the Type options with the [↕] key.

When choosing the Step type (load increase in steps), define the basic load (from 6 to 100 W), the stage time (from 1 to 30 min) and the stage rate (increment, from 1 to 400 W). When choosing the Ramp type (continuous load increase), define the basic load (from 6 to 100 W) and the load increase (from 1 to 50 W).

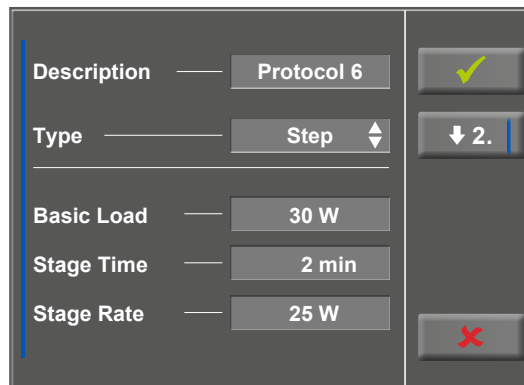


Figure 7-68: Setup – protocols, screen 4

To configure the protocol parameters (light gray fields), touch one of the parameters. Edit the parameter as appropriate and confirm the modification with the [✓] key.

Touch the Cancel key [✕] to exit the menu item.

With the [↓2.] and [↑1.] keys, you toggle between the different screens.

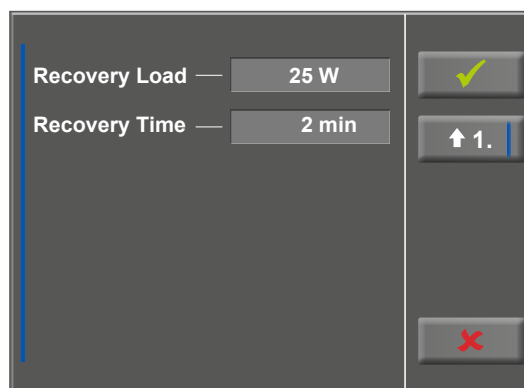


Figure 7-69: Setup – protocols, screen 5

ECG Type

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

To prevent an accidental change, this setting is protected with a password.

A submenu opens when you touch ECG Type on the display. Enter the code number "3" via the numeric keypad and confirm with the [✓] key.

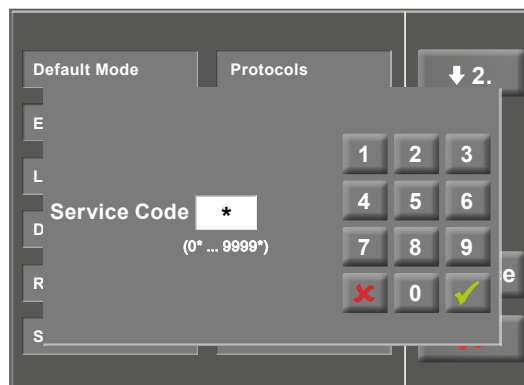


Figure 7-70: Setup menu

The following communication modes are supported:

- **Analog with pulse**
Remote start mode; before advancing to the next load level, the reclining 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 reclining 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.

Choose the appropriate communication mode and confirm with the [✓] key.

Load Change

With this function, you select the increments for load changes.

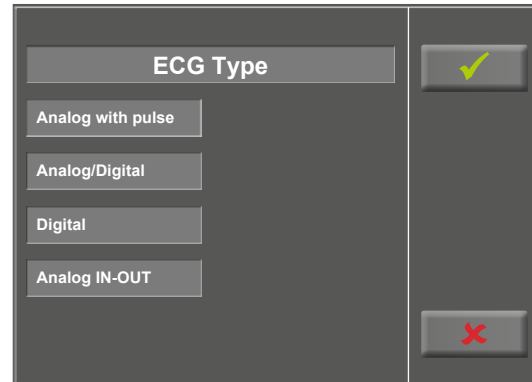


Figure 7-71: Setup – ECG type

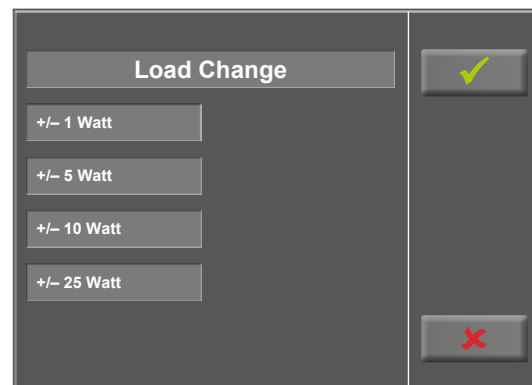


Figure 7-72: Setup – load change

Date/Time

Touch the respective fields to adjust date and time.

Enter day, month, year as well as hours, minutes and seconds via the numeric keypad.

Inputs are confirmed with the [✓] key.

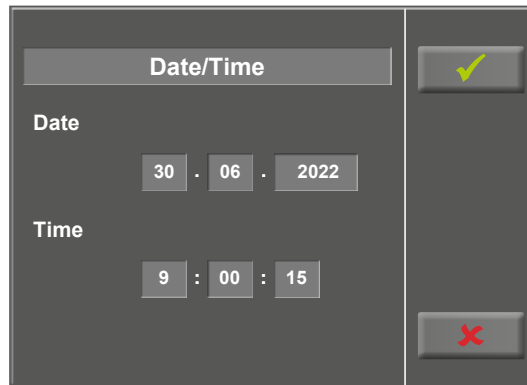


Figure 7-73: Setup – date and time, screen 1

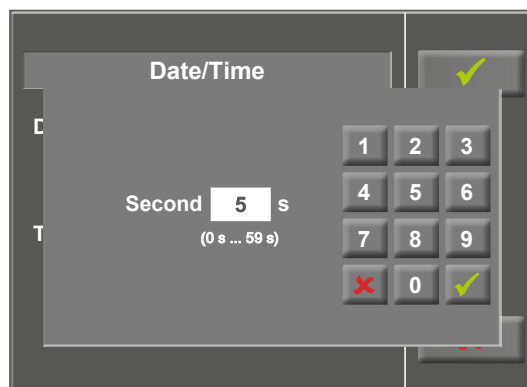


Figure 7-74: Setup – date and time, screen 2

Regulation

At Regulation, you can specify the load details, such as:

- load control (flat, normal, steep)
- duration: load + (0 min to 15 min) and
- duration load – (0 min to 15 min)

You scroll through the load control options (flat, normal, steep) by tapping the light gray text field.

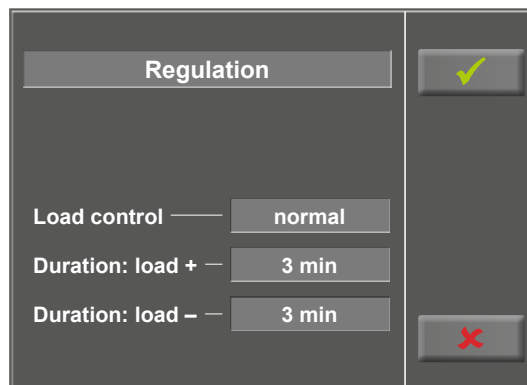


Figure 7-75: Setup – regulation method, screen 1

When you touch the light gray field to the right of 'Duration: load +' or 'Duration: load -', the time can be entered via the numeric keypad.

Inputs are confirmed with the [✓] key.

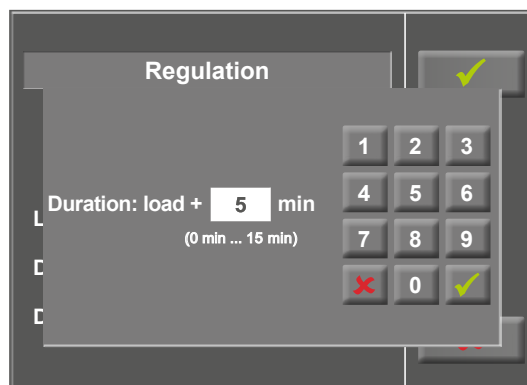


Figure 7-76: Setup – regulation method, screen 2

RPM

In this menu, you determine the limits for the RPM indication.

The 3 LEDs on the control terminal show the patient whether the pedal speed is high, low or correct.

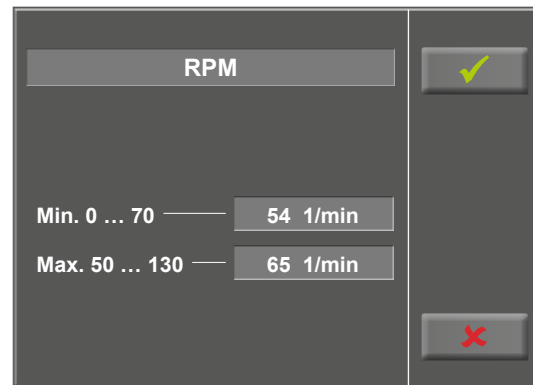


Figure 7-77: Setup – RPM, screen 1

Touch the light gray field to the right of Min. or Max. and enter the value via the numeric keypad.

Confirm the input with the [✓] key or cancel the input with the [✗] key.

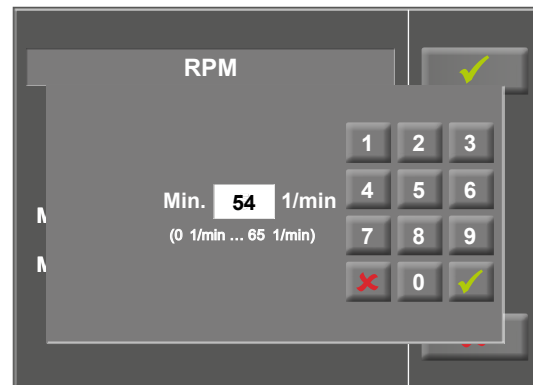


Figure 7-78: Setup – RPM, screen 2

Beep

A short beep confirms each key press. The audible feedback can be enabled and disabled.



Figure 7-79: Beep setup

Software Version

This menu shows the software version and the date of the technical inspection of the measuring system (MTK).



Figure 7 – 80: Setup – software version

Language

Here you choose the language for the user interface.



Figure 7 – 81: Setup – language

Display

Press the [▼2.] key to display the next screen and touch Display.

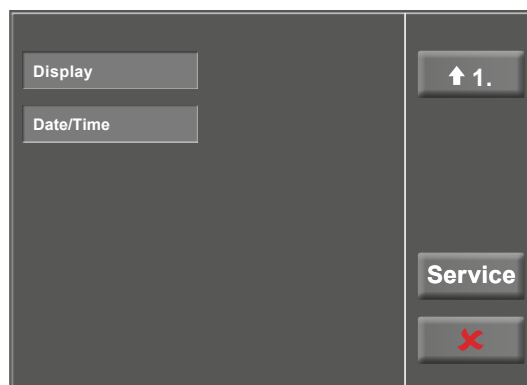


Figure 7 – 82: Setup – screen display 1

Switch the pulse readout on or off.

Select the blood pressure unit: mmHg (millimeter of mercury) or kPa (kilopascal).

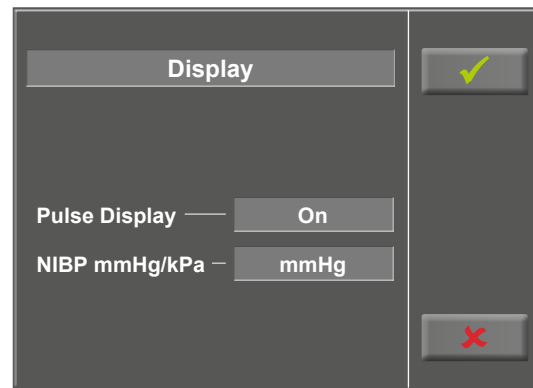


Figure 7-83: Setup – screen display 2

8 Cleaning, Disinfection, and General Hygiene Measures

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

9 General Product Information

9.1 Checks Before Each Use

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

9.2 Technical Safety Inspections and Inspections of the Measuring System

The German Medical Device Operator Ordinance (MPBetreibV) requires system operators to have technical safety inspections (STK) and inspections of the measuring system (MTK) performed by a service engineer authorized by ergoline GmbH every 2 years at the latest.

For inspections of the measuring system (MTK) and calibration, the ergoline test bench ergoTest 550 is available as a calibration tool.

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

9.3 Disposal

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

Please contact your authorized manufacturer ergoline GmbH for information concerning the disposal of your equipment. There is no waste disposal certificate. Proper disposal is documented by ergoline GmbH. Consult Operator's Manual!



Note

The (rechargeable) batteries that power the motor controller in the device must not be disposed of as unsorted municipal waste. They must be disposed of as hazardous waste.

Used (rechargeable) batteries may contain harmful substances which can endanger human health and harm the environment if stored or disposed of improperly.

10 Accessories

Part no.	Description
705956	Hand grip with bracket
705957	Armrest, curved, with bracket
705958	Armrest, flat, with bracket
705960	Swiveling armrest
707227	Floor stand, large (for control terminal)
705883	Saddle, standard
705979	Saddle, wide

11 Technical Specifications

11.1 Ergometer

Model	Modular reclining ergometer system ergoselect Model ergoselect 10 M/P/T																																														
Operating mode	Saddle motor: ON 2min/OFF 18min Motor for table inclination: ON 1min/OFF 9min																																														
Load unit	<p>The times refer to a cold start of the ergometer at a maximum ambient temperature of 40°C. This means that the temperature of the ergometer may not exceed the maximum allowed room temperature when starting the first interval.</p> <p>If operation of the ergometer continues after the indicated time interval, it is mandatory to observe the OFF and ON times.</p>																																														
	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Load</th> <th>Revolutions</th> <th>1st interval in minutes*</th> <th rowspan="9" style="writing-mode: vertical-rl; transform: rotate(180deg);">followed by</th> <th>OFF time in minutes</th> <th>ON time in minutes</th> </tr> </thead> <tbody> <tr> <td>450 watts</td> <td>85 rpm</td> <td>30</td> <td>25</td> <td>5</td> </tr> <tr> <td>400 watts</td> <td>85 rpm</td> <td>35</td> <td>24</td> <td>6</td> </tr> <tr> <td>350 watts</td> <td>80 rpm</td> <td>45</td> <td>23</td> <td>7</td> </tr> <tr> <td>300 watts</td> <td>75 rpm</td> <td>55</td> <td>22</td> <td>8</td> </tr> <tr> <td>250 watts</td> <td>70 rpm</td> <td>65</td> <td>21</td> <td>9</td> </tr> <tr> <td>200 watts</td> <td>65 rpm</td> <td>100</td> <td>18</td> <td>12</td> </tr> <tr> <td>150 watts</td> <td>60 rpm</td> <td>120</td> <td>15</td> <td>15</td> </tr> <tr> <td>100 watts</td> <td>55 rpm</td> <td colspan="3">continuous operation</td> </tr> </tbody> </table>	Load	Revolutions	1st interval in minutes*	followed by	OFF time in minutes	ON time in minutes	450 watts	85 rpm	30	25	5	400 watts	85 rpm	35	24	6	350 watts	80 rpm	45	23	7	300 watts	75 rpm	55	22	8	250 watts	70 rpm	65	21	9	200 watts	65 rpm	100	18	12	150 watts	60 rpm	120	15	15	100 watts	55 rpm	continuous operation		
Load	Revolutions	1st interval in minutes*	followed by	OFF time in minutes		ON time in minutes																																									
450 watts	85 rpm	30		25		5																																									
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300 watts	75 rpm	55		22		8																																									
250 watts	70 rpm	65		21		9																																									
200 watts	65 rpm	100		18		12																																									
150 watts	60 rpm	120		15		15																																									
100 watts	55 rpm	continuous operation																																													
Power	~ 100 – 240 V AC/50 – 60 Hz/200 VA max. Fuses: 2 x T 2.5 AH																																														
Backup battery	Type: CR 2032/3 V 230 mAh																																														
Braking principle	Computer-controlled eddy current brake																																														
Load range	6 – 450 W, speed-independent																																														
Load accuracy	<p>Deviation of measured load: ≤ 5% or 3 watts, whichever is greater (DIN VDE 0750-238:2002-10)</p> <p>Deviation of measured RPM: ≤ 2 rpm (DIN VDE 0750-238:2002-10)</p>																																														
RPM range	30 – 130 RPM																																														
Load increments	User-configurable (control terminals P/T)																																														

Internal protocols	<p>Control Terminal P:</p> <ul style="list-style-type: none"> • 5 fixed and 5 user-configurable exercise test protocols • manual load control <p>Control Terminal T:</p> <ul style="list-style-type: none"> • 10 exercise test protocols (5 preconfigured, editable and 5 user-configurable protocols) • 10 additional, user-configurable training/exercise test protocols • manual load control • 3 preconfigured performance tests
Permitted patient weight	200 kg
Saddle adjustment	Motor-assisted, continuous adjustment via remote control
Swivel range of the couch surface	0–38° continuous incline adjustment, motor-driven via remote control
Crank length	170 mm
Displays	<p>Control Terminal T: TFT LCD, 165 x 104 mm, 800 x 480 pixels</p> <p>Control Terminals M and P: LCD, 68 x 34 mm, 128 x 64 pixels</p>
Interfaces	RS-232, USB Bluetooth (option) WLAN (option)
Dimensions, weight	<p>Couch surface: 200 cm x 65 cm</p> <p>Device: ca. 220 cm x 90 cm x 180 cm (L x W x H) in maximum tilt position</p> <p>Weight: approx. 240 kg</p>
Safety standards	DIN EN 60601-1, DIN EN 60601-1-2, DIN VDE 0750-238
Protection class	I (with protective ground)
Applied part type	B
Medical device class	Ila (in accordance with MDR)
RF emission	Class A to DIN EN 55011 (VDE 0875-11) / 04/2011, DIN EN 60601-1-2
Environment	<p>Operation:</p> <p>temperature: +10 to +40°C</p> <p>rel. humidity: 30 to 75%, no condensation</p> <p>atmospheric pressure: 800 to 1060 hPa</p> <p>Transport and storage:</p> <p>temperature: –20 to +70°C</p> <p>rel. humidity: 10 to 95%, no condensation</p> <p>atmospheric pressure: 500 to 1060 hPa</p>

11.2 Exercise Test Protocols

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

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

11.3 Test Protocols (control terminal T only)

Protocol	Basic Load [W]	Duration [sec]	Load Change [W]	Stage Time [sec]	Recovery Load [W]	Recovery Time [min]
Ramp Test	0	120	25	10	25	99
PWC-130 (*)	25	0	25	120	25	99
PWC-150 (*)	50	0	25	120	25	99
PWC-170 (*)	50	0	50	120	25	99

(*) the protocol advances to the recovery phase as soon as the target heart rate (130/150/170) is reached

11.4 Family of characteristics of the braking torque control range

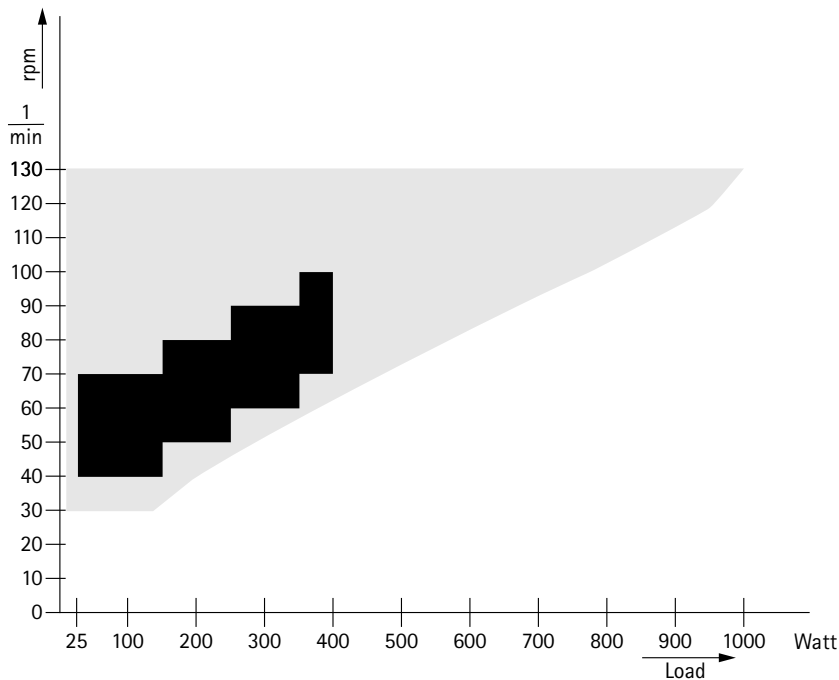


Figure 11 – 1: black: speed-independent range to DIN VDE 0750-0238
 black + gray: speed-independent range of the ergoselect ergometer

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

Load	RPM	1st interval in minutes*	followed by	OFF time in minutes	ON time in minutes
450 watts	85 rpm	30		25	5
400 watts	85 rpm	35		24	6
350 watts	80 rpm	45		23	7
300 watts	75 rpm	55		22	8
250 watts	70 rpm	65		21	9
200 watts	65 rpm	100		18	12
150 watts	60 rpm	120	15	15	
100 watts	55 rpm	continuous operation			

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

Caution

When the defined load periods are exceeded or the required pauses are not observed, the exposed parts of the medical device may reach excessive temperatures.

12 Electromagnetic Compatibility EN 60601-1-2

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

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

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

Warning

- RF Interference •

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


Caution

- Equipment Malfunction •

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

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The ergoselect 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 A	The device characteristics determined by emissions allow the device to be used in industrial environments and in hospitals (CISPR 11, class A). When used in domestic surroundings (which normally requires compliance with CISPR 11 class B), the device may not offer adequate protection for radio services. If required, the user may have to take remedial action by relocating or re-orienting the device.
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	± 2 kV contact ± 2 kV air ± 4 kV air ± 8 kV air ± 15 kV air	± 2 kV passed ± 15 kV passed	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/output lines	± 2 kV passed	Mains power quality should be that of a typical commercial or hospital environment.
Surge to EN 61000-4-5	± 0.5 / 1 kV L-N ± 0.5 / 1/2 kV L-PE ± 0.5 / 1/2 kV N-PE	± 1 kV passed ± 2 kV passed ± 2 kV passed	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines to EN 61000-4-11	0% / 0.5 cycle from 0° to 315° in 45° increments 0% / 1 cycle 70% / 25 cycles 0% / 250 cycles	passed passed passed passed	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	30 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 2.7 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 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).</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> 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			
<p>(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ergoselect 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.</p> <p>(b) Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the ergoselect ergometer			
The ergoselect 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 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 the transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			



ergoline 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