ASPEL S.A.
PL 32-080 Zabierzów, os. H. Sienkiewicza 33
tel. +48 12 285 22 22, fax +48 12 285 30 30
www.aspel.com.pl

CE
0197

Operation Manual

Ergometer

CRG 200

v.5xx

Zabierzów, 19.05.2020, Edition I

Congratulations on your purchase of Ergometer CRG 200 which has been developed as a result of years of research and experience acquired due to direct contacts with our clients. Quality, durability and efficiency are the characteristic features of Ergometer CRG 200.

ASPEL also proposes a wide variety of medical equipment for ECG Holter Systems as well as blood pressure meters, ABPM Systems, spirometers, Exercises Stress Test Systems, electrocardiographs with accessories, such as: trolleys, carry bags, ECG cables, electrodes and ECG paper. You are gladly invited to visit our website: www.aspel.com.pl.

Please, read the following manual carefully as it contains important guidelines on safe installation, usage and upkeep of equipment. It can also help to optimize the maintenance of the device.

For further consultation, please keep the following manual.

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1. General information

1.1. Manufacturer's instructions pertaining to safety of operation

Instruction of use

- **Before you start using the Ergometer, read carefully the Operation Manual, PC operation manual and warranty card.**
- **We recommend you keep the Operation Manual with the device in order to make it helpful with your routine usage and in case you have any problems with the device.**
- **Operation Manual shall be helpful in proper operating and maintaining the device.**
- **Following these instructions guarantees efficient functioning, reliability and carrying out tasks expected from Ergometer by the user, as well as safety during operation.**

Staff

- **Ergometer should always be used under supervision of qualified and properly trained medical staff.**

Patient

- **Using the device with artificial cardiac pacemaker or other electric stimulator does not cause danger neither for patient nor for operator.**

Ergometer CRG 200 v.5xx

- **Ergometer meets appropriate safety requirements and can be placed near a patient (in an area of 1.5 m of free space surrounding a patient).**
- **Time of proper work of the device mainly depends on efficiency of its elements, which in normal conditions are estimated to work for ten years. When this time is exceeded, probability of damages resulting from wearing down of elements increases, what can lead to device failure.**
- **All repairs should be performed in authorised service points of ASPEL S.A.**
- **Making any modifications in the device is forbidden.**
- **Efficiency of Ergometer and its accessories should be checked periodically. Every time any failures in functioning of the device are noticed, you should contact with authorised service point of ASPEL.**

Usage environment

- **It is forbidden to use Ergometer in places which are damp or wet, exposed to direct sunlight or rainfall, where dust may be present, in the vicinity of flammable or explosive materials or in atmosphere polluted with corrosion triggering factors.**
- **Ergometer is not suitable for use in an environment where flammable gases or vapours may be present. It is also not suitable for use in oxygen rich environment.**
- **Portable and mobile RF communication devices, e.g. mobile phones (including peripherals such as antenna cables and antennas) should be used in a distance no closer than 30 cm (12 in) to any part of the device, including cables mentioned by the manufacturer. Otherwise, malfunction of the device may occur.**
- **Ergometer and its accessories should not be placed near temperature heat reservoirs such as stoves, heaters, etc.**

Accessories

- **Only accessories provided by the manufacturer are suitable to use with Ergometer.**
- **Use of accessories or cables other than provided by the manufacturer may lead to rise in electromagnetic emission or decline in electromagnetic immunity of Ergometer and cause malfunctions.**

Usage

- **Inappropriate use of the device may be the cause of an accident.**
- **The device is not suitable to direct usage on open heart.**
- **The device is not adapted to interaction with surgical equipment of high frequency.**
- **Conductive parts of electrodes, including neutral electrode, should not touch neither metal parts, nor grounding.**
- **Operator cannot touch simultaneously patient and non-medical devices, with which he can stay in contact.**
- **It is forbidden to train on faulty Ergometer – the device should not be used until repaired.**
- **The patient's cable should not be pulled, as it could cause mechanical or electrical damage. Fold patient's cable in a loose loop before storing.**
- **It is forbidden to use devices with faulty power supply cable.**
- **The patient's cable should not be put in places exposed to damage, e.g. puncture or stepping on. In case of mechanical damage of patient's cable, there is a risk of losing measurement's accuracy and replacement of the patient's cable with a new one is necessary.**
- **During defibrillation, special precautions must be taken. Staff mustn't touch neither defibrillated patient, nor devices connected to him or her.**
- **Please note that if a patient is connected to several devices, risk resulting from build-up of leakage currents of each device should be taken into**

consideration.

- **Ergometer CRG 200 should be used only with external AC adapter CRG200-M24 and power supply cable provided by the manufacturer. It is forbidden to use other devices attached to external AC adapter's socket.**
- **Ergometer CRG 200 should be used only with ECG cable provided by the manufacturer.**
- **To unplug Ergometer CRG 200 you should pull the plug of AC adapter from a socket.**
- **It is forbidden to use a device with damaged power supply cable.**
- **Neither Ergometer CRG 200, nor external AC adapter CRG200-M24 should be placed in a way that could cause any difficulties with unplugging the device.**
- **Pay special attention for children staying unsupervised and keep them away from the device.**
- **RS-232 connector can be connected only to those devices that will not cause appearance of voltage exceeding value of very low safe voltage (25V for alternating current or 60V for direct current) on this connector.**
- **Connecting devices to RS-232 connector can cause a risk unidentified before for patients, operators or third parties. Therefore, it has to be checked, identified, analyzed, estimated and controlled before every single connection. Moreover, every changes made in connections to RS-232 connector could cause new risk and need additional analysis.**
- **When Ergometer and PC computer are working at the same time and ECG analysis is performed, it is necessary for such constructed system to comply with requirements of isolation and leakage current for medical electric systems (EN 60601-1) and for PC devices to be out of patient's surrounding (min. 1,5 meter of free space around patient).**

Environmental protection

- **Disposal of the device and cables after their service life may potentially be dangerous for the environment. Ergometer and accessories should be utilized according to applicable legal regulations.**

General guidelines

- **Non-compliance with these regulations can result in safety hazard, for which the manufacturer shall not be held responsible.**
- **The manufacturer is not responsible for possible injuries or Ergometer damages or other objects resulting from:**
- **not studying and noncompliance with this manual**
- **improper power supply**
- **wrong operation practices**
- **wrong maintenance**
- **repairs performed by unauthorized service**

- **using parts and accessories which are not authentic or not recommended by the manufacturer**
- **operation of the device in inappropriate conditions.**

1.2. Working, transportation and storage conditions

Ergometer CRG 200 is intended for operation in the following conditions:

- ambient temperature + 10°C ÷ + 40°C
- relative humidity 25% ÷ 95% (non condensation)
- atmospheric pressure 70 kPa ÷ 106 kPa

Ergometer CRG 200 should be stored and transported in the following conditions:

- ambient temperature -20°C ÷ +60°C
- relative humidity 10% ÷ 95% (non condensation)
- atmospheric pressure 70 kPa ÷ 106 kPa

Air should not be contaminated with corrosion-inducing components.

If the Ergometer has been stored or transported at temperatures exceeding the operating conditions, then after unpacking, leave it for a period of time necessary for the device to adapt to the conditions and temperature of the room in which it will be used.

Before moving the device, make sure it is switched off and disconnected from the power supply and control computer.

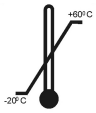
In order to move the device, take the handlebars with both hands and bend the device to a position in which it can be moved with the use of wheels.

Ergometer should be gently moved back to normal position; otherwise it may be damaged.

If there is a need to move Ergometer to another building, always use its original packaging or a wooden pallet.

PC computer and LCD monitor storage, transport and operation conditions are specified in documentation of the foregoing devices.

1.3. Symbols meaning

	Notes and warnings related to the safety of use and essential performance
	Important comments of the manufacturer
	Act according to the operation manual
	General warning sign - CAUTION
	Date of manufacturing
	Manufacturer's address
	Application part type CF defibrillation resistant
	Proceedings instruction
	Transportation packaging should be kept dry
	Indicates proper vertical position of transportation packaging
	Transportation packaging contains fragile materials and it should be moved carefully
	Indicates maximum number of identical packages that can be placed on one another
	Indicates temperature range in which transportation packaging should be stored and moved.
	Getting rid of waste equipment with other waste is forbidden
	Second IEC protection class

2. Description of Ergometer CRG 200

2.1. Intended use

Ergometer CRG 200 is intended to be used for the purposes of cardiologic rehabilitation and exercise stress tests of adult patients and paediatric patients who are higher than 140 centimetres (4,59 feet), in rehabilitation centres, etc., where an authorised person governs access and supervises the tests. Accurate cardiologic supervision of patients is conducted during physical effort. Ergometer CRG 200 can operate in the following systems: AsTER (rehabilitation trainings), CardioTEST (exercise stress tests).

2.2. General description

Ergometer has been designed according to modern technologies. Microprocessor-controlled brake ensures accurate load adjustment. The construction guarantees comfort and safety of use as well as easy operation and cleaning.

2.3. Ergometer's appearance

Fig. 1. Ergometer CRG 200

1. Handlebar adjustment knob.
2. Control board.
3. Saddle adjustment knob.
4. Saddle height adjustment knob.
5. Wheels for moving the Ergometer.
6. Socket panel.

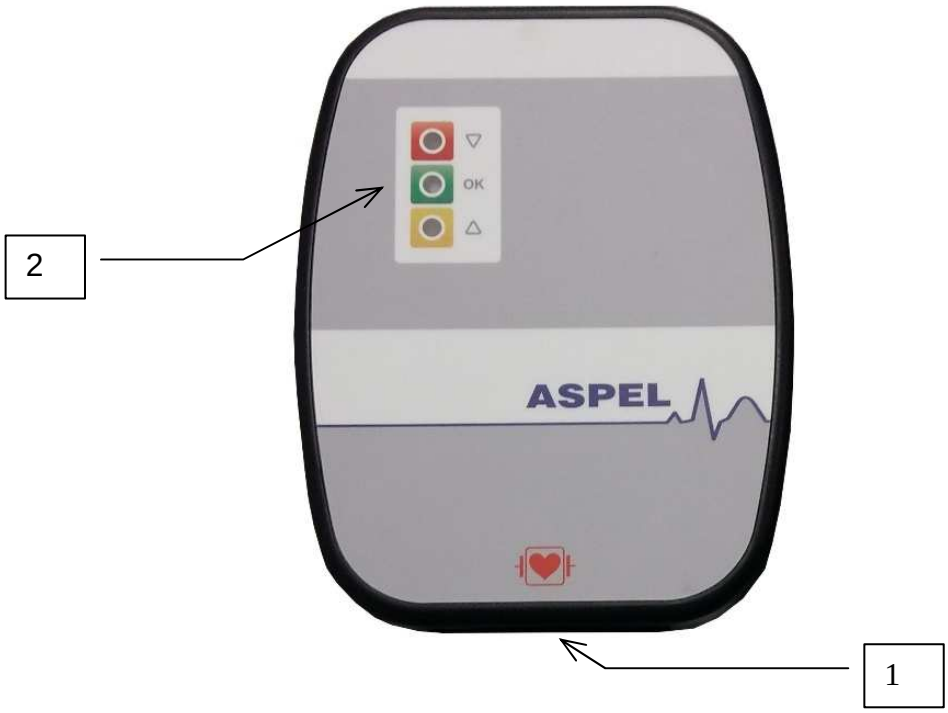


Fig. 2. Ergometer CRG 200 - control board

1. Patient's cable socket.
2. Signalling LEDs.

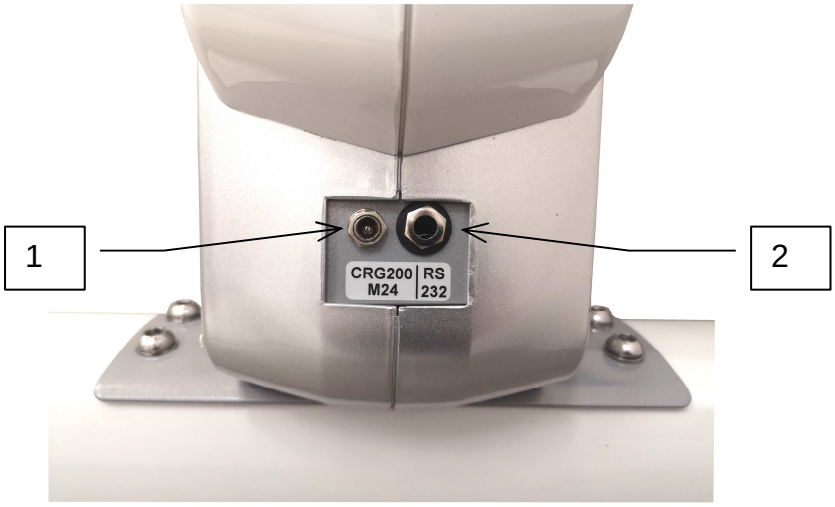


Fig. 3. Ergometer CRG 200 - socket panel

1. DC socket.
2. RS-232 socket.

Ergometer CRG 200 can operate in the following systems:

1. AsTER – rehabilitation trainings after past cardiologic surgery; multi-station system.
2. CardioTEST – exercise tests for evaluating physical efficiency and the risk of myocardial infarction.

A complete system contains:

1. Ergometer CRG 200 (acc. to EN 60601-1) with accessories.
2. PC compatible with IBM (acc. to EN 60950).
3. LCD monitor.
4. CD with software.

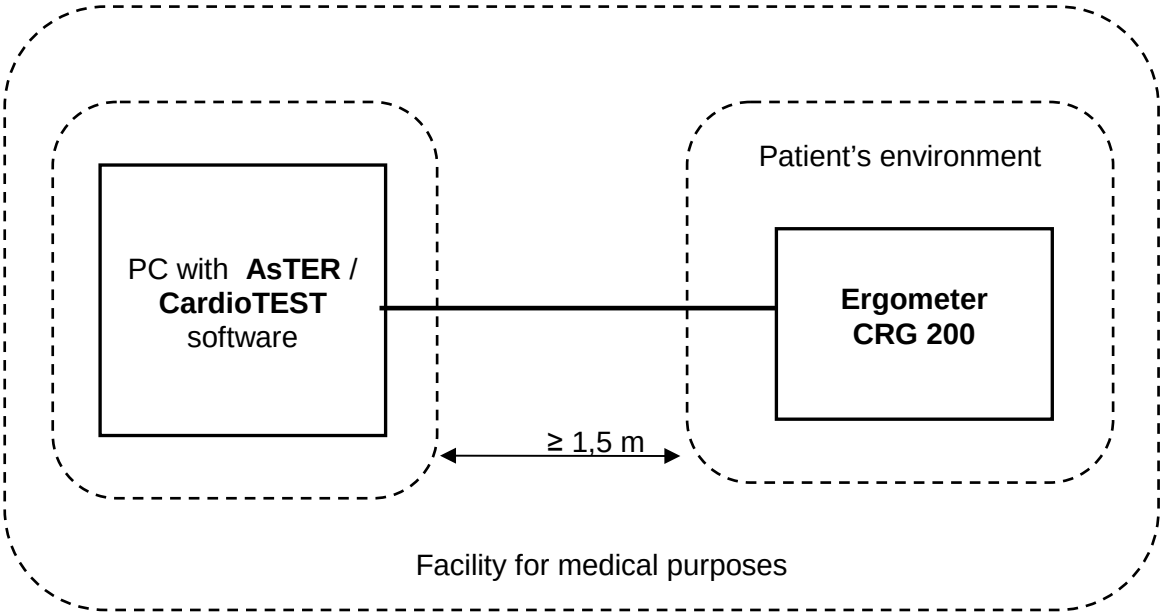


Fig. 4. Recommended arrangement of CRG 200 and PC.

In the patient's environment only an Ergometer CRG 200 can be installed.

Devices which are not part of the system shall not be connected to it.

2.4. Functions

Ergometer enables load adjustment within the range of 25 – 1001 W. Rotation measuring rate is 20 – 150 rpm. Ergometer is controlled by a PC computer through RS-232 interface.

Load level is controlled by a microprocessor, therefore it does not depend on speed, which in turn can be adjusted according to patient's individual needs.

Ergometer is equipped with ECG mode recording 12 standard leads.

Together with Cardio TEST software, Ergometer CRG 200 is used to carry out exercise tests.

Together with AsTER software, Ergometer CRG 200 it is intended for cardiologic rehabilitation.

2.5. Main technical and operational parameters

Dimensions (LxWxG):	1030 x 580 x 1240 mm
Weight:	41 kg
Supply:	External power supply CRG 200-M24 (integral part of Ergometer CRG 200)
Supply voltage:	100 ÷240V AC; 47 ÷ 63 Hz
Max current consumption:	2A (for 100÷120V); 1A (for 220÷240V)
DC socker:	24V; 2A max
Braking:	processor-controlled brake with torque measurement (load does not depend on speed)
Communication interface:	RS-232
Load level:	25 ÷ 1001 W,
Load accuracy	± 5 W to the power level 50W and ± 10 % above 50 W
Rotational speed:	20 ÷ 150 rpm ± 4 rpm
Max weight of the user:	201 kg
Operation modes:	○ Continuous operation – average load max 100W ○ Continuous operation with intermittent load- average load max 200 W – working completion factor 66% (2:1) (maximum working time 30 min; idle time 15 min.) ○ Continuous operation with intermittent load- average load max 200 W – working completion factor 40% (2:3) (maximum working time 10 min; idle time 15 min.) ○ Continuous operation with intermittent load- average load max 200 W – working completion factor 40% (1:4) (maximum working time 3 min; idle time 12 min.)

Safety of use:	EN 60601-1
Electromagnetic compatibility:	EN 60601-2
Medical device class:	IIa (rule 10)
Type of anti-electric shock protection (EN 60601-1):	Class II
Classification of training equipment (EN 957-1):	Class SA
Equipment class and group acc. to CISPR-11:	Class A, group 1
IP protection class:	IP X0

ECG parameters:

ECG signals:	12 standard leads (diagnostic mode), 2 leads (training mode)
Sensitivity:	2,5/5/10/20 mm/mV ± 5%
Recording speed:	25/50/100 mm/s ± 5%
Frequency range:	0,05 ÷ 150 Hz
HR measuring range:	15 - 240 bpm
HR measuring error:	± 2 %
HR resolution:	1 bpm
Digital filters:	25 Hz, 35 Hz, 50 Hz, anti-drift filter
Monitoring range of ST section:	± 3 mm (10mm/mV)
ST measuring error:	± 0,2 mm (10mm/mV)
ST resolution:	0,1 mm (10mm/mV)
Applied part (EN 60601-1):	defibrillation-resistant type CF

Input circuit is secured against defibrillating impulse. After the impulse, the ECG line will appear after no longer than 10 seconds.

2.6. Equipment

- AC/DC power supply CRG 200-M24.
- Power cable.
- Data cable.
- KEKG 51 v.103 patient cable (for an exercise test).
- KEKG 52 v.105 patient cable (for cardiological rehabilitation).
- Disposable ECG leads (50 pcs).
- Abrasive paste.
- Warranty card.

2.7. Manufacturer and designation

ASPEL S.A.
os. H. Sienkiewicza 33
PL 32-080 Zabierzów
tel. +48 12 285 22 22, fax +48 12 285 30 30
sprzedaz@aspel.com.pl
www.aspel.com.pl

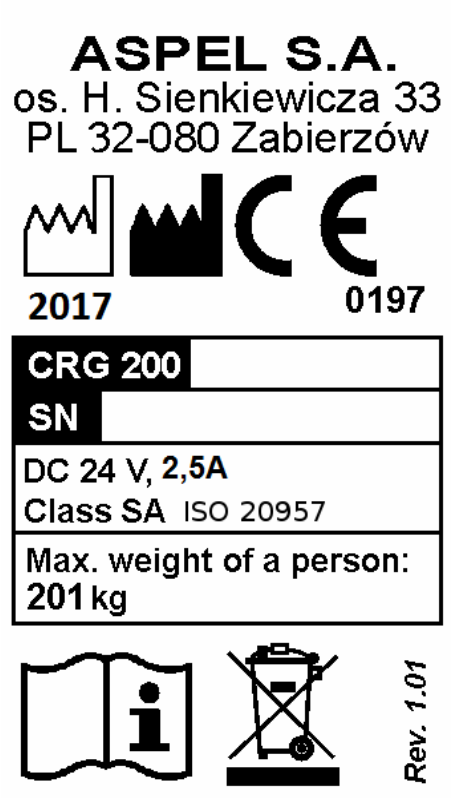


Fig.5. Rating plate

3. Operation of Ergometer

Aspel S.A. offers training course on Ergometer CRG 200 operation.

3.1. Start-up of the device

Before first start-up after few days of using it is necessary to check mounting of all connections.

Ergometer should be positioned on an even, stable ground and properly leveled (with feet regulating knobs).

Before a training session height of the seat and position of handlebars should be adjusted in the way of letting a person performing exercises feel comfortable. Power supply should be connected to Ergometer's DC socket and power supply network.

Moving the seat's pillar post beyond marked regulation range is forbidden.

Electrical system of a room, where cyclometer is to be installed should fulfill IEC requirements for electrical system safety.

Connect data cable to the Ergometer and to PC’s USB / RS-232 port.

Installation and start-up should be performed according to this description (location of devices acc to fig. 4) and PC computer user manual (supplied with computer set).

Only a PC computer with CE Declaration of Conformity (compliant with EN 60950) can be connected to the USB / RS232 socket (by data cable).

Use the patient’s cable and the data cable supplied by the manufacturer.

Connect patient’s cable to ECG socket placed on Ergometer’s control board.

- **When using the Ergometer, place the power supply, power cable and data cable in such a way that they are not exposed to mechanical damage.**
- **After installing and starting the device, prepare an acceptance protocol (signed by a person installing the device and the client) confirming that the device has been appropriately installed and commissioned, according to this manual and EN 60601-1 standard.**
- **Apart from the acceptance protocol, the client should be provided with Operation Manual for the Ergometer CRG 200 and computer set and relevant declarations of conformity.**
- **It is forbidden to conduct any modifications of location and composition of the devices without prior written consent of the manufacturer.**
- **After any modification in terms of device composition, compliance with EN 60601-1: section 16 standard should be verified again.**
- **Free space required for safe use of Ergometer should not be smaller than 0.6 m from the side with access to the device and must include the landing area (free space can be shared if there is other training equipment placed nearby).**
- **In order to get off from Ergometer safely you should stop pedaling and while holding the handlebar go down on either right or left side of the device.**

Fig.6. Free space required for safe use

3.2. Patient preparation

After a cardiologist has established types of leads appropriate for a given patient it is necessary to comply with the following guidelines for the examinations to be of high-quality:

- Attach electrodes to the ossified area above the ribs or sternum in order to reduce muscle interferences. When an electrode is placed over large muscle areas or between the ribs a high-frequency artefact is formed that significantly disturbs the signal. Placing an electrode over fatty areas also causes signal disturbances.
- All hair at the site of electrode placement should be removed during dry shaving.
- The electrode placement site needs to be carefully cleaned of dirt and fat from the superficial epithelium. It should be done by rubbing the site with abrasion cream (do not use spirit, use gauze not a compress due to better abrasive properties.)
- The middle of the site where a contact part of an electrode will be in contact with the skin should be wiped with gauze with abrasive cream so as to remove the superficial layer of dead epithelial cells (epithelial abrasion.) Before sticking electrodes remove the remains of abrasive cream and exfoliated epithelial cells with a gauze pad. As a result the electrical contact between the skin and electrode surface will be better and a signal of high-quality will be obtained.
- Electrodes should be stuck in a way ensuring their good adhesion and so as not to squeeze electrolyte gel from a sponge placed between the skin and the metal part of the electrode.
- When connecting electrodes special attention should be paid so as the conducting parts of electrodes and the patient cable would not touch each other or other metal parts including protective grounding.
- When the electrodes are attached inappropriately the letters INOP are visible (in a window of Ergometer controlling software.)

3.2.1. Electrode placement for an exercise test

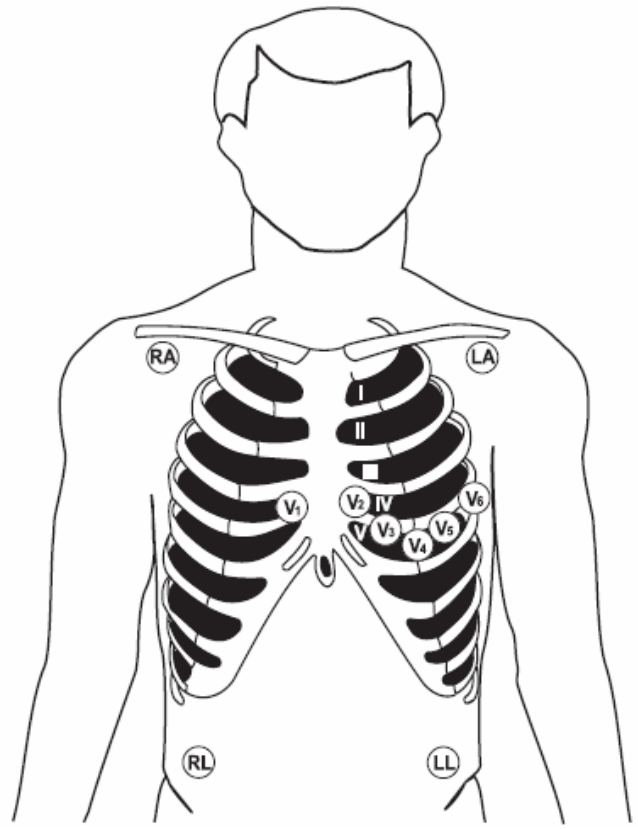


Fig. 7. Electrode placement for an exercise test

Limb electrodes:

RA	red	right arm,
LA	yellow	left arm,
LL	green	left leg,
RL	black	right leg.

Precardiac electrodes:

V1	white-red	fourth intercostal space on the right of the sternum,
V2	white-yellow	fourth intercostal space at the left edge of the sternum,
V3	white-green	in the mid-distance between V2 and V4,
V4	white-brown	fifth intercostal space in the left midclavicular line,
V5	white-black	along the straight line from V4 vertically to the left anterior axillary line at the cross-section with this line,
V6	white-purple	at the same level as V5 but in the left mid-axillary line.

3.2.2. Electrode placement for cardiological rehabilitation

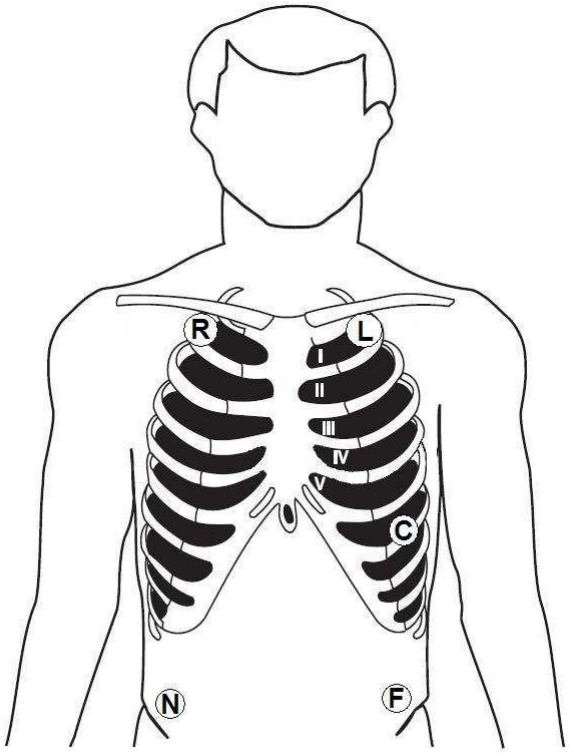


Fig. 8.. Electrode placement for cardiological rehabilitation

R	- red	intercostal space below right collarbone,
L	- yellow	intercostal space below left collarbone,
F	- green	left space below ribs,
N	- black	right space below ribs,
C	- white	fifth intercostal space in the intersection with left anterior axillary line.

3.3. Using Ergometer

Check the following before turning on and starting a test or training session:

- attachment of the handlebars and saddle of the Ergometer,
- attachment of the pedal crank and pedals.

Incorrect mounting, tightening the steering wheel, saddle, crank and pedals can cause damage to the patient's health and mechanical damage to the above-mentioned components of the ergometer.

After power has been supplied to the Ergometer, an internal test is performed (two short sounds are heard and LEDs of the rotation indicator become on).

When the test ends with a constant modulated sound the device should be turned off and authorised service should be notified about a failure.

Software controlling the Ergometer operation (CardioTEST or AsTER) sends appropriate orders to the device. Power establishing and planning of training sessions are described in manuals of above-mentioned computer programs. During a training session Ergometer is in control of rotation speed. When a patient's speed is proper, the middle green diode is lit. If a necessity of increasing or decreasing speed appears, it is signaled by turning on lower or upper red diode together with intermittent audio signals.

- Use the device only according to its indications and operation conditions.
- Training sessions can be conducted only when qualified medical personnel manages the course of a training session and the load level.
- The patient doing an exercise or stress test on Ergometer should be in a seated position.
- Excessive training session that is inappropriately conducted may result in health injury.
- Always comply with the duration of exercise and the average load level when training sessions are prepared.
- It is not allowed to cover side and bottom vents when the Ergometer is operating.

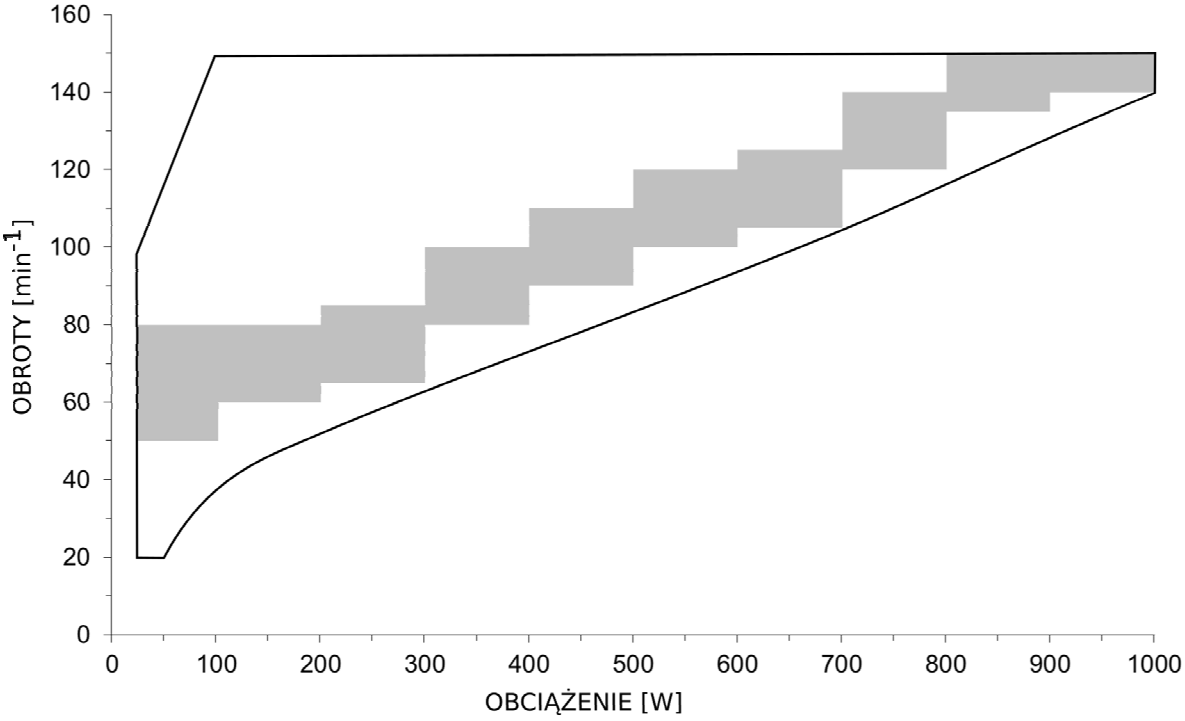


Fig. 9. Working area for power adjustment

For the Ergometer to reach reference power it is necessary to keep rotation in a power regulation working area according to fig. 9 (darker colour shows recommended rotation speed).

During work it is necessary to maintain the constant rotation speed, so that green LED on Ergometer's control panel is on (recommended rotation speed).

Load level	**Recommended rotation speed**
25÷100 W	50 rpm ÷ 80 rpm
101÷200 W	60 rpm ÷ 80 rpm
201÷300 W	65 rpm ÷ 85 rpm
301÷400 W	80 rpm ÷ 100 rpm
401÷500 W	90 rpm ÷ 110 rpm
501÷600 W	100 rpm ÷ 120 rpm
601÷700 W	105 rpm ÷ 125 rpm
701÷800 W	135 rpm ÷ 150 rpm
801÷1001 W	140 rpm ÷ 150 rpm

when a LED is on it means it is necessary to reduce the rotation speed.

when a LED is on it means to maintain the correct rotation speed.

when a LED is on it means it is necessary to increase the rotation speed.

Signal	Explanation
green LED	proper rotation speed.
green LED + red LED	rotation speed slightly higher then the recommended.
red LED + short sound signal	rotation speed higher than the recommended.
red LED + medium sound signal	rotation speed is much higher than the recommended.
red LED + long sound signal	rotation speed too high to achieve requested power.
green LED + yellow LED	rotation speed slightly lower than the recommended.
yellow LED + short sound signal	rotation speed lower than the recommended.
yellow LED + medium sound signal	rotation speed is much lower than the recommended.
yellow LED + long sound signal	rotation speed too low to achieve requested power.

To end training, stop pedaling, disconnect ECG cable from patient and unplug power Ergometer if it is not to be used for a long time.

Cycle Ergometer CRG 200 has an option which allows to switch the audio signalling system into rotation rhytm mode. In this mode Ergometer generates cyclic short sounds indicating optimum rotation speed during the training session. Follow the instructions for using the CardioTEST or AsTER software.

4. Maintenance and technical service

4.1. Cleaning, disinfection, maintenance and service

Before starting cleaning make sure the power cable has been disconnected.

Mild, non-corrosive detergents such as water with soap or diluted ammonia or diluted bleach (sodium solution) might be used for cleaning. The device should be wiped with a soft, damp cloth.

Diluted sodium solution from 550 ppm (solution dilution of 1:100) to 5000 ppm (solution dilution 1:10) is very effective. The dilution level should depend on the type of contaminants that are to be removed.

Ergometer may be cleaned with ethanol indicated for hospital purposes and dried with dry air or wiped with a soft, dry cloth.
Do not use any corrosive chemicals to clean the device.
Do not use materials that can scratch surfaces.

Cleaning agents should be diluted before use according to the recommendations of their manufacturer.
Do not allow for entry of a cleaning agent inside the device.
Do not spill any fluid on the device.
Do not leave a cleaning agent on the device.

	**Information regarding cleaning a PC computer and LCD monitor are specified in the documentation of the foregoing devices.**

Before disinfection, the device and accessories should be cleaned.

To disinfect the device use commercially available specialist disinfecting agents indicated for the disinfection of medical products e.g. BACILLOL, DESCOSEWPT, SEKUSEPT, ALDEWIR, HEXAQUART, BIGUASID, IMPULS, GIGASEPT FF etc.

It is recommended to clean and disinfect the Ergometer, especially the saddle and handlebars after it has been used by one patient.

Single-use electrodes are not to be disinfected – they should not be reused when the test is finished.

To prove basic functions and general safety it is needed to control periodically (after every 12 months of use) Ergometer's CRG200 efficiency. Service should be performed in a manufacturer's service point or in other authorised point. It should include:
- visual inspection - checking readability and completeness of labels, checking technical condition of Ergometer's mechanical elements, power supply lead, power supply, patient's cable – verification if any damage or dirt did not occur,
- safety parameters control - insulation resistance and leakage measurements,
- functional parameters control: reinforcement, frequency wavelength.

Apart from planned (warranty and post-warranty) services of Ergometer, one should systematically control power supply cable, power supply, ECG cable, each time before use - it is necessary to check if there are any visible damages. Any noticed improprieties should be repaired by an authorised ASPEL service point.

The device is not intended to sterilization.

4.2. Environmental protection

Waste hazardous to the environment is not produced during operation of the Ergometer CRG 200.

The Ergometer CRG 200 should be utilised when its work life has been over. For that purpose, it can be sent to the manufacturer or one should contact a specialist electronic and electromechanic waste company.

4.3. Customer service

If you need help in diagnosing any problems with work of the device please contact ASPEL S.A. service.

4.4. Dealing with common problems

PROBLEM	SOLUTION
No contact with a PC.	Restart PC. Restart Ergometer (unplug, wait few seconds, plug again). Check the cable connection between the Ergometer CRG 200 and a PC. Replace the old cable with a new one. If the problem persists, contact an authorised service representative.
Straight lines on the (ECG curves) diagram, INOP message displayed.	Check ECG cable attachment to socket on Egrometer's control board. Check and improve electrodes attachment to patient, using ECG gel. If necessary, change place of electrodes contact.
Noises on ECG curves.	Check and improve electrodes attachment to patient, using ECG gel. If necessary, turn on digital filtration.

5. Electromagnetic compatibility declaration

Guidance and manufacturer's declaration–electromagnetic immunity		
The Ergometer CRG 200 is intended for use in the electromagnetic environment specified below. The customer or the user of the Ergometer CRG 200 should assure that the device is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - advices**
RF emission EN 55011/ CISPR 11	Group 1	The Ergometer CRG 200 uses RF energy (radio frequency) only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission EN 55011/ CISPR 11	Class A	The Ergometer CRG 200 is suitable for use in industrial facilities and hospitals. If it is used in household environment (for which usually class B CISPR 11 is required), the device may then not provide necessary protection for radio communication services. User may need to deal with this problem by moving or changing direction of the device.
Harmonic Emission EN 61000-3-2	Class A	----
Voltage Fluctuations and Flicker Emission EN 61000-3-3	Meets requirements	----

Guidance and manufacturer's declaration–electromagnetic immunity			
The Ergometer CRG 200 is intended for use in the electromagnetic environment specified below. The customer or the user of the Ergometer CRG 200 should assure that the device is used in such an environment.			
Immunity test	**EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – advices**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV (contact) ±2 kV, ±4kV, ±8 kV, ±15 kV (air)	±8 kV (contact) ±2 kV, ±4 kV, ±8 kV, ±15 kV (air)	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient (BURST) IEC 61000-4-4	±2 kV (for power supply lines) ± 1 kV (for signal lines)	±2 kV (for power supply lines) ±1 kV (for signal lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV between line (lines) and line (lines) ± 2 kV between line (lines) and ground	±1 kV between line (lines) and line (lines)	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 (PQT) IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 and 0º, 45º ,90º ,135º ,180º, 225º, 270º, 315º angle <5% U_T (>95% dip in U_T) for 1 and 0º angle 70% U_T (30% dip in U_T) for 25 cycles and 0º angle <5 % U_T (>95% dip in U_T) for 250 cycles and 0º angle	<5 % U_T (>95 % dip in U_T) for 0.5 and 0º, 45º ,90º ,135º ,180º, 225º, 270º, 315º angle <5% U_T (>95% dip in U_T) for 1 and 0º angle 70% U_T (30% dip in U_T) for 25 cycles and 0º angle <5 % U_T (>95% dip in U_T) for 250 cycles and 0º angle	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration–electromagnetic immunity			
The Ergometer CRG 200 is intended for use in the electromagnetic environment specified below. The customer or the user of the Ergometer CRG 200 should assure that the device is used in such an environment.			
Immunity test	**EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – advices**
Magnetic field of electrical grid frequency (POWERM) IEC 6100-4-8	30 A/m (50 Hz / 60 Hz)	30 A/m (50 Hz / 60 Hz)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of test level.			

Guidance and manufacturer's declaration–electromagnetic immunity			
The Ergometer CRG 200 is intended for use in the electromagnetic environment specified below. The customer or the user of the Ergometer CRG 200 should assure that the device is used in such an environment.			
Immunity/resistance test	**EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – advices**
RF conducted interference EN 61000-4-6	3 Vrms 150 kHz ÷ 80 MHz	3 Vrms	Portable RF communication equipment, e.g. phones (including peripheral devices such as antenna cable and external antennas) should be used no closer than 30 cm (12 in) to any part of Ergometer CRG 200, including cables specified by the manufacturer. Field strength from fixed RF transmitters, specified by local measurement [b] should be no smaller than compliance level in every frequency range [c].
	6 Vrms ISM between 150 kHz ÷ 80 MHz [a]	6 Vrms	
RF radiated interference EN 61000-4-3	3 V/m 80 MHz ÷ 2,7 GHz	3 V/m	
Near-field free of radio devices EN 61000-4-3	27 V/m 385 MHz	27 V/m	
	28 V/m 450 MHz	28 V/m	
	9 V/m (710, 745, 780) MHz	9 V/m	
	28 V/m (810, 870, 930) MHz	28 V/m	
	28 V/m (1720, 1845, 1970) MHz	28 V/m	
	28 V/m 2450 MHz	28 V/m	
	9 V/m (5240, 5500, 5785) MHz	9 V/m	

[a] ISM bands (industrial, science and medical) between 0,15 MHz ÷ 80 MHz to 6,765 MHz ÷ 6,795 MHz; 13,553 MHz ÷ 13,567 MHz; 26,957 MHz ÷ 27,283 MHz; and 40,66 MHz ÷ 40,70 MHz.

[b] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, 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 Ergometer CRG 200 is used exceeds the applicable RF compliance level above, the Ergometer CRG 200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Ergometer CRG 200.

[c] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

6. Appendix A – Cooperation of Ergometer CRG 200 with other devices

A1. Introduction

Ergometer CRG 200 is electromedical equipment that fulfills appropriate safety requirements.

Using of RS-232 socket to communicate with external devices allows Ergometer to operate with non-electromedical equipment (PC), therefore electromedical system is created.

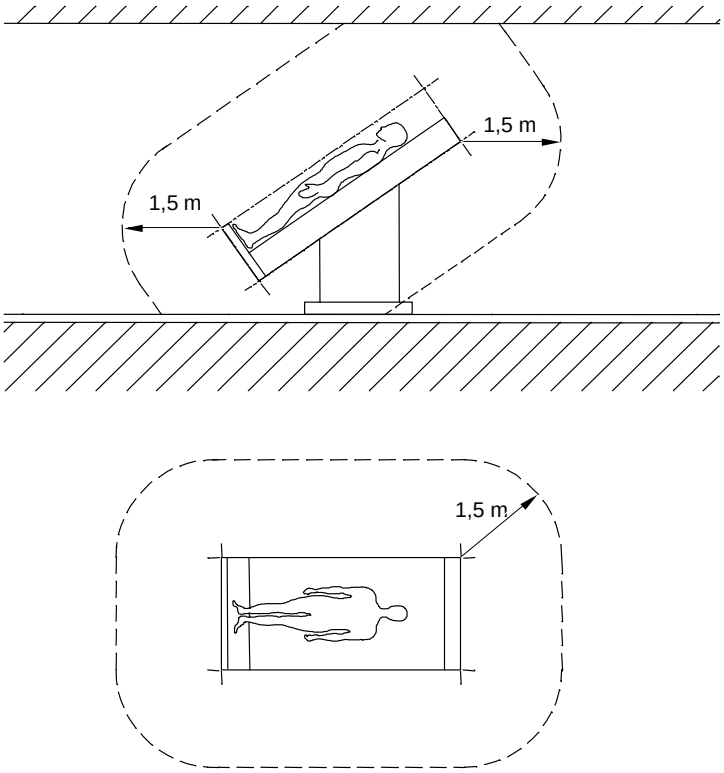
It is often practised to connect electromedical equipment and other medical or non-electromedical devices to multiple sockets creating electromedical system in this way (devices don’t need to be coupled with a combination of hardware).

For example: connection of Ergometer CRG 200 with PC to multiple sockets creates electromedical system.

A2. General requirements for electromedical systems

Electromedical system should ensure:

- in the patients surrounding: safety level equivalent to the electromedical device in accordance with EN 60601-1 standard,
- outside patients surrounding: safety level equivalent to the device in accordance with IEC or ISO safety norms adequate for this device.



Rys. 10. Example of patient's environment

Non-electromedical device used in electromedical system should comply with requirements of IEC or ISO safety standards adequate for this particular device.

Devices, in which protection against electric shock depends only on basic insulation, should not be used in electromedical system,

Responsible divisions should remember, that electromedical system installations and its modifications during the usage period are the subject to EN 60601- 1 standard requirements.

Responsible division may be: hospital, single doctor or unprofessional person. In the private usage patient, operator and responsible division may be in one person.

All non-medical devices, complied with safety standards proper to its original purposes, and placed in the patients surrounding, require additional appropriations to reduce touch current, if it exceeds following values:

- 500 μA from electromedical system or between such systems in a patients surrounding in case of cut off of any not installed permanently protective earth conductor.

A3. Example of creating electromedical system with Ergometer CRG 200

To simplify, only two devices were used: Ergometer CRG 200 (device A) and non-medical device, complying with safety standards, proper to its original purposes (device B).

Both devices A and B placed in the patient's surrounding

Example: Ergometer CRG 200 connected by RS-232 socket with laptop computer- both devices placed in the patient surrounding, which is a part of medical space.

Device B's touch current should be limited, by using additional protecting grounding or isolation transformer for device B, but only if any single ground conductor or equivalent conductor in the device is cut off.

Device A placed in a patients surrounding, device B placed outside patients surrounding

Example: Ergometer CRG 200 connected by its RS-232 socket with a PC computer, connected to a power source, without additional input/output devices. Computer is placed outside patients surrounding, but in the same medical space.

In case of device B's mass touch current, separation unit assuring galvanic isolation of the RS-232 interface should be applied.