GB

REHABILITATION and MEDICAL EQUIPMENT

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OPERATING MANUAL

Fisiotek ® 3000 G

DEVICE FOR PASSIVE
EXERCISE OF THE LOWER LIMBS

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1. GENERAL INFORMATION

1.1 EC CERTIFICATION AND CE MARKING

Fisiotek 3000 G carries the CE Marking as it was produced in compliance with EU Directive 93/42 concerning medical devices, as amended by 2007/47/EEC.

1.2 WARRANTY

The duration of the Warranty is laid down by EC Directive 99/44 and, therefore, by its transposition on behalf of the EU Member States.

Not included: damage caused by transport and/or handling, faults and/or breakage due to machine misuse.

1.3 STRUCTURE OF THE MANUAL

The Customer should read all the information contained in this Manual carefully, since it is an integral part of the equipment from a Functional and Safety point of view.

1.3.1 SCOPE AND CONTENT

This Manual is intended to provide the Customer with all the necessary information to use the machine adequately but also to be able to manage it autonomously and safely. This manual contains information on Technical aspects, Operation, Maintenance, Spare parts and Safety.

Before carrying out any type of work on the machine, the Operators and Qualified Technicians should carefully read the instructions provided in this Manual. If you are not sure to have correctly understood these instructions, please contact the Manufacturer to get the necessary clarifications.

1.3.2 RECIPIENTS

This Manual is both for the Operator and the Technicians authorized to carry out maintenance in the machine.

Operators must not perform tasks reserved to Qualified Technicians (see Maintenance chapter)**.**

The manufacturer is not liable for any damage resulting from failure to comply with this prohibition.

1.3.3 STORING THE MANUAL

This Instruction Manual should always go with the Machine and must be kept away from anything that may compromise its readability.

1.4 MANUFACTURER

RIMEC s.r.l.
Loc. Braine 57/a - 40036 Rioveggio BOLOGNA - ITALY
☏ ++39 051/ 67 77 798 🖷 ++39 051/ 67 77 357
✉ rimec@rimec.it web : www.rimec.it

2. DESCRIPTION OF THE EQUIPMENT

2.1 OPERATING PRINCIPLE

Fisiotek 3000 G allows the passive mobilization of the knee and hip. It works through a DC motor that transmits motion to a worm screw. The motor, in turn, is controlled by a microprocessor-based electronic card. There is a fixed keyboard on the outside, from which to program each function, and a mobile keyboard.

- ***Start-Stop mobile keyboard:*** *allows the patient to stop and start the motion and is fitted with the START and STOP keys. When you press the STOP key, the device stops in "Standby".*
  N.B. the device will not work if the mobile keyboard is faulty or disconnected. Instead of the Start-Stop mobile keyboard, it is possible to use the Programming mobile keyboard (see "Accessories" p. 6.2)

The upper part of the device is where to position the limb; adjust the device according to the size of the limb.

- ***Size of patient's limb:*** *in order to perform this adjustment you need to know the length of the patient's limb from the knee to the trochanter major. The device can accommodate limbs with a length from 32 to 49 cm, which corresponds to a patient's height of about 140 and 200 cm, respectively.*

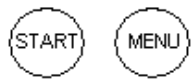
The programmable functions are as follows:

* **working range:**
  - knee from an extension of -10° to a flexion of 120°
  - hip, with patient completely spread out, ranges from 15° to 70° considering a limb of average length. When patient is half seated, the flexion angle increases in proportion to the patient's torso angle.
  The flexion degrees of the hip are not displayed.
  The minimum range of movement is 5°.
* **flexion and extension speed:** (considering a limb of average length) min. 0.8°/sec. max. 3.5°/sec. It is divided from 1 to 10.
  N.B. During operation, you can change the set value without stopping the movement.
* **force:** max. 40 kg, divided from 1 to 30; this function is used to adjust the thrust to which the limb is subjected during flexion, causing the carriage to reverse when it encounters resistance greater than the set force. An acoustic signal indicates when the carriage reverses due to an overload. Increase force to exit from this situation.
  Attention: the force value to be set varies from patient to patient, depending on the limb's weight and resistance to flexion. Therefore, the value suitable to the patient must be sought each time.
  N.B. You can change the set value during operation without stopping motion.
* **working time:** you can program the rehabilitation session from 5 to 60 minutes after which motion will stop automatically. The display shows a value in minutes (blinking) that decreases. Or, if you select "∞", the movement continues until stopped manually and the display shows an increasing value in hours and minutes (after 10 hours of operation the value is shown in hours only).
* **auto-increase during flexion:** automatically increases the flexion angle, every 3 cycles (forward and back), by a programmable value ranging from 0.2° to 3.0°.

- **auto-increase limit during flexion:** stops the auto-increase on reaching the desired flexion angle. This function is active only when auto-increase is other than "0.0"
- **auto-increase during extension:** automatically increases the extension angle, every 3 cycles (forward and back), by a programmable value ranging from 0.2° to 3.0°.
- **auto-increase limit during extension:** stops the auto-increase on reaching the desired extension angle. This function is active only when auto-increase is other than "0.0"
- **flexion pause:** from 0 to 30 sec.
- **extension pause:** from 0 to 30 sec.
- **flexion limit repetitions:** for repeating, every 3 cycles (forward and back) the last 10° of flexion for a programmable number of times, from 0 to 20.
- **extension limit repetitions:** to repeat, every 3 cycles (forward and back), the last 10° of extension for a programmable number of times, from 0 to 20.
- **warm up:** the joint warms up by setting the device automatically to a lower flexion angle than that achieved at the end of the last session.

Available accessories: a carriage for transport and stops. Also available is a mobile programming keyboard, see chapter "Accessories".

The following symbols are used on the display:

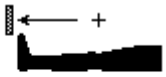


To use the START or MENU key


Flexion limit


Flexion speed


Working Time


Auto-increase limit during extension


Auto-increase limit during flexion

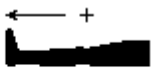
Flexion pause


Flexion limit repetitions


Extension limit


Extension speed


Force adjustment

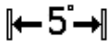

Auto-increase during extension


Auto-increase during flexion

Extension pause


Extension limit repetitions


Heating cycles

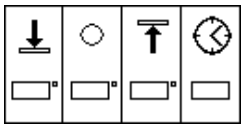


Minimum distance between motion range limits

Error message

Paused

Mobile keyboard not connected



Data displayed during operation:

Extension programmed limit

Position in real time

Flexion programmed limit

Working Time

2.2 ENVIRONMENTAL CONDITIONS

This device does not require special environmental conditions but must be used indoors. Allowed temperatures range from 5°C to 40°C, with humidity from 30% to 75% and pressure from 700 to 1060 hPa.
Storage temperature from -5°C to +50°C.

2.3 TECHNICAL FEATURES

- Continuous-use device
- Electrical safety: class 1 B device, according to EN 60601-1 standards
- Electromagnetic compatibility: group 1 class B according to EN 60601-1-2 standards
- Power supply: 90-250 V ~ 50/60 Hz
- Fuses: 1 A T
- Weight: 9.5 kg
- Protection rating: IPX0

2.4 SYMBOLS USED

type B applied parts

type BF applied parts

Mandatory separate collection

2.5 ELECTROMAGNETIC ENVIRONMENT

- Commission Fisiotek according to the information on Electromagnetic Compatibility provided in this manual.
- Portable radio communication equipment can affect Fisiotek operation.
- Fisiotek has been tested for Electromagnetic Compatibility, using the following cables:
  - power cable 3x0.75, 3 meters long;
  - mobile keyboard cable 6x0.25, 1.5 meters long.

  The use of cables other than those specified above may result in increased emissions or decreased immunity of the device.

Manufacturer guide and declaration – electromagnetic emissions		
Fisiotek is intended for use in the electromagnetic environment specified below. Fisiotek customers or users must ensure it is used in such an environment.		
Emission Test	***Conformity***	***Electromagnetic Environment - guidelines***
RF emissions CISPR 11	Group 1	Since Fisiotek uses RF energy only for its internal operation, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Fisiotek is suitable for use in all buildings, including homes, as well as those directly connected to the public low-voltage supply network, which feeds buildings for domestic use.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliant	
Continuous conducted disturbances	Compliant	

EN55011		
Radiated noise EN55011	Compliant	

Manufacturer guide and declaration – electromagnetic immunity			
Fisiotek is intended for use in the electromagnetic environment specified below. Fisiotek customers or users must ensure it is used in such an environment.			
Immunity test	***Test level IEC 60601***	***Level of conformity***	***Electromagnetic Environment - guidelines***
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Regular operation without interruptions	Floors must be made of wood, concrete or ceramic. If floors are covered with synthetic material, relative humidity should be 30%.
Radiofrequency Electromagnetic Fields EN61000-4-3	Frequency range 80 MHz -2.5 GHz Field strength 3 V/m	Regular operation without interruptions	Check that in the vicinity there is no equipment having emission levels higher than Fisiotek's immunity level.
Electrical fast transients/bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Regular operation without interruptions	The quality of the mains voltage should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	±1 kV differential ±2 kV common	Regular operation without interruptions	The quality of the mains voltage should be that of a typical commercial or hospital environment.
Radio frequency conducted disturbances EN61000-4-6	Frequency range 150 KHz -80 MHz	Regular operation without interruptions	Check that in the vicinity there is no equipment having emission levels higher than Fisiotek's immunity level.
Voltage dips, short interrupts and voltage variations on power supply	Reduction 100% *Ut* Duration 5000 ms	Operation interruption. Press Start to	The quality of the mains voltage should be that of a typical commercial or hospital environment. If the user

input lines IEC61000-4-11	(@50 Hz)	resume the movement.	requires continuous operation, even in the case of power outage, a UPS unit is recommended.
	Reduction 100% *Ut* Duration 10 ms (@50 Hz)	Regular operation without interruptions	
	Dip 40% *Ut* Duration 100 ms (@50 Hz)	Regular operation without interruptions	
	Dip 70% *Ut* Duration 500 ms (@50 Hz)	Regular operation without interruptions	

Note: Ut is the mains AC voltage before test level application.

2.6 DISPOSAL

Separate collection is mandatory for this equipment. Offenders subject to administrative sanction in accordance with local rules.

3. SAFETY

3.1 GENERAL WARNINGS

The operator must carefully read the information contained in this Manual, especially with regard to the safety precautions outlined in this chapter.

The control parameters of this device must be determined by physicians experienced in the field of passive rehabilitation.

ATTENTION: do not modify this device in any way without the permission of the Manufacturer.

3.2 INTENDED USE

The purpose of this device is to recover mobility of the joints of the lower limbs, through a passive mobilization of the limb itself.

3.3 USE CONTRAINDICATIONS

Do not use this machine:

- For uses other than those specified in section 3.2
- In explosive atmosphere
- In fire-risk atmosphere
- In bad weather
- With electrical and/or mechanical jumpers which exclude parts of the machine
- Connected to a power supply system that does not conform to current standards.

3.4 OPERATOR PROFILE

The values of the various programmable functions, which determine the range of motion, speed, etc., must be decided by qualified staff (orthopedic surgeon, physiatrist, physical therapist) taking into account the patient's condition.
The Patient, or another person who may be the Operator, sets the device using parameters defined beforehand by qualified personnel as outlined above. The Operator must have the following minimum requirements:

- *Level of education*: not relevant.
- *Basic knowledge*: casual reading skills, knowledge of the linear and angular measuring system, ability to use a simple keyboard and follow simple instructions.
- *Knowledge of languages*: not relevant.
- *Experience*: not relevant.
- *Physical conditions*: (if the Patient is the Operator) must have a sufficient degree of mobility to position himself/herself on the device alone.

3.5 TRAINING

No operator training is required.

3.6 STOP FUNCTIONS

The machine stops as follows:

- via the master switch located on the machine's front panel

3.7 SPECIAL WARNINGS

- The foot and leg rests can only come into contact with healthy skin; adequately protect any injuries from contact.
- Use this device only on a stable surface, supported by the edges of the surface by a good margin.
- Do not pull the cable of the mobile keyboard.
- Do not sit on the device.
- Check, on a regular basis, the integrity of the foot and leg rests, paying special attention to the state of the seams and the hold of the closing buttons.
- Check, on a regular basis, the condition of all the knobs that lock the adjustable rods.
- Replace both the mobile keyboard and its power cable with original spare parts only.
- This device must be tested periodically to confirm that safety features against electrical hazards are maintained, see chapter "Electric safety tests"
- The Physical Therapist must instruct the Patient on how to use the mobile keyboard.
- If the Patient is not able to manage himself/herself during the rehabilitation session, he/she must be assisted.

4. SET- UP

4.1 COMMISSIONING

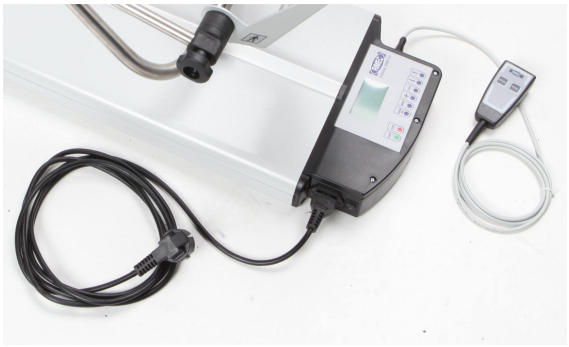


Fig1

After removing the device from the box, mount the separate components as shown in Fig.1. Connect the device to the mains.

Attention: before connecting the device to the mains, check that line current matches that specified in the machine's technical data sheet.

Turn on the device through the switch on the front panel. Each time it is turned on, the microprocessor runs a control procedure lasting a few seconds. During this time, the display shows RIMEC Fisiotek 3000G V.xx and no other keyboard key is enabled; at the end, the display shows START MENU ; now the device is ready to work.

4.2 **RODS ADJUSTMENT ACCORDING TO LIMB LENGTH**

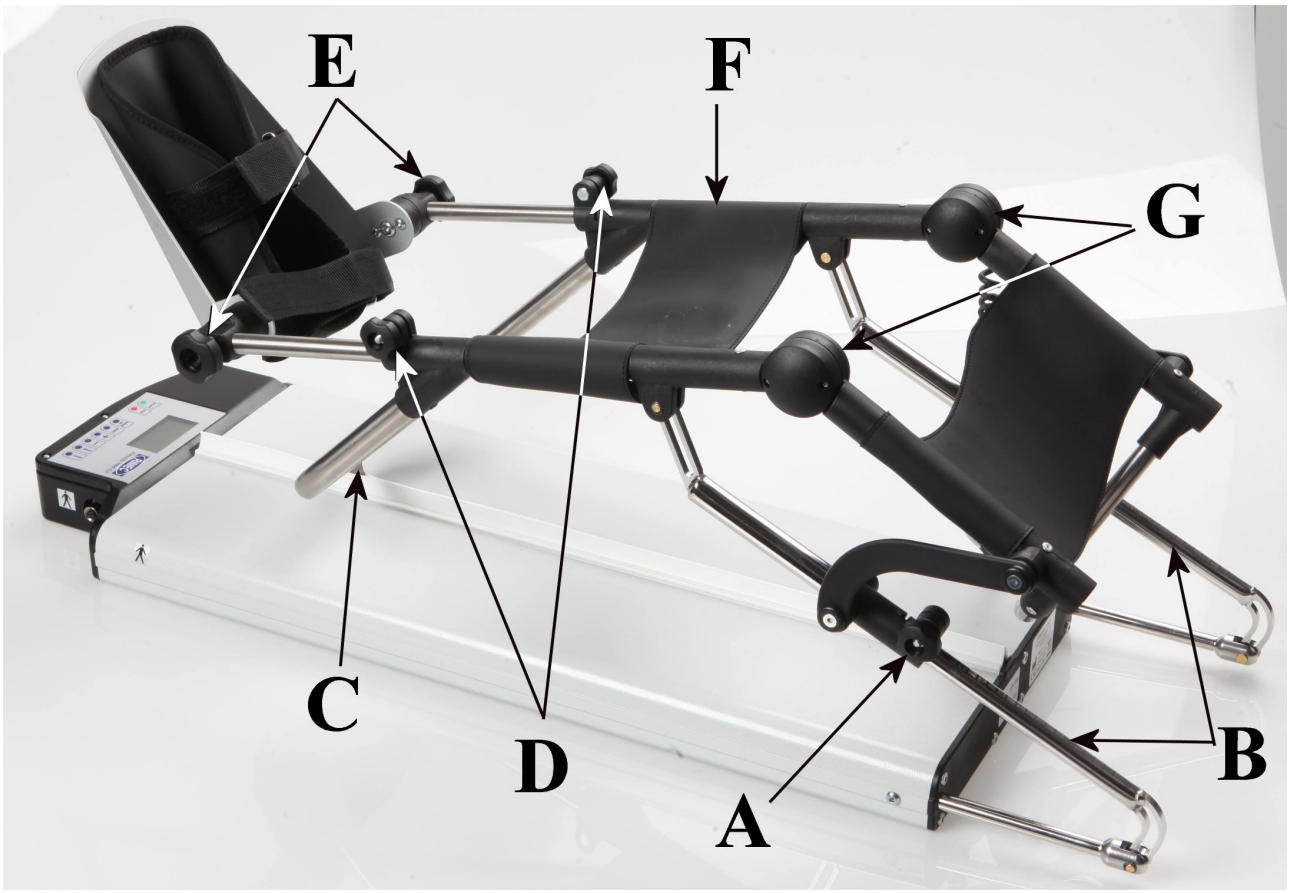


Fig.2

- Measure the length of the patient's femur in centimeters.
- Use key ↓ or ↑ to move the carriage (C) approximately halfway.
- Loosen the two knobs (A) and set the length of the patient's femur on the graduated rods (B) and then tighten the knobs.
- Use key ↓ or ↑ to move the carriage in the most comfortable position for the patient's limb (may even be 0°).
- Loosen the knobs (D) and slide out the black metal shoe until it reaches max. position.
- Using the knobs (E), tilt the metal shoe to the desired position.
- Place the patient's limb on the device, aligning the knee with the joints (G).
- Set the black metal shoe against the patient's foot and tighten the knobs (D).
- Using the lower Velcro strip, adjust the support (F), which should only be in contact with the patient's calf without pressing too much.

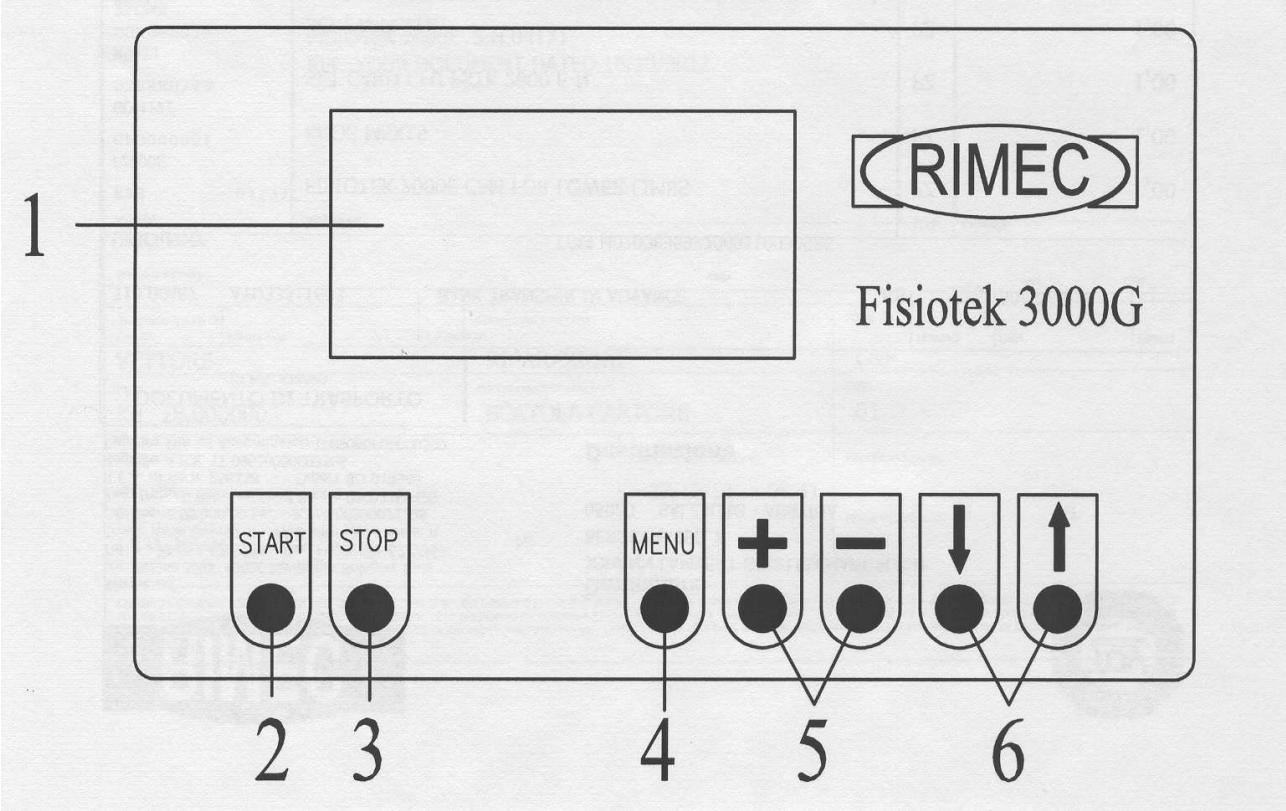


Fig. 3

1. Display
2. Key for starting the motion
3. Key for stopping the motion
4. Key for entering and exiting from the MENU
5. Keys for changing the value of the functions
6. Keys for scrolling through the pages inside the MENU. Or, outside the MENU, to move the carriage

5. PROGRAMMING

5.1 GENERAL NOTES

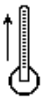
Standby

This condition is reached by pressing the STOP key once. Stand - by appears on the display. In this situation, the set Working Time does not reset and you can enter the Menu to change all parameters except the Working Time. Press START to resume work or STOP to enter the Stop condition described below.

Stop
This condition is reached by pressing the STOP key twice and the Working Time resets. START MENU appears on the display. This situation allows you to access all the device's functions.

Programmable functions
Programmable functions are listed in paragraph 2.1 "Operating Principle" and are collected in a menu divided into two levels: choice of the joint and programmable functions, accessed by pressing the MENU key.
N.B. The programmed values of the "Speed" and "Force" functions can be changed while the machine is running, without stopping the movement. Simply enter the menu as explained in the programming example.

Warm up
Allows you to "get used to" the movement of the patient's articulation, making him/her carry out a few cycles in a range of motion that will be less than during the rest of the session.

When you enter the menu and screenshot  appears, you can set a reduction in the range of motion in degrees. This reduction involves the range's two limits (e.g.: a reduction of 10° in a range from 0° to 100° will change it from 10° to 90°). When the device starts, the first five cycles will be performed with the set reduction and then 1° will be recovered at each cycle until the set reduction ends and the basic program begins. To let you know that the device is warming up, the sections of the display, which correspond to the two limits of the range of motion, will turn on and off intermittently throughout the warm up.

5.2 PROGRAMMING EXAMPLE FOR KNEE REHABILITATION

Data.
Suppose Mr. X is about to begin his first passive rehabilitation session of the Left knee.
First measure the length of his limb. As such: Mr. X, LEFT knee, Length 44 cm.
Now let's program the device with the following values:

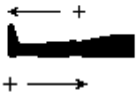
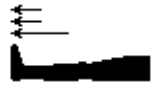
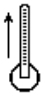
- Extension limit -5°
- Flexion limit 40°
- Extension speed 7
- Flexion speed 5
- Force (it must be established during the movement with respect to the resistance of the patient's limb)
- Working Time 30’
- Extension auto-increase 0.0°
- Flexion auto-increase 0.6°
- Flexion auto-increase limit 90°
- Extension pause 0"
- Flexion pause 5"

- Extension repetitions 0
- Flexion repetitions 3
- Warm up: flexion decrease 0°

Actions.

- Make the adjustments as outlined in paragraph 4.2.

The display shows START MENU

- On pressing MENU, the display shows  press + or − until you reach -5°
- Press ↓ the display shows  press + or − until you reach 40°
- Press ↓ the display shows  press + or − until you reach 7
- Press ↓ the display shows  press + or − until you reach 5
- Press ↓ the display shows  press + or − until you reach 30 (may be changed during the movement)
- Press ↓ the display shows  press + or − until you reach 30’
- Press ↓ the display shows  press + or − until you reach 0.0°
- Press ↓ the display shows  press + or − until you reach 0.6°
- Press ↓ the display shows  press + or − until you reach 90°
- Press ↓ the display shows  press + or − until you reach 0"
- Press ↓ the display shows  press + or − until you reach 5"
- Press ↓ the display shows  press + or − until you reach 0
- Press ↓ the display shows  press + or − until you reach 3
- Press ↓ the display shows  press + or − until you reach 0°
- Press MENU to exit from the menu

- Press START to begin the movement

The following information is displayed during the movement (from left):
- the programmed or reached extension limit if auto-increase is active
- the position of the carriage in real time expressed in degrees
- the programmed or reached flexion limit if auto-increase is active
- the working time (the digit is intermittent if you chose a value from 5' to 60')

Now adjust the "Force" value.

- Press MENU and the display shows  and a value between 1 and 10
- Press ↓ twice and the display will show  with the previously set value of 30. Press — to lower the ***"Force"*** until motion reverses accompanied by a beep, which signals a reversal due to "overload", i.e. the limb's resistance is greater than the Force. Press + to gradually increase the ***"Force"*** until you find a value that is just enough to reach the limits of the motion range, without there being the "overload reversal". If there is a spasm in this condition, resistance will increase and motion will reverse.

- Press MENU to exit from the menu.

But if you want the articulation to reach the set flexion limit, despite any increase in the patient's resistance, you can set a max "Force" value.

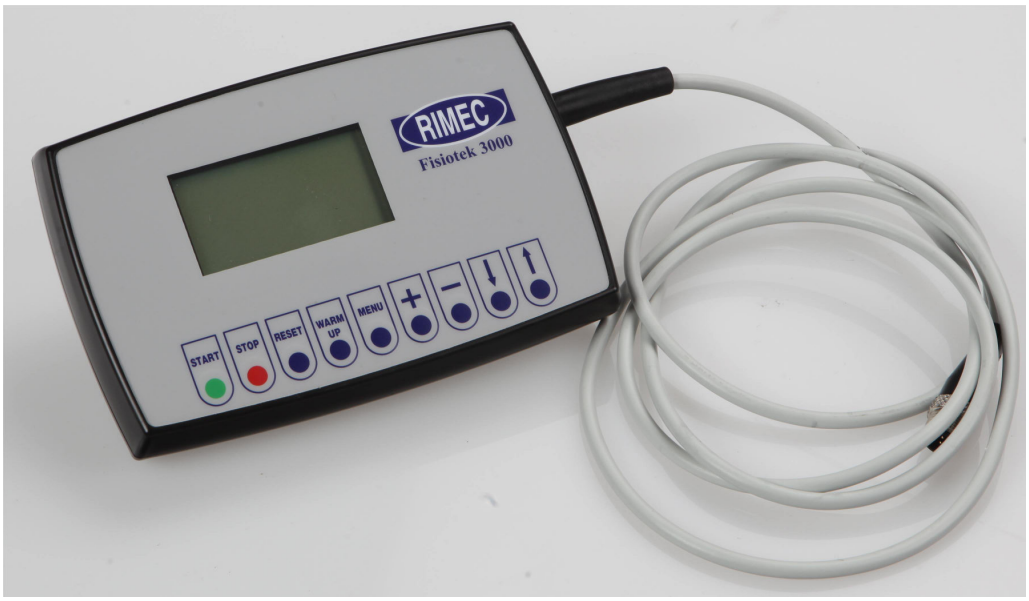
6. ACCESSORIES

6.1 ORDERING ACCESSORIES

Orders of accessories have to be made to Chinesport or your area Distributor.
Be sure to specify clearly both the code and the required quantity.

6.2 PROGRAMMING MOBILE KEYBOARD

There is a "Programming mobile keyboard" that can be connected to the device using the same standard "Start-Stop mobile keyboard" connector supplied. Since this accessory is common to all models, it has all the keys you may need. As soon as you connect the keyboard to a specific model, only the necessary keys will be activated, which are the same that are on the device's fixed keyboard.



6.3 FISIOTEK TROLLEY

A very small trolley is available that can be used for both transporting and parking the device when it is not being used.

7. MAINTENANCE

7.1 SAFETY WARNINGS

For special maintenance, please refer to the "Technical Support Manual" since these operations must always be carried out by qualified personnel.

7.2 ROUTINE MAINTENANCE

Fisiotek **3000 G** requires no special maintenance.

7.3 CLEANING

Clean the device after unplugging it from the mains. Use a damp cloth and do not use chemicals that may damage the rubber parts. Do not let water or other fluids penetrate inside the device but if this happens, please contact your Authorized Service Center.

7.4 SERVICE CALL

Should you run into any kind of technical problem, **please contact Chinesport directly** or your area Distributor, from whom you will receive the quickest and safest solution to your problem.

8. ELECTRIC SAFETY TESTS

8.1 DESCRIPTION OF TESTS

The tests listed below must be carried out with suitable equipment and by Qualified Personnel.

- Conductor resistance to earth: should be less than 0.1 Ohm.
- Dielectric strength: insulation must withstand 1500V AC for 1 minute.
- Measurement of leakage current to ground: on powering-on the device at nominal voltage plus 10%, leakage current to ground must be less than 0.5 mA.

8.2 TESTING FREQUENCY

Run these tests several times during the device's lifespan to ensure its safety features are always maintained against electrical hazards. Therefore, tests should be carried out as follows:

- Every two years.
- Each time the device is repaired, involving its primary power supply circuit.

9. SPARE PARTS

9.1 ORDERING SPARE PARTS AND ACCESSORIES

Make you spare parts orders directly to Chinesport or your area Distributor.
Below are the codes for ordering Accessories and parts subject to wear. For all the parts that need repair, please refer to the "Service Manual".

Description	*Code*
Fisiotek trolley	FACAR
Programming mobile keyboard F3000GS-G-E	FATMPR
Start-Stop mobile keyboard F3000GS-G-E	DGR006048
Foot support shoe	DGE0SC366
Calf support F3000	DGE006054
Thigh support F3000	DGE006055