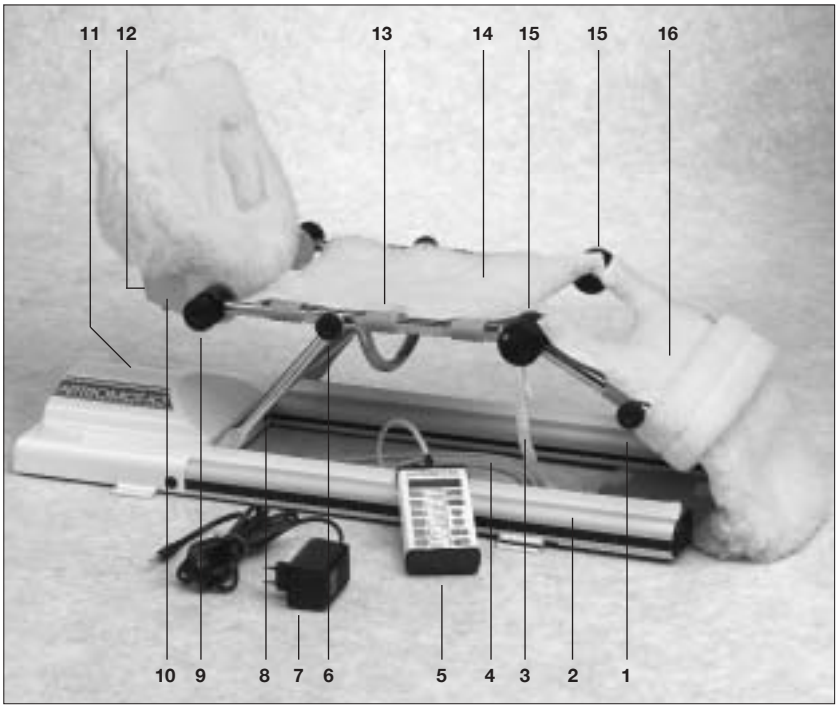
ARTROMOT®-K3

Operation Manual

Device description



1 Knob for femur length adjustment
2 Base
3 Coiled cord
4 Controller cable
5 Hand-held controller
6 Knurled knob for length adjustment of lower leg
7 Power adapter
8 On/Off switch
9 Knurled knob for angle of foot inclination
10 Footplate with patient kit
11 Socket for power adapter
12 Knurled knob for rotating foot plate
13 Kit straps
14 Lower leg patient kit
15 Knee pivot point
16 Thigh patient kit

Contents

1. How to use ARTROMOT®- K3

1.1. Application

The ARTROMOT®-K3 is a motor-operated motion device used for Continuous Passive Motion (CPM) of the knee and hip joints.

Suitable for use in hospitals, clinics, general practices and rental services, it is an important supplement to medical and therapeutic treatment.

1.2. Objectives of therapy

CPM therapy with ARTROMOT®-K3 is mainly used in the avoidance of immobilization injuries, the early re-establishment of painless movement of joints and the promotion of faster healing with a positive functional result.

Other objectives of therapy include:

- the improvement of joint metabolism
- the prevention of joint stiffness
- the promotion of the healing of cartilage areas and damaged ligaments
- the speeding up of haematoma resorbtion
- the improvement of lymph and blood circulation
- the prevention of thrombosis and embolism

1.3. Indications

The **ARTROMOT®-K3** CPM device is indicated in the treatment of most injuries, postoperative states and diseases of the knee and hip joint. For example:

- joint distorsions and contusions
- arthrotomy and arthroscopy procedures in combination with synovectomy, arthrolysis or other intra articular measures
- mobilizations of joints in narcosis
- operative treatments on fractures, pseudarthrosis and inversion operations
- criciate ligament replacement surgery (ACL/PCL)
- endoprothetic implants

⚠ CAUTION!

The **ARTROMOT®-K3** should not be used with:

- acute inflammatory processes in the joint area, if not explicitly prescribed by the doctor
- spastic paralysis
- unstable osteosynthesis

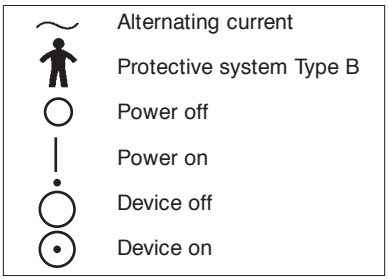
Movement should not cause any pain

2. Description of the ARTROMOT®- K3

The **ARTROMOT®-K3** CPM device allows extension and flexion of the knee joint in the range of –5-0-110 degrees. There is no need to convert the device when switching from the right to left side (or vice versa).

The **ARTROMOT®-K3** features a hand-held programming unit that can be used to program and store any treatment values.

Explanation of symbols



Explanation of functioning elements

Note: Fold out page 1

1 Knob for femur length adjustment

2 Base

3 Coiled cord

4 Controller cable

5 Hand-held programming unit

6 Knob for length adjustment of lower leg

7 Power adapter

8 Main switch

9 Knob for angle adjustment of foot inclination

10 Foot plate with patient kit

11 Socket for power adapter

12 Knob for rotation footplate

13 Kit straps

14 Lower leg patient kit

15 Knee pivot point

16 Thigh patient kit

3. Safety instructions

⚠ CAUTION!

these instructions must be read before start- up!

- The **ARTROMOT®-K3** may only be operated by **authorized persons**.
- Make sure that the patient is supported in an anatomically correct way. Check the following settings/ positioning:

  1. Femur length
  2. knee joint axis
  3. calf length and leg rotation setting
  4. patient kits

- In case of patients who are **adipose, particular large or very small**, you should pay attention to the following:
  - Avoid abrasion and pressure
  - If necessary support the leg in a slightly abductive position
- The maximum continuous load on the leg support element is 30 kg
- Movement must always be free of pain and irritation
- The patient must be **fully conscious** during instruction and when using the splint.
- The doctor or therapist must decide on a case-to-case basis wether the device can be used with the patient

⚠ CAUTION!

Before treatment begins, a test run involving several movement cycles should be carried out first without and then with the patient.

- The hand-held programming unit should be explained to the patient and must be located **within the patient´s reach**, so that the therapy can be interrupted if necessary.
- Make sure that the characteristic values of your **power supply** correspond to the voltage and frequency data indicated on the ID plate.
- Only connect the **ARTROMOT®-K3** to correctly installed safety sockets.
- **Repair** and **maintenance** work may only be carried out by authorized persons, as otherwise all warranty services and liabilities shall be void.
- Perform regular checks on all components for possible damage or loose connections
- Damaged or worn parts should be replaced immediately with original spare parts by an authorized specialist.
- Before cleaning and repair **disconnect the device from the main socket**.
- When carrying out any work on the device, **never allow liquids** to get inside the housing or the hand-held programming unit.
- Only use the AC-AC adapter supplied with the unit.

⚠ CAUTION!

The ARTROMOT®-K3 may only be operated with the attached power supply NTEV20

To disconnect the device from mains, unplug the AC-AC adapter from the wall socket.

4. Adjusting the device

Note: Fold out pages 1 and 17
To get a better understanding of the individual steps.

4.1. Connecting the device

- Connect the **power adapter (7)** to a safety socket (120 Volt, 60 Hertz)
- Turn on the device with the **main switch (8)**

4.2. Adjusting the femur length

Set the device at a knee-angle position that is not likely to cause the patient any pain.

Positioning the upper leg

- Open the black knurled knob (1), and move thigh support to the desired length (figure 2)

Positioning the lower leg

- Loosen the two knobs (6), move the foot support horizontally and adjust precisely to the patients lower leg length. (figure 3)

Positioning of foot dorsi- / plantar flexion

- Loosen the two knobs (9) and adjust the foot plate at a comfortable angle. (figure 4)

Positioning of foot rotation

- Loosen the knurled knob (12) and move the foot plate into the required rotation position. (figure 5)

4.3. Adjusting the patient kit

- Fix patient kit (14) for the lower leg and patient kit (16) for the upper leg by using the velcro tapes. (figure 6 and figure 7)
- Control correct adjustment. Exercise only in painfree range of motion. Patient should be positioned with maximum comfort.

⚠ CAUTION!

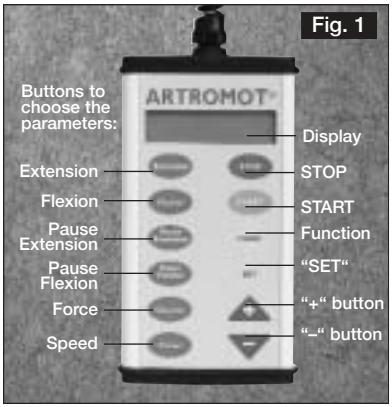
The knee and hip axis of the ARTROMOT®-K3 should align with the patients knee and hip axis (Figure 8)
After adjustments have been made, perform several test runs. When correctly adjusted, there should be no excursion of the knee and hip joint during motion.

5. Setting the treatment values

5.1. Programming the ARTROMOT®-K3

The following **treatment values** can be stored by means of the **hand-held programming unit.** (5)

- Knee extension
- Knee flexion
- Pause extension
- Pause flexion
- Force
- Speed



5.1.1. Programming the treatment values

IMPORTANT:
It is possible to program single or all parameters. If only some parameters were changed, the other parameters will be saved with current settings.

1. Pressing the **Extension and STOP** keys at the same time for one second or holding down the **STOP** key for five seconds enables you to change to **programming mode**.
2. You can now select the treatment values in succession by pressing the parameter keys.
3. Change the value by pressing the **+/-** keys.
4. Continue programming (with 2 and 3) until all required values are entered.
5. Press the **STOP** key to save all previous values.
6. Press **START** button: programmed values were checked automatically.
7. Press **START** button again to start the device in therapy mode.
8. Pressing the parameter buttons in stop mode the display shows the **current stored values**.

5.1.2. Information about treatment values

Setting the range of motion ROM

- Maximun **knee extension**: -5 degrees
- Maximum **knee flexion**: 110 degrees

⚠ CAUTION!
The programmed value and the actual angle measured at the patient´s knee may vary.

The criterion for correct adjustment is that it should be possible to move the extremity without pain or irritation.

Adjusting the pauses

- The pauses occur in the final position of extension or flexion and can be set separately for extension and flexion.
- Possible values for pauses: 0 – 30 seconds

Adjusting the force (reverse on load)

- Minimum setting for reverse on load: **25 kp**
- Maximum setting for reverse on load: **45 kp**

Settings are approximate!

Tensile force is measured on the frame around the foot.

The input setting determines the maximum resistance needed to automatically reverse the direction of motion.

> ⚠ **CAUTION!**
> **The reverse circuit is purely a safety measure for cramps, spasms, locked joints, etc. The manufacturer accepts no liability if used improperly.**

Speed
Minimum setting for speed: **1%**

Maximum setting for speed: **100%**

5.1.3. Programming the special functions

Special functions are:

- Center warm-up
- Full speed & motion (double speed setting)
- Runtime (patient runtime)
- Device runtime

Programming the special functions:

1. Switch to programming mode (section 5.1.1)
2. Press **FUNC** key
3. Select special functions using + or – key
4. Follow the instructions on the display
5. Quit and save with **STOP** button

Center warm-up

Warm-up allows the patient to attain gradually full programmed range of motion. The device starts in the middle between the two values set for extension and flexion. With each movement cycle the extent of movement is increased by 2 degrees until the set value is reached. The device then moves between these values.

Full speed & motion

The full speed & motion function is only for service. The device runs at twice the maximum programmable speed to facilitate a rapid device set up.

WARNING: Do not run the device in full speed & motion when patient is in the device!

Run time

This is the individual run time for each treatment. To reset press **SET** key in the programming mode.

Device run time

The total device run time is counted from the first usage of the device. Press + button for 5 seconds until setting appears. Device run time cannot be deleted.

Save data

To save the programmed special functions, press the **STOP** key.
Press the **START** key: the device checks programmed values.

6. Maintenance

- Always unplug the device before cleaning
- The **ARTROMOT®-K3** can be wiped clean with disinfectant and therefore complies with the required standards of hygiene for medical equipment.
- The housing can be cleaned using commonly available disinfectants and mild household detergents.
- The device itself should only be wiped down with damp cloth.

⚠ CAUTION!

Never allow liquids to get inside the housing or hand-held programming unit.

- The plastics used are not resistant to mineral acids, formic acid, phenol, cresol, oxidizing or strong organic and inorganic acids with a pH value of less than 4.
- Protect the device from intensive ultraviolet radiation (sunlight)

Surrounding Conditions

Surrounding temperature	-11°F to +140°F
Relative humidity	20% to 85%
Air pressure	700hPa to 1060 hPa

Operational Conditions

Surrounding temperature	+50°F to +104°F
Relative humidity	30% to 75%
Air pressure	700hPa to 1060 hPa

7. Specifications

Electrical rating	115/230V~ 50/60Hz 15V/27VA
Input current	0.3 Amps
Rated	1.33 A
Transformer	Safety transformer EN 60742
Protection class	II
Length	36.6 inches/93 cm
Width	14 inches/36 cm
Height	16.53 inches without foot plate/43 cm
Length adjustment for lower leg (approximate length)	16.7 inches/42,5 cm – 22 inches/56 cm
Length adjustment for upper leg (approximate length)	2.75 inches/7 cm
Weight	24.4 lb./ 11.8 kg
Materials used	Steel: 1.4301; 1.4305; 1.4310 Aluminium: AlMg3; AlCuMgPb F38, Brass Synthetic material: PA6.6; Polystyrol PVC; PE 1000; FR4 Electronic board; Polyurethane; rubber Support: synthetic fleece (Polyester)

Technical data subject to change

MPG:	Class 2a
Power supply	NTEV20 Safety Transformer In: 115/230V ~ 50/60 HZ 27VA Out: 15V ~ 1.33A Manufacturer: Ulmer

8. Service

If you have any questions regarding product or service, please do not hesitate to contact us:

ORMED international
Please contact your local dealer or

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⚠ CAUTION!

Carry out regular checks at short intervals for possible damage and loose connections. Damaged or worn parts should be replaced immediately with original spare parts by an authorized specialist.

To avoid transport damages, use only the original packing boxes. These boxes can be ordered from Ormed. Before carrying the device, always make sure the femur length adjustment is locked.

Maintenance:
Not necessary

Guarantee:
2 years warranty on mechanical and electronical parts

Manufacturer:
ORMED GmbH & Co. KG
Merzhauser Straße 112
D-79100 Freiburg, Germany

DECLARATION OF CONFORMITY

Declaration of Conformity

According to the EC-Regulation for medical devices the
EC Medical Devices Directive (MDD) 93/42/EEC dated 14th June 1993,
appendix 2

The Manufacturer
ORMED GmbH & Co. KG
Merzhauser Straße 112
D-79100 Freiburg

herewith declares that the following units

Type	**Knee & Hip**
Name	**ARTROMOT®-K3**

meets all requirements of following EC-directives:

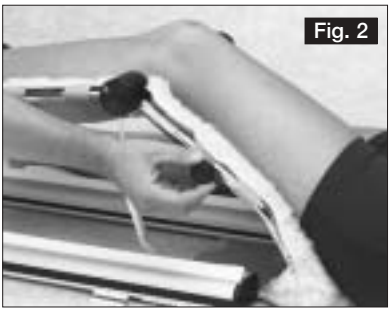
EN 60 601-1	**1990**	Electrical Medical Devices, Part 1, Basic Rules for Safety
EN 60 601-2	**1993**	Electrical Medical Devices, Part 1 and 2, additional norm: electromagnetic compatibility – requirements and testing
		The adherence to the standard specifications entitles to marking of these devices with CE 0297.

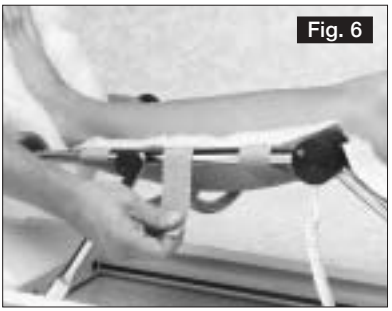
CE
0297

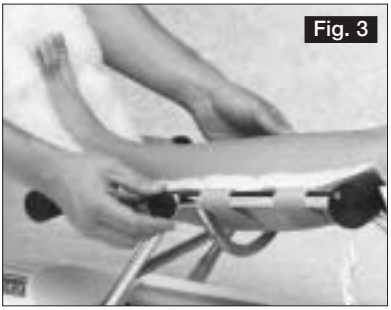
Freiburg, January 20, 2002

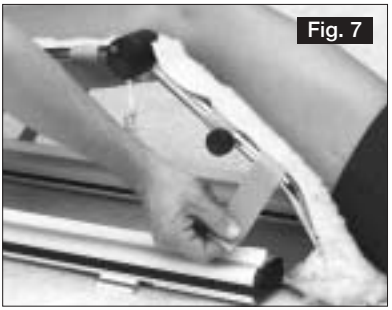
Quality Control Manager

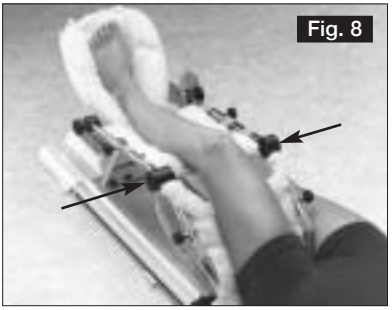
Figures











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