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
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 resorption
- 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 joints. For example:
- joint distortions and contusions
- arthroscopy and arthroscopy procedures in combination with synovectomy, arthrosis or other intra articular measures
- mobilizations of joints in narcosis
- operative treatments on fractures, pseudarthroses and inversion operations
- cruciate 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 −50° to 110°. 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 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

### Explanation of symbols

Alternating current
Protective system Type B
Power off
Power on
Device off
Device on

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 kit
- 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 abuctive 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 whether the device can be used with the patient.

⚠️ **CAUTION!**

The ARTROMOT®-K3 may only be operated with the attached power supply NTE20

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

- 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 repairing disconnect the device from the mains socket.
- When carrying out any work on the device, never allow liquids to get inside the housing of the hand-held programming unit.
- Only use the AC-AC adapter supplied with the unit.
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 patient's lower leg length. (figure 3)

**Positioning of foot dorsiflexion**
- 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 pain-free 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

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[Image of ARTROMOT®-K3 control panel]

5.1.2. Information about treatment values

**Setting the range of motion ROM**

- Minimum 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 normally 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)

7. Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Electrical rating</td>
<td>115/230V ~ 50/60Hz</td>
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<tr>
<td></td>
<td>15V/27VA</td>
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<tr>
<td>Input current</td>
<td>0.3 Amps</td>
</tr>
<tr>
<td>Rated</td>
<td>1.33 A</td>
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<tr>
<td>Transformer</td>
<td>Safety transformer</td>
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<td></td>
<td>EN 60742</td>
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<tr>
<td>Protection class</td>
<td>II</td>
</tr>
<tr>
<td>Length</td>
<td>36.6 inches/93 cm</td>
</tr>
<tr>
<td>Width</td>
<td>14 inches/36 cm</td>
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<tr>
<td>Height</td>
<td>16.53 inches without foot plate/43 cm</td>
</tr>
<tr>
<td>Length adjustment</td>
<td>16.7 inches/42.5 cm</td>
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<tr>
<td></td>
<td>(approximate length) - 22 inches/56 cm</td>
</tr>
<tr>
<td>Length adjustment</td>
<td>2.75 inches/7 cm</td>
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<tr>
<td></td>
<td>(approximate length)</td>
</tr>
<tr>
<td>Weight</td>
<td>24.4 lb / 11.8 kg</td>
</tr>
<tr>
<td>Materials used</td>
<td>Steel: 1.4301; 1.4305; 1.4310</td>
</tr>
<tr>
<td></td>
<td>Aluminium: AlMg3; AlCuMgPb F38,</td>
</tr>
<tr>
<td></td>
<td>Brass</td>
</tr>
<tr>
<td></td>
<td>Synthetic material: PA6.6, Polystyrol PVC, PE 1000; FR4 Electronic board; Polyurethane; rubber Support: synthetic fleece (Polyester)</td>
</tr>
</tbody>
</table>

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

Headquarters Germany
ORMED GmbH & Co. KG
Merzhauser Straße 112
D-79100 Freiburg, Germany
Tel: +49 761 4566-281
Fax: +49 761 4566-55281
e-mail: s.goeger@ormed.de

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Technical hotline:
Do you have any technical questions?
Do you need technical service?
Tel: +49 180 51 ormed.de
+49 180 51 676 333
Fax: +49 180 53 ormed.de
+49 180 53 676 333

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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 electronic parts

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

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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

<table>
<thead>
<tr>
<th>Type</th>
<th>Knee &amp; Hip</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>ARTROMOT®-K3</td>
</tr>
</tbody>
</table>

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.

Freiburg, January 20, 2002

[Signature]
Quality Control Manager