1. How to use ARTROMOT*-K4

1.1 Application

The ARTROMOT*-K4 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*-K4 is mainly used in the avoidance of immobilisation injuries, the early reestablishment 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*-K4 CPM device is indicated in the treatment of:
- injuries, postoperative states and diseases of the knee and hip joints.

For example:
- joint distorsions and contusions
- arthroscopy and arthroscopy procedures in combination with synovectomy, arthrolisis or intra articular measures
- mobilisation of joints in narco-sedation
- operative treatments on fractures, pseudarthrosis and inversions
- cruciate ligament replacements (ACL/PCL)
- endoprothetic implants

⚠️ PRECAUTION

The ARTROMOT*-K4 should not be used with:
- acute inflammatory processes in the joint area, if not prescribed by the doctor
- spastic paralysis
- unstable osteosynthesis
- Movement should not cause pain.
Description of the ARTROMOT®-K4

ARTROMOT®-K4 CPM device

- Description:
  - Rotation and flexion of the hip in the range of 0-0-125 degrees.
  - Adjustment of the hip joint in the range of 0-0-125 degrees.

- Features:
  - Lower leg support
  - Lower leg patient kit
  - Knee pivot point
  - Thigh patient kit
  - Thigh support
  - Knob for femur length adjustment
  - Hip axis pivot point

Explanation of symbols:

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

3. Safety instructions

⚠️ PRECAUTION!
these instructions must be read before start-up!

- The ARTROMOT®-K4 may only be operated by authorised 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. Hip joint axis
  4. Calf length and leg rotation setting
  5. 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 whether the device can be used with the patient.

⚠️ PRECAUTION!
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 their reach, so that they can be interrupted if necessary.
- Make sure that the character values of your power supply correspond to the voltage and frequency data indicated on the ID plate.
- Only connect the ARTROMOT® to correctly installed safety sockets.
- Repair and maintenance work may only be carried out by authorised persons, as otherwise all warranties and guarantees shall lapse.
- Performed regular checks on all components for possible damage or connections.
- Damaged or worn parts should be replaced immediately with original or spare parts by an authorised specialist.
- Before cleaning and repair disconnect the device from the mains supply.
- When carrying out any work on the device, never allow liquids inside the housing or the hand-held programming unit.
- Only use the AC-DC adapter with the unit.

⚠️ PRECAUTION!
The ARTROMOT®-K4 may only be operated with the attached power supply NTEV20.

To disconnect the device from the mains, unplug the AC-DC adapter from the socket.
4.3 Adjusting the patient kit

- Fix patient kit (18) for the lower leg and patient kit (20) 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.

⚠️ PRECAUTION!
The knee and hip axis of the ARTROMOT*-K4 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.

4.4 Conversion

ARTROMOT*-K4 features a true anatomical knee and hip axis for maximum patient comfort.

ARTROMOT*-K4 has to be set up either for the right or left leg.

The device can be converted quickly. The procedure is easiest at an angle of approximately 80 – 90 degrees (section 5.1.1).
- Hand-held programming unit (7) is in STOP mode.
- Press buttons (3) simultaneously pull square lube (2) associated with the height adjustment mechanism from profile (figure 11). Slide opposite profile until it "click" audibly.
- Pull button for height adjustment mechanism (1) and remove thigh support (21) (figure 9).
- Hold the thigh support. Release length adjustment mechanism (1/4 rotation) from the bayonet lock (figure 10). Remove entire part and slide into the opposite side and fix in place with the bayonet lock.
- Slide the height adjustment together again and allow it to "click" home at the same height turning point of the hip (figure 12).
Programming the treatment values

Programming the treatment values can be done by means of the hand-held control unit.

1. You can now select the treatment values in succession by pressing the parameter keys.
2. Change the value by pressing the +/- keys.
3. Continue programming (2 and 3) until all required values are entered.
4. Press the STOP key to save all previous values.
5. Press START button: programme values were checked automatically.
6. Press START button again to start the device in therapy mode.
7. 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
  - Maximum knee extension: -10 degrees
  - Maximum knee flexion: 125 degrees

5.1.3 Programming the special functions

Special functions are:
- Center warm up
- Full speed & motion (double speed setting)
- Run time (patient run time)
- Device run time

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

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.

⚠️ PRECAUTION!
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 %
# Maintenance

Unplug the device before cleaning.

The ROMOT®-K4 can be wiped with a damp cloth using disinfectant and therefore complies with the required standards for medical equipment.

Cleaning can be performed using readily available disinfectant and/or household detergents.

The device itself should only be wiped with a damp cloth.

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### 7. Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical rating</td>
<td>115 V/230 V - 50/60 Hz</td>
</tr>
<tr>
<td></td>
<td>15 V/27 VA</td>
</tr>
<tr>
<td>Input current</td>
<td>0.3 Amps</td>
</tr>
<tr>
<td>Rated</td>
<td>1.33 A</td>
</tr>
<tr>
<td>Transformer</td>
<td>Safety transformer</td>
</tr>
<tr>
<td>Protection class</td>
<td>II</td>
</tr>
<tr>
<td>Length</td>
<td>45.27 inches/115 cm</td>
</tr>
<tr>
<td>Width</td>
<td>15.5 inches/39.5 cm</td>
</tr>
<tr>
<td>Height</td>
<td>21.7 inches/55 cm</td>
</tr>
<tr>
<td>Length adjustment</td>
<td>15.5 inches/39.5 cm</td>
</tr>
<tr>
<td>for lower leg</td>
<td>-22 inches/56 cm</td>
</tr>
<tr>
<td>Length adjustment</td>
<td>12.5 inches/32 cm (approximate length)</td>
</tr>
<tr>
<td>for upper leg</td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td>26 lb./11.3 kg</td>
</tr>
<tr>
<td>Materials used</td>
<td>Steel: 1.4301; 1.4305; 1.4310;</td>
</tr>
<tr>
<td></td>
<td>AlMg3; AlCuMgPb F38; Brass</td>
</tr>
<tr>
<td>Synthetic material</td>
<td>PA6.6; Polystyrol</td>
</tr>
<tr>
<td>Polyurethane</td>
<td>rubber</td>
</tr>
<tr>
<td>Support: synthetic</td>
<td>fleece (Polyester)</td>
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Technical data subject to change

MPG: Class 2a

Power supply: NTEY20

Safety Transformer
In: 115/230 V - 50/60 HZ, 27 VA
Out: 15 V - 1.33 A

Manufacturer: Ulmer

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### 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-(0)-761-4566-281
Fax +49-(0)-761-4566-55 281
e-mail: s.goeger@ormed.de

**USA, St. Paul**
Tel. 1-800-440-2784
Fax 1-651-415-7414
e-mail: s.sudderland@ormedusa.com

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Tel. 02-84094650
Fax 02-84094660
e-mail: miroslav.fila@ormed.cz

Internet: www.ormed.de
e-mail: s.goeger@ormed.de
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**Technical hotline:**
Do you have any technical questions? Do you need Technical service?

Tel. +49-180-5-1-ormed.de
+49-180-5-1-676 333
Fax +49-180-5-3-ormed.de
+49-180-5-3-676 333

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⚠️ **PRECAUTION**

Carry out regular checks at regular intervals for possible dama-

Age, wear, and replacement of parts are recommended.

The original packing boxes. The original packing boxes are recommended.

Before carrying the device, always make sure the femur length and size is correct.

**Maintenance:** Not necessary

**Guarantee:** 2 years warranty on mechanical and electronic components

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

hereby 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*-K4</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.

0297

Freiburg, January 20, 2002

Quality Control Manager