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.

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

PRECAUTION! The ARTROMOT®-K4 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®-K4

The ARTROMOT®-K4 CPM device allows extension and flexion of the knee joint in the range of -10-0-125 degrees and of the hip joint in the range of 10-100 degrees.

The ARTROMOT®-K4 features a hand-held programming unit that can be used to program and store any treatment values.

Explanation of the functioning elements

Note: Fold out page 2

1. Button for height adjustment of hip pivot point
2. Spare tube
3. Release tubes for square tube
4. Patient kit straps
5. Coiled cord
6. Controller cable
7. Hand-held programming unit
8. Knob for length adjustment of lower leg
9. Base
10. Knob for angle adjustment of foot inclination
11. Knob for rotation footplate
12. Power adapter
13. Cable of power adapter
14. Socket for power adapter
15. Main switch
16. Footplate with patient kit
17. Lower leg support
18. Lower leg patient kit
19. Knee pivot point
20. Thigh patient kit
21. Thigh support
22. Knob for femur length adjustment
23. 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!
The ARTROMOT®-K4 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.

Note: Fold out page 2

- 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®-K4 to correctly installed safety sockets.
- Repair and maintenance work may only be carried out by authorised 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 authorised 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.
4. Adjusting the device

Note: Fold out pages 2 and 3. 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 (15).

4.2 Adjusting the femur length

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

Positioning the upper leg
- Open the black knurled knob (22), push button and move thigh support (21) to the desired length (figure 2).
- For correct alignment of the hip axis pivot point (23) and anatomical hip axis of the patient pull button (1) and align pivot point (23) to height of trochanter major of the patient.

Positioning the lower leg
- Loosen the two knobs (8), move the foot support horizontally and adjust precisely to the patient's lower leg length (figure 3).

Positioning of foot dorsi-/plantar flexion
- Loosen the two knobs (10) and adjust the foot plate at a comfortable angle (figure 4).

Positioning of foot rotation
- Loosen the knurled knob (11) and move the foot plate into the required rotation position (figure 5).

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.

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.

- Pull button for height adjustment mechanism (1) and remove thigh support (21) (figure 9).

PRECAUTION!
The knee and hip axis of the ARTROMOT®-K4 should align with the patient's 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.

- 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 elements together again and allow hinge to click home at the same height as the turning point of the hip (figure 12).

PRECAUTION!
For correct insert and lock position of the bayonet lock refer to sticker on the device.
5. Setting the treatment values

5.1 Programming the ARTROMOT®-K4

The following treatment values can be stored by means of the hand-held programming unit. (7)

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

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: programme 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.

5.1.1 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: programme 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

- Maximum knee extension: -10 degrees
- Maximum knee flexion: 125 degrees

⚠️ PRECAUTION!
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 of flexion and can be set separately for extension and flexion.
- Possible values for pauses: 0–30 seconds.

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

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%

5.1.4 Information about treatment values

PRECAUTION!
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 of flexion and can be set separately for extension and flexion.
- Possible values for pauses: 0–30 seconds.

5.2 Information about the device

Center warm up

Warm up allows the patient gradually attain 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

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®-K4 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.

**PRECAUTION!**

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, oxidising 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>
</thead>
<tbody>
<tr>
<td>Electrical rating</td>
<td>115 V/230 V~ 50/60 Hz 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>
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<tr>
<td>Transformer</td>
<td>Safety transformer EN 60742</td>
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<tr>
<td>Protection class</td>
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<tr>
<td>Length</td>
<td>45.27 inches/115 cm</td>
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<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 for lower leg</td>
<td>15.5 inches/39.5 cm - 22 inches/56 cm</td>
</tr>
<tr>
<td>Length adjustment for upper leg (approximate length)</td>
<td>-19.7 inches/50 cm</td>
</tr>
<tr>
<td>Weight</td>
<td>26 lb./13 kg</td>
</tr>
<tr>
<td>Materials used</td>
<td>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)</td>
</tr>
</tbody>
</table>

Technical data subject to change

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
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Fax +49-(0)-761-4566-55 281
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**Technical hotline:**
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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

PRECAUTION!

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
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></th>
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</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.

Freiburg, January 20, 2002

[Signature]
Quality Control Manager