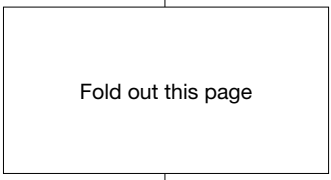
ARTROMOT®-K3

USA/GB

Operation Manual

Starting with serial number higher than 10000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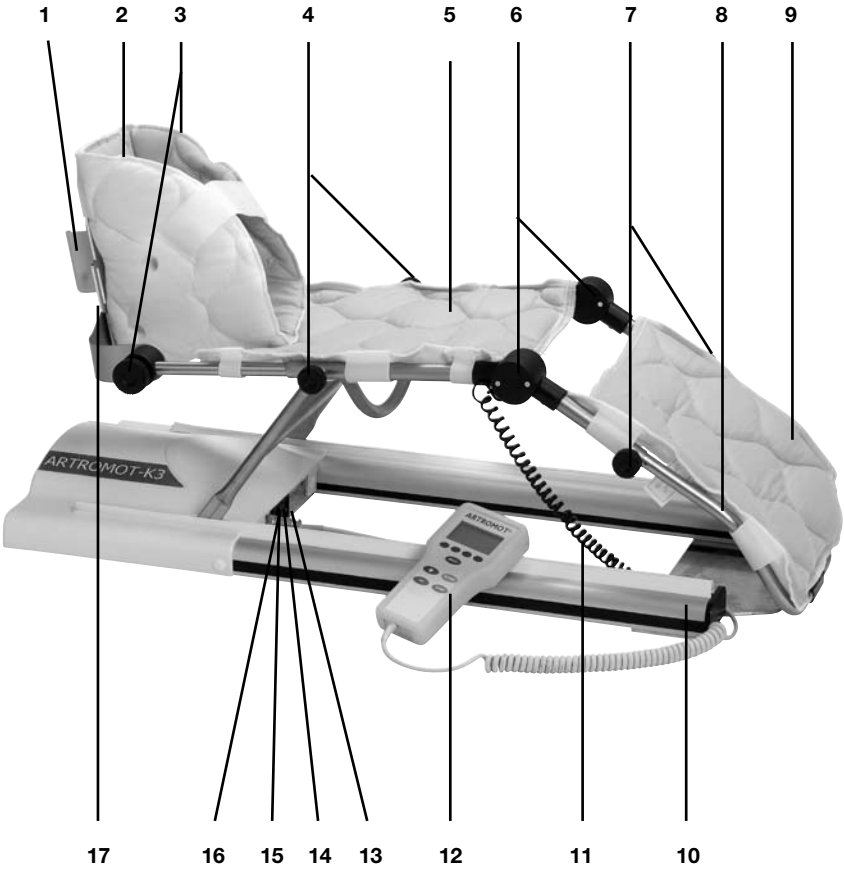
Device description



1. How to use the CPM device

1.1 Fields of application

ARTROMOT®-K3 is a motor-operated motion device used for **C**ontinuous **P**assive **M**otion (CPM) for 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 Therapy objectives

CPM therapy with **ARTROMOT®-K3** is mainly used to prevent the negative effects of immobilization, to allow patients to regain painless movement of joints at an early stage and to promote healing and achieve a positive functional result.

Other objectives of therapy include:

- improvement of joint metabolism
- prevention of joint stiffness
- promotion of the regeneration and healing of cartilage areas and damaged ligaments
- faster hematoma/fluid resorption
- improved lymph and blood circulation
- thrombosis and embolism prophylaxis

1.3 Indications

The CPM device is indicated in the treatment of most injuries and diseases of the knee and hip joints as well as in the postoperative treatment after knee and hip joint surgery. Examples:

- joint distortion and contusion
- arthrotomy and arthroscopy procedures in combination with synovectomy, arthrolysis or other intra-articular interventions
- mobilization of joints in anesthetized patients
- operative treatment of fractures, pseudarthrosis and corrective osteotomy
- cruciate ligament replacement or reconstruction
- endoprosthetic implants

1.4 Contraindications

Do NOT use **ARTROMOT®-K3** on patients with:

- acute inflammatory processes in the joints, unless on the order of a physician
- spastic paralysis
- unstable osteosynthesis

2. Description of the ARTROMOT®-K3

The motorized CPM device permits extension and flexion of the knee joint in the range of -5 ° - 0 ° - 110 °,

and of the hip joint in the range of

0 ° - 8 ° - 86 °.

It can be used on either side and requires no configuration change.

These are some of the

ARTROMOT®-K3 features:

- programming unit for precise adjustment of patient-specific therapy values
- symbols for easy operation of the programming unit

Biocompatibility

Those parts of the ARTROMOT®-K3 device that come into contact with the patient when the device is used as intended, are designed to fulfil the biocompatibility requirements of the applicable standards.

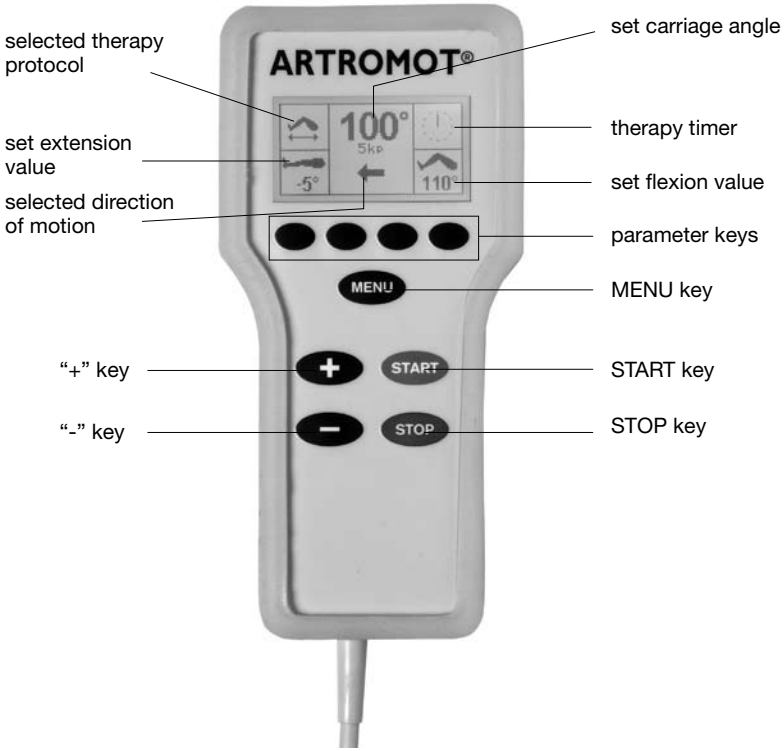
2.1 Description of the device components

Note: Please fold out page 2!

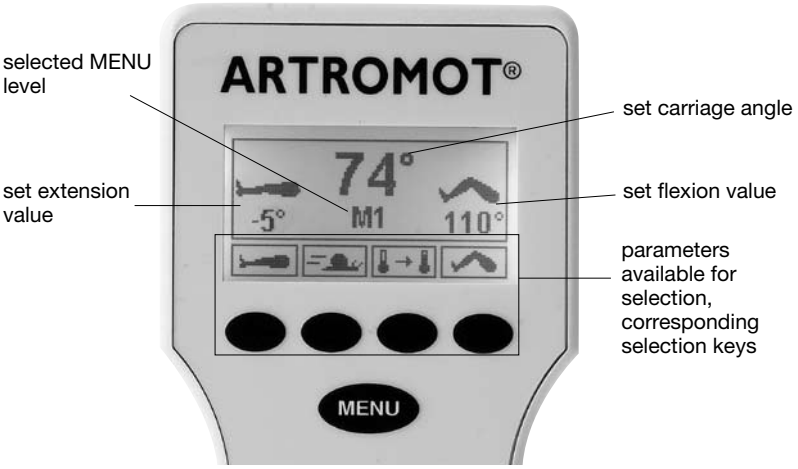
1. Compartment for storage of programming unit
2. Footplate with patient kit
3. Knobs for ankle adjustment of foot inclination
4. Knobs for length adjustment of lower leg
5. Lower leg patient kit
6. Knee pivot point
7. Knob for femur length adjustment
8. Thigh support
9. Thigh patient kit
10. Base
11. Coiled cord
12. Hand-held programming unit
13. Power switch (ON/OFF)
14. Fuse cap
15. Connection for power cord
16. Connection for programming unit
17. Knob for rotation of footplate

2.2 Description of the programming unit

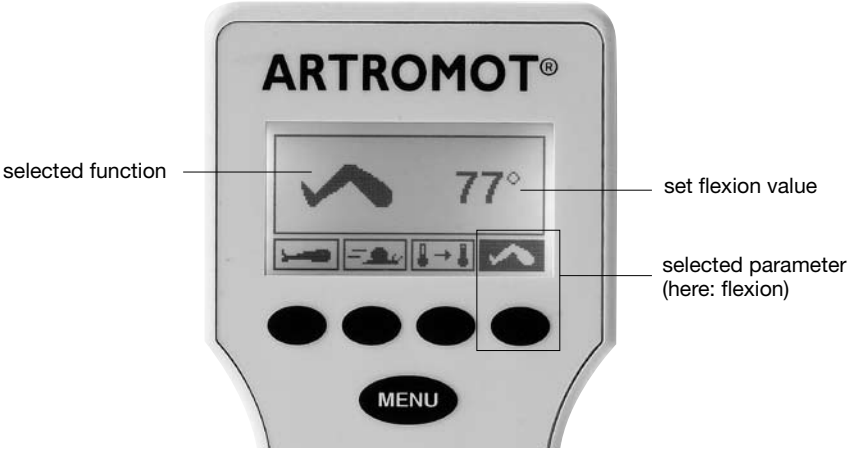
2.2.1 Programming unit in normal mode



2.2.2 Programming unit in MENU selection mode



2.2.3 Programming unit in programming mode



2.3 Explanation of symbols

Also refer to symbol overview on page 29

	extension (stretching the knee)
	flexion (bending the knee)
	speed
	warm-up protocol
	extension pause
	flexion pause
	therapy timer
	reverse on load feature for patient safety
	transport setting
	new patient
	total therapy time
	service menu

2.4 Explanation of symbols (connections and nameplate)

	alternating current
	protective earth connection
	type B applied part
O	power switch OFF
I	power switch ON
	Refer to accompanying documents
	Do not dispose of product with unsorted household or municipal waste.

3. Safety statements

Definitions

It is mandatory to read the safety statements before use of the CPM device. The safety statements are classified as follows:

⚠ Danger!

This term indicates an imminent hazard. If not avoided, this hazard will result in death or serious injury.

⚠ Warning

This term indicates a hazard. If not avoided, this hazard can result in death or serious injury.

⚠ Caution

This term indicates a potential hazard. If not avoided, this hazard can result in minor personal injury and/or product/property damage.

Safety information

⚠ Danger

Explosion hazard—

ARTROMOT®-K3 is not designed for use in areas where an explosion hazard may occur. An explosion hazard may result from the use of flammable anesthetics, skin cleansing agents and disinfectants.

⚠ Warning!

Patient hazard—

- Only authorized individuals are allowed to operate the **ARTROMOT®-K3** device. Individuals are authorized after receiving training in the operation of the device and reading this operation manual.
- Before using the device, the operator must ascertain that it is in correct working order and operating condition. In particular, the cables and connectors must be checked for signs of damage. Damaged parts must be replaced immediately, before use.
- **Before therapy**, a **test run** consisting of several exercise cycles must be completed, first without and then with the patient. Check that all setting screws are tightened.
- Stop therapy immediately, when you have doubts about the device settings and/or the therapy protocol.
- It is important that the patient‘s position is **anatomically correct**. Check the following settings/positions:
  1. femur length
  2. knee joint axis
  3. lower leg length and rotational position of the leg
  4. patient kits
- Movements must **not** cause **any pain or irritation**.
- Patients must be **fully conscious** while being instructed in the use of the CPM device and during therapy.

– The **choice** of the **therapy parameters** to program and of the **therapy protocols** to use is **restricted to** the responsible **physician** or **therapist**. It is the physician‘s or therapist‘s decision whether or not to use the CPM device on a specific patient.

– The patient must be familiar with the functions of the **ARTROMOT®-K3** programming unit and the unit must be **within easy reach** of the patient, allowing him or her to stop therapy, if needed. **Patients unable to operate** the **programming unit**, e.g. paralytic patients, must never be left unattended during therapy.

– All accessories used with the **ARTROMOT®-K3** device must first be approved by ORMED.

– Do not allow **parts of the body or any objects** (such as blankets, cushions or cables) to get caught **in the moving parts** of the CPM device.

⚠ Warning!

Shock hazard —

Strictly observe the following warnings. Failure to do so endangers the lives of the patient, the user and other persons involved.

– **Before use** allow the **ARTROMOT®-K3** to reach room temperature. If the device has been transported at **temperatures below 0 °C (32°F)**, leave it to dry at room temperature for about 2 hours, until any condensation has disappeared.

– The ARTROMOT®-K3 device must only be operated in **dry rooms**.

– When disconnecting the device from the power line, remove the plug from the wall outlet first, before disconnecting the cable from the device.

– When connecting the device to other equipment or when creating a medical system, check that the sum of leakage currents will not cause any hazard. Please contact ORMED, if you have questions in this matter.

– Do not use multiple portable socket outlets (MPSO) to connect the device to the power line. ARTROMOT®-K3 must be connected to a **properly installed wall outlet with a non-fused earthed wire**. Before connecting the power cord, it must be completely unrolled and placed such that it will not get caught in the moving parts of the device.

– Before cleaning and service interventions, **disconnect the device from the power line** by removing the power cord from the wall outlet.

– Liquids must not be allowed to enter the CPM device or the programming unit. If liquids have entered into the devices, ARTROMOT®-K3 must be immediately checked by a service technician, before it can be reused.

⚠ Warning!

Equipment malfunction —

– Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the CPM device comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems and cell phones are possible sources of interference as they may emit higher levels of electromagnetic radiation. Keep the CPM device away from these devices and verify its performance before use.

– Refer **repair** and **maintenance** to authorized persons.

– **Route all cables below the device frame to either side**, ensuring that they cannot get caught in the moving parts during operation.

– Inspect ARTROMOT®-K3 for damage and loose connections at least **once a year**. Damaged and worn parts must immediately be replaced with original spare parts by authorized staff.

⚠ Caution!

Preventing chafing and pressure sores — If your patient is adipose, very tall or very short, be sure to prevent chafing and pressure sores. Place the leg concerned in a moderate abductive position, if deemed appropriate.

⚠ Caution!

Equipment damage —

– Check that the voltage and frequency ratings of your local **power line** are those indicated on the nameplate.

– The leg support element withstands a **maximum continuous load** of **30 kg (66.13 lb**).

– Do not allow **any objects** (such as blankets, cushions, or cables) to get caught in the **moving parts** of the CPM device.

– Do not expose the ARTROMOT®-K3 device to direct sunlight, because some of the components may reach inadmissibly high temperatures.

4. Device setup

Note: For a better understanding of each step, please fold out pages 3 and 32.

4.1 Connecting the device, performance check

1. Connect the **power cord** to socket (15) of the device and connect the mains plug to a wall outlet with a non-fused earthed wire (100 to 240 Volt, 50/60 Hz).
2. Connect the **programming unit** (12) to socket (16) of the device.
3. Turn the **power switch** (13) on.
4. Follow these steps to set the carriage to the **home position**:
   - Press the **MENU** button on the programming unit until you reach programming level 3.
   - Press the New Patient parameter key →0← .
   - Press the **START** key. The CPM device automatically enters the **home position**.

Performance check

If the programming unit can be operated as described above and **ARTROMOT®-K3** enters the home position (for home position values, refer to section 5.3), the device has passed the performance check.

The device also runs performance checks regularly during operation. This is what happens, if a problem is identified:

– An audio signal sounds.

– The device switches off immediately.

– The message „ERR“ and an error code (e.g. ERR 5) appear on the display.

In this situation, you may attempt to restart the device by turning it briefly off and on again with the power switch. If the error message persists, have the device inspected by a Service technician, before using it again.

⚠ Caution!

Equipment damage—

Connect only the original programming unit designed for the device in use. Any attempt to connect another programming unit to this device may cause damage.

4.2 Mechanical Settings

1. Set the carriage to the home position (see 4.1) or to an angle that allows the patient to position the leg on the support without experiencing any pain.
2. Adapting the carriage to the femur length (Fig. 2)
   - Loosen the two fixation screws (7).
   - Adjust the appropriate femur length (8).
   - Tighten the screws (7) to fix the setting.

⚠ Caution!

Equipment damage—

Please do not try to pull out the femur length adjustment past the stop.

3. Adapting the carriage to the tibia length (Fig. 3)
   - Loosen the two fixation screws (4).
   - Adjust the appropriate tibia length. The setting should exactly match the length of the patient‘s lower leg.
   - Tighten the screws (4) to fix the setting.

4. Adjusting the dorsal extension / plantar flexion position (Fig. 4)
   - Loosen the two fixation screws (3).
   - Set the foot plate (2) to an angle that is comfortable for the patient.
   - Tighten the screws (3) to fix the angle setting.

5. Adjusting the foot rotation position (Fig. 5)
   - Loosen the fixation screw (17).
   - Set the foot plate (2) to a rotation position that is comfortable for the patient.
   - Tighten the screw (17) to fix the setting.

4.3 Adjusting the Patient Kit

1. Using the Velcro tapes, attach the patient kits for lower leg (5) and thigh (9) to the frame of the motion element. (Fig. 6 an Fig. 7)
2. Now position the patient‘s leg on the carriage and adjust the height with the help of the Velcro tapes and by repeating the steps at 1.

Ensure that the exercise will only be performed in a range of motion that does not cause any pain and provides maximum comfort for the patient,

⚠ Caution!

Patient hazard —

Ensure that the rotational axes of the CPM device and of the knee joint coincide both in the vertical and in the horizontal plane (Fig. 8).

5. Setting the treatment values

⚠ Warning!

Patient hazard —

Before therapy, a **test run** consisting of several exercise cycles must be completed without the patient. Then repeat the test run with the patient and check that the movement does not cause any pain.

Note: See also 2.2 and 2.3 as well as page 29!

5.1 General information on programming ARTROMOT®-K3

1. You activate the programming mode by briefly pressing the **MENU** key on the programming unit.
2. The treatment parameters and functions are allocated to three programming levels (four per level).
   To be able to program a parameter you will have to access the corresponding programming level. This is also done with the **MENU** key. With each key press you advance one level. The code M1, M2, etc. that appears in the middle of the display indicates the programming level.

   If you wish to return to the previous programming level (e.g. from level 3 to 2), press the **MENU** key and hold it pressed for a short time.
3. You activate the treatment parameters and functions with the four parameter keys below the display. The symbols above the **four parameter keys** indicate the assigned parameters and functions.
   This is what happens when you press one of the parameter keys to select a parameter:
   - The corresponding symbol appears on the display in a larger format.
   - The set value is displayed.
   - The symbol above the parameter key appears in reverse video.
4. With the **+ / -** keys (plus/minus) you change the displayed value. When you press and hold the key, the value will change at a higher rate.
   Some of the (special) functions can only be enabled and disabled. This is done by pressing the corresponding parameter key or with the + / - keys. Active parameters are identified with a check mark in the circle next to the symbol.
5. Then press the **START** key to start therapy.
   If a special function is activated, the carriage will first move to the middle position. Press the **START** key again to start therapy.

Note!

- Refer to section 5.3 for a description of the parameters.
- To **view** the **set parameter values**, press the corresponding parameter key. However, this is only possible when you press the **STOP** key first.
- To prevent accidental changes of the parameter settings, **lock the keys** by simultaneously pressing the **+ (plus) and – (minus)** keys.

Press both keys again to unlock.

- **Emergency stop function**: ARTROMOT®-K3 will stop immediately, when any of the keys is pressed during therapy. Patient treatment can be resumed by pressing the START key. The device will automatically change the direction.

- If the carriage is positioned within the programmed range of motion at the time therapy begins, the therapy session will start immediately.
- If the carriage is positioned outside the programmed range of motion at the time therapy begins, it will first move to the angle setting „extension +10°“. It will stop in this position and you can start the therapy session by pressing the START key.

5.2 Programming ARTROMOT®-K3

To program the different settings of the **ARTROMOT®-K3**, access the respective programming level.

You change between levels by pressing the **MENU key** repeatedly.

The display always indicates the currently selected level.

The following **treatment values, settings** and **information** can be entered/viewed on the programming unit (12):

LEVEL 1:

- Extension (stretching the knee)
- Speed
- Warm-up protocol
- Fexion (bending the knee)

MENU

LEVEL 2:

- Extension pause
- Therapy timer
- Reverse on load feature for patient safety
- Flexion pause

MENU

LEVEL 3:

- Transport setting
- New patient
- Total therapy time
- Service menu

Note!

It is possibe to modify individual treatment parameters or all parameters together. If individual treatment parameters are modified, the settings of all other parameters remain unchanged.

5.3 Therapy parameter details

- You access the different programming levels by repeated depressions of the **MENU key**.
- You select the treatment parameters with the corresponding **parameter key**.
- You change the treatment values with the **+ / - keys** and you enable/disable functions by pressing the corresponding parameter key again.
- You save the settings by pressing the **STOP key**.

LEVEL 1:

■ **Extension (stretching)**

- Maximum **knee extension: -5 degrees**
- Maximum **hip extension: 8 degrees**

■ **Flexion (bending)**

- Maximum **knee flexion: 110 degrees**
- Maximum **hip flexion: 86 degrees**

Note!

The programmed value and the value measured at the patient‘s knee may deviate slightly.

■ **Speed**

The speed can be adjusted between 1 % and 100 % in steps of 1 %.
Default: 100 %

■ **Warm-up protocol**

During warm up, the patient will slowly become used to the set maximum extension and flexion values, starting from the center position.

The warm up protocol starts in the middle between the two maximum values set for stretching and bending. With each cycle, the range of motion is increased, within 15 cycles the maximum value is attained.
Default: disabled

LEVEL 2:

■ **Extension pause**

Pauses occur at the extension limit, just before the bending movement starts. Pauses are adjustable in steps of 1 second between 0 and 30 seconds.
Default: no pause

■ **Flexion pause**

Pauses occur at the flexion limit, just before the stretching movement starts. Pauses are adjustable in steps of 1 second between 0 and 30 seconds.
Default: no pause

■ **Therapy timer**

Default setting is continuous operation.

A clock symbol in the upper right-hand corner of the display identifies the **continuous mode** of operation. The clock indicates the elapsed therapy time.
In the continuous mode, the device must be stopped with the **STOP** key.

However, the therapy timer can be set in steps of 1 minute to any value between 1 and 300 minutes.

When the time has elapsed, the device switches **automatically** off and stops in the position - set extension value +10°.

In this case, a circle replaces the clock symbol. The circle fills as the therapy time progresses.

■ **Reverse on load feature for patient safety**

The device automatically starts moving in the opposite direction of the last movement when the patient's resistance (load) exceeds the set value. Adjustable levels for reverse on load feature: 1-25

minimum setting **1 = 25 kp**

maximum setting **25 = 45 kp**

At 1/25 kp very little resistance will cause the device to reverse;
at 25/45 kp, a high resistance is required to initiate the reversal.
Default: 45 kp

Note!

- These values are approximate values.
- The force needed is measured at the frame around the foot.

⚠ Caution!

Patient hazard —

The reverse on load feature is a safety measure to protect the patient in the event of cramps, spasms, locked joints and similar situations. The manufacturer cannot be held liable for misuse of this feature.

LEVEL 3:

■ **Transport setting**

With this function, the carriage will move to a position optimally suited for packing the CPM device. Select the function and press the **START** key. The carriage moves to the transport position.

■ **New patient** →0←

With this function, the CPM device will move to the home position, allowing the mechanical settings to be completed. Select the function and press the **START** key. The device enters the home position and existing therapy parameters will be deleted.

The „new patient“ function (home position) selects the following settings:

- extension: 25 °
- flexion: 35 °
- speed: 100 %
- warm up: disabled
- extension pause: 0
- flexion pause: 0
- timer: continuous operation
- reverse on load: 45 kp
- total therapy time: 0

■ **Total therapy time** ∑

The total therapy time is the added sum of operating hours.

If the device is used by only one patient, this time is equivalent to the duration of all the patient‘s therapy sessions.

Deleting the stored therapy time
Press and hold the parameter key for 5 seconds or select the New Patient function.

■ **Service menu**

For service purposes only, refer to Service Manual.

Reminder

You save the selected parameter values by pressing the **STOP** key.

6. Care, Maintenance

6.1 Care

⚠ Warning!

Shock hazard —

Remove the power cord from the wall outlet before cleaning.

Shock hazard, equipment damage
Liquids must not enter the device or the programming unit.

- ARTROMOT®-K3 can be disinfected by **wiping down** with a disinfectant. Thus, it complies with the special hygiene standards for medical technical equipment.
- **The enclosure** can be cleaned with common **disinfectants** and **mild household** cleaning agents.
- Only use a damp cloth to wipe the CPM device down.

⚠ Caution!

Equipment damage —

– The plastic material used is **not resistant** to mineral acids, formic acid, phenols, cresols, oxidants and strong organic or inorganic acids with a pH value below 4.

– Use only clear disinfectants to prevent discoloration of the device.

– Do not expose the CPM device to strong ultraviolet radiation (sunlight) and fire.

– Do not use cleaning agents that contain chloride.

6.2 Maintenance (fuse replacement)

Check before each use

Visually inspect the device for signs of mechanical damage before each use.

If you detect damage or malfunctions that may impair the safety of the patient or of the operator, have the device repaired before using it.

Technical inspections

For safety, the devices require regular maintenance. To maintain the functional and operational safety, check all components for damage and loose connections at least once a year.

These checks should be performed by persons with adequate training and experience. Damaged and worn parts must immediately be replaced with original spare parts by authorized staff.

The device does not require additional regular maintenance.

Fuse replacement

⚠ Warning!

Patient hazard, equipment malfunction and damage —

The replacement of fuses must be referred to specialists as defined in IEC 60364 or other applicable standards (e.g. biomedical technicians, electricians, electronics installers).

Before replacing fuses, turn off the ARTROMOT®-K3 and disconnect the device from the power line.

Fuses used must be T1A fuses.

Use an appropriate tool to remove the fuse holder situated between the power switch and the power connector (Fig. 1). Replace the fuses and reinsert the fuse holder (Fig. 2). Ensure that the fuse holder properly locks into place.

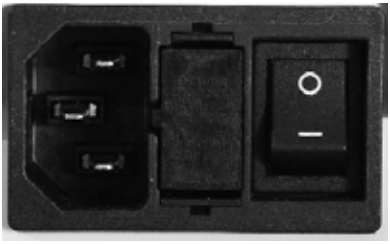


Fig. 1

Fig. 2

7. Environmental Protection Statement

The product described in this operation manual must not be disposed of with unsorted household or municipal waste. It requires separate disposal.

Please contact ORMED or your local dealer for information about the possible recycling of the product.

8. Specifications

Input ratings:	100 – 240 V AC / 50 – 60 Hz
Current consumption:	850 - 370 mA
Fuses:	2 x T1A (slow-blow)
Protection class:	I
IP degree of protection:	IPX0
Applied part:	type B
Max. load on carriage:	30 kg (66.13 lb)
Physical:	
Length:	93 cm (36.61 In)
Width:	35 cm (13,78 In)
Height:	43 cm (16.93 in)
Adjustment ranges (min./max.):	
femur range:	approx. 36 – 46 cm (14.17 – 18.11 In)
lower leg range:	approx. 42.5 – 56 cm (16.73 – 22.04 In)
Weight:	11.8 kg (26.01 lb)

Materials used:
ABS, POM (Delrin 100), PUR, PA, FR4, aluminum, stainless steel, brass
Steel: 1.4301; 1.4305; 1.4310

MDD: class 2a

Standards compliance:	IEC 60601-1:1988 + A1:1991 + A2: 1995
Certification:	ANSI / UL 60601-1
	CAN / CSA C22.2 No. 601.1
EMC (electromagnetic compatibility)	IEC 60601-1-2:2001
Ambient conditions (storage, transport)	
Ambient temperature:	-24 ºC to +60 ºC (50 to +104 °F)
Relative humidity:	20 % to 85 %
Atmospheric pressure:	700 hPa to 1060 hPa
Ambient conditions (operation)	
Ambient temperature:	+10 ºC to +40 ºC (50 to +104 °F)
Relative humidity:	30% to 75%
Atmospheric pressure:	700 hPa to 1060 hPa

Subject to change without notice (10/07)

9. IEC 60601-1-2:2001

The ARTROMOT®-K3 device is subject to particular precautions regarding electromagnetic compatibility (EMC). The device must be installed and put into service strictly in compliance with the EMC directives put forth in the accompanying documents.

Portable and mobile RF communication systems may affect the ARTROMOT®-K3 device.

The ARTROMOT®-K3 device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, ARTROMOT®-K3 should be observed to verify normal operation in the configuration in which it will be used.

If you detect damage or malfunctions that may impair the safety of the patient or of the operator, have the device repaired before using it.

If it is necessary to replace assemblies or cables

only the manufacturer‘s original parts may be used to ensure

continued compliance with EMC requirements after repair. This requirement applies to the power supply unit, cables and cable lengths, drive unit consisting of the motor and the control system, the programming unit incl. the coiled cable and the connector.

Electromagnetic emissions

9.1 Electromagnetic emissions

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

ARTROMOT®-K3 is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the **ARTROMOT®-K3** device is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions to CISPR 11	Group 1	ARTROMOT®-K3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions to CISPR 11	Class B	ARTROMOT®-K3 is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions to IEC 61000-3-2	not applicable	
Voltage fluctuations/flicker emissions to IEC 61000-3-3	not applicable	

9.2 Electromagnetic immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

ARTROMOT®-K3 is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the **ARTROMOT®-K3** device is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) to IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst to IEC 61000-4-5	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power should be that of a typical commercial or hospital environment.
Surges to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines to IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 seconds	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	Mains power should be that of a typical commercial or hospital environment. If the user of the ARTROMOT®-K device requires continued operation during power mains interruptions, it is recommended that the ARTROMOT®-K3 device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

9.2 Electromagnetic immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

ARTROMOT®-K3 is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the **ARTROMOT®-K3** device is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment are used no closer to any part of the ARTROMOT®-K3 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF to IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms	d =
Radiated RF to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 80MHz to 800 MHz
			d = 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a , is less than the compliance level in each frequency range b.. Interference may occur in the vicinity of equipment marked with the following symbol 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ARTROMOT®-K3 device is used exceeds the applicable RF compliance level above, the ARTROMOT®-K3 device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ARTROMOT®-K3 device.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

9.3 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the ARTROMOT®-K3 device

The ARTROMOT®-K3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARTROMOT®-K3 device can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARTROMOT®-K3 device as recommended below, according to the maximum output power of the communications equipment.

rated maximum output power of transmitter W	**separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: For calculation of the recommended separation distance of transmitters in the frequency range from 80 MHz to 2.5 GHz an additional factor of 10/3 was taken into account to reduce the probability of mobile/portable communications equipment brought into the patient environment by accident causing any malfunction.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

10. Contact

We would be happy to answer any questions you may have about our products and services.

■ **Ormed international**
Please contact your local dealer or the ORMED headquarters in Germany.

■ **Headquarters Germany**
Ormed GmbH & Co. KG
Merzhauser Strasse 112
D-79100 Freiburg - Germany
Tel. +49/761/45 66-01
Fax +49/761/45 66 55-01

■ **Website**
www.ormed.de
e-mail: info@ormed.de

Warranty:
2 years (mechanical parts)
2 years (electronics)

Sales:
Ormed GmbH & Co. KG
Merzhauser Strasse 112
D-79100 Freiburg - Germany

11. Technical service

11.1 Technical Hotline

Do you have any technical questions?
Do you need technical service?

Telephone: +49-180-5-1 ormed de
+49-180-5-1 67 63 33
Fax: +49-180-5-3 ormed de
+49-180-5-3 67 63 33

11.2 Shipment

To prevent damage during transport, only use the original shipping box. These boxes can be obtained from ORMED or from your local dealer.

Before packing the CPM device, set it to the transport position (see chapter 5).

11.3 Spare Parts

Refer to the Service Manual for the most recent list of spare parts. The Service Manual can be obtained from ORMED or from your local dealer.

When ordering spare parts, always specify:

- item
- Description
- Part number
- Qty
- Serial number of the CPM device

Note!

Refer repairs to authorized, specially trained staff.

DECLARATION OF CONFORMITY

Declaration of conformity

In compliance with the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, the company

ORMED GmbH & Co.KG
Merzhauser Strasse 112
D-79100 Freiburg - Germany

declares that the products of the product line

ARTROMOT® (see Annex)

fulfill the requirements of the Council Directive 93/42/EEC of 14 June 1993, Annex II as well as the essential requirements of Annex I.

With reference to Rule 9 of the Directive 93/42/EEC, these products are devices of risk class IIa.

CE
0297

Freiburg, 22.10.07

- QA Management Representative -

This certificate is valid through: 22. October 2010

Annex:

ARTROMOT®-S2PRO
ARTROMOT®-S3
ARTROMOT®-S3 Comfort
ARTROMOT®-K1
ARTROMOT®-K2
ARTROMOT®-K2PRO
ARTROMOT®-K2PRO Chip
ARTROMOT®-K3
ARTROMOT®-K4
ARTROMOT®-SP2
ARTROMOT®-SP3
ARTROMOT®-E2
ARTROMOT®-E2compact

Symbol overview

LEVEL 1:

Extension (stretching)

speed

warm-up protocol

Flexion (bending)

LEVEL 2:

pause Extension

Therapy Time

reverse on load feature for patient safety

pause Flexion

LEVEL 3:

transport setting

new patient

total therapy time

Service Menu

Notes

Notes

Illustrations for device setup

Fig. 2

Fig. 3

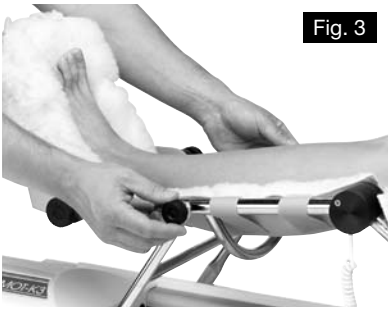


Fig. 4

Fig. 5

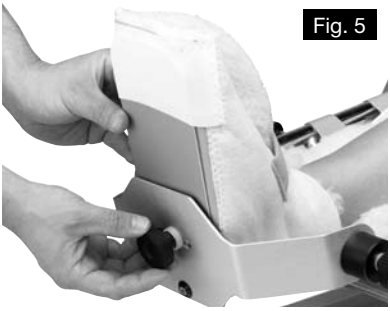


Fig. 6

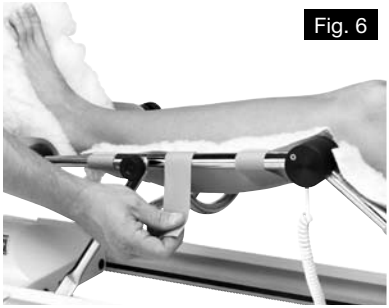
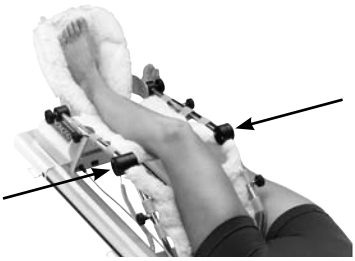


Fig. 7

Fig. 8



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