

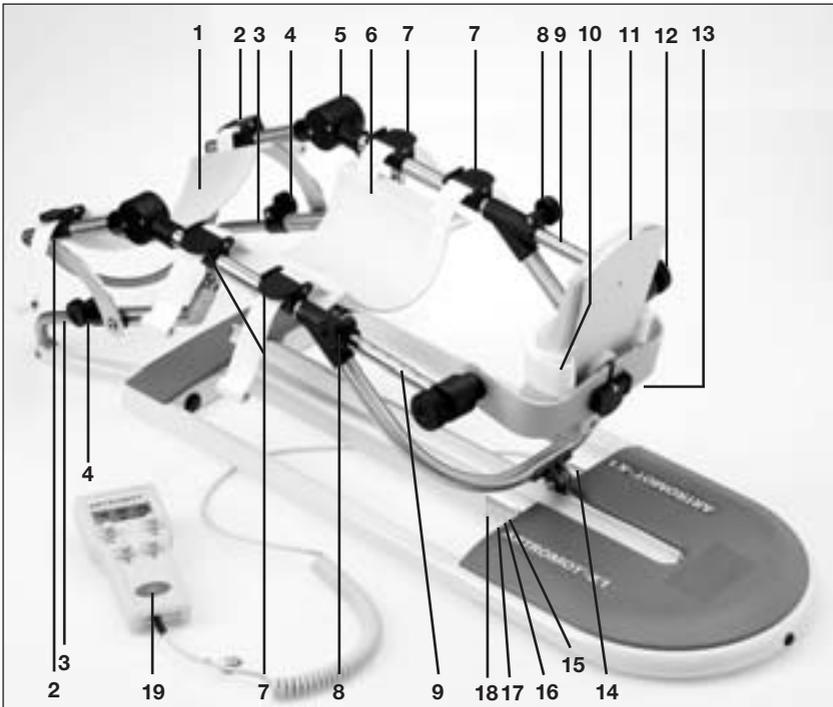
ARTROMOT®-K1 classic



USA/GB

Operation Manual

Device description



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1. How to use the CPM device

1.1 Fields of application

ARTROMOT®-K1 classic is a motor-operated **C**ontinuous **P**assive **M**otion (**CPM**) device used to mobilize 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®-K1 classic** is mainly used to prevent the negative effects of immobilization, to allow patients to regain painless mobility 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 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, pseudoarthrosis and osteotomy
- cruciate ligament replacement or reconstruction
- endoprosthetic implant

1.4 Contraindications

Do NOT use **ARTROMOT®-K1 classic** on patients with:

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

2. ARTROMOT®-K1 classic description

The motorized CPM device permits extension and flexion of the knee joint in the range of $-10^{\circ}/0^{\circ}/120^{\circ}$, and of the hip joint in the range of $0^{\circ}/7^{\circ}/115^{\circ}$.

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

These are some of the outstanding **ARTROMOT®-K1 classic** features:

- anatomically correct setup
- physiological movements
- programming unit for precise adjustment of patient-specific therapy parameters
- symbols for easy operation of the programming unit

Biocompatibility

The parts of the **ARTROMOT®-K1 classic** device that come in contact with the patient during the intended use, are designed to fulfill the biocompatibility requirements of the applicable standards.

2.1 Description of the device components

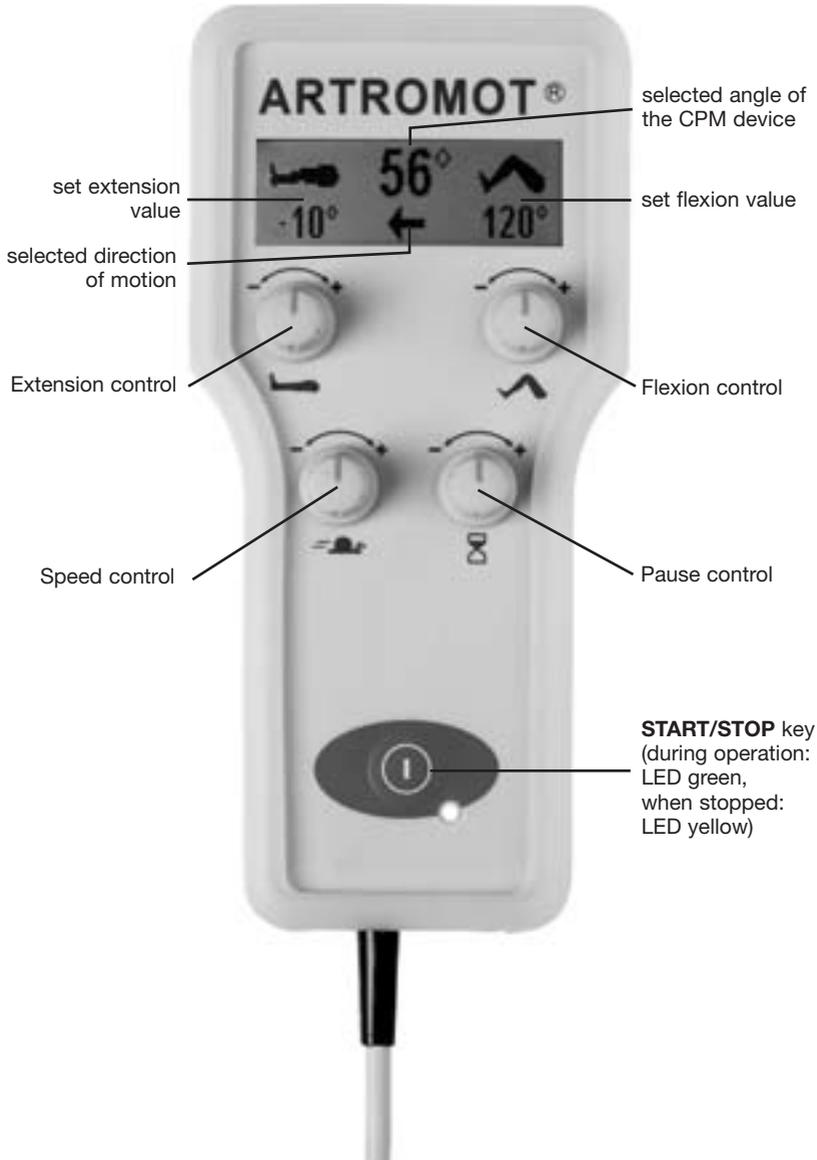
Note: Please fold out page 3!

1. Thigh support assembly
2. Clamping lever to adjust the height of the thigh support assembly
3. Thigh length scale (femur length scale)
4. Thigh length fixation screws (femur length)
5. Knee hinge
6. Calf support assembly

7. Clamping lever to adjust the height of the calf support assembly
8. Calf length fixation screws (tibia length)
9. Calf length scale (tibia length scale)
10. Strap to secure the foot to the footplate
11. Footplate
12. Footplate angle fixation screw
13. Clamping lever to adjust footplate rotation and level and to remove the footplate
14. Connection for programming unit
15. Connection for power cord
16. Fuse cap
17. Power switch (ON/OFF)
18. Nameplate
19. Programming unit

2.2 Description of the programming unit

2.2.1 Programming unit in normal mode



2.2.2 Programming unit in speed or pause programming mode



2.3 Explanation of symbols

Symbols on the programming unit:

	Extension (stretching the knee)
	Flexion (bending the knee)
	Speed
	Pause (extension and flexion)

Symbols that may appear in the display

	Go to start position (see Notes in 4.1)
	Controls on programming unit locked (see Notes in 5.1)
	Controls on programming unit unlocked (see Notes in 5.1)
	Service menu activated, for service purposes only (also refer to Service Manual)

2.4 Explanation of symbols (connections and nameplate)

	Alternating current
	Protective earth connection
	Type B applied part
	Power switch OFF
	Power switch ON
	Refer to accompanying documents
	Do not dispose product with unsorted household or municipal waste.

3. Safety information

Introduction and definitions

Read the safety statements before use of the CPM device. The safety statements are classified as follows:

DANGER!

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

WARNING!

Indicates a hazard. If not avoided, this hazard can result in death or serious injury.

CAUTION!

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®-K1 classic 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®-K1 classic 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, with original spare parts.
- **Before therapy**, a test run consisting of several exercise cycles must be completed, first without and then with the patient. Check that all fixation screws are tightened.
- Stop therapy immediately, when you have doubts about the device settings and/or the therapy protocol.

WARNING!

Patient hazard –

- It is important that the **patient's position is anatomically correct**. Therefore, carefully verify the following settings/positions:
 1. femur length
 2. knee joint axis
 3. tibia length and leg rotation
 4. leg support assemblies
- Movements must **not cause pain or irritation**.
- Patients must be **fully conscious** while being instructed in the use of the CPM device and during therapy.
- Only the responsible **physician or therapist** is able and allowed to choose the **therapy parameters** to use. 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®-K1 classic 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.
- Any **accessories** used with **ARTROMOT®-K1 classic** must first be approved by ORMED.
- Do not allow **parts of the body or 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.

- Allow **ARTROMOT®-K1 classic** to reach room temperature **before use**. If the device has been transported at **temperatures below 0 °C/ 30°F**, leave it to dry at room temperature for about 2 hours, until any condensation has disappeared.
- The **ARTROMOT®-K1 classic** 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®-K1 classic** 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 by 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®-K1 classic 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 and radio systems 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 by the moving parts during operation.
- **Inspect** ARTROMOT®-K1 classic 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 –

When your patient is **adipose, very tall or very short**, be sure to prevent chafing and pressure sores. Place the leg concerned in a moderate abduction 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 20 kg**.
- 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®-K1 classic 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 150.

4.1 Connecting the device, performance check

1. Connect the **power cord** to socket (15) of the device and **mains plug** to a wall outlet with a non-fused earthed wire (100 to 240 Volt, 50/60 Hz).
2. Turn the **power switch** (17) on.
3. Follow these steps to set the carriage to the **home position**.

Press the **Extension** key



and, holding it depressed, rotate until **30°** appears in the display above the control.

In the same manner, select a **Flexion** value of **35°**.



Then press the **START/STOP** key.

When the carriage has reached this range and does not stop automatically, press the **START/STOP** key again to stop any movement.

Note!

ARTROMOT®-K1 classic will stop automatically in the home position range, only if it was positioned outside this range (30° to 35°) at the time of programming (also refer to 5.2)

Performance check

If the programming unit can be operated as described above and

ARTROMOT®-K1 classic enters the home position (for home position values, refer to section 4.1), 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 "ERROR", accompanied by a code number (e.g. ERROR 5), appears on the display.

In this situation, you may attempt to restart the device by turning the device 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.

4.2 Adjusting the device to the femur length

1. Measure the **length of the patient's thigh (femur)** from the greater trochanter to the lateral knee joint cavity (Fig. A).
2. Set the carriage to the home position (see 4.1).
3. Set the measured value at the **femur scale** (3) of the carriage.
 - Loosen the two fixation screws (4).
 - Extend the scale (3) to the required length.
 - Tighten the fixation screws (4) to set the scale to the new length.

CAUTION!

Equipment damage –

Do not attempt to extend the femur scale beyond the stop.

4.3 Adapting the leg support assemblies/footplate

1. Set the **leg support assemblies** and the **footplate** (1, 6, 11) to the expected positions before accommodating the patient.
 - Loosen fixation screws (8) to adjust the **footplate** (11) to the length of the patient's lower leg (Fig. C).

Loosen clamping lever (13) and adapt the footplate's rotation and height to the patient (Fig. D).

Loosen fixation screw (12) and adapt the angle to the patient's foot (turn the screw a few revolutions until the footplate can be easily adjusted).

For **short patients** you can reverse the footplate's bracket 180° (Fig. H) to adapt the footplate to shorter calves:

- Loosen clamping lever (13) and remove the footplate (11).
- Loosen the fixation screws (12).
- Reverse the bracket 180°.
- Screw the footplate to the bracket and tighten the clamping lever.

Note!

When reversing the footplate, ensure that the pins below the clamping lever engage with the recesses in the bracket.

- To adjust the height of the **support assemblies for calf (1) and thigh (6)**, loosen clamping levers (2) and (7) (Figs. E/F).

2. Place the patient's leg on the carriage and repeat the steps outlined under 1 above to adjust the device to the patient.

⚠ CAUTION!

Equipment damage –

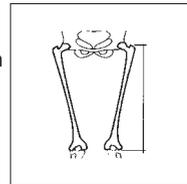
Cover the leg **support assemblies with disposable tissues** when using ARTROMOT®-K1 classic immediately after surgery. This helps prevent discoloration.

⚠ CAUTION!

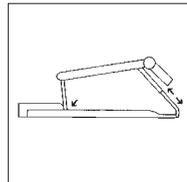
Patient hazard –

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. G).

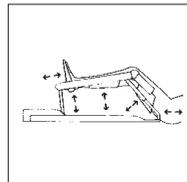
Symbol 1:
Measurement of the patient's femur length from the greater trochanter to the knee joint cavity



Symbol 2:
Set the carriage to the home position (see 4.1) and adjust it to the measured femur length.



Symbol 3:
Adjust height of calf and thigh support assemblies. Adjust the footplate to the height and length of the lower leg.



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 150!

5.1 General information on programming ARTROMOT®-K1 classic

1. You activate a function by briefly pressing a control on the programming unit.
2. You select a treatment value by pressing the respective control and turning it in either direction.

You increase a value by turning the control clockwise towards the + (**plus**) symbol and you decrease a value by turning the control counter-clockwise towards the - (**minus**) symbol.

For the first 5° the values in the display change in steps of 1°, then the interval changes to 5° so that you reach the target value faster.

During adjustment of the extension and flexion angles, the values in the display change as you turn the control after pressing it.

When adjusting speed or pause, the information shown in the display changes automatically as you press the control.

The selected parameter (speed or pause) is immediately represented by its symbol in a large format plus the current value (also refer to 2.2.2).

The current value can be changed by turning the depressed control.

When you have set the new value, release the control and the standard display reappears automatically after approx. 5 seconds (see also 2.2.1).

3. Subsequently press the **START/STOP** key to start therapy.

Note!

Refer to sections 5.2 for a description of the parameters.

- To prevent accidental changes of the parameter settings, lock the programming unit by simultaneously pressing the "Extension" and "Speed" controls.



Press both controls again to unlock.



- **Emergency stop function:** ARTROMOT®-K1 classic will stop immediately, when any of the keys is pressed during therapy. Patient treatment can be resumed by pressing the **START/STOP** 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 starts, it will first enter the position "extension +10°". The carriage will stop in this position and you can initiate the therapy session by pressing the START/STOP key again.

5.2 Information about the ARTROMOT®-K1 classic therapy parameters

- You select a function by pressing the corresponding control
- You change the treatment values by turning the depressed control.
- You initiate the treatment session by pressing the **START/STOP** key

■ Extension (stretching)

- Maximum **knee extension**:
-10 degrees
- Maximum **hip extension**:
7 degrees

■ Flexion (bending)

- Maximum **knee flexion**:
120 degrees
- Maximum **hip flexion**:
115 degrees

Note!

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

■ Speed

The speed can be adjusted between 5 % and 100 % in steps of 5 %.
Default setting: 50 %

■ Pauses

Pauses occur at the selected limits where stretching turns into bending and bending into stretching (selected extension and flexion values). The value entered applies to both extension and flexion pause.

Pauses can be set to any value between 0 and 59 seconds in steps of 1 second, and to values between 1 and 59 minutes in steps of 1 minute.

When selecting the seconds, the value changes in 1-second steps for the first five seconds. Subsequently the interval changes to 5-second steps.

The minutes are always adjusted in 1-minute steps.

Default setting: no pause

6. Care, maintenance, transport

6.1 Care

WARNING!

Shock hazard –

Unplug the device from the power line before cleaning.

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

- **ARTROMOT®-K1 classic** can be **disinfected** by wiping down with a disinfectant. Thus, it complies with the special hygiene standards for medical technical equipment.
- The **enclosure** and removable **leg support assemblies** can be cleaned with commonly used **disinfectants** and **mild household detergents**.
- Use only a **damp cloth** to wipe the carriage down.

Clean the sheath of the programming unit on a regular basis. Remove it from the programming unit before cleaning. Allow the sheath to dry before inserting the programming unit again.

CAUTION!

Equipment damage –

- The plastic material used is not resistant to mineral acids, formic acid, phenols, cresols, oxidizing agents 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.

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 checks can be carried out by ORMED within the framework of a service agreement.
Contact ORMED for details.

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 similar standards (e.g. biomedical technicians, electricians, electronics installers).

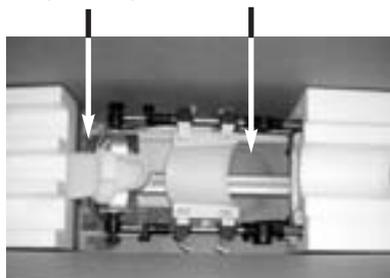
Fuses used must be T1A fuses.

6.3 Transport

Follow these steps to prepare the ARTROMOT®-K1 classic for transport:

1. Adjust the femur length to 49 cm and the tibia length to 45 cm.
2. Set the carriage to 0° by pressing the START/STOP key when the carriage is in the 0° position. This will stop the carriage in that position.
3. Push the power switch to turn off the ARTROMOT®-K1 classic.
4. Disconnect the power cord and the programming unit.
5. The device must be stored in its original shipping box for transport. ORMED GmbH & Co. KG cannot be held liable for damage in transit, if the original shipping box was not used.
6. Insert the programming unit into the space provided in the molded polystyrene pads and secure with adhesive tape.
7. Set the footplate to a horizontal position.
8. Now slide the polystyrene pads onto the ARTROMOT®-K1 classic.
9. Place the power cord at the bottom of the box before inserting the ARTROMOT®-K1 classic including the polystyrene pads.

Programming Unit Power Cord



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 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

Protection class: I

Applied part: type B

Max. load on carriage: 20 kg

Dimensions

length: 96 cm
width: 35 cm
height: min. 23 cm to
max. 56 cm

Adjustment ranges (min./max.):

Femur range: approx. 31 – 49 cm

Lower leg range: approx. 25 – 57 cm

Weight: 11 kg

Materials used: ABS, POM (Delrin 100), PUR, PA, FR4, aluminium, stainless steel, brass

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)
 temperature: -24 °C to +60 °C (-12 °F to +140 °F)
 relative humidity: 20 % to 85 %
 atmospheric pressure: 700 hPa to 1060 hPa

Ambient conditions (operation)
 temperature: +10 °C to +40 °C (50 °F to +104 °F)
 relative humidity: 30 % to 75%
 atmospheric pressure: 700 hPa to 1060 hPa

Subject to change without notice. (08/06)

9. IEC 60601-1-2:2001

The **ARTROMOT®-K1 classic** 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®-K1 classic** device.

ARTROMOT®-K1 classic should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, **ARTROMOT®-K1 classic** should be observed to verify normal operation in the configuration in which it will be used.

We can guarantee the specified electromagnetic emission and immunity data only if the manufacturer's original spare parts are used in repair and maintenance of the device.

9.1 Electromagnetic emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

ARTROMOT®-K1 classic is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the **ARTROMOT®-K1 classic** device is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions to CISPR 11	Group 1	ARTROMOT®-K1 classic 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®-K1 classic 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®-K1 classic is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the **ARTROMOT®-K1 classic** 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	± 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	± 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 $\frac{1}{2}$ cycle $40\% U_T$ (60% dip in U_T) for 5 cycle $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 s	$< 5\% U_T$ ($> 95\%$ dip in U_T) for $\frac{1}{2}$ cycle $40\% U_T$ (60% dip in U_T) for 5 cycle $70\% U_T$ (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®-K1 classic device requires continued operation during power mains interruptions, it is recommended that the ARTROMOT®-K1 classic 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. Portable and mobile RF communications equipment are used no closer to any part of the ARTROMOT®-K1 classic device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

ARTROMOT®-K1 classic is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the **ARTROMOT®-K1 classic** device is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
			Recommended separation distance:
Conducted RF to IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 V _{rms}	$d = 1.2\sqrt{P}$
Radiated RF to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			<p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and^a is the recommended separation distance in meters (m).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol</p> 

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®-K1 classic** device is used exceeds the applicable RF compliance level above, the **ARTROMOT®-K1 classic** 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®-K1 classic** 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 between portable and mobile RF communications equipment and the ARTROMOT®-K1 classic device.

The **ARTROMOT®-K1 classic** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **ARTROMOT®-K1 classic** device can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **ARTROMOT®-K1 classic** 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 $d = 2.3\sqrt{P}$
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. How to reach us

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

■ ORMED international

Please contact your local dealer or the ORMED headquarters in Germany.

■ Headquarters Germany

ORMED GmbH & Co. KG
Merzhauser Straße 112
79100 Freiburg - Germany
Tel. +49 761 45 66-01
Fax +49 761 45 66 55-01

■ Internet

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

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.

Before packing the CPM device, set it to
the transport position (see chapter 6.3).

11.3 Spare parts

Refer to the Service Manual for
the most recent list of spare parts.

When ordering spare parts, always
specify:

- item
- description
- part number
- quantity
- serial number of the CPM device

Note!

Refer repairs to authorized,
specially trained staff.

ORMED GmbH & Co. KG offers
service training for your personnel.

Surcharges may apply in certain cases
to spare parts ordered in low quantities.

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

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.

CE

0297

Freiburg, August 28th, 2006



- QA Management Representative-

Annex:

ARTROMOT®-S2 *PRO*
ARTROMOT®-S3
ARTROMOT®-S3 Comfort
ARTROMOT®-K1
ARTROMOT®-K2
ARTROMOT®-K2 *PRO*
ARTROMOT®-K2 *PRO* Chip
ARTROMOT®-K3
ARTROMOT®-K4
ARTROMOT®-SP2
ARTROMOT®-E2
ARTROMOT®-E2 compact

ARTROMOT®-K1 classic setup illustrations



