ARTROMOT®

ARTROMOT® ACTIVE-K

CPM · CAM · Coordination

US/GB · Operating Instructions SW2.x

DJO®

Content

1. How to use the physiotherapy unit (Intended Use)

1.1 Fields of application

The **ARTROMOT® ACTIVE-K** is a motorized physiotherapy unit. It combines the benefits of **CPM** therapy (= **C**ontinuous **P**assive **M**otion), post-operative mobilization, and **CAM** therapy (= **C**ontrolled **A**ctive **M**otion), neuromuscular training to reduce functional instability. With these features, it promotes rehabilitation by allowing both, continuous passive motion and, after initial therapy, controlled active motion of the knee and hip joints.

The **ARTROMOT® ACTIVE-K** physiotherapy unit should not be considered as an exercise machine, but as a therapy unit for early mobilization, offering active exercising to promote coordination and preservation of functional strength at an early stage.

Suitable for use in hospitals, clinics, general practices and rental services as well as in the patient's home, the **ARTROMOT® ACTIVE-K** physiotherapy unit is an important supplement to medical and therapeutic treatment.

1.2 Therapy objectives

CPM therapy with the **ARTROMOT® ACTIVE-K** 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.

Furthermore, the active component of the therapy unit is intended to enhance proprioception at an early stage and thus improve coordination following joint surgery.

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
- Bridging the gap between passive motion and active training with exercise machines during rehabilitation
- Enhancing coordination/sensory perception after surgery

1.3 Indications

The physiotherapy unit is indicated in the treatment of most injuries and diseases of the knee and hip joints as well as in 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 implants

1.4 Contraindications

Do NOT use ARTROMOT® ACTIVE-K on patients with:

- Acute inflammatory processes in the joints, unless on the order of a physician
- Spastic paralysis
- Unstable osteosynthesis

1.5 Secondary effects

Currently, there is no evidence of desired or undesired secondary effects of CPM or CAM units.

2. Description of the ARTROMOT® ACTIVE-K

The motorized physiotherapy unit permits active and passive motion of the knee joint in the form of

extension / flexion in the range of
–10 – 0 – 120 degrees

and of the hip joint in the form of

extension / flexion in the range of
0 – 10 – 115 degrees

The range of motion can be set very precisely in steps of 1 degree.

Additionally, in the active mode, a resistance in the direction of motion or in the opposite direction can be set individually in the range from 1 kg to 30 kg in steps of 1 kg.

Furthermore, the physiotherapy unit comes with special protocols to enhance proprioception, i.e., coordination, and functional stability at an early stage.

These are some of the **ARTROMOT® ACTIVE-K** features:

- anatomically correct setup
- physiological movements
- control pendant for precise adjustment of patient-specific therapy values
- symbols for easy operation of the control pendant
- chip card for storage of the programmed therapy parameters

Biocompatibility

Those parts of the **ARTROMOT® ACTIVE-K** 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.

Essential Performance Features

- The programmed angles are accurately maintained with a tolerance of +/- 2°.
- The programmed speeds are accurately maintained with a tolerance of +/- 5% .
- The programmed force is accurately maintained with a tolerance of +/- 1kg.
- The selected mode and mechanical settings do not change during operation.

Frequently used functions:

a) Unpacking (device and accessories)

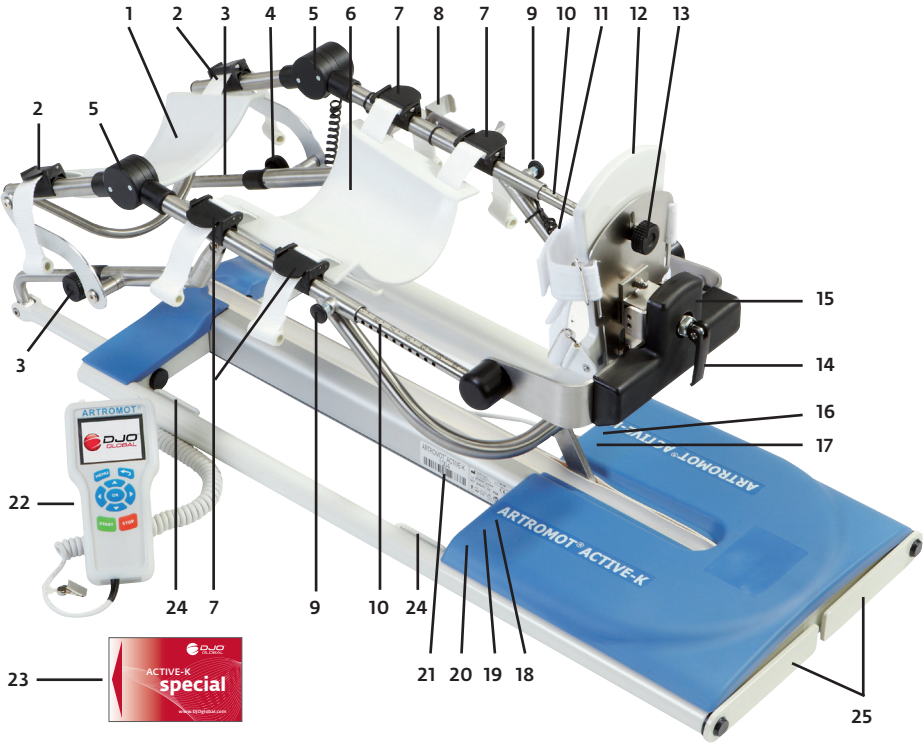
b) Device connections (mains power connection, connecting the control pendant and the motion element)

c) Mechanical adjustments of the motion element on the rotational axes

d) Programming the control pendant (range of motion, speed, functions)

e) Storage

2.1 Description of the device components



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 with LED indicating the force exerted in active mode
6. Calf support assembly
7. Clamping levers to adjust the height of the calf support assembly
8. Support for storage of control pendant
9. Calf length locking catch (tibia length)
10. Calf length scale (tibia length scale)
11. Straps to secure the foot to the footplate
12. Footplate
13. Locking screw for adjustment of the footplate height
14. Clamping lever or locking screw to adjust the footplate rotation
15. Sensor for measurement of the exerted force
16. Connection for ARTROSTIM®-FOCUSplus control cable
17. Connection for control pendant
18. Connection for power cord
19. Instrument fuse
20. Power switch (ON/OFF)
21. Rating plate
22. Control pendant
23. Patient chip card
24. Grommets for attachment of fastening straps
25. Supports to secure the unit at the end of the bed/couch

2.2 Description of the control pendant

2.2.1 Buttons on the control pendant

Patient chip card
Stores the entered therapy parameter values

MENU button
Displays the menu for setting the therapy parameters in each operating mode

Display

Return button
Used to return to the previous level

Arrow up
- Moves the focus (blue field) for selection of a function up
- Increases values during setup
- Activates functions

Arrow to the right
Moves the focus (blue field) for selection of a function to the right

OK button
- Confirms a selection
- Confirms a setting

Arrow to the left
Moves the focus (blue field) for selection of a function to the left

Arrow down
- Moves the focus (blue field) for selection of a function down
- Decreases values during setup
- Deactivates functions

START button
Starts a treatment from the current setup menu or if treatment has been suspended

STOP button
Stops a treatment and saves the values

Note!

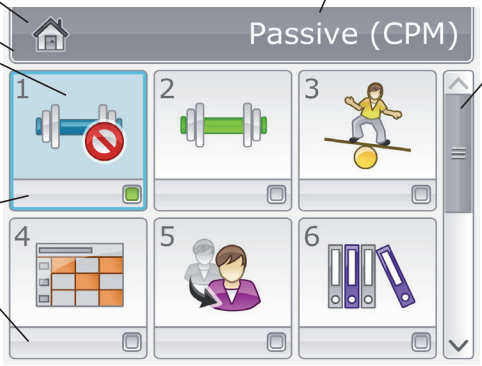
During operation of the unit, ALL buttons double as EMERGENCY STOP buttons.

2.2.2 Control pendant with main menu

Header showing:

Current display/function
Here: symbol for Main Menu

Currently highlighted function
Here: passive (CPM)



Focus
(Field with blue background) highlights the currently selectable function

Scroll bar,
indicates whether or not additional functions are available above or below the function currently displayed

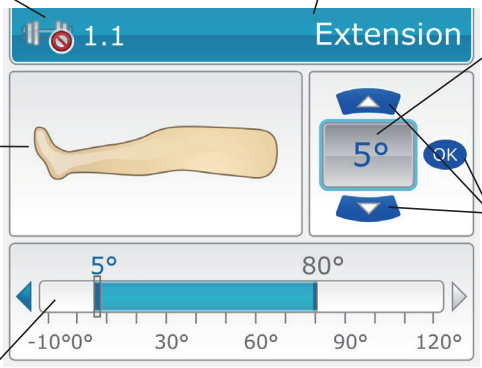
Status lines,
indicate the current status of each function:

- Green indicator, function active
- Value of the selected function

2.2.3 Control pendant in parameter programming mode

Selected operating mode
Here: passive (CPM) and operating mode reference number, here: 1.1

Selected parameter
Here: setting for passive extension



Status of the selected function
Here:
Extension angle

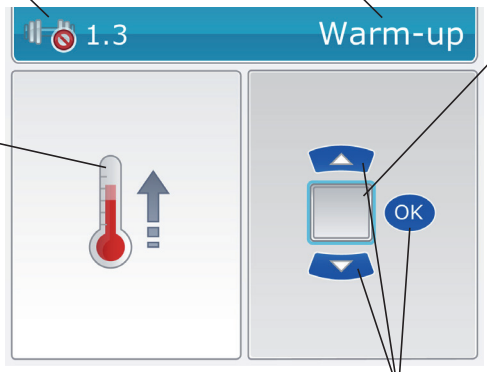
Symbol for selected parameter
Here: setting for passive extension

Control buttons for changing the current setting
Here:

- Arrow up, increases the value
- Arrow down, decreases the value
- OK, saves the setting

Additional information
Appears only when needed
Here: current ROM limits
Blue = adjustable value (here: extension)
Grey = status of the second, corresponding value (here: flexion) and current position of the carriage (small bar)

2.2.4 Control pendant in programming mode for functions that can be activated



Selected operating mode
Here: passive (CPM)

Selected parameter
Here: warm-up protocol

Symbol for selected parameter
Here: warm-up protocol

Status of the selected function
Here: warm-up protocol inactive

When the function is activated, the square is solid green and displays a check mark.

Control buttons for changing the current setting
Here:
- Arrow up, activates the function
- Arrow down, deactivates the function
- OK, saves the setting

2.3 Explanation of symbols

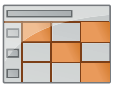
2.3.1 General treatment parameters

Operating modes


Passive (CPM)

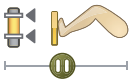

Active (CAM)


Coordination


Therapy protocols

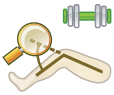
Protocols available for selection under "operating mode"

Coordination:


Maintain force, static


Maintain force, dynamic


Find angle, passive


Find angle, active


Free training

Therapy protocols:


Cruciate ligament (ACL/PCL)


Cartilage


Total knee/hip replacement (TEP)

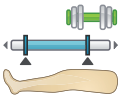

Level selection


Demo

Adjustable parameters


Passive extension (stretching) adjustment


Passive flexion (bending) adjustment


Active adjustment (range of motion - ROM)


Timer (therapy timer)


Speed


Warm-up protocol (passive)


Extension pause


Flexion pause

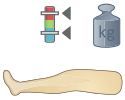

Muscle stimulation

Load reversal

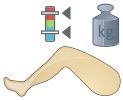
Extension force

Flexion force


Active zone

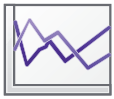


Extension force range



Flexion force range

2.3.2 Other symbols

Parameter	Available functions/adjustments
 New Patient	
 Documentation	 Total patient therapy time  Therapy documentation
 Settings	 Language selection  Brightness  Volume  Time/date  Transport  Total unit run time  Service menu
 Lock-out function	 Lock-out function disabled  Lock-out function enabled Level 1  Lock-out function enabled Level 2  Lock-out function enabled Level 3  Lock-out function enabled Level 4

2.4 Explanation of symbols (connections and rating plate)

Alternating current

For serial numbers < 2,000:
protection class I equipment. The medical device must be connected to a system with protective earth conductor!

For serial numbers > 2,000:
protection class II equipment. The medical device has a double or reinforced insulation.

Type B applied part

Power switch OFF

Power switch ON

The year and month of manufacture are indicated next to this factory symbol.

The name next to this factory symbol is the manufacturer.

The number next to this symbol is the article reference number.

Device complies with Council Directive 93/42/EEC about medical devices, tested and approved by DQS Medizinprodukte GmbH.

The number next to this symbol is the serial number.

Caution! Observe warnings set forth in operation manual!

Observe Operation Manual! ISO 7010-M002

Refer to instruction manual! ISO 7000-1641

Do not dispose with unsorted municipal waste.

Protect from moisture.

IP21

The IP rating indicates the level of protection and thus the suitability of the device for use under different ambient conditions.

The rating IP21 means:
2 is the level of protection against contact and solid objects.
The digit 2 means:
- Protection from contact: protected from contact with a finger.
- Protection against foreign object: protected against solid foreign object (diameter of 12.5 mm and greater).

1 indicates the degree of protection against water.
The digit 1 means: protection against vertically falling water drops.

3V type CR2032 (Not user-replaceable! Contact Technical Service).

Warning symbol pinch point hazard!

Warning! Depending on the device settings, the moving parts of the device present pinch points!

Pay particular attention to small children and babies!

Observe temperature limits (storage)! ISO 7000-0632

The overall weight of the device is indicated next to this symbol.

3. Safety information

Definitions

Read the safety statements before use of the physiotherapy unit. 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, the hazard can result in death or serious injury.

⚠ Caution!

Indicates a potential hazard. If not avoided, the hazard may result in minor injury and/or product/property damage.

Safety information

⚠ Danger!

Explosion hazard –

The ARTROMOT® ACTIVE-K is not designed for use in areas of rooms used for medical purposes 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® ACTIVE-K. Individuals are authorized after receiving training in the operation of the unit and reading this operation manual.
- Before using the device, the operator must ascertain that it is in correct working order and operating condition.
  The cables and connectors, in particular, 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.

⚠ 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 physiotherapy unit and during therapy.
- Only the responsible physician or therapist is able and allowed to choose the therapy parameters and protocols to use. It is the physician's or therapist's decision whether or not to use the unit on a specific patient.
- The patient must be familiar with the functions of the ARTROMOT® ACTIVE-K control pendant and the pendant must always be within easy reach of the patient, allowing him or her to stop treatment if needed. Patients unable to operate the control pendant, e.g. paralytic patients, must always be supervised by specially trained staff during therapy.
- After data storage, write the patient's name on the patient chip card. The card should only be used for this particular patient. If the patient chip card is used for another patient, be sure to delete the previous patient's data from the card first (see: "New Patient", section 5.3.2). Use original chip cards only.
- Any accessories used with the ARTROMOT® ACTIVE-K must first be approved by DJO.
- Modifications to the medical device described in this document without the manufacturer's written consent is prohibited.
- Do not allow parts of the body or objects (such as blankets, cushions, or cables) to get caught in the moving parts of the physiotherapy unit.
- The simultaneous treatment of both legs by simultaneous use of two CPM devices is not permitted because the motion elements might interfere with each other.
- If the physiotherapy unit is used in the active mode or in the coordination mode, the side supports (25) must be folded down to stabilize the unit and protect it against moving at the end of the mattress.
- The sole purpose of the side supports is to prevent that the unit moves while in use. Do not use them to adjust the angle setting of the unit. The supports are not designed for this purpose.
- For transporting the ARTROMOT® ACTIVE-K, the side supports must be folded in to prevent pinching fingers.
- Stability of the physiotherapy unit must always be ensured while it is in use. The ARTROMOT® ACTIVE-K must only be setup of surfaces that guarantee its stability. Very soft or instable surfaces (such as waterbeds) are NOT suitable.
- The utmost caution is advised under the following conditions. Depending on the judgement of the responsible physician, the unit may only be applied under supervision and with the parameters defined by the responsible physician. Otherwise the exercise may be too strenuous for the patient:
  1. Hypertension (> stage 2), ischemic heart disease and cerebrovascular diseases
  2. Cardiovascular diseases
  3. Pregnancy
  4. Age: under 16 years

⚠ Warning!

- Extreme caution should be taken when in use around small children and babies! Sufficient distance to the device is mandatory for their safety!
- Never leave the device unattended when it is switched on! Switch the device off and disconnect the power line from the wall outlet!
- After use, store the device in a safe place! Ensure device stability also during storage!
- **This device is not a toy!**

⚠ 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 the ARTROMOT® ACTIVE-K to reach room temperature **before use**. 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® ACTIVE-K must only be operated in **dry rooms**.
- When disconnecting the unit from the power line, remove the plug from the wall outlet first, before disconnecting the cable from the device.
- When connecting the unit to other equipment or when creating a medical system, check that the sum of leakage currents will not cause any hazard. Please contact DJO if you have questions in this matter.
- Do not use multiple portable socket outlets (MPSO) to connect the unit to the power line. The ARTROMOT® ACTIVE-K 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 unit.
- Before cleaning and service interventions, **disconnect the unit from the power line** by removing the power cord from the wall outlet.
- **Liquids must not be allowed** to enter the physiotherapy unit or the control pendant. If liquids have entered into the units, ARTROMOT® ACTIVE-K 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 unit. For this reason make sure that all external devices operated in the vicinity of the unit comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems, cell phones, etc. are possible sources of interference as they may emit higher levels of electromagnetic radiation. Keep the unit away from such equipment and verify its performance before use.
- Refer **repair** and **maintenance** to authorized persons.
  Persons are authorized after training by a specialist trained and commissioned by the manufacturer.
- **Route all cables below the device frame to either side**, ensuring that they cannot get caught by the moving parts during operation.
- Inspect the ARTROMOT® ACTIVE-K 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 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 rating plate.
- The leg support element withstands a **maximum continuous load** of **30 kg on both axes (horizontal and vertical).**
- Do not allow **any objects** (such as blankets, cushions, or cables) to get caught in the **moving parts** of the unit.
- Do not expose the ARTROMOT® ACTIVE-K to direct sunlight, because some of the components may reach inadmissibly high temperatures.
  Furthermore, the device must be set up at a safe distance from radiators to prevent excessive temperature rises.
- The presence of children, pets and rodents does not normally impair the functioning of the device. However, avoid contamination of the device by children or animals, from dust and lint, and keep them at a safe distance from the device. The safety statements set forth apply.

4. Device setup

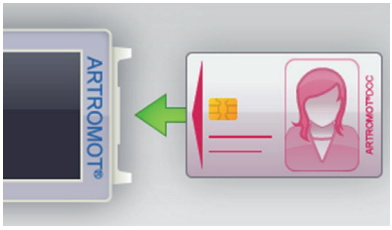
Note: For an illustration of the individual device components, see page 5.

4.1 Connecting the unit, performance check, Equipment supplied

The equipment supplied includes these items: base unit, programming unit (control pendant, 22), patient chip card (23), power cord (not shown), footplate (12), clamping lever to adjust the footplate rotation and to fasten the footplate (14), operating instructions

1. Mount the footplate (12) by slipping the pin through the sensor housing (15) at the foot bracket, screwing the clamping lever (14) onto the end of the pin and locking the clamping lever.
2. Connect the programming unit (22) to the provided socket (17) by plugging it in and screwing it tight.
3. Connect the **power cord** to socket (18) of the unit and connect the **mains plug** to a wall outlet with a non-fused earthed wire (100 to 240 Volt, 50/60 Hz).
4. Turn the **power switch** (20) on.
5. Follow these steps to set the carriage to the **home position**.

   – **Initial setup for new patients** Insert the original patient chip card (23) into the control pendant (22).



Press the **MENU** button MENU on the control pendant until you see the **main menu** (for selection of the operating mode).

Using the arrow buttons, move the focus (blue field) for selection of a function (field displayed with a blue frame) to highlight the New Patient function  .

Select the function with OK, then activate the function by pressing the arrow up button ▲.

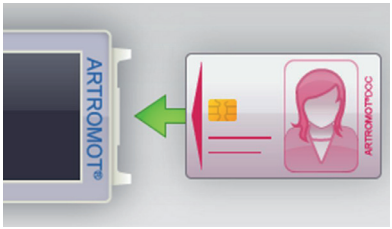
Confirm the selection with OK. The initial screen for setting the unit to the home position will be displayed.

Press START.

The unit automatically enters the home position allowing you to perform the mechanical adjustment (40° flexion). On the display, you will see the main menu.

– **Adjustment with programmed chip card**

Insert the original patient chip card (23) into the control pendant (22).



Press START.

The unit automatically enters the mounting position (set extension + 10°).

Performance check:

If the control pendant can be operated as described above and the **ARTROMOT® ACTIVE-K** enters the home position, the therapy unit has passed the performance check.

The home position is:

– if a programmed chip card is used:

  set extension angle + 10°

– after programming for New Patient:
  stop position = 40 °

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

– an audio signal sounds

– the unit switches off immediately

– the message ERROR and an error code (e.g. ERROR 5) appear on the display.

In this situation, you may attempt to restart the unit by turning it briefly off and on again with the power switch. With the unit switched off, check that all plugs are correctly connected. If the error message persists when the unit is switched on again.

4.2 Connecting the external muscle stimulator

⚠ Caution!

Patient hazard, equipment malfunction –

Only the **ARTROSTIM® FOCUS®plus** muscle stimulator with EN 60601-1 approval, from ORMED GmbH (manufacturer: Empi, Inc., USA) may be connected to the **ARTROMOT® ACTIVE-K** physiotherapy unit.

Use the "muscle stimulation" cable (part no. 2.0037.024) to connect the muscle stimulator. Other cables are not approved. The cable can be ordered separately from DJO.

1. Plug the jack into the **ARTROSTIM® FOCUS® plus** muscle stimulator.

2. Connect the round plug to connector (16) of the ARTROMOT® ACTIVE-K and turn it a little clockwise to lock.
3. Turn on the ARTROMOT® ACTIVE-K first, then turn on the muscle stimulator.

Note!

– For information on connecting and programming the muscle stimulator, refer to the operation manual that comes with the **ARTROSTIM® FOCUS®plus**.

– The EMS control function is only available in the "passive" operating mode.

– The **ARTROMOT® ACTIVE-K** only synchronizes motion therapy and electrotherapy; the therapy parameters must be programmed at each device.

4.3 Adjusting the unit to the femur length

1. Measure the **length of the patient's thigh (femur)** from the greater trochanter to the outer knee joint gap (Fig. A).

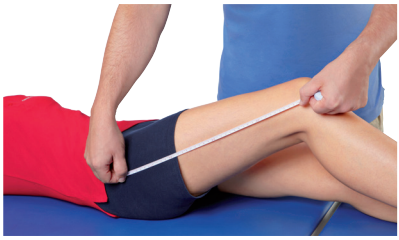


Fig. A

2. Set the carriage to the home position (see 4.1).
3. Adjust the measured value at the **femur scale** (3) of the carriage (Fig. B):

Fig. B

- Loosen the two fixation screws (4). (Open the screws as far as necessary to enable adjusting the slide without any resistance.)
- 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.

4.4 Adapting the leg support assemblies/footplate

1. Set the **leg support assemblies** and the footplate (1, 6, 12) to the expected positions before accommodating the patient.
   - Loosen locking catch (9) to adjust the **footplate** (12) to the length of the patient's lower leg (Fig. C). The locking catches can be secured in the open position for this purpose.

Fig. C

Loosen clamping lever / locking screw (14) to adapt the footplate's rotation and loosen locking screw (13) to adjust the height to the patient (Figs. D and E).

Fig. D

Fig. E

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

Fig. F

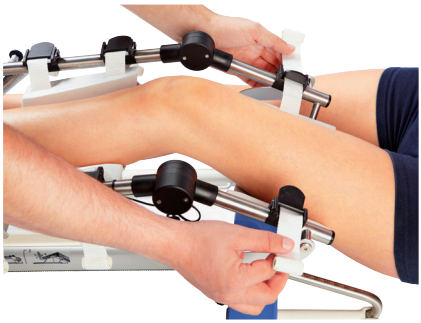


Fig. G

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

⚠ Caution!

Equipment damage –

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

⚠ Caution!

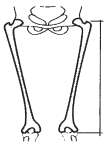
Patient hazard –

Ensure that the rotational axes of the physiotherapy unit and of the knee joint coincide both in the vertical and in the horizontal plane (Fig. H).

Fig. H

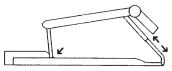
Symbol 1:

Measure the length of the patient's thigh (femur) from the greater trochanter to the outer knee joint gap



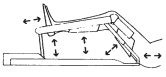
Symbol 2:

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



Symbol 3:

Adjust the height of calf and thigh support assemblies; adjust the footplate to the height and length of the lower leg.



Note!

To optimize the stability of the ARTROMOT® ACTIVE-K while it is in use, it can be secured to the therapy couch by means of straps. The straps can be fastened at the four grommets (24) on the unit.

Furthermore, two adjustable side supports (25) are fitted at the end of the carriage. The supports can be folded out to secure the carriage at the end of a therapy couch or bed. For this purpose, fold the supports down. If used in a bed, the supports are best placed between the mattress and the bed frame so as to optimally absorb movements of pulling and pushing.

⚠ Caution!

Patient hazard –

The sole purpose of the supports is to secure the unit in the patient's bed. Do not use them to adjust the angle setting. The supports are not designed for this purpose.

When transferring the unit with the supports folded out, be careful not to pinch your fingers.

Ensure the stability of the physiotherapy unit. This is only guaranteed on solid surfaces. Do not use the unit in waterbeds, for example, or on other unstable surfaces.

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 movements do not cause any pain.

Note: See also 2.2 and 2.3!

5.1 General information on programming ARTROMOT® ACTIVE-K

Initial adjustment with chip card "Special" (red)

Turn on the unit's power switch (20).

The display will show the main menu for selection of an operating mode (passive, active, coordination), the therapy protocols, the documentation function, the New Patient function, or the Settings function. The active setting is indicated with a green dot in the box below the symbol.

The header displays the  symbol, which represents the main menu. Next to it, you see the current selection (here: passive (CPM)).

The scroll bar in the margin on the right shows whether or not additional functions can be selected. You select the options that are currently out of sight by moving the focus (blue field) past the top or bottom line of symbols.

The focus highlights the "passive" operating mode.

You shift the focus by pressing the appropriate arrow button.

Select one of the fields and activate the corresponding setup menu with the MENU button.

The display will show the available therapy parameters or sub-functions and the current selections below the corresponding symbol.

You select a treatment parameter or function by pressing the OK button while the focus is on that particular field.

This is what happens when you press the OK button to select a parameter:

– The corresponding symbol appears enlarged on the display.

– The set value is displayed.

With the **arrow up/arrow down** buttons you change the displayed value. When you press and hold the button, the value will change at a faster rate.

Some of the (special) functions can only be enabled and disabled. This is done with the arrow up/arrow down buttons. Active parameters are identified with a green square next to the symbol and a check mark.

To confirm a selection, press the OK button.

Then the display returns to the higher-level menu and you can continue making selections.

Next, press the **START** button: ARTROMOT® ACTIVE-K automatically verifies the set values and the sessions starts.

Note!

- Refer to sections 5.2, 5.3 and 6 for a description of the parameters.
- To **view** the **set parameters and the currently selected values**, press the MENU button. However, this is only possible when you press the STOP button first.
- To prevent accidental changes of the parameter settings, you can **lock the buttons**. To do so, simultaneously press the **arrow left/arrow right buttons for approx. 4 seconds** while the carriage is stopped (all menus closed): You will see the lockout menu that allows you to disable to specific menu levels (for details, see: section 5.3.2). Press both buttons again for approx. 4 seconds to unlock and disable the lockout function in the lockout menu.
- Selecting the New Patient (Reset) function will automatically delete the data on the patient chip card. When you have finished programming the unit and press the **STOP** button, the settings will automatically also be saved to the patient chip card.
- **Emergency stop function**: The ARTROMOT® ACTIVE-K will stop immediately, when any of the buttons is pressed during therapy. Patient treatment can be resumed by pressing the START button. The unit will automatically change the direction of movement.
- **Chip cards:** The explanations given for the initial adjustment with a new patient are based on the chip card "Special". With this chip card, all available operating modes and functions can be selected. To simplify the use of the device, the display and choice of operating modes and functions can be limited. This is done by inserting different pre-programmed patient chip cards on which certain functions are locked.

You can choose among the following chip cards:

Limited to CPM functions

Limited to CAM functions

Limited to therapy plans

Free programming, no limitations

If you use limited chip cards with locked functions, the basic functions such as "Settings", "Load reversal" or "Documentation" are accessed via the icon "More" .

Patients with a programmed chip card

- Insert the chip card (the patient is not yet positioned on the carriage).
- Press the **START** button: the carriage will move to the middle position of the parameters stored on the chip card and stops.
- Perform the mechanical adjustments of the unit (femur length, etc.).
- Position the patient on the carriage and press the **START** button to initiate therapy.

5.2 Therapy parameter details

5.2.1 Overview of the parameters available in each operating mode

			Coordination				
Operating mode / Parameter	Passive	Active	Maintain force, static	Maintain force, dynamic	Find angle, passive	Find angle, active	Free training
Passive extension (stretching) adjustment							
Passive flexion (bending) adjustment							
Timer (therapy timer)							
Speed							
Warm-up protocol (passive)							
Extension pause							
Flexion pause							
Active adjustment (ROM-range of motion)							
Muscle stimulation							
Load reversal							
Extension force							
Flexion force							
Active zone							
Extension force range							
Flexion force range							
Angle tolerance							

5.2.2 Overview of the parameters available in each operating mode

Passive extension (stretching) adjustment

- maximum **knee extension: -10 degrees**
- maximum **hip extension: 10 degrees**

Passive flexion (bending) adjustment

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

Note!

- **During passive adjustment of the extension/flexion values**, the carriage moves to the set positions and the display indicates the movement in steps of 1 degree. This allows you to easily and quickly determine the ROM where the patient does not experience pain.
- The programmed value and the value measured at the patient's knee or hip may differ slightly.
- The difference between the set extension and flexion values must be 10° minimum. Therefore, it is not possible to select values with which this difference would be less.
- For a uniform, smooth and gentle transition between the two directions of motion, the speed is automatically reduced before reaching the reversal point and, on reaching the reversal point, it is continuously increased until it reaches the set speed.

Speed

The speed can be adjusted between 5 % and 100 % in steps of 5 % and depends on the operating mode (passive or active).

Default: 50 %

Therapy timer

The default setting for the carriage is **continuous operation** (= ∞ min). A clock symbol in the upper right-hand corner of the display (header) 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** button.

However, you can also select therapy durations of **1 to 59 minutes in steps of 1 minute** and of **1 to 24 hours in steps of 30 minutes**.

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

In this case, a stopwatch replaces the standard clock symbol. Next to the stopwatch, the remaining therapy time is indicated in numeric form by a count-down timer.

Note!

In the "Therapy plans" mode, the default therapy timer setting is 20 minutes.

The timer can be set to any interval from 20 minutes to 2 hours. The duration of the individual steps within the therapy plan adapt automatically. The duration of the warm-up step, however, is fixed, as indicated in the table.

Note!

The manufacturer recommends an application period of up to 1 hour per therapy session.

Warm-up protocol

The warm-up protocol allows the patient to slowly become used to the set maximum values for extension and flexion. Once activated, the carriage first moves to the programmed maximum values minus 10° in each direction. Then both the flexion and extension range of motion is increased by 2° per cycle until the maximum range of motion is reached after 5 cycles.

The warm-up protocol can be selected to precede any function in any operating mode. Warm-up protocols, however, are always passive.

Default: disabled

Extension pause

Pauses occur at the set extension limit, just before the bending movement starts. 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.

Default: no pause

Flexion pause

Pauses occur at the set flexion limit, just before the stretching movement starts. 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.

Default: no pause

Load reversal (reverse on load feature for patient safety/spasm protection)

The device automatically starts moving in the opposite direction of the last movement when the patient's resistance (load) exceeds the set force.

Load reversal is automatically active in the passive operating mode of the unit, e.g., during the warm-up phase or when a movement is to be performed passively in the active mode. Therefore, it can be selected in all operating modes.

Adjustable forces for reverse on load feature: 10 kg to 60 kg, in steps of 5 kg. The force setting determines the trigger threshold for load reversal in kg. The smaller the force, the lower is the trigger threshold.

Default: 60 kg

⚠ 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 conditions. The manufacturer cannot be held liable for misuse of this feature.

Muscle stimulation (EMS control)

This special function allows the **ARTROMOT® ACTIVE-K** unit to be operated in conjunction with the electrical muscle stimulator **ARTROSTIM® FOCUS®plus**, for which it is ideally suited.

For this modality, first plug the "muscle stimulation" connection cable (part no. 2.0037.024) into the ARTROSTIM®-FOCUSplus device (see ARTROSTIM®-FOCUSplus operation manual) and then into the ARTROMOT® ACTIVE-K unit (see 4.2).

Then activate the EMS control program at the ARTROMOT® ACTIVE-K. Select the function: the display will show the corresponding symbol and indicates "0 sec" (the function is disabled). Press the arrow up button to activate the function. The readout automatically changes to 20 seconds which ensures the optimal combination with the three preset protocols of the ARTROSTIM®-FOCUS®plus. At this point, you can change the stimulation period if a special setting was selected at the EMS device or if you wish to use a longer or shorter stimulation period.

Confirm the selection with the OK button.

Start therapy by pressing the **START** button. Starting from the middle position, the carriage will move to the programmed flexion angle, then to the programmed extension setting. At this point, the carriage will stop and simultaneously send a trigger pulse to the ARTROSTIM® FOCUS®plus device. For the duration of the stimulation period/pause set at the carriage **(default: 20 seconds**), the muscle stimulation protocol that you programmed at the **ARTROSTIM® FOCUS®plus** unit will be completed with the selected intensity (for programming of the EMS device, see: **ARTROSTIM® FOCUS®plus** operation manual). After the pause, the **ARTROMOT® ACTIVE-K** will turn off the EMS device and the carriage moves to the programmed maximum flexion angle.

The electrical muscle stimulation will be repeated in the next extension pause.

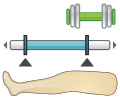
Note!

- **In addition** to activating the special function "EMS control" you can adjust the extension and flexion pauses separately and independently of the stimulation period.
- Electrical muscle stimulation can **only** take place during **extension pauses**.
- If an additional extension pause has been programmed, it will take place after each stimulation phase.
- During the set pause/stimulation period, the **ARTROSTIM® FOCUS®plus** electrotherapy unit operates independently of this setting. If a setting different from the default setting of the carriage or of the stimulation parameters of the electrotherapy unit is desired, the desired therapy parameters must be set at the **ARTROSTIM® FOCUS®plus**.

⚠ Caution!

Patient hazard –

The only approved device for electrical muscle stimulation is the ARTROSTIM®-FOCUSplus® muscle stimulator with EN 60601-1 approval, manufactured by ORMED GmbH (manufacturer: Empi, Inc. USA).



Active ROM adjustment

With this function, the patient is able to actively set the range of motion.

Select the function with the OK button and activate it with the START button.

The patient will then be prompted to bend and extend the knee. The carriage automatically saves the maximum extension and flexion values attained as the new range of motion.

Confirm the setting with the OK button.

Note!

The "active ROM adjustment" function is primarily intended for use of the active operating modes of the carriage because with most patients the passive ROM is greater than the active ROM. If used in the passive mode, patients would therefore most likely exercise in a much narrower range than actually possible.

Extension force

This function allows you to set the magnitude and direction of the force for extension movements in the active mode.
The force can be adjusted between -30 kg and +30 kg in steps of 1 kg.

Adjustable forces:

0 kg =	passive mode, extension
1 to 30 kg =	force that the patient is required to exert actively in the direction of motion (push) so as to move the carriage in the extension direction.
-1 to -30 kg =	force that the patient is required to exert actively in the opposite direction of motion (pull) so as to move the carriage in the extension direction.

Note!

- A positive value between 1 kg and 30 kg always means that the patient is required to press down onto the footplate, irrespective of the carriage's current direction of motion.
- A negative value between 1 kg and 30 kg always means that the patient is required to pull, irrespective of the carriage's current direction of motion.
- A value of 0 kg always means a passive movement executed by the carriage in the current direction of motion.
- During programming of the desired force, the current direction of the force will be indicated by an arrow in the field of the corresponding function and in addition to the +/- indication.

Flexion force

This function allows you to set the magnitude and direction of the force for flexion movements in the active mode.
The force can be adjusted between -30 kg and +30 kg in steps of 1 kg.

Adjustable forces:

0 kg =	passive mode, flexion
1 to 30 kg =	force that the patient is required to exert actively in the opposite direction of motion (push) so as to move the carriage in the direction of flexion.
-1 to -30 kg =	force that the patient is required to exert actively in the direction of motion (pull) so as to move the carriage in the direction of flexion.

Note!

- A positive value between 1 kg and 30 kg always means that the patient is required to press down onto the footplate, irrespective of the carriage's current direction of motion.
- A negative value between 1 kg and 30 kg always means that the patient is required to pull, irrespective of the carriage's current direction of motion.
- A value of 0 kg always means a passive movement executed by the carriage in the current direction of motion.
- During programming of the desired force, the current direction of the force will be indicated by an arrow in the field of the corresponding function and in addition to the +/- indication.

Active zone

The active zone determines the extension and flexion range in which the patient can exercise in the active mode.

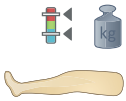
During operation this range is always at least 5° less than the current extension and flexion ROMs.

These 5° in extension and flexion are executed in the passive mode.

Maximum adjustable active zone: 0°- 90°

Note!

- The maximum settings for the active zone are 0° for extension and 90° for flexion. If the current ROM is below these values, the active movement will be limited to this range -5° for extension and flexion. The range of motion (ROM) thus limits the active zone.
- The limitation of the active zone is only possible with the functions "active operating mode" and "maintain force". No limitation is possible for the "free training" function. In this mode, the patient is free to exercise over the entire ARTROMOT® ACTIVE-K range of motion (from -10 to 120°), even against resistance. In the "Find angle, active" function, the active zone corresponds to the current range of motion.
- If the range of motion exceeds the active zone, the movement outside the active zone will be performed in the passive mode.



Extension force range

The force range can only be set for the functions "Maintain force, static" and "Maintain force, dynamic".

With these functions, the patient is prompted to maintain a random force for 3 seconds while the carriage is moving in the extension direction.

The range from which the force will be selected, is set under Extension Force Range. The parameters to define are the intensity and direction of the force.

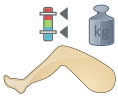
The force range can be adjusted between -30 kg and +30 kg in steps of 1 kg.

Adjustable values:

0 kg =	passive mode, extension The patient is not required to exercise actively.
1 to 30 kg =	limits of the force range from which a random resistance is selected that the patient is required to overcome actively in the direction of motion (push) so as to move the carriage in the extension direction.
-1 to -30 kg =	limits of the force range from which a random resistance is selected that the patient is required to overcome actively opposite to the direction of motion (pull) so as to move the carriage in the extension direction.

Note!

- The option "Hi limit = Lo limit" means that the same force setting is permanently set and that the requested force will not alternate.
- It is not possible to select a setting beyond 0 (one positive and one negative value). During extension, the patient is always required either to push in the direction of motion or to pull opposite to the direction of motion.



Flexion force range

The force range can only be set for the functions "Maintain force, static" and "Maintain force, dynamic".

With these functions, the patient is prompted to maintain a random force for 3 seconds while the carriage is moving in the flexion direction.

The range from which the force will be selected, is set under Flexion Force Range.

The parameters to define are the intensity and direction of the force.

The force range can be adjusted between -30 kg and +30 kg in steps of 1 kg.

Adjustable values:

0 kg =	passive mode, flexion The patient is not required to exercise actively.
1 to 30 kg =	limits of the force range from which a random resistance is selected that the patient is required to overcome actively opposite to the direction of motion (push) so as to move the carriage in the flexion direction.
-1 to -30 kg =	limits of the force range from which a random resistance is selected that the patient is required to overcome actively in the direction of motion (pull) so as to move the carriage in the flexion direction.

Note!

- The option "Hi limit = Lo limit" means that the same force setting is permanently set and that the requested force will not alternate.
- It is not possible to select a setting beyond 0 (one positive and one negative value). During flexion, the patient is always required either to push in the opposite direction of motion or to pull in the direction of motion.

Angle tolerance

This tolerance setting is only available for the "Find angle, passive" and "Find angle, active" functions. The function allows users to expand or reduce the tolerance within which the patient will receive a positive feedback.

Adjustable values: +/- 5° to +/-20°, in steps of 1°

Default: +/- 10°

5.3 Other functions/settings

5.3.1 Therapy protocols

This is the symbol for selection of therapy protocols:

The therapy protocols allow you to run preprogrammed combinations of operating modes and specific functions in one session.

Therapy protocols exist for the three most frequent indications.

For rehabilitation after:

– ruptured cruciate ligament

– cartilage injuries

– prosthesis implantation

Each therapy protocol comprises six consecutive levels. Each level roughly corresponds to one week of therapy, but the responsible physician can define the appropriate periods for any level. Additionally, the responsible physician can define how often patients should repeat a level each day (sessions/day) and whether they should exercise at different levels.

The **default therapy duration** at each level is **20 minutes** (minimum setting). The maximum duration is 2 hours. The duration of the individual steps adapts automatically. The duration of the passive warm-up step, however, is fixed, as indicated in the table.

The patient is informed of each change of the operating mode during the session.

After the therapy session, the carriage switches automtically off, enters the mounting/dismounting position – set extension value + 10° – and stops.

These are the parameters you can define for each therapy plan:

	Passive extension (stretching) adjustment
	Passive flexion (bending) adjustment
	Level selection
	Timer (therapy duration for a level)

	Demo, for teaching the patient quickly what happens at the different levels of a therapy plan
	More, direct access to basic functions, such as "Settings", "Load reversal" or "Documentation"

⚠ Caution!

Patient hazard –

To ensure patient safety, the reverse on load feature is always active in the passive operating mode of the carriage. To avoid misuse, the trigger threshold for load reversal is set from the Passive (CPM) menu. The value is applied automatically.

Demo

With the demo function, the therapist can give patients a quick rundown of each level of the therapy protocol, so that patients learn quickly what the therapy session involves.

Default: disabled

To use the function:

1. Set the range of motion
2. Select the level
3. Activate the demo function
4. Press the START button

Subsequently, the following sequences of the respective levels are represented in tabular form.

Initiate the demo mode with START.

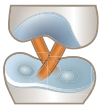
During the demo mode and when the patient has learned the current function, press ▶ to advance to the next function of the level.

After the demonstration, the therapy session can be started with START as usual. The therapy session will then proceed for the set period of time.

The demo function ends automatically.

5.3.1.1 Cruciate ligament (ACL/PCL) therapy protocol

This is the symbol for the cruciate ligament (ACL) protocol:



With the default therapy duration of 20 minutes, the session proceeds as follows:

Levels	Duration in minutens	Function/sequence	Default parameters
Level 1	5	PASSIVE WARM-UP	
	15	PASSIVE	
Level 2	5	PASSIVE WARM-UP	Speed: 75 %
	5	ACTIVE	ACTIVE ZONE: 0°/10°/60° Extension: Push - 5 kg Flexion: Passive
	3	PASSIVE	Speed: 75 %
	5	ACTIVE	See above
	2	PASSIVE COOL - DOWN	
Level 3	3	PASSIVE WARM-UP	Speed: 75 %
	5	ACTIVE	ACTIVE ZONE: 0°/0°/60° Extension: Push - 7 kg Flexion: Pull - 7 kg
	5	PASSIVE	Speed: 75 %
	5	MAINTAIN FORCE, STATIC	Extension: Push - 5 kg to 8 kg Flexion: Pull - 5 kg to 8 kg
	2	PASSIVE COOL - DOWN	

Levels	Duration in minutens	Function/sequence	Default parameters
Level 4	2	FREE TRAINING	Extension: Push - 3 kg Flexion: Pull - 3 kg
	5	ACTIVE	Extension: Push - 10 kg Flexion: Passive
	5	MAINTAIN FORCE, STATIC	Extension: Push - 5 kg to 10 kg Flexion: Pull - 5 kg to 10 kg
	5	ACTIVE	Extension: Push - 7 kg Flexion: Pull - 7 kg
	3	PASSIVE COOL - DOWN	
Level 5	2	FREE TRAINING	Extension: Push - 3 kg Flexion: Pull - 3 kg
	5	ACTIVE	Speed: 75 % Extension: Push - 10 kg Flexion: Push - 8 kg
	3	MAINTAIN FORCE, STATIC	Extension: Push - 10 kg to 14 kg Flexion: Pull - 10 kg to 14 kg
	5	ACTIVE	See above
	2	FIND ANGLE ACTIVE	Extension: Push - 3 kg Flexion: Pull - 3 kg
	3	PASSIVE COOL - DOWN	
Level 6	5	FREE TRAINING	Extension: Push - 8 kg Flexion: Pull - 5 kg
	3	PASSIVE	
	5	FREE TRAINING	Extension: Push - 12 kg Flexion: Pull - 8 kg
	2	FIND ANGLE ACTIVE	Extension: Push - 3 kg Flexion: Pull - 3 kg
	3	ACTIVE	Speed: 75 % Extension: Push - 15 kg Flexion: passive
	2	PASSIVE COOL - DOWN	

Note!

- Preset parameters for all functions, unless otherwise stated:
  - speed: 50 %
  - active zone: 0° / 0° / 90° (for maximum setting, see 5.2.2).
- The "cool-down" function is the opposite of the "warm-up" function. After the session, the carriage stops in the position equivalent to the set extension value + 10°.
- The indicated minutes are approximate values. Depending on the programmed maximum range of motion and the set femur length, the times may vary.
- Normally the range of motion is set by means of the extension and flexion settings, outside the therapy plans. If a session starts with the "free training" function, the final extension and flexion values of this phase automatically become the ROM for the rest of the session.
- The operating modes and functions are described in detail in chapter: 6.
- The response threshold of the load reversal for the passive mode is set under "More" – "Load Reversal".
- During operation, the symbol representing the selected therapy plan and the actual level are indicated in the header.

5.3.1.2 Cartilage therapy protocol

This is the symbol for the cartilage protocol:

With the default therapy duration of 20 minutes, the session proceeds as follows:

Levels	Duration in minutens	Function/sequence	Default parameters
Level 1	5	PASSIVE WARM-UP	
	15	PASSIVE	
Level 2	5	PASSIVE WARM-UP	
	5	ACTIVE	ACTIVE ZONE limited: 0°/10°/60° Extension: Push - 5 kg Flexion: passive
	3	PASSIVE	
	5	ACTIVE	ACTIVE ZONE limited: 0°/10°/60° Extension: passive Flexion: Pull - 5 kg
	2	PASSIVE COOL - DOWN	
Level 3	3	PASSIVE WARM-UP	
	5	ACTIVE	Extension: Push - 5 kg Flexion: Pull - 4 kg
	5	PASSIVE	
	5	ACTIVE	Extension: Push - 8 kg Flexion: Pull - 4 kg
	2	PASSIVE COOL - DOWN	

Levels	Duration in minutens	Function/sequence	Default parameters
Level 4	3	PASSIVE WARM-UP	
	5	ACTIVE	Extension: Push - 6 kg Flexion: Pull - 4 kg
	5	MAINTAIN FORCE, STATIC	Extension: Push - 5 kg to 8 kg Flexion: passive
	5	ACTIVE	Extension: Push - 8 kg Flexion: Pull - 8 kg
	2	PASSIVE COOL - DOWN	
Level 5	3	PASSIVE WARM-UP	
	5	ACTIVE	Extension: Push - 7 kg Flexion: Pull - 7 kg
	5	MAINTAIN FORCE, STATIC	Extension: Push - 7 to 10 kg Flexion: Pull - 7 to 10 kg
	5	ACTIVE	Extension: Push - 10 kg Flexion: Pull - 10 kg
	2	PASSIVE COOL - DOWN	
Level 6	3	FREE TRAINING	Extension: Push - 3 kg Flexion: Pull - 3 kg
	2	FIND ANGLE ACTIVE	Extension: Push - 5 kg Flexion: Pull - 5 kg
	5	ACTIVE	Extension: Push - 10 kg Flexion: Pull - 10 kg
	3	PASSIVE	
	5	ACTIVE	See above
	2	PASSIVE COOL - DOWN	

Note!

- Preset parameters for all functions, unless otherwise stated:
  - speed: 50 %
  - active zone: 0° / 0° / 90° (for maximum setting, see 5.2.2).
- The "cool-down" function is the opposite of the "warm-up" function. After the session, the carriage stops in the position equivalent to the set extension value + 10°.
- The indicated minutes are approximate values. Depending on the programmed maximum range of motion and the set femur length, the times may vary.
- Normally the range of motion is set by means of the extension and flexion settings, outside the therapy plans. If a session starts with the "free training" function, the final extension and flexion values of this phase automatically become the ROM for the rest of the session.
- The operating modes and functions are described in detail in chapter: 6.
- The response threshold of the load reversal for the passive mode is set under "More" – "Load Reversal".
- During operation, the symbol representing the selected therapy plan and the actual level are indicated in the header.

5.3.1.3 Total knee/hip replacement (TEP) therapy protocol

This is the symbol for the total knee/hip replacement (TEP) protocol:

With the default therapy duration of 20 minutes, the session proceeds as follows:

Levels	Duration in minutens	Function/sequence	Default parameters
Level 1	5	PASSIVE WARM-UP	
	15	PASSIVE	
Level 2	5	PASSIVE WARM-UP	
	5	ACTIVE	Extension: Push - 4 kg Flexion: Pull - 4 kg
	3	PASSIVE	
	5	ACTIVE	See above
	2	PASSIVE COOL - DOWN	
Level 3	3	PASSIVE WARM-UP	
	5	ACTIVE	Extension: Push - 6 kg Flexion: Pull - 6 kg
	5	MAINTAIN FORCE, STATIC	Extension: Push - 4 to 7 kg Flexion: PASSIVE
	5	ACTIVE	See above
	2	PASSIVE COOL - DOWN	

Levels	Duration in minutens	Function/sequence	Default parameters
Level 4	3	PASSIVE WARM-UP	
	5	ACTIVE	Extension: Push - 8 kg Flexion: Pull - 8 kg
	5	MAINTAIN FORCE, STATIC	Extension: Push - 6 – 10 kg Flexion: Pull - 5 – 8 kg
	5	ACTIVE	See above
	2	PASSIVE COOL - DOWN	
Level 5	2	FREE TRAINING	Extension: Push - 3 kg Flexion: Pull - 3 kg
	5	ACTIVE	Speed: 75 % Extension: Push - 10 kg Flexion: Pull - 8 kg
	5	MAINTAIN FORCE, STATIC	Extension: Push - 6 – 10 kg Flexion: Pull - 6 – 10 kg
	5	ACTIVE	See above
	3	PASSIVE COOL - DOWN	
Level 6	5	FREE TRAINING	Extension: Push - 5 kg Flexion: Pull - 5 kg
	5	ACTIVE	Speed: 75 % Extension: Push - 10 kg Flexion: Pull - 8 kg
	2	FIND ANGLE ACTIVE	Extension: Push - 5 kg Flexion: Pull - 5 kg
	5	ACTIVE	See above
	3	PASSIVE COOL - DOWN	

Note!

- Preset parameters for all functions, unless otherwise stated:
  - speed: 50 %
  - active zone: 0° / 0° / 90° (for maximum setting, see 5.2.2).
- The "cool-down" function is the opposite of the "warm-up" function. After the session, the carriage stops in the position equivalent to the set extension value + 10°.
- The indicated minutes are approximate values. Depending on the programmed maximum range of motion and the set femur length, the times may vary.
- Normally the range of motion is set by means of the extension and flexion settings, outside the therapy plans. If a session starts with the "free training" function, the final extension and flexion values of this phase automatically become the ROM for the rest of the session.
- The operating modes and functions are described in detail in chapter: 6.
- The response threshold of the load reversal for the passive mode is set under "More" – "Load Reversal".
- During operation, the symbol representing the selected therapy plan and the actual level are indicated in the header.

5.3.2 General functions

New Patient

With this function, the carriage will move to the home position (at 40° flexion), allowing the mechanical settings to be performed. All values stored on the chip card will be deleted.

Press the OK button to select the function, press the arrow up button to activate the function and then press the OK button to confirm your selection. The main menu will be displayed again. Then press the START button: the carriage enters the home position and existing therapy parameters will be deleted.

Next, you will see the main menu where you can select the operating mode.

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

– extension:	10°
– flexion:	60°
– speed:	50 %
– extension pause:	0
– flexion pause:	0
– timer:	disabled
– reverse on load:	60 kg
– active zone:	0° to 90°
– extension force:	+ 5 kg
– flexion force:	- 5 kg
– extension force range:	+ 1 kg to + 5 kg
– flexion force range:	- 1 kg to – 5 kg
– therapy protocols:	Level 1
– special functions:	disabled
– operating mode:	no operating mode (CPM/CAM) selected

Documentation

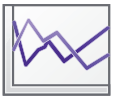
The Documentation function allows you to reproduce the therapy data saved by the carriage.

The following documented data can be reviewed:

Total patient therapy time

The total patient therapy time is the added sum of operating hours stored **on the chip card**. (added sum of all therapy sessions stored on the chip card)

Deleting the stored therapy time on the chip card:
Select the function with the OK button: the stored period of time will be displayed with large digits. To delete the graph, press the arrow down button and confirm with OK or activate the New Patient function.



Therapy documentation

This is a special function of ARTROMOT® ACTIVE-K which allows the entire therapy documentation to be reviewed on the display.

The recorded data are the carriage run times, the range of motion of the sessions, the selected mode of operation as well as the forces set at the therapy unit.

The collected data of the ROM trend are presented graphically in a coordinate system (X-axis = range of motion / Y-axis = time) where the upper curve illustrates the trend of the flexion movement and the lower curve the trend of the extension movement.

For the active operating mode, an additional axis on the graph indicates the intensity of the force exerted.

Deleting the stored therapy documentation:
Select the function with the OK button: the stored graph will be displayed enlarged. To delete the graph, press the arrow down button and confirm with OK or activate the New Patient function.

Settings

With Settings you access the setup menu. From this menu, a number of basic settings for the carriage can be performed.

Adjustable parameters:

Language selection

You can choose the following languages:

- Danish
- German
- English
- French
- Italian
- Dutch
- Portuguese
- Polish
- Russian
- Spanish
- Swedish
- Czech
- Turkish
- Hungarian
- Chinese
- Japanese
- Korean

Brightness

Adjustment of the display brightness.
Default: 100 %

Volume

Adjustment of the volume of audio signals.
0 = no audio signal
Default: 100 %

Time/date

Adjustment of the carriage's internal clock.
Adjustable parameters:

- Time in: hh/mm
- Date in dd/mm/yy
- Indication of time of day during operation: ON/OFF

Transport setting

With this function, the carriage will automatically move to a position optimally suited for packing the therapy unit. Press the OK button to select the function, press the arrow up button to activate the function and then press the OK button to confirm your selection. Next, press START and the carriage will automatically move to the transport setting.

Total unit run time

The total unit run time is the overall number of carriage operating hours stored in the unit. (added sum of all stored therapy sessions)

Deleting the stored therapy time:

Select the function with the OK button: the stored period of time will be displayed with large digits. To delete the value, press the arrow down button and confirm with OK.

The "total unit run time" cannot be deleted with the New Patient function.

Service menu

For service purposes only, refer to Service Manual.

Lock-out function

With the lock-out function, access to individual operating modes or functions can be blocked. This reduces the scope of programming options and makes operation easier.

To activate the lock-out feature, simultaneously press the arrow left and arrow right buttons for approx. 4 seconds. The carriage must be in the stop mode of the operating mode concerned (no active menu). The display automatically shows the lock-out menu.

Five different lock-out levels are available:

Lock-out level	Symbol	Description
0		The lock-out feature is deactivated. All features are available and can be selected.
1		Level 1 of the lock-out feature is enabled. This means that the selected operating mode is fixed and no other operating mode can be selected. However, all parameters of this operating mode can be selected and modified.
2		Level 2 of the lock-out feature is enabled. Same as lock-out level 1. Additionally, it is not possible to switch between the different protocols of the coordination and therapy protocol modes, such as between "ACL" and "Cartilage" or between "Find angle, active" and "Find angle, passive". However, all parameters of the operating mode/protocol can be selected and modified.
3		Level 3 of the lock-out feature is enabled. Same as lock-out level 2. Additionally, all programming features are locked and only the range of motion can be modified.
4		Level 4 of the lock-out feature is enabled. The menu for modification of the treatment parameters cannot be accessed. Only the START and STOP buttons can be used. All other buttons are locked. The treatment parameters cannot be modified. However, in the passive mode all buttons can be used as "Emergency stop" buttons.

If the lock-out function is activated, the lock-out status and the locked level are indicated in the header during operation.

6. Operating mode details

The ARTROMOT® ACTIVE-K offers three operating modes for early functional rehabilitation therapy:

– Passive (CPM) mode

– Active (CAM) mode

– Coordination

In the "coordination" mode, you can choose from five specialized protocols to further enhance the patient's coordination capabilities.

These are the coordination protocols:

– maintain force, static

– maintain force, dynamic

– find angle, passive

– find angle, active

– free training

6.1 Passive operating mode (CPM)

The passive operating mode is intended for early mobilization of the knee and hip joints by CPM therapy (Continuous Passive Motion).

This is the symbol for the CPM mode:

6.1.1 Adjustable CPM parameters

Passive extension (stretching) adjustment

Passive flexion (bending) adjustment

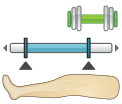
Therapy timer

Speed

Warm-up protocol (passive)

Extension pause

Flexion pause

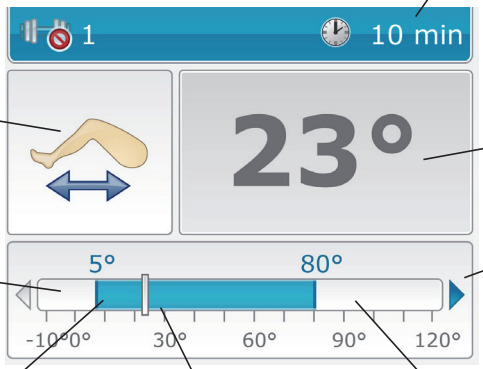


Active adjustment (ROM - range of motion)

Muscle stimulation

Load reversal

6.1.2 Display in CPM mode



Elapsed therapy time
OR, if the timer is activated **Remaining therapy time**

Indication of the active function:
Here: Movement in extension and flexion

Dialog field, indication **Current position of the carriage**
Here: 23°

Indication of the overall available ROM
-10° / 0° / 120°

Current direction of the carriage
Here: extension

Set extension angle
Here: 5°

Current position of the carriage in relation to the overall ROM
Here: 23°

Set flexion angle
Here: 80°

6.2 Active operating mode (CAM)

The active operating mode (CAM – Controlled Active Motion) allows the patient to actively exercise with a preset resistance between -30 kg / 0 kg / +30 kg. Negative values between -30 kg and -1 kg always mean that the patient is required to pull against the set resistance, while positive values between +1 kg and +30 kg mean that the patient is required to push. If no resistance is set, the carriage will operate in the passive mode, moving in the direction of extension or flexion. The resistance values (force) can be set separately for extension and flexion. The tolerance is 20 % of the set force. If the patient is not capable of exerting the required force, the carriage will not move.

For functions that require the active cooperation of the patient, the range of motion in which the patient exercises actively, the so-called active zone, can be preset.

The maximum settings for the acive zone are: **0° / 0° / 90°**.

This range can be reduced as desired and the extension and flexion range is always 5° less than the current ROM to allow for a smooth transition between the directions of movement.

If the range of motion exceeds the active zone, the movement of the joint outside the active zone will always be performed in the passive mode.

Example of a range of motion smaller than the preset active zone:

Set range of motion: 0° / 10° / 60°

Set active zone: 0° / 0° / 90° (maximum setting)

True active zone: 0° / 15° / 55°

Extension force: 10 kg

Flexion force: -5 kg

This is what the settings mean:
Although the active zone is larger than the current range of motion, the patient will only be able to actively exercise within the set range of motion. This is meant to protect the patient.

Within the active zone of 0° / 15° / 55°, the patient in order to initiate a movement is required to push in the extension direction against an additional 10 kg (+/-20%). In the flexion direction, in order to initiate a movement, the patient is required to pull a weight of 5 kg (+/- 20%).

Example of a range of motion greater than the preset active zone:

Set range of motion: 5° / 0° / 110°

Set active zone: 0° / 0° / 90° (maximum setting)

True active zone: 0° / 0° / 90°

Extension force: 10 kg

Flexion force: -5 kg

This is what the settings mean:
Active exercising is only possible in the range between 0° and 90°. Outside this range, the joint is moved in the passive mode.

Within the active zone of 0° / 0° / 90°, the patient in order to initiate a movement is required to push in the extension direction against an additional 10 kg (+/-20%). In the flexion direction, in order to initiate a movement, the patient is required to pull a weight of 5 kg (+/- 20%).

This is the symbol for the CAM mode:

6.2.1 Adjustable CAM parameters

In the CAM mode, the following treatment parameters can be adjusted:

Passive extension (stretching) adjustment

Passive flexion (bending) adjustment

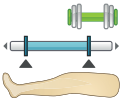
Therapy timer

Speed

Warm-up protocol (passive)

Extension pause

Flexion pause



Active adjustment (ROM - range of motion)

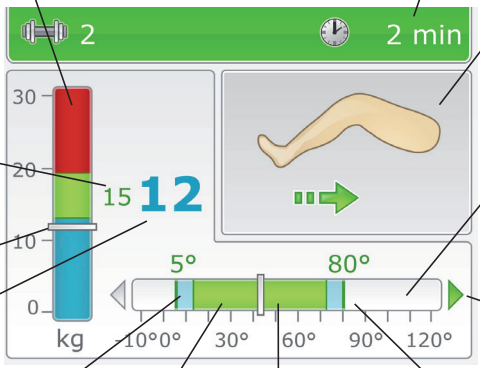
Extension force

Flexion force

Active zone

Load reversal (passive)

6.2.2 Display in CAM mode



Zone/range of force
Indication of the currently exerted and requested force:

- red: too much force
- green: tolerance range for force to be exerted
- blue: insufficient force

Elapsed therapy time
OR, if the timer is activated
Remaining therapy time

Dialog field
Indication of the direction in which the requested force

Currently requested force
Here: 15 kg

Indication of the overall available ROM
-10° / 0° / 120°

Currently exerted force, shown graphically and as a numeric value
Here: 12 kg

Current direction of the carriage
Here: extension

Set extension angle
Here: 5°

Current active zone:
Here: 11° bis 71°

Current position of the carriage in relation to the overall ROM
Here: 41°

Set flexion angle
Here: 80°

Note!

In addition to the data on the display, the force exerted in the active mode is indicated by an LED at the knee hinge. The color coding is the same as on the display:

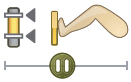
- Blue LED: insufficient force is exerted
- Green LED: the exerted force is within the tolerance range
- Red LED: too much force is exerted

6.3 Coordination mode

The coordination mode offers five different protocols that help improve the coordination skills.

This is the symbol for the coordination mode:

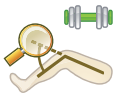
These are the protocols available in the coordination mode:



Maintain force, static

Maintain force, dynamic

Find angle, passive



Find angle, active

Free training

6.3.1 Information about the "maintain force" coordination protocols

The "maintain force" coordination protocols require the patient in regular intervals to maintain a random force either in the direction of the carriage movement or in the opposite direction for 4 seconds.

The range from which the force is randomly selected can be preset.

The ranges for minimum and maximum force can be set separately for extension and flexion movements.

The forces for extension and flexion can be set in the following ranges:
0 kg to +30 kg or -30 kg to 0 kg.

Note!

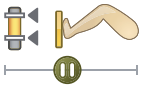
- Negative values (resistances) between -30 kg and -1 kg mean that the patient is required to pull to overcome the set resistance, irrespective of the current direction of motion.
- Positive values (resistances) between +1 kg and +30 kg mean that the patient is required to push to overcome the set resistance, irrespective of the set direction of motion.
- If no resistance is set, the carriage will operate in the passive mode, moving in the direction of extension or flexion.
- When you adjust the force range, the minimum value is shown on the left of the display and the maximum value is shown in the right. The random values are selected from this range only.
- It is not possible to define a range that spans the value of 0 kg. The forces can be set to values either greater than/equal to 0 or less than/equal to 0 in the respective direction of motion.
- If the set maximum value of a range equals the set minimum value, the patient always has to exert this force; no random selection will be made.
- The random force value is only selected from the active range (see also: 5.3.2) and is only requested for the duration of 4 seconds. Outside this range, the movement is always passive.

Maintain force, static

If the "Maintain force, static" function is activated, the patient is required to maintain the requested force for 4 seconds. The carriage will not move during this period, it stands still (static).

A progress bar in the dialog window indicates the elapsed time. The progress bar fills only as long as the patient exerts the required force. When the progress bar is filled (after a total of 4 seconds of exerted force), the passive movement of the joint is continued in the current direction of motion.

This is the symbol for the "Maintain force, static" function:



Maintain force, dynamic

If the "Maintain force, dynamic" function is activated, the patient is required to maintain the requested force for 4 seconds.

Contrary to the "Maintain force, static" function, however, the patient will continue to move the carriage actively (dynamic).

A progress bar in the dialog window indicates the elapsed time. The progress bar fills only as long as the patient exerts the required force. When the progress bar is filled (after a total of 4 seconds of exerted force), the passive movement of the joint is continued in the current direction of motion.

This is the symbol for the "Maintain force, dynamic" function:

6.3.1.1 Adjustable parameters in the "maintain force" protocols

The following treatment parameters can be adjusted in the "hold force" coordination protocols:

Passive extension (stretching) adjustment

Passive flexion (bending) adjustment

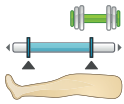
Therapy timer

Speed

Warm-up protocol (passive)

Extension pause

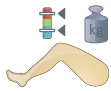
Flexion pause



Active adjustment (ROM - range of motion)

Active zone

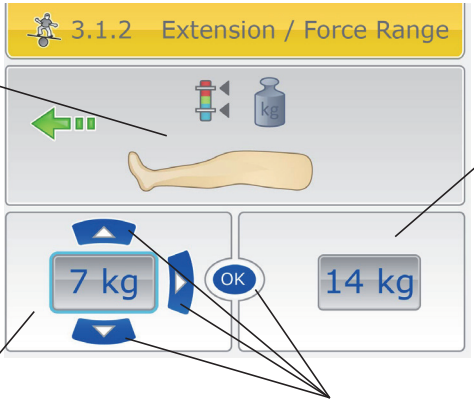
Extension force range



Flexion force range

Load reversal (passive)

6.3.1.2 Display in the force range setting mode



Symbol for the currently selected parameter
Here: setting the extension force range

Set upper limit of the force range for random selection
Here: 14 kg pressure

Set lower limit of the force range for random selection
Here: 7 kg pressure

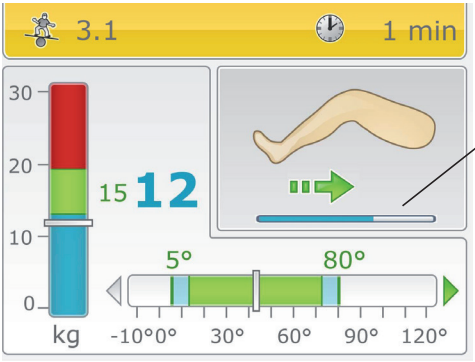
Buttons to change settings or confirm entries
Here: up, down, right, OK

Note!

- Negative values (resistances) between -30 kg and -1 kg mean that the patient is required to pull to overcome the set resistance, irrespective of the current direction of motion.
- Positive values (resistances) between +1 kg and +30 kg mean that the patient is required to push to overcome the set resistance, irrespective of the set direction of motion.
- If no resistance is set, the carriage will operate in the passive mode, moving in the direction of extension or flexion.
- When you adjust the force range, the minimum value is shown on the left of the display and the maximum value is shown on the right. The random values are selected from this range only.
- It is not possible to define a range that spans the value of 0 kg. The forces can be set to values either greater than/equal to 0 or less than/equal to 0 in the respective direction of motion.
- If the set maximum value of a range equals the set minimum value, the patient always has to exert this force; no random selection will be made.
- The random force value is only selected from the active range (see also: 5.3.2) and is only requested for the duration of 4 seconds. Outside this range, the movement is always passive.

6.3.1.3 Display in the "maintain force, active" mode

The display is essentially the same as in the "active" mode. In addition, a progress indicator is shown in the dialog window below the arrow indicating the direction of the requested force.



6.3.2 Information about the "Find angle, passive" coordination protocols

This is the symbol for the "Find angle, passive" protocol:

The "Find angle" protocol is based on the so-called angle reproduction test.

With this protocol, the patient is prompted to press the OK button when the knee reaches a number of preset angles. The current carriage position is not indicated on the display in this case. This exercise is meant to improve the patient's capabilities to perceive the current knee joint angle.

This is a passive operating mode.

In all cycles between extension and flexion, the patient is prompted to indicated the angle. If the patient believes that the knee angle has been attained, he is prompted to confirm this with the OK button. The angle to find is indicated until the OK button is pressed.

When OK is pressed, the carriage displays the angle attained and assesses the result in relation to the angle wanted.

If the deviation is within the tolerance of, e.g., 10°, the attempt was successful and a positive feedback icon is displayed:

If the deviation is outside the tolerance of, e.g., 10°, the attempt failed and a negative feedback icon is displayed:

The number of successful and failed attempts is permanently displayed for reference.

At the end of the session, the patient can assess his success and compare it with the previous session.

If the carriage is stopped with OK, the requested angle as well as the actual angle are is displayed. Patient treatment can be resumed by pressing the OK button. Subsequently, the patient will be prompted for the next angle.

The carriage indicates the following angles which must be identified in this order.

30°

15°

60°

45°

0°

90°

The patient will only be prompted for angles from the current range of motion set at the carriage. After all possible angle settings have been displayed, the cycle starts over with the first angle.

Example:
The currently set range of motion is:
0° / 10° / 60°

The patient is prompted for the following angles in this order:

30°

15°

45°

6.3.2.1 Adjustable parameters in the "Find angle, passive" protocol

The following treatment parameters can be adjusted in the "Find angle, passive" coordination protocols:

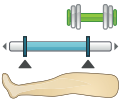
Passive extension (stretching) adjustment

Passive flexion (bending) adjustment

Therapy timer

Speed

Warm-up protocol (passive)



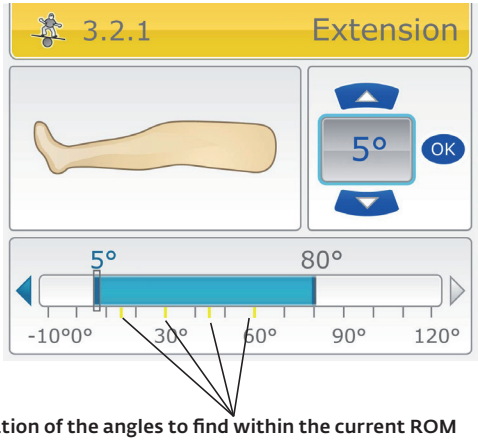
Active adjustment (ROM - range of motion)

Load reversal (passive)

Angle tolerance

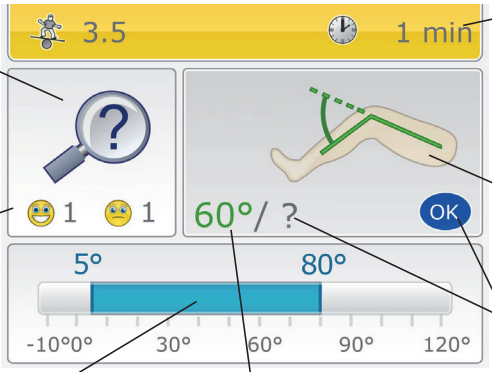
6.3.2.2 Display in the "Find angle, passive" programming mode

The programming mode display is essentially the same as for adjustment of the passive ROM. Additionally, during adjustment of the maximum extension and flexion angles, the angles to attain within the ROM are marked yellow on the ROM bar indicator.



Indication of the angles to find within the current ROM during adjustment of the extension angle
Here: 15° / 30° / 45° / 60° with an increasing ROM, further angles will be displayed as soon as they come to lie within the range

6.3.2.3 Display in the "Find angle" mode



Prompt to search for angles

Elapsed therapy time
OR, if the timer is activated **remaining therapy time**

Symbol indicating the angle to find

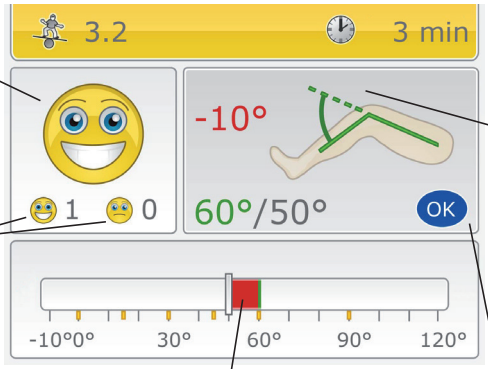
Indication of successful/failed attempts to search for angles

Prompt to find angles and to press OK when done
Indication: blinking

Indication of the current angle to find

Indication of the currently set ROM
while the patient is trying to find the angle, the current position will not be indicated

6.3.2.4 Feedback display with deviation between set and actual angle



Rating

Sum of successful/ failed attempts

Indication of requested and attained angles and deviation
Here:

– 60° requested

– stopped at 50°

– deviation -10°

Prompt to press OK to continue the treatment
Indication: blinking

Indication of the deviation (angle wanted/angle attained) in graphic form
Here:

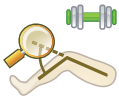
– 60° requested

– stopped at 50°

– deviation -10°, marked red

6.3.3 Information about the "Find angle, active" coordination protocol

This is the symbol for the "Find angle, active" protocol:



The workflow of the "Find angle, active" protocol is similar to that of the "Find angle, passive" protocol.

The only difference is the operating mode, which in this case is "active".

This means that patients are required to actively bend and extend their knee until they believe that the requested angle has been reached. Then they press the OK button.

In addition, a resistance can be set and the carriage requests an angle with each movement.

With this protocol, the active zone is the entire range of motion. Further limitations do not apply.

6.3.3.1 Adjustable parameters in the "Find angle, active" protocol

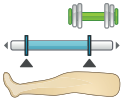
The following treatment parameters can be adjusted in the "Find angle, active" coordination protocols:

Passive extension (stretching) adjustment

Passive flexion (bending) adjustment

Therapy timer

Warm-up protocol (passive)



Active adjustment (ROM - range of motion)

Extension force

Flexion force

Load reversal (passive)

Angle tolerance

6.3.3.2 Display in the "Find angle, active" mode

The display is similar to those shown in 6.3.2.3 and 6.3.2.4 (Find angle, passive).

6.3.4 Information about the "free training" coordination protocol

The "free training" coordination protocol allows the patient to actively exercise over the entire range of motion of 10° / 0° / 120° of the ARTRO-MOT® ACTIVE-K.

As soon as you enable the function and press the START button, the patient will be prompted to actively bend and extend the knee.

The maximum extension and flexion angles attained will be displayed.

The purpose of the exercises is to expand the range of motion.

In addition, a resistance can be set which the patient must overcome. The resistance is effective in the direction of motion (flexion = pull, extension = push).

This is the symbol for the "free training" protocol:

6.3.4.1 Adjustable parameters in the "free training" protocol

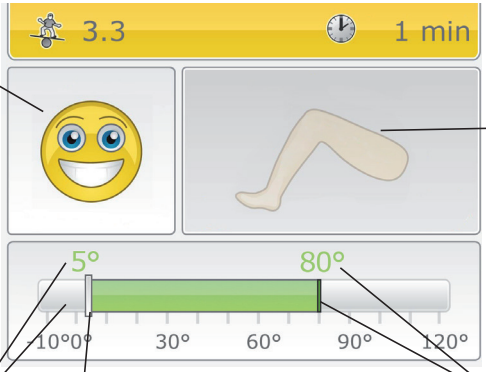
Therapy timer

Extension force

Flexion force

6.3.4.2 Display in the "free training" mode

The display is essentially the same as in the active setting of the range of motion. In addition, patients are given a positive feedback when they attain a greater extension and flexion angle.



Positive feedback when the angle reached is greater than in the previous attempt

Dialog field with prompt to bend and stretch actively

Indication of the maximum extension angle attained, shown graphically and as a numeric value
Here: 5°

Current position of the carriage, shown graphically and as a numeric value
Here: 5°

Indication of the maximum flexion angle attained, shown graphically and as a numeric value
Here: 80°

7. Care, Maintenance, Transport

7.1 Care/re-use

The **ARTROMOT® ACTIVE-K** is suitable for re-use if the following points are observed.

⚠ Warning!

Shock hazard –

Unplug the device from the power line before cleaning.

Shock hazard, equipment damage –

Liquids must not enter the device or the control pendant. If liquids have entered into the units, ARTROMOT® ACTIVE-K must be immediately checked by a service technician, before it can be reused.

- The **ARTROMOT® ACTIVE-K** 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**.
- Only use a **damp cloth** to wipe the therapy unit down.

⚠ Warning!

Patient hazard –
patient contamination

- Before using the device on another patient, be sure to clean and disinfect it according to the instructions given here.

Note!

The manufacturer recommends using only special disinfectants approved for medical devices and with the characteristics specified below under "Caution".

Disinfection with the following disinfectants and in compliance with the instructions for use has been evaluated and approved by the manufacturer in the risk assessment:

- DESCOSEPT AF lemon
  (Part no.: 00-311L-xxx)
  BAuA Reg.No. N-55153, CE-0482
  Manufacturer: Dr. Schumacher GmbH.

  Contact time: 2 minutes minimum

⚠ 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 therapy unit to strong ultraviolet radiation (sunlight) and fire.

7.2 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

Due to their design, the bearings and joints of the ARTROMOT® ACTIVE-K do not require maintenance and all materials are protected from corrosion, BUT: 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.

⚠ Warning!

Patient hazard, equipment malfunction and damage –

– Refer repair and maintenance to authorized persons. Persons are authorized after training by a specialist trained and commissioned by the manufacturer.

  ORMED GmbH will make all documents required for servicing, such as circuit diagrams, parts lists, descriptions or calibration instructions, available to authorized experts.

The inspections can be carried out by DJO Technical Service within the framework of a service agreement.

Other than that, the manufacturer does not require any other regular maintenance.

Note!

Regarding further technical or other inspections or inspection intervals, observe applicable local requirements, such as IEC 62353, DGUV3 or similar regulations to be observed by users of medical equipment or electric devices.

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).

serial numbers < 2000
Fuses used must be T1A fuses.

serial numbers > 2000:
Fuses used must be T2A fuses.

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

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.

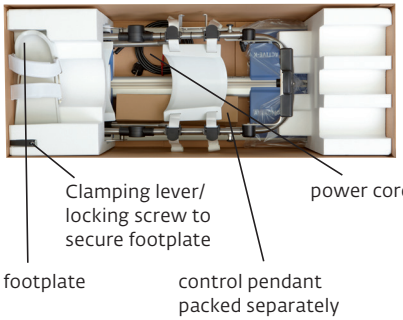
Fig. 1

Fig. 2

7.3 Transport

The following operating steps must be completed before transporting the ARTROMOT® ACTIVE-K :

1. Adjust the carriage to a femur length of 49 cm and a tibia length of 42 cm.
2. Activate the "transport setting" function in the menu (see also 5.3) by selecting the function, activating it withthe arrow up button and confirming the selection with OK.
3. The initial screen will automatically be displayed, allowing the carriage to be moved to the transport position. Press START and the carriage will automatically move to the transport setting.
4. Turn off the ARTROMOT® ACTIVE-K power switch (20).
5. Disconnect the power cord and the control pendant.
6. Remove the footplate by fully opening and unscrewing the clamping lever / locking screw (14) for adjustment of the footplate rotation.
7. Only use the original shipping box for transporting the device. Ormed GmbH cannot be held liable for transport damage if the device is not packed in its original shipping box.
8. Push the molded polystyrene blocks onto the ARTROMOT® ACTIVE-K.
9. Place the clamping lever and the footplate in their designated cut-outs in the lower polystyrene board.
10. Store the power cord at the bottom of the box, then place the ARTROMOT® ACTIVE-K with attached polystyrene blocks in the box as well.
11. Put the control pendant (22) in the supplied cardboard container and store it in the box of the ARTROMOT® ACTIVE-K.



8. 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 DJO for information about the possible recycling of the product.

The expected service life of the device and all supplied parts and accessories is 6 years. The application beyond this period is the responsibility of the user.

9. Specifications

Model:	ARTROMOT® ACTIVE-K
Part no.	80.00.070
Input ratings:	100 – 240 Vac / 50 – 60 Hz tolerance -15% to +10%
Current consumption: standby (ON): operation (maximum):	100V 240V 5VA 5VA 85VA 90VA 850mA 370mA
Fuses:	serial number < 2,000: 2x T1A L250 Vac interrupting rating 35A, according to IEC 60127-2/3, UL 248-14, CSA C22.2 no. 248.14 serial number > 2,000: 2x T2A L250 Vac interrupting rating 35A, according to IEC 60127-2/3, UL 248-14, CSA C22.2 no. 248.14 serial number > 4,000: 2x T2A H250 Vac interrupting rating 1500A according to IEC 60127-2/3, UL 248-14, CSA C22.2 no. 248.14
Battery:	type CR2032, 3V, 230 mAh, cannot be replaced by the user!
Battery life:	approx. 5 years
Protection class:	serial number < 2,000: I serial number > 2,000: II
IP class:	serial number < 2,000: IPX0 serial number > 2,000: IP21
Applied part:	type B
Max. load on carriage:	30 kg
Physical:	
length: width: height:	96 cm 38 cm 57 cm max.

Adjustment ranges (min./max.):	
femur range: lower leg range:	approx. 31 to 49 cm approx. 38 to 58 cm
Accuracy of measured values:	
goniometer in the measuring range: accuracy:	from -10° to +120° +/- 2°
force gauge in the measuring range: accuracy:	from -30 kg to +30 kg +/-1 kg
speed in the measuring range: accuracy:	from 10° to +120° +/- 5%
Weight:	17 kg
Materials used:	ABS, POM, PUR, PA, FR4, aluminum, stainless steel, brass
MDD:	class II a
Standards compliance	93/42/EEC IEC 60601-1 IEC 60601-1-6 IEC 60601-1-9 IEC 60601-1-11 (S# >2,000) IEC 62366 IEC 62304 EN ISO 14971 ANSI AAMI ES 60601-1 1st Edition CAN CSA 22.2 No. 60601-1-08
EMC (electromagnetic compatibility)	IEC 60601-1-2
Manufactured in compliance with:	EN ISO 13485
Ambient conditions (storage, transport)	
temperature: relative humidity: atmospheric pressure:	-25 °C to +70 °C at 70 °C up to 93%, no condensation 500 hPa to 1060 hPa
Ambient conditions (operation)	
temperature: relative humidity: atmospheric pressure:	+5 °C to +40 °C 15 % to 93 % 700 hPa to 1060 hPa

Subject to change without notice.

10. IEC 60601-1-2 and IEC 60601-1-11

For detailed technical information (tables and data) concerning electromagnetic emissions, electromagnetic immunity and recommended separation distances, please refer to the separate document MOT-AC-328-IEC on the CD "MOT-AC-328-REV.5", or request this information from DJO.

Notice!

(for home use)

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

For this reason, make sure that wireless communication equipment, such as wireless home network devices, cell phones, cordless telephones and their base stations and walkie-talkies operate at a minimum distance of 3.3 m from the device. (Calculated on the basis of the maximum power output of a typical cell phone of 2 W).

11. Contact

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

ARTROMOT® International:
Please contact your local dealer, the DJO Headquarters in the USA, the DJO International Headquarters in England or DJO in Germany.

DJO International
Headquarters: DJO UK Ltd.
1a Guildford Business Park
Guildford
Surrey, GU2 8XG
United Kingdom
Phone: +44 (0)1483 459659
Fax: +44 (0)1483 459470
E-mail: info@DJOglobal.eu
Web: www.DJOglobal.eu

DJO Headquarters
DJO, LLC
1430 Decision Street
92081 Vista – California / USA
Phone: +1 760 727 1280
Fax: +1 800 936 6569
E-mail: webmaster@DJOglobal.com
Web: www.DJOglobal.com

Manufacturer / Headquarters Germany:
DJO
ORMED GmbH
Merzhauser Strasse 112
79100 Freiburg, Germany
Phone: +49 (0) 761 4566 01
Fax: +49 (0) 761 456655-01
E-mail: medizintechnik@DJOglobal.com
Web: www.DJOglobal.de

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

12. Technical service

12.1 Technical hotline

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

Phone: +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

12.2 Shipment

To prevent damage during transport, only use the original shipping box. These boxes can be obtained from DJO.

Before packing the therapy unit, set it to the transport position (see chapter 7).

12.3 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
- Qty
- Serial number of the device

Note

Refer repairs to authorized, specially trained staff.

DJO offers service training for your personnel.

Note

Country-specific power cords are available from DJO. Please contact DJO or your DJO distributor.

13. Accessories and Parts for Use with the Device

Item	Description	Part no.	Qty
1.	Patient chip cards ARTROMOT® ACTIVE-K		
	Passive – blue (CPM functions only)	0.0040.210	☐
	Active – green (CAM functions only)	0.0040.211	☐
	Protocol – orange (therapy plans only)	0.0040.212	☐
	Special – red (free programming)	0.0040.213	☐
2.	Marker pen for patient chip card	0.0031.006	☐
3.	Connection cable for muscle stimulator Shielded, 1,6 m	2.0037.024	☐
4.	Strap fixation set	0.0040.100	☐
5.	Power cord EU version H05VV-F3G 3 x 1 mm² length 4 m	0.0034.118	☐

14. CE-Declaration of conformity

DECLARATION OF CONFORMITY

In compliance with the provisions of the Council Directive 93/42/EEC, Annex II, of 14 June 1993 / Amendment of 5 September 2007, concerning medical devices, the company

ORMED GmbH
Merzhauser Straße 112
D-79100 Freiburg

declares under its sole responsibility that the products of the product line

ARTROMOT® (see Annex)

fulfill the essential requirements of Annex I of the Council Directive 93/42/EEC.

With reference to Rule 9 of the Directive 93/42/EEC, Annex 9, the product is a device of risk class IIa.

CE 0297

Notified body:
DQS Medizinprodukte GmbH
August-Schanz-Straße 21
60433 Frankfurt am Main

Freiburg, 17 August 2018

_____

- QA Management Representative-
-Bernhard Krohne-

This certificate is valid until expiry of the certificate referred to.
(The certificate for the year of manufacture can be downloaded from: https://www.djoglobal.de/arzt/qualitaet.html)

Anhang:
ARTROMOT®-S3
ARTROMOT®-S4
ARTROMOT® ACTIVE-K
ARTROMOT®-K1
ARTROMOT®-SP3
ARTROMOT®-E2

MOT-AC-328-US/GB-REV.06-08/2018

CE-0297

Hersteller/Manufacturer:

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a DJO Company
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