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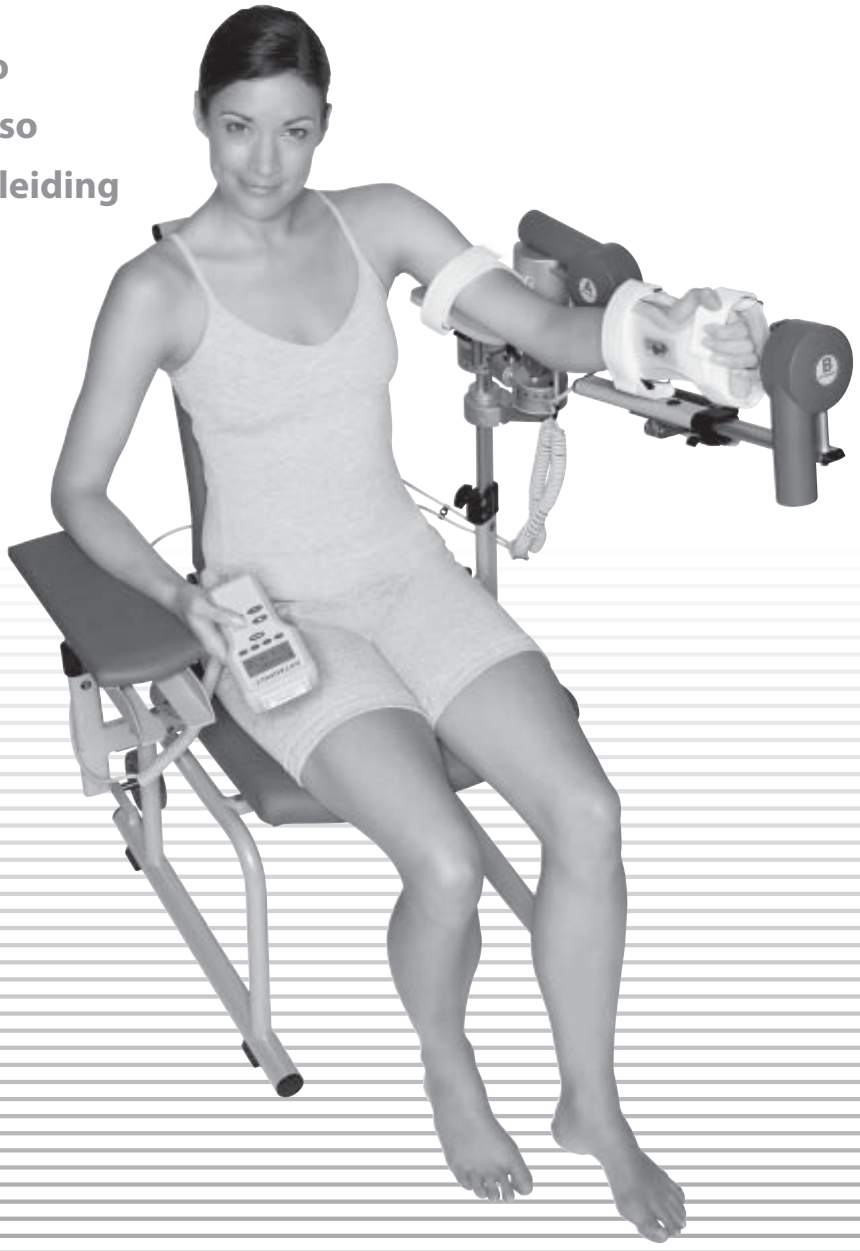
ARTROMOT®-E2
ARTROMOT®-E2 COMPACT

- **D** Gebrauchsanweisung
- **E** Operation Manual
- **F** Mode d'emploi
- **ES** Modo de empleo
- **I** Istruzioni per l'uso
- **NL** Gebruikershandleiding



Contents

1. How to use the CPM device

1.1 Fields of application

The **ARTROMOT®-E2/-E2 compact** is a motor-operated **C**ontinuous **P**assive **M**otion (**CPM**) device providing motion to the elbow joint.

Suitable for use in hospitals, clinics, general practices and rental services, it is an important supplement to medical and therapeutic treatment.

1.2 Therapy objectives

CPM therapy with the **ARTROMOT®-E2/-E2 compact** is mainly used to prevent the negative effects of immobilization, to allow patients to regain painless mobility of joints at an early stage and to promote healing and achieve a positive functional result.

Other objectives of therapy include:

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

1.3 Indications

The CPM device is indicated in the treatment of most injuries and postoperative conditions and diseases of the elbow joint. Examples:

- joint distortion and contusion
- arthrotomy and arthroscopy procedures in combination with synovectomy, arthrolysis or other intra-articular interventions
- all types of arthoplasty
- mobilization of joints in anesthetized patients
- exercise-stable fractures after surgery and pseudoarthrosis
- endoprosthetic implants
- myoplasty
- corrective osteotomy

1.4 Contraindications

Do NOT use the ARTROMOT®-E2/-E2 compact on patients with:

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

2. Description of the ARTROMOT®-E2/-E2 compact

The motorized CPM device supports the following movements of the elbow joint:

Extension/flexion 5°- 0° -140°

Pronation/supination 90°- 0° - 90°

It can be reconfigured for use on either side.

> **Note!**
>
> To unambiguously represent the current position of the CPM device, pronation and extension values below 0° are marked with the symbol "-" both on the display and in this document.

These are some of the outstanding ARTROMOT®-E2/-E2 compact features:

- anatomically correct setup
- physiological movements
- maximum possible ranges of motion
- programming unit for precise adjustment of patient-specific therapy values
- chip card for storage of the programmed therapy parameters
- easy transport

Biocompatibility

Those parts of the ARTROMOT®-E2/-E2 compact that come into contact with the patient when the device is used as intended, are designed to fulfil the biocompatibility requirements of the applicable standards.

2.1 Description of the ARTROMOT®-E2 device components

Note: See device description on pages 2 and 3

1. Knob for horizontal adduction/abduction (horizontal extension/flexion)
2. Screw for double joint
3. Double joint
4. Screw for height adjustment
5. Upper arm support
6. Locking pin for height adjustment of upper arm support
7. Screw for elbow angle adjustment
8. Cam lever for forearm length adjustment
9. Slider
10. Screw for adjustment of the backrest angle
11. Pin for swivel motion of upper arm support
12. Screw for forearm module swivel motion
13. Locking screw for right/left positioning
14. Armrest for healthy arm
15. Programming unit
16. Compartment for storage of programming unit
17. Patient chip card
18. Connection for power cord
19. Power switch (ON/OFF)
20. Fuse
21. Connectors for motion element
22. Locking pins
23. Straps for forearm support
24. Motor A
25. Motor B
26. Palmar hand support
27. Dorsal hand support
28. Folds down the backrest (transport position)
29. Wheels
30. Bracket for adjustment of the positioning angle
31. Strap for upper arm support
32. Connector for programming unit

Subject to technical modifications (07/2008)

2.2 Description of the ARTROMOT®-E2 compact device components

Note: See device description on pages 268 and 269

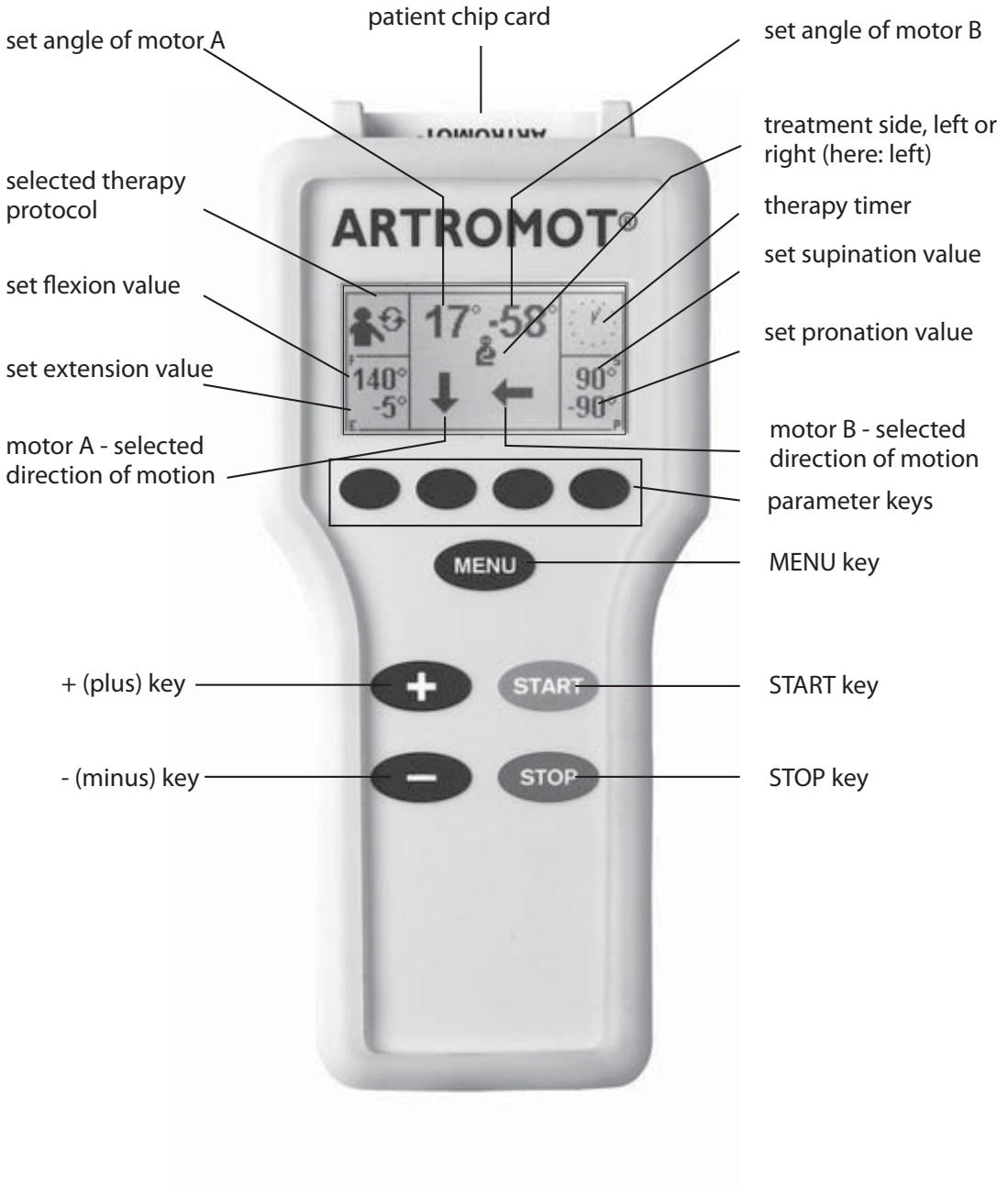
1. Screw for height adjustment
2. Screw for elbow angle adjustment
3. Cam lever for forearm length adjustment
4. Slider
5. Pin for swivel motion of upper arm support
6. Screw for forearm module swivel motion
7. Locking screw for right/left positioning
8. Fuse
9. Connectors for motion element
10. Straps for forearm support
11. Motor A
12. Motor B
13. Palmar hand support
14. Dorsal hand support
15. Programming unit
16. Connector for programming unit
17. Patient chip card
18. Connection for power cord
19. Power switch (ON/OFF)
20. Upper arm support
21. Strap for upper arm support
22. Wheel locks
23. Compartment for storage of programming unit
24. Locking screw
25. Wheels
26. Pin for height adjustment of upper arm support
27. Bracket for adjustment of the positioning angle

Subject to change without notice

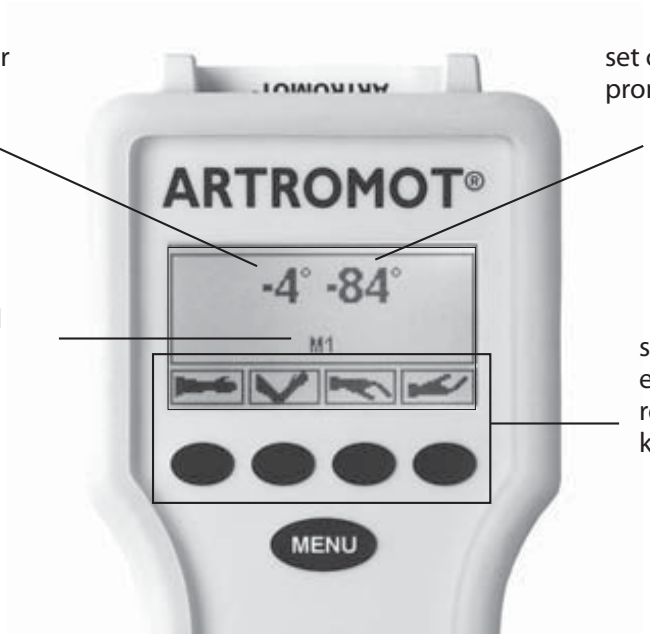
(07/2008)

2.3 Description of the programming unit

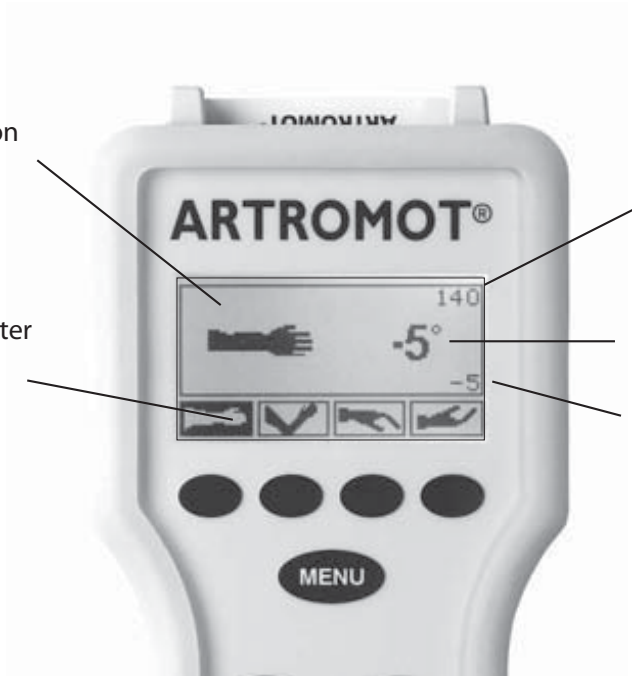
2.3.1 Programming unit in normal mode



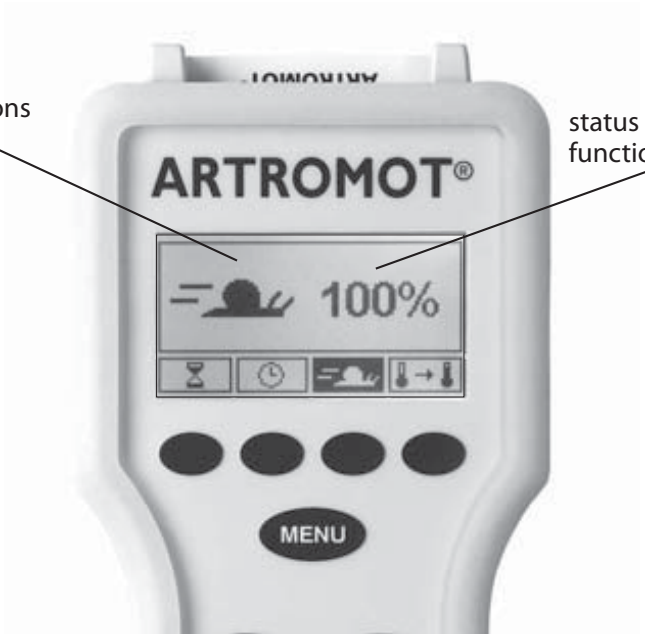
2.3.2 Programming unit in MENU selection mode



2.3.3 Programming unit in ROM programming mode (range of motion)



2.2.4 Programming unit in general programming mode



2.4 Explanation of symbols

Also refer to symbol overview on page 266.


extension


flexion


pronation


supination


pause


timer


speed


warm-up protocol

load reversal motor A

load reversal motor B

motor A ON/OFF

motor B ON/OFF

isolation program


total therapy time


extension/flexion therapy documentation


pronation/supination therapy documentation


stretching in extension


stretching in flexion


stretching in pronation


stretching in supination


EROM repeat extension/pronation


EROM repeat flexion/supination


transport setting

new patient

synchronized/non-synchronized mode


service menu

English

2.5 Explanation of symbols (connections and nameplate)

	alternating current
	protective earth connection
	type B applied part
	power switch OFF
	power switch ON
	Refer to accompanying documents
	Do not dispose with unsorted municipal waste

3. Safety information

Definitions

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

⚠ Danger!

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

⚠ Warning!

indicates a hazard. If not avoided, 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®-E2/-E2 compact** is not designed for use in areas of medical locations 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®-E2/E2 compact. Individuals are authorized after receiving training in the operation of the device and reading this operation manual.
- Before using the device, the operator must ascertain that it is in correct working order and operating condition. In particular, the cables and connectors must be checked for signs of damage. Damaged parts must be replaced immediately, before use.
- **Before therapy**, a **test run** consisting of several exercise cycles must be completed, first without and then with the patient. Check that all setting screws are tightened.
- Stop therapy immediately, when you have doubts about the device settings and/or the therapy protocol.
- Ensure an **anatomically correct setup of the CPM device** suitable for the patient to be treated. Therefore, carefully verify the following settings/positions:

  (also refer to the numbers on the device):

  1. Horizontal adduction/abduction (horizontal extension/flexion)
  2. Height adjustment
  3. Adjustment of the positioning angle
  4. Adjustment of the forearm length
  5. Axis adjustment motor A and motor B
  6. Backrest adjustment
  7. ROM adjustment

- It is not permitted to change the adjustment of 1 through 6 while the CPM device is applied on a patient.

- Movements must **not cause any pain** or **irritation**.
- Patients must be **fully conscious** while being instructed in the use of the CPM device and during therapy.
- The **choice** of the **therapy parameters** to program and of the **therapy protocols** to use is restricted to the responsible **physician or therapist**. It is the physician's or therapist's decision whether or not to use the CPM device on a specific patient.
- The patient must be familiar with the functions of the ARTROMOT®-E2/-E2 compact programming unit and the unit must be **within easy reach** of the patient, allowing him or her to stop therapy, if needed. **Patients unable to operate the programming unit**, e.g. paralytic patients, must never be left unattended during therapy.
- Write the patient's name on the **patient chip card**. The card should only be used for this 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 sections 4.1 and 5.3, paragraph "New Patient"). Use **original chip cards only**.
- All **accessories** used with the ARTROMOT®-E2/-E2 compact must be approved by ORMED.DJO.
- Do not allow **parts of the body or any objects** (such as blankets, cushions or cables) to get caught in the moving parts of the CPM device.
- Always seat the patient on a chair with four legs and without armrests when using the **ARTROMOT®-E2 compact**.

⚠ Warning!

Shock hazard—

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

- **Before use** allow the ARTROMOT®-E2/-E2 compact to reach room temperature. If the device has been transported at **temperatures below 0 °C (32°F)**, leave it to dry at room temperature for about 2 hours, until any condensation has disappeared.
- The ARTROMOT®-E2/-E2 compact must only be operated in **dry rooms**.
- When disconnecting the device from the power line, remove the plug from the wall outlet first, before disconnecting the cable from the device.
- When connecting the device to other equipment or when creating a medical system, check that the sum of leakage currents will not cause any hazard. Please contact ORMED.DJO, if you have questions in this matter.
- Do not use multiple portable socket outlets (MPSO) to connect the device to the power line. The ARTROMOT®-E2/-E2 compact must be connected to a **properly installed wall outlet with a non-fused earthed wire**. Before connecting the power cord, it must be completely unrolled and placed such that it will not get caught in the moving parts of the device.
- Before cleaning and service interventions, **disconnect the device from the power line by removing the power cord from the wall outlet**.
- **Liquids must not be allowed to enter the CPM device** or the **programming unit**. If liquids have entered into the device, the ARTROMOT®-E2/-E2 compact must be checked by a service technician, before it can be reused.

⚠ Warning!

Equipment malfunction—

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

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

– **Route all cables** such that they will not get caught by the moving parts during operation and that they do not present a stumbling hazard.

– **Inspect** the ARTROMOT®-E2/-E2 compact for damage and loose connections at least once a year.

⚠ Caution!

Preventing chafing and pressure sores — If your patient is **adipose,** very **tall** or very **short**, be sure to prevent chafing and pressure sores.

Patient hazard, damage to the CPM device — The CPM device **ARTROMOT®-E2** must not be used to transport people.

⚠ Caution!

Equipment damage—

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

– The **seat** withstands a **maximum continuous load**of **150 kg** / 330 lb.

– The **arm support element** withstands a **maximum continuous load** of **9 kg** / 20 lb.

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

– Do not expose the ARTROMOT®-E2/-E2 compact to direct sunlight, because some of the components may reach inadmissibly high temperatures.

– Be aware that the connectors can only be inserted in the correct orientation and secure all connections with the locks.

4. Device setup

Note: See device description on pages 2/3 and 268/269.

4.1 Connecting the ARTROMOT®-E2/-E2 compact, performance check

1. Connect the **power cord** to **socket** (18) of the device and connect the mains plug to a wall outlet with a non-fused earthed wire (100 to 240 Volt, 50/60 Hz).
2. Turn the **power switch** (19) on.
3. Follow these steps to set the carriage to the **home position**:

Initial adjustment for new patients

Write the patient's name down on the back of the chip card. Insert the original patient chip card (17) into the programming unit (15).

Press the **MENU** key on the programming unit seven times in rapid succession or give it one long press to access programming level seven (with each key press, you advance one level).

Press the "new patient" parameter key →0← and select this function (a check mark appears in the circle next to the function).

Press the **START** key. The CPM device automatically enters the **home position**.

Adjustment with programmed chip card

Insert the original patient chip card (17) into the programming unit (15).

Press the **START** key.

The CPM device automatically moves to the **starting position** (middle position of the set extension/flexion and pronation/supination values).

Performance check

If the programming unit can be operated as described above and the ARTROMOT®-E2/-E2 compact moves to the home position (for home position values, please refer to sections 5.3), the CPM device has passed the performance check.

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

– An audio signal sounds.

– The device switches off immediately.

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

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

If it has been determined that the ARTROMOT®-E2/-E2 compact operates perfectly, ask the patient to sit down on the ARTROMOT®-E2/-E2 compact chair.

4.2 Adjusting the device to the patient

Note!

For the following adjustments, the patient's arm should not yet be placed on the armrest. After you have adjusted the device to the approximate patient measurements, the patient can place his/her arm on the armrest for a check of the setup and for the fine adjustment.

The settings are numbered 1 through 5. For easy orientation, you will find the same numbers on the CPM device. Always set up the CPM device in this order.

Write the settings down on the back of the patient's chip card.

Before you adjust the ARTROMOT®-E2/-E2 compact to the patient, you may have to convert the device for use on the left or right elbow joint. (see section 6.4 Conversion)

Before any treatment is possible, adjust the device as follows:

ARTROMOT®- E2: backrest, armrest

Before you start setting up the device for the exercise protocol, you must adjust it to a position that is anatomically correct for the respective patient.

- Open thumbscrew (10) and adjust the backrest to a position that is comfortable for the patient (Fig. F).
- Set the armrest for the healthy arm to a height that allows the patient to sit up straight (locking screw 14).

ARTROMOT®- E2 compact: positioning the chair and the CPM device

Before you start setting up the device for the exercise protocol, you must adjust it to a position that is anatomically correct for the respective patient.

- Only use chairs with four legs and without armrests. The patient must be seated safely and straight on the chair.
- Once you have set up the ARTROMOT®- E2 compact, lock the brakes (22) of the castor wheels (25).

4.2.1 Adjusting the ARTROMOT®-E2 to the patient

Note: The individual steps are illustrated on page 4.

❶ a,b and c Horizontal Extension/Flexion (Fig. A)

Horizontal adduction/abduction is set manually. It is the purpose of the adjustment to achieve congruent axes of the motor axis and the elbow joint.

- To begin with, press knob (1). Leave it engaged in the open position.
- Now open screw (2). The double joint now moves freely.
- Set the motion element with motor A to the appropriate position. Make sure that a congruence of the axis of motor A and the elbow joint is achieved.
- Push knob (1) in the opposite direction.
- Tighten screw (2).

❷ Height adjustment (Fig. B)

Before opening locking screw (4), hold the moving part of the CPM device by grasping the double joint (3), to prevent the part from falling down.

- Open screw (4) and set the motion element to the appropriate height. Ensure that the entire upper arm lies on the support (5). The patient should sit up straight and be relaxed.
- Tighten screw (4).
- Now check the agreement of the axis of motor A and the elbow joint. If required, make a fine adjustment of the vertical orientation, using locking pin (6).

❸ Adjustment of the positioning angle (Fig. C)

⚠ Caution!

Patient hazard / equipment damage—
Hold motor B for this adjustment to secure the device.

- Hold the motion element at bracket (30).
- Now open screw (7) and set the appropriate angle.
- Tighten screw (7).

❹ Adjustment of the forearm length (Fig. D)

⚠ Caution!

Patient hazard / equipment damage—
Hold motor B for this adjustment to secure the device.

- Open the cam lever (8) and set the appropriate length. Make sure that the slider (9) is free to move at least 2 cm in either direction. There must be enough space for the fingers between the hand support and motor B.
- Tighten the cam lever (8).

❺ Axis adjustment motor B (Fig. E)

In most cases the setting is 0 on the scale. In cases of a deformed forearm, the setting may have to be changed.

- Open the locking screw (13) and perform the adjustment.
- Tighten the locking screw (13).

❻ Backrest adjustment (Fig. F)

Set the backrest to the foremost position before setting the motion element to an angle of 0° for horizontal adduction/abduction. To do so, open adjusting screw (10), set the backrest to the foremost position and tighten the screw.

To achieve optimal congruence between the axis of motor A and the patient's rotational axis of the elbow joint, the backrest angle can be individually adjusted in all other horizontal adduction/abduction positions.

Checking the setup, fine adjustment

Please check the following before using the CPM device on a patient:

- Check settings 1 to 6 and make sure that the pivot of motor A agrees with the pivot of the elbow joint, i.e., that the axis of motor B vertically passes through the elbow joint.
- Check that all locking screws and clamping levers are tight.

4.2.2 Adjusting the ARTROMOT®-E2 compact to the patient

Note:
The individual steps are illustrated on page 82.

Note:
Step 1 does not exist for the ARTROMOT®-E2 compact.

❷ Height adjustment (Fig. A)

Before opening locking screw (1), hold the moving part of the CPM device by grasping motor A (11), to prevent the part from falling down.

- Open screw (1) and set the motion element to the appropriate height. Ensure that the entire upper arm lies on the support (20). The patient should sit up straight and be relaxed.
- Tighten screw (1).
- Now check the agreement of the axis of motor A and the elbow joint. If required, make a fine adjustment of the vertical orientation, using locking pin (26).

❸ Adjustment of the positioning angle (Fig. B).

⚠ Caution!

Patient hazard / equipment damage—
Hold motor B for this adjustment to secure the device.

- Hold the motion element at bracket (27).
- Now open screw (2) and set the appropriate angle.
- Tighten screw (2).

❹ Adjustment of the forearm length (Fig. C)

⚠ Caution!

Patient hazard / equipment damage—
Hold motor B for this adjustment to secure the device.

- Open the cam lever (3) and set the appropriate length. Make sure that the slider (4) is free to move at least 2 cm in either direction. There must be enough space for the fingers between the hand support and motor B.
- Tighten the cam lever (3).

❺ Axis adjustment motor B (Fig. D)

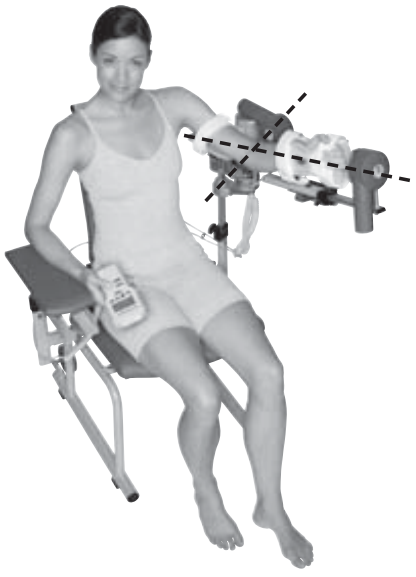
In most cases the setting is 0 on the scale. In cases of a deformed forearm, the setting may have to be changed.

- Open the locking screw (7) and perform the adjustment.
- Tighten the locking screw (7).

Checking the setup, fine adjustment

Please check the following before using the CPM device on a patient:

- Check settings 2 to 5 and make sure that the pivot of motor A agrees with the pivot of the elbow joint, i.e., that the axis of motor B vertically passes through the elbow joint.
- Check that all locking screws and clamping levers are tight.



5. Setting the treatment values

⚠ Warning!

Patient hazard—

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

Note: See also 2.2 and 2.3

Note!

Programming is only possible when the patient's chip card has been inserted.

For information about therapy parameters and programming of special functions, please refer to sections 5.1 to 5.3.

See section 5.4 for programming examples.

Important!

The programming unit **ARTROMOT®-E2/-E2 compact "Graphics"** can be connected to all products of the **ARTROMOT® family of elbow CPM machines**.

It is possible to exchange chip cards between the "Text" and "Graphics" versions.

Please note:

1. If a "Graphics" programming unit is operating with a formatted "Text" chip card
   - the **selected language** of the "Text" version remains activated; it is irrelevant for the "Graphics" version.
   - the **reverse on load** setting saved in the "Text" version is automatically used for both motors.
   - the **key lock** is disabled.
2. If a "**Text**" programming unit is operating with a formatted "Graphics" chip card
   - the **selected language** automatically changes to the default setting: German.
   - the **reverse on load** setting saved for motor A in the "Graphics" version is automatically used for both motors.
   - a **key lock** set in the "Graphics" version will remain active, only when no changes were made with the "Text" version; the key lock function is **not an option with the "Text" version.**

5.1 General information on programming the ARTROMOT® -E2/ -E2 compact

1. You activate the programming mode by briefly pressing the **MENU** key on the programming unit.
2. The treatment parameters and functions are allocated to seven programming levels (four functions per level).

   To be able to program a parameter you will have to access the corresponding programming level. This is also done with the **MENU** key. With each brief key press you advance one level. The code M1, M2, etc. that appears in the middle of the display indicates the programming level. To back up one level, e.g. from level 2 to 1 or from level 1 to 7, hold the MENU key down for some seconds.

3. You activate the treatment parameters and functions with the **four parameter keys** below the display. The symbols above the four parameter keys indicate the assigned parameters and functions.

   This is what happens when you press one of the parameter keys to select a parameter:

   - The corresponding symbol appears on the display in a larger format.
   - The set value is displayed.
   - The symbol above the parameter key appears in reverse video.

4. With the + / - keys (plus/minus) you change the displayed value. When you press and hold the key, the value will change at a higher rate.

   Some of the (special) functions can only be enabled and disabled. This is done by pressing the corresponding parameter key or with the + / - keys. Active parameters are identified with a check mark in the circle next to the symbol.

5. Having programmed all parameters, press the **STOP** key to save the values.

6. Then press the **START** key: the ARTROMOT®-E2/-E2 compact checks the set values, moves to the position halfway between the set extension and flexion values as well as to the set supination and pronation values and stops.

7. Press the **START** key again to start therapy.

   The CPM device will now begin with the set physiological motion pattern in the **synchronized mode**. The motor with the larger range of motion operates at the programmed speed, while the speed of the second motor is adapted. This ensures that both motors will reach their target positions at almost the same time.

   After activation of the **START** key in the **non-synchronized mode** the motors will perform random movements, each motor reversing after reaching the maximum values. The programmed speed is valid for both motors.

Note!

– Refer to section 5.3 for a description of the parameters.

– To **view** the **set parameter values**, press the corresponding parameter key. Before, however, you have to press the **STOP** key and access the correct menu level.

– To prevent accidental changes of the parameter settings, you can **lock the keys**. To do so, simultaneously press **keys + and –** for **approx. 3 seconds**.

Press both keys again for approx. 3 seconds to unlock.

– Selecting the "new patient" function will automatically delete the data on the patient chip card. When you have finished programming the unit and press the **STOP** key, the settings will automatically also be saved to the patient chip card.

– **Emergency stop function**: When any of the keys is pressed during therapy, the ARTROMOT®-E2/-E2 compact switches immediately off.

– When the **START** key is pressed again in the synchronized mode and in the non-synchronized mode, the carriage will reverse its direction.

Patients with a programmed chip card

- First complete the mechanical adjustments.
- Then insert the chip card (the patient is not yet positioned on the CPM device).
- Press the **START** key: the device will move to the starting position as specified by the parameters stored on the chip card and stops.
- Position the patient on the CPM device and press the **START** key to initiate therapy.

5.2 Programming the ARTROMOT®-E2/ -E2 compact

Different programming levels are provided to program the ARTROMOT®-E2/-E2 compact.

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

The currently selected level is indicated on the display.

The following **treatment values, settings** and **information** can be entered/viewed on the programming unit (15):

LEVEL 1:

- extension
- flexion
- pronation
- supination

LEVEL 2:

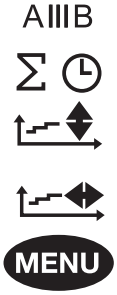
- pause
- therapy timer
- speed
- warm-up protocol

LEVEL 3:

- reverse on load - motor A
- reverse on load - motor B
- motor A ON/OFF
- motor B ON/OFF

LEVEL 4:

- isolation protocol
- total therapy time
- therapy documentation: extension/flexion
- therapy documentation: pronation/supination



LEVEL 5:

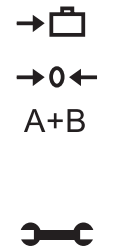
- stretching in extension
- stretching in flexion
- stretching in pronation
- stretching in supination

LEVEL 6:

- EROM repeat extension/ pronation
- EROM repeat flexion/supination

LEVEL 7:

- transport setting
- new patient
- operating mode synchronized/ non-synchronized
- Service menu



Note!

- **While you adjust the values**, the carriage will move to the set range. This allows you to easily and quickly determine the ROM where the patient does not experience any pain.
- The angle entered last for the respective directions of motion will be saved in each case.

5.3 Therapy parameter details

- To access the programming level you need, repeatedly press the **MENU key**.
- The treatment parameters are selected with the different **parameter keys**.
- To change the treatment values, press the **+ / – keys**.
- To enable/disable a function, press the respective **parameter key** again.
- To save the entered values, press the **STOP key**.

LEVEL 1:

■ **extension**
maximum value: **- 5 degrees**

■ **flexion**
maximum value: **140 degrees**

■ **pronation**
maximum value: **- 90 degrees**

■ **supination**
maximum value: **90 degrees**

Note!

- The programmed values and the values (degrees) measured on the patient may deviate slightly.
- To ensure a physiological motion, the carriage simultaneously moves to the following positions in the synchronized mode:
  – maximum extension value and maximum pronation value
  – maximum flexion value and maximum supination value.
- To ensure that the movements you program are physiological in nature, we recommend to program the carriage in the following order:
  1. maximum extension value
  2. maximum pronation value
  3. supination **= 0°** (to relieve the elbow)
  4. maximum flexion value
  5. maximum supination value
- When the **START** key is pressed in the synchronized mode, the carriage will first move to the position halfway between the set maximum extension/flexion values as well as the pronation/supination values. The carriage will stop in this position. Treatment begins when you press the **START key** again.
- Horizontal adduction/abduction is adjusted manually. These are possible settings:

  horizontal adduction : **120°**

  horizontal abduction: **0°**

English

LEVEL 2:

■ Pauses

Pauses occur at each programmed maximum value.

These are the two pause points:

– maximum extension value and maximum pronation value

– maximum flexion value and maximum supination value.

Pauses are separately adjustable for motor A and motor B between 1 second and 60 minutes. Pauses can be set in steps of 1 second to any value between 0 and 59 seconds, and in steps of 1 minute to any value between 1 and 60 minutes.

Default: no pause

Follow these steps to program pauses:

- Access menu level 2, then press the parameter key to select the special function .
- The display shows the symbol for the special function and the selected pause durations.

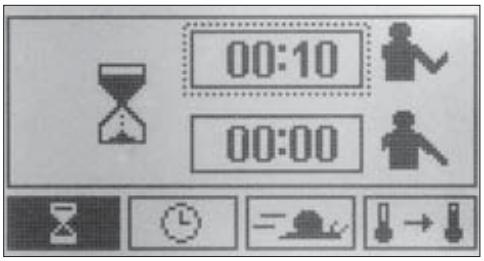
  The display shows the symbol for the special function and the selected pause durations.

  top: flexion/supination pause .

  bottom: extension/pronation pause .

  The flexion/supination pause duration appears in a box.
- To change the flexion/supination pause, press the "**+**" or "**-**" key.

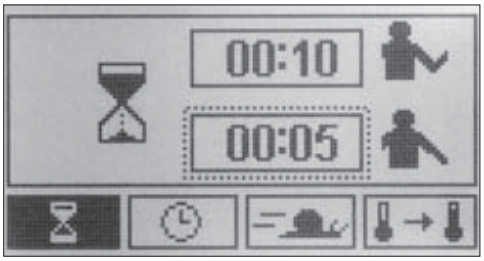
  Select a duration of 10 seconds, for instance.



- Press the **parameter key** again when done. The frame automatically moves to the line below, indicating that the extension/pronation pause can be adjusted .

  The **parameter key** is only used to toggle between these two functions.
- To modify the value, press the "**+**" (plus) or "**-**" (minus) key.

  Select a duration of 5 seconds, for instance.



- Save the programmed values by pressing the **STOP** key, then press the **START** key to initiate the treatment.

■ **Therapy timer**

Default setting is **continuous operation**.
A clock symbol in the upper right-hand corner of the display identifies the **continuous mode of operation**. The clock indicates the elapsed therapy time.

In the **continuous mode**, the device must be stopped with the **STOP** key.

However, the therapy timer can be set in **steps of 1 minute to any value between 1 and 59 minutes and in steps of 30 minutes to any value between 1 and 24 hours**. When the time has elapsed, the device switches automatically off and stops in the middle between the set limit values.

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

■ **Speed**

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

1 % is equivalent to 14°/minute
100 % is equivalent to 230°/minute

Default: 100 %

■ **Warm-up protocol**

During warm-up, the patient will slowly become used to the set maximum values for extension/flexion and pronation/supination.

The warm-up protocol starts in the middle between the two maximum values set for extension/flexion and pronation/supination. The range of motion increases with each cycle, until the programmed maximum values are reached after a total of 15 cycles.

After reaching the maximum values, the device automatically enters the normal mode.

If a therapy time is activated, the system restarts with the warm-up protocol when the therapy time has elapsed and the devices is started again.

During warm-up, the display will show the symbol in the upper, left-hand corner.

Default: disabled

LEVEL 3:

■ **Reverse on load - motor A (safety feature)** A

The device automatically reverses both motors when the patient's resistance (load) exceeds the set value.

Adjustable levels for reverse on load feature: 1 - 25. At level 1, very low resistance will cause the device to reverse; at level 25, a high resistance is required to initiate the reversal.

Default: level 25

■ **Reverse on load - motor B (safety setting)** B

The device automatically reverses both motors when the patient's resistance (load) exceeds the set value.

Adjustable levels for reverse on load feature: 1 - 25.
At level 1, very low resistance will cause the device to reverse; at level 25, a high resistance is required to initiate the reversal.

Default: level 25

⚠ Caution!

Patient hazard—

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

■ **Motor A ON/OFF** A

To permit fully isolated movements, the motors can individually be turned on and off. Motor A effects the extension and flexion movements, while motor B effects the pronation and supination movements.

For an isolated pronation/supination movement, set motor A to the appropriate position (extension/flexion), then turn the motor off.

In normal mode the display indicates the symbol "**OFF**" during therapy, instead of the programmed extension/flexion angles.

Default: motor A ON

■ **Motor B ON/OFF** ⊙ B

To permit fully isolated movements, the motors can individually be turned on and off. Motor A effects the extension and flexion movements, while motor B effects the pronation and supination movements.

For an isolated extension/flexion movement, set motor B to the appropriate position (pronation/supination), then turn the motor off.

In normal mode the display indicates the symbol "**OFF**" during therapy, instead of the programmed pronation/supination angles.

Default: motor B ON

Note!

Please note that one motor (A or B) must always be turned on. Otherwise the following symbol will be displayed when you press **START**:

Ⓐ OFF Ⓑ

LEVEL 4:

■ **Isolation protocol** AIIIB

For this special function, both motors are turned on, but they will never move simultaneously.

These are the steps of the function:

- To begin with, motor A moves to the programmed maximum values for extension and flexion for three cycles and then stops. In this phase, motor B is disabled (symbol for motor B: **OFF**)
- Then motor B will move to the programmed maximum values for pronation and supination for one cycle and stops, then the full cycle will start over with motor A. Motor A is disabled while motor B is operating (symbol for motor A: OFF)
- The stop position at the end of the last cycle (for both extension/flexion and pronation/supination) can be selected in steps of 25% between 0% and 100% of the programmed maximum range of motion.
- Steps 1 and 2 can be repeated as often as needed. You can stop treatment with the STOP key; after the programmed therapy duration, it will stop automatically.

  During warm-up, the display will show the symbol  III in the upper, left-hand corner.

  Default: disabled

Follow these steps to program the special function:

- Access menu level 4, then press the parameter key to select the special function AIIIB.

  The display will indicate:

  - the symbol representing the special function
  - the status of the special function (circle with or without check mark)
  - two boxes with the current percentage of the stop positions for motor A and B
  - a check mark in a circle.
- You activate the function with the "+" key and deactivate it with the "-" key.

  In this case it is not possible to activate/deactive the function by pressing the parameter key again.

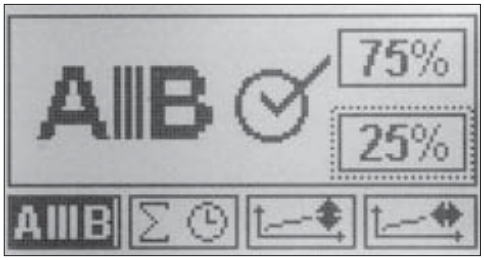
  A check mark in the circle identifies the activated function.
- Next press the parameter key of the isolation protocol. The marking moves to the upper percentage value, allowing you to enter the stop position for motor A.
- To modify the value, press the "+" (plus) or "-" (minus) key.

  Select 75%, for instance.
- Press the **parameter key** again when done. The marking automatically moves to the lower box, allowing you to adjust the stop position of motor B.

- To modify the value, press the "**+**" (plus) or "**-**" (minus) key.

  Select 25%, for instance.

- Save the programmed values by pressing the **STOP** key, then press the **START** key to begin the treatment.



This is what happens:

Extension/flexion is treated three times first (motor A). Motor B is positioned at 25% of the programmed range of motion for pronation and supination.

Subsequently, pronation/supination is treated once (motor B). Motor A is positioned at 75% of the programmed range of motion for extension and flexion.

> **Note!**
>
> The percentage values can be modified only when the special function is enabled (check mark).

■ Total therapy time ∑

Under menu item "total therapy time" you can view each patient's total therapy time (duration of all the patient's therapy sessions).

Deleting the stored therapy time:
Press and hold the **parameter key** for 5 seconds or select the "new patient" function.

■ Extension/flexion therapy documentation

This is a special function of the ARTROMOT®-E2/-E2 compact which allows the entire therapy documentation to be represented.

The carriage run times as well as the range of motion of the sessions are recorded.

The collected data are presented graphically in the form of 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.

■ Pronation/supination therapy documentation

This is a special function of the ARTROMOT®-E2/-E2 compact which allows the entire therapy documentation to be represented.

The carriage run times as well as the range of motion of the sessions are recorded.

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

LEVEL 5:

■ Stretching in extension

With the special "stretching in extension" function the joint will be gently stretched (arm stretching movement). Only the extension/flexion movement is treated here. Motor B is automatically disabled. The position of motor B cannot be changed once this special function has been activated.

Starting at the middle position the carriage will first move to the programmed flexion limit and then to the programmed extension limit.

Subsequently the carriage reverses 5 ° towards flexion and then moves very slowly back to the programmed extension value (symbol:). Subsequently the carriage attempts to attain another 5 ° at an even slower speed (symbol:).

If a high resistance toward the additional 5 ° is sensed, the reverse on load function is automatically activated and the carriage moves in the opposite direction.

This stretch cycle is repeated ten times.

After that the carriage moves to the programmed flexion limit and restarts the stretching in extension cycle.

This sequence can be repeated as often as needed. You can stop treatment with the STOP key; after the programmed therapy duration, it will stop automatically.

Default: disabled

Note!

- If a pause has been programmed, the carriage will stop for the pause each time the maximum stretching value is attained.
- Enabling the stretching in extension function automatically disables motor B. The only movement performed is extension/flexion.
- It is not possible to combine a second stretching function with the special function "stretching in extension".
- During operation, the display will show the symbol in the upper, left-hand corner.

■ Stretching in flexion

With the special "stretching in flexion" function the joint will be gently stretched (arm bending movement). Only the extension/flexion movement is treated here. Motor B is automatically disabled. The position of motor B cannot be changed once this special function has been activated.

Starting at the middle position the carriage will first move to the programmed extension limit and then to the programmed flexion limit.

Subsequently the carriage reverses 5 ° towards extension and then moves very slowly back to the programmed flexion value (symbol:). Then the carriage attempts to attain another 5 ° at an even slower speed **(**symbol:).

If a high resistance toward the additional 5 ° is sensed, the reverse on load function is automatically activated and the carriage moves in the opposite direction.

This stretch cycle is repeated ten times.

After that the carriage moves to the programmed extension limit and restarts the stretching in flexion cycle.

This sequence can be repeated as often as needed. You can stop treatment with the **STOP** key; after the programmed therapy duration, it will stop automatically.

Default: disabled

Note!

- If a pause has been programmed, the carriage will stop for the pause each time the maximum stretching value is attained.
- Enabling the stretching in flexion function automatically disables motor B. The only movement performed is extension/flexion.
- It is not possible to combine a second stretching function with the special function "stretching in extension".
- During operation, the display will show the symbol  in the upper, left-hand corner.

■ Stretching in pronation 

With the special "stretching in pronation" function the joint will be gently stretched in the pronation direction. Only the pronation/supination movement is treated here. Motor A is automatically disabled. The position of motor A cannot be changed once this special function has been activated.

Starting at the middle position the carriage will first move to the programmed supination position and then to the programmed pronation position.

Subsequently the carriage reverses 5 ° towards supination and then moves very slowly back to the programmed pronation value (symbol: ). Subsequently the carriage attempts to attain another 5 ° at an even slower speed (symbol: ).

If a high resistance toward the additional 5 ° is sensed, the reverse on load function is automatically activated and the carriage moves in the opposite direction.

This stretch cycle is repeated ten times.

After that the carriage moves to the programmed maximum supination position and restarts the stretching in pronation cycle.

This sequence can be repeated as often as needed. You can stop treatment with the **STOP** key; after the programmed therapy duration, it will stop automatically.

Default: disabled

Note!

- If a pause has been programmed, the carriage will stop for the pause each time the maximum stretching value is attained.
- Enabling the stretching in pronation function automatically disables motor A. The only movement performed is pronation/supination.
- It is not possible to combine a second stretching function with the special function "stretching in pronation".
- During operation, the display will show the symbol  in the upper, left-hand corner.

■ Stretching in supination 

With the special "stretching in supination" function the joint will be gently stretched in the supination direction. Only the pronation/supination movement is treated here. Motor A is automatically disabled. The position of motor A cannot be changed once this special function has been activated.

Starting at the middle position the carriage will first move to the programmed pronation position and then to the programmed supination position.

Subsequently the carriage reverses 5 ° towards pronation and then moves very slowly back to the programmed supination value (symbol: ). Subsequently the carriage attempts to attain another 5 ° at an even slower speed (symbol: ).

If a high resistance toward the additional 5 ° is sensed, the reverse on load function is automatically activated and the carriage moves in the opposite direction.

This stretch cycle is repeated ten times.

After that the carriage moves to the programmed maximum pronation position and restarts the stretching in supination cycle.

This sequence can be repeated as often as needed. You can stop treatment with the **STOP** key; after the programmed therapy duration, it will stop automatically.

Default: disabled

Note!

- If a pause has been programmed, the carriage will stop for the pause each time the maximum stretching value is attained.
- Enabling the stretching in supination function automatically disables motor A. The only movement performed is pronation/supination.
- It is not possible to combine a second stretching function with the special function "stretching in supination".
- During operation, the display will show the symbol in the upper, left-hand corner.

LEVEL 6:

■ **EROM repeat extension/pronation**

The special "EROM repeat extension/pronation" function allows a more efficient exercise in the last 10 ° before the set maximum extension and pronation values.

For this protocol, the CPM device starts in the middle between the set maximum extension/flexion and pronation/supination values. First of all the carriage moves simultaneously to the maximum flexion angle and to the maximum supination angle. Then it moves simultaneously to the maximum extension angle and to the maximum pronation angle.

When the set extension/pronation value has been reached, the carriage reverses 10 ° toward flexion/supination and then moves back again to the maximum extension/pronation angle. The movement through the final 10 ° is repeated five times at a slow speed.

At the end of the cycle, the carriage will again move to the maximum flexion value, at the same time as the maximum supination value, and then starts another cycle with five repetitions through the last 10 ° of extension/pronation.

This sequence can be repeated as often as needed. You can stop treatment with the **STOP** key; after the programmed therapy duration, it will stop automatically.

Default: disabled

■ **EROM repeat flexion/supination**

The special "EROM repeat flexion/supination" function allows a more efficient exercise in the last 10 ° before the set maximum flexion and supination values.

For this protocol, the CPM device starts in the middle between the set maximum extension/flexion and pronation/supination values. First of all the carriage moves simultaneously to the maximum extension angle and to the maximum pronation angle. Then it moves simultaneously to the maximum flexion angle and to the maximum supination angle.

When the flexion/supination value has been reached, the carriage reverses 10 ° toward extension/pronation and then moves back again to the maximum flexion/supination angle. The movement through the final 10 ° is repeated five times at a slow speed.

At the end of the cycle, the carriage will again move to the maximum extension value, at the same time as the maximum pronation value, and then starts another cycle with five repetitions through the last 10 ° of flexion/supination.

This sequence can be repeated as often as needed. You can stop treatment with the **STOP** key; after the programmed therapy duration, it will stop automatically.

Default: disabled

LEVEL 7:

■ Transport setting →🧳

With this function, the carriage will move to a position optimally suited for packing the CPM device. Select the function and press the START key. The carriage moves to the transport position. In the top left-hand corner of the display you will see →🧳 (also refer to chapter 6 Transport).

■ New patient →0←

With this function, the CPM device will move to the home position.

- Select the function and press the START key:
  - The carriage moves to the home position.
  - The programmed treatment parameters are deleted.
  - All values stored on the chip card are deleted.
  - The carriage stops in the middle position of the extension/flexion and pronation/supination angles.

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

- extension: 25°
- flexion: 35°
- pronation: -5°
- supination: 5°
- pauses: 0
- timer: continuous operation
- speed: 100 %
- reverse on load motor A: 25
- reverse on load motor B: 25
- motor A: ON
- motor B: ON
- synchronized mode: ON
- total therapy time: 0
- special functions: disabled

■ Operating mode A+B synchronized/non-synchronized

Motors A and B can run in synchronized or non-synchronized mode.

synchronized:

Motors A and B perform a synchronized movement according to the elbow joint's physiological motion pattern:

Starting at the middle position of the set extension/flexion and pronation/supination angles, the carriage first moves simultaneously to the maximum extension value and the maximum pronation value. Afterwards it moves simultaneously to the maximum flexion and maximum supination values. After reaching this position, the cycle restarts: maximum extension and maximum pronation.

During operation the synchronized mode is indicated in the top left-hand corner by the symbol  .

non-synchronized:

Both motors run independently of each other within the selected ranges of motion.

To enable the non-synchronized mode, disable the synchronized mode.

During operation the non-synchronized mode is indicated in the top left-hand corner by the symbol  .

Default: synchronized mode enabled

⚠ Caution!

Patient hazard—

The synchronized operation is recommended as a general rule. However, medical and/or therapeutic indications may call for the non-synchronized mode. In the non-synchronized mode, particular caution and attention on the part of the physician/therapist is required to rule out any risk for the patient.

■ **Service MENU**

For service purposes only, refer to Service Manual.

Reminder:

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

5.4 Application and programming examples

5.4.1 Isolated extension/ flexion

1. Complete the mechanical settings and adjust the carriage to the patient as described in section 4.2.
2. Press the **MENU key** on the programming unit to access level 1 (M1).
3. Press the **pronation** ( ) **or supination parameter key** ( ), the press the **+ / - keys** to set the carriage to the appropriate rotation position to be maintained during the isolated extension/flexion movements.
4. Next set the desired range of motion for extension/flexion by first pressing the **extension parameter key** ( ), then set the values with the **+ / - keys**.
5. Set the flexion value ( ) in the same way.

Note!

- For an exclusive extension/flexion protocol, motor B for the rotation movement must be turned off as described in steps 6 through 8 below.
- Having programmed the ranges of motion, you can program additional options, such as pause or speed.

6. Press the **MENU key** on the programming unit to access level 3 (M3).
7. Press the **Motor B ON/OFF** parameter key (⊙ B) to activate the parameter.
8. Deactivate motor B by pressing the parameter key **Motor B ON/OFF** again or the **–** (minus) key. The check mark in the circle next to the symbol must have disappeared.
9. Save the settings with the **STOP key**, set the carriage to the starting position with the **START key** and initiate therapy by pressing the **START key** again.

5.4.2 Isolated pronation/ supination

1. Complete the mechanical settings and adjust the carriage to the patient as described in section 4.2.
2. Press the **MENU key** on the programming unit to access level 1 (M1).
3. Activate the **parameter key extension** ( ) or flexion ( ), then press the **+ / - keys** to set the carriage to the appropriate position to be maintained during the isolated pronation/supination movements.
4. Next set the desired range of motion for pronation/supination by first pressing the **pronation parameter key** ( ), then set the values with the **+ / – keys**.
5. Set the supination value ( ) in the same way.

Note!

- For an exclusive rotation protocol, motor A for extension/flexion must be turned off as described in steps 6 through 8 below.
- Having programmed the ranges of motion, you can program additional options, such as pause or speed.

6. Press the **MENU key** on the programming unit to access level 3 (M3).
7. Press the **Motor A ON/OFF** parameter key (⊙ A) to activate the parameter.
8. Deactivate motor A by pressing the parameter key **Motor A ON/OFF** again or the **–** (minus) key. The check mark in the circle next to the symbol must have disappeared.
9. Save the settings with the **STOP key**, set the carriage to the starting position with the **START key** and initiate therapy by pressing the **START key** again.

6. Care, Maintenance, Transport, Conversion

6.1 Care

⚠ Warning!

Shock hazard – Unplug the device from the power line before cleaning.

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

- The ARTROMOT®-E2/-E2 compact 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 **support assemblies** can be cleaned with **commonly used** disinfectants and **mild household detergents**.
- Only use a **damp cloth** to wipe the CPM device down.

⚠ Caution!

Equipment damage –

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

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

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

6.2 Maintenance (fuse replacement)

Check before each use

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

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

Technical inspections

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

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

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

The device does not require additional regular maintenance.

Fuse replacement

⚠ Warning!

Patient hazard, equipment malfunction and damage—

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

Fuses used must be T1A fuses.

- Before replacing fuses turn off the ARTROMOT®-E2/-E2 compact and remove the power cord from the wall outlet.
- Use an appropriate tool to remove the fuse holder (20/8) situated between the power switch (19) and the power connector (18) (Fig. 1).
- Replace the fuses and reinsert the fuse holder (Fig. 2). Check that the fuse holder locks properly into place.

Fig. 1

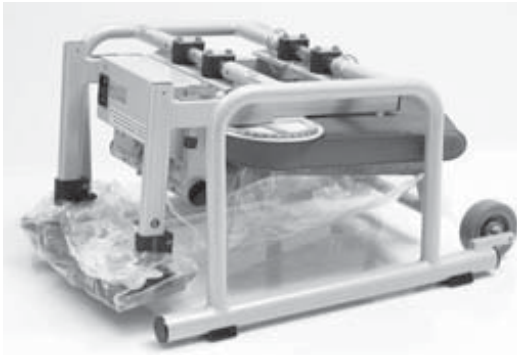
Fig. 2

6.3 Transport

6.3.1 ARTROMOT®-E2

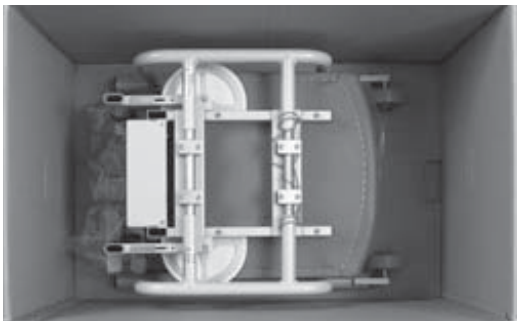
The following operating steps must be completed before transporting the **ARTROMOT®-E2**:

1. Activate the "transport setting" function → in the menu (see also 5.3) and start the ARTROMOT®-E2.
2. Turn off the ARTROMOT®-E2 power switch (19).
3. Remove the power cord (18) and disconnect the motion element (21) and the programming unit (32).
4. Open locking screw (4) and pull out the armrest (14) for the healthy arm.
5. Grasping the motion element at the bracket (30) for adjustment of the positioning angle, open the locking screw (4) and pull out the motion element.
6. Set horizontal adduction/abduction to 0° (indexing knob 1).
7. Open the locking screw for adjustment of the backrest (10), fold the backrest to the front all the way until flat on the seat and tighten the screw.
8. Remove the two locking pins (22). Pull out the legs towards the sides, reverse and reinsert. Then put the locking pins back in place.



9. Only use the original shipping box for transporting the device. Ormed GmbH & Co. KG cannot be held liable for transport damage, if the device was not shipped in its original shipping box.

10. Place the ARTROMOT®-E2 - legs first - on the bottom of the box. The markings on the bottom of the box indicate the correct position.



11. Then put the enclosed polystyrene block on the chair, observing the cut-outs in the block.
12. Put the programming unit (15) in the supplied box. Place the motion element, the armrest and the power cord in the respective cut-outs in the polystyrene block of the package.

13. Then close the box.

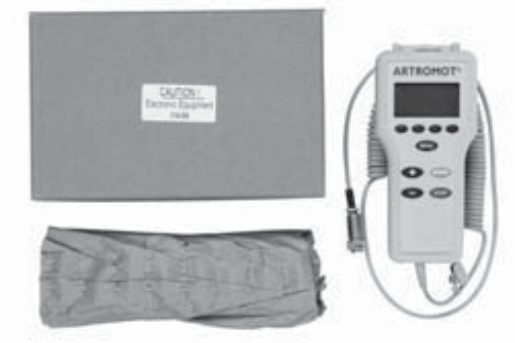
Reverse the above steps to reassemble the device after transport.

> **⚠ Warning!**
>
> Shock hazard—
>
> **Allow the ARTROMOT®-E2 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.

6.3.2 ARTROMOT®-E2 compact

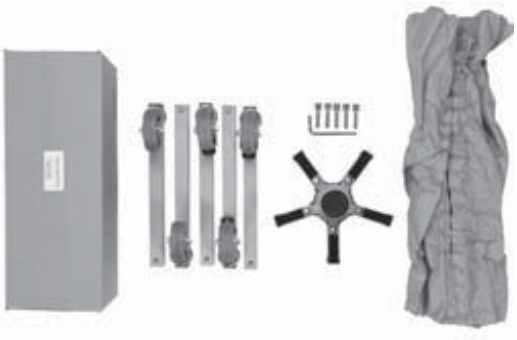
The following operating steps must be completed before transporting the ARTROMOT®-E2 compact:

1. Activate the "transport setting" function → 🧳 in the menu (see also 5.3) and start the ARTROMOT®-E2 compact.
2. Turn off the ARTROMOT®-E2 compact power switch (19).
3. Remove the power cord (18) and disconnect the motion element (9) and the programming unit (16).
4. Remove pin (26) on the underside and take off the upper arm support.
5. Remove pin (5) and take off the swiveling mechanism of the upper arm support. Set the guide of the upper arm support to the transport setting (parallel with motor A).
6. Grasping the motion element at the bracket (27) for adjustment of the positioning angle, open the locking screw (1) and pull out the motion element.
7. Open the locking screw for adjustment of the elbow angle adjustment (2) and separate the oval tube from the motion element.
8. Open locking screw (24) on the underside of the stand, then remove the column with the electronics box from the star-shaped stand.
9. Disassemble the stand by loosening the five legs with the special tool supplied and remove them.
10. Unscrew the locking screw (7) from motor B (12), remove the entire forearm support including the slider (4) and the hand support (13 + 14). Afterwards screw the locking screw (7) back into motor B.
11. Only use the original shipping box for transporting the device. Ormed GmbH & Co. KG cannot be held liable for transport damage, if the device was not shipped in its original shipping box.
12. Put the programming unit (15) in the supplied box, using sufficient padding.

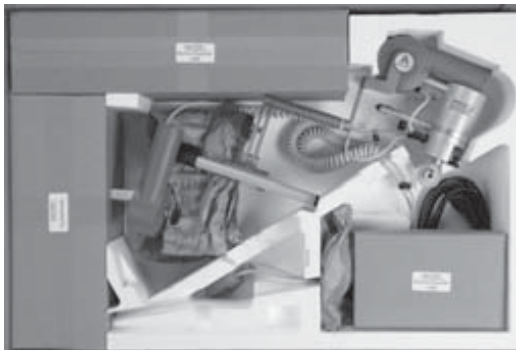


13. Pack the following items in the longer box provided, again using sufficient padding:
    - Upper arm support
    - Oval tube of the motion element
    - Column with electronics box
    - Entire forearm support with slider and hand support

14. Pack the following items in the shorter box provided, again using sufficient padding:
    - Star-shaped stand
    - 5 legs with castors
    - 5 screws to attach the legs
    - 5 washers to attach the legs
    - 1 Allen key



15. Please put the motion element, the power cord and the three smaller boxes in the respective cut-outs of the polystyrene block.



16. Then close the box.

⚠ Warning!

Shock hazard—

Allow the ARTROMOT®-E2 compact 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.

6.4 Conversion

Note!

On the display the respective sides are indicated as follows:

- The CPM device (upper arm support) is prepared for the left elbow.
- The CPM device (upper arm support) is prepared for the right elbow.
- This symbol appears during conversion of the CPM device.

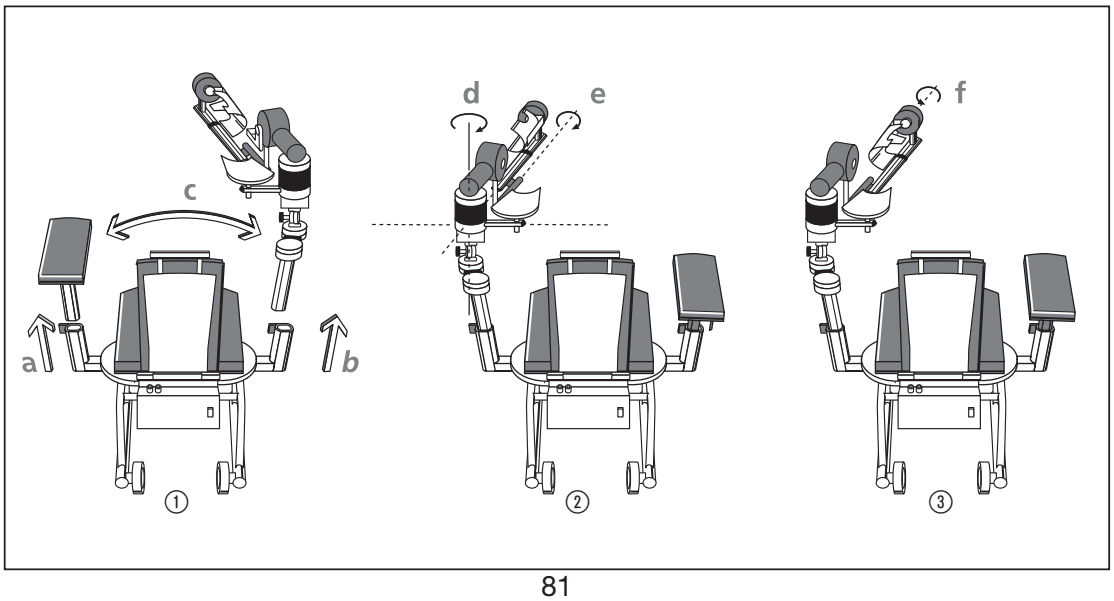
6.4.1 Reconfiguration of the ARTROMOT®-E2

The ARTROMOT®-E2 can be used on the left and on the right elbow joint. However, the device must be converted first. This is done very quickly.

1. Activate the "transport setting" function → in the menu (see also 5.3) and start the ARTROMOT®-E2.
2. Adjust an angle of 90° for horizontal adduction/abduction (indexing knob 1) (see conversion drawing ①).
3. Open locking screw (4) for the height adjustment, remove the armrest for the healthy arm and place it on the seat (see conversion diagram ①).
4. Hold the double joint (3) of the motion element and open the locking screw for height adjustment (4) on this side as well.
5. Remove the motion element and insert it on the opposite side. Tighten the locking screw (4).
   (see conversion diagram ① b, c).
6. Pull the pin for the swiveling movement of the upper arm support (11) downward and swing the support 180° towards the inside.

   Attention: Release the pin (11) while the support is swinging; you will hear it lock into place on the other side (see conversion diagram ② d)
7. Open the locking screw for the swiveling movement of the forearm support (12) and swing the support with motor B 180°. Tighten locking screw (12) (see conversion diagram ② e).
8. Open the locking screw for right/left positioning (13) two revolutions. Move the forearm support to the lower recess in the slot and turn it 180° in this position. Then move the forearm support back to the middle position (setting 0) and tighten locking screw (13) again (see conversion diagram ③ f).

Conversion diagram ARTROMOT®-E2:



6.4.2 Reconfiguration of the ARTROMOT®-E2 compact

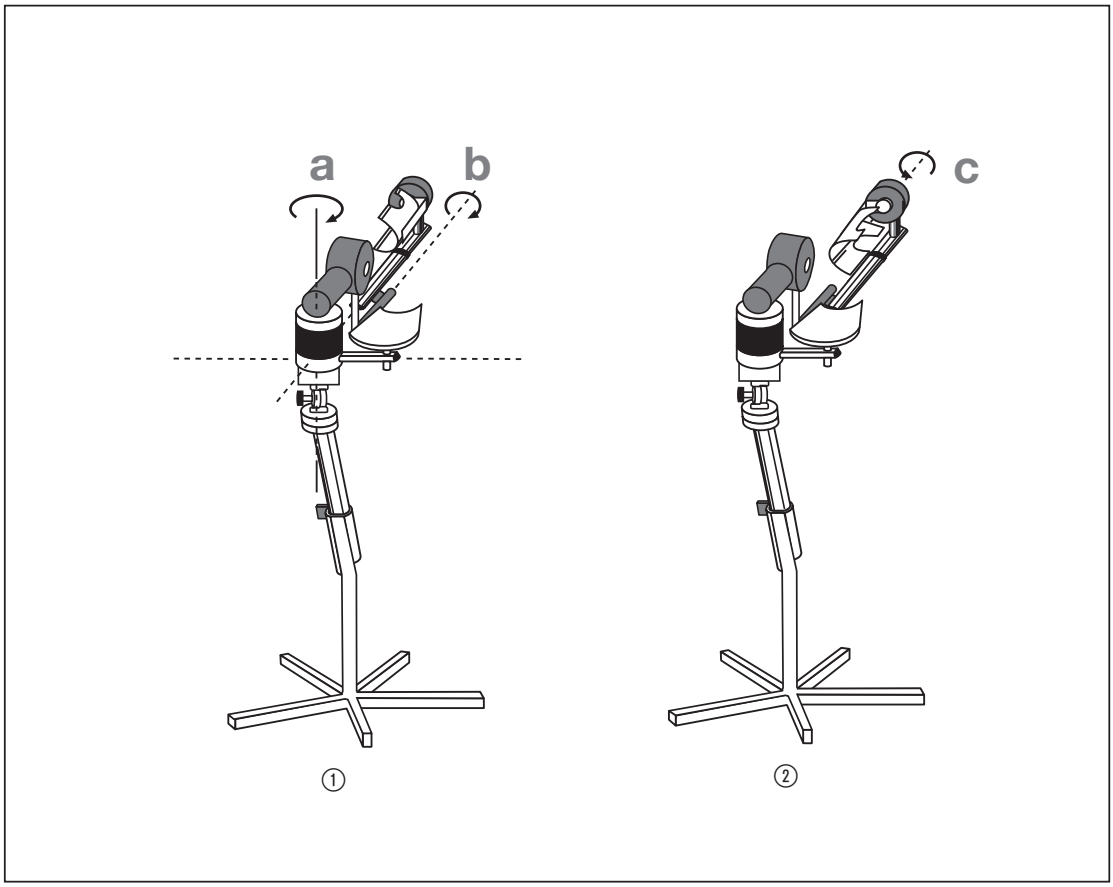
The ARTROMOT®-E2 compact can be used on the left and on the right elbow joint. However, the device must be converted first. This is done very quickly.

1. Activate the "transport setting" function → in the menu (see also 5.3) and start the ARTROMOT®-E2 compact.
2. Release the wheel brakes (22) and roll the ARTROMOT®-E2 compact to the side of the elbow to be treated.
3. Pull the pin for the swiveling movement of the upper arm support (5) downward and swing the support 180° towards the inside.

   Attention: Release the pin (5) while the support is swinging; you will hear it lock into place on the other side (see conversion diagram ① a).
4. Open the locking screw for the swiveling movement of the forearm support (6) and swing the support with motor B 180°.

   Tighten locking screw (6) (see conversion diagram ① b).
5. Open the locking screw for right/left positioning (7) two revolutions. Move the forearm support to the lower recess in the slot and turn it 180° in this position. Then move the forearm support back to the middle position (setting 0) and tighten locking screw (7) again (see conversion diagram ② c).

Conversion diagram ARTROMOT®-E2 compact:



7. Environmental Protection Statement

The product described in this operation manual must not be disposed of with unsorted household or municipal waste. It requires separate disposal. Please contact ORMED.DJO for information about the possible recycling of the product.

8. Specifications

Input ratings:	100 – 240 V AC / 50 – 60 Hz
Rated current - motor:	2 A max.
Power consumption	33 VA
Fuses:	2 x T1A
Protection class:	I
Applied part:	type B

Dimensions (transport):

ARTROMOT®-E2	
Length:	87.5 cm
Width:	57.5 cm
Height:	58 cm
ARTROMOT®-E2 compact	
Length:	87.5 cm
Width:	57.5 cm
Height:	29 cm

Adjustment ranges (min./max.):

Height adjustment:	35 – 71 cm
(ARTROMOT®-E2 measured from the seat)	
Forearm length:	29 – 46 cm

Seat height:

ARTROMOT®-E2	48 cm

Weight:

ARTROMOT®-E2	25 kg
ARTROMOT®-E2 compact	17 kg
Materials used:	ABS, POM (Delrin 100), PUR, PA, FR4, aluminum, stainless steel, brass
MDD:	class 2a
Standards compliance:	IEC 60601-1:1990 + A1:1993 + A2: 1995 No. 601.1-M90 UL 2601-1
EMC (electromagnetic compatibility)	IEC 60601-1-2:2001

Ambient conditions (storage, transport)

Ambient temperature:	-24 °C to +60°C
Relative humidity:	20 % to 85 %
Atmospheric pressure:	700 hPa to 1060 hPa

Ambient conditions (operation)

Ambient temperature:	+10 °C to +40°C
Relative humidity:	30 % to 75 %
Atmospheric pressure:	700 hPa to 1060 hPa

Subject to change without notice (06/2008)

English

9. IEC 60601-1-2:2001

The ARTROMOT®-E2/-E2 compact is subject to particular precautions regarding electromagnetic compatibility (EMC). The device must be installed and put into service strictly in compliance with the EMC directives put forth in the accompanying documents.

Portable and mobile RF communication systems may affect the ARTROMOT®-E2/-E2 compact.

The ARTROMOT®-E2/-E2 compact should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ARTROMOT®-E2/-E2 compact should be observed to verify normal operation in the configuration in which it will be used.

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

If it is necessary to replace assemblies or cables, only the manufacturer's original parts must be used to ensure continued compliance with EMC requirements after repair. This requirement applies to the power supply unit, cables and cable lengths, drive unit consisting of the motor and the control system, the programming unit incl. the coiled cable and the connector.

9.1 Electromagnetic emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The ARTROMOT®-E2/-E2 compact is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the ARTROMOT®-E2/-E2 compact is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions to CISPR 11	Group 1	The ARTROMOT®-E2/-E2 compact uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions to CISPR 11	Class B	The ARTROMOT®-E2/-E2 compact is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions to IEC 61000-3-2	not applicable	
Voltage fluctuations/flicker emissions to IEC 61000-3-3	not applicable	

9.2 Electromagnetic immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The ARTROMOT®-E2/-E2 compact is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the ARTROMOT®-E2/-E2 compact is used in such an environment.

Immunity test	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) to IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst to IEC 61000-4-5	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power should be that of a typical commercial or hospital environment.
Surges to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines to IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5s	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5s	Mains power should be that of a typical commercial or hospital environment. If the user of the ARTROMOT®-E2/-E2 compact requires continued operation during power mains interruptions, it is recommended that the ARTROMOT®-E2/-E2 compact be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

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

9.2 Electromagnetic immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The ARTROMOT®-E2/-E2 compact is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the ARTROMOT®-E2/-E2 compact is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment are used no closer to any part of the ARTROMOT®-E2/-E2 compact, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF to IEC 61000-4-6	3 V_{rms} 150 kHz to 80MHz	3 V_{rms}	$d = 1.2\sqrt{P}$
Radiated RF to IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], is less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol 

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

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

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ARTROMOT®-E2/-E2 compact is used exceeds the applicable RF compliance level above, the ARTROMOT®-E2/-E2 compact device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ARTROMOT®-E2/-E2 compact.

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

9.3 Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the ARTROMOT®-E2/-E2 compact

The ARTROMOT®-E2/-E2 compact is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARTROMOT®-E2/-E2 compact can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARTROMOT®-E2/-E2 compact as recommended below, according to the maximum output power of the communications equipment.

rated maximum output power of transmitter W	**separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

10. Contact

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

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

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

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

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

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

11. Technical service

11.1 Technical hotline

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

11.2 Shipment

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

Before packing the CPM device, set it to the transport position (see chapters 5 and 6).

11.3 Spare parts

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

When ordering spare parts, always specify:

- Item
- Description
- Part no.
- Quantity
- Serial number of the CPM device

Note!

Refer repairs to authorized, specially trained staff.

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

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

Item	Description	Part no.	Qty
1.	Patient chip card	0.0034.048	
2.	Patient chip card (protocol)	0.0037.035	
3.	Marker pen for patient chip card	0.0031.006	

DECLARATION OF CONFORMITY

English

Declaration of conformity

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

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

declares that the products of the product line

ARTROMOT® (see Annex)

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

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

CE
0297

Freiburg, 28 July 2008

- QA Management Representative -

This certificate is valid through: 28 July 2010

Annex:

ARTROMOT®-S2 PRO
ARTROMOT®-S3
ARTROMOT®-S3 Comfort
ARTROMOT®-K1
ARTROMOT®-K2
ARTROMOT®-K2 PRO
ARTROMOT®-K2 PRO Chip
ARTROMOT®-K3
ARTROMOT®-K4
ARTROMOT®-SP2
ARTROMOT®-SP3
ARTROMOT®-E2
ARTROMOT®-E2 compact

Piktogrammübersicht ARTROMOT®-E2/-E2 compact

Symbol Overview ARTROMOT®-E2/-E2 compact

EBENE 1/LEVEL 1:

			
Extension	Flexion	Pronation	Supination

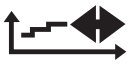
EBENE 2/LEVEL 2:

			
Pause	Timer	Geschwindigkeit speed	Aufwärmprogramm warm up protocol

EBENE 3/LEVEL 3:

			
Lastumkehr Motor A load reversal motor A	Lastumkehr Motor B load reversal motor B	Motor A Ein/Aus motor A ON/OFF	Motor B Ein/Aus motor B ON/OFF

EBENE 4/LEVEL 4:

			
Isolationsprogramm isolation protocol	Gesamttherapiezeit total therapy time	Therapieverlaufs-dokumentation Extension/Flexion abduction/adduction therapy documentation	Behandelverloop-documentatie pronatie/supinatie pronation/supination therapy documentation

EBENE 5/LEVEL 5:

			
Dehnung Extension stretching in extension	Dehnung Flexion stretching in flexion	Dehnung Pronation stretching in pronation	Dehnung Supination stretching in supination

EBENE 6/LEVEL 6:

			
Endgradige Wiederholung EROM repeat Extension/Pronation			Endgradige Wiederholung EROM repeat Flexion/Supination

EBENE 7/LEVEL 7:

		A+B	
Transporteinstellung transport setting	Neuer Patient new patient	Betriebsart Synchron/Asynchron synchronized/non-synchronized mode	Service-Menü service menu

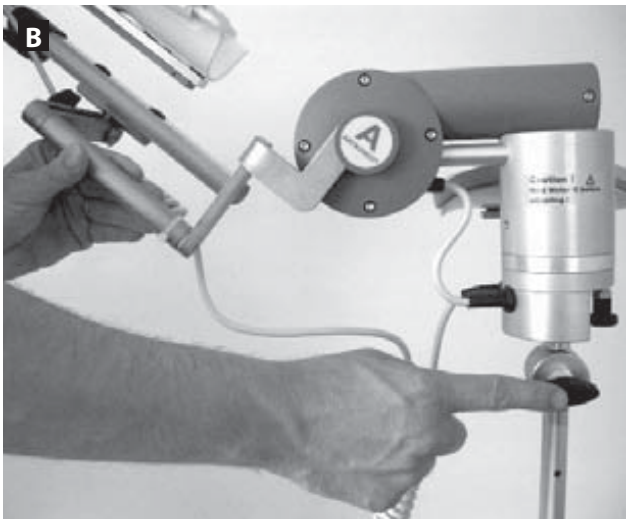
Abbildungen ARTROMOT®-E2 compact

Figures
Illustrations

Ilustraciones
Illustrazioni

A

B

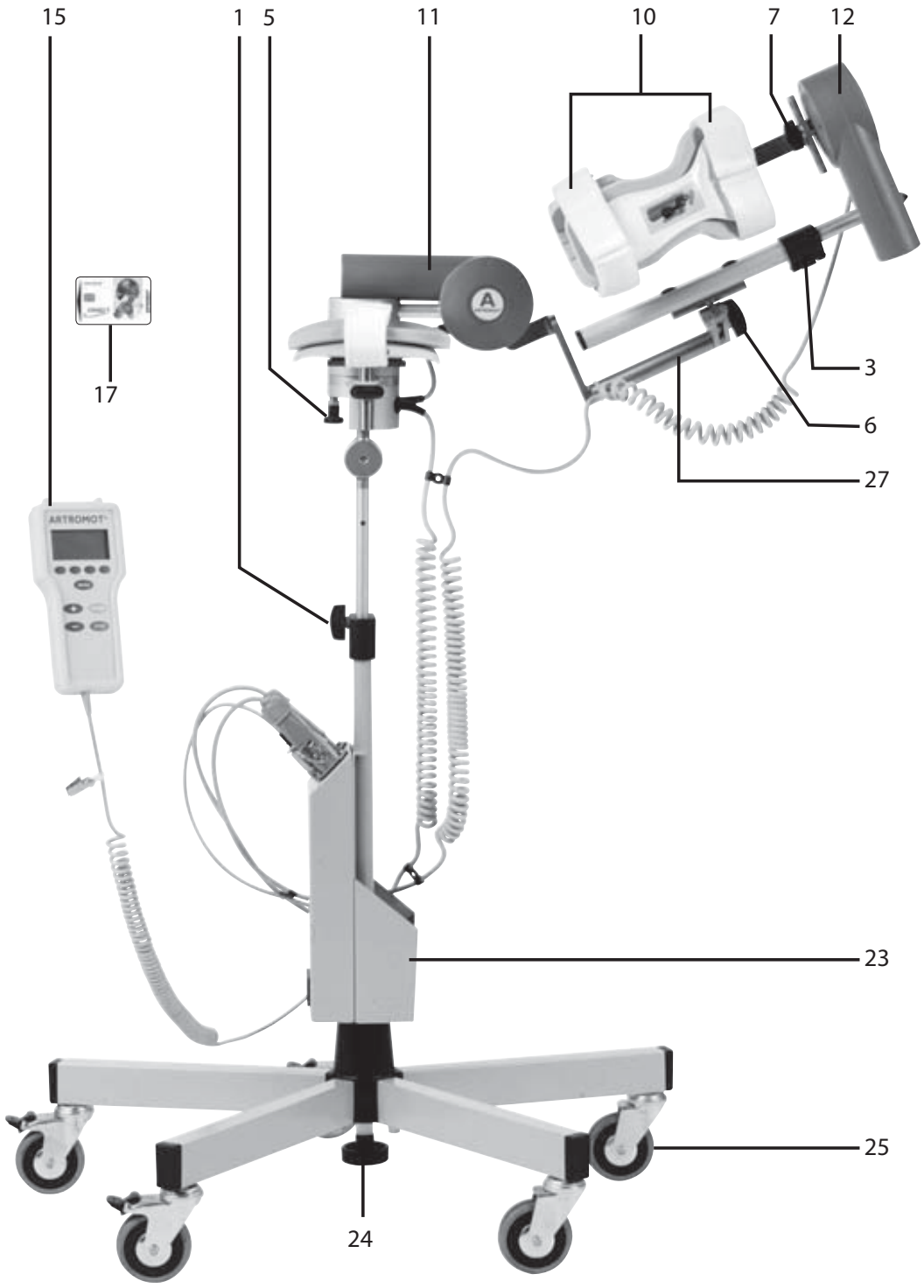


C

D

Gerätebeschreibung ARTROMOT®-E2 compact

Device description
Description de l'appareil
Descripción del aparato
Descrizione dell'apparecchiatura
Beschrijving van het apparaat



Gerätebeschreibung ARTROMOT®-E2 compact

Device description
Description de l'appareil
Descripción del aparato
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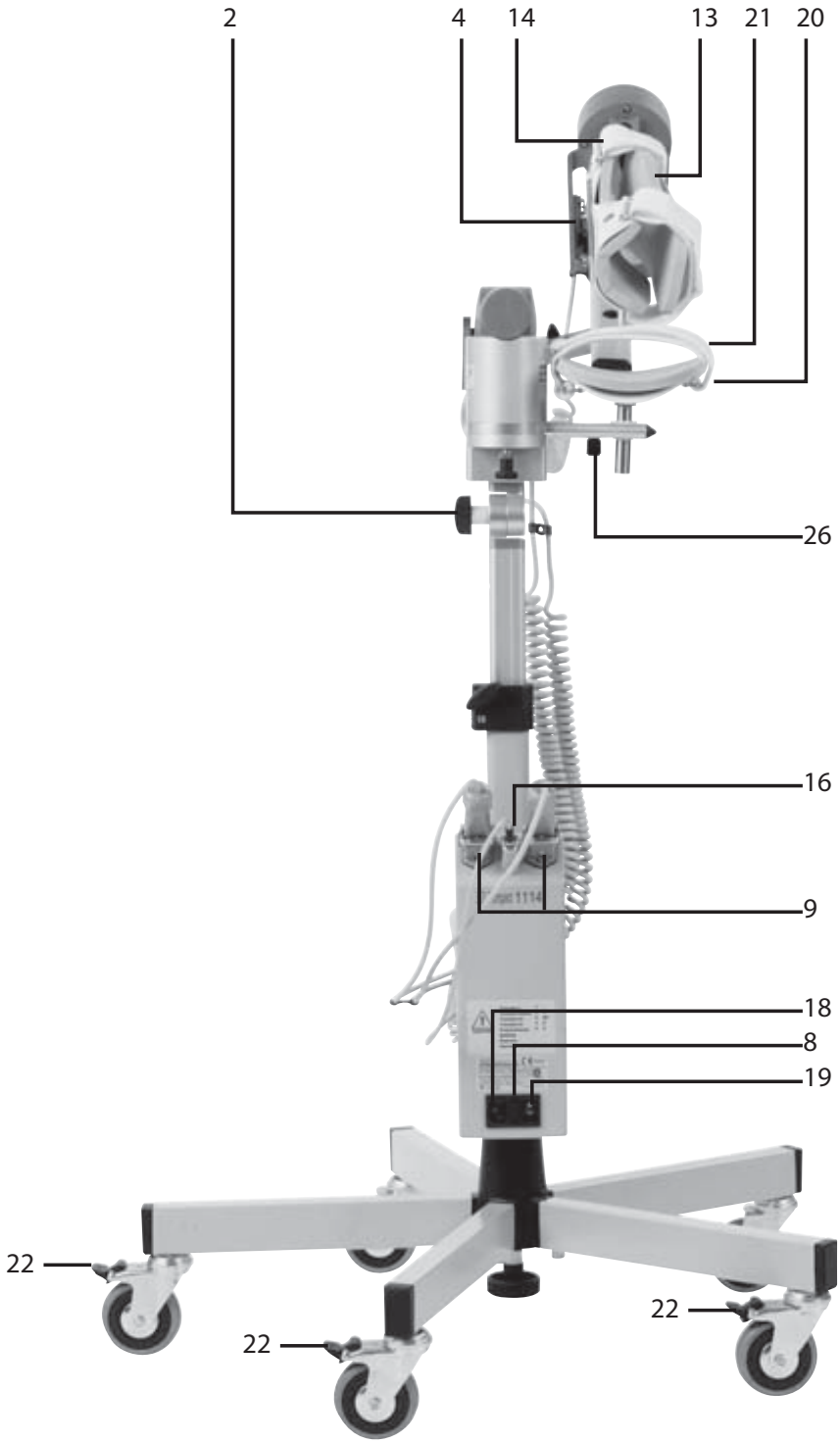
Beschrijving van het apparaat



ORMED.DJO-MOT-324-01/01-8/08

DIN EN 13485 ORMED Nr. 018829-01

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ORMED.DJO