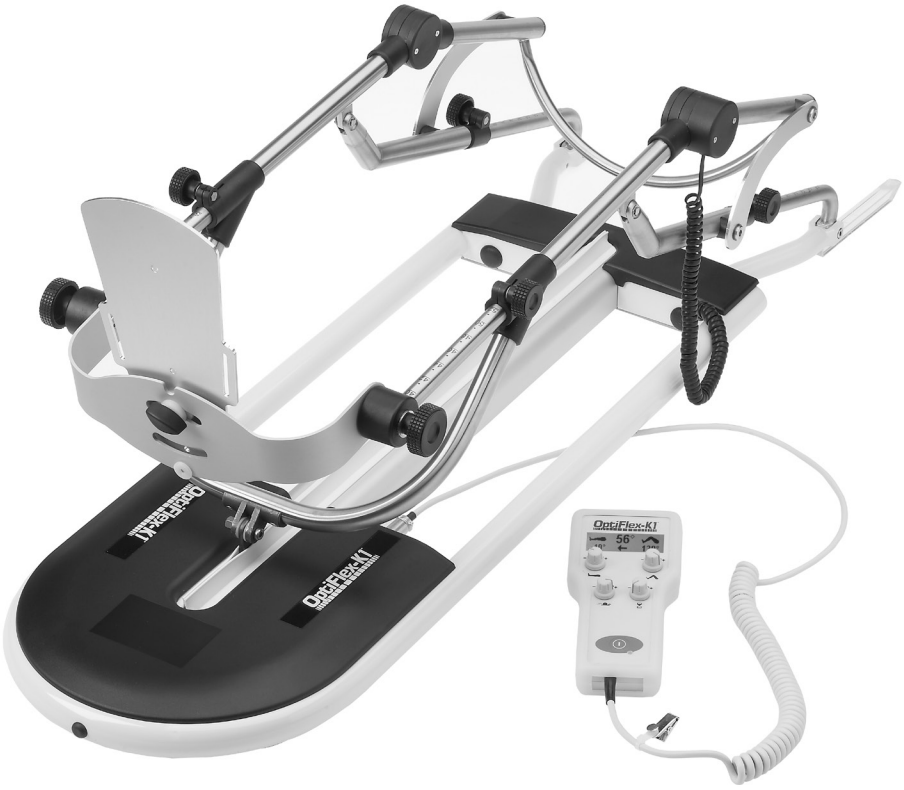
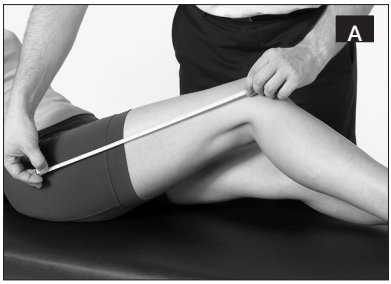
OptiFlex-K1™

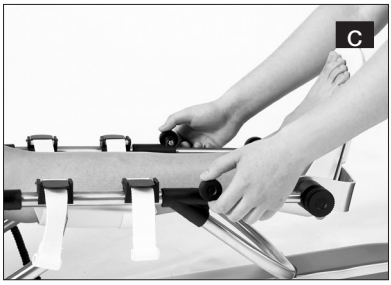


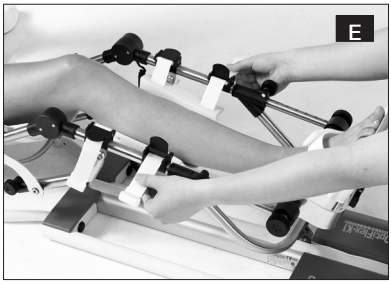
Operation Manual

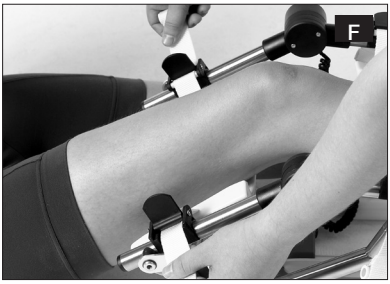
Contents

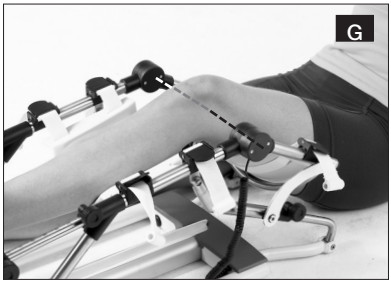
OPTIFLEX®-K1 Setup Illustrations

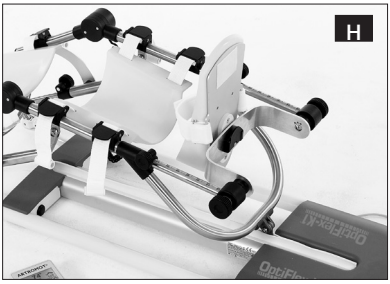












1. How to use the CPM device

1.1 Fields of application

OPTIFLEX®-K1 is a motor-operated **C**ontinuous **P**assive **M**otion **(CPM)** device used to mobilize knee and hip joints.

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

1.2 Therapy objectives

CPM therapy with **OPTIFLEX®-K1** is mainly used to prevent the negative effects of immobilization, to allow patients to regain painless mobility of joints at an early stage and to promote healing and achieve a positive functional result.

Other objectives of therapy include:

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

1.3 Indications

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

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

1.4 Contraindications

Do NOT use **OPTIFLEX®-K1** on patients with:

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

2. OPTIFLEX®-K1 description

The motorized CPM device permits extension and flexion of the knee joint in the range of -10°/0°/120°, and of the hip joint in the range of 0°/7°/115°.

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

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

Biocompatibility

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

2.1 Description of the device components

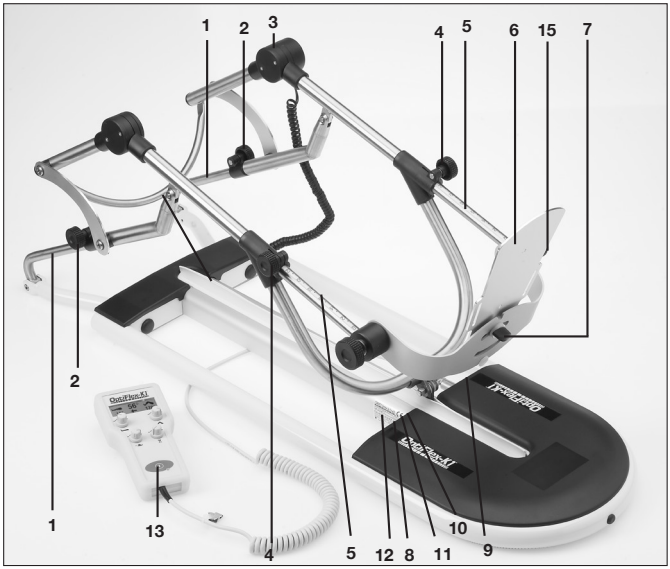
1. Thigh length scale (femur length scale)
2. Thigh length fixation screws (femur length)
3. Knee hinge
4. Calf length fixation screws (tibia length)
5. Calf length scale (tibia length scale)
6. Footplate angle fixation screw
7. Tightening screw for adjusting foot place rotation and to allow removal of foot plate.
8. Connection for programming unit
9. Connection for power cord
10. Fuse cap
11. Power switch (ON/OFF)
12. Nameplate
13. Programming unit
14. Patient chip card[1]
15. Compartment for storage of programming unit

---

[1] **OPTIFLEX®-K1** devices **with patient chip card only.**

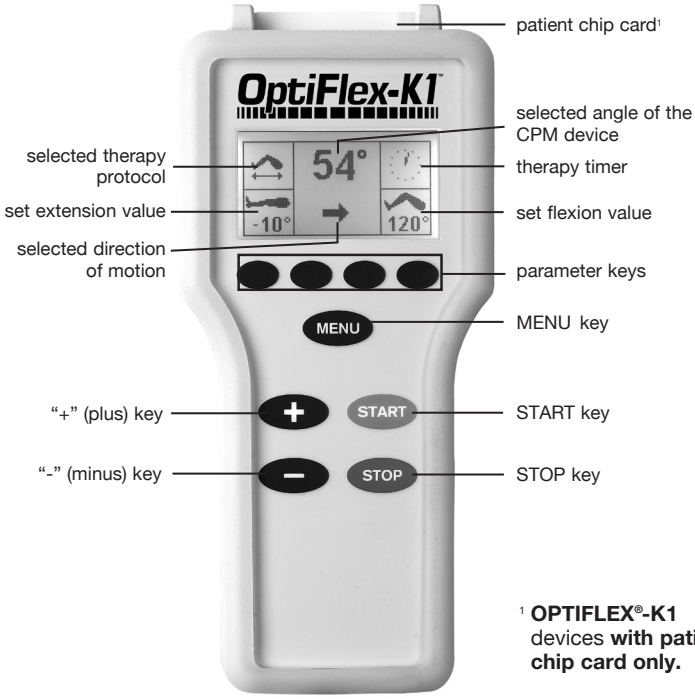
[2] **OPTIFLEX®-K1 Comfort** devices only.

2.1 Device description (continued)



2.2 Description of the programming unit

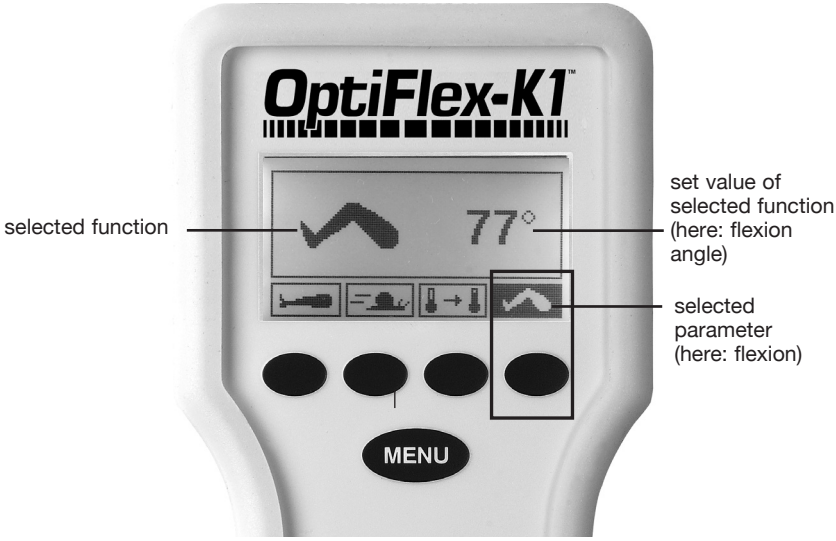
2.2.1 Programming unit in normal mode



[1] **OPTIFLEX®-K1** devices **with patient chip card only.**

2.2.2 Programming unit in MENU selection mode

2.2.3 Programming unit in programming mode



2.3 Explanation of symbols

Standard protocols:


extension
(stretching the knee)


flexion
(bending the knee)


speed


warm up protocol


extension pause


flexion pause


therapy timer


reverse on load
(feature for patient
safety)


transport setting


new patient


total therapy time


service menu

Comfort protocols:


stretch extension


stretch flexion


workout protocol


Comfort protocol


EROM
repeat extension


EROM
repeat flexion


EMS control


therapy
documentation

2.4 Explanation of symbols (connections and nameplate)


protective earth
connection


type B applied part


power switch OFF

power switch ON


Refer to accompanying
documents


Do not dispose product
with unsorted house-
hold or municipal waste.

3. Safety information

Introduction and definitions

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

⚠ DANGER!

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

⚠ WARNING!

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

⚠ CAUTION!

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

Safety information

⚠ DANGER!

Explosion hazard –

OPTIFLEX®-K1 is not designed for use in areas where an explosion hazard may occur. An explosion hazard may result from the use of flammable anesthetics, skin cleansing agents and disinfectants.

⚠ WARNING!

Patient hazard –

- Only authorized individuals are allowed to operate the OPTIFLEX®-K1 device. Individuals are authorized after receiving training in the operation of the device and reading this operation manual.
- Before using the device, the operator must ascertain that it is in correct working order and operating condition. In particular, the cables and connectors must be checked for signs of damage. Damaged parts must be replaced immediately, before use.
- **Before therapy**, a test run consisting of several exercise cycles must be completed, first without and then with the patient. Check that all fixation screws are tightened.
- Stop therapy immediately, when you have doubts about the device settings and/or the therapy protocol.

⚠ WARNING!

Patient hazard –

- It is important that the **patient's position** is **anatomically correct.** Therefore, carefully verify the following settings/positions:

  1. femur length
  2. knee joint axis
  3. tibia length and leg rotation
  4. leg support assemblies

- Movements must **not cause pain** or **irritation**.

- Patients must be **fully conscious** while being instructed in the use of the CPM device and during therapy.

- Only the responsible **physician or therapist** is able and allowed to choose the **therapy parameters** and **protocols** to use. It is the physician's or therapist's decision whether or not to use the CPM device on a specific patient.

- The patient must be familiar with the functions of the **OPTIFLEX®-K1 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.

- After data storage, 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: section 5.2 Programming: "New Patient").
  Use **original chip cards only**.[1]

- Any **accessories** used with **OPTIFLEX®-K1** must first be approved by DJO.

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

[1] **OPTIFLEX®-K1** devices **with patient chip card** only

⚠ 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 **OPTIFLEX®-K1** to reach room temperature **before use**. If the device has been transported at **temperatures below 0 °C/ 30°F)**, leave it to dry at room temperature for about 2 hours, until any condensation has disappeared.

- The OPTIFLEX®-K1 device must only be operated in **dry rooms**.

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

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

- Do not use multiple portable socket outlets (MPSO) to connect the device to the power line. OPTIFLEX®-K1 must be connected to a **properly installed wall outlet with a non-fused earthed wire**. Before connecting the power cord, it must be completely unrolled and placed such that it will not get caught by the moving parts of the device.

- Before cleaning and service interventions, disconnect the device from the power line by **removing the power cord from the wall outlet.**
- Liquids must not be allowed to enter the CPM device or the programming unit. If liquids have entered into the devices, OPTIFLEX®-K1 must be immediately checked by a service technician, before it can be reused.

⚠ WARNING!

Equipment malfunction –

- Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the CPM device comply with the relevant EMC requirements. X-ray equipment, MRI devices and radio systems are possible sources of interference as they may emit higher levels of electromagnetic radiation. Keep the CPM device away from these devices and verify its performance before use.
- Refer **repair and maintenance** to authorized persons.
- **Route all cables below the device frame to either side**, ensuring that they cannot get caught by the moving parts during operation.
- Inspect OPTIFLEX®-K1 for damage and loose connections at least once a year. Damaged and worn parts must immediately be replaced with original spare parts by authorized staff.

⚠ CAUTION!

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

⚠ CAUTION!

Equipment damage –

- Check that the voltage and frequency ratings of your local **power line** are those indicated on the nameplate.
- The leg support element withstands a **maximum continuous load** of **20 pounds**.
- 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 OPTIFLEX®-K1 device to direct sunlight, because some of the components may reach inadmissibly high temperatures.

4. Adjusting the device

4.1 Connecting the device, performance check

1. Connect the **power cord** to socket (16) of the device and **mains plug** to a wall outlet with a non-fused earthed wire (100 to 240 Volt, 50/60 Hz).
2. Turn the **power switch** (18) on.
3. Follow these steps to set the carriage to the **home position**.

OPTIFLEX®-K1
without patient chip card

Press the **MENU** key on the programming unit until you reach program level 3 (standard model) or program level 5 (Comfort model).

Press the “New Patient” parameter key.

→0←

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

OPTIFLEX®-K1
with patient chip card

Initial adjustment for new patients
Insert the original patient chip card (21) into the programming unit (20).

Press the **MENU** key on the programming unit until you reach program level 3 (standard model) or program level 5 (Comfort model). Press the “New Patient” parameter key.

→0←

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

Adjustment with programmed chip card.

Insert the original patient chip card (21) into the programming unit (20).

Press the **START** key.

The CPM device automatically enters the **home position**.

Performance check

If the programming unit can be operated as described above and **OPTIFLEX®-K1** enters the home position (for home position values, refer to sections 5.3 and 5.5), the device has passed the performance check.

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

- An audio signal sounds.
- The device switches off immediately.
- The message “ERR”, accompanied by a code number (e.g. ERR 5), appears on the display.

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

4.2 Adjusting the device to the femur length

1. Measure the **length of the patient‘s thigh (femur)** from the greater trochanter to the lateral knee joint cavity (Fig. A).
2. Set the carriage to the home position (see 4.1).

3. Set the measured value at the **femur scale** (3) of the carriage.
   - Loosen the two fixation screws (4).
   - Extend the scale (3) to the required length.
   - Tighten the fixation screws (4) to set the scale to the new length.

⚠ CAUTION!

Equipment damage –

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

4.3 Adapting the leg support assemblies/ footplate

1. Set the **leg support assemblies** and the **footplate** (1, 6, 11) to the expected positions before accommodating the patient.

- Loosen fixation screws (8) to adjust the **footplate** (11) to the length of the patient‘s lower leg (Fig. C).

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

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

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

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

Note!

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

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

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

⚠ CAUTION!

Equipment damage –

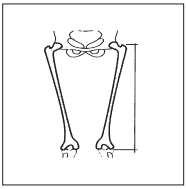
Cover the leg **support assemblies with disposable tissues** when using OPTIFLEX®-K1 immediately after surgery. This helps prevent discoloration.

⚠ CAUTION!

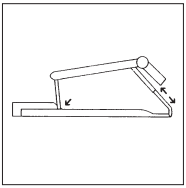
Patient hazard –

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

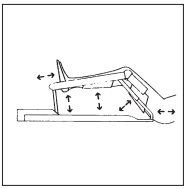
Symbol 1:
Measurement of the patient‘s femur length from the greater trochanter to the knee joint cavity



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



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



5. Setting the treatment values

⚠ WARNING!

Patient hazard –

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

Note!

See also 2.2 and 2.3.

5.1 General information on programming OPTIFLEX®-K1

1. You activate the programming mode by briefly pressing the **MENU** key on the programming unit.

2. The various treatment parameters and functions are allocated to three (standard model) or five (Comfort model) programming levels (four per level).

   To be able to program a parameter you will have to access the corresponding programming level. This is also done with the **MENU** key. With each key press you advance one level. The code M1, M2, etc. that appears in the middle of the display indicates the programming level.

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 will only be enabled and disabled. This is done by pressing the corresponding parameter key or with the **+/-** keys. Activated 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 to start therapy.

Note!

- Refer to sections 5.3 and 5.5 for a description of the parameters.
- To **view the set parameter values**, press the corresponding parameter key. However, this is only possible when you press the STOP key first.
- To prevent accidental changes of the parameter settings, 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**: OPTIFLEX®-K1 will stop immediately, when any of the keys is pressed during therapy. Patient treatment can be resumed by pressing the START key. The device will automatically change the direction.

Patients with a programmed chip card

- Insert the chip card (the patient is not yet positioned on the CPM device).
- Perform the mechanical adjustments of the CPM device (femur length, etc.).
- Position the patient on the CPM device and press the **START** key to initiate therapy.

5.2 Programming OPTIFLEX®-K1 standard models

Different programming levels are provided to program the **OPTIFLEX®-K1 Standard** models.

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

The display always indicates on which level you are.

The following **treatment values, settings** and **information** can be entered/viewed on the programming unit (20):

LEVEL 1:

- extension (stretching the knee) 
- flexion (bending the knee) 
- speed 
- warm up protocol 

LEVEL 2: 

- extension pause 
- flexion pause 
- therapy timer 
- reverse on load (feature for patient safety) 

LEVEL 3: 

- transport setting 
- new patient 
- total therapy time 
- Service menu 

Note!

- **While you adjust the extension/ flexion values**, the CPM device will move to the set range. This allows you to easily and quickly determine the ROM where the patient does not experience pain.
- **Special functions** can be programmed and retrieved with **OPTIFLEX®-K1 Comfort** devices (see sections 5.4 and 5.5).
- Only **OPTIFLEX®-K1** chip card models allow therapy protocols to be saved to an inserted chip card.

5.3 Treatment value details – standard models

You access the different programming levels by repeated depressions of the **MENU** key.

- You select the treatment parameters with the corresponding parameter key.
- You change the treatment values with the **+/-** keys and you enable/disable functions by pressing the corresponding parameter key again.
- You save the settings by pressing the **STOP** key.

LEVEL 1:

■ **extension (stretching)**

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

■ **flexion (bending)**

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

Note!

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

■ **speed**

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

■ **warm up protocol**

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

The warm up protocol starts in the middle between the two maximum values set for stretching and bending. The range of motion increases with each cycle, until the programmed maximum values are reached after a total of 15 cycles.
default setting: disabled

LEVEL 2:

■ **extension pause**

Pauses occur at the 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 setting: no pause

■ **flexion pause**

Pauses occur at the 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 setting: no pause

■ **therapy timer**

Default setting is continuous operation of the carriage.
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, 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 device switches **automatically** off and stops in the position: extension + 10°. In this case, a circle replaces the clock symbol. The circle fills as the therapy time progresses.

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

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

LEVEL 3:

■ **transport setting**

With this function, the carriage will move to a position optimally suited for packing the CPM device. Set the femur length on 49 inches and the lower leg on 45 inches.
Select the function and press the **START** key. The carriage moves to the transport position. (see 6.3)

■ **new patient** →0←

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

With **OPTIFLEX®-K1** devices with patient chip card, the factory defaults will be restored. All values stored on the chip card will be deleted.

The carriage will stop in the home position.

The "New Patient" function (home position) selects the following settings:

- extension:	25°
- flexion:	35°
- speed:	50%
- warm up:	disabled
- extension pause:	0
- lexion pause:	0
- timer:	continuous operation
- reverse on load::	25
- total therapy time:	0

■ **total therapy time** ∑

OPTIFLEX®-K1 models without patient chip card
The total therapy time is the added sum of operating hours. If the device is used by only one patient, this time is equivalent to the duration of all the patient's therapy sessions.

Under menu item "total therapy time" of **OPTIFLEX®-K1 models with chip card** 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.

■ **Service MENU**

For service purposes only, refer to Service Manual.

Reminder:

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

5.4 Programming OPTIFLEX®-K1 Comfort models

OPTIFLEX®-K1 devices of the **Comfort** series offer two more programming levels for additional functions.
The programming levels are selected in the same way as with the standard models.

Programming levels 1 and 2 are identical with programming levels 1 and 2 of the standard models.

All **special functions** are disabled upon delivery and in the "New patient" mode.

The following **treatment values**, **settings** and **information** can be entered/viewed on the programming unit (20):

LEVEL 1:

- extension (stretching the knee)
- flexion (bending the knee)
- speed
- warm up protocol

MENU

LEVEL 2:

- extension pause
- flexion pause
- therapy timer
- reverse on load (feature for patient safety)

MENU

LEVEL 3:

- stretch extension
- stretch flexion
- workout protocol
- Comfort protocol

MENU

LEVEL 4:

- EROM repeat extension
- EROM repeat flexion
- total therapy time ∑

Continued on next page.

MENU

LEVEL 5:

- transport setting
- new patient
- therapy documentation
- Service menu

5.5 Protocol details – Comfort models

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

All **special functions** are disabled upon delivery and in the “New patient” mode.

Note!

LEVEL 1: equivalent to level 1 of the standard model (see: 5.3)

LEVEL 2: equivalent to level 2 of the standard model (see: 5.3)

LEVEL 3:

■ **stretch extension**

With the special “stretch extension” function the joint will be gently stretched beyond the extension limit.

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 ° toward the flexion angle and then moves very slowly back again to the programmed extension limit (display <=). After that it attempts to stretch the joint another 5 °, moving even slower than before (display <<).

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 10 times. After that the carriage moves to the programmed flexion limit and restarts the stretch extension cycle.

It is not possible to activate the special “stretch extension” and “stretch flexion” functions at the same time.

Note!

If an extension pause has been programmed, the carriage will stop for the pause each time the maximum stretching value is attained.

■ **stretch flexion**

With the special “stretch flexion” function the joint will be gently stretched beyond the flexion limit.

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 ° toward the extension angle and then moves very slowly back again to the programmed flexion limit (display =>). After that it attempts to stretch the joint another 5 °, moving even slower than before (display >>).

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 10 times. After that the carriage moves to the programmed extension limit and restarts the stretch flexion cycle.

It is not possible to activate the special “stretch flexion” and “stretch extension” functions at the same time.

Note!

If a flexion pause has been programmed, the carriage will stop for the pause each time the maximum stretching value is attained.

■ workout protocol 

With the special “workout” function, a series of special, programmed protocols can be completed in one session.

The program includes the following protocols in a given sequence: warmup, stretch extension, EROM repeat extension, stretch flexion, EROM repeat flexion, and cool-down.

The **entire workout protoco**l takes approx. **38 to 40 minutes** to complete.

Protocol stages:

- 5-minute protocol: **warmup**
  Starting from the middle position, the range of motion is gradually increased toward extension and flexion in steps of 1 °
- 5-minute exercise according to **programmed settings**
- 5-minute protocol: **stretch flexion**
- 5-minute protocol: **EROM repeat flexion**
- 5-minute protocol: **stretch extension**
- 5-minute protocol: **EROM repeat extension**
- 5-minute exercise according to **programmed settings**
- 3-minute protocol: cool-down
  The cool-down protocol is the warm-up protocol of the workout mode reversed. Starting from the maximum values, the carriage reduces the range of motion by 1 ° per cycle, until the middle position is reached.

The device switches off, when the protocol has been completed.

The indicated minutes are approximate values. Depending on the programmed maximum range of motion, the times may vary.

■ Comfort protocol 

With the special “Comfort” function, the range of motion is gradually extended until the patient attains the maximum programmed extension and flexion values.
For this protocol, the maximum values are programmed first, then the special function is activated and, eventually, the treatment is started.
OPTIFLEX®-K1 Comfort will now complete five cycles in both directions with the maximum programmed values minus 5 °. Then the range of motion is increased by 1 ° per cycle in both directions until the programmed limit values are reached. Once the limit values have been attained, the CPM device continues in the programmed range of motion until the end of the therapy session.

LEVEL 4:

■ EROM repeat extension 

The special “EROM repeat extension” function allows a more efficient exercise in the last 10 ° before the set maximum extension value.
For this protocol, the CPM device starts in the middle between the set extension and flexion values. It will first move to the programmed flexion value and then to the programmed extension value. When the extension value has been reached, the carriage reverses 10 ° toward the flexion angle and then moves back again to the maximum extension value. 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 and then starts another cycle with five repetitions through the last 10 ° of the extension angle.

■ **EROM repeat flexion**

The special „EROM repeat flexion" function allows a more efficient exercise in the last 10 ° before the set maximum flexion value.

For this protocol, the CPM device starts in the middle between the set extension and flexion values.
It will first move to the programmed extension value and then to the programmed flexion value.
When the flexion value has been reached, the carriage reverses 10 ° toward the extension angle and then moves back again to the maximum flexion value. 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 and then starts another cycle with five repetitions through the last 10 ° of the flexion angle.

■ **total therapy time** Σ

OPTIFLEX®-K1 models without patient chip card
The total therapy time is the added sum of operating hours.
If the device is used by only one patient, this time is equivalent to the duration of all the patient's therapy sessions.

Under menu item "total therapy time" of **OPTIFLEX®-K1 models with chip card** 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.

LEVEL 5:

■ **transport setting** →

With this function, the carriage will move to a position optimally suited for packing the CPM device. Set the femur length on 49 inches and the lower leg on 45 inches.
Select the function and press the **START** key. The carriage moves to the transport position. (see 6.3)

■ **new patient** →0←

With this function, the CPM device will move to the home position, allowing the mechanical settings to be completed. Select the function and press the **START** key. The carriage moves to the home position.

With **OPTIFLEX®-K1 devices with patient chip card**, the factory defaults will be restored. All stored values will be deleted.
The carriage will stop in the home position.

The New Patient (home position) function selects the following settings:

- extension:	25°
- flexion:	35°
- speed:	50%
- warm up:	disabled
- extension pause:	0
- flexion pause:	0
- timer:	continuous operation
- reverse on load:	25
- total therapy time:	0
- stretch extension:	disabled
- stretch flexion:	disabled
- EROM repeat extension:	disabled
- EROM repeat flexion:	disabled
- Comfort protocol:	disabled
- workout protocol:	disabled
- therapy documentation:	reset

■ **therapy documentation** 

OPTIFLEX®-K1 devices of the Comfort series with patient chip card have a special documentation function which provides a log of all therapy sessions.
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.

■ **Service menu** 

For service purposes only, refer to Service Manual.

Reminder:

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

6. Care, Maintenance, Transport

6.1 Care

⚠ WARNING!

Shock hazard –

Unplug the device from the power line before cleaning.

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

- **OPTIFLEX®-K1** 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 l**eg support assemblies** can be cleaned with commonly used **disinfectants** and **mild household detergents**.
- Use only a **damp cloth** to wipe the carriage down.

⚠ CAUTION!

Equipment damage –

- The plastic material used is not resistant to mineral acids, formic acid, phenols, cresols, oxidizing agents and strong organic or inorganic acids with a pH value below 4.
- Use only clear disinfectants to prevent discoloration of the device.
- Do not expose the CPM device to strong ultraviolet radiation (sunlight) and fire.

6.2 Maintenance (fuse replacement)

Check before each use

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

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

Technical Inspections

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

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

The device does not require additional regular maintenance.

Fuse replacement

⚠ WARNING!

Patient hazard, equipment malfunction and damage –

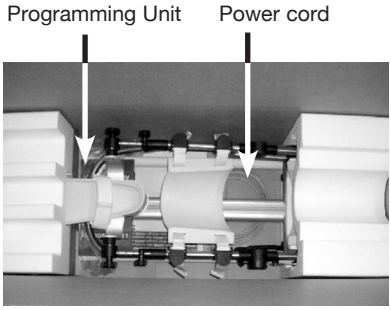
The replacement of fuses must be referred to specialists as defined in IEC 60364 or other applicable standards (e.g. biomedical technicians, electricians, electronics installers).

Fuses used must be T1A fuses.

6.3 Transport

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

1. Adjust the femur length to 49 inches and the tibia length to 42 inches.
2. Select the “Transport setting” → from the menu (refer to 5.3 for details).
3. Push the power switch to turn off the OPTIFLEX®-K1.
4. Disconnect the power cord and the programming unit.
5. The device must be stored in its original shipping box for transport. DJO cannot be held liable for damage in transit, if theoriginal shipping box was not used.
6. Set the footplate to a horizontal position.
7. Now slide the polystyrene pads onto the OPTIFLEX®-K1.
8. Place the power cord at the bottom of the box before inserting the OPTIFLEX®-K1 including the polystyrene pads.
9. Put the programming unit (20) in the supplied box, and store both in the OPTIFLEX®-K1 box.



7. Environmental protection statement

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

8. Specifications

Input ratings:	100 – 240 V AC/ 50 – 60 Hz
Current consumption:	850 – 370 mA
Fuses:	2 x T1A
Protection class:	I
Applied part:	type B
Max. load on carriage:	20 pounds

Dimensions

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

Adjustment ranges (min./max.):

femur range:	approx. 31 – 49 inches
lower leg range:	approx. 25 – 57 inches
weight:	11 pounds
materials used:	ABS, POM (Delrin 100), PUR, PA, FR4, aluminium, stainless steel, brass
MPG	class 2a
Standards compliance:	IEC 60601-1:1988 + A1:1991 + A2:1995
Certification:	ANSI/UL 60601-1 CAN/CSA C22.2 No. 601.1

Ambient conditions (storage, transport)

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

Ambient conditions (operation)

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

Subject to change without notice.
(06/06)

9. IEC 60601-1-2:2001

The **OPTIFLEX®-K1** device is subject to particular precautions regarding electromagnetic compatibility (EMC). The device must be installed and put into service strictly in compliance with the EMC directives put forth in the accompanying documents.

Portable and mobile RF communication systems may affect the **OPTIFLEX®-K1** device.

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

9.1 Electromagnetic emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions to CISPR 11	Group 1	**OPTIFLEX®-K1** 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	**OPTIFLEX®-K1** 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

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

Immunity test	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) to IEC 61000-4-2 ± 6 kV contact	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst to IEC 61000-4-5 ± 2 kV for power supply lines	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power should be that of a typical commercial or hospital environment.
Surges to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines to IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	Mains power should be that of a typical commercial or hospital environment. If the user of the **OPTIFLEX®-K1** device requires continued operation during power mains interruptions, it is recommended that the OPTIFLEX®-K1 device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment. Portable and mobile RF communications equipment are used no closer to any part of the OPTIFLEX®-K1 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
			Recommended separation distance:
Conducted RF to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	$d = 1.2\sqrt{P}$
Radiated RF to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			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 **OPTIFLEX®-K1** device is used exceeds the applicable RF compliance level above, the **OPTIFLEX®-K1** device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **OPTIFLEX®-K1** device.

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

9.3 Recommended separation distances between portable and mobile RF communications equipment and the OPTIFLEX®-K1 device

The **OPTIFLEX®-K1** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **OPTIFLEX®-K1** device can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **OPTIFLEX®-K1** device as recommended below, according to the maximum output power of the communications equipment.

rated maximum output power of transmitter W	**separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

10. How to reach us

Service, warranty or repair, please contact the selling dealer or your local DJO customer service.

11. Technical Service

11.1 Technical Hotline

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

DJO, LLC
1430 Decision St
Vista, CA 92081 USA
T: 1-800-592-7329 USA
T: + 1-317-406-2209
F: + 1-317-406-2014
chattgroup.com

11.2 Shipment

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

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

11.3 Spare parts

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

When ordering spare parts, always specify:

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

Note!

Refer repairs to authorized, specially trained staff.

DJO 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	0.0034.035	
2.	marker pen for patient chip card	0.0031.006	

DJO, LLC
A DJO Global Company
1430 Decision Street
Vista, CA 92081-8553 • USA

T 760.727.1280 • F 760.734.5608
DJOglobal.com

13-7467_A