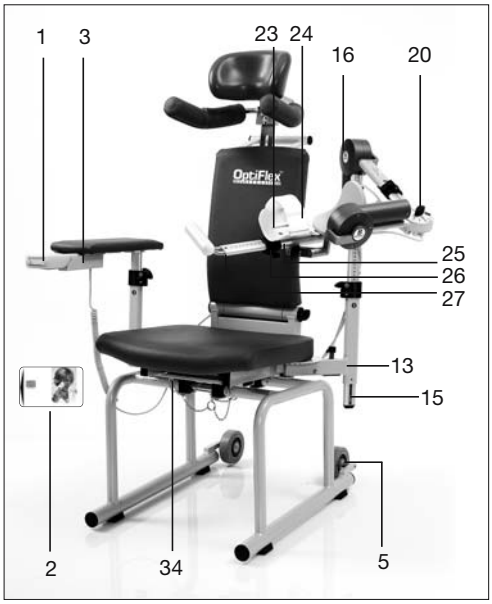
OptiFlex®
SHOULDER CPM

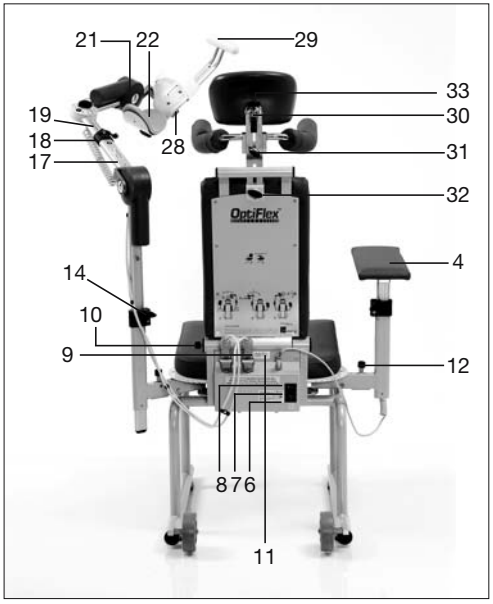
USA/GB Operating Instructions

ES Modo de empleo

Device description

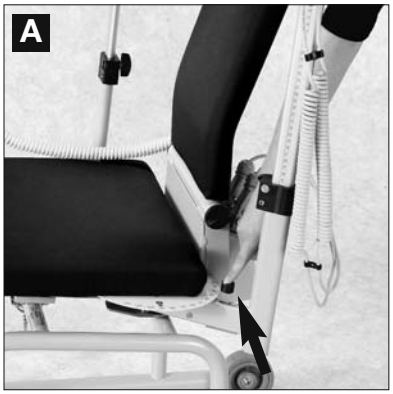
Descripción del aparato

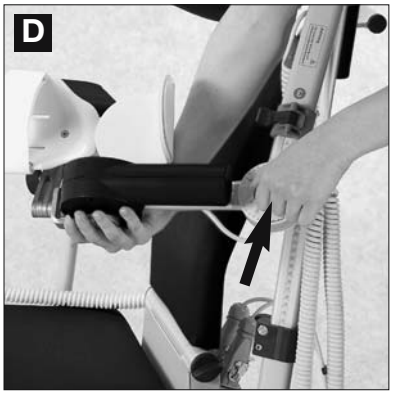


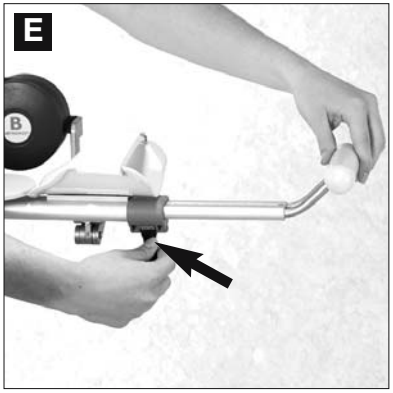


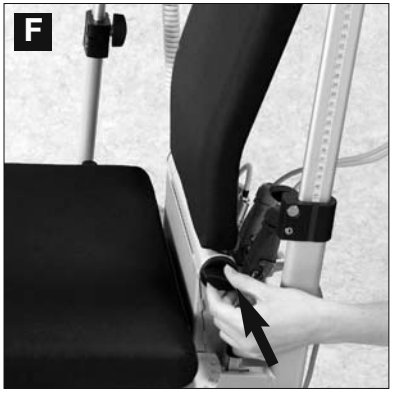
Figures

Illustraciones









Contents

1. How to use the CPM device

1.1 Fields of application

OptiFlex®S is a motor-operated **C**ontinuous **P**assive **M**otion **(CPM**) device providing motion to the shoulder 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 **OptiFlex®S** 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 shoulder 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
- operative treatment of fractures, pseudoarthrosis, if exercise-stable
- decompression surgery (acromioplasty)
- endoprosthetic implants
- soft tissue surgery in the armpit and the shoulder girdle
- tumor surgery in the shoulder region

1.4 Contraindications

Do NOT use OptiFlex®S on patients with:

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

English

2. OptiFlex®S description

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

Adduction/abduction 0° - 30° - 175°

Internal/external rotation 90° - 0° - 90°

Elevation (flexion) 0° - 30° - 175°
with elbow bent between 60° and 90°

Horizontal adduction/abduction 0° -120°
(manual adjustment only)

It can be reconfigured for use on either side.

Note !

To allow the current position of the CPM device to be clearly indicated, the internal rotation values on the display and throughout this document are identified with "-".

These are some of the outstanding **OptiFlex®S** 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 **OptiFlex®S** device that come into contact with the patient when the device is used as intended, are designed to fulfil the biocompatibility requirements of the applicable standards.

2.1 Description of the device components

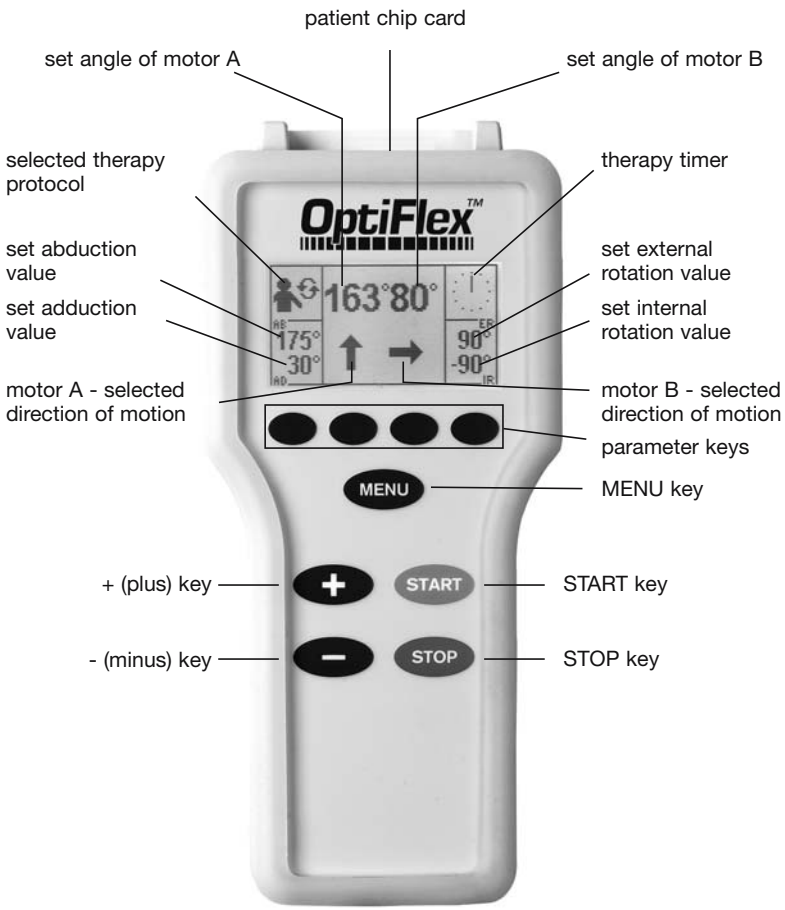
Note: Please see also page 2!

1. Programming unit
2. Patient chip card
3. Compartment for storage of programming unit
4. Armrest for healthy arm
5. Wheels
6. Connection for power cord
7. Power switch (ON/OFF)
8. Instrument fuse
9. Connection for motion element
10. Thumbscrew for adjustment of the backrest angle
11. Folds down the backrest (transport position)
12. Adjustment for horizontal adduction/abduction
13. Holding tube for height adjusment
14. Locking screw for height adjustment
15. Insertion tube for height adjustment
16. Motor A
17. Holding tube for length adjustment (upper arm)
18. Clamping lever for length adjustment (upper arm)
19. Insertion tube for length adjustment (upper arm)
20. Locking screw for elbow range
21. Motor B
22. Elbow support
23. Forearm support
24. Strap for forearm restraint
25. Holding tube for length adjustment (forearm)
26. Clamping lever for length adjustment (forearm)
27. Insertion tube for length adjustment (forearm)
28. Locking screw for swivel mechanism
29. Handle
30. Headrest adjustment
31. Height adjustment for shoulder restraint
32. Height adjustment for shoulder restraint
33. Ball joint for headrest
34. Locking pin

Subject to technical modifications (06/2007)

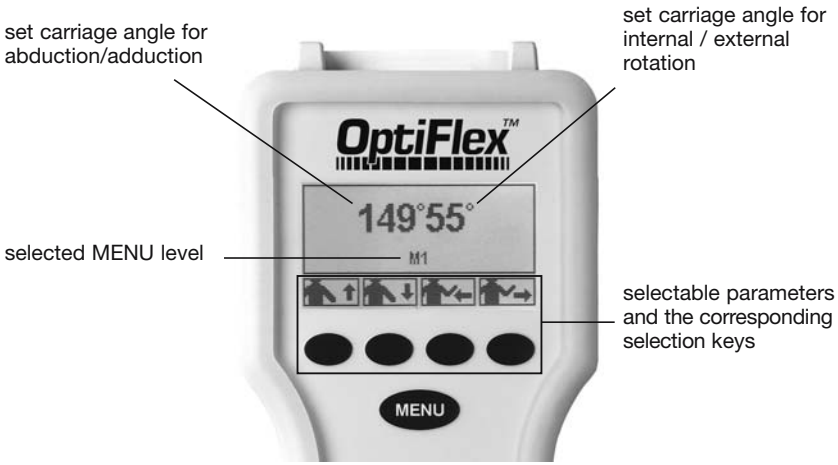
2.2 Description of the programming unit

2.2.1 Programming unit in normal mode



English

2.2.2 Programming unit in MENU selection mode



2.2.3 Programming unit set to ROM programming

2.2.4 Programming unit in general programming mode

2.2.3 Explanation of symbols

	Abduction
	Adduction
	Internal rotation
	External rotation
	Pause
	Timer
	Speed
	New patient
	Reverse on load - motor A
	Reverse on load - motor B
	Motor A ON/OFF
	Motor B ON/OFF
	Transport setting
A+B	Synchronized/ non-synchronized mode
	Total therapy time
	Service menu

2.3 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 of product with unsorted household or municipal waste.

English

3. Safety information

Definitions

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

⚠ Danger!

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

⚠ Warning!

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

⚠ Caution!

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®S 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 **OptiFlex®S** device. Individuals are authorized after receiving training in the operation of the device and reading this operation manual.

– Before using the device, the operator must ascertain that it is in correct working order and operating condition. In particular, the cables and connectors must be checked for signs of damage. Damaged parts must be replaced immediately, before use.

– **Before therapy**, a **test run** consisting of several exercise cycles must be completed, first without and then with the patient. Check that all setting screws are tightened.

– Stop therapy immediately, when you have doubts about the device settings and/or the therapy protocol.

– Ensure an **anatomically correct setup of the CPM device** suitable for the patient to be treated. For this purpose, check the following settings/positions (see numbers on device):

1. Horizontal adduction/abduction
2. Height adjustment
3. Adjustment of upper arm length
4. Adjustment of elbow angle
5. Adjustment of forearm length
6. Adjustment of headrest
   When the optional
   patient restraint is used
7. Adjustment of
   headrest and shoulder restraint

– It is not permitted to change the adjustment of 1 through 7 while a patient is sitting in the CPM device.

– 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 **OptiFlex®S 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 **OptiFlex®S** device must first be approved by CHATTANOOGA.

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

⚠ Warning!

Shock hazard —

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

– **Before use** allow the **OptiFlex®S** 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 **OptiFlex®S** 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 CHATTANOOGA, if you have questions in this matter.

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

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

– **Liquids must not be allowed to enter the CPM device** or the **programming unit**. If liquids have entered into the devices, **OptiFlex®S** 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 such** that they will not get caught in the moving parts during operation and that they do not present a stumbling hazard.

– **Inspect** the OptiFlex®S for damage and loose connections at least **once a year**.

⚠ Caution!

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

Patient hazard, damage to the carriage — Do not use the carriage to transport patients.

⚠ 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 (330.7 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 **OptiFlex®S** device 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: For a better understanding of each step, please see also pages 2 and 3.

4.1 Connecting the device, performance check

1. Connect the power cord to socket (6) of the device and 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 (7) 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 (2) into the programming unit (1).

Press the MENU key on the programming unit three times to access programming level 3 (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**.

Setup with programmed chip card

Insert the original patient chip card (2) into the programming unit (1).

Press the **START** key.

The device automatically enters the **starting position** (maximum adduction, halfway between internal / external rotation).

Performance check

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

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

– An audio signal sounds.
– The device switches off immediately.
– The message "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 OptiFlex®S device operates perfectly, ask the patient to sit down on the OptiFlex®S chair.

English

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 der OptiFlex®S to the patient, you may have to convert the device for use on the left or right shoulder.
(see section 6.4 Conversion)

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

Backrest, headrest, shoulder restraint, 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)
- In the next step adjust the **headrest**: Height adjustment with locking screw (32), headrest adjustment with locking screw (30), fine adjustment with ball joint (33).
- Use locking screw (31) to position the **shoulder restraint** approx. 1 cm above the shoulders.
- Set the **armrest** for the healthy arm to a height that allows the patient to sit up straight (locking screw 14).

Anatomically correct adjustment

① Horizontal adduction/abduction (Fig. A)

It is the purpose of the adjustment procedures to accommodate the patient in the most comfortable position possible.

- Press on the indexing knob (12) and make sure that it locks into place after the adjustment.

② Height adjustment (Fig. B)

Before opening locking screw (14), hold the moving part of the CPM device by grasping the holding tube for the length adjustment (17), to prevent the part from falling down.

- Adjust the height so that the axis of motor A is level with the pivot of the shoulder joint (see illustration on page 16). The pivot of motor A and the pivot of the shoulder joint must be on the same level.
- Tighten the locking screw.

③ Upper arm length (Fig. C)

The device for adjustment of the upper arm length is self-locking.
During adjustment, slightly lift motor B and ensure that the insertion tube does not wedge in the holding tube.

- Loosen clamping lever (18) and slightly lift the motor during adjustment.
- Tighten the clamping lever.

④ Elbow angle (Fig. D)

In most cases an angle of 90° to 60° is adjusted for elbow flexion.

- Loosen locking screw (20). To facilitate the adjustment, slightly lift motor B.
- Complete the adjustment and tighten the locking screw.

Note!

If the elbow angle is changed to a flexion value of greater than or less than 90°, the setting for the upper arm length will have to be changed, too.

⑤ Forearm length (Fig. E)

- Loosen clamping lever (26) and pull out the handle until the forearm can easily be accommodated between elbow support and handle.
- Tighten the clamping lever.

Note!

The armrest inclination can be adjusted until optimally suited to the arm.

To do so, loosen the locking screw (28) below the armrest. Adjust the inclination and tighten the locking screw.

Checking the setup, fine adjustment

- Place the patient's arm on the armrest.
- Check adjustments 1 through 5 to ensure that
  - the pivot of motor A and the pivot of the shoulder joint are on the same level
  - the axis of motor B, the center of the elbow joint and the center of the shoulder joint form a straight line.
    To adapt the armrest even better to the patient, you can also adjust its height and inclination. To do so, loosen the locking screw (28) below the armrest.
- Check that all locking screws are tightened and all clamping levers properly closed.

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

See section 5.6 for programming examples.

Important!

The programming unit **OptiFlex®S** "Graphics" can be connected to all products of the **OptiFlex®S** shoulder series with **serial numbers 3000 and higher**.

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

Please note:

1. If you use a "Graphics" programming unit with a formatted chipcard of the "Text" version, please note the following
   - 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 you use a "Text" programming unit with a formatted chipcard of the "Graphics" version, please note the following
   - 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, because it is **irrelevant for the "Text" version**.

5.1 General information on programming OptiFlex®S

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 four 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 faster 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: OptiFlex®S checks the set values, moves to the position halfway between the set internal and external rotation values as well as to the set maximum adduction value and stops.

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

   Next the carriage will move the maximum internal rotation value in the **synchronized mode**. The carriage will then simultaneously move to the maximum external rotation position and the maximum abduction position and subsequently to the maximum adduction position and the maximum internal rotation position. After reaching this position, the cycle restarts: maximum abduction and maximum external rotation.

   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.

Note!

- Refer to sections 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, **lock the keys** by simultaneously pressing the **+ (plus) and – (minus)** keys.

Press both keys again 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®S 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

- 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 OptiFlex®S

Different programming levels are provided to program the OptiFlex®S.

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

The display always indicates the currently selected level.

The following **treatment values**, **settings** and **information** can be entered/viewed on the programming unit (1):

LEVEL 1:

- Abduction
- Adduction
- Internal rotation
- External rotation

MENU

LEVEL 2:

- Pause
- Therapy timer
- Speed
- New patient

MENU

LEVEL 3:

- Reverse on load - motor A
- Reverse on load - motor B
- Motor A ON/OFF
- Motor B ON/OFF

MENU

LEVEL 4:

- Transport setting
- Synchronized/ non-synchronized mode
- Total therapy time
- 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 pain.
- The angle entered last for the respective direction of motion will be saved in each case.

5.3 Treatment value details

- To access the programming level you need, press the **MENU key** repeatedly.
- 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:

■ **Abduction**
Maximum value: 175 degrees

■ **Adduction**
Maximum value: 30 degrees

⚠ Caution!

Patient hazard —

When using the shoulder restraint, be sure not to program abduction values greater than 80°.

■ **Internal rotation** 
Maximum value: - 90 degrees

■ **External rotation** 
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 abduction value simultaneous with maximum external rotation value
  - Maximum adduction value simultaneous with maximum internal rotation value
- To ensure that the movements you program are physiological in nature, we recommend to program the carriage in the following order:
  1. Maximum adduction value 
  2. Maximum internal rotation value 
  3. External rotation (to relieve the shoulder) **= 0°** 
  5. Maximum abduction value 
  6. Maximum external rotation value 
- In the synchronized mode, after activation of **START** the carriage will first move to the maximum adduction position and to the position halfway between internal and external rotation. Then the carriage will stop, allowing the patient to be positioned. When the **START key** is pressed again (start of therapy), the carriage will first move to the maximum internal rotation position. Motor A (abduction/adduction) stops during this procedure. Once the maximum internal rotation position has been reached, both motors (A and B) will simultaneously move to the maximum abduction and external rotation position. After reaching this position, the cycle restarts: maximum adduction and maximum internal rotation.
- The elevation movement (flexion) is programmed by means of the abduction/adduction values (for mechanical adjustment instructions, refer to section 5.6 "Examples of use").
- Horizontal adduction/abduction is adjusted manually. These are possible settings:

  Horizontal adduction: **120°**

  Horizontal abduction: **0°**

LEVEL 2:

■ **Pauses** 

Pauses occur at each programmed maximum value.

These are the two pause points:
- Maximum adduction value simultaneous with maximum internal rotation value
- Maximum abduction value simultaneous with maximum external rotation value

Pauses are adjustable in steps of 1 second between 0 and 30 seconds.

Default: no pause

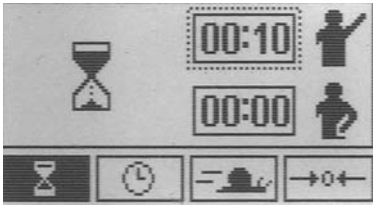
Follow these steps to program pauses:

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

  top: abduction/external rotation pause

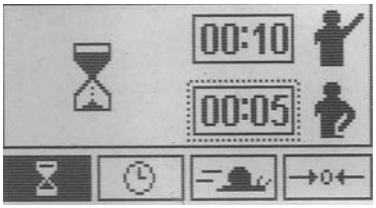
  bottom: adduction/internal rotation pause (see display image)

  The pause duration for abduction/external rotation appears in a dotted frame.
- To change the abduction/external rotation pause, press the "+" or "-" key. Select a duration of 10 seconds, for instance.



- Press the **parameter key** again when done. The dotted frame automatically moves to the line below, indicating that the adduction/internal rotation 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 begin 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 300 minutes**.

At the end of the therapy time, the device automatically stops in the starting position (maximum adduction position / halfway between internal and external rotation).

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 %. 100 % is equivalent to 230°/minute

Default: 100 %

■ 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 device stops halfway between the abduction/adduction and internal/external rotation position.

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

- Abduction: 41°
- Adduction: 39°
- Internal rotation: 1°
- External rotation: -1°
- 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

LEVEL 3:

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

The motors automatically switch to opposite directions of 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: level 25

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

The motors automatically switch to opposite directions of 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: 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 adduction and abduction, motor B effects internal rotation and external rotation.

For an isolated internal / external rotation movement, set motor A to the programmed position (abduction/adduction), then turn the motor off.
In normal mode the display indicates the symbol "**OFF**" during therapy, instead of the programmed adduction/abduction 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 adduction and abduction, motor B effects internal rotation and external rotation.

For an isolated adduction/abduction movement, set motor B to the programmed position (internal / external rotation), then turn the motor off.
In normal mode the display indicates the symbol "OFF" during therapy, instead of the programmed internal/external rotation 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:

■ **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 section 6.3 Transport).

■ **Synchronized/ non-synchronized mode** A+B

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

Synchronized:
Motors A and B perform a synchronized movement according to the shoulder joint's physiological motion pattern:
Starting from the initial position (maximum adduction / halfway between internal and external rotation position), the carriage will first move to the maximum internal rotation position. The carriage will then simultaneously move to the maximum abduction position and the maximum external rotation position and subsequently to the maximum adduction position and the maximum internal rotation position. After reaching this position, the cycle restarts: maximum abduction and maximum external rotation.

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.

■ **Total therapy time** Σ🕒

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

To delete the stored therapy time:

Press and hold the **parameter key** for 5 seconds or select the "New patient" function.

■ **Service menu** 🔧

For service purposes only, refer to Service Manual.

Reminder:

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

5.4 Examples of use/ sample protocols

5.4.1 Isolated adduction/abduction

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 **parameter key** for **internal rotation** or **external rotation** and press the **+/- keys** to set the carriage to the desired rotation position to be maintained during the isolated abduction/adduction movements.
4. Next set the desired range of motion for adduction and abduction by first pressing the **parameter key** for **adduction** and set the values with the **+/- keys**.
5. Set the abduction value in the same way .

Note!

- For an exclusive adduction/abduction protocol, motor B for the rotation movement must be turned off as described in steps 6 to 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 internal rotation/external rotation

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 **parameter key** for **adduction** or **abduction** and press the **+/- keys** to set the carriage to the desired position to be maintained during the isolated rotation movements.
4. Next set the desired range of motion for internal/external rotation by first pressing the **parameter key** for **internal rotation** and set the values with the **+/-**keys.
5. Set the **external rotation** value in the same way .

Note!

- For an exclusive rotation protocol, motor A for adduction/abduction must be turned off as described in steps 6 to 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** ⊙ A parameter key 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.

5.4.3 Isolated elevation (flexion)

1. First adjust an angle of 90° for external rotation and deactivate motor B as follows:
   a. Press the MENU key on the programming unit to access level 1 (M1).
   b. Press the **parameter key** for **external rotation** and move the carriage to the rotation position of 90°, using the **+ / - keys**.

Note!

- For an exclusive elevation protocol, motor B for the rotation movement must be turned off as described in steps c to e below.
- Having programmed the ranges of motion, you can program additional options, such as pause or speed.

   c. Press the **MENU key** on the programming unit to access level 3 (M3).
   d. Press the **Motor B ON/OFF** ⊙ B parameter key to activate the parameter.
   e. 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.
   f. Save the entered values by press the **STOP key**.

2. Complete the mechanical settings and adjust the carriage to the patient as follows:
   a. Adjust an angle of 90° for horizontal adduction/abduction ①, using indexing knob (12).
   b. Secure and hold the motion element at the holding tube for length adjustment and open the locking screw (14) for height adjustment ②. Select a height at which the pivot points of motor A and the shoulder are at the same level.
   c. Now open clamping lever (18) for adjustment of the upper arm length ③, locking screw (20) for adjustment of the elbow angle ④ and locking screw (28) for adjustment of the forearm rest inclination and set the motion element to a position that is comfortable to the patient and suitable for the therapy session. When done, tighten all screws and levers.
   d. Open clamping lever (26), adjust the forearm length ⑤ to the patient and close the clamping lever.
3. In the next step, program the elevation range of motion as follows:
   a. Press the **MENU key** on the programming unit to access level 1 (M1).
   b. Next set the desired range of motion for adduction and abduction by first pressing the **parameter key** for **adduction** and set the values with the **+/-** keys.
   c. Set the **abduction** value in the same way.

Note!

Having programmed the ranges of motion, you can program additional options, such as pause or speed.

4. 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.

- OptiFlex®S 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 **armrest 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 device does not require additional regular maintenance.

English

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 OptiFlex®S and disconnect the device from the power line.
- Use an appropriate tool to remove the fuse holder (8) situated between the power switch (7) and the power connector (6) (Fig. 1).
- Replace the fuses and reinsert the fuse holder (Fig. 2). Check that the fuser holder locks properly into place.

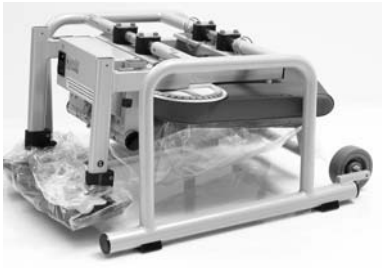
Fig. 1

Fig. 2

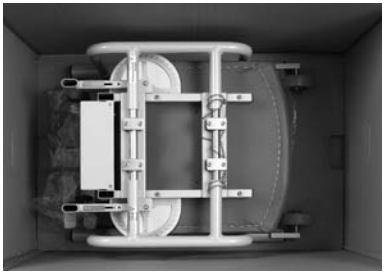
6.3 Transport

The following operating steps must be completed before transporting the OptiFlex®S:

1. Activate the "transport setting" function → in the menu (see also 5.3) and start the OptiFlex®S.
2. Turn off the OptiFlex®S power switch (7).
3. Remove the power cord (6) and disconnect the motion element and the programming unit (9).
4. Open locking screw (14) and pull out the armrest (4) for the healthy arm.
5. Grasping the holding tube (17) of the motion element, open locking screw (14) and pull out the motion element.
6. Set horizontal adduction/abduction to 0° (indexing knob 12).
7. Open the locking screw for the headrest adjustment (30) and remove the headrest.
8. Open the locking screw for the shoulder restraint (31) and remove.
9. Open the locking screw for the height adjustment of the patient restraint (32) and remove.
10. 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.
11. Remove the two locking pins (34). Pull out the legs towards the sides, reverse and reinsert. Then put the locking pins back in place.



12. Only use the original shipping box for transporting the device. Chattanooga cannot be held liable for transport damage, if the device was not shipped in its original shipping box.
13. Place the OptiFlex®S – legs down – on the bottom of the box. The markings on the bottom of the box indicate the correct position.



14. Then put the enclosed polystyrene block on the chair, observing the cut-outs in the block.
15. Put the programming unit (1) in the supplied box. Place the motion element, the armrest, the components of the neck and shoulder restraint and the power cord in the respective cut-outs in the polystyrene block.

16. Then close the box.

Reverse the above steps to reassemble the device after transport.

⚠ Warning!

Shock hazard – **Before use** allow the OptiFlex®S 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.

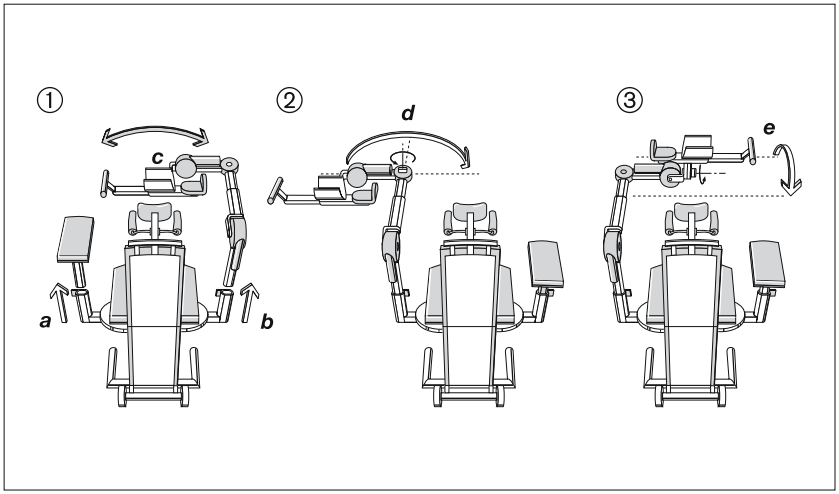
English

6.4 Conversion

The OptiFlex®S can be used on the left and on the right shoulder 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 OptiFlex®S.
2. On both sides adjust an angle of 90° for horizontal adduction/abduction (indexing knob 12) (see conversion drawing ①).
3. Open locking screw (14), remove the armrest for the healthy arm and place it on the seat (see conversion diagram ① a).
4. Grasping the holding tube (17) of the motion element, open locking screw (14).
5. Remove the motion element and insert it on the opposite side. Tighten locking screw (14) (see conversion diagram ① b, c).
6. Open locking screw (20) and rotate the forearm rest 180°. Tighten locking screw (20) (see conversion diagram ② d).
7. Hold the forearm rest and open locking screw (28).
8. Swivel the forearm rest to the other side around motor B and tighten locking screw (28) (see conversion diagram ③ e).
9. Insert the armrest for the healthy arm into the holding tube and tighten locking screw (14).
10. Set horizontal adduction/abduction to the desired value on the side of the motion element (normally a value between 0° and 40°, as needed).

Conversion diagram:



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 CHATTANOOGA 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):

Length:	87.5 cm (34.4 In)
Width:	57.5 cm (22.6 In)
Height:	58 cm (22.8 In)

Adjustment ranges (min./max.):

Height adjustment: (measured from the seat)	35 – 71 cm (13.7 – 28.0 In)
Upper arm length:	20 – 32 cm (7.8 – 12.6 In)
Forearm length:	29 – 46 cm (11.4 – 18.1 In)
Seat height:	48 cm (18.9 In)
Weight:	25 kg (55.1 lb)
Materials:	ABS, POM (Delrin 100), PUR, PA, FR4, aluminum, stainless steel, brass
MDD:	class 2a
Standards compliance:	IEC 60601-1:1990 + A1:1993 + A2: 1995 CSA 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 (-12 to +140 °F)
Relative humidity:	20 % to 85 %
Atmospheric pressure:	700 hPa to 1060 hPa

Ambient conditions (operation)

Ambient temperature:	+10 °C to +40 °C (50 to +105 °F)
Relative humidity:	30% to 75 %
Atmospheric : pressure	700 hPa to 1060 hPa

Subject to change without notice (06/2007)

9. IEC 60601-1-2:2001

The OptiFlex®S 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®S device.

The OptiFlex®S device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, OptiFlex®S 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

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

Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions to CISPR 11	Group 1	OptiFlex®S 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®S 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®S is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the **OptiFlex®S** device is used in such an environment.

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

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

English

9.2 Electromagnetic immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment are used no closer to any part of the **OptiFlex®S** device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF to IEC 61000-4-6	3 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
			$d = 1.2\sqrt{P}$ 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 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®S** device is used exceeds the applicable RF compliance level above, the **OptiFlex®S** 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®S** device.

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

9.3 Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the OptiFlex®S device

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

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

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

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

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

10. Contact

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

■ **Chattanooga Group**
4717 Adams Road
Hixon TN. 37343
Phone 1-800-592-7329
Fax 1-800-242-8329
www.chattgroup.com

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

11. Technical Service

11.1 Technical hotline

Do you have any technical questions?

Do you need technical service?

Chattanooga Technical Service

Phone: 1-800-266-0026 ext. 6981

Fax: 1-423-870-7407

11.2 Shipment

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

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 number
- Quantity
- Serial number of the CPM device

Note!

Refer repairs to authorized, specially trained staff.

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