KINETEC® Spectra

| | | |
|---|---|---|
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The CPM concept

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# SUMMARY



## SAFETY RECOMMENDATIONS

- The physician defines the protocol and ensures that it is correctly implemented (adjustments, session time and frequency of use).
- We recommend that you lock the hand control when you give it to the patient.
- For optimum safety, always give the hand control to the patient before starting the system.
- Explosion hazard: KINETEC Spectra is not designed for use in the presence of flammable anaesthetics.
- Check that the electrical socket is in good condition and is suitable for the splint power supply cord. The latter complies with current standards and has a grounding socket. The plug may be connected to any standard socket. The socket must however have a grounded pin.
  To connect the power supply, only use the original cable supplied with the machine.
  Check that the cables remain free around the device so that they do not get damaged.

Manuel N°467896275 - Updated 21/02/03

## Definition

The KINETEC Spectra is a Knee PASSIVE mobilization device enabling the extension and flexion movement from -10° to 120°.

## • Indications

- Knee replacement surgery.
- Fractures (patellar, tibia plateau, femoral,...).
- Arthrolysis
- Hip surgery, including hip replacement, hip pinning, osteotomy,...).
- Ligament repairs.
- Arthroscopic surgery (menisectomies, patellectomies,...)
- Burns, joints sepsis,...

## • Clinical Benefits

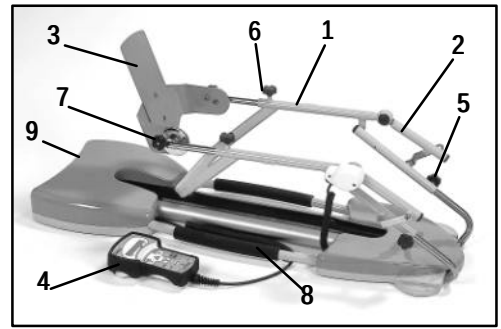
- Breaks the cycle of trauma, inflammation and the loss of range of motion.
- Prevents joint stiffness.
- Speeds the recovery of post-operative range of motion.
- Maintains the quality of the joint surface.
- Reduces pain and edema.
- Promotes joint cartilage healing.
- Reduces hospitalization time
- Reduces the need for pain medication.
- Provides immediate post-operative continuous passive motion.
- Digital ROM readout on the patient hand control for positive reinforcement.
- Maintains desired positions for stretching and muscular rest.

## • Contraindications

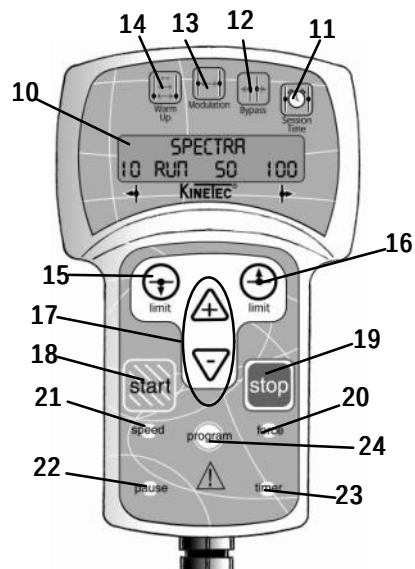
Bone Cancer, Warped joint surfaces, Spastic paralyses, Unstable fractures, Uncontrolled infection.
The machine are not adapted for patients height more 2 m(6'7") or under 1,40m (4'7").

KINETEC Spectra consists of the following components:

1 • Lower limb support.
2 • Thigh support.
3 • Foot support and hand control location for transport.
4 • Hand control.
5 • Thigh support setting lock.
6 • Lower limb support setting lock .
7 • Foot support positioning setting lock.
8 • Transport handle.
9 • ON/OFF switch and fuses.




10 • Liquid-crystal display (2 lines of 16 characters).
11 • SESSION TIME display key.
12 • BYPASS mode key.
13 • MODULATION key.
14 • WARM UP key.
15 • EXTENSION setting key.
16 • FLEXION setting key.
17 • Increase / decrease keys.
18 • START key.
19 • STOP key.
20 • FORCE key.
21 • SPEED key.
22 • PAUSE key.
23 • TIMER key.
24 • PROGRAM access key.

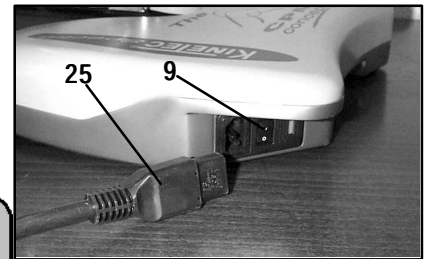


The physician defines the protocol and ensures that it is correctly implemented (adjustments, session duration and frequency of use).
The patient must know the start/stop/reverse function on the control handle. Hand control must be accessible to patient at all times. (See page 7).
KINETEC Spectra complies with Directive 93/42/CEE.

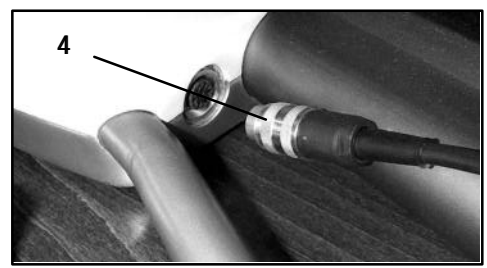
**EXPLOSION HAZARD:**
**KINETEC Spectra is not designed for use in the presence of flammable anesthetics.**

In case of electromagnetic interference with other devices move the device.
KINETEC Spectra is in compliance with standards in force (IEC 601.1.2), electromagnetic compatibility standard for medical devices.

KINETEC Spectra is a type B class I device.
Before connecting the device to the power supply, check that the mains voltage matches that shown on the identification plate (100-240 V~ 50-60Hz).
Connect the hand control (4)
Connect the power supply cable (25).




**IMPORTANT**
Check that the electrical socket is in good condition and is suitable for the splint power supply cord. The latter complies with current standards and has a grounding socket.
The plug may be connected to any standard socket.
The socket must however have a grounded pin.
To connect the power supply, only use the original cable supplied with the machine.
Check that the cables remain free around the device so that they do not get damaged.




## Starting the unit

Switch on (9).
While the unit begins an auto diagnostic, the display shows the following :

| KINETEC<br>Spectra V01.0 | ⇨ | Please wait | ⇨ | Kinetec<br>30 STOP 15 90 |
|---|---|---|---|---|

Your KINETEC Spectra is ready to be used.

## Select your language

| Beginning | Keys to press | Display | Remarks |
|---|---|---|---|
| Switch the unit ON | | KINETEC<br>Spectra V01.0<br><br>Please wait<br>Kinetec<br>30 STOP 15 90 | Check if the hand control is not blocked (See page 7). |
| Press the 2 keys in the same time | speed + force | Language:<br>english | The display indicate the language selected. |
| To change the language |  | Language:<br>English | The English language is selected.<br><br>English<br>French<br>German<br>Italian<br>Spanish |
| To validate the new language. |  | Ok<br>Switch on/off | To exit and confirm the new language, switch OFF and Switch ON the unit. |

## Locking the hand control setting

The hand control allows the patient to control the machine as appropriate.

Simultaneously press the  and  keys to lock the hand control,

The display reads "LOCK", you can not change the parameters, if you try the display reads "LOCK".

To unlock the hand control, simultaneously press the  and  keys, The display reads "UNLOCK".

**We recommend that you lock the hand control when you give it to the patient.**

Comment: The hand control is unlocked when you switch the unit ON/OFF.

## START/STOP/REVERSE function

As with all KINETEC systems, KINETEC Spectra is equipped with a START/STOP/REVERSE function.
When the unit is running, the display reads RUN

Press the 

key of the hand control. The movement stops. The display reads STOP.

Press the 

key of the hand control. The movement starts in the opposite direction and the display reads RUN.

**Caution:**
**For optimum safety, always give the hand control to the patient before starting the system.**

## Quick Start

Set up the patient and proceed as below:

| Beginning | Keys to press | Display | Remarks |
|---|---|---|---|
| Switch the unit ON | | KINETEC<br>Spectra V01.0<br><br>Please wait<br>Kinetec<br>30 STOP 15 90<br>Or<br>WARMUP<br>30 STOP 15 90 | Check if the hand control is not blocked (See page 7).<br><br>If the Warm Up mode is selected, switch OFF this mode by pressing on the key  |
| Start the session with the original parameters of the movement (default setting). |  | KINETEC<br>30 run 45 90 | The value change at the speed of the movement. |

## Possible values for each parameter:

| | Possible values | Default setting |
|---|---|---|
| • Treatement Mode | | Normal |
| • Extension limit | -10 to 115° | 30° |
| • Flexion limit | -5° to 120° | 90° |
| • Speed | 1 to 5 (from 30° to 160° per minute) | 2 |
| • Force | 1 to 6 | 6 |
| • Extension pause | 0 to 900 seconds (15minutes) | 0 |
| • Flexion pause | 0 to 900 seconds (15minutes) | 0 |
| • Timer | No timer(00H00) to 24H00 | 0 |

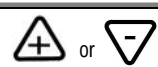
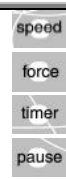
## How to adjust the basic parameters of the movement

| Beginning | Keys to press | Display | Remarks |
|---|---|---|---|
| To stop the unit | stop | KINETEC<br>30 STOP 15 90 | Check if the hand control is not blocked (See page 7). |
| To display the extension or flexion limit of the movement | limit or limit | KINETEC<br>30 Ext 15 90<br>KINETEC<br>40 Flex 15 90 | The value blinks. |
| To change the limit if necessary | Or | KINETEC<br>40 Flex 15 110 | The new value blinks. |
| To validate the new value, press another key or wait more than 3 seconds. | speed<br>force<br>timer | KINETEC<br>SPEED 2<br>FORCE _ ▂ ▃ ▅ ▇<br>No timer | While the value blinks press the or key to change if necessary. |
| Or<br>Or to display pause in extension or flexion limit | pause | KINETEC<br>PAUSE HIGH 0<br>Pause low 0 | Successive presses on this key selects the pause at the extension or flexion limit. |
| To change the pause if necessary | Or | KINETEC<br>PAUSE low 15 | The new pause value blinks. |
| To validate the new value press another key or wait more than 3 seconds. The display shows the selected mode. | | KINETEC<br>40 STOP 15 110 | The unit is ready to start with the new parameters. |

## How to modify programs PROGRAM MODE

| Beginning | Keys to press | Display | Remarks |
|---|---|---|---|
| **To switch off the unit** | | | Check if the hand control is not blocked (See page 7). |
| Press the two keys at the same time and switch the unit ON |  | KINETEC<br>Spectra V01.0 | Welcome text during 3 seconds. |
| Then | | Program 2<br>EMPTY | The program number blinks. |
| To change the program if necessary |  or | Program 10<br>25 kinetec 110 | The new program number blinks. |
| To choose the treatment mode |  | Program 10<br>25 warmup 110 | The display indicates the selected treatment mode, the program number blinks again. |
| Or |  | Program 10<br>25 kinetec 110 | |
| To display the extension or flexion limit of the movement |  or | Program 10<br>30 warmup 100<br>Program 10<br>30 warmup 110 | The value blinks. |

## How to modify programs PROGRAM MODE (continued)

| Beginning | Keys to press | Display | Remarks |
|---|---|---|---|
| To change the limit of movement if necessary |  | Program 11<br>30 warmup 120 | The new value blinks. |
| To validate the new value, press another key or wait more than 3 seconds |  | Program 10<br>SPEEd: 2<br>FORCE _ ▬ ▬ ■ ■<br>No timer<br>Pause low 0 | While the value blinks press the  or  key to change if necessary. |
| To record the program 10 |  | Program 10<br>Save:+ clear:- | |
| Then |  | Program 10<br>Save<br>Program 11<br>EMPTY | The program 10 has been recorded and the display indicates the next program so you can change another program. |
| OR<br>To cancel the program |  | Program 10<br>clearing<br>Program 11<br>EMPTY | The program 10 has been cancelled and the display indicates the next program so you can change another program. |
| To exit program mode, switch OFF and switch ON the unit. |  | KINETEC<br>Spectra V01.0 | To use the modified program see page 10. |

**Comments**:

- When a program has been deleted, the display shows


**Program table:**

| • Program number | Treatment Mode | Flexion limit | Extension limit | Speed | Force | Flexion Pause | Extension Pause | Timer |
|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
| 5 | | | | | | | | |
| 6 | | | | | | | | |
| 7 | | | | | | | | |
| 8 | | | | | | | | |
| 9 | | | | | | | | |
| 10 | | | | | | | | |
| 11 | | | | | | | | |
| 12 | | | | | | | | |
| 13 | | | | | | | | |
| 14 | | | | | | | | |
| 15 | | | | | | | | |
| 16 | | | | | | | | |

## program Using Programs

The KINETEC Spectra allows you to store up to 16 programs, including the type of treatment, ROM, speed, load, pauses and timer.

The original parameter values of the program are empty.
These values can be modified and recorded at any time (see 'How to enter a program' page 10).

| Beginning | Keys to press | Display | Remarks |
|---|---|---|---|
| To stop the unit | stop | KINETEC<br>40 STOP 15 110 | Check if the hand control is not blocked (See page 7). |
| To access the program mode | program | PROGRAM 1<br>70 WARMUP 110 | The program number blinks. |
| To change the program if necessary | + or - | PROGRAM 3<br>25 warmup 90 | The new program number blinks. |
| To exit and validate the selected program | start | KINETEC<br>Please wait | The current parameters have been recorded in program 3. |
| To exit without validation of selected program | stop | KINETEC<br>40 STOP 15 110 | Back to the starting parameters. |
| Start the unit | start | warmup<br>25 run 20 90 | The value change at the speed of the movement. |

**Comments:**

- The values shown in the 'Display' column are examples. They actually depend on the stored programs.
- The current movement parameters can be changed while using that program but no data will be stored in the original program. See the programming mode (p 10) to modify programs.

## Reading the values of a program: example SPEED

| Beginning | Keys to press | Display | Remarks |
|---|---|---|---|
| To stop the unit | stop | KINETEC<br>40 STOP 15 110 | Check if the hand control is not blocked (See page 7). |
| To access the program mode | program | Program 1<br>70 WARMUP 110 | The program number blinks. |
| To change the program if necessary | + or - | PROGRAM 3<br>25 warmup 90 | To change the program if necessary. |
| To read the speed value | speed | PROGRAM 3<br>Speed 5 | Displays the speed value. |
| After 15 seconds or after pressing on another key | | PROGRAM 3<br>70 WARMUP 110 | |
| To exit and validate the selected program | start | KINETEC<br>40 STOP 15 110 | The current parameters have been recorded in program 3. |
| Start the unit | start | KINETEC<br>40 run 15 110 | The value change at the speed of the movement. |

**Comments:**

- The values shown in the 'Display' column are examples. They actually depend on the stored programs.
- The current movement parameters can be changed while using that program but no data will be stored in the original program. See the programming mode (p 10) to modify programs.

## How to use the WARM UP key

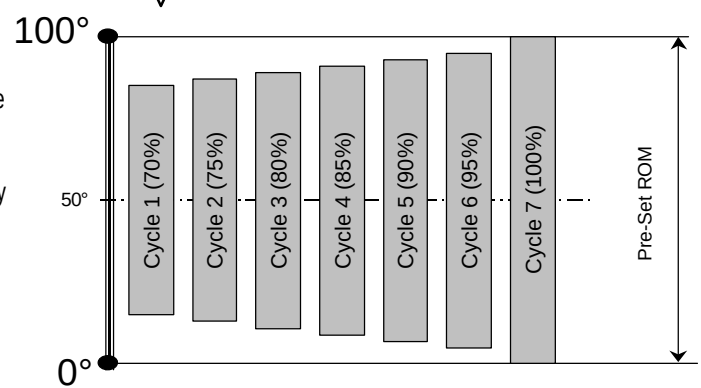
| Beginning | Keys to press | Display | Remarks |
|---|---|---|---|
| To stop the unit | stop | KINETEC<br>40 STOP 15 110 | Check if the hand control is not blocked (See page 7). |
| To select the Warm Up mode | Warm Up | WARM UP<br>30 STOP 15 90 | The display shows the default settings (see page 8).<br>To change the movement value if necessary see page 9. |
| Start the movement | start | WARM UP<br>15 RUN 15 110 | The value change at the speed of the movement. |

Warm Up rules:

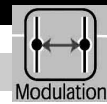
The Kinetec Spectra starts at 70% of the full ROM, increasing 5% of the range every other cycle until the pre-set ROM is reached.

**Comments**:
The calculation mode used enables reaching the pre-set ROM in approximately seven full cycles.

**Example**:
For a Warm Up treatment with a pre-set ROM from 0° to 100°.
The first cycle starts from 15° to 85° to 15° and increase 5% each cycle.



## How to define the patient tolerance • At the start of a session




This function, MODULATION Mode is a way to set within the tolerance of a patient at the beginning of a session.

Set up the patient and proceed as below:

| Beginning | Keys to press | Display | Remarks |
|---|---|---|---|
| Switch the unit ON | | KINETEC<br>Spectra V01.0<br><br>Please wait<br>Kinetec<br>30 STOP 15 90<br>Or<br>WARMUP<br>30 STOP 15 90 | Check if the hand control is not blocked (See page 7).<br><br>If the Warm Up mode is selected, switch OFF this mode by pressing on the key Warm Up |
| To select the MODULATION Mode | Modulation | MODUL.: use + or -<br>30 STOP 15 90 | The display indicates the keys to be used to drive the machine, this message is displayed 3 seconds. |
| To select the pain level<br>( + for flexion, - for extension) | + or - | MODUL.: use + or -<br>30manual 50 90 | The unit is moving to the selected way.<br>It is waiting for you to select new limits. |
| To set the pain level when reached, immediately press | limit or limit | MODUL.: use + or -<br>30manual 50 50 | The new limit of the movement is recorded |
| To start the session with the new movement limits | start | KINETEC<br>30 run 45 50 | The angle display changes with current movement. |


## How to define the patient tolerance • During the session

This function, The BY-PASS MODE is a way to address the pain threshold of a patient during a session.

**IMPORTANT: Can be used only when the machine RUN.**

| Beginning | Keys to press | Display | Remarks |
|---|---|---|---|
| The unit is running | start | Kinetec<br>30 RUN 15 90<br>Or<br>WARMUP<br>30 RUN 15 90 | Check if the hand control is not blocked (See page 7). |
| To select the BYPASS mode | Bypass | PYPASS: use + or -<br>30 RUN 15 90 | The display indicates the keys used to run the machine.<br>This message is displayed 3 seconds. |
| To select the NEW pain level | or | BYPASS: use + or -<br>30bypass 100 90 | The unit is moving to the selected way.<br>It is waiting for you to select new limits. |
| To set the NEW pain level when reached, immediately press | limit or limit | bypass.: use + or -<br>30manual 50 50 | The new limit of the movement is recorded. |
| Continue the session with the new movement limits. | | WARMUP<br>30 run 45 50 | The angle display changes with current movement. |

## Session Time


This function shows the running time (in minutes) of the session (motor functioning).

- It directly accessible by the key 

, the display shows

| | | | |
|---|---|---|---|
| | TIME | 02h25 | |
| 30 | STOP | 15 | 90 |

This counter is reset each time the unit is switched ON.

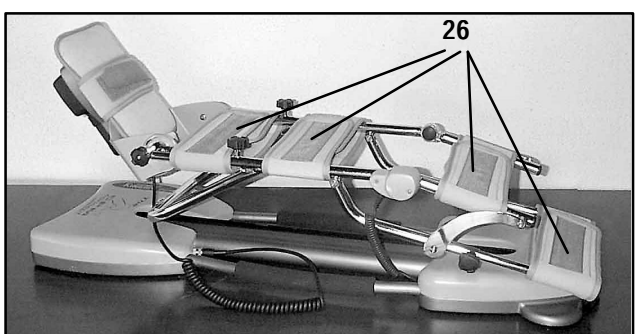
The KINETEC Patient Pad Kit is designed for rapid fitting, optimal hygiene and maximum patient comfort.
- For using and positioning the straps, please refer to here under. Make sure that the self-adhesive parts (26) are visible.
- Place the sponge side next to the skin.

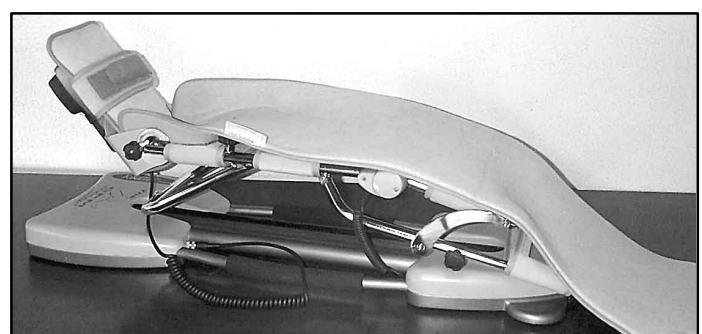
**FOR OPTIMAL HYGIENE, A NEW SET OF PADS SHOULD BE USED FOR EACH PATIENT.**
**Each cover is provided with a label to record the patient's name**

CLEANING:
- Sterilization of the pads ( if necessary): Sterilized at 134 °C during 18 minutes.
- Disinfecting of the pads: Washing at 30°C with use of a disinfecting solution during the rising cycle.

Example of product that can be used: Solution " Baclinge" at 0.125 % or "Souplanios" at 0,125% from ANIOS Laboratory.
A complete list of distributors in your country is available on request.

The KINETEC Spectra is delivered with a complete set. Components:
- 4 straps
- 1 foot support
- 1 cover



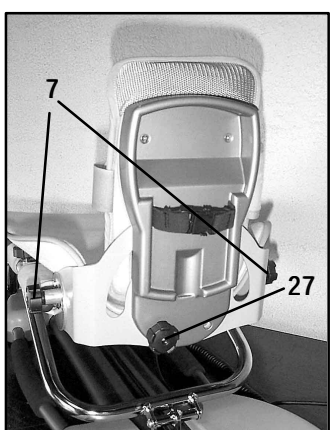
## Setting up the patient

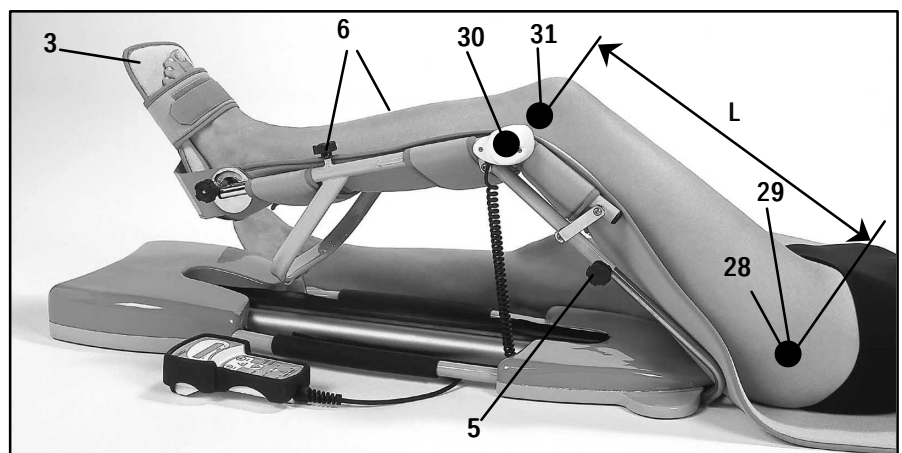
Place the KINETEC Spectra machine in a position that will be comfortable for the patient.

- Measure in cm or inches the length of the patient's femur (L); adjust the thigh support to this measurement using knobs (5)
- To install the patient on the KINETEC Spectra machine.
- Push the foot plate (3) up to the patient and tighten the knobs (6).
- Adjust the plantar flexion (40°) or the dorsal flexion (30°) of the foot, with the knobs (7).
- Adjust the internal (30°) or external (30°) flexion of the foot, with the knob (27).

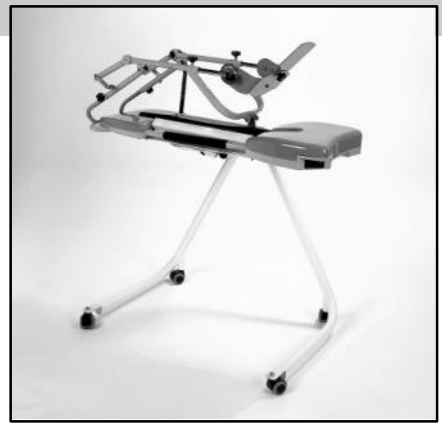
**IMPORTANT**

Adjust the axis of the patient's hip (28) with the axis rotation (29) of the KINETEC Spectra machine, and the axis of the patient's knee (30) with the axis rotation (31) of the KINETEC Spectra machine.



## Cart



## Maintenance

After 2,000 hours of operation, KINETEC Spectra requires a few lubrication and maintenance operations (lubrication of the joints, pointer stops and ball screws).
The need for maintenance is indicated by display of the message SERV. MOTOR when the system is switched on.
Despite that warning, you can continue to use your KINETEC Spectra by pressing START, but you should contact your nearest KINETEC technician to have the maintenance operations conducted as soon as possible.

- A motor running time counter is available. Simultaneously press keys limit and limit , the displays shows

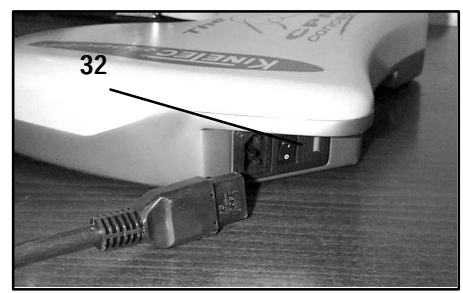
RESET TIME 924H
Reset: limit low

this counter can be resetting by pressing the key limit .

## Troubleshooting

A spare parts list and technical catalog are available to you on request from your KINETEC distributor.
If, after connecting the power supply cable to the power supply and switching on KINETEC Spectra:

- The display does not indicate any information:
  - Check that the electrical socket is live using another device.
  - Replace the fuse(s) (32) of the connector with fuses of the same type and calibre:
    2 fuses T 750 mA 250V (6.3 x 32) (KINETEC order: 4610007434).
  - If the display still does not indicate any information, contact your nearest KINETEC technician.
- Your KINETEC Spectra does not work and the display indicates 50 STOP 25 115,
  Press START again.
  Your KINETEC Spectra still does not function: Contact your nearest KINETEC technician.
- Your KINETEC Spectra does not function and the display indicates:
  ANGULAR POSI.: angle measurement function failure,
  or NO MOVEMENT: no movement,
  or BAD WAY: motor rotation failure,
  or LOAD MAXI: abnormal consumption,
  or POWER SUPPLY: power failure;
  Contact your nearest KINETEC technician if the same message is displayed after having switched the device off, then on, and started it by pressing START.



## Cleaning

Before conducting any cleaning operation, SWITCH the unit OFF and disconnect the power supply.

Use a DISINFECTANT (PROPANOL/ISOPROPANOL or ALDEHYDE-based solution). Spray the disinfectant on the SURFACES (plastic shells and metal components).

In order to ensure optimal hygiene, you are advised to clean the covers for each new patient. All the consumables enable hazard-free disposal.

## Technical specifications

**Product:**

| | |
|---|---|
| Weight: | 11Kg (24 pounds) |
| Splint dimensions: | 94cm (37 inches) x 33cm (13 inches) x 33cm (13 inches) |
| Angular limits: | -10° to 120° |
| Speed: | from 30 to 160° per minute for average femur length |
| Patient height: | full leg: 71 to 104 cm (28 to 41 inches)<br>Tibia: 38 to 58 cm (15 to 23 inches)<br>Femur: 33 to 46 cm (13 to 18 inches) |

**Electricity:**

Power supply: 100-240 V~
Frequency: 50-60 Hz
Power consumption: 50 VA
Device of type B class I
IP 20.
Fuse T 750mA 250V 6.3x32mm (KINETEC order: 4610007434)

**Environment**

| | |
|---|---|
| - Storage/transport conditions: | Temperature: -40 to 70°C / -40 to 160°F<br>Relative humidity: up to 90% |
| - Operating conditions: | Room temperature: 10 to 40°C / 50 to 105°F<br>Relative humidity: up to 80% |

## Symbols used

| | |
|---|---|
|  | TYPE B device (protection against electric shocks) |
|  | Caution (consult the accompanying documents) |
|  | STOP (power off) |
|  | ON (power on) |
|   | Start movement |
|   | Stop movement |
|   | Program access |

| | |
|---|---|
|   | Speed |
|   | Timer |
|   | Force |
|   | Pause |
|  | Increase |
|  | Decrease |
|   | Extension limit |

| | |
|---|---|
|   | Flexion limit |
|   | Warm Up |
|   | Modulation |
|   | Bypass |
|   | Session time |
| ~ | Alternative current |
| | |

## Warranty

The KINETEC warranty is strictly limited to the replacement free of charge or repair in the plant of the component or components found to be defective.
KINETEC guarantees its joint passive mobilization systems for 1 year against all defects of manufacture from the date of purchase by the consumer.
KINETEC is the only organization able to assess the application of the warranty to its systems.
The warranty will be considered null and void if the device has been used abnormally or under conditions of use other than those indicated in the user's manual.
The warranty will also be considered null and void in the event of deterioration or an accident due to negligence, inappropriate surveillance or inappropriate maintenance, or due to transformation of the equipment or an attempt to repair the equipment.

## Maintenance sheet

Serial number: _____

Purchasing date: _____

Date: _____ Operations done: _____

Technician: _____ _____

Running time (see page 22): _____ _____

Exchange parts: _____ _____

_____ _____

Date: _____ Operations done: _____

Technician: _____ _____

Running hours (see page 22): _____ _____

Exchange parts: _____ _____

_____ _____

GROUPEMENT POUR L'ÉVALUATION DES DISPOSITIFS MÉDICAUX

**ATTESTATION/** *CERTIFICATE* **N° 0912 / B2P3 / 1**
Renouvellement de l'attestation N°0214/B2P3/1 du 12/11/1997

**Délivrée à Fontenay aux Roses le 16 octobre 2002**
*Issued in Fontenay aux Roses on October 16th, 2002*

**LCIE** **Membre du GIE G-MED**

# ATTESTATION CE / *EC CERTIFICATE*

**Approbation du Système Qualité Complet d'Asssurance Qualité** / *Approval of full Quality Assurance System*
**ANNEXE II point 3 Directive 93/42/CEE relative aux dispositifs médicaux**
*ANNEX II section 3 DIRECTIVE 93/42/EEC concerning medical devices*

**Fabricant (nom et adresse)**
*Manufacturer (name and address)*

**ABILITYONE KINETEC S.A.**
**Zone Industrielle**
**Rue Albert Deville**
**TOURNES**
**08014 CHARLEVILLE MEZIERES CEDEX**
**FRANCE**

**Catégorie du(des) dispositif(s)**
*Device(s) category*

**Dispositifs d'immobilisation, de mobilisation et d'évaluation des articulations du corps humain de marque KINETEC**
*Immobilization, mobilization and testing devices of the human joints sold under the KINETEC name*

**Le G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé 60000010, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II point 3 de la Directive 93/42/CEE.**
*G-MED certifies that, on the basis of the results contained in the file referenced 60000010, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II section 3.*

**Cette attestation est valable jusqu'au : 16 octobre 2005 (inclus)**
*This certificate is valid until : October 16th, 2005 (included)*

CE 0459

**Pour l'Administrateur**
*For the Administrator*
**Isabelle HELLER**

B2P3 1999-03-15

33, AVENUE DU GÉNÉRAL LECLERC - BP 8 - F 92260 FONTENAY AUX ROSES - TEL. : 01 40 95 63 54 - FAX : 01 40 95 62 43
TEL. INTER. : +33 1 40 95 63 54 - FAX INTER. : +33 1 40 95 62 43 - e.mail : gmed@lcie.fr - TVA Intracomm : FR 64395030505
Groupement d'intérêt économique régi par l'ordonnance du 23 septembre 1967 modifiée - SIREN 395 030 505 RCS Nanterre

GROUPEMENT POUR L'ÉVALUATION DES DISPOSITIFS MÉDICAUX

# CERTIFICAT
# CERTIFICATE OF REGISTRATION
## N° 0912 / 9001 - 46001 / 1

Renouvellement du certificat N°0214/9001-46001/1 du 15/10/1997

**LCIE** **Membre du GIE G-MED**

**Le G-MED certifie que le système qualité développé par**
*G-MED certifies that the quality assurance system developed by*

**ABILITYONE KINETEC S.A.**
**Zone Industrielle**
**Rue Albert Deville**
**TOURNES**
**08014 CHARLEVILLE MEZIERES CEDEX**
**FRANCE**

**pour les activités**
*for the activities*

**Conception, fabrication, vente et service après-vente de dispositifs d'immobilisation, de mobilisation et d'évaluation des articulations du corps humain de marque KINETEC**
*Design, manufacturing, sales and servicing of immobilization, mobilization and testing devices of the human joints sold under the KINETEC name*

**réalisées sur le(s) site(s) de**
*performed on the location of*

**même adresse** *(same address)*

**est conforme aux exigences des normes internationales**
*complies with the requirements of the international standards*

**ISO 9001 (2000) – EN 46001 (1996)**

Date de délivrance : 16 octobre 2002
*Date of issue October 16th, 2002*

Date d'échéance de validité : 16 octobre 2005 (inclus)
*Limit expiry date October 16th, 2005 (included)*

cofrac
3F 0 0023
PORTÉE DISPONIBLE SUR LE SITE WWW.COFRAC.FR

**Pour l'Administrateur**
*For the Administrator*
**Isabelle HELLER**

**Ce certificat est délivré selon les règles G-MED de certification.** */This certificate is issued according to the G-MED's rules of certification.*
**G-MED Organisme notifié pour les Dispositifs Médicaux** */G-MED Notified Body for Medical Devices*

*SQ* *1999-03-15*

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TEL. INTER. : +33 1 40 95 63 54 - FAX INTER. : +33 1 40 95 62 43 - e.mail : gmed@lcie.fr - TVA Intracomm : FR 64395030505
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