Kinetec Spectra™

Manuel d'utilisation	Avant toute utilisation lire ce document. Kinetec SAS se réserve le droit de toutes modifications techniques.	**FR**
User manual	Before use, please read this document. Kinetec SAS reserves the right to effect technical modifications.	**EN**
Bedienungsanleitung	Vor Benutzung unbedingt dieses Dokument lesen. Kinetec SAS behält sich das Recht vor, jegliche technische Änderung durchzuführen.	**DE**
Istruzioni per l'uso	Prima di mettere in funzione l'apparecchio leggere con attenzione il presente documento. La Kinetec SAS si riserva il diritto di apportare modifiche tecniche.	**IT**
Manual de empleo	Antes de cualquier utilización, lea este documento. Kinetec SAS se reserva el derecho a cualquier modificación técnica.	**ES**
Gebruikershandleiding	Lees voor ieder gebruik dit document door. Kinetec SASbehouden zich het recht voor technische wijzigingen aan te brengen.	**NL**

CE 0459

IFU-Spectra-467896361-1
03/2016
Série 4
Notice Originale

Kinetec SAS
Zone Industrielle de Tournes
Rue Maurice Périn
F-08090 Tournes
France

+33 (0)3 24 29 85 05

+33 (0)3 24 33 51 05

contact@kinetec.fr

www.kinetec.fr

kinetec®

USER MANUAL

Summary

Page

- **Definition** ____ **2**
- **Warning and safety instructions** ____ **3**
- **Compliance** ____ **4**
- **Unpacking and packing** ____ **4**
- **Installing the device** ____ **4**
- **Description** ____ **5**
- **Electrical connection** ____ **6**
- **Procedure to start the machine** ____ **6**
- **Using the hand control**
  - Changing the display language ____ 6
  - START/STOP/REVERSE function ____ 7
  - Locking the hand control setting ____ 7
  - Possible values for each parameter ____ 7
  - Session time ____ 7
  - Quick Start ____ 8
  - How to adjust the basic parameters of the movement? ____ 8
  - How to use the WARM UP key? ____ 9
  - How to use the Modulation key? ____ 9
  - How to use the Bypass key? ____ 10
  - How to enter a program? ____ 11
  - Using Programs ____ 12
  - Reading the values of a program ____ 12
- **Using the Plastic Comfort Case kit** ____ **13**
- **Using the Kinetec® Patient Pad kit** ____ **13**
- **Setting up the patient** ____ **14**
- **Options** ____ **14**
- **Product information**
  - Maintenance ____ 15
  - Troubleshooting guide ____ 15
  - Cleaning ____ 16
  - Disposal and recycling ____ 16
  - Warranty ____ 16
  - Technical specifications ____ 17
  - Symbols used ____ 17
  - Guidance and manufacturer's declaration ____ 18
- **Programming help sheet (for photocopying)** ____ **20**

Definition

The device Kinetec Spectra™ is a PASSIVE mobilisation device of the KNEE, enabling extension and flexion movements from -10° to 120°.

With the Kinetec Spectra™ linked to a computer, you can:
- program the device,
- monitor a list of patients,
- produce device usage reports per patient.

For more information, refer to the instruction manual for the Kinetec Data Capture™ software.

Indications

- Arthroplasties of the knee and hip joints.
- Osteosynthesised femoral or tibial fractures.
- Patellar fractures.
- Arthrolysis and palliative surgery (cartilage lesions, removal of osteomas, etc.).
- Osteotomies of the pelvis or femur.
- Ligament repairs (LCI, LCE, LLI, LLE).
- Freeing the knee extensor mechanism (Judet's operation).
- Synovectomies, Meniscectomies, Patellectomies, Arthroscopies.

Clinical Benefits

- Effectively breaks the vicious circle of trauma, immobility, effusion and atrophy.
- Prevents joint stiffness of the knee and hip.
- Speeds the recovery of post-operative range of motion.
- Maintains the quality of the joint surface.
- Promotes joint cartilage healing.
- Prevents venous thrombosis.
- Provides immediate post-operative continuous passive motion.
- Reduces hospitalization time.
- Reduces the need for pain medication.

Contraindications

Rheumatoid arthritis in the inflammatory phase, gout, algodystrophy in the inflammatory phase (hyper painful), para-osteo-arthroplasty, unhealed infected wounds, established phlebitis, bone cancer, myositis ossificans of the quadriceps, arthrodesis of the hip, infectious arthritis, deformed joint surfaces, paralysed limbs (atonic or spastic), non-stabilised fractures.
The machine is not suitable for patients over 1.95 m (6'7") or under 1.45m (4'7") tall.

WARNING: The machine must be installed and commissioned according to the information provided in this manual.

WARNING: If you need any assistance in the assembly, use or maintenance of the device, please contact your Kinetec® distributor.

WARNING: The practitioner determines the protocol and ensures its proper implementation (settings, session duration and frequency of use).

WARNING: Run a cycle with the device unloaded before installing the patient on the machine.

WARNING: For optimum safety, always give the hand control to the patient before starting the system. The patient must know the start/stop/reverse function on the hand control, see page 7.

WARNING: To avoid the parameters being changed, lock the machine's hand control before giving it to the patient, see page 7.

WARNING: Danger, risk of explosion: Do not use the machine with anaesthetic gas or in an environment that is rich in oxygen.

WARNING: Before using this machine, always check that the electrical socket is in good condition and is suitable for the splint power supply cord. 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.

WARNING: Before using this machine, always check that the machine is not damaged, in particular the protective housings.

WARNING: In case of electromagnetic interference with other devices move the device.

WARNING: Please do not touch the fixed or moving parts while the unit is running: pinching or crushing risk. Keep children and pets away from the machine.

WARNING: Modifying the machine in any way is strictly forbidden.

WARNING: Always check the motion parameters displayed on the hand control before starting the device.

WARNING: Only the accessories, spare parts and supplies described in this manual should be used with this machine.

WARNING: Do not connect the device to other devices not described in this manual.

WARNING: If unforeseen events or malfunctions occur, please contact your Kinetec® distributor.

WARNING: Wireless communications devices, such as domestic wireless devices in networks, mobile phones, wireless telephones and their base stations and walkie-talkies, may affect the machine. You are recommended to keep at least a distance d between these devices and the machine. See the table on page 18.

WARNING: Under maximum temperature conditions mentioned in the user's manual, the maximum temperature which can be reached by the hand control is 47,9°C.

Compliance

The device Kinetec Spectra™ complies with the standards of Directive 93/42/EEC, and bears the EC mark.
The device Kinetec Spectra™ complies with the standards in force IEC 60601-1-2 concerning the electromagnetic compatibility of medical devices, IEC 60601-1 concerning electrical safety and IEC 60601-1-11 concerning the utilisation in home care environment.
The device Kinetec Spectra™ meets the requirements of the Machinery Directive No. 2006/42/EC.

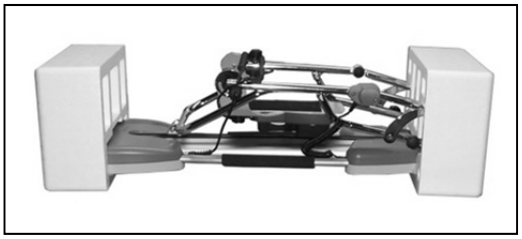
Unpacking and packing

Unpacking

When you unpack the machine, don't forget that you may need to pack it up again. We recommend that you keep the packaging materials, boxes and plastic bags.

Recommendations for plastic bags: do not put them over the head as there is a risk of suffocation, and keep them out of the reach of children. Be careful with small-sized pieces: they could be swallowed by a child. Be careful with cables and wires: risk of strangulation.

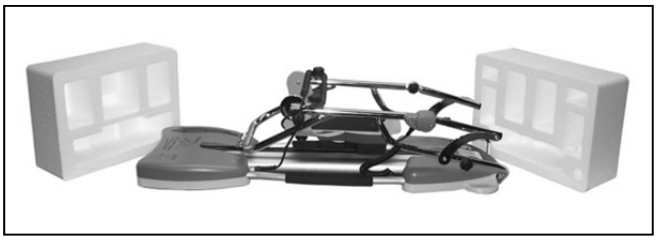
Before using your machine you must move the foot plate into its working position. (See page 14).



Your machine is ready to be connected to the power supply. (See page 6).

Packing

To prevent any problems when the machine is transported, only pack it using its original packaging.
- Set the leg support to 42cm
- Stop the unit at 5° of flexion.
- Move the foot plate back into its packing position.



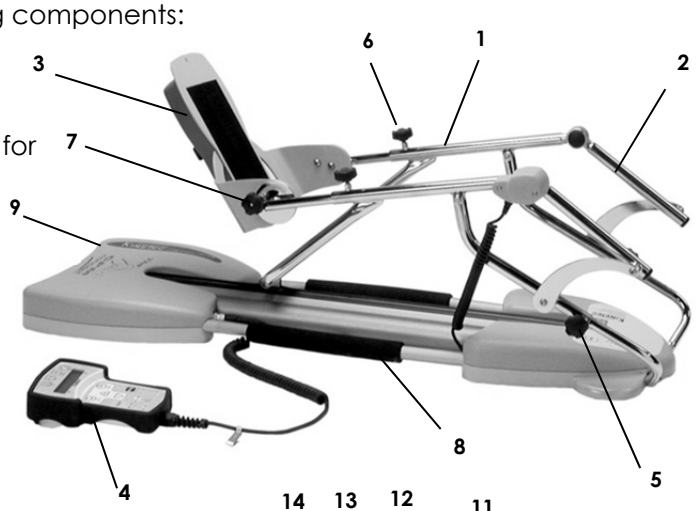
Installing the device

The device Kinetec Spectra™ is designed to be used in hospitals, clinics, doctors' offices or in private homes (rental).

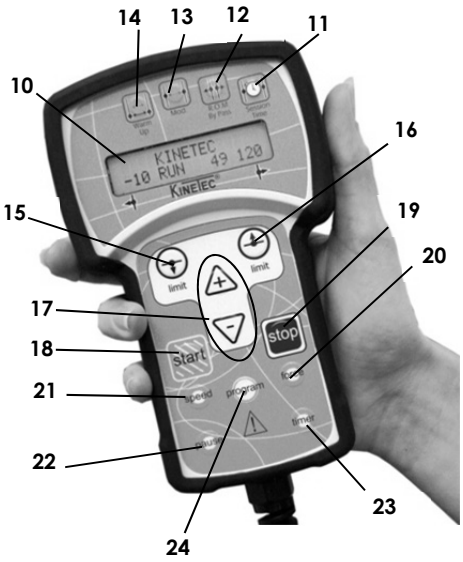
The machine must be installed on a flat surface that is wide enough to accommodate the entire device plus the other leg.
We recommend using the machine with a physiotherapy table, a healthcare bed, a bed or a bench.
We do not recommend the use of an air mattress.

Description

The device Kinetec Spectra™ consists of the following components:



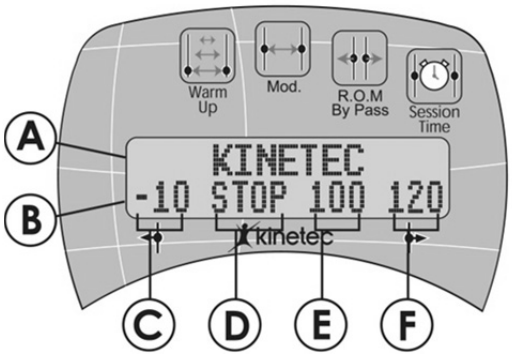
1 • Lower limb support.
2 • Thigh support.
3 • Articulated foot plate and hand control location for transport.
4 • Hand control.
5 • Thigh support setting lock.
6 • Lower limb support setting lock.
7 • Foot plate position setting lock.
8 • Transport handle.
9 • ON/OFF switch and fuses.



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.

Display Details:

A • 16-character line, used to display various messages when starting up the machine, then the type of movement during operation (KINETEC or Warm Up).
B • 16-character line, used to display various messages when starting up the machine; then it displays the operational parameters.
C • 3-character area showing the extension limit.
D • 4-character area showing various messages: RUN, STOP, EXT, FLEX …
E • 3-character area showing the real-time angle of the knee; this value changes with the current movement.
F • 3-character area showing the flexion limit.
G – USB key slot
H – USB key
I – Sliding protective cover

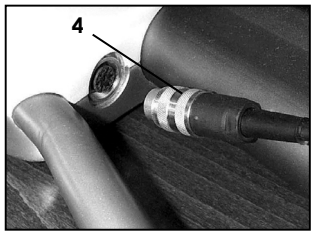


See the Kinetec Data Capture™ software user manual for more information.

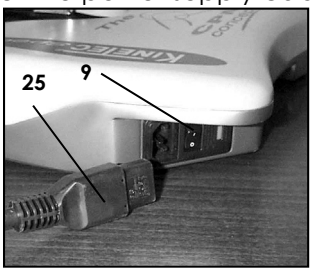
Electrical connection: safety first

Before connecting the device to the power supply, check that the mains voltage matches that shown on the identification plate (100-240V~ 50/60Hz).

Connect the hand control (4).



Connect the power supply cable (25).



IMPORTANT
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.
Check that the machine is not damaged, in particular the protective housings.

Procedure to start the machine

Switch on the unit (9).
The display comes on, the machine carries out a self-test and the display shows in succession

KINETEC **Spectra Vxx.x**

Then

Movement Verify. **Please Wait**

Then

Hello **Patient's first name**

Then

KINETEC **30 STOP 15 70**

Your Kinetec Spectra™ is ready to be used with the parameters from the previous session, unless you are using a daily program (see the instruction manual for the Kinetec Data Capture™ software).

Warning: Always check the motion parameters displayed on the hand control before starting the device.

Note: Before using the device with data recording, please refer to the instruction manual for the Kinetec Data Capture™ software. The splint can be used immediately without the USB key being connected to a computer, or even with no USB key; in this case no data will be recorded.

Changing the display language

Beginning	Keys to press	Display	Remarks
Switch the unit on		**KINETEC** **40 STOP 50 110**	Check if the hand control is not locked (See page 7).
Press simultaneously on the 2 keys	speed + force	**LANGUAGE** **ENGLISH**	The display indicates the language selected.
To change the language	+ Or -	**LANGUAGE** **FRENCH**	The French language is selected. Available languages: English, French, German, Italian and Spanish.
To confirm the new language	limit	**OK** **SWITCH ON/OFF**	Switch the machine off and then on again to apply the changed display language.

START / STOP / REVERSE function

As with all Kinetec® systems, the devices Kinetec Spectra™ are equipped with ON/OFF/REVERSE functions.

Press the stop key of the hand control. The movement stops,

Press the start key of the hand control. The movement starts in the opposite direction.

CAUTION
For optimum safety, always give the hand control to the patient before starting the system.

Procedure to stop the machine:

To stop the machine's movement: press the [stop] button, stop

To switch power off: press the ON / OFF switch (9) (see page 6)

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 cannot change the parameters; if you try the message **LOCK** will be displayed. The Start and Stop keys are still active.

To unlock the hand control, simultaneously press the same keys. The display will show **UNLOCK**.

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

Note: the hand control locking is preserved when you switch the unit ON/OFF.

Possible values for each parameter

	Possible values	Default setting
• Treatment mode		Normal
• Extension limit	-10 to 115°	30°
• Flexion limit	-5° to 120°	70°
• Speed	1 to 5 (from 45° to 155° per minute)	2
• Force	1 to 6	6
• Extension Pause	0 to 900 seconds (15 minutes)	0
• Flexion pause	0 to 900 seconds (15 minutes)	0
• Timer	No timer (00H00) to 24H00	0
• Number of Programs	16	Empty

Session Time

Session Time

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

It is directly accessible by the key Session Time, the display shows TIME 02H35

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

Quick Start

The device Kinetec Spectra™ continuously records the session data (only if the USB key is connected).

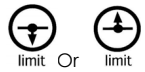
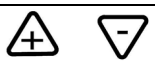
Set up the patient and proceed as below:

Beginning	Keys to press	Display	Remarks
Switch the unit on		**KINETEC Spectra Vxx.x**	
		Movement Verify. Please Wait	
		Hello Patient's first name	
		KINETEC usb 30 STOP 35 70	Displays the last movement used, except for the daily program. Check if the hand control is not locked (See page 7).
		Warm up usb 30 STOP 35 70	
Starting the session with the parameters from the previous session, unless you are using a daily program (see the instruction manual for the Kinetec Data Capture™ software).		**KINETEC usb 30 RUN 45 70**	The angle display changes with the current movement.

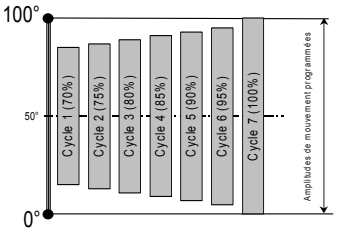
When the USB bar is connected the symbol "usb" is displayed in the upper right of the display.

Warning: Always check the motion parameters displayed on the hand control before starting the device.

How to adjust the basic parameters of the movement?

Beginning	Keys to press	Display	Remarks
To stop the unit		**KINETEC 30 STOP 45 70**	Check if the hand control is not locked (See page 7).
To display the extension or flexion limit of the movement		**KINETEC 30 EXT 45 70**	The value blinks.
		KINETEC 40 FLEX 45 70	
To change the limit if necessary		**KINETEC 40 FLEX 45 110**	The new value blinks.
To confirm the new value, press another key or wait more than 3 seconds for automatic confirmation.		**KINETEC SPEED 2**	While the value blinks press the  or  key to change if necessary.
		**KINETEC FORCE _ _ _ _ _ _**	
		**KINETEC TIMER 00H00MIN**	
To display pause in flexion limit		**KINETEC PAUSE FLEX 0S**	Successive presses on this key selects the pause at the extension or flexion limit.
or in extension limit		**KINETEC PAUSE EXT 0S**	
To change the pause if necessary		**KINETEC PAUSE EXT 15S**	The new pause value blinks.
To confirm the new value press another key or wait more than 3 seconds. The display shows the selected mode		**KINETEC 40 STOP 45 110**	The unit is ready to start with the new parameters.

How to use the WARM UP key?



Warm Up rules.
The device Kinetec Spectra™ starts at 70% of the full ROM, increasing 5% of the range each full cycle until the pre-set ROM is reached.

Beginning	Keys to press	Display	Remarks
To stop the unit	stop	**KINETEC** **40 STOP 45 110**	Check if the hand control is not locked (See page 7).
To select Warm Up mode	Warm Up	**WARM UP** **Please Wait**	
		WARM UP **40 STOP 45 110**	To change the movement value if necessary (see page 8).
To start the movement	start	**WARM UP** **40 RUN 50 110**	The angle display changes with the current movement.

Note:
- The parameters should only be modified while the unit is stopped.
- Pauses and ByPass mode are not available during warm up cycles.
- The Warm Up cycles are only performed when the movement is first started.
- To start a new Warm Up session, press the "Warm Up" key twice.
- The calculation mode used enables the pre-set ROM to be reached in approximately seven full cycles.

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

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

Mod.

This function, MODULATION MODE, allows the maximum limits that a patient can tolerate to be defined and recorded 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** **40 STOP 50 110**	Check if the hand control is not locked (See page 7). If Warm Up mode is selected, switch OFF this mode by pressing the "Warm Up" key.
To select MODULATION Mode	Mod.	**MODUL.: use +or-** **40 STOP 50 110**	The display indicates the keys used to run the machine. This message is displayed 3 seconds.
To select the pain level (⊕ for flexion, ⊖ for extension)	⊕ ⊖ Or Continuous press	**MODUL.: use +or-** **40 MANUAL 60 110**	The unit begins to move as selected. It is waiting for you to select new limits.
To set the pain level when reached, immediately press	limit limit Or	**MODUL.: use +or-** **40 MANUAL 60 60**	The new limit of the movement is recorded.
To start the session with the new movement limits	start	**KINETEC** **40 STOP 55 60**	The angle display changes with the current movement.

Comments: When the maximum or minimum range of motion of the machine is reached, this limit is recorded and the MODULATION MODE is automatically switched OFF.

This function, BYPASS Mode, allows the maximum limits that a patient can tolerate to be defined and recorded, which allows you to work on increasing amplitude.

IMPORTANT: Can be used only when the machine is RUNNING.

Beginning	Keys to press	Display	Remarks
The unit is running	start	**KINETEC** **40 RUN 55 60** **WARM UP** **40 RUN 55 60**	Check if the hand control is not locked (See page 7). Or, if Warm Up mode is selected.
To select BYPASS Mode	R.O.M By Pass	**BYPASS: use +or-** **40 RUN 55 60**	The display indicates the keys used to run the machine. This message is displayed 3 seconds.
To select the NEW pain level	+ / - Or Continuous press	**BYPASS: use +or-** **40 BYPASS 72 60**	The unit begins to move as selected. It is waiting for you to select new limits.
To set the new pain level when reached, immediately press	limit limit Or	**BYPASS: use +or-** **40 BYPASS 72 72**	The new limit of the movement is recorded.
Continue the session with the new movement limits.	start	**KINETEC** **40 RUN 64 72**	The angle display changes with the current movement.

Comments: When the maximum or minimum range of motion of the machine is reached, this limit is recorded and the BYPASS Mode is automatically switched OFF.

The device 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 saved at any time by following the procedure below or by using the Kinetec Data Capture™ software.
Note: this function is not available when a USB key is connected.
See the Kinetec Data Capture™ software user manual for more information.

Beginning	Keys to press	Display	Remarks
To switch off the unit			Check if the hand control is not locked (See page 7).
Press the two keys at the same time and switch the unit ON	+ -	**KINETEC SPECTRA VXX.X**	Welcome text displayed for 3 seconds
Then		**PROGRAM Nr2 EMPTY**	The program number blinks.
To change the program if necessary	+ - Or	**PROGRAM Nr10 25 KINETEC 110**	The new program number blinks.
To choose the treatment mode	Warm Up	**PROGRAM Nr10 30 WARM UP 90**	The display indicates the selected treatment mode, the program number blinks again.
Or	Warm Up	**PROGRAM Nr10 30 KINETEC 90**	
To display the extension or flexion limit of the movement	limit Or	**PROGRAM Nr10 30 KINETEC 90**	The value blinks.
	limit	**PROGRAM Nr10 30 KINETEC 90**	
To change the limit if necessary	+ - Or	**PROGRAM Nr10 30 KINETEC 120**	The new value blinks.
To confirm the new value, press another key or wait more than 3 seconds	speed	**PROGRAM Nr10 SPEED: 2**	While the value blinks press the + or - key to change if necessary.
	force	**PROGRAM Nr10 LOAD: _ _ _ _ _**	
	timer	**PROGRAM Nr10 TIMER 00H00MIN**	
	pause	**PROGRAM Nr10 PAUSE EXT 0S**	
To record program 10	program	**PROGRAM Nr10 SAVE:+ CLEAR:-**	
Then	+	**PROGRAM Nr10 SAVING**	Program 10 has been recorded and the display indicates the next program so you can change another program.
		PROGRAM Nr11 EMPTY	
Or To cancel the program	-	**PROGRAM Nr10 CLEARING**	Program 10 has been removed and the display indicates the next program so you can change another program.
		PROGRAM Nr11 EMPTY	
To exit program mode, switch the unit OFF and switch back ON.	O I	**KINETEC SPECTRA VXX.X**	To use the modified program see page 12.

Using Programs

Beginning	Keys to press	Display	Remarks
To stop the unit		**KINETEC** **40 STOP 45 110**	Check if the hand control is not locked (See page 7).
To access program mode		**PROGRAM Nr1** **EMPTY**	The program number blinks.
To change the program if necessary	 Or	**PROGRAM Nr7** **30 WARM UP 90**	The new program number blinks.
To exit and confirm the selected program		**WARM UP** **Please Wait**	The current parameters are those recorded in program 7.
To exit without confirming the selected program		**KINETEC** **40 STOP 45 110**	Back to the starting parameters.
Start the unit		**WARM UP** **30 RUN 50 90**	The angle display changes with the current movement.

Warning: Always check the motion parameters displayed on the hand control before starting the device.
When a USB key is connected the programs stored on the USB key have priority.

Reading the values of a program: e.g. SPEED

Beginning	Keys to press	Display	Remarks
To stop the unit		**KINETEC** **40 STOP 45 110**	Check if the hand control is not locked (See page 7).
To access program mode		**PROGRAM Nr1** **EMPTY**	The program number blinks.
To change the program if necessary	 Or	**PROGRAM Nr7** **30 WARM UP 90**	The new program number blinks.
To read the speed value		**PROGRAM Nr7** **SPEED: 2**	Displays the speed value.
After 5 seconds or after pressing another key		**KINETEC** **40 STOP 45 110**	
To exit and confirm the selected program		**WARM UP** **30 STOP 45 90**	The current parameters are those recorded in program 7.
Start the unit		**WARM UP** **30 RUN 50 90**	The angle display changes with the current movement

Note: The current movement parameters can be changed while using that program but no data will be stored in the original program. See programming mode (page 11) to modify programs.
When a USB key is connected the programs stored on the USB key have priority.

Using the Plastic Comfort Case kit

Plastic Comfort Cases are specially designed to improve comfort and hygiene for the patient. They have clips, fixed directly on the tubes of the machine's thigh and lower limb support segments, and straps with protection stops to precisely and quickly adjust to the patient's leg dimensions.

Cleaning

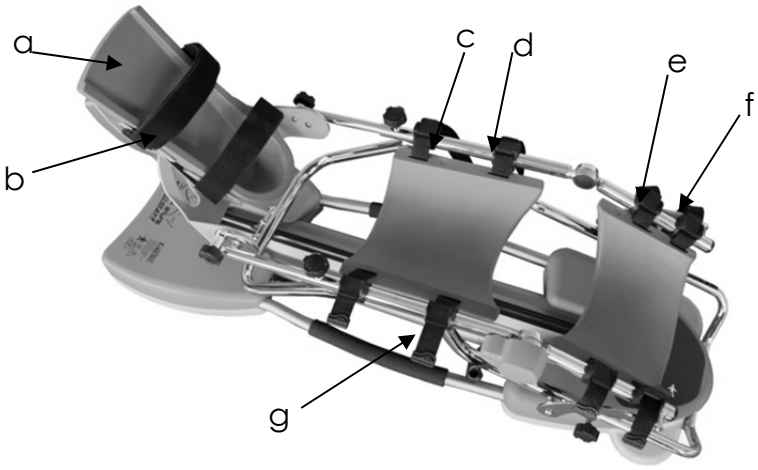
To ensure optimal hygiene, clean the supports after each patient use.
Use a DISINFECTANT product (alcohol-free or <5% alcohol solution) in spray (plastic cases and metal components).

We recommend changing the cases every 500 hours of operation.
(See the Maintenance chapter for the running time counter).

Replacement parts

a 4670024048 Complete foot support
b 4635010561 Foot support strap kit
c 4635010157 Tibia case only
d 4670024329 Tibia case with straps
e 4635010165 Femur case only
f 4670024337 Femur case with straps
g 4650001876 Single strap

Part number to order a complete kit:
- fastening with clips: 4670024345
- fastening without clips: 4670023701 (if your machine is not fitted with clips).



Using the Kinetec® Patient Pad kit

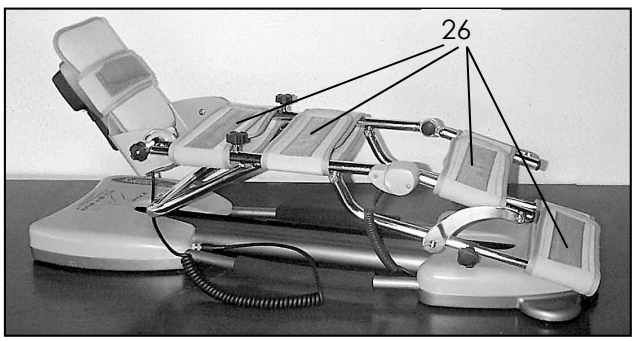
The Kinetec® Patient Pad Kit is designed for rapid fitting, optimal hygiene and maximum patient comfort.
- Please refer to the instructions below for using and positioning the straps. Make sure that the self-adhesive parts (26) are visible.
- Place the sponge side next to the skin.

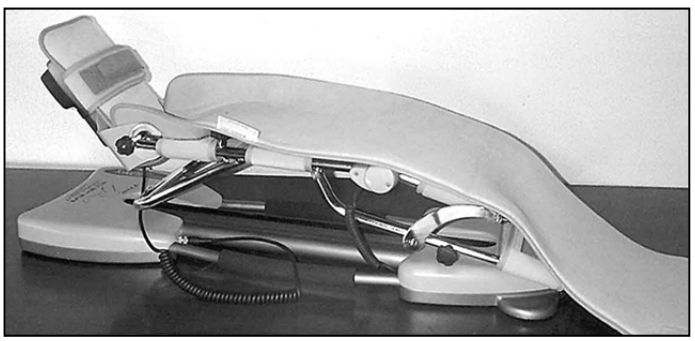
FOR OPTIMAL HYGIENE, A NEW SET OF PADS SHOULD BE USED FOR EACH PATIENT.
Each cover is provided with a label to record the patient's name

CLEANING:
- Disinfecting the pads: Wash at 30°C, using a disinfectant solution during the rinse cycle. Examples of products 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 device Kinetec Spectra™ is delivered with a complete set, comprising:
- 4 straps (4650001107)
- 1 foot support (4650001420)
- 1 cover (4650001090)

Part number to order the complete set: 4650001868



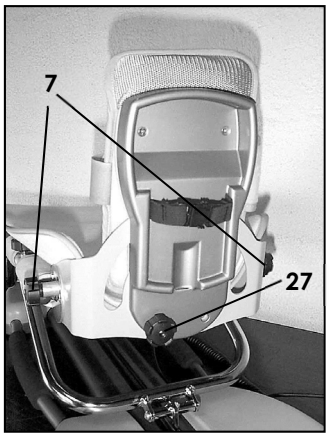


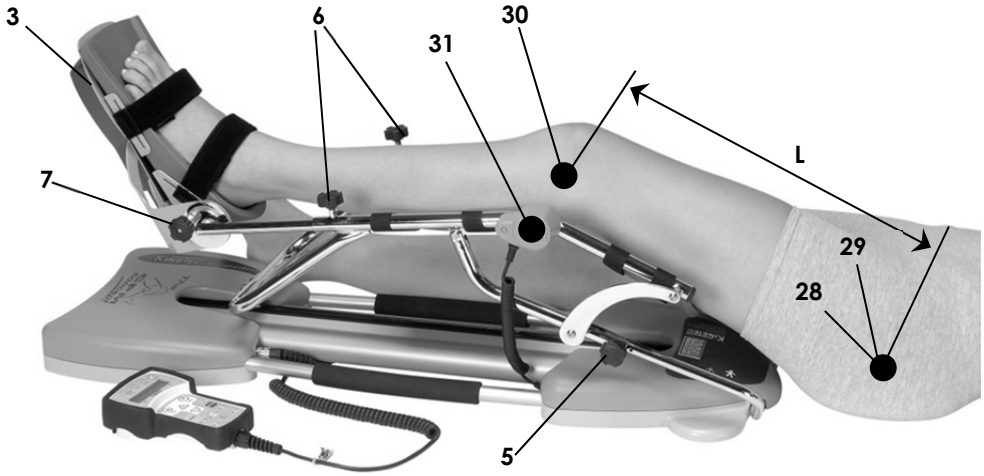
Setting up the patient

See page 4, "Installing the Device" chapter, for the positioning conditions.
Place the unit in a position that will be comfortable for the patient.

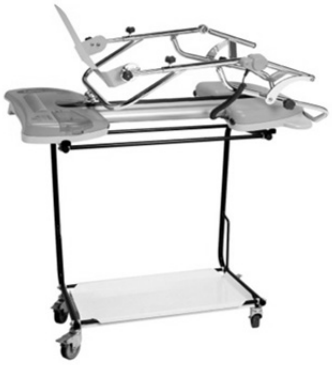
- Measure the length of the patient's femur in cm or inches (L); adjust the thigh support to this measurement using knobs (5).
- Install the patient on the machine.
- Bring the foot plate (3) into contact with the patient's foot, then tighten both buttons (6).
- Adjust the plantar flexion (40°) or the 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).

CAUTION
Adjust the axis of the patient's hip (28) with the "THEORETICAL" axis of rotation (29) of the unit, and the axis of the patient's knee (30) with the axis of articulation (31) of the unit.

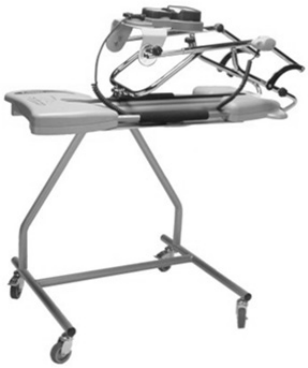




Options

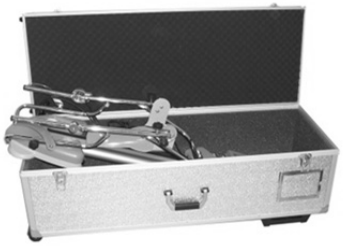


Trolley for all CPM
Part number to order:
4655001053



Cart for bed use
Part number to order:
4665003297

Seat Adaptor
Part number to order:
4670024098



Transport box
Part number to order:
4640001927

Paediatric foot plate
Part number to order:
4670023777

Box of USB keys and software
Part number to order:
4670025632 (5 USB keys + software)
4670025640 (20 USB keys + software)

Maintenance

After 2,000 hours of operation, or once a year, the device Kinetec Spectra™ requires lubrication and maintenance operations (lubrication of the joints, pointer stops and ball screws). If the message **SERVICE TIME Mx** is displayed when the system is switched on, this indicates that maintenance is required.
Despite this indication, you can continue to use your machine by pressing [START], but you should contact your nearest Kinetec® technician to have the maintenance operations carried out as soon as possible.
An after-sales service inspection sheet and the technical catalogue are available on request from your Kinetec® distributor.

WARNING: Before using this machine, always check that the electrical socket is in good condition and is suitable for the splint power supply cord. 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.

WARNING: Before using this machine, always check that the machine is not damaged, in particular the protective housings.

When the machine is no longer in working condition, please return it to us, together with its accessories, for destruction.
Change the battery if there is no stored date (see the Technical Catalogue).

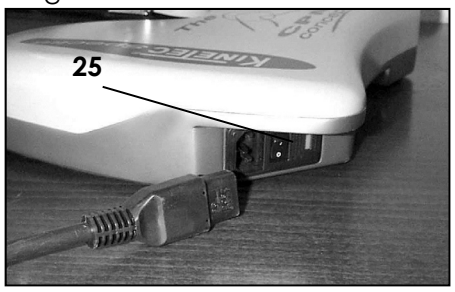
A motor running time counter is available by simultaneously pressing keys limit and limit ;

the displays shows **RESET TIME 215H** (this is an example).

This counter can be reset by pressing the key limit .

Troubleshooting guide

A spare parts list and technical catalogue are available on request from your Kinetec® distributor.
If, after connecting the power supply cable to the power supply and switching on the machine:



- The display does not indicate any information:
  - Check that the electrical socket is live using another device or voltmeter.
  - Replace the fuse(s) (25) of the connector with fuses of the same type and calibre: 2 fuses T 750 mA 250V (6.3 x 32) (Kinetec® order: 4610007434).
  - Check that the hand control is connected properly.
  - If the display still does not indicate any information, contact your nearest Kinetec® technician.
- Your machine does not work and the display indicates **50 STOP 25 115**,
  Press [START] again.
  If your machine still does not work, contact your nearest Kinetec® technician.
- Your machine does not work and the display indicates:
  SERVICE D1: angle measurement function failure,
  or SERVICE D2: no movement,
  or SERVICE D3: abnormal consumption,
  or PUSH STOP/START: power failure or disconnected motor,
  or SERVICE D7: the USB key was disconnected while in use;
  contact your nearest Kinetec® technician if the same message is displayed after switching the device off, then on or SERVICE D8: the USB key used has not been programmed for use on Kinetec Centura™;
  See the Kinetec Data Capture™ software user manual for more information.
- The USB is connected and the logo "usb" does not appear in the top right of the display:
  Contact your nearest specialist Kinetec®.

Cleaning

Before carrying out any cleaning operation, SWITCH OFF the unit and disconnect the power supply. In order to ensure optimal hygiene, you are advised to clean the machine for each new patient.
Cleaning should be carried out in the environmental conditions specified in the "Technical Specifications" section below.
Use a DISINFECTANT product (alcohol-free or <5% alcohol solution) in spray (plastic cases 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.

Disposal and recycling

- **a • Packaging**: The packaging must be separated into plastic and paper / cardboard components and taken to special recycling sites.
- **b • Kinetec® patient pad kit:** Clean with a disinfectant product then take it to special recycling sites.
- **c • Unit:** It contains electronic components, cables, aluminium, steel and plastic parts. When the machine is no longer operational, disassemble it, separate it into different types of material and take these to authorised recycling centres or return the machine to Kinetec SAS for destruction. Or contact the local authorities to determine the appropriate method of disposal for parts and accessories that are potentially hazardous to the environment.

Warranty

The Kinetec® warranty is strictly limited to the replacement, free of charge, or to factory repairs of part(s) recognised as defective.
Kinetec SAS guarantees its continuous passive motion systems for 2 years against all defects of manufacture from the date of purchase by the consumer.
Kinetec SAS 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.

Technical specifications

Product:

Lifespan of the machine:	12 years	
Weight:	12Kg (26 pounds)	
Splint dimensions:	95cm (37 inches) x 33cm (13 inches) x 33cm (13 inches)	
Angular limits:	-10° to 120°	
Speeds:	from 45 to 155° per minute	
Patient sizes:	Full leg:	71 to 99 cm (28 to 39 inches)
	Tibia:	38 to 53 cm (15 to 21 inches)
	Femur:	33 to 46 cm (13 to 18 inches)
Maximum weight of the user:	135 kg (297 pounds)	
Acoustic pressure:	<70dB	
Applied parts:	Hygienic pads and/or comfort support	

Electricity:

Power supply:	100-240V~
Frequency:	50-60 Hz
Power consumption:	50 VA
Class:	Device of Type BF Class II
Protection class (device):	IP 20 (protected against solid objects greater than 12.5mm, but not protected against liquids)
Protection class (carrying case):	IP 01 (non-protected against solid foreign objects, protected against vertically falling water drops)
Fuse:	T 750mA 250V 6.3 x 32mm (Kinetec® order: 4610007434)
Data backup:	3V – CR1620 battery (Kinetec© order: 4610008987)

Environment:

Storage/transport conditions:	Temperature:	-25 to 70°C / -13 to 158°F.
	Relative humidity:	up to 93% without condensation.
Operating conditions:	Temperature:	5 to 40°C / 41 to 104°F.
	Relative humidity:	15% to 93% without condensation.
	Atmospheric pressure:	700 hPa to 1060 hPa.

Symbols used

	Warning or CAUTION (consult the accompanying documentation)
	STOP (power off)
	ON (power on)
program	Program access(see page 11)
Warm Up	Warm Up, see page 9
Session Time	Session time, see page 7
	Right way up when box is stored
IP20 IP01	See "Protection class" in section "Technical specifications"
~	Alternating current
	Class II device

speed	Speed
pause	Pause
	Increase
	Decrease
timer	Timer, see page 8
Mod.	Modulation, see page 9
-70°C 25°C	Temperature Limit during storage or transport
	Keep dry during storage or transport
	Follow the instructions for use
	TYPE BF device (protection against electric shocks)

limit	Flexion limit
limit	Extension limit
start	Start movement
stop	Stop movement
force	Force
R.O.M By Pass	Bypass
	Fragile
93% 0%	Humidity limit during storage or transport
	Contains electric and electronic components; do not throw away with household refuse.

Guidance and manufacturer's declaration

Electromagnetic emissions		
The device Kinetec Spectra™ is intended for use in the electromagnetic environment specified below. The customer or user of the device Kinetec Spectra™ should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
Radio frequency emissions CISPR 11	Group 1	The device Kinetec Spectra™ 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.
Radio frequency emissions - CISPR 11	Class B	The device Kinetec Spectra™ is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions - IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions - IEC 61000-3-3	Complies	

Electromagnetic immunity			
The device Kinetec Spectra™ is intended for use in the electromagnetic environment specified below. The customer or user of the device Kinetec Spectra™ should ensure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV, ±6 kV contact ±2 kV, ±4 kV, ±8 kV air	±2 kV, ±4 kV, ±6 kV contact ±2 kV, ±4 kV, ±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 IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV between lines	±0.5 kV, ±1 kV between lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage interruptions IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 5 seconds	< 5% U_T (>95% dip in U_T) for 5 seconds	When the interruption occurs, the device Kinetec Spectra™ is reset. After turning on, push START to begin the session.
Voltage dips and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 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 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device Kinetec Spectra™ requires continued operation during power supply interruptions, we recommend powering the device Kinetec Spectra™ using an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field - EC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - Electromagnetic immunity

The device Kinetec Spectra™ is intended for use in the electromagnetic environment specified below. The customer or user of the device Kinetec Spectra™ should ensure that it is used in such an environment.

Immunity test	Test level according to EIC 60601	Compliance level	Electromagnetic environment – guidance
Conducted RF interference IEC 61000-4-6	3 Veff from 150 kHz to 80 MHz	3 V	Mobile and portable RF communication devices should not be used closer to any part of the device Kinetec Spectra™, including its cables, than the recommended separation distance, calculated based on the equation applicable to the emitter's frequency. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF interference IEC 61000-4-3	3 V/m from 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ from 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ from 800 MHz to 2.5 GHz where *P* is the emitter's maximum output power characteristic in watts (W), according to the emitter's manufacturer, and *d* is the recommended separation distance in metres (m). The field intensities of fixed RF emitters, determined by an on-site electromagnetic investigation[a], should be below the compliance level in each frequency range[b]. There may be interference near appliances bearing the following symbol: 

NOTE 1 At 80 and 800 MHz, the highest frequency range is applicable.
NOTE 2 These directives cannot be applied in every situation. Electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

[a] The field intensity of fixed emitters such as base stations for radio-telephones (cellular/cordless) and land mobile radios, amateur radio, AM/FM radio broadcasts and TV broadcasts cannot be predicted exactly in theory. To evaluate the electromagnetic environment due to fixed RF emitters, an on-site electromagnetic investigation should be considered. If the field intensity measured where the device Kinetec Spectra™ is used exceeds the aforementioned applicable RF compliance level, the device Kinetec Spectra™ should be monitored to check that it is working normally. If abnormal results are observed, additional measures may be necessary, such as reorienting or repositioning the device Kinetec Spectra™.

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

Recommended separation distances between mobile and portable RF communication devices and the device Kinetec Spectra™

The device Kinetec Spectra™ is designed to be used in an electromagnetic environment in which radiated RF interference is controlled. The customer or user of the device Kinetec Spectra™ can help prevent electromagnetic interference by maintaining a minimum distance between mobile and portable RF communication devices (emitters) and the device Kinetec Spectra™, as recommended below, according to the communication device's maximum output power.

Maximum assigned output power for the emitter W	Separation distance according to the emitter's frequency m		
	from 150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	from 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 emitters whose assigned maximum emitted power is not given above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the emitter frequency, where *P* is the emitter's maximum emission power characteristic in watts (W), according to the latter's manufacturer.
NOTE 1 At 80 and 800 MHz, the separation distance for the highest frequency range is applicable.
NOTE 2 These directives cannot be applied in every situation. Electromagnetic propagation is affected by absorption and reflection by structures, objects and people.

Kinetec Spectra™

Programming help sheet

To use pre-recorded programs:
- Stop the machine's movement by pressing the [stop] button,
- Press the [program] button,
- Select the required program by using the [+] and [-] buttons
- Start the movement by pressing the [start] button twice.

Program number	Movement type	Flexion limit	Extension limit	Speed	Force	Flexion pause	Extension pause	Timer
program				speed	force	pause	pause	timer
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
Example	Warm Up	112	18	5	Max.	15s	15s	00H30Min

Refer to the user manual for more information (see page 11 for programming mode).

kinetec®

Kinetec SAS
Zone Industrielle de Tournes
Rue Maurice Périn
F-08090 Tournes
France


+33 (0)3 24 29 85 05


+33 (0)3 24 33 51 05


contact@kinetec.fr


www.kinetec.fr