Kinetec Performa™

User manual

Before use, please read this document.
Kinetec SAS reserves the right to effect technical modifications.
The English version is a translation of the original in French. In case of a discrepancy, the French original will prevail.

EN

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Série 3
Notice Originale

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kinetec®

Summary

1. General information

1.1. Intended use

The device Kinetec Performa™ is a PASSIVE Knee mobilization device enabling the extension and flexion movement from de -3° à 130°.

With the Kinetec Performa™ 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.

1.2. 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.

1.3. 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.

1.4. 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 2,06 m (6'7") or under 1,12m (3'7") tall.
- The machine is not suitable for patients over 135kg.

1.5. Compliance

The device Kinetec Performa™ complies with the standards of Directive 93/42/EEC, and bears the EC mark.
The device Kinetec Performa™ 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 Performa™ meets the requirements of the Machinery Directive No. 2006/42/EC.

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 8.

WARNING: To avoid the parameters being changed, lock the machine's hand control before giving it to the patient, see page 8.

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: The USB connector of the hand control must be connected only to a USB stick.

WARNING: In case of liquid projection on the device when it is used outside its transport case, immediately disconnect the power cord and contact your KINETEC® distributor.

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 17.

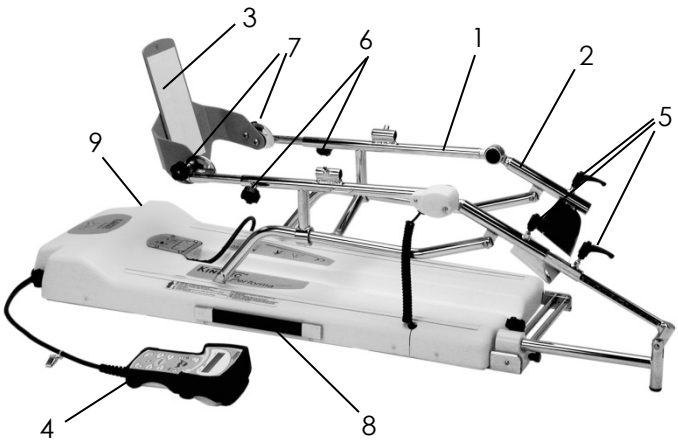
WARNING: Under maximum temperature conditions mentioned in the user's manual, the maximum temperature which can be reached by the hand control is 48.8°C.

3. Presentation

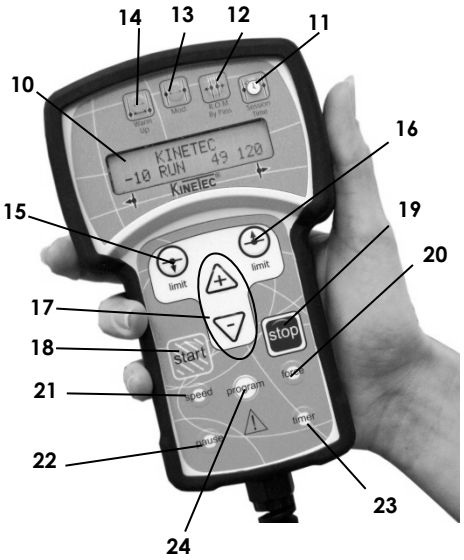
3.1. Description

The device Kinetec Performa™ consists of the following components:

1 • Lower limb support.
2 • Thigh support.
3 • Foot support.
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.

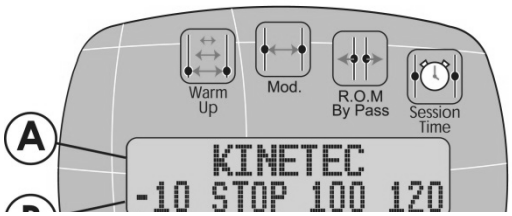


10 • Liquid-crystal display (2 lines of 16 characters).
11 • SESSION TIME display key.
12 • BYPASS mode key.
13 • MODULATION key.
14 • WARM UP key.
15 • EXTENSION setting key.
16 • FLEXION setting key.
17 • Increase / decrease keys.
18 • START key.
19 • STOP key.
20 • FORCE key.
21 • SPEED key.
22 •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



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

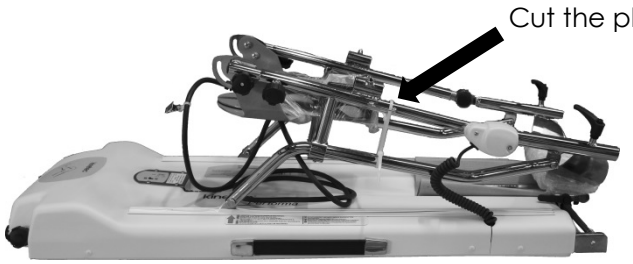


See the Kinetec Data Capture™ software user manual for more information.

3.2. Unpacking and packing

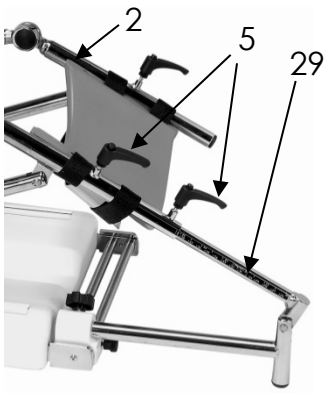
Unpacking
When you unpack the machine, don't forget that you may need to pack it up again. We recommend that you keep the packaging materials, boxes and plastic bags.

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 4).

Your machine is ready to be connected to the power supply. (see page 5)



Packing
To prevent any problems when the machine is transported, only pack it using its original packaging.
- Set the thigh support (2) to 38cm.
- Stop the unit at -3° of flexion.
- Withdraw the hip bar (29) from thigh support bar (2).
- Move the foot plate back into its packing position.

3.3. Installing the device

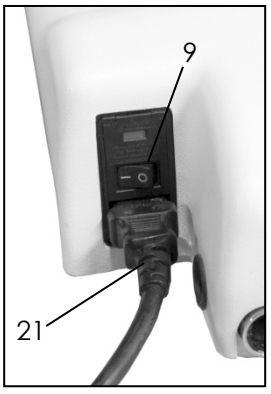
The device Kinetec Performa™ is designed to be used in hospitals, clinics, doctors' offices or in private homes (rental).

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.

3.4. Electrical connection: safety first

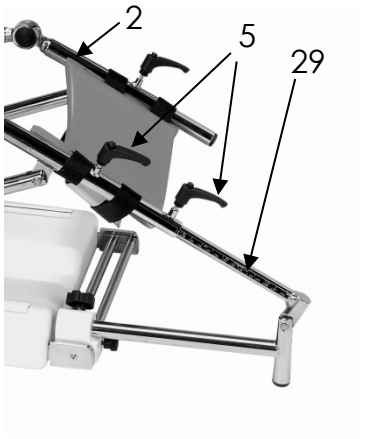
Before connecting the device to the power supply, check that the mains voltage matches that shown on the identification plate (100-240V~ 50/60Hz).

Connect the power supply cable (21).



WARNING
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.

3.5. Adjusting for right or left leg



The device Kinetec Performa™ is designed anatomically. Because of this the thigh slide (29) should always be placed on the same side as the leg to be mobilised.

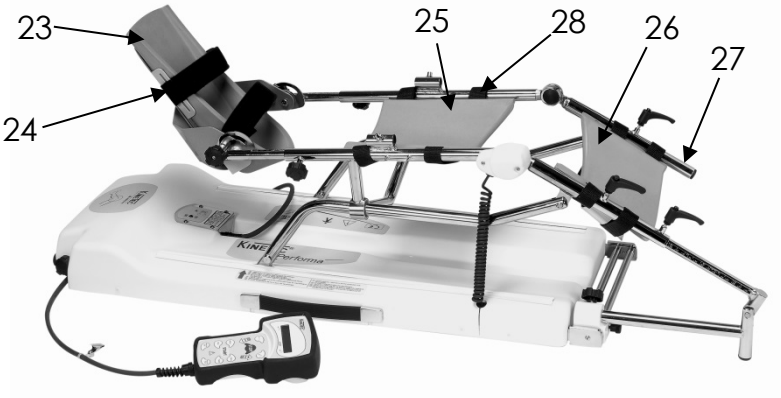
To change legs, proceed as follows:
- Withdraw the hip bar (29) from thigh support bar (2).
- Slide the hip bar into the thigh support bar on the other side of the exerciser and attach the hip bar on the thigh support. (an index confirms the good position).

WARNING: if the knobs (5) are not tighten the device stops and the display reads **SERVICE D2**.
However, it is possible to control the device MANUALLY with the MODULATION MODE (see page 11).

3.6. Using the Plastic Comfort Case kit

Specially designed to improve comfort and hygiene for the patient, the Plastic Comfort Cases come with straps 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.



Replacement parts
23 4670024048 Complete foot support
24 4635010561 Foot support strap kit
25 4670023686 Tibia case with straps
26 4670023694 Femur case with straps
27 4670016657 Thigh bar
28 4645000841 Single strap
Part number to order
a complete kit : 4670017655

3.7. Using the Kinetec® Patient Pad kit

The Kinetec® Patient Pad Kit is designed for rapid fitting, optimal hygiene and maximum patient comfort.
- Position the straps on the leg and thigh cradles, make sure that the self-adhesive parts 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.)

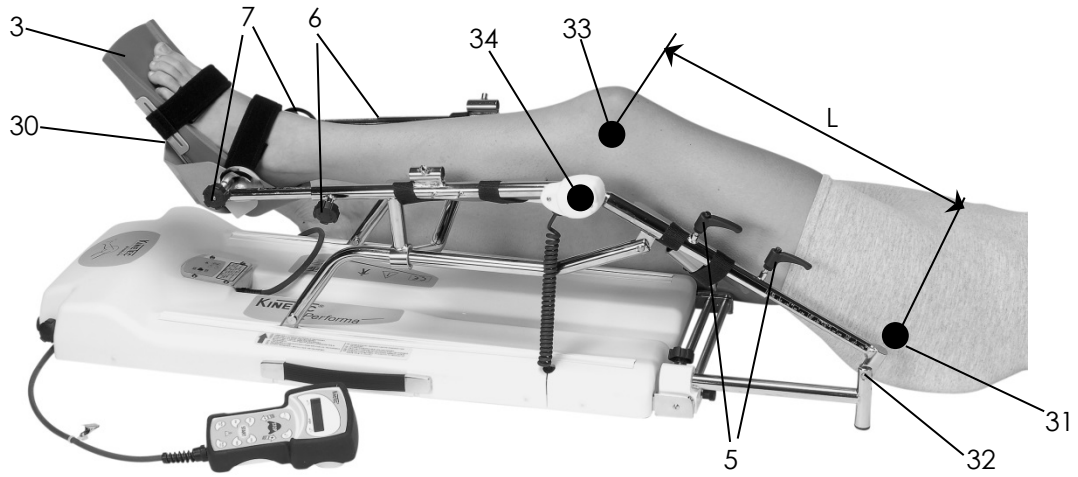
CLEANING:
- Disinfecting the pads: Wash at 30°C, using a disinfectant solution during the rinse cycle. Examples of products that can be used: Solution "Baclinge" at 0.125 % or "Souplanios" at 0.125% from ANIOS Laboratory. A complete list of distributors in your country is available on request.

The complete Kinetec® Patient Pad Kit is delivered with:
- 4 straps (4650001107)
- 1 foot support (4650001131)
- 1 cover (4650001090)
- Part number to order the complete set: 4650001058

3.8. Setting up the patient

Place the Kinetec Performa™ 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 Performa™ 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 (30).

IMPORTANT
Adjust the axis of the patient's hip (31) with the axis rotation (32) of the Kinetec Performa™ machine, and the axis of the patient's knee (33) with the axis rotation (34) of the Kinetec Performa™ machine.



4. Hand control use

4.1. 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 PERFORMA Vxx.x

Then

Movement Verif. Please Wait

Then

Hello Name of patient

Then

KINETEC 30 STOP 15 70

Your Kinetec Performa™ 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.

4.2. 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 8).
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.

4.3. START / STOP / REVERSE function

As with all Kinetec® systems, the devices Kinetec Performa™ are equipped with ON/OFF/REVERSE functions.
L'appareil Kinetec Performa™ est doté, comme tous les appareils KINETEC®, de la fonction MARCHE/ARRET/INVERSION.

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.

4.4. Procedure to stop the machine

To stop the machine's movement: press the button stop

To switch power off: press the ON / OFF switch (9) (see page 5)

4.5. Locking the hand control setting

The hand control allows the patient to control the machine as appropriate.
Simultaneously press the + et - keys to lock the hand control.

The display reads LOCK, you cannot change the parameters; if you try the message LOCK SOFT 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.

4.6. Setting the movement parameters

Select the parameter to be set:
Extension limit, flexion limit, speed, pause at the extension or flexion limit, force or timer; the setting to change will flash.

Press the + ou - buttons to modify the setting; the new setting will flash.

To confirm the new setting, press another function button or wait approximately 3 seconds for automatic confirmation.

Movement parameters can be set either when the machine is stopped or when it is in operation.

4.7. Possible values for each parameter

	Possible values
• Extension limit	-3 to 125°
• Flexion limit	2° to 130°
• Speed	1 to 5 (from 50° to 220° per minute)
• Force	1 to 6
• Extension Pause	0 to 900 seconds (15 minutes)
• Flexion Pause	0 to 900 seconds (15 minutes)
• Timer	0 à 24h00
• Number of programs	16

4.8. Session Time

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

It is directly accessible by the key 

, the display shows **TIME 02H35**

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

4.9. Quick Start

The device Kinetec Performa™ 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	I	KINETEC PERFORMA Vxx.x	
		Movement Verif. Please Wait	
		Hello Patient's first name	
		KINETEC usb 30 STOP 35 70	Displays the last movement used, except for the daily program.
		WARM UP usb 30 STOP 35 70	Check if the hand control is not locked (See page 8).
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).	start	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.

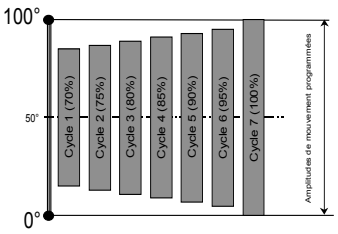
Warning: Always check the motion parameters displayed on the hand control before starting the device.

4.10. How to adjust the basic parameters of the movement ?

Beginning	Keys to press	Display	Remarks
To stop the unit	stop	KINETEC 30 STOP 45 70	Check if the hand control is not locked (See page 8).
To display the extension or flexion limit of the movement	limit OR limit	KINETEC 30 EXT 45 70 KINETEC 40 FLEX 45 70	The value blinks.
To change the limit if necessary	+ OR -	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.	speed force timer	KINETEC SPEED 2 KINETEC FORCE _ _ _ _ _ _ KINETEC TIMER 00H00MIN	While the value blinks press the + or - key to change if necessary.
To display pause in flexion limit or in extension limit	pause pause	KINETEC PAUSE FLEX 0S KINETEC PAUSE EXT 0S	Successive presses on this key selects the pause at the extension or flexion limit.
To change the pause if necessary	+ OR -	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.

4.11. How to use the WARM UP key ?

Warm Up



Warm Up rules.

The device Kinetec Performa™ starts at 70% of the full ROM, increasing 5% of the rar 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 8).
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 10).
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.

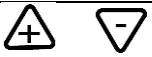
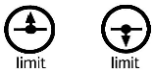
Example:

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.

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

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:

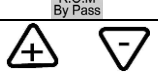
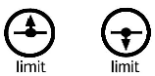
Beginning	Keys to press	Display	Remarks
Switch the unit ON		KINETEC 40 STOP 50 110	Check if the hand control is not locked (see page 8). If Warm Up mode is selected, switch OFF this mode by pressing the "Warm Up" key.
To select MODULATION Mode		MODUL. : use +or- 40 STOP 50 110	The display indicates the keys used to run the machine. This message is displayed 3 seconds.
To select the pain level (⊕ for flexion, ⊖ for extension)	 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	 OR	MODUL. : use +or- 40 MANUAL 60 50	The new limit of the movement is recorded.
To start the session with the new movement limits		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.

4.13. How to define the patient tolerance? • During the session

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		KINETEC 40 RUN 55 60 WARM UP 40 RUN 55 60	Check if the hand control is not locked (see page 8). Or, if Warm Up mode is selected.
To select BYPASS Mode		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	 Continuous press	BYPASS : use +or- 40 BYPASS r2 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	 OR	BYPASS : use +or- 40 BYPASS r2 r2	The new limit of the movement is recorded.
Continue the session with the new movement limits.		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.

4.14. PROGRAM MODE: How to enter a program ?

The device Kinetec Performa™ 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 8).
Press the two keys at the same time and switch the unit ON	+ −	KINETEC PERFORMA 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 limit	PROGRAM Nr10 30 KINETEC 90 PROGRAM Nr10 30 KINETEC 90	The value blinks.
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 Nr11 EMPTY	Program 10 has been recorded and the display indicates the next program so you can change another program.
Or To cancel the program	−	PROGRAM Nr10 CLEARING PROGRAM Nr11 EMPTY	Program 10 has been removed and the display indicates the next program so you can change another program.
To exit program mode, switch the unit OFF and switch back ON.	O I	KINETEC PERFORMA VXX.X	To use the modified program see page 13.

4.15. Using Programs

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 8).
To access program mode	program	PROGRAME 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	start	WARM UP Please Wait	The current parameters are those recorded in program 7.
To exit without confirming the selected program	stop	KINETEC 40 STOP 45 110	Back to the starting parameters.
Start the unit	start	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.

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

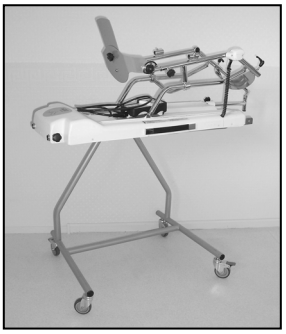
Beginning	Keys to press	Display	Remarks
To stop the unit	stop	KINETEC 40 STOP 45 110	Check if the hand control is not locked (see page 8).
Accès au mode programme	program	PROGRAM Nr1 EMPTY	The program number blinks.
Changement de programme si nécessaire	+ OR -	PROGRAM Nr7 30 WARM UP 90	The program number blinks.
Visualisation de la vitesse	speed	PROGRAM Nr7 SPEED : 2	Displays the speed value.
Après environ 5 secondes ou après l'appui sur un autre paramètre		KINETEC 40 STOP 45 110	
Sortie et validation du programme sélectionné	start	WARM UP 30 STOP 45 90	The current parameters are those recorded in program 7.
Start the unit	start	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 12) to modify programs.

When a USB key is connected the programs stored on the USB key have priority.

5. Options

Trolley for all CPM
Part number to order: 4655001053



Cart for bed use
Part number to order: 4665003297
Performa adaptation plate
Part number to order: 4665003560

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

6. Product information

6.1. Maintenance

After 2,000 hours of operation, or once a year, the device Kinetec Performa™ 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.

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.

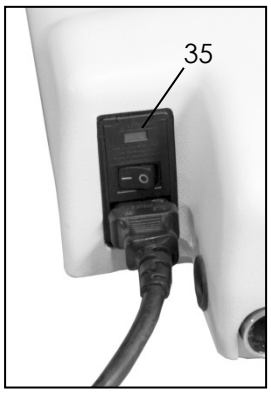
When the machine is no longer in working condition, please return it to us, together with its accessories, for destruction.

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.

6.2. 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:
  1. Check that the electrical socket is live using another device or voltmeter.
  2. Replace the fuse(s) (35) of the connector with fuses of the same type and calibre: 2 fuses T 750 mA 250V (6.3 x 32) (Kinetec® order: 4610007434).
  3. Check that the hand control is connected properly.
  4. 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®.
- If there is no stored date, change the battery (PILE1) with the same type CR1620 (Ref. KINETEC® : 4610008987) (see the Technical Catalogue).

6.3. 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.

6.4. 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.

7. 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.

8. Technical specifications

Product:

Weight:	15 kg (33 lbs)
Splint dimensions:	109cm (43 inches) x 33cm (13 inches) x 33cm (13 inches)
Angular limits:	-3° to 130°
Speeds:	from 50 to 220° per minute.
Patient sizes:	112 to 206 cm (44 to 81 inches)
	Full leg: 58 to 110 cm (23 to 43 inches)
	Tibia: 32 to 60 cm (13 to 24 inches)
	Femur: 26 to 50 cm (10 to 20 inches)
Maximum weight of the user:	135kg (297 lbs)
Acoustic pressure:	<70dB
Applied parts:	Hygienic pads and/or comfort support

Electricity:

Power supply:	100-240 V~
Frequency:	50/60Hz
Power consumption:	50VA
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.

9. Symbols used

	Follow the instructions for use
	STOP (power off)
	ON (power on)
program	Program access see pages 12 and 13
Warm Up	Warm Up see page 10
Session Time	Session time see page 9
	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
Mod.	Modulation see page 11
+70°C -25°C	Temperature Limit during storage or transport
	Keep dry during storage or transport
	Warning or CAUTION (consult the accompanying documentation)
	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 see page 11
	Fragile
93% % 0%	Humidity limit during storage or transport
	Contains electric and electronic components; do not throw away with household refuse.

10. Guidance and Manufacturer's declaration

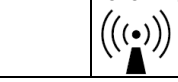
Electromagnetic emissions		
The device Kinetec Performa™ is intended for use in the electromagnetic environment specified below. The customer or user of the device Kinetec Performa™ should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
Radio frequency emissions CISPR 11	Group 1	The device Kinetec Performa™ 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 Performa™ 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 Performa™ is intended for use in the electromagnetic environment specified below. The customer or user of the device Kinetec Performa™ 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 Performa™ 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 Performa™ requires continued operation during power supply interruptions, we recommend powering the device Kinetec Performa™ 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.			

11. Guidance and manufacturer's declaration

Electromagnetic immunity

The device Kinetec Performa™ is intended for use in the electromagnetic environment specified below. The customer or user of the device Kinetec Performa™ 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 Performa™, 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 Performa™ is used exceeds the aforementioned applicable RF compliance level, the device Kinetec Performa™ 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 Performa™.

[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 Performa™

The device Kinetec Performa™ is designed to be used in an electromagnetic environment in which radiated RF interference is controlled. The customer or user of the device Kinetec Performa™ can help prevent electromagnetic interference by maintaining a minimum distance between mobile and portable RF communication devices (emitters) and the device Kinetec Performa™, 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.

Respect of programmed range of motion is the essential performance of the device Kinetec Performa™.

kinetec®

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