

• User manual • ANKLE

Before use, please read this document.

Smith & Nephew Kinetec reserves the right to effect technical modifications.

I INTRODUCING THE MACHINE

- Definition	Page
- Description	2 - 3

II CONNECTING THE MACHINE

- Unpacking the splint	4
- Security characteristics	4
- Starting up the apparatus	4

III HOW TO USE THE CONTROL UNIT

- Description	5
- Key functions	5 to 8
- How to key in a program?	9 to 13
- Reading the values of a program	13
- How do you change programs?	14
- How do you modify one program value?	14 to 15

IV STARTING UP THE APPARATUS

- with the same program and the same patient as at the previous session.	16
- when changing the program and the patient	17
- Modifying the session time	18

V POSITIONING THE PATIENT

- Use in a chair	19
- Use in bed	19

VI FIXING THE FOOT TO THE MACHINE

- Adjustment of the ankle support	20
- Adjusting the height of the foot	20
- Adjusting the calf support	21
- Fixing the patient's leg to the machine	21
- Final adjustment	22
- Fixing the machine to the bed	23
- Protection of the opposite foot	23

VI INSTRUCTIONS IN CASE OF A BREAKDOWN 24

- List of errors	24
- Cleaning	24
- Specifications	25
- Symbols	25
- Guarantee Limits	25

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Leadership in Worldwide Healthcare

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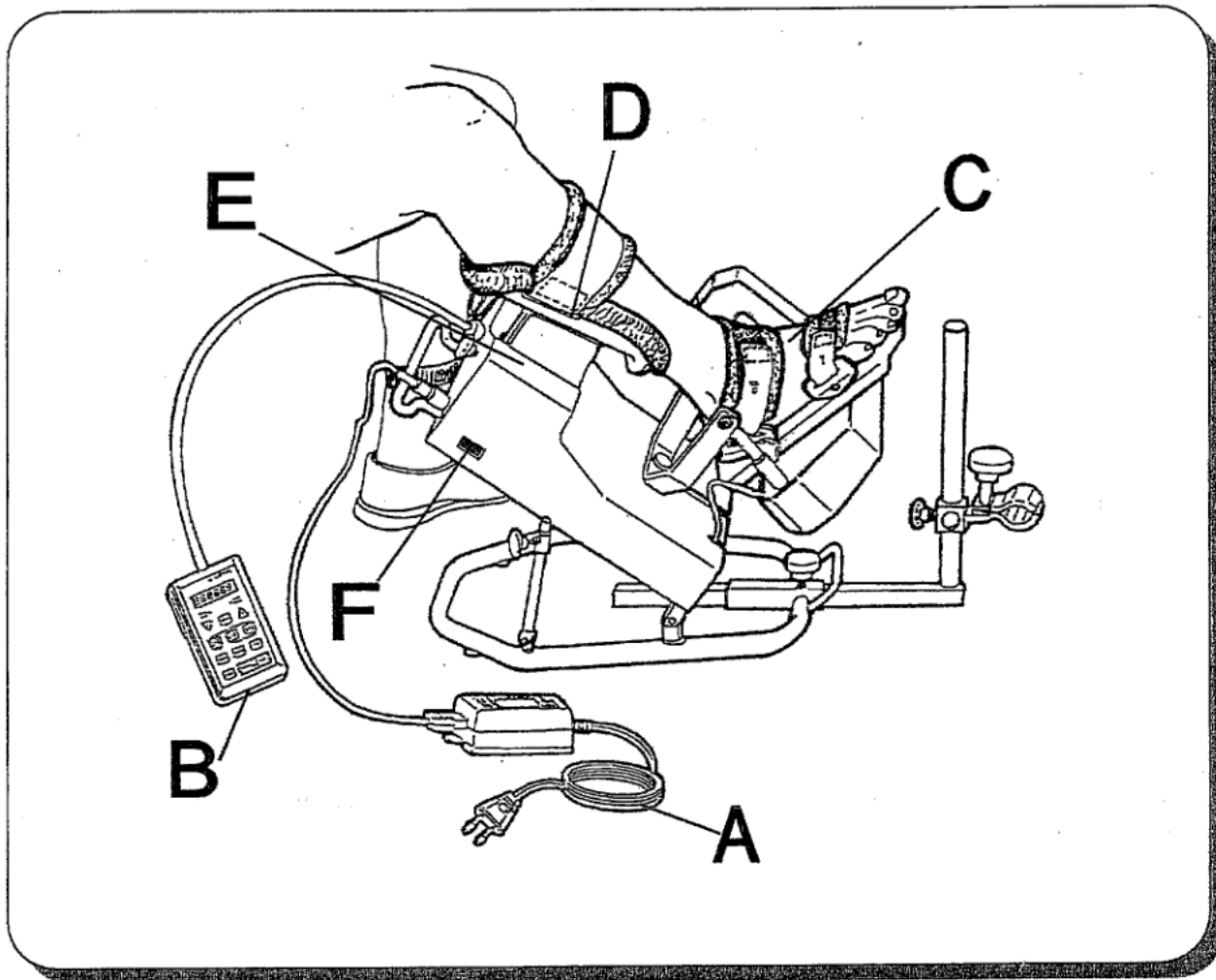
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ENGLISH

5190 s1-2





I INTRODUCING THE MACHINE

DEFINITION

The KINETEC 5190 may be used for all ankyloses provided the articular surface have been respected or are only slightly out of shape. the use of KINETEC 5190 machine during the immediate post operative period allows to have better R.O.M for the 3 joints, Tibio-tarsal, Sub-talar and Medio-tarsal.

DESCRIPTION

The rear foot joint passive mobilization apparatus gives the foot a three-dimensional movement reproducing the foot movements exactly :

- Plantar flexion / Dorsal flexion
- Adduction, Varus / Abduction, Valgus
- Inversion / Eversion

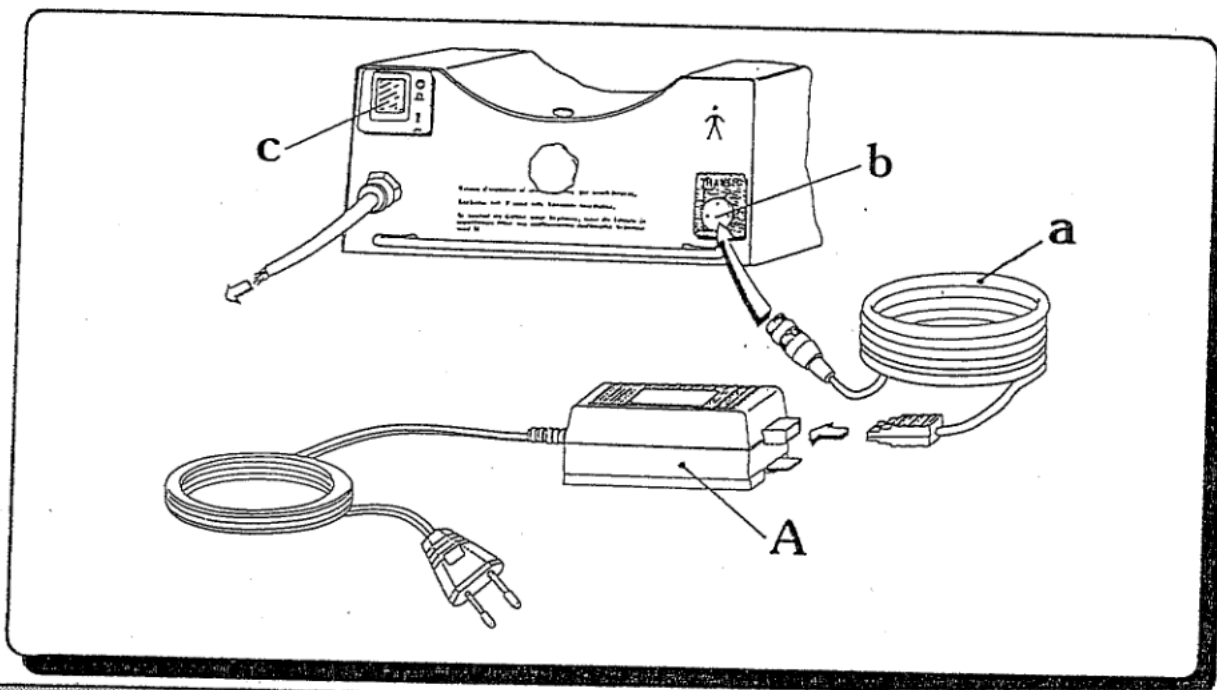
The KINETEC 5190 is made up :

- A - The plug-in transformer
This transforms 240/220 V - 110 V or 100 V current into 12-volt current, this avoiding any risk to the patient.
- B - The control unit
It enables you to programme and to visualize various parameters.
- C - The foot moving device
This mobile part reproduces the various foot movements.
- D - The support for the patients leg.
- E - The machine body
This includes the control electronics in particular.
- F - Data processing liaison
This make it possible to find out the results of a sitting.

II CONNECTING THE MACHINE

UNPACKING THE SPLINT

- Connect the (a) cable to the transformer (A).
- Connect the (a) cable to the exerciser in (b).
- Connect the transformer (A) to a 240/220 volts -50Hz or 110 V -60Hz or 100 V - 50Hz current outlet. (Electric power : 40 VA)



SECURITY CHARACTERISTICS

- The machine has now been powered with a safe voltage : 12 Volts .
- Appareil of CLASS II and TYP B.
- The flexion or extension drive force setting enables the practitioner to vary the force exerted by the apparatus.
- The control unit has a STOP key for stopping the movement and a START key for reversing the movement.

STARTING UP THE APPARATUS

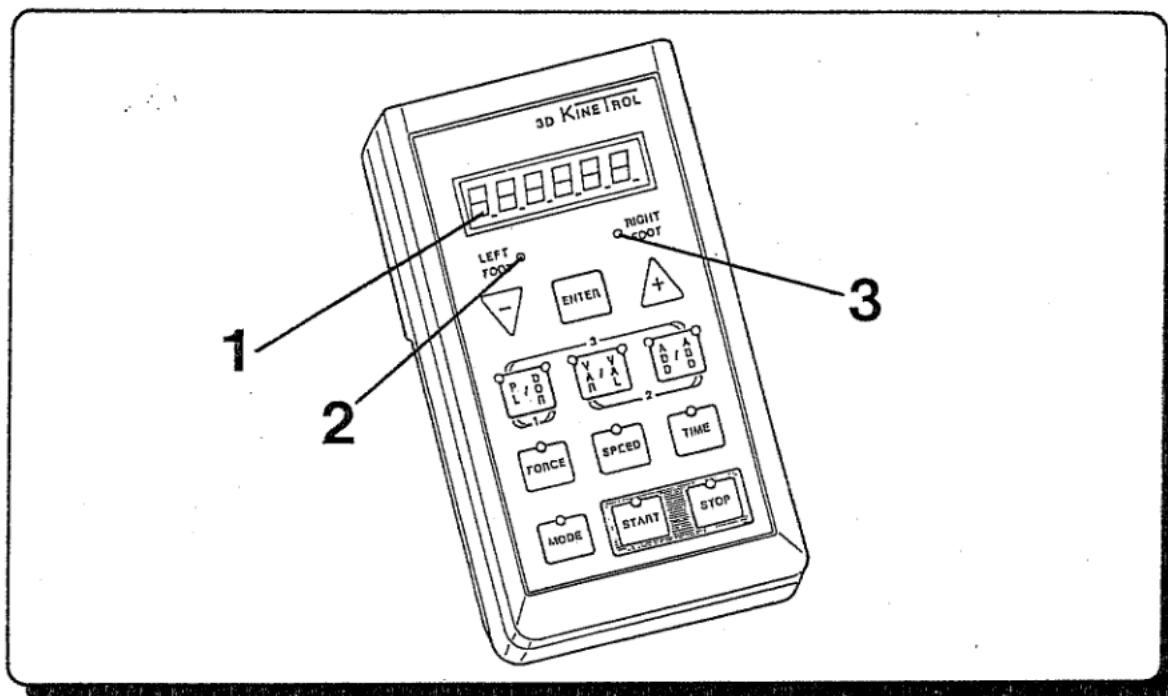
- Press the ON/OFF button (item c)

The button (item c) lights up
The control unit shows a patient CODE number,
if this one is programmed, if not TIME OF SESSION is displayed.

If the button (item c) fails to light up, and if the control unit shows no data, see chapter VII TECHNICAL AID.

III HOW TO USE THE CONTROL UNIT

DESCRIPTION



- The display panel (Item 1) displays 6 letters or 6 ciphers.
- The pilot lights or LEDs (Item 2 and 3) let you know at all times which foot the machine is set for.
 - the No.2 LED lights up when the splint is set for the left foot, and
 - the No.3 LED lights up when the splint is set for the right foot.

KEY FUNCTIONS



While programming, this key allows you to :

- REDUCE the values,
 - by punching (applying pressure for less 2 seconds), by 1 unit of value, and
 - by prolonged pressure (over 2 seconds), by 3 units of value per second; and to
- PROGRAM the work on the LEFT FOOT.



While programming, this key allows you to :

- INCREASE the values,
 - by punching (applying pressure for less 2 seconds), by 1 unit of value, and
 - by prolonged pressure (over 2 seconds), by 3 units of value per second; and to
- PROGRAM the work on the RIGHT FOOT.

ENTER

This key is to VALIDATE every change in values. It lends a helping hand to the user for the rest of his or her "dialogue" with the apparatus.



Key to read or to program PLANTAR or DORSAL FLEXION

When the left-hand LED lights up, the displayed value is PLANTAR FLEXION.

When the right-hand LED lights up, the displayed value is DORSAL FLEXION.

RANGE :

Maximum PLANTAR FLEXION = 40°

Maximum DORSAL FLEXION = 30°



Key to read or to program VARUS / VALGUS

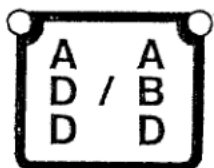
When the left-hand LED lights up, the displayed value is the VARUS

When the right-hand LED lights up, the displayed value is the VALGUS

RANGE :

Maximum VARUS = 25°

Maximum VALGUS = 25°



Key to read or program ABDUCTION / ADDUCTION

When the left-hand LED lights up, the displayed value is the ADDUCTION

When the right-hand LED lights up, the displayed value is the ABDUCTION

RANGE :

Maximum ADDUCTION = 25°

Maximum ABDUCTION = 25°

SPEED

Key to read or program SPEED

When the LED lights up, the displayed value is the SPEED.
The values shown go from 1 to 10

RANGE :

SPEED 1 = Minimum SPEED

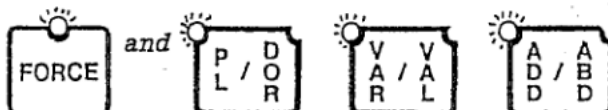
SPEED 10 = Maximum SPEED



Key to read or program the FORCE

When the LED lights up, the displayed value is FORCE. This LED always lights up at the same time as other LEDs located above the movement read-or-program keys indicating the direction of the force displayed.

Example :



The FORCE displayed = Force set for the PLANTAR FLEXION / VARUS / ADDUCTION movement

The values recorded may go from 1 to 5

RANGE :

FORCE 1 = Minimum FORCE

FORCE 5 = Maximum FORCE



Key to program the SESSION TIME and to read the TIME REMAINING to end of SESSION.

When the LED lights up, the value displayed is the SESSION TIME, or the time remaining until the end of the session. The values recorded vary by 15-minute intervals

RANGE :

Maximum SESSION TIME = 23.45 hours

Minimum SESSION TIME = 15 minutes



Key to START OPERATING

When the LED lights up, the machine is operational and the display shows the real value of the angle :

- in MODE 1 or 3, the angle of the PLANTAR FLEXION or the DORSAL FLEXION
- in MODE 2, the angle of VARUS or VALGUS



Key to STOP MOVEMENT

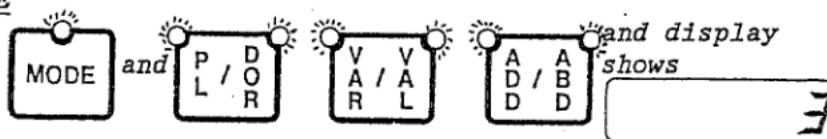
When the led lights up, the movements have been stopped and a START key for reversing the movement.

MODE

Key to read or program the WORKING MODE

When the LED lights up, the displayed value is the number of the programmed WORKING MODE. This led always lights up at the same time as other leds located above the movement read-or-program keys indicating the MODE displayed.

EXAMPLE



The WORKING MODE displayed is the MODE 3..

REMARK :

In read, leds of motions light up and the led of the key MODE is blinking.

In program, leds of motions are blinking and the led of the key MODE lights up.

RANGE : 3 different MODES available

- MODE 1 = 1 single movement in
PLANTAR FLEXION / DORSAL FLEXION
- MODE 2 = 2 synchronized movements in
ADDUCTION - VARUS / ADDUCTION - VALGUS
with a set component of 15° PLANTAR FLEXION.
- MODE 3 = 3 synchronized movements respecting the
physiological movement.
PLANTAR FLEXION - ADDUCTION - VARUS /
/ DORSAL FLEXION - ABDUCTION - VALGUS

HOW TO KEY IN A PROGRAM ?

PROCEDURE TO FOLLOW

- Fill out the "HELP IN PROGRAMMING SHEET" on the basis of the clinical examination of the foot.
- Define the values to be programmed.
- Stop the machine. The STOP LED must be lighted up.

REMARKS : Throughout the programming operation, it is important that you should answer all the questions indicated on the LEDs and the DISPLAY PANEL.

Programming example

PATIENT PROTOCOL PROGRAMMING SHEET																	
PATIENT'S FAMILY NAME : <u>NORMAND</u>										DATE : <u>10/12/90</u>							
FIRST NAME : <u>PASCAL</u>																	
DATE OF BIRTH : <u>14/03/66</u>										PATIENT HOSPITAL CODE : <u>1</u>							
INDICATIONS : _____																	
MODE 1 PL. / DO.		MODE 2 VAR. / ADD VAL. / ABD		MODE 3 PL. / DO. VAR. / ADD VAL. / ABD		AMCULATION PROGRAM PRG. 1 to 10										RESULT OF THE CLINICAL EXAMINATION DATE	
				<u>10/12/90</u>												<u>1/1</u>	
FOOT		RIGHT LEFT		L L L L L L L L L												RIGHT LEFT	
MODE				1 1 2 2 3 3 3 3													
PLANTAR FLEXION				10 8 10		15 25 33 40											
DORSAL EXTENSION				(5) 2 5		0 10 15 20											
VARUS		5				5 10 ** ** *											
VALGUS		0				0 5 ** ** *											
ADDUCTION		5				* * ** ** *											
ABDUCTION		0				* * ** ** *											
SPEED				3 3 3 3 5 6 8 10													
FLEXION				1 1 1 2 2 3 4 5													
EXTENSION				1 1 1 2 2 3 4 5													
SESSION TIME				1" 1" 1" 1" 1" 1" 1" 1"													
NUMBER OF SESSIONS				1 1 1 1 1 1 1 1													
OBSERVATIONS : _____																	

* On MODE 2 the ADDUCTION / ABDUCTION amplitudes are calculated automatically from the VALGUS / VARUS programmed.

** On MODE 3 the VARUS / VALGUS and ADDUCTION / ABDUCTION amplitudes are calculated automatically from the PLANTAR FLEXION / DORSAL EXTENSION programmed amplitudes.


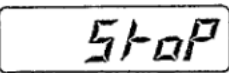



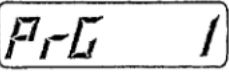


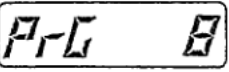




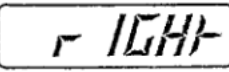

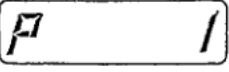



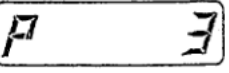

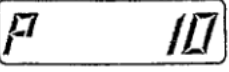

* On MODE 2 the ABDUCTION / ADDUCTION amplitudes are calculated automatically from the VARUS / VALGUS amplitudes programmed.






















** On MODE 3 the VARUS / VALGUS and ABDUCTION / ADDUCTION amplitudes are calculated automatically using the PLANTAR FLEXION / DORSAL FLEXION amplitudes programmed.


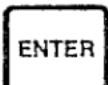




















If the amplitudes calculated are not suitable, see the TECHNICAL DATA SHEET.





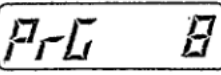

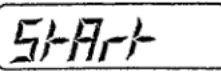


The following procedure may be applied to all types of programs.

AS A PROGRAMMING EXAMPLE, WE HAVE CHOSEN THE RETRIEVAL OF PROGRAM N°. 8 FROM THE HELP IN PROGRAMMING SHEET (the most complex case - all the values must be programmed).

Beginning	keys to press	Display	Remarks
			Display shows STOP
- Press all three keys at once	  		
- Release keys			The number displayed is the program number.
- To change the program number	 OU 		The number displayed is the new program number.
- To validate the program number			The display is giving LEFT OR RIGHT LEFT for left foot RIGHT for right foot The green light concerning programmed foot key goes on.
- To change the programmed foot	 OU 		The light of foot goes on.
- To validate and to Display the MODE			A "P" is displayed to indicate that the user is in a program. The light of the  key goes on and leds of concerning motions are blinking. The display is giving the programmed MODE.
- To change the MODE if necessary	 OU 		The display gives the new MODE forecasted and leds of new concerning motions are blinking.
- To validate the MODE 3			The next value is displayed, wich is PLANTAR FLEXION. The left light of the  key goes on

Beginning	keys to press	Display	Remarks
- To change the PLANTAR FLEXION if necessary	 OU 		The value displayed is the new value of the PLANTAR FLEXION.
- To validate the PLANTAR FLEXION			The next value is displayed, which is the DORSAL FLEXION. The right light of the  key goes on.
- To change the DORSAL FLEXION if necessary	 OU 		The value displayed is the new value of the DORSAL FLEXION.
- To validate the DORSAL FLEXION			The next value is displayed, which is varus. The left light of the  key goes on. It is possible to read the value only.
-To validate			The left light of the  key goes off and the right light goes on. The value displayed is the VALGUS value.
- To validate			The right light of the  key goes off.
			The left light of the  key goes on. The value displayed is the ADDUCTION value.
- To validate			The left light of the  key goes off.

Beginning	keys to press	Display	Remarks
		 16	The right light goes on. The value displayed is ABDUCTION value.
- To validate		 7	The next value is displayed, which is SPEED. The green light of the  key goes on.
- To change the SPEED if necessary	 OU 	 10	The value displayed is the new value of the SPEED.
- To validate the SPEED		 4	The next value is displayed, which is PLANTAR LOAD. The green light of the  key goes on and
			leds of concerning motions are blinking.
- To change the LOAD way + if necessary	 OU 	 5	The value displayed is the new value of LOAD way + .
- To validate the LOAD way +		 1	The next value is displayed, which is DORSAL LOAD. The green light of the  stay key goes on
			and leds of concerning motions are blinking.
- To Change the LOAD way - if necessary	 OU 	 5	The value displayed is the new value of LOAD way - .
- To validate the LOAD way -		cod 27	The next value is displayed, which is the PATIENT CODE if this one is programmed (if not, TIME OF SESSION is displayed)
- To validate the PATIENT CODE		345	The next value is displayed, which is the SESSION TIME. The green light of the the  key goes on.

Beginning	keys to press	Display	Remarks
- To change the <i>SESSION TIME</i> , if necessary	 OU 		The value displayed is the new <i>SESSION TIME</i> value.
- To validate the <i>SESSION TIME</i>			The display gives the <i>PROGRAM N°</i> selected.
- To validate the <i>PROGRAM N°</i>			The green light of the  key starts blinking. At this point, the key  is the only one you are allowed to press.

The movement begins where it left off.

READING THE VALUES OF A PROGRAM

Whether the machine is operating or whether it has been stopped, the patient or the practitioner can **READ THE PROGRAMMED VALUES** at any time.















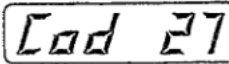


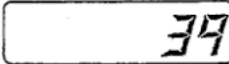
All he has to do is press the desired key, and the diode over that key blinks while the programmed value is displayed on the display panel for 3 seconds.

Reading the amplitudes (+ goniometer function) :

- when you push the key the left led blinks and the display indicates the program value of this movement,
- after 3 seconds or when you push again this key, the right led blinks and the display indicates the program value of the selected movement,
- after 3 seconds or when you push, always the same key, the display indicates the actual angle of the selected movement and the led of this movement lights.


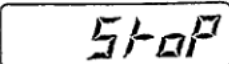




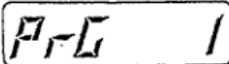
After 3 seconds or when you push again on this key, the LED stops blinking, and the display panel indicates the real angle values once again. (in *MODE 1* or *3*, the angle of the *PLANTAR FLEXION* or the *DORSAL FLEXION*, in *MODE 2*, the angle of *VARUS* or *VALGUS*)



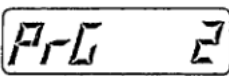

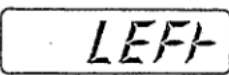

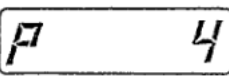



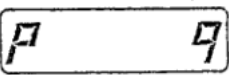

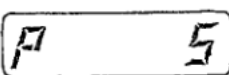




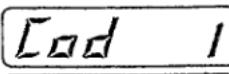
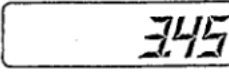


HOW DO YOU CHANGE PROGRAMS ?

Beginning	keys to press	Display	Remarks
- Stop the splint in order to access the programming mode			The red light of the  key goes on.
- Press all three keys at once	  		
- Release keys			The number displayed is the program number.
- To change the program number	 OU 		The number displayed is the new program number.
- To validate the program number			The display is giving LEFT OR RIGHT LEFT for left foot RIGHT for right foot The green light concerning programmed foot key goes on.
- Exit from program	 OU 	 	The display gives the PATIENT CODE if this one is programmed (if not, TIME OF SESSION is displayed)
- Start a cycle			The number displayed is the actual angle of the foot.

HOW DO YOU MODIFY ONE PROGRAM VALUE ?


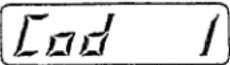
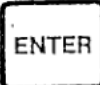
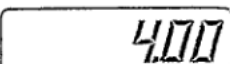





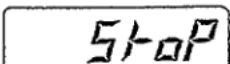



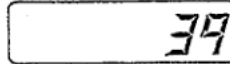

FOR EXAMPLE : SPEED

Beginning	keys to press	Display	Remarks
- Stop the splint in order to access the programming mode			The red light of the  key goes on.
- Press all three keys at once	  		
- Release keys			The number displayed is the program number.

Beginning	keys to press	Display	Remarks
- To change the program number	 OU 		The number displayed is the new program number.
OR			
- To validate the program number			The display is giving LEFT OR RIGHT LEFT for left foot RIGHT for right foot The green light concerning programmed foot key goes on.
- Choise the SPEED			A "P" is displayed to indicate that the user is in a program. The displayed value is the SPEED The green light of the  key goes on.
- To change the SPEED	 OU 		The value displayed is the new SPEED value.
- To validate the SPEED			The green light of the  key goes off. The next value is displayed, which is the LOAD, the green light of the  goes on and the leds of concerning motions are blinking.
- Exit from program	 OU 	 	The displayed value is the PATIENT CODE if this one is programmed (if not, TIME OF SESSION is displayed)
- Start a cycle			The number displayed is the actual angle of the foot.


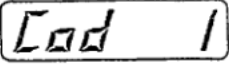


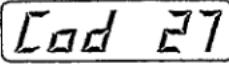
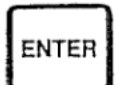
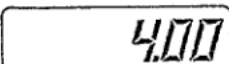



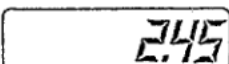
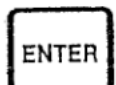



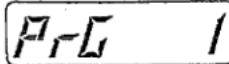






IV STARTING UP THE APPARATUS

WITH THE SAME PROGRAM AND THE SAME PATIENT AS AT THE PREVIOUS SESSION

Beginning	keys to press	Display	Remarks
- Start a run			Patient code if this one is programmed (if not, TIME OF WORKING is displayed)
- To validate			Displays the time of the last session. The green light of the  key goes on.
- Start a cycle			The green light of the  key goes on. The value displayed is the actual angle of the foot (PLANTAR / DORSALE FLEXION with MODE 1 and 3; VARUS / VALGUS with MODE 2). The value changes at the speed of the movement. The light emitting LEDs of the movements under way light up and go off when you go through the zero point.
- Stop a cycle			The green light of the  key goes off. The red light of the  key goes on.
- Start a cycle			The green light of the  key goes on. Movement starts back up in opposite direction. The values displayed is the actual angle.


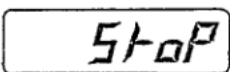

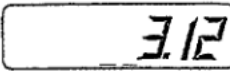



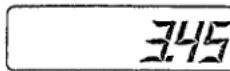
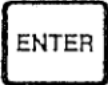
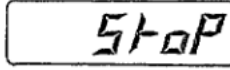

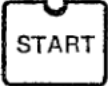



Remark : The figures shown in the display column are examples. In reality, the values displayed depend on what is stored in memory.

WHEN CHANGING THE PROGRAM AND THE PATIENT

Beginning	keys to press	Display	Remarks
- Start a run			Patient code if this one is programmed (if not, TIME OF WORKING is displayed)
- To change the PATIENT CODE	 OU 		
- To validate the PATIENT CODE			Displays time of the last session. The green light of the  key goes on.
- To change the SESSION TIME	 OU 		One pulse change the time by 15'. Holding the key down causes the values to go up or down
- To validate the new SESSION TIME			The preceding program number displayed.
- To change the PROGRAM NUMBER	 OU 		One pulse change the number by one unit.
- To validate the PROGRAM NUMBER			The green light of the  key starts blinking.
- Start a cycle			The green light of the  key goes on. The number displayed is the actual angle of the foot (PLANTAR / DORSALE FLEXION with MODE 1 and 3; VARUS / VALGUS with MODE 2). The value change at the speed of the movement.

Remark : The figures shown in the display column are examples. In reality, the values displayed depend on what is stored in memory.

MODIFYING THE SESSION TIME

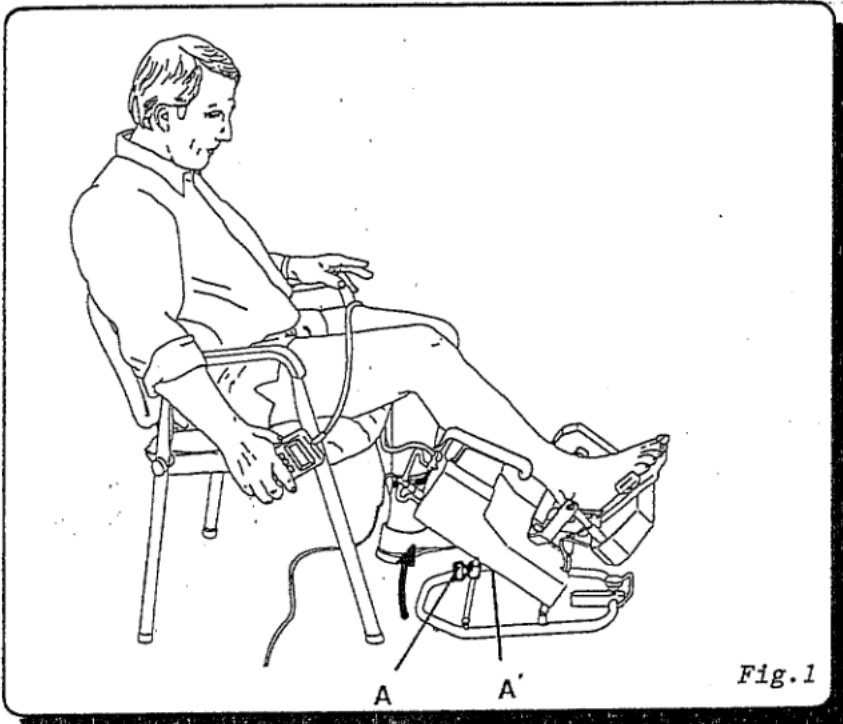
Beginning	keys to press	Display	Remarks
- Stop the splint			Display shows STOP.
- Press the button			Display shows remaining SESSION TIME. 
IMPORTANT : If any modification it is, after 3 second the display shows			
- Modifying duration SESSION TIME	 OU 		Display shows the new remaining time of the session
- To validate the new SESSION TIME			The red light of the  key goes on.
- Start a cycle			The red light of the  key goes off. the green light of the  key goes on.
			The number displayed is the actual angle of the foot (PLANTAR / DORSALE FLEXION with MODE 1 and 3; VARUS / VALGUS with MODE 2).
			The value change at the speed of the movement.

V POSITIONING THE PATIENT

The KINETEC ankle machine (5190) may be used in a chair (Fig.1) or in a bed with the prop (Ref: 4670012176.)

USE IN A CHAIR

Fig.1



- The patient is comfortably positionned in his chair.
- Place the machine in front of him.
- The machine should be at maximum tilt obtained by :
 - unscrew knobs A and A'
 - raise the machine gently to the end stop
 - re-tighten knobs A and A'
- Place the patient's leg on the machine.

These first adfustments should be fine tuned after fixing the foot to the machine.

USE IN BED

Fig.2

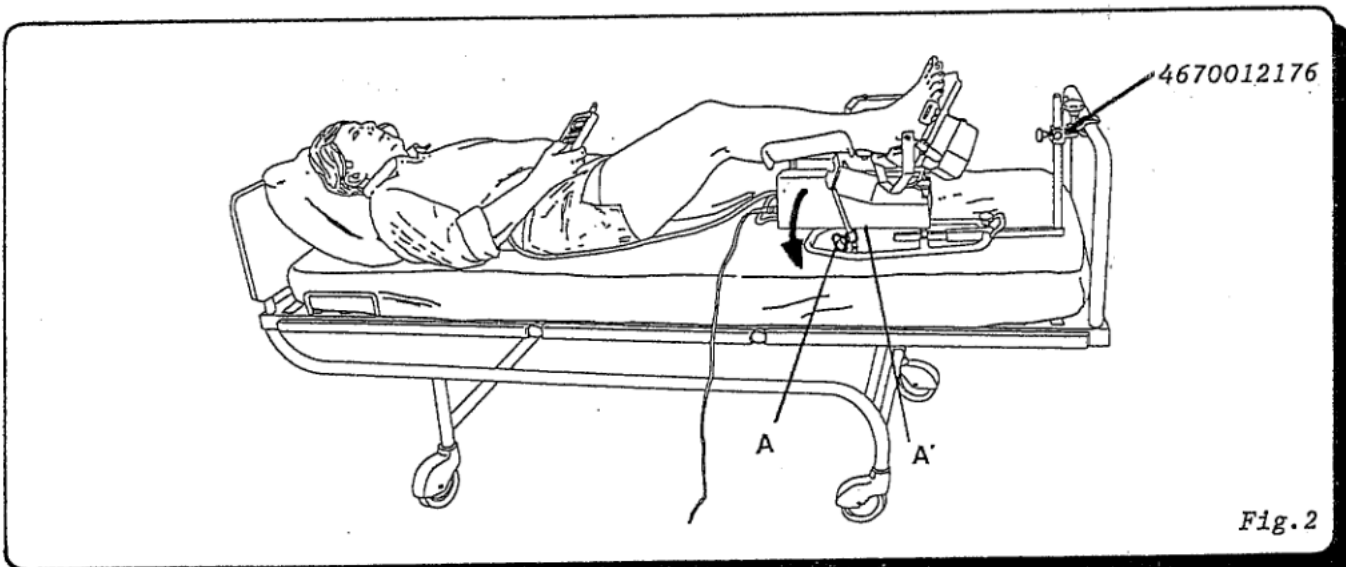


Fig.2

- Place the machine on the foot of the bed.
- The machine should be at maximum tilt obtained by :
 - unscrew knobs A and A'
 - gently lower the machine to the end stop
 - re-tighten knobs A and A'.
- Position the patient's leg.

To improee stability on the mattress the machine has a prop to fix the base ring to the bed (see " FIXING THE MACHINE TO THE BED").

These first adjustments should be fine tuned after fixing the foot to the machine..

VI FIXING THE FOOT TO THE MACHINE

ADJUSTMENT OF THE ANKLE SUPPORT

Fig.3

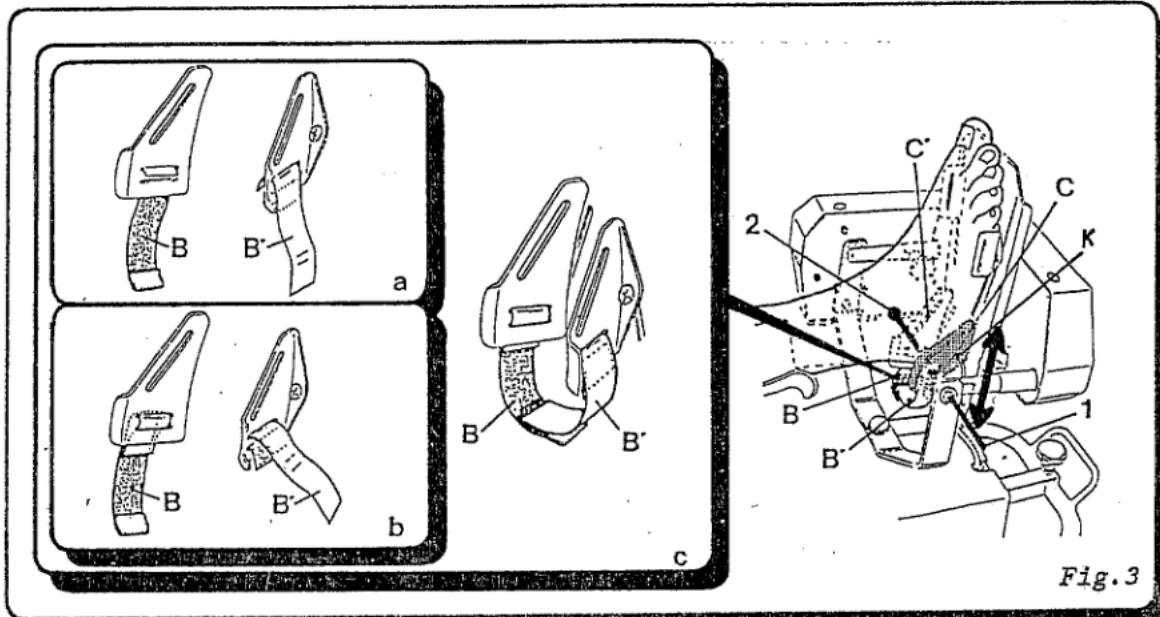


Fig.3

- Unscrew 2 screw K with the screwdriver (to ship with the exerciser)
- Position straps B and B' as shown in diagrams a, b and c.
- Place the foot on the sole plate matching the axis of the machine's hinge (1) to the axis of the ankle joint (2) by raising or lowering the two supports C and C'.
- Re-tighten 2 screw K.
- Adjust the straps B and B'.

ADJUSTING THE HEIGHT OF THE FOOT

Fig.4

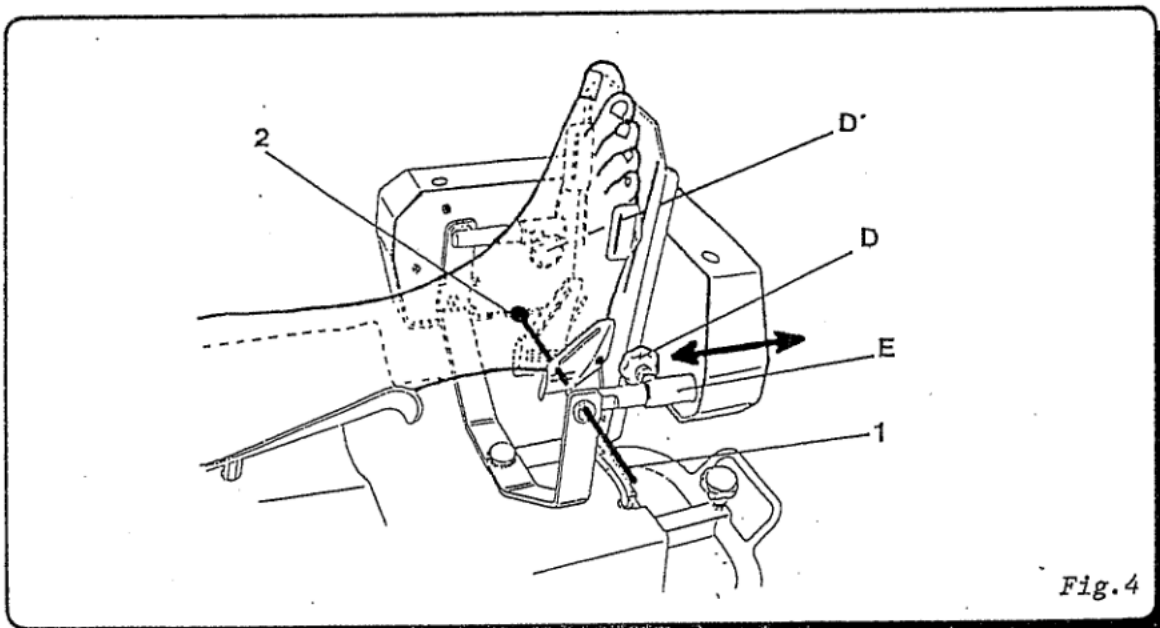
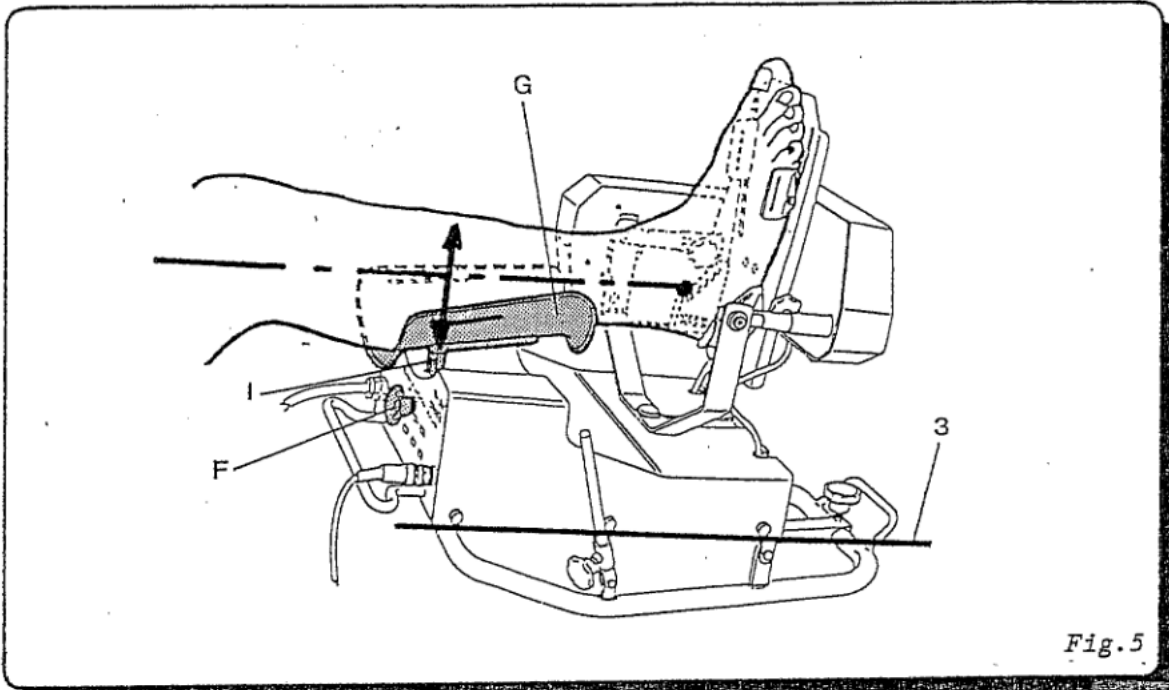


Fig.4

- Unscrew the knobs D and D'.
- Measure the height of the foot.
- Report this value on the machine by sliding the assembly E forwards or backwards.
- Re-tighten the knobs D and D'.

ADJUSTING THE CALF SUPPORT

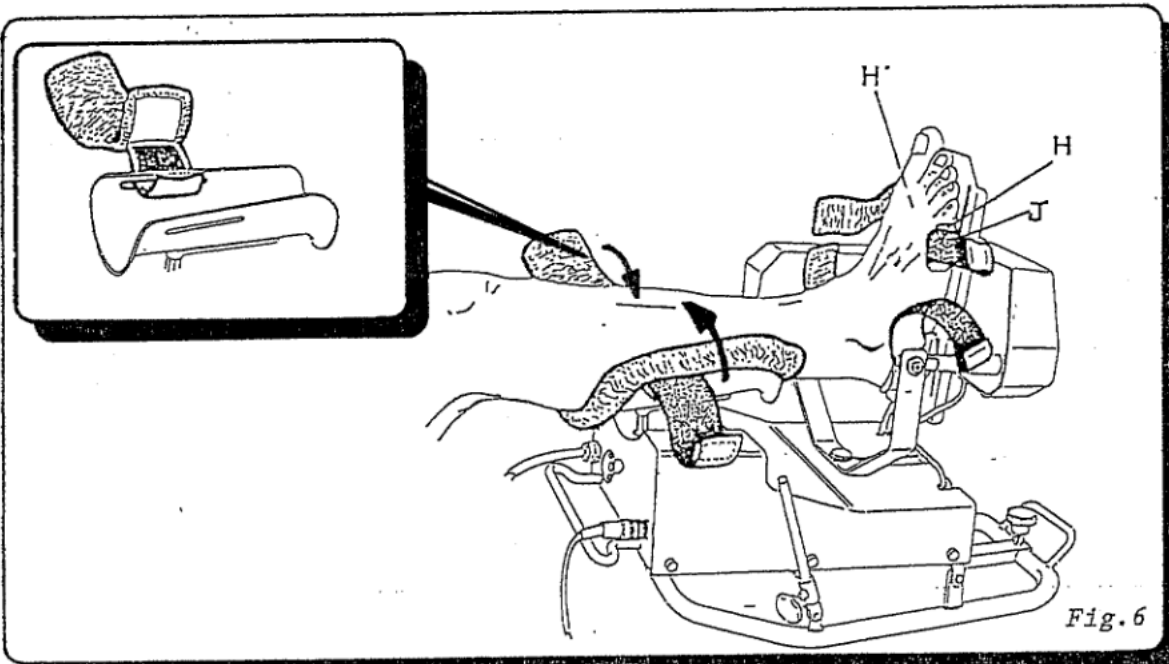
Fig.5



- Unscrew the knob F.
- Raise or lower the calf support G, so that the axis of the leg becomes parallel to the bases (3) of the machine.
- Re-tighten the knobs F.
- Look the label I for further setting.

FIXING THE PATIENT'S LEG TO THE MACHINE

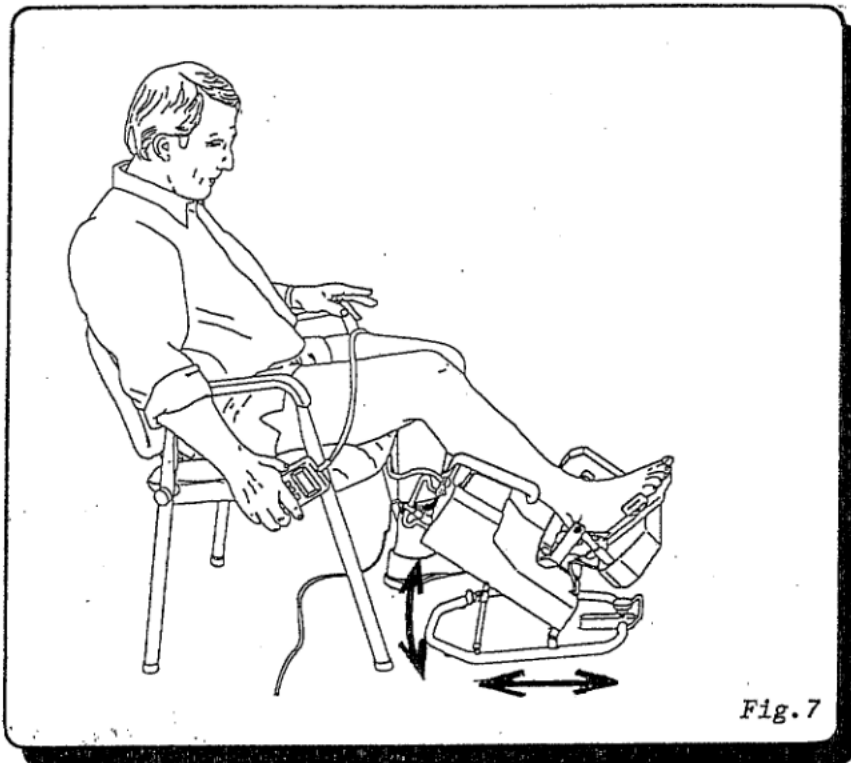
Fig.6



- Unscrew the 2 screws J.
 - Jam the foot between the two pads H and H' by sliding them as needed in their grooves. Re-tighten the 2 screws J.
 - Fix the patient's leg to the machine using the circular straps supplied :
 - for the calf use the 8cm (3,1inch) wide strap
 - for the ankle use the large use the large 3,5cm (1,4inch) wide strap
 - for the top of the foot use the small 3,5cm (1,4inch) wide strap.
- Order number for a complete set of circular straps : 4650000167.

FINAL ADJUSTMENT

Fine tune the adjustment of the machine's position to obtain the most comfortable position for the patient, depending on the mode of use :



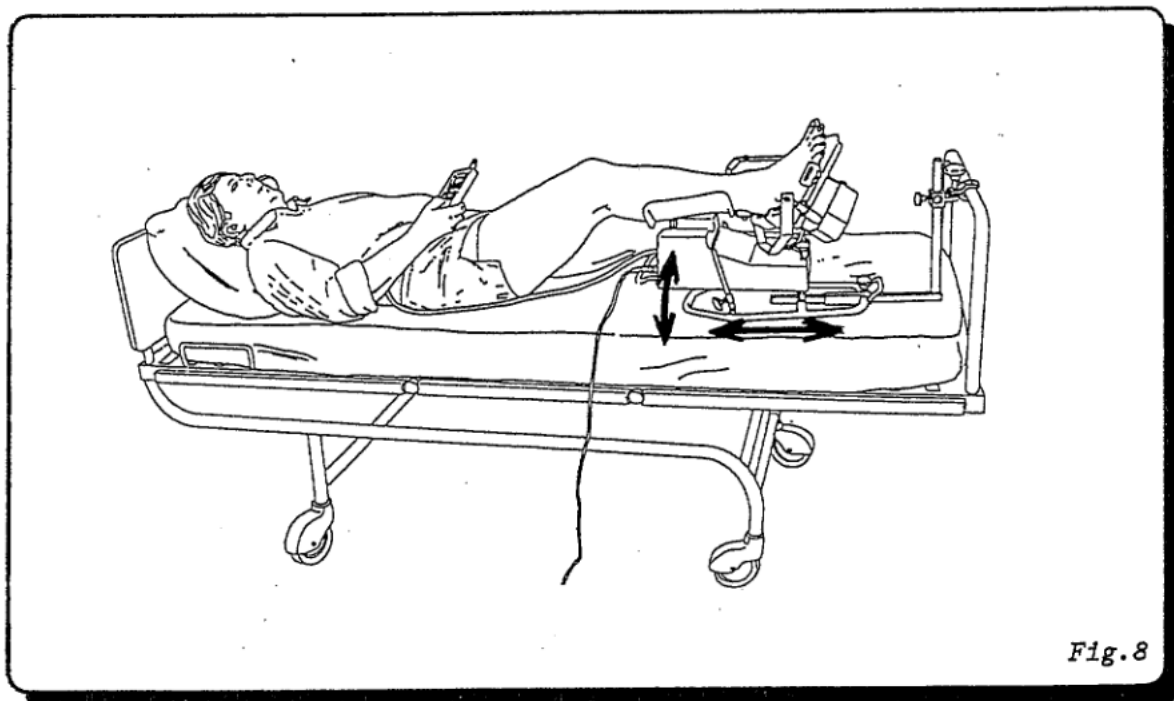
IN A CHAIR

Fig.7

Shift the machine on the bed and adjust it's tilt.

IN A BED

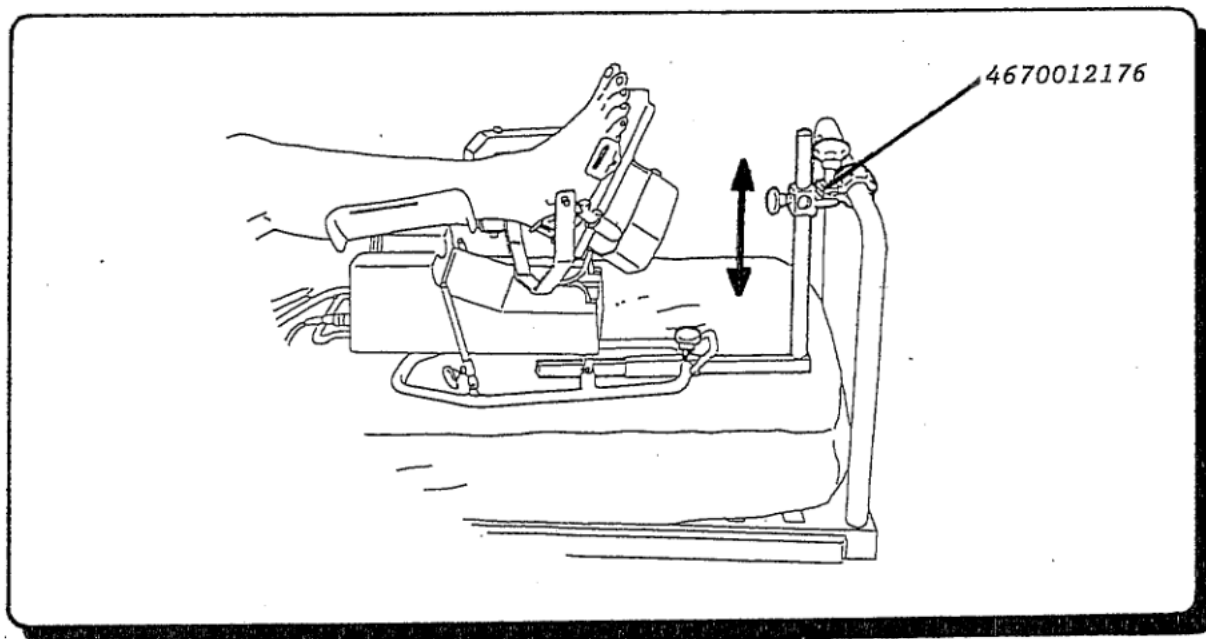
Fig.8



Shift the machine on the bed and adjust it's tilt.

FIXING THE MACHINE TO THE BED

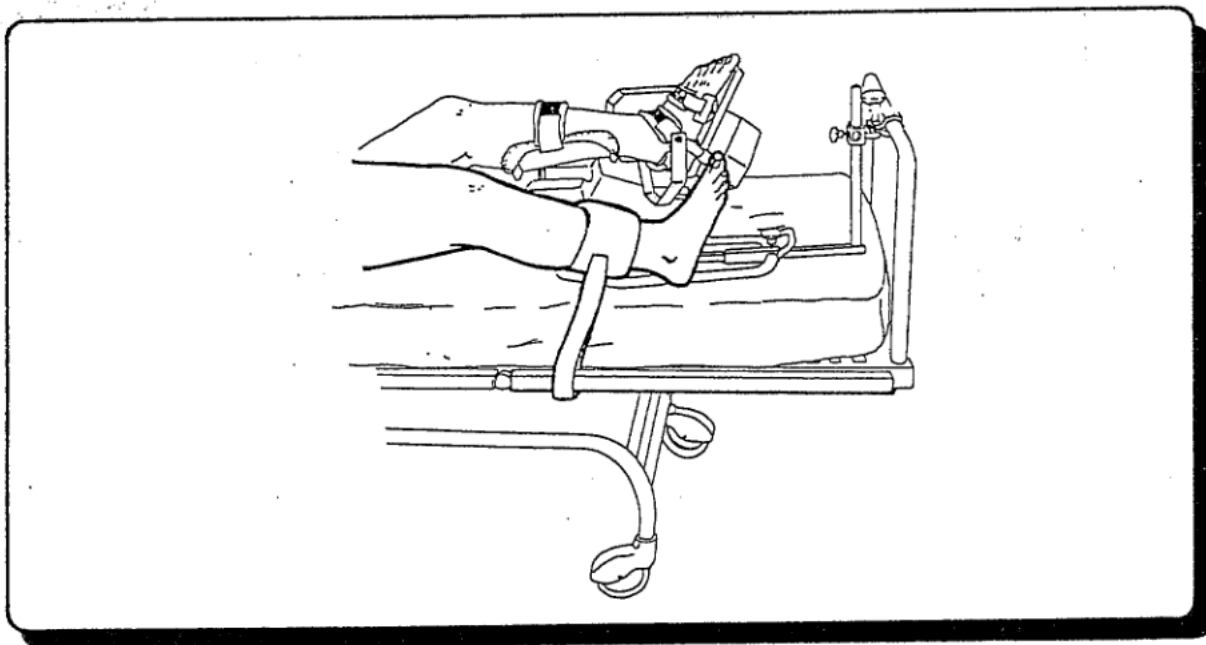
Fig.9



To improve the stability of the machine on the bed use the prop for the of the bed (Ref :4670012176), supplied with the machine. It is fixed to the horizontal bar of the bed or one of the bars of a traction frame.

PROTECTION OF THE OPPOSITE FOOT

Fig.10



EXTRA SAFETY


When using the machine in bed it is recommended to restrain the opposite foot so that it does not impede the correct working of the machine. Use the strap supplied with the machine for this purpose. Order number for a replacement strap : 4650000927

VI INSTRUCTIONS IN CASE OF A BREAKDOWN

After switching on the power supply to the machine using the switch (C)(cf. Page 3) :

- If the machine fails to operate, and if no pilot light lights up:
 - Check the electrical connections.
 - Check at the mains socket that power supply is switched on by using another electrical device.
- If the machine fails to operate, but the pilot lights are lit up ;
 - Press the START button once again.
- If the machine still fails to operate after that :
 - Return the machine to your nearest specialist.

LIST OF ERRORS

N°	COMMENTS
00	Microprocessor error (parasites, operating defect). Switch OFF the current.
02	Memory full. Data memorized to be erased. When powerer, the display unit indicates  then, after 5 seconds  (print-out ?) you must : <ul style="list-style-type: none">- Either connect the splint to a PC and use the data transfer in the KINETEC software.- Or connect the splint to a printer (the data can no longer be transferred to a PC and press the  key all the data are inscribed on the printer, and erased from the splint memory.- Or you can erase the latest session recorded from the memory, (this only makes it possible to re-do a single new session) by pressing the  key.- Or erase some of the elements stored in the memory by typing F0 (technical catalog § 1.2).
03	Value requested is outside the authorized limits Return to prior display after 3 seconds.
11	Connection error at control box. To change the code, consult the nearest specialist; either this or several keys have been pressed in the course of switching on the power supply then switch on again.
13	Maximum motor intensity authorized has been exceeded: <ul style="list-style-type: none">- Return the machine to your nearest specialist.
14	P1, P2 or P3 position measurement cut off: <ul style="list-style-type: none">- Return the machine to your nearest specialist.

CLEANING

First, switch the CPM unit OFF and remove the power cord from the receptacle.

Spray a DISINFECTANT product (e.g., PROPANOL/ISOPROPANOL or ALDEHYDE solution) one used onto the SURFACES (plastic support, plastic covers and metal parts).





The pads for forearm support are machine-washable (30°C, 90°F) with chlorine bleach.

For optimal hygiene, a new set of pads should be used for each patient, all device's consumable can be throw without warning.

SPECIFICATIONS

SPECIFICATIONS	Electrical	Environmental
Weight: 15 Kg	Power supply:	- Storage / shipping conditions:
Dimensions: 45cm x 34cm x 34cm (17,7x13,3x13,4 inches)	100 or 110 or 230 V~	Ambient temperature: -40°C to +70°C
Range of motion: from 40° plantareflexion to 30° dorsalflexion	per countries	(-40°F to +160°F).
from 25° adduction to 25° abduction	Frequency: 50/60Hz	Relative humidity up to 90%.
from 25° varus to 25° valgus.	Electrical power: 40VA	- Operating conditions:
Speed: from 30° to 65°/minute	Type B Class II device	Ambient temperature: +10°C to +40°C
Patient sizing: from 1,40m to 1,90m		(+50°F to +105°F).
		Relative humidity 80%.

SYMBOLS

	TYPE B EQUIPMENT (insulated against electric shock)
	WARNING (consult accompanying documents)
	OFF (disconnected from the mains)
	ON (connected to the mains)

POWER	Transformator
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GUARANTEE LIMITS

The KINETEC guarantee is strictly limited to free replacement or to repair of the part or parts acknowledged as defective, at the Smith & Nephew factory.

Smith & Nephew Kinetec guarantees its passive motion device against any manufacturing defect for 1 year from the date of purchase by the consumer.

Smith & Nephew Kinetec alone is qualified to judge whether the guarantee applies to the specific problem.

The guarantee cannot be applied if the apparatus has been subjected to abnormal use or has been used in circumstances other than those stipulated in our user manual.

The guarantee will not be applied in case of deterioration or accident due to negligence, lack of supervision or maintenance or an attempt to repair the equipment.

DECLARATION "CE" DE CONFORMITE "EC" DECLARATION OF CONFORMITY

Nous

Smith & Nephew Kinetec

We

(nom du fabricant ou de son mandataire dans la Communauté Européenne)
(Name of manufacturer or his representative established within the European Community)
Zone Industrielle de Tournes-Cliron - TOURNES - F 08090

déclarons sous notre seule responsabilité que le produit
declare on our own responsibility that product



0459 reconnaît que son certificat CE est
valide pour les dispositifs méd. décrits
recognizes that its EC certificate is valid for the medica
devices listed

KINETEC de cheville modèle 5190

Ankle KINETEC model 5190

(nom, type ou modèle, (éventuellement n° de lot, d'échantillon ou de série, sources et nombre d'exemplaires))
(Brand name, model, (N° of lot or series if necessary))

satisfait aux dispositions des Directives du Conseil :
complies with the assessment criteria of Council's Directives:

- n° 93/42/CEE du 14 juin 1993 - DISPOSITIFS MEDICAUX (selon l'annexe II)
- n° 93/42/CEE of June 14, 1993 - MEDICAL DEVICES (Annex II)
obligatoire à partir du 14 Juin 1998 / mandatory date : June 14, 1998
- n° 89/336/CEE du 3 mai 1989 - COMPATIBILITE ELECTROMAGNETIQUE
- n° 89/336/CEE of May 3, 1989 - ELECTROMAGNETIC COMPATIBILITY
obligatoire à partir du 1er janvier 1996 / mandatory date : January 1, 1996

et que le système qualité du fabricant est conforme aux normes ou autres documents normatifs suivants :
and the quality system of the manufacturer is in conformity with the following standard (s) :

EN 46001/96 - ISO 9001/94

Certificat n° 0214/46001/9001/1 délivré par le Gmed le 15/10/97
Certificate n° 0214/46001/9001 established by Gmed on 15/10/97

Attestation de conformité à l'annexe II.3 délivrée par le Gmed N°0214/B2P3/1
Certificate for approval of full Quality Assurance System - Annexe II.3 - N° 0214/B2P3/1 established by Gmed

Information complémentaire :
Additional information :

Fiche Produit 5190 du 01/02/2002
Product file 5190 dated 01/02/2002

Année d'apposition du Marquage CE : 1998
Year in which CE mark was affixed : 1998

P. SONNET

Directeur Général / General Manager
(Nom, titre et signature du signataire autorisé)
(Name, function and sign of authorised people)

Tournes, le 1^{er} Février 2002
Tournes, February 1st, 2002
(lieu et date / place and date)

