

USER MANUAL

INDICATIONS

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

CLINICAL BENEFITS

- Breaks the cycle of trauma, inflammation and the loss of range of motion.
- Prevents joint stiffness.
- Speeds the recovery of post-operative range of motion.
- Maintains the quality of the joint surface.
- Reduces pain and oedema.
- Promotes joint cartilage healing.
- Reduces hospitalization time
- Reduces the need for pain medication.
- Provides immediate post-operative continuous passive motion.

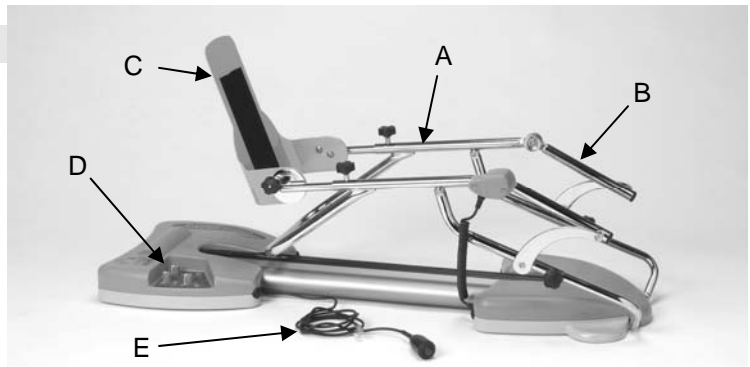
CONTRAINDICATIONS

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

1 • DESCRIPTION

KINETEC Prima Advance is a Knee PASSIVE mobilization device enabling the extension and flexion movement from -5° to 115° .

- A - Lower limb support
- B - Thigh support
- C - Foot support
- D - Control panel
- E - Hand control



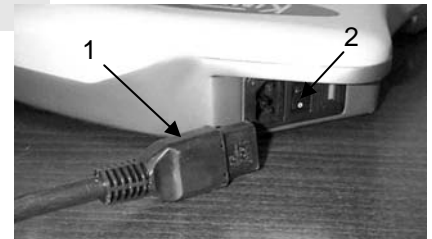
2 • ELECTRICAL CONNECTION: SAFETY FIRST.

KINETEC Prima Advance is a type B class I device.

Plug the power cord (1) on the KINETEC Prima Advance unit into a receptacle (Voltage between 100 to 240 Vac 50/60 Hz).

IMPORTANT: Before use:

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



Fuse change

Warning: Replace the fuse with one of the same type and value: - on main socket, 2 fuses T 500 mA 250V (6.3x32)
- on power supply PCB, 1 fuse F 2 A 250V (5x20)
- on PCB, 1 fuse T1.25 A (5x20))

3 • SAFETY

The physician defines the protocol and ensures that it is correctly implemented (adjustments, session duration and frequency of use).

The patient must know the start/stop/reverse function on the control handle.

Hand control must be accessible to patient at all times. (See page 2).

KINETEC Prima Advance complies with Directive 93/42/CEE.

EXPLOSION HAZARD:

KINETEC Prima Advance is not designed for use in the presence of flammable anesthetics.

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

KINETEC Prima Advance is in compliance with standards in force (IEC 601.1.2), electromagnetic compatibility standard for medical devices.

Please, do not touch the moving parts while the unit is running, pinching risk.

4 • STARTING THE UNIT

Turn on the power switch (2). The yellow light (3) on the control panel is on.

START / STOP / REVERSE function

The KINETEC Prima Advance is fitted with a START/STOP/REVERSE function.

First, press the hand control switch; the machine stops.

Press the hand control switch again; the mobilization reverses.

IMPORTANT: for maximum safety, the hand control should always be given to the patient.

Adjusting the FLEXION and EXTENSION limits

Select the extension and flexion angles via button (4) for flexion and button (5) for extension.

Modification of the extension or flexion limit can be done while the machine is running or stationary.

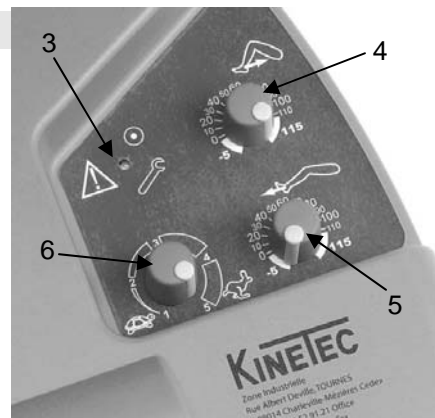
Adjusting the SPEED

The SPEED is set by turning button (6).

At maximum speed, the machine moves at 145° per minute (for medium femur length).

At minimum speed, the machine moves at 40° per minute (for medium femur length).

Modification of the speed can be done while the machine is running or stationary.



5 • USE OF THE KINETEC PATIENT PAD KIT

The KINETEC Patient Pad Kit is designed for rapid fitting, optimal hygiene and maximum patient comfort.

For optimal hygiene, a new set of pads should be used for each patient.

- For using and positioning the straps, please refer to here under.

CLEANING:

Disinfecting of the pads: Washing at 30°C with use of a disinfecting solution during the rising cycle.

Example of product that can be used: Solution "Baclinge" at 0.125 % or "Souplanos" at 0,125% from ANIOS Laboratory.

Part number to order the complete set:

- Set of 4 straps: 4650001107

- Foot support: 4650001131



6 • SETTING UP THE PATIENT

- Place the KINETEC Prima Advance machine in a position that will be comfortable for the patient.

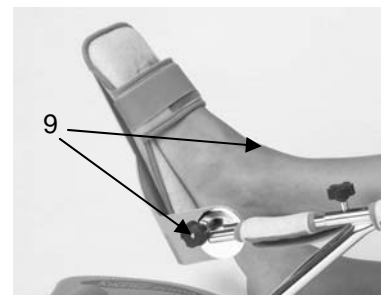
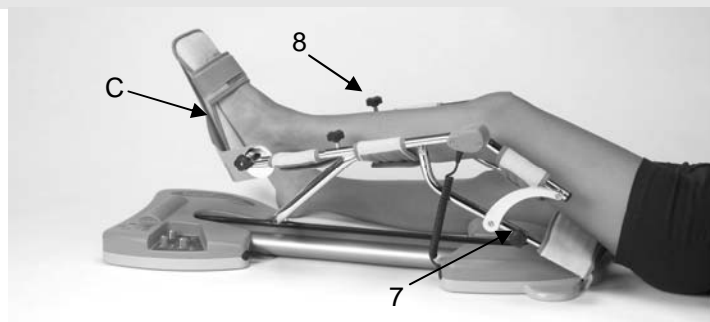
- Measure in cm or inches the length of the patient's femur; adjust the thigh support to this measurement using knobs (7).

- To install the patient on the KINETEC Prima Advance machine.

- Push the foot plate (C) up to the patient and tighten the knobs (8).

IMPORTANT

Adjust the axis of the patient's hip with the axis rotation of the KINETEC Prima Advance machine, and the axis of the patient's knee with the axis rotation of the KINETEC Prima Advance machine.



7 • POSITIONING THE FOOT PLATE

The articulated foot plate allows the positioning of the foot from 40° of PLANTAR FLEXION to 30° of DORSIFLEXION.

- The knob (9) allows positioning the foot in plantar flexion or dorsiflexion.

8 • MAINTENANCE

After 2,000 hours of operation, KINETEC Spectra requires a few lubrication and maintenance operations (lubrication of the joints, pointer stops and ball screws). When the machine is switched on the yellow light blinks 5 times to indicate that the service interval has been reached.

Despite that warning, you can continue to use your KINETEC Prima Advance by pressing START, but you should contact your nearest KINETEC technician to have the maintenance operations conducted as soon as possible.

9 • CLEANING

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

In order to ensure optimal hygiene, you are advised to clean the machine for each new patient.

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

To clean the KINETEC hygienic pads, please refer to paragraph 5.

10 • ELIMINATION AND RECYCLING

a • Packing: Packing must be separated from the components plastic and paper/cardboard and given to the specific sites from recycling.

b • KINETEC PATIENT PAD KIT: To clean with a product of disinfection then to give it to the specific sites of recycling.

c • Prima Advance unit: It contains electronic components, cables, aluminum, steel and plastic parts. When the splint is not operational any more, to dismount and separate in groups from materials and to give them to correct unit of recycling or to turn over the machine to Kinetec for destruction.

11 • TROUBLESHOOTING

A spare parts list and technical catalog are available to you on request from your KINETEC distributor.

If, after connecting the power supply cable to the power supply and switching on KINETEC Prima Advance:

- The light is off:
 - Check that the electrical socket is live using another device.
 - Replace the fuse(s) of the connector (2) with fuses of the same type and caliber: 2 fuses T 500 mA 250V (6.3 x 32).
 - If the led still does off, contact your nearest KINETEC technician.
- If the machine fails to operate but the yellow light remains on,
 - Press the START/STOP switch 1 more times.

Your KINETEC Prima Advance still does not function: Contact your nearest KINETEC technician.

Your KINETEC Prima Advance does not function and the led indicates:

The LED blinks 1 time → angle measurement function failure

The LED blinks 2 times → no movement

The LED blinks 3 times → abnormal consumption

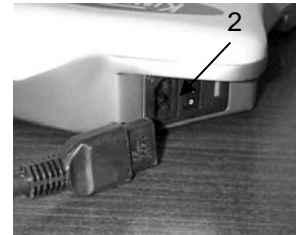
The LED blinks 4 times → the motor PCB provides the energy but motor consumption is null.

The LED blinks 5 times → Service Time ≥ 2000h

The LED blinks 6 times → not enough power

The LED blinks 7 times → START/STOP switch failure.

Contact your nearest KINETEC technician.



12 • TECHNICAL SPECIFICATIONS

Product
Weight: 11,8 Kg
Splint dimensions:
94 cm (37 in) x 33 cm (13 in) x 33cm (13 in)
Angular limits: -5 to 115°
Speed: from 40 to 145° per minute.
Patient height: from 1.5 m (4,92 ft) to 1.95 m (6,40 ft)

Electricity
Power supply: 100-240 V~
Frequency: 50-60Hz
Power consumption: 50VA
Device of type B class I
IP 20.

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

13 • SYMBOLS USED

	Caution (consult the accompanying documents)
	TYPE B device (protection against electric shocks)
	STOP (power off)
	ON (power on)

	PCB is powered (12Vdc)
	Service
	Minimum SPEED
	Maximum SPEED

	FLEXION limit
	EXTENSION limit
	Contains electric and electronic components; not to throw in the dustbins of household refuse

14 • WARRANTY

The KINETEC warranty is strictly limited to the replacement free of charge or repair in the plant of the component or components found to be defective. KINETEC guarantees its joint passive mobilization systems for 2 years against all defects of manufacture from the date of purchase by the consumer. KINETEC is the only organization able to assess the application of the warranty to its systems.

The warranty will be considered null and void if the device has been used abnormally or under conditions of use other than those indicated in the user's manual.

The warranty will also be considered null and void in the event of deterioration or an accident due to negligence, inappropriate surveillance or inappropriate maintenance, or due to transformation of the equipment or an attempt to repair the equipment.

15 • OPTIONS

- 15.1 • 4665003297 • Trolley
- 15.2 • 4655001053 • Cart
- 15.3 • 4650001090 • Mattress
- 15.4 • 4650001868 • Patient pad Kit (4 straps + foot support + 1 mattress)
- 15.5 • 4650001123 • Leg strap
- 15.6 • 467000xxxx • Plastic support kit

GUIDANCE AND MANUFACTURER'S DECLARATION

Electromagnetic emissions		
The « KINETEC Prima Advance » is intended for use in the electromagnetic environment specified below. The customer or the user of the « KINETEC Prima Advance » should assure that it is used in such an environment.		
Emissions test	Emissions test	Emissions test
Radio electric-Frequency emissions CISPR 11	Group 1	The « KINETEC Prima Advance » 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 electric-Frequency emissions CISPR 11	Class B	The « KINETEC Prima Advance » 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 « KINETEC PRIMA Advance » is intended for use in the electromagnetic environment specified below. The customer or the user of the « KINETEC PRIMA Advance » should assure that it is used in such an environment.			
Immunity test	Immunity test	Immunity test	Immunity test
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%. If the movement stops, push the start button, the movement starts again. If the yellow LED is lighting, switch off then on the apparatus and push the start button, the movement starts again.
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	±1 kV between lines ±2 kV between line and earth	±1 kV between lines ±2 kV between line and earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage interruptions CEI 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	At the interruption, there is a reset of the « KINETEC PRIMA Advance ». After turning on, push START to begin the session.
Voltage dips and voltage variations on power supply input lines CEI 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 « KINETEC PRIMA Advance » requires continued operation during power supply interruptions, it is recommended that the « KINETEC PRIMA Advance » be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 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 a.c. mains voltage prior to application of the test level.			