Prima Advance

User manual

Before use, please read this document.
Kinetec reserves the right to effect technical modifications.

EN

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Notice Originale

USER MANUAL

Summary

Definition

The device KINETEC® Prima Advance is a PASSIVE KNEE mobilisation device enabling extension and flexion movements from -5° to 115°.

Indications

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

Clinical Benefits

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

Contraindications

Rheumatoid arthritis in the inflammatory phase, gout, algodystrophy in the inflammatory phase (hyper painful), para-osteo-arthroplasty, unhealed infected wounds, established phlebitis, bone cancer, myositis ossificans of the quadriceps, arthrodesis of the hip, infectious arthritis, deformed joint surfaces, paralysed limbs (atonic or spastic), non-stabilised fractures.

The machine is not suitable for patients over 1.95 m (6'7") or under 1.45m (4'7") tall.

Warning and safety instructions

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 5.
WARNING:	To avoid the parameters being accidentally changed, you are recommended to close the protective cover on the control panel.
WARNING:	Danger, risk of explosion: Do not use the machine with anaesthetic gas or in an environment that is rich in oxygen.
WARNING:	For Type B Class I devices, and to avoid all risks of electric shock, the machine should only be connected to a power supply that has protective earthing, see page 4.
WARNING:	Before using this machine, always check that the electrical socket is in good condition and is suitable for the splint power supply cord. Only use the original cable supplied with the machine. Check that the cables remain free around the device so that they do not get damaged.
WARNING:	Before using this machine, always check that the machine is not damaged, in particular the protective housings.
WARNING:	In case of electromagnetic interference with other devices move the device.
WARNING:	Please do not touch the fixed or moving parts while the unit is running: pinching or crushing risk. Keep children and pets away from the machine.
WARNING:	Modifying the machine in any way is strictly forbidden.
WARNING:	Always check the motion parameters displayed on the hand control before starting the device.
WARNING:	Only the accessories, spare parts and supplies described in this manual should be used with this machine.
WARNING:	Do not connect the device to other devices not described in this manual.
WARNING:	If unforeseen events or malfunctions occur, please contact your KINETEC distributor.
WARNING:	Wireless communications devices, such as domestic wireless devices in networks, mobile phones, wireless telephones and their base stations and walkie-talkies, may affect the machine. You are recommended to keep at least a distance *d* between these devices and the machine. See the table on page 11.

Compliance:

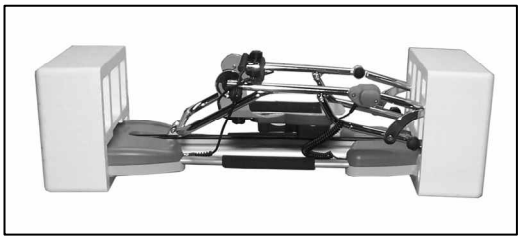
The device KINETEC® Prima Advance complies with the standards of Directive 93/42/EEC, and bears the EC mark.
The device KINETEC® Prima Advance complies with the standards in force (IEC 60601-1-2) concerning the electromagnetic compatibility of medical devices and IEC 60601-1 concerning electrical safety.
The device KINETEC® Prima Advance meets the requirements of the Machinery Directive No. 2006/42/EC.

Unpacking and packing

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

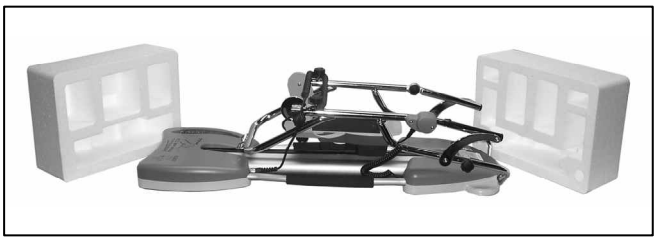
Recommendations for plastic bags: do not put them over the head as there is a risk of suffocation, and keep them out of the reach of children. Be careful with small-sized pieces: they could be swallowed by a child. Be careful with cables and wires: risk of strangulation.

Before using your machine you must move the foot plate into its working position. (See page 7).



Your machine is ready to be connected to the power supply. (See page 4).

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



Installing the device

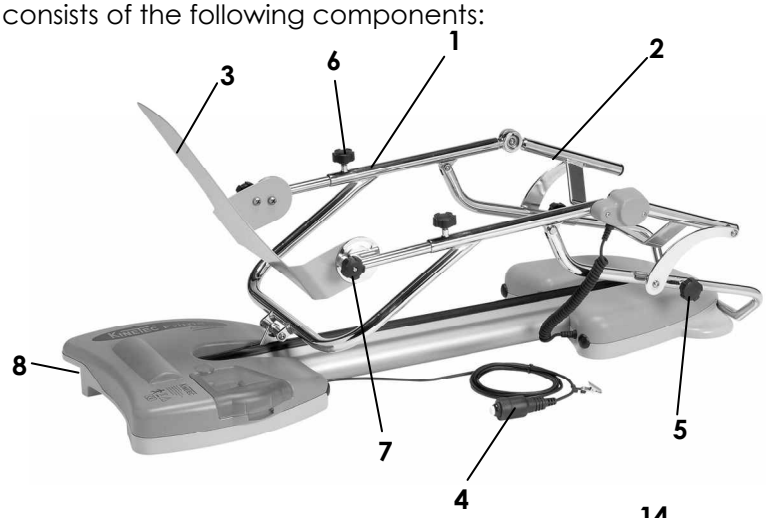
The device KINETEC® Prima Advance machine is designed to be used in hospitals, clinics, doctors' offices or in private homes (rental).

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

Description

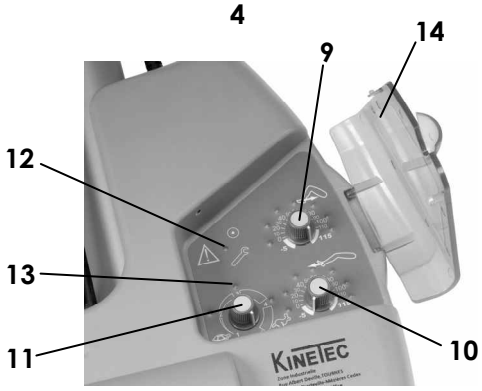
The device KINETEC® Prima Advance machine consists of the following components:

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

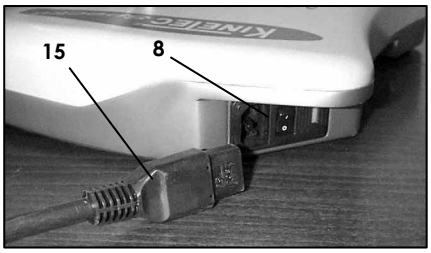


Control panel

9 • Flexion setting knob.
10 • Extension setting knob.
11 • Speed setting knob.
12 • Fault or power-on indicator.
13 • Setting indicator for visually-impaired people.
14 • Control panel protective cover.



Electrical connection: safety first.



2 versions of electrical protection are available for the device KINETEC® Prima Advance machine. The identification label shows which version a machine is equipped with:

Type BF, Class II devices,
for home use, bear the following symbols:

Type B class I devices,
for use in a professional environment, bear the following symbol:

See page 9 for the meaning of the symbols.

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 (15).

IMPORTANT
For Type B Class I devices, and to avoid all risks of electric shock, the machine should only be connected to a power supply that has protective earthing.
To connect the power supply, only use the original cable supplied with the machine.
Check that the cables remain free around the device so that they do not get damaged.
Check that the machine is not damaged, in particular the protective housings.

Procedure to start the machine

Press the ON / OFF switch (8).
The yellow LED (12) on the control panel lights up.

Warning: Always check the motion parameters settings on the control panel before starting the device.

START / STOP / REVERSE function

As with all KINETEC systems, the device KINETEC® Prima Advance is equipped with a START/STOP/REVERSE function.

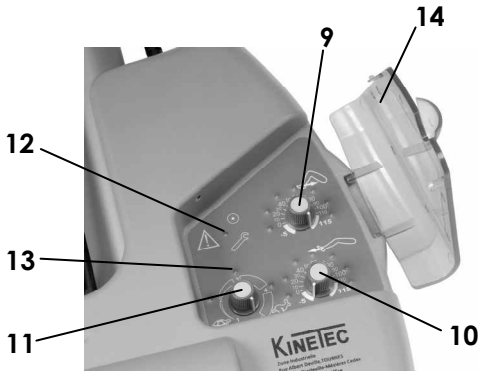
First, press the hand control switch; the machine stops.
Press the hand control switch again; the mobilization reverses.

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

Procedure to stop the machine

To stop the machine's movement: press the hand control switch.
To switch the unit off: press the ON / OFF switch (8) (see page 4).

Setting the FLEXION and EXTENSION limits



Select the extension and flexion angles via knob (9) for flexion and knob (10) for extension.
Modification of the extension or flexion limit can be done while the machine is running or stationary.
To avoid the parameters being accidentally changed, you are recommended to close the protective cover on the control panel. (14).

Setting the SPEED

The SPEED is set by turning knob (11).
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.
To avoid the parameters being accidentally changed, you are recommended to close the protective cover on the control panel (14).

Using the Plastic Comfort Case kit

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

Cleaning

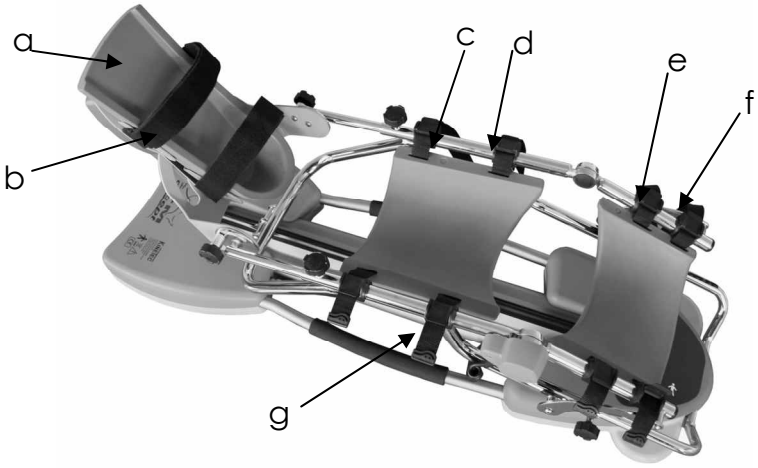
To ensure optimal hygiene, clean the supports after each patient use.
Use a DISINFECTANT product (alcohol-free or <5% alcohol solution) in spray (plastic cases and metal components).

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

Replacement parts

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

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



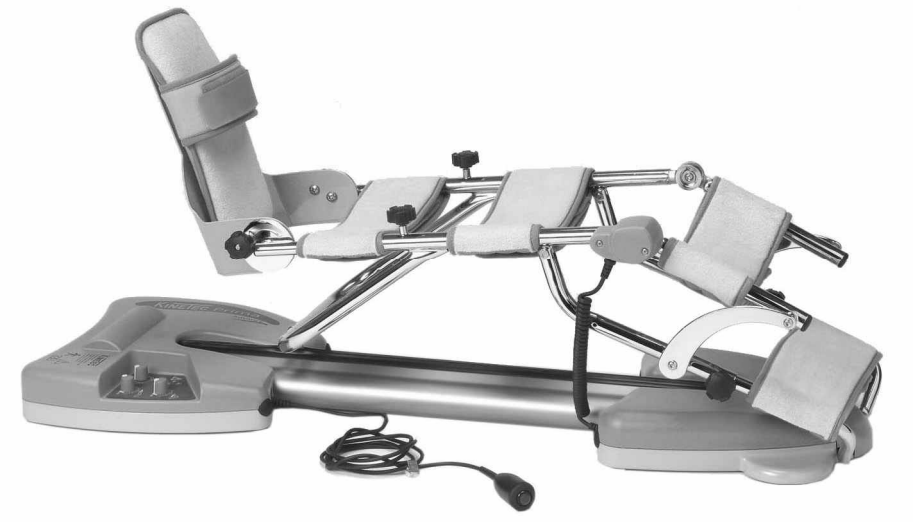
Using the Kinetec Patient Pad kit

The KINETEC Patient Pad Kit is designed for rapid fitting, optimal hygiene and maximum patient comfort.
- Please refer to the instructions below for using and positioning the straps.

FOR OPTIMAL HYGIENE, A NEW SET OF PADS SHOULD BE USED FOR EACH PATIENT.

CLEANING:
- Sterilizing the pads (if necessary): Sterilize at 134 °C for 18 minutes.
- Disinfecting the straps: Wash at 30°C, using a disinfectant solution during the rinse cycle. Example of product that can be used: Solution "Bac linge" at 0.125 % or "Souplanios" at 0.125% from ANIOS Laboratories. A complete list of distributors in your country is available on request.

The complete Patient Pad kit comprises:
- Set of 4 straps: 4650001107
- Foot support: 4650001131

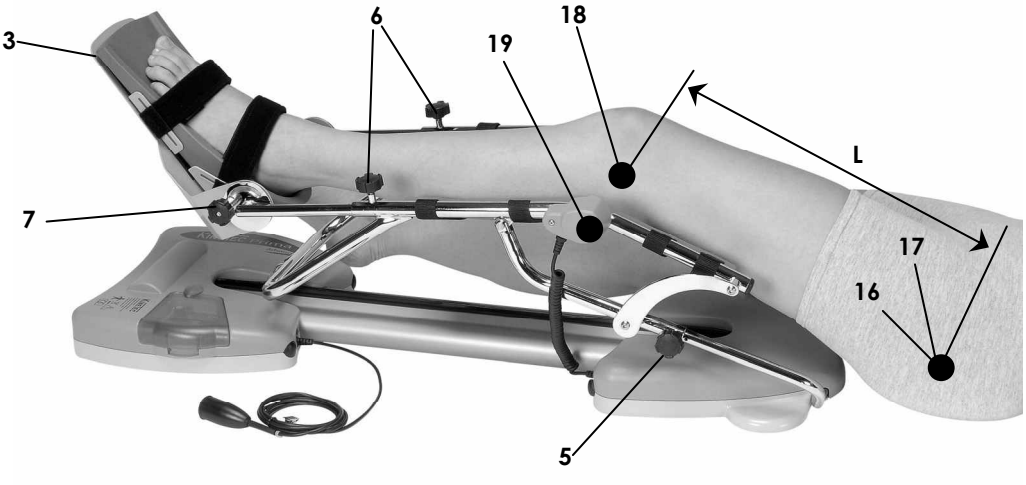


Setting up the patient

See page 3, Installing the Device chapter, for the positioning conditions.
Place the unit in a position that will be comfortable for the patient.

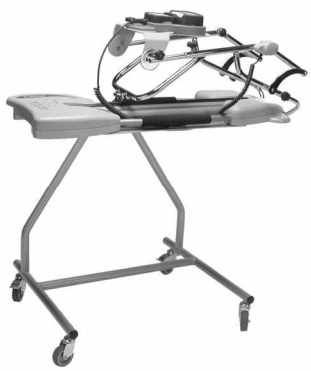
- Measure the length of the patient's femur in cm or inches (L); adjust the thigh support to this measurement using knobs (5).
- Install the patient on the machine.
- Bring the foot plate (3) into contact with the patient's foot, then tighten both buttons (6).
- Adjust the plantar flexion (40°) or the dorsal flexion (30°) of the foot, with the knobs (7).

CAUTION
Adjust the axis of the patient's hip (16) with the "THEORETICAL" axis of rotation (17) of the unit, and the axis of the patient's knee (18) with the axis of articulation (19) of the unit.



Options

Trolley for all CPM
Part number to order:
4655001053



Cart for bed use
Part number to order:
4665003297

Seat adaptor
Part number to order:
4670024098

Transport box
Part number to order:
4640001927

Paediatric foot plate
Part number to order:
4670023777

Maintenance

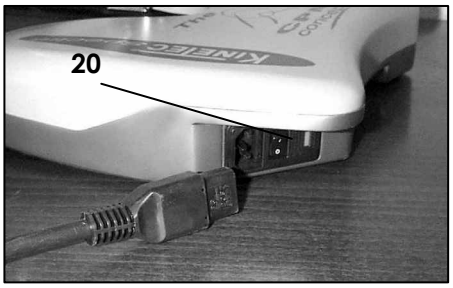
After 2,000 hours of operation, or once a year, the device KINETEC® Prima Advance requires lubrication and maintenance operations (lubrication of the joints, pointer stops and ball screws).
When the machine is switched on the LED blinks 5 times to indicate that the service interval has been reached.
Despite this warning, you can continue to use your KINETEC™ Prima Advance by pressing the hand control switch, but you should contact your nearest KINETEC technician to have the maintenance operations carried out as soon as possible.
An after-sales service inspection sheet and the technical catalogue are available on request from your KINETEC distributor.

WARNING:	Before using this machine, always check that the electrical socket is in good condition and is suitable for the splint power supply cord. Only use the original cable supplied with the machine. Check that the cables remain free around the device so that they do not get damaged.
WARNING:	Before using this machine, always check that the machine is not damaged, in particular the protective housings.

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

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 LED on the control panel does not light up:
  - Check that the electrical socket is live using another device or voltmeter.
  - Replace the fuse(s) (20) of the connector with fuses of the same type and calibre:
    2 fuses T 750 mA 250V (6.3 x 32) (KINETEC order: 4610007434).
  - If the display still does not indicate any information, contact your nearest KINETEC technician.
- Your machine does not work but the LED on the control panel lights up,
  Press the hand control switch once.
  If your machine still does not work, contact your nearest KINETEC technician.
- The LED on the control panel indicates a fault:
  The LED blinks 1 time → angle measurement function failure (copy potentiometer problem)
  The LED blinks 2 times → no movement
  The LED blinks 3 times → abnormal motor consumption or motor short-circuit
  The LED blinks 4 times → the motor PCB is providing power but motor consumption is zero.
  The LED blinks 5 times → Service Time ≥ 2,000 hrs, maintenance required
  The LED blinks 6 times → not enough power
  The LED blinks 7 times → START/STOP switch failure
  Contact your nearest KINETEC technician.

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

Disposal and recycling

a • **Packaging**: The packaging must be separated into plastic and paper / cardboard components and taken to special recycling sites.
b • **Kinetec patient pad kit:** Clean with a disinfectant product then take it to special recycling sites.
c • **Unit:** It contains electronic components, cables, aluminium, steel and plastic parts. When the machine is no longer operational, disassemble it, separate it into different types of material and take these to authorised recycling centres or return the machine to Kinetec 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.

Technical specifications

Product:

Lifespan of the machine:	12 years
Weight:	11 Kg (24 pounds)
Splint dimensions:	95cm (37 inches) x 33cm (13 inches) x 33cm (13 inches)
Angular limits:	-5° to 115°
Speeds:	from 40 to 145° per minute
Patient sizes:	Full leg: 71 to 99 cm (28 to 39 inches) Tibia: 38 to 53 cm (15 to 21 inches) Femur: 33 to 46 cm (13 to 18 inches)
Maximum weight of the user:	135 kg (297 pounds)
Acoustic pressure:	<70dB

Electricity:

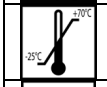
Power supply:	100-240V~
Frequency:	50-60 Hz
Power consumption:	50 VA
Class:	Device of Type BF Class II or Type B Class I
Protection classification:	IP 20 (Protected against solid objects greater than 12.5mm, but not protected against liquids)
Fuse:	T 750mA 250V 6.3 x 32mm (KINETEC order: 4610007434)

Environment:

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

Symbols used

	Warning or CAUTION (consult the accompanying documentation)
	STOP (power off)
	ON (power on)
	Right way up when box is stored
	Contains electric and electronic components; do not throw away with household refuse.
	Class II device
	TYPE BF device (protection against electric shocks)

	PCB is powered (12Vdc)
	Faults
	Minimum SPEED
	Maximum SPEED
	Temperature Limit during storage or transport
	Fragile
	TYPE B device (protection against electric shocks)

	FLEXION limit
	EXTENSION limit
	Follow the instructions for use
	Follow the instructions for use
	Alternating current
	Keep dry during storage or transport

Warranty

The KINETEC warranty is strictly limited to the replacement, free of charge, or to factory repairs of part(s) recognised as defective.
KINETEC guarantees its continuous passive motion 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.

Guidance and manufacturer's declaration

Guidance and manufacturer's declaration - Electromagnetic emissions		
The device KINETEC® Prima Advance is intended for use in the electromagnetic environment specified below. The customer or the user of The device KINETEC® Prima Advance should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
Radio frequency emissions (RF) CISPR 11	Group 1	The device 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 frequency emissions - CISPR 11	Class B	The device 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	
Electromedical appliances require special precautions concerning EMC. They therefore need to be installed and commissioned following the EMC information supplied. Electromedical appliances may be affected by mobile and portable RF communication devices. WARNING: using cables and accessories other than those specified, except for those sold by Kinetec as replacements for internal components, may lead to an increase in emissions or a decrease in The device KINETEC® Prima Advance machine's immunity. WARNING: The device KINETEC® Prima Advance should not be used next to other appliances. If The device KINETEC® Prima Advance must be used next to other appliances, it should be under constant supervision to check that it is working normally in the given configuration.		

Guidance and manufacturer's declaration - Electromagnetic immunity			
The device KINETEC® Prima Advance is intended for use in the electromagnetic environment specified below. The customer or the user of The device KINETEC® Prima Advance 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	±6 kV - contact ±8 kV - air	±6 kV - contact ±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 blinking, switch the machine OFF then ON again and push the START button: the movement will start again.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for electrical power lines ±1 kV for input/output lines	±2 kV for electrical power lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV phase-to-phase ±2 kV phase-to-earth	1 kV phase-to-phase ±2 kV phase-to-earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions 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 5 seconds	< 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 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of The device KINETEC® Prima Advance requires continued operation during power supply interruptions, we recommend powering The device KINETEC® Prima Advance using an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field - EC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration

Guidance and manufacturer's declaration – Electromagnetic immunity

The device KINETEC® Prima Advance is intended for use in the electromagnetic environment specified below. The customer or the user of The device KINETEC® Prima Advance should ensure that it is used in such an environment.

Immunity test	Test level according to IEC 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® Prima Advance machine, 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® Prima Advance machine is used exceeds the aforementioned applicable RF compliance level, The device KINETEC® Prima Advance machine 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 KINETEC™ Prima Advance.

[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® Prima Advance machine

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