



User manual

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

EN

467896340 – 12-2009
Serie 1 - 2

Spectra Essential



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A Patterson Medical Company
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PATTERSON
MEDICAL

Definition

The KINETEC Spectra Essential is a PASSIVE Knee mobilisation device enabling the extension and flexion movement from -10° to 120°.

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.
- Digital ROM readout on the patient hand control for positive reinforcement.
- Maintains desired positions for stretching and muscular rest.

Contraindications

Bone Cancer, warped joint surfaces, spastic paralysies, unstable fractures, uncontrolled infection.
The machine is not suitable for patients over 2 m (6'7") or under 1,40m (4'7").

Warning and Safety instructions

- | | |
|----------|---|
| Warning: | The physician/physiotherapist defines the protocol and ensures that it is correctly implemented (adjustments, session time 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 3. |
| Warning: | To avoid the parameters being changed, lock the machine's hand control before giving it to the patient. |
| Warning: | Danger, risk of explosion: Do not use the machine with anaesthetic gas or in an environment that is rich in oxygen |
| Warning: | To avoid all risks of electric shock, the machine should only be connected to a power supply that has protective earthing |
| 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 moving parts while the unit is running, pinching risk. |
| Warning: | Modifying the machine in any way is strictly forbidden. |

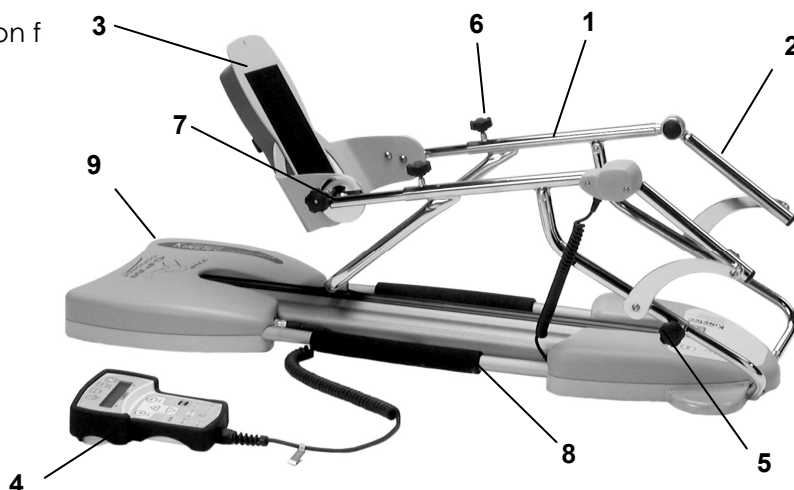
Compliance:

KINETEC *Spectra Essential* complies with the standards of Directive 93/42/EEC, and bears the CE mark.
KINETEC *Spectra Essential* complies with the standards in force (IEC 601.1.2) concerning the electromagnetic compatibility of medical devices.
Kinetec Spectra Essential complies with the standards of Directives Machine n°2006/42/CE.

Description

The KINETEC *Spectra Essential* machine consists of the following components:

- 1 • Lower limb support.
- 2 • Thigh support.
- 3 • Foot support and hand control location for transport.
- 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.

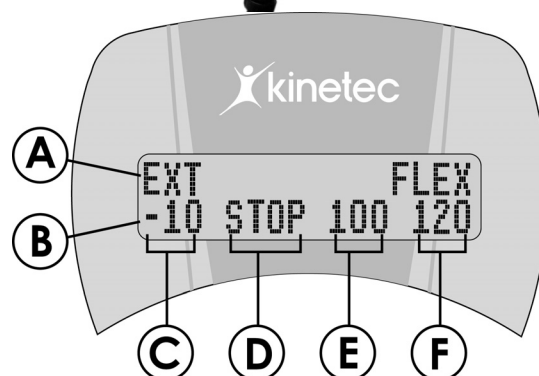


- 10 • Liquid-crystal display (2 lines of 16 characters).
- 11 • Increase / decrease keys.
- 12 • EXTENSION setting key.
- 13 • FLEXION setting key.
- 14 • STOP key.
- 15 • START key.
- 16 • PAUSE key.
- 17 • SPEED key.



Display Details:

- A • 16-character line, used to display various messages when starting up the machine; then the display does not change while the machine is being used.
- 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 in line with the movement.
- F • 3-character area showing the flexion limit.

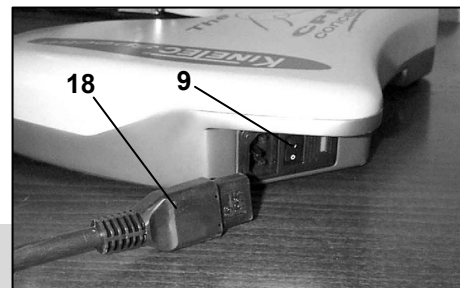


Electrical connection: SAFETY FIRST.

The KINETEC *Spectra Essential* Machine is a type B class I device I.
Before connecting the device to the power supply, check that the mains voltage matches that shown on the identification plate (100-240 V~ 50-60Hz).

Connect the hand control (4)

Connect the power supply cable (18).



IMPORTANT

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.

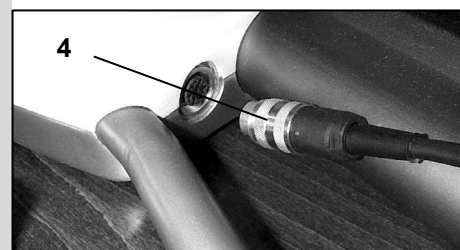
The plug may be connected to any standard socket.

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.

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



Starting the unit

Switch on the unit (9).

The display comes on, the machine carries out a self-test, and then the display shows:

Your KINETEC *Spectra Essential* is ready to be used.

EXT 30 STOP 15 FLEX 70

Changing the display language

Press the following buttons simultaneously:



and



, followed by



or



to

Press the



button to confirm,

then switch the machine off and then on again to apply the changed display language.

Available languages: English, French, German, Italian and Spanish.

START/STOP/REVERSE function

As with all KINETEC systems, KINETEC *Spectra* is equipped with a START/STOP/REVERSE function.

When the unit is running, the display reads RUN.

Press the



key of the hand control. The movement stops.

Press the



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

Caution:

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

Procedure to stop the machine:

To stop the machine's movement: Press the



button.

To switch power off: press the ON / OFF switch (9).

Locking the hand control setting

The hand control allows the patient to control the machine as appropriate.

Simultaneously press the



and



keys to lock the hand control,

The display reads **LOCK**, you cannot change the parameters, if you try the display reads **LOCK SOFT**, To unlock the hand control, simultaneously press the same keys, The display reads **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.

Setting the movement parameters

Select the parameter to be set:

Extension limit  or flexion limit  or speed  or pause  at the extension or flexion limit; the setting to change will flash.

Press the  or  buttons to modify the setting; the new setting will flash.

To confirm the new setting, press another function button or wait approximately 5 seconds for automatic confirmation.

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

NB: pressing the  button repeatedly allows you to select pausing at the extension or flexion limit.

Possible values for each parameter:

	Possible values	Default setting
• Extension limit	-10 to 115°	30°
• Flexion limit	-5° to 120°	70°
• Speed	1 to 5 (from 45° to 155° per minute)	2
• Extension pause	0 to 900 seconds (15minutes)	0
• Flexion pause	0 to 900 seconds (15minutes)	0

Using the Plastic Comfort Case kit

Specially designed to improve comfort and hygiene for the patient.

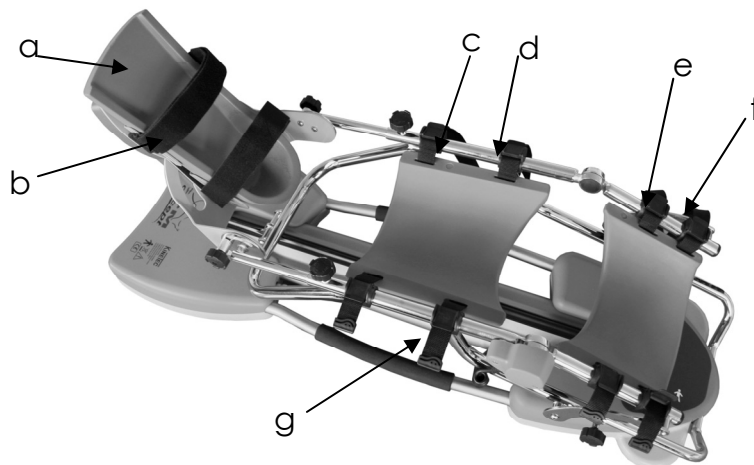
Plastic Comfort Cases come with clips, fixed directly on the tubes of the machine's thigh and lower limb support segments, and straps with protection stops to precisely and quickly adjust to the patient's leg dimensions.

CLEANING

To ensure optimal hygiene, clean the supports after each patient use. To clean, spray the surfaces with disinfectant (use a propanol/isopropanol or aldehyde-based solution).

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).



Use of the Kinetec Patient Pad Kit

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

- For using and positioning the straps, please refer to here under. Make sure that the self-adhesive parts (19) 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

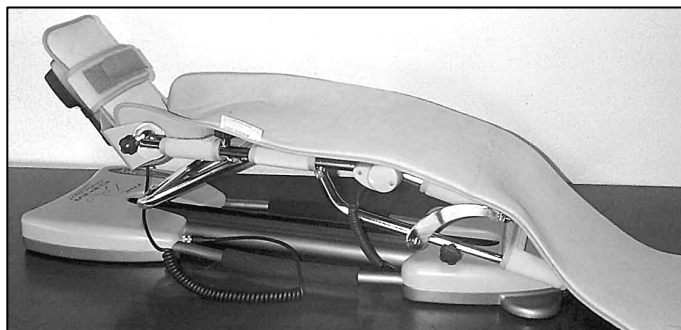
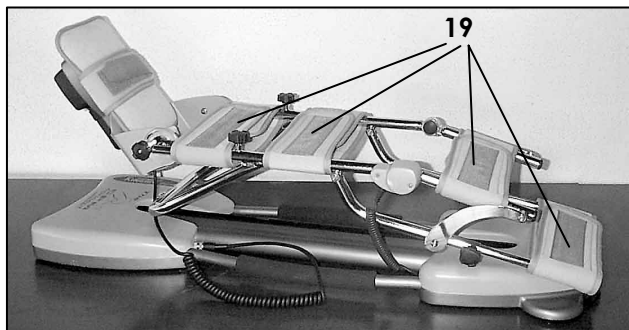
CLEANING:

- Sterilization of the pads (if necessary): Sterilized at 134 °C during 18 minutes.
- Disinfecting of the pads: Washing at 30°C with use of a disinfecting solution during the rising cycle.
Example 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 KINETEC Spectra is delivered with a complete set. Components:

- 4 straps (4650001107)
- 1 foot support (4650001420)
- 1 cover (4650001090)

Part number to order the complete set: 4650001868



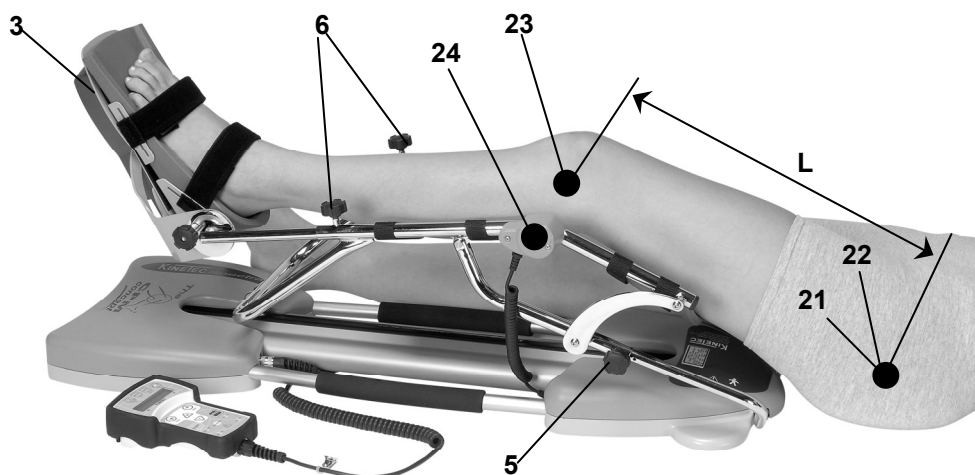
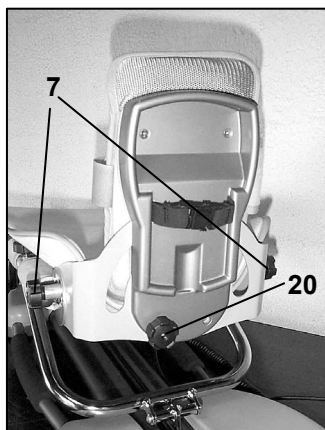
Setting up the patient

Place the KINETEC Spectra Essential 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 Spectra Essential 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 (20).

IMPORTANT

Adjust the axis of the patient's hip (21) with the axis rotation (22) of the KINETEC Spectra Essential machine, and the axis of the patient's knee (23) with the axis rotation (24) of the KINETEC Spectra Essential machine.



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, the KINETEC Spectra Essential requires lubrication and maintenance operations (lubrication of the joints, pointer stops and ball screws).

The need for maintenance is indicated by display of the message **SERV. MOTOR** when the system is switched on.

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

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. Simultaneously press keys



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

this counter can be reset by pressing the key



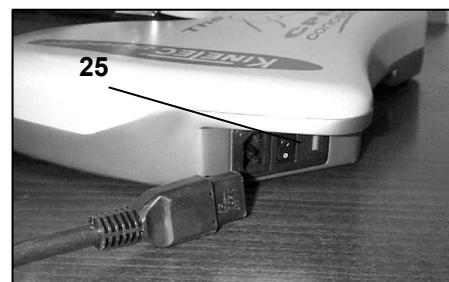
Troubleshooting

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 the KINETEC Spectra Essential:

- The display does not indicate any information:
 - Check that the electrical socket is live using another device.
 - Replace the fuse(s) (25) of the connector with fuses of the same type and calibre: 2 fuses T 750 mA 250V (6.3 x 32) (KINETEC order: 4610007434).
 - If the display still does not indicate any information, contact your nearest KINETEC technician.
- Your KINETEC Spectra does not work and the display indicates **50 STOP 25 115**, Press START again.
 - Your KINETEC Spectra Essential still does not function: Contact your nearest KINETEC technician.
- Your KINETEC Spectra Essential does not function and the display indicates:
 - SERVICE D1: angle measurement function failure,
 - or SERVICE D2: no movement,
 - or SERVICE D3: abnormal consumption,
 - or SERVICE D4: power failure or disconnected motor,

Contact your nearest KINETEC technician if the same message is displayed after having switched the device off, then on, and started it by pressing START



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.

Cleaning should be carried out in the environmental conditions specified in the "Technical Specifications" section below.

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

Elimination and recycling

- a • **Packing:** Packing must be separated from the components plastic and paper/cardboard and given to the specific sites for recycling.
- b • **KINETEC PATIENT PAD KIT:** Clean with disinfectant then to give it to the specific sites for recycling.
- c • **Unit:** It contains electronic components, cables, aluminium, 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 return the machine to Kinetec for destruction.

Technical specifications

Product :

Weight: 12Kg (24 pounds)

Splint dimensions:

95cm (37 inches) x 33cm (13 inches) x 33cm (13 inches)

Angular limits: -10° to 120°

Speed: from 45 to 155° per minute.

Patient height: full leg: 71 to 99 cm (28 to 39 inches)

Tibia: 38 to 53 cm (15 to 23 inches)

Femur: 33 to 46 cm (13 to 18 inches)

Electricity:

Power supply: 100-240 V~

Frequency: 50-60 Hz

Power consumption: 50 VA

Device of type B class I

IP 20.

Fuse T 750mA 250V 6.3x32mm (KINETEC order: 4610007434)

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%

Symbols used

	TYPE B device (protection against electric shocks)
	Warning or CAUTION (check accompanying documentation)
	STOP (power off)
	ON (power on)
	Refer to the operating instructions
	Right way up when box is stored
	Contains electric and electronic components; not to throw in the dustbins of household refuse

	Speed
	Pause
	Increase
	Decrease
	Temperature Limit during storage or transport
	Fragile

	Flexion limit
	Extension limit
	Start movement
	Stop movement
	Alternative current
	Keep dry during storage or transport

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.

GUIDANCE AND MANUFACTURER'S DECLARATION

Electromagnetic emissions

The « KINETEC Spectra Essential » is intended for use in the electromagnetic environment specified below. The customer or the user of the « KINETEC Spectra Essential » should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
Radio electric-Frequency emissions CISPR 11	Group 1	The « KINETEC Spectra Essential » 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 The « KINETEC Spectra Essential » 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.
Radio electric-Frequency emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

The « KINETEC Spectra Essential » is intended for use in the electromagnetic environment specified below. The customer or the user of the « KINETEC Spectra Essential » 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	Complies	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.
	±2 kV, ±4 kV, ±8 kV air	Complies	
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines	Complies	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	Complies	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	Complies	At the interruption, there is a reset of the « KINETEC Spectra Essential ». 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	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the « KINETEC Spectra Essential » requires continued operation during power supply interruptions, it is recommended that the « KINETEC Spectra Essential » be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	Complies	
	70% U_T (30% dip in U_T) for 25 cycles	Complies	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	Complies	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.



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