

Breva

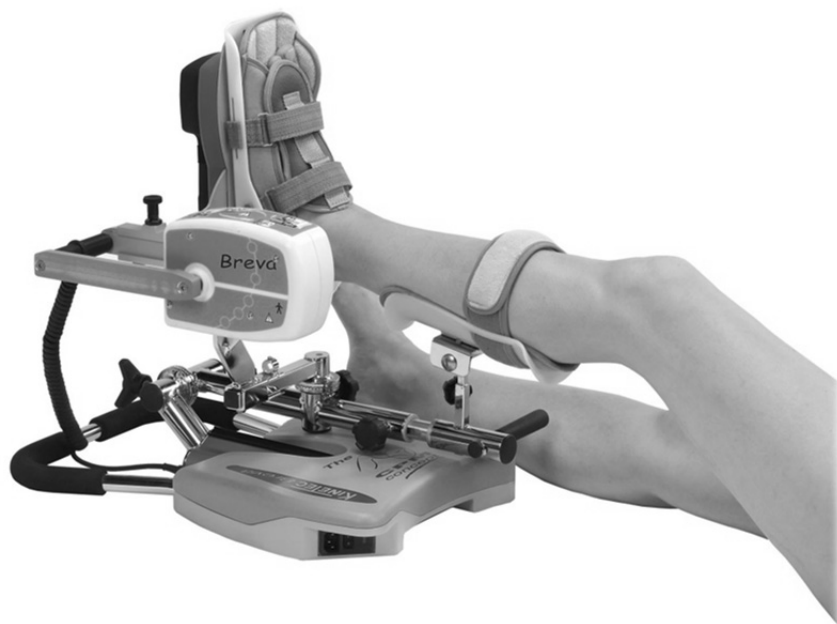
User manual

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

EN



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1. Definition

The device KINETEC® Breva is a PASSIVE mobilisation device for the rear foot and allows the following movements:

- Plantar Flexion / Dorsiflexion
- Eversion / Inversion

2. Indications

Passive mobilization of the following fractures after osteosynthesis:

- Malleolar fractures,
- Tibial pilon fractures,
- Talar fractures,
- Calcaneal fractures.

Mobilisation of the joints of the foot after operative or other treatment of lesions of the:

- Achilles tendon,
- Lateral collateral ligament,
- Medial collateral ligament.

Surgical lengthening of the Achilles tendon for post-traumatic stiffness.

3. Clinical Benefits

- Effectively breaks the vicious circle of trauma → immobility → effusion → atrophy.
- Improves the nutrition of joint surfaces.
- Speeds the recovery of post-operative range of motion.
- Stimulates the venous circulation of the lower leg.
- Speedy recovery of the motor pattern for the limb operated on.
- Promotes joint cartilage healing.
- Prevents venous thrombosis.
- Provides immediate post-operative continuous passive motion.
- Reduces hospitalization time.
- Reduces the need for pain medication.
- Visual feedback for users.
- Realization of postures (resting, stretching muscles).

4. Contraindications

Rheumatoid arthritis in the inflammatory phase, algodystrophy in the inflammatory phase (hyper painful), para-osteo-arthroplasty, unhealed infected wounds, bone cancer, infectious arthritis, deformed joint surfaces, paralysed limbs (atonic or spastic), non-stabilised fractures.

5. 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 7.
- WARNING: To avoid the parameters being changed, lock the machine's hand control before giving it to the patient, see page 7.
- 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 6.
- 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 20.

6. Compliance

The device KINETEC® Breva complies with the standards of Directive 93/42/EEC, and bears the EC mark.

The device KINETEC® Breva 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® Breva meets the requirements of the Machinery Directive No. 2006/42/EC.

7. 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.

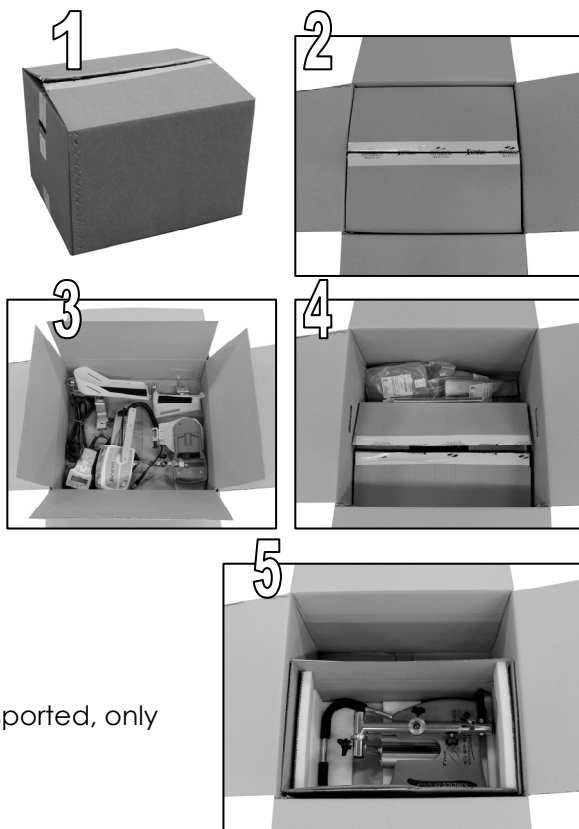
Be careful with cables and wires: risk of strangulation.

Your machine is ready to be connected to the power supply. (See page 6)

Packing

To prevent any problems when the machine is transported, only pack it using its original packaging.

- Stop the motor at 0°
- Remove all accessories from the machine
- Set the leg extension to its minimum length
- Fold up the central bar and tighten the fastening knob
- Place the machine's base in the bottom box (step 5)
- Place the straps in the free space (step 4)
- Place the second box, containing the unit's other accessories



8. Installing the device

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

The Brevia machine can be used with a physiotherapy table, a healthcare bed, a bed or a chair.

The machine must be installed on a flat surface that is wide enough to accommodate the entire device plus the other leg.

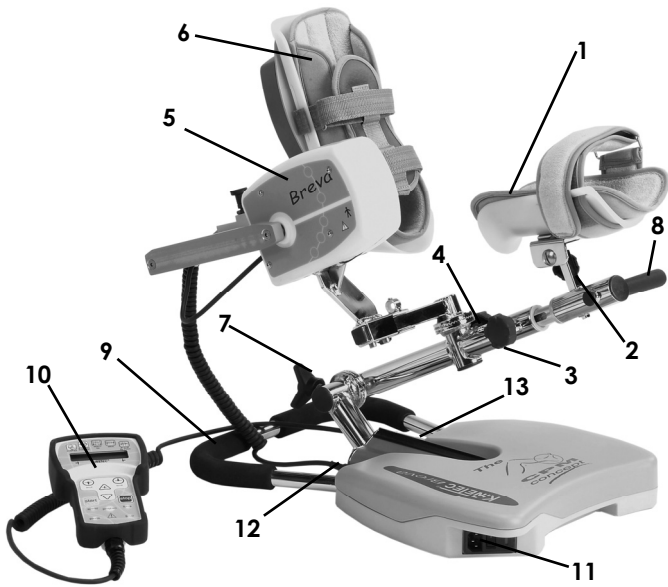
If a chair is used, we recommend checking whether the floor is slippery in order to ensure that the machine does not move during the session.

We do not recommend using the machine with a bench.

We do not recommend the use of an air mattress.

9. Description

The device KINETEC® Brevá is a portable, one-piece device. It consists of the following components:

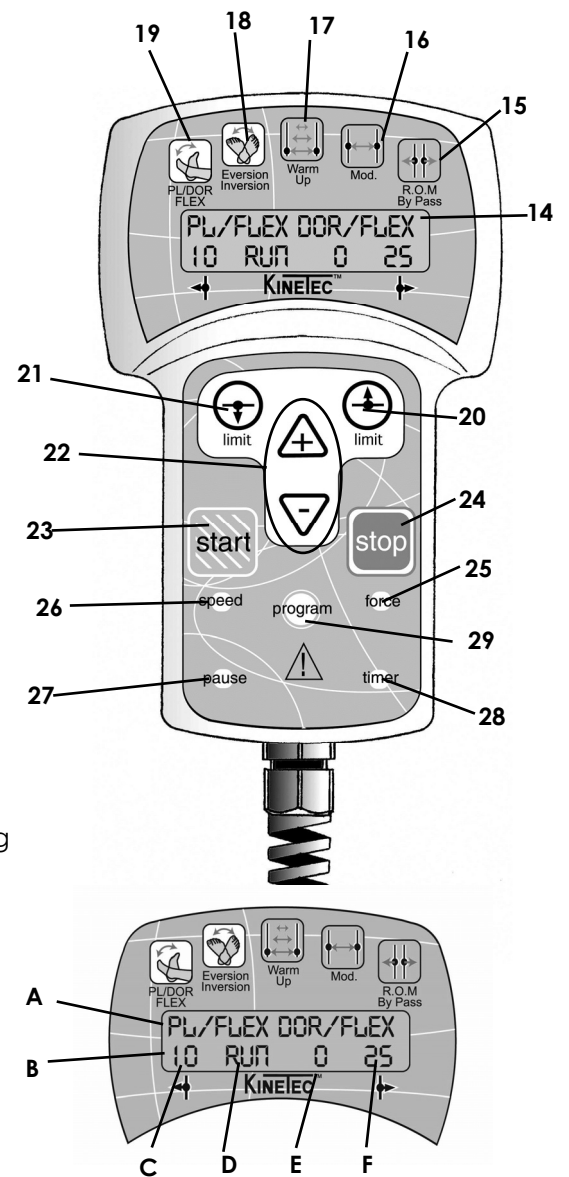


- 1 • Calf support
- 2 • Calf support setting lock
- 3 • Lower limb setting lock
- 4 • Motor position setting lock
- 5 • Motor
- 6 • Foot support
- 7 • Bed or chair position setting lock
- 8 • Position handle
- 9 • Transport handle
- 10 • Hand control
- 11 • ON/OFF switch
- 12 • Motor connector
- 13 • Hand control connector

- 14 • Liquid-crystal display (2 lines of 16 characters)
- 15 • BYPASS mode key
- 16 • MODULATION key
- 17 • WARM UP key
- 18 • Eversion / Inversion key
- 19 • Plantar flexion/dorsiflexion key
- 20 • Upper limits setting
- 21 • Lower limits setting
- 22 • Increase / decrease keys
- 23 • START key
- 24 • STOP key
- 25 • FORCE key
- 26 • SPEED key
- 27 • PAUSE key
- 28 • TIMER key
- 29 • PROGRAM access key

Display Details:

- A • 16-character line, used to display various messages when starting up the machine, then the type of movement during operation.
- 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 lower limit.
- D • 4-character area showing various messages: RUN, STOP, EXT, FLEX ...
- E • 3-character area showing the real-time angle of the knee; this value changes with the current movement.
- F • 3-character area showing the upper limit.



10. Electrical connection: safety first.

2 versions of electrical protection are available for the device KINETEC® Breva 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:

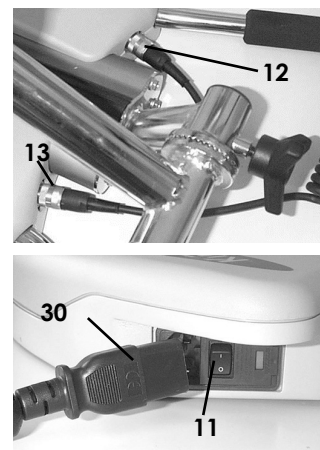


See page 18 for the meaning of the symbols.

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

Connect the hand control (13) and the motor (12).

Connect the power supply cable (30).



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.

11. Using the hand control

11.1. Starting the unit

Press the ON / OFF switch (11).

The display comes on, the machine carries out a self-test and the display shows in succession



Your device KINETEC® Breva is ready to be used.

Note: The parameters from the last session are retained when the machine is switched on/off. (except Timer and Warm Up mode)

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


11.2. Changing the display language

Beginning	Keys to press	Display	Remarks
Switch the unit ON		KINETEC 40 STOP 50 110	Check that the hand control is not locked (See page 7).
Press simultaneously on the 2 keys	speed force	LANGUAGE ENGLISH	The display indicates the language selected.
To change the language	+ - Or	LANGUAGE FRENCH	The French language is selected. Available languages: English, French, German, Italian and Spanish.
To confirm the new language	limit	OK SWITCH ON/OFF	To exit and confirm the new language, switch OFF and Switch ON the unit.

11.3. START / STOP / REVERSE function

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

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.

11.4. Procedure to stop the machine:

To stop the machine's movement: press the  key

To switch the unit off: press the ON / OFF switch (11) (see page 6)

11.5. Locking-Unlocking 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 message "LOCK" will be displayed.

To unlock the hand control, simultaneously press the  and  keys, the display reads **"UNLOCK"**.

We recommend that you lock the hand control when you give it to the patient.






Note: hand control locking is preserved when you switch the unit ON/OFF.

11.6. Possible values for each parameter
















	Possible values		Default setting	
	Plantar Flexion/Dorsiflexion	Inversion/Eversion	Plantar Flexion/Dorsiflexion	Inversion/Eversion
• Lower limit	Plantar Flexion 40° Dorsiflexion 25°	25° inversion to 20° eversion, right foot 25° eversion to 20° inversion, left foot	Plantar flexion 20°	10° Inversion or Eversion, depending on the foot
• Upper limit	Plantar Flexion 35° Dorsiflexion 30°	20° inversion to 25° eversion, right foot 20° eversion to 25° inversion, left foot	Dorsiflexion 0°	10° Eversion or Inversion, depending on the foot
• Speed	1 to 5 (from 50 to 150° per minute)		2	
• Force	1 to 6		6	
• Extension pause	0 to 900 seconds (15 minutes)		0	
• Flexion pause	0 to 900 seconds (15 minutes)		0	
• Timer	No timer (00H00) to 24H00		0	

11.7. Quick Start

Set up the patient and proceed as below:

Beginning	Keys to press	Display	Remarks
Switch the unit ON		PL/FLEX DOR/FLEX 20 STOP 0 20	The display indicates the last movement selected.
To select the Inversion/Eversion movement	 or  or 	INVERSION/EVERS. RIGHT:+ LEFT:- EV RIGHT INV 10 STOP 0 10 INV LEFT EV 10 STOP 0 10	The display shows the movement selected and then the key to select the foot (+ for right or - for left).
To select the Plantar Flexion/Dorsiflexion movement		PL/FLEX PL/FLEX 20 STOP 0 0	The display shows the movement selected, with the default settings.
To start the session with the original parameters for the movement (default setting).		PL/FLEX PL/FLEX 20 RUN 3 0	The angle display changes with the current movement.

11.8. To adjust the basic parameters of the movement

Beginning	Keys to press	Display	Remarks
To stop the unit		PL/FLEX PL/FLEX 20 STOP 5 0	Check that the hand control is not locked (See page 7).
To select the Inversion/Eversion movement	 or  or 	INVERSION/EVERS. RIGHT:+ LEFT:- EV RIGHT INV 10 STOP 5 10 INV LEFT EV 10 STOP 5 10	The display shows the movement selected and then the key to select the foot (+ for right or - for left).
To select the Plantar Flexion/Dorsiflexion movement		PL/FLEX PL/FLEX 20 STOP 5 0	The display shows the movement selected, with the default settings.
To display the limit for the movement	or  or 	PL/FLEX PL/FLEX 20 PL 5 0 PL/FLEX PL/FLEX 20 DOR 5 0	The value blinks.
To change the limit if necessary	 or 	PL/FLEX DOR/FLEX 20 DOR 5 15	The new value blinks.
To confirm the new value, press another key or wait more than 3 seconds for automatic confirmation.	  	PL/FLEX DOR/FLEX SPEED 2 PL/FLEX DOR/FLEX FORCE ___ PL/FLEX DOR/FLEX Timer disable	While the value blinks press the (+) or (-) key to change if necessary.
Or To display the pause at the movement's upper or lower limit		PL/FLEX DOR/FLEX PAUSE DOR 0S PL/FLEX DOR/FLEX PAUSE PL 0S	Successive presses on this key selects the pause at the movement's upper or lower limit.
To change the pause if necessary	 or 	PL/FLEX DOR/FLEX PAUSE PL 15S	The new pause value blinks.
To confirm the new value press another key or wait more than 3 seconds. The display shows the selected mode		PL/FLEX PL/FLEX 20 STOP 5 15	The unit is ready to start with the new parameters.

Comments: The values in the display column are given as an example.

11.9. PROGRAM MODE: To enter a program



Beginning	Keys to press	Display	Remarks
To switch off the unit			
Press the 2 keys at the same time and switch the unit ON		KINETEC BREVA V01.0	Welcome text displayed for 3 seconds
Then		Program 1 EMPTY	The program number blinks.
To change the program if necessary	or	Program 10 EMPTY	The new program number blinks.
To choose the movement		RIGHT PROG No.10 10 INV/EVE 10	The display indicates the movement. After selecting the movement press the Warm Up key to confirm Warm Up.
		LEFT PROG No.10 10 INV/EVE 10	
		Program 10 20 PL/DOR 0	
To display the extension or flexion limit of the movement		Program 10 20 PL/DOR 0	The value blinks.
	or	Program 10 20 PL/DOR 0	
To change the limit if necessary	or	Program 10 20 PL/DOR 20	The new value blinks.
To confirm the new value, press another key or wait more than 3 seconds		Program 10 Speed: 1	While the value blinks press the (+) or (-) key to change if necessary.
		Program 10 Force: _____	
		Program 10 Timer disable	
		Program 10 Pause PL 0s	
To record program 10		Program 10 Save:+ clear:-	
Then		Program 10 Saving	Program 10 has been recorded and the display indicates the next program so you can change another program.
		Program 11 EMPTY	
OR To cancel the program		Program 10 CLEARING	Program 10 has been removed and the display indicates the next program so you can change another program.
		Program 11 EMPTY	
To exit program mode, switch the unit OFF and switch back ON.		KINETEC BREVA V01.0	To use the modified program see page 10.











Comments: The values in the display column are given as an example.

Comments:

- When a program has been deleted, the display shows










Program table:

Program number	Movement type	Lower limit	Upper limit	Speed	Force	Pause at upper limit	Pause at lower limit	Timer
1	  							
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								








11.10. Using Programs

The device KINETEC® Breva allows you to store up to 16 programs (numbered 1 to 16), including the type of movement, ROM, speed, force, pauses and timer.

The original parameter values of the program are empty. These values can be modified and saved at any time (see 'To enter a program', page 9)

Beginning	Keys to press	Display	Remarks
To stop the unit		PL/FLEX DOR/FLEX 20 STOP 5 20	Check that the hand control is not locked (See page 7).
To access program mode		PROGRAM 1 EMPTY	The program number blinks.
To change the program if necessary	 or 	PROGRAM 10 20 PL/DOR 0	The new program number blinks.
To exit and confirm the selected program		PL/FLEX PL/FLEX 20 STOP 5 0	The current parameters are those recorded in program 10.
To exit without confirming the selected program		PL/FLEX DOR/FLEX 20 STOP 5 20	Back to the starting parameters.
To start the unit		PL/FLEX PL/FLEX 20 STOP 10 0	The angle display changes with the current movement.

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

Beginning	Keys to press	Display	Remarks
To stop the unit		PL/FLEX PL/FLEX 20 STOP 10 0	Check that the hand control is not locked (See page 7).
To access program mode		PROGRAM 1 EMPTY	The program number blinks.
To change the program if necessary	 or 	PROGRAM 10 20 PL/DOR 0	The new program number blinks.
To read the speed value		PROGRAM 10 SPEED: 1	Displays the speed value.
After 5 seconds or after pressing on another key		PL/FLEX PL/FLEX 20 STOP 10 0	
To exit and confirm the selected program		PL/FLEX PL/FLEX 20 STOP 10 0	The current parameters are those recorded in program 10.
To start the unit		PL/FLEX PL/FLEX 20 STOP 10 0	The angle display changes with the current movement.

Comments:

- The values shown in the 'Display' column are examples. They actually depend on the stored programs.
- The current movement parameters can be changed while using that program but no data will be stored in the original program. See programming mode (page 9) to modify programs.

11.12. To use the WARM UP key



Beginning	Keys to press	Display	Remarks
To stop the unit		PL/FLEX DOR/FLEX 20 STOP 10 5	Check that the hand control is not locked (See page 7).
To select the Plantar Flexion/Dorsiflexion movement		PL/FLEX DOR/FLEX 20 STOP 10 5	
To select Warm Up mode		PL/DOR FLX W.UP 20 STOP 10 5	To set movement values, see page 8.
OR To select the Inversion/Eversion movement		INVERSION/EVERS. RIGHT:+ LEFT:-	
To select the right or left foot		EV Right INV 10 STOP 10 10	
To select Warm Up mode		EV W UP RIGHT INV 10 STOP 10 10	The angle display changes with the current movement.
To start the movement		EV W UP RIGHT INV 10 RUN 10 10	

Warm Up rules.

The device KINETEC® Breva starts at 70% of the full ROM, increasing 5% of the range each full cycle until the pre-set ROM is reached.

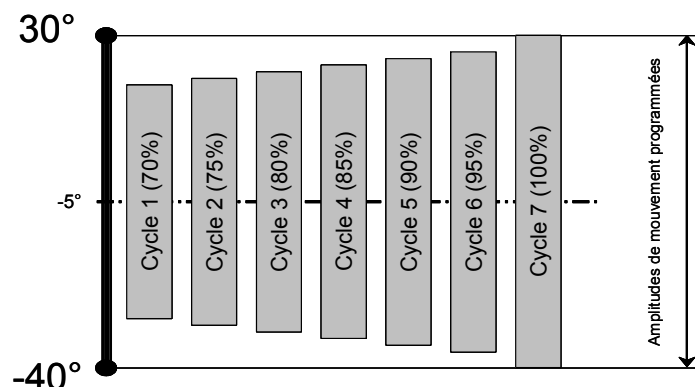
Note:

- The parameters should only be modified while the unit is stopped.
- Pauses and ByPass mode are not available during warm up cycles.
- The Warm Up cycles are only performed when the movement is first started.
- To start a new Warm Up session, press the "Warm Up" key twice.
- The calculation mode used enables the pre-set ROM to be reached in approximately seven full cycles.

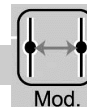
Example:

For a Warm Up treatment with a pre-set ROM from 40° to 30°.







The first cycle starts at 32° plantar to 22° dorsal, increasing 5% of the range each cycle.



11.13. To define the patient tolerance • At the start of a session



This function, MODULATION MODE, allows the maximum limits that a patient can tolerate to be defined and recorded at the beginning of a session.
Set up the patient and proceed as below:

Beginning	Keys to press	Display	Remarks
Switch the unit ON		KINETEC BREVA V01.0	
		PL/FLEX DOR/FLEX Please wait	
		PL/FLEX DOR/FLEX 20 STOP 18 20	
To select the desired movement	 Eversion Inversion	EV RIGHT INV 10 STOP 18 18	The display shows the movement selected, with the default settings.
	 FL/DOR FLEX	PL/FLEX DOR/FLEX 20 STOP 18 20	
To select MODULATION MODE	 Mod.	: use +or- 20 STOP 18 20	The display indicates the keys used to run the machine. This message is displayed 3 seconds.
To select the pain level (+ key for flexion, - key for extension)	 Continuous press	MODUL.: use +or- 20 MANUAL 28 28	The unit begins to move as selected. The settings are controlled by you.
To set the pain level when reached	 limit	MODUL.: use +or- 20 MANUAL 28 28	The new limit of the movement is recorded.
To start the session with the new movement limits		PL/FLEX DOR/FLEX 20 RUN 15 28	The angle display changes with the current movement.





Note: when the movement's max. limit is reached, the max. angle is automatically recorded and the function is exited.

11.14. To define the patient tolerance • During the session



This function, BYPASS MODE, allows the maximum limits that a patient can tolerate to be defined and recorded, which allows you to work on increasing amplitude.

IMPORTANT: this function can be only used when the machine is running (but not during Warm Up cycles).

Beginning	Keys to press	Display	Remarks
The unit is running		PL/FLEX DOR/FLEX 20 RUN 15 28	Check that the hand control is not locked (See page 7).
To select BYPASS MODE	 R.O.M By Pass	BYPASS: USE +or- 20 RUN 20 28	The display indicates the keys used to run the machine. This message is displayed 3 seconds.
To select the NEW pain level	 continuously press	BYPASS: USE +or- 20BYPASS 30 28	The unit begins to move as selected. The settings are controlled by you.
To set the new pain level when reached	 limit	BYPASS: USE +or- 30BYPASS 30 28	The new limit of the movement is recorded.
Continue the session with the new movement limits		PL/FLEX DOR/FLEX 30 RUN 17 28	The angle display changes with the current movement.

Note: when the movement's max. limit is reached, the max. angle is automatically recorded and the function is exited.

12. Using the device KINETEC Patient Pad kit

The device 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.

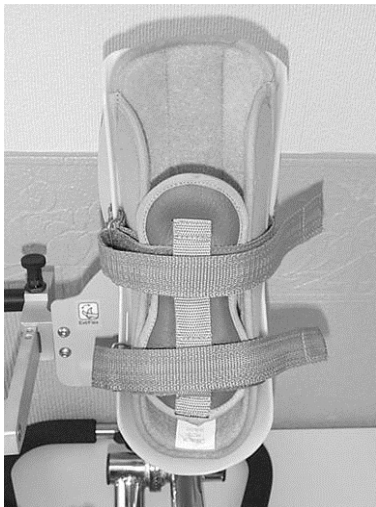
CLEANING:

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 "Souplanos" at 0.125% from ANIOS Laboratories.

A complete list of distributors in your country is available on request.

Adult slipper



Paediatrics slipper



Pads for calf support.

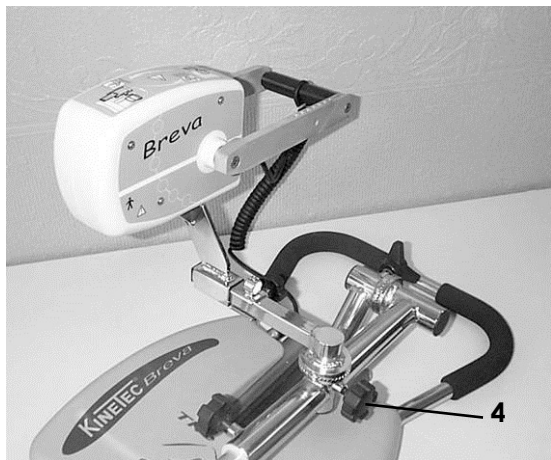


13. Possible movements

13.1. Extension / Flexion



The device KINETEC® Breva provides movements from 40° of plantar flexion to 30° of dorsiflexion.



Loosen the button (4).
Position the motor as shown above.
Tighten the button (4).



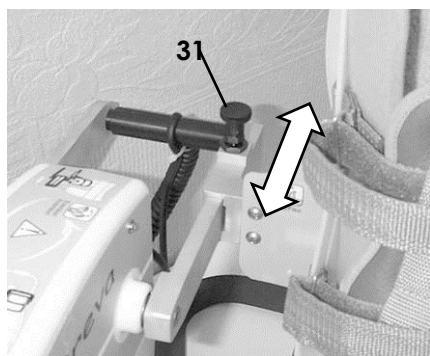
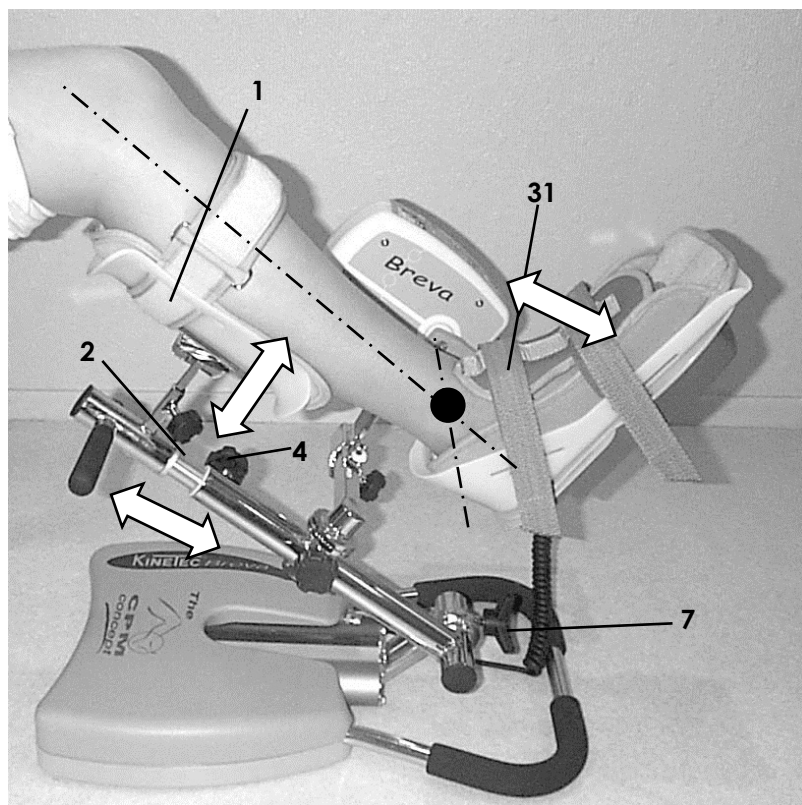
Position the Extension/Flexion footplate as shown. A label indicates which footplate is to be used.

Setting up the patient.


Adjust the slope of the splint with the button (7), in either the sitting or lying-down position.

Adjust the calf support position (1) with the knobs (2) and (4). The calf support slope is free.

The knob (31) allows the depth of the foot to be adjusted.



• Select the Extension/Flexion movement:

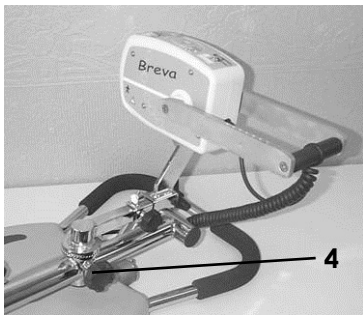
- Press  and set the movement parameters (see page 8).

- or select a program  (see page 11).

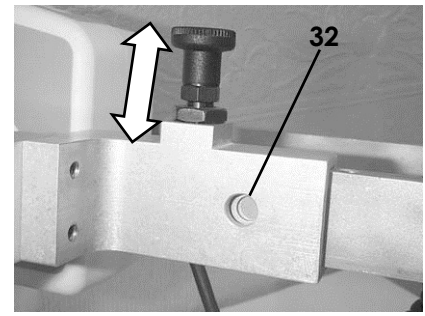
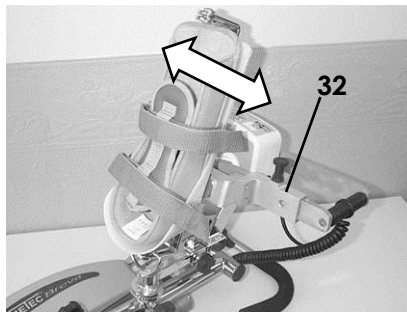


13.2. Eversion / Inversion

The device KINETEC® Breva provides movements from 25° of abduction to 25° of adduction, with a Valgus/Varus component.

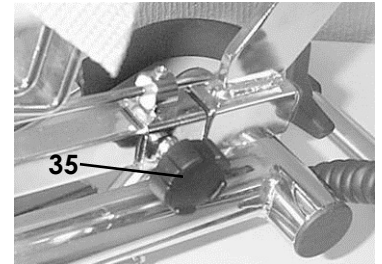
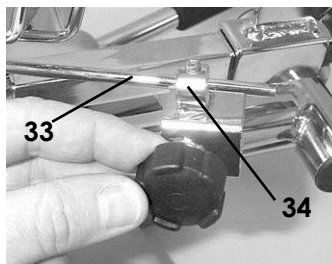


Loosen the button (4).
Position the motor as shown above.
Tighten the button (4).



Position the Extension/Flexion footplate as shown. A label indicates which footplate is to be used.
The green indicator (32) shows when it is in the correct position.

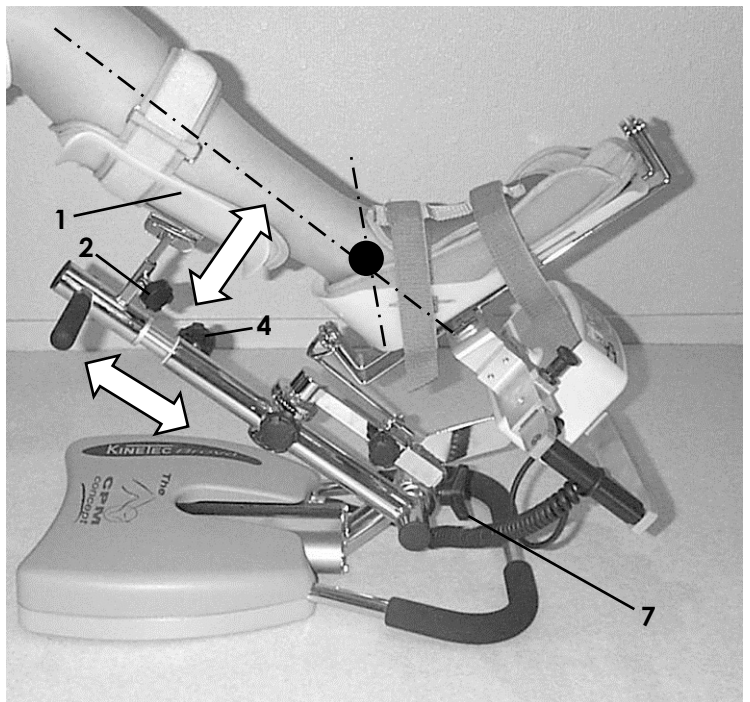
Position the synchronization bar (33) in its guide (34) and tighten the knob (35).



Setting up the patient.

Adjust the slope of the splint with the button (7), in either the sitting or lying-down position.

Adjust the calf support position (1) with the knobs (2) and (4). The calf support slope is free.



• Select the Eversion/Inversion movement:

- Press  and set the movement parameters (see page 8).

- or select a program  (see page 11).

14. Product information

14.1. Maintenance

After 2,000 hours of operation, or once a year, the device KINETEC® Breva requires lubrication and maintenance operations (lubrication of the joints and pointer stops). The need for maintenance is indicated by display of the message **SERVICE TIME Mx** when the system is switched on.

Despite this indication, you can continue to use your machine by pressing **[START]**, but you should contact your nearest KINETEC technician to have the maintenance operations carried out as soon as possible.

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.

A motor running time counter is available by simultaneously pressing keys




and



;

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

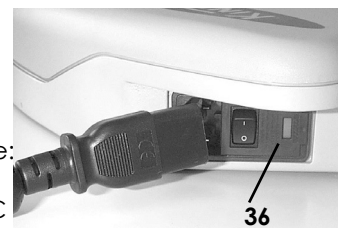
This counter can be reset by pressing the key .

14.2. Troubleshooting guide

A spare parts list and technical catalogue are available on request from your KINETEC distributor.

If, after connecting the power supply cable to the power supply and switching on the machine:

- The display does not indicate any information:
 - Check that the electrical socket is live using another device or voltmeter.
 - Check if the remote control is well connected.
 - Replace the fuse(s) (36) 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 device KINETEC® Breva does not work and the display indicates **"0 STOP 25 25"**, press **START** again.
If your KINETEC machine still does not work, contact your nearest KINETEC technician.
- Your device KINETEC® Breva does not work and the display indicates:
 - "SERVICE D1": angle measurement function failure,
 - or "SERVICE D2": no movement,
 - or "SERVICE D3": abnormal electrical consumption by motor,
 - or "PUSH STOP/START": power failure or disconnected motor.switch the machine off then on,
contact your nearest KINETEC technician if the same message is displayed



14.3. Cleaning

Before carrying out any cleaning operation, SWITCH OFF the unit and disconnect the power supply. In order to ensure optimal hygiene, you are advised to clean the machine for each new patient.

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

Use a DISINFECTANT product (alcohol-free or <5% alcohol solution) in spray.

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

14.4. Disposal and recycling

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

14.5. Technical specifications

Product:

Lifespan of the machine:	12 years
Weight:	10.9 kg (24 pounds)
Splint dimensions:	56cm (22in.) x 37cm (14.5in.) x 45cm (17in.)
Angular limits:	see page 7
Speeds:	from 50 to 150° per minute
Foot sizes:	from 19cm (7.5in.) to 29cm (11.4in.)
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.

14.6. Symbols used

	CAUTION (consult the accompanying documentation)		Speed		Flexion limit
	STOP (power off)		Timer		Warm up
	ON (power on)		Force		Modulation
	Start movement		Pause		ByPass
	Stop movement		Increase		Key for Plantar Flexion/Dorsiflexion movement
	Program access		Decrease		Eversion/Inversion movement
	Right way up when box is stored		Extension limit		Alternating current
	Contains electric and electronic components; do not throw away with household refuse.		Fragile		Keep dry during storage or transport
	Temperature Limit during storage or transport		Follow the instructions for use		Follow the instructions for use
	Class II device		TYPE BF device (protection against electric shocks)		TYPE B device (protection against electric shocks)

14.7. Warranty

The device 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.

14.8. Guidance and manufacturer's declaration

Guidance and manufacturer's declaration - Electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidance
Radio frequency emissions CISPR 11	Group 1	The device KINETEC® Breva 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® Breva 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	

Guidance and manufacturer's declaration - Electromagnetic immunity


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

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV, ±6 kV contact	±2 kV, ±4 kV, ±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±2 kV, ±4 kV, ±8 kV air	±2 kV, ±4 kV, ±8 kV air	
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0,5 kV, ±1 kV between lines	±0,5 kV, ±1 kV between lines	Mains power quality should be that of a typical commercial or hospital environment.
	±0,5 kV, ±1 kV, ±2 kV between line and earth	±0.5 kV, ±1 kV, ±2 kV between line and earth	
Voltage interruptions IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 5 seconds	< 5% U_T (>95% dip in U_T) for 5 seconds	When the interruption occurs, the device KINETEC® Breva is reset. After turning on, push START to begin the session.
Voltage dips IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle	< 5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device KINETEC® Breva requires continued operation during power supply interruptions, we recommend powering the device KINETEC® Breva using an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
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 AC mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - Electromagnetic immunity

The device KINETEC® Breva is intended for use in the electromagnetic environment specified below. The customer or the user of the device KINETEC® Breva 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 V _{eff} 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® Breva 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® Breva machine is used exceeds the aforementioned applicable RF compliance level, the device KINETEC® Breva 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 device KINETEC® Breva.
- ^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® Breva machine

The device KINETEC® Breva 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® Breva machine can help prevent electromagnetic interference by maintaining a minimum distance between mobile and portable RF communication devices (emitters) and the device KINETEC® Breva 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.

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