Before use, please read this document. Kinetec reserves the right to effect technical modifications.
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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® Breva machine is designed to be used in hospitals, clinics, doctors’ offices or in private homes (rental).

The Breva 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® Breva 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.

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

![Image](https://example.com/image1)

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

<table>
<thead>
<tr>
<th>Beginning</th>
<th>Keys to press</th>
<th>Display</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switch the unit ON</td>
<td></td>
<td>KINETEC BREVA V01.0</td>
<td>Check that the hand control is not locked (See page 7).</td>
</tr>
<tr>
<td>Press simultaneously on the 2 keys</td>
<td>speed, force</td>
<td>LANGUAGE ENGLISH</td>
<td>The display indicates the language selected.</td>
</tr>
<tr>
<td>To change the language</td>
<td>triangle, triangle</td>
<td>LANGUAGE FRENCH</td>
<td>The French language is selected. Available languages: English, French, German, Italian and Spanish.</td>
</tr>
<tr>
<td>To confirm the new language</td>
<td>triangle, triangle</td>
<td>OK SWITCH ON/OFF</td>
<td>To exit and confirm the new language, switch OFF and Switch ON the unit.</td>
</tr>
</tbody>
</table>

![Image](https://example.com/image2)
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 [stop] key of the hand control. The movement stops,

Press the [start] 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 [stop] 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 [up] and [down] 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 [up] and [down] 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

<table>
<thead>
<tr>
<th>Possible values</th>
<th>Default setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plantar Flexion/Dorsiflexion</td>
<td>Inversion/Eversion</td>
</tr>
<tr>
<td>• Lower limit</td>
<td>Plantar Flexion 40°</td>
</tr>
<tr>
<td></td>
<td>Dorsiflexion 25°</td>
</tr>
<tr>
<td>• Upper limit</td>
<td>Plantar Flexion 35°</td>
</tr>
<tr>
<td></td>
<td>Dorsiflexion 30°</td>
</tr>
<tr>
<td>• Speed</td>
<td>1 to 5 (from 50 to 150° per minute)</td>
</tr>
<tr>
<td>• Force</td>
<td>1 to 6</td>
</tr>
<tr>
<td>• Extension pause</td>
<td>0 to 900 seconds (15 minutes)</td>
</tr>
<tr>
<td>• Flexion pause</td>
<td>0 to 900 seconds (15 minutes)</td>
</tr>
<tr>
<td>• Timer</td>
<td>No timer (00H00) to 24H00</td>
</tr>
</tbody>
</table>
## 11.7. Quick Start

Set up the patient and proceed as below:

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

## 11.8. To adjust the basic parameters of the movement

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

**Comments:** The values in the display column are given as an example.
### PROGRAM MODE: To enter a program

<table>
<thead>
<tr>
<th>Beginning</th>
<th>Keys to press</th>
<th>Display</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>To switch off the unit</td>
<td>Press the 2 keys at the same time and switch the unit ON</td>
<td>![Key icon] ![Key icon]</td>
<td>KINETEC BREVA V01.0</td>
</tr>
</tbody>
</table>

**Welcome text displayed for 3 seconds**

Then | Program 1 EMPTY | The program number blinks.

To change the program if necessary | ![Key icon] or ![Key icon] | Program 10 EMPTY |

**The new program number blinks.**

To choose the movement | LEFT 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.

To display the extension or flexion limit of the movement | Program 10 20 PL/DOR 0 | The value blinks.**

To change the limit if necessary | ![Limit icon] or ![Limit icon] | Program 10 20 PL/DOR 20 |

**The new value blinks.**

To confirm the new value, press another key or wait more than 3 seconds | ![Speed icon] | Program 10 Speed: 1 |

**While the value blinks press the (+) or (-) key to change if necessary.**

To record program 10 | Program 10 Save:+ clear:- |

Then | Program 10 Saving |

Program 11 EMPTY | Program 11 EMPTY |

OR | Program 10 CLEARING |

To cancel the program | Program 11 EMPTY |

To exit program mode, switch the unit OFF and switch back ON. | ![Checkmark icon] | 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:

<table>
<thead>
<tr>
<th>Timer</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pause at lower limit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pause at upper limit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Force</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Speed</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Upper limit</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Lower limit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Movement type

Program number

Program table:

<table>
<thead>
<tr>
<th>Program number</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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).

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

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

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

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

<table>
<thead>
<tr>
<th>Beginning</th>
<th>Keys to press</th>
<th>Display</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>To stop the unit</td>
<td>stop</td>
<td>PL/FLEX DOR/FLEX 20 STOP 10 5</td>
<td>Check that the hand control is not locked (See page 7).</td>
</tr>
<tr>
<td>To select the Plantar Flexion/Dorsiflexion movement</td>
<td>PL/FLEX DOR/FLEX 20 STOP 10 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To select Warm Up mode</td>
<td>PL/DOR FLX W.UP 20 STOP 10 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td>INVERSION/EVERS. RIGHT:+ LEFT:-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To select the Inversion/Eversion movement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To select the right or left foot</td>
<td>EV Right INV 10 STOP 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To select Warm Up mode</td>
<td>EV W UP RIGHT INV 10 STOP 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To start the movement</td>
<td>EV W UP RIGHT INV 10 RUN 10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:

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

**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 only be used when the machine is running (but not during Warm Up cycles).

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

**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 "Souplanios" 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 \( \text{limit} \) and \( \text{limit} \); the displays shows RESET TIME 215H (this is an example).

This counter can be reset by pressing the key \( \text{limit} \).

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. Kinetic 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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Caution</td>
</tr>
<tr>
<td>STOP</td>
<td>Stop</td>
</tr>
<tr>
<td>ON</td>
<td>Start</td>
</tr>
<tr>
<td>-</td>
<td>Stop</td>
</tr>
<tr>
<td>Program</td>
<td>Program</td>
</tr>
<tr>
<td>Right</td>
<td>Right way up when box is stored</td>
</tr>
<tr>
<td>Fragile</td>
<td>Contains electric and electronic components; do not throw away with household refuse.</td>
</tr>
<tr>
<td>Flexion limit</td>
<td></td>
</tr>
<tr>
<td>Timer</td>
<td>Timer</td>
</tr>
<tr>
<td>Force</td>
<td>Force</td>
</tr>
<tr>
<td>Pause</td>
<td>Pause</td>
</tr>
<tr>
<td>Increase</td>
<td></td>
</tr>
<tr>
<td>Decrease</td>
<td></td>
</tr>
<tr>
<td>Extension limit</td>
<td></td>
</tr>
<tr>
<td>Fragile</td>
<td></td>
</tr>
<tr>
<td>Follow the instructions for use</td>
<td></td>
</tr>
<tr>
<td>Type BF device (protection against electric shocks)</td>
<td></td>
</tr>
<tr>
<td>Type B device (protection against electric shocks)</td>
<td></td>
</tr>
</tbody>
</table>

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.
## 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.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radio frequency emissions CISPR 11</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>Radio frequency emissions - CISPR 11</td>
<td>Class B</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonic emissions - IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / Flicker emissions - IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

## 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.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601</th>
<th>Compliance level</th>
<th>Electromagnetic environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±2 kV, ±4 kV, ±6 kV contact</td>
<td>±2 kV, ±4 kV, ±6 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>±2 kV, ±4 kV, ±8 kV air</td>
<td>±2 kV, ±4 kV, ±8 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient / burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±0,5 kV, ±1 kV between lines</td>
<td>±0,5 kV, ±1 kV between lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±0,5 kV, ±1 kV, ±2 kV between line and earth</td>
<td>±0,5 kV, ±1 kV, ±2 kV between line and earth</td>
<td></td>
</tr>
<tr>
<td>Voltage interruptions IEC 61000-4-11</td>
<td>&lt; 5% $U_t$ (40% dip in $U_t$) for 5 seconds</td>
<td>&lt; 5% $U_t$ (40% dip in $U_t$) for 5 seconds</td>
<td>When the interruption occurs, the device KINETEC® Breva is reset. After turning on, push START to begin the session.</td>
</tr>
<tr>
<td></td>
<td>(&gt;95% dip in $U_t$)</td>
<td>(&gt;95% dip in $U_t$)</td>
<td></td>
</tr>
<tr>
<td>Voltage dips IEC 61000-4-11</td>
<td>&lt; 5% $U_t$ (40% dip in $U_t$) for 0.5 cycle</td>
<td>&lt; 5% $U_t$ (40% dip in $U_t$) for 0.5 cycle</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>(&gt;95% dip in $U_t$)</td>
<td>(&gt;95% dip in $U_t$)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>for 5 cycles</td>
<td>for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>40% $U_t$ (60% dip in $U_t$) for 5 cycles</td>
<td>40% $U_t$ (60% dip in $U_t$) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>for 25 cycles</td>
<td>for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% $U_t$ (30% dip in $U_t$) for 25 cycles</td>
<td>70% $U_t$ (30% dip in $U_t$) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field - IEC 61000-4-8</td>
<td>3A/m</td>
<td>3A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>Test Level according to IEC 60601</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF interference</td>
<td></td>
<td>3 V</td>
<td>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.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td></td>
<td>3 V eff</td>
<td></td>
</tr>
<tr>
<td>Radiated RF interference</td>
<td></td>
<td>3 V/m</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td></td>
<td>3 V/m</td>
<td></td>
</tr>
</tbody>
</table>

**Recommended separation distance**

\[ d = 1.2 \sqrt{P} \]

-\[ d = 1.2 \sqrt{P} \]

-\[ d = 2.3 \sqrt{P} \] 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:

![Interference Symbol](image)

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 80 MHz, field intensities should be less than 3 V/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.

<table>
<thead>
<tr>
<th>Maximum Assigned Output Power for the Emitter (W)</th>
<th>Separation Distance According to the Emitter’s Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>from 150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>( d = 1.2 \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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.