Kinetec Spectra Kompanion™

User manual

Before use, please read this document.
Kinetec SAS reserves the right to effect technical modifications.
The English version is a translation of the original in French. In case of a discrepancy, the French original will prevail.

EN

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Série 1
Notice Originale

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kinetec®

Contents

1. General information

1.1. Intended purpose of the device

The Kinetec Spectra Kompanion™ is a motorized mobilization device, also known as CPM (Continuous Passive Motion).
The Kinetec Spectra Kompanion™ is a PASSIVE KNEE mobilisation device enabling extension and flexion movement from -10° to 120°.

1.2. Clinical advantages

- Effectively breaks the vicious circle: injury, immobility, effusion, atrophy.
- Prevents joint stiffness in the knee and hip.
- Rapid recovery of motor schema in the affected limb.
- Improvement of quality of the joint surface.
- Encourages cartilage regeneration.
- Prevents venous thrombosis.
- Immediate post-operative passive mobility.
- Reduced hospitalization durations.
- Reduced analgesia.

1.3. Indications

- Knee and hip arthroplasty.
- Osteosynthesis of tibia or femur fracture.
- Patella fractures.
- Arthrolysis and palliative surgery (cartilage lesions, ablation of osteoma etc.).
- Osteotomy of pelvis or femur.
- Ligamentoplasty (LCI, LCE, LLI, LLE).
- Release of extensor system for knee (Judet surgery).
- Synovectomy, Meniscectomy, Patellectomy, Arthroscopy.

1.4. Contra-indications

- Rheumatoid arthritis in inflammatory phase,
- Gout,
- Algodystrophy in inflammatory phase (supra painful),
- Para-osteo-arthroplasty,
- Non-healed infected wounds,
- Constituted phlebitis,
- Bone cancer,
- Ossifying myositis of quadriceps,
- Hip arthrodesis,
- Infectious arthritis,
- Deformed articular surfaces,
- Paralysed limbs (atonic or spastic),
- Unstable fractures.
- The device is not suitable for patients over 1.95 m (6'7") or under 1.45 m (4'7").
- The device is not suitable for patients over 135 kg (297 lbs).

1.5. Intended patient population

The Kinetec Spectra Kompanion™ device can be used by patients who meet the following criteria:

- Age: no age restriction.
- Height: from 1.45m (4'7") to 1.95m (6'7").
- Weight: less than or equal to 135kg (297 lbs).
- If the patient is the operator: he must be alert, mentally competent (must assimilate the stop/start/reverse function when the practitioner gives him the tablet).
- If the patient is not the operator: the practitioner determines whether the patient is physiologically and mentally able to be subjected to the mobilization of his joint.

2. Warnings and safety instructions

Carefully read this user manual before using the Kinetec Spectra Kompanion™ device for the first time.

WARNING: The device must be installed in accordance with the information provided in this manual.

WARNING: If assistance is required with the assembly, use or maintenance of the device, contact your Kinetec® distributor.

WARNING: The practitioner will determine the protocol and ensure its proper running (settings, session time and frequency of use).

WARNING: Perform a dummy run before installing a patient on the device.

WARNING: For maximum safety, the tablet must always be given to the patient. Check that the patient has understood the stop/start/reverse function for the tablet, *see "12.5. STOP / START / REVERSE function", page 9*.

WARNING: To avoid changes to settings, lock the tablet when you give it to the patient, *see "12.6.* Locking - unlocking the tablet*", page 10*.

WARNING: Risk of explosion: do not use your device with anaesthetic gas or in an oxygen-rich environment.

WARNING: Before use, check that the power socket is in good condition and can accommodate the power supply lead for the device. Only use the lead supplied with the device. Ensure that leads are clear of the device to avoid damaging them.

WARNING: Before use, check that the device is not damaged, particularly the protective casings and the cable of the tablet.

WARNING: Do not touch the fixed or mobile parts of the machine during operation. Risk of pinching or crushing. Keep away from children and domestic animals.

WARNING: Changes to the device are strictly forbidden.

WARNING: The tablet is protected against manipulation, it is forbidden to try to bypass the protection measures put in place by any means whatsoever and to modify its content. In the event of non-compliance with these instructions, the user will be held responsible for any damage caused to the device. The manufacturer, Kinetec SAS, reserves the right to take legal action against offenders.

WARNING: The device contains nickel-containing stainless-steel parts. Those parts contain low concentrations of nickel that might cause an allergic reaction.

WARNING: Always check the movement settings displayed on the tablet before starting the machine.

WARNING: Do not use accessories, removable parts or supplies other than those described in this manual.

WARNING: Do not connect the device to other machines not described in this manual.

WARNING: If fluids come into contact with the device when it is used outside its transport case, immediately disconnect the mains lead and contact your Kinetec® distributor.

WARNING: In the event of unforeseen operation or events, contact your Kinetec® distributor.

WARNING: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

WARNING: In usage conditions at the highest admissible ambient temperature, the maximum temperature that could be reached by the control handle is 47.9°C

WARNING: In the event of reciprocal, electromagnetic or other interference with other devices, move the device.

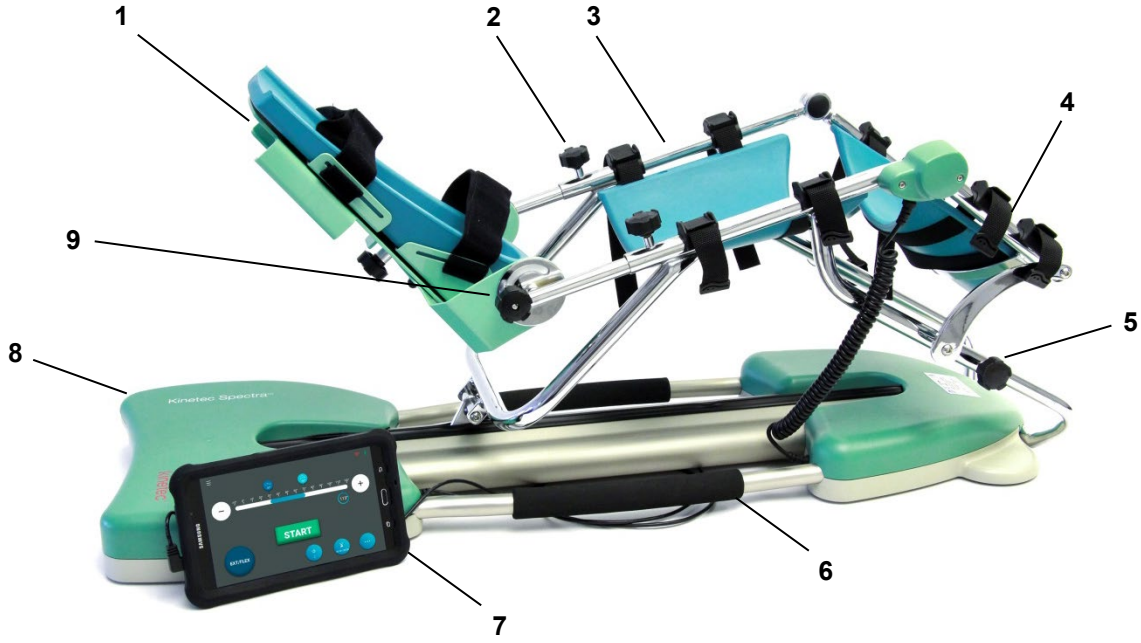
WARNING: The Kinetec Spectra Kompanion™ device must not be used next to other devices or stored with the latter because this can cause incorrect operation. If such use is necessary, the device and other machines should be monitored to ensure normal operation.

WARNING: The use of accessories and cables other than those specified or provided by KINETEC SAS can increase electromagnetic emissions or reduce immunity of the device and cause inappropriate operation.

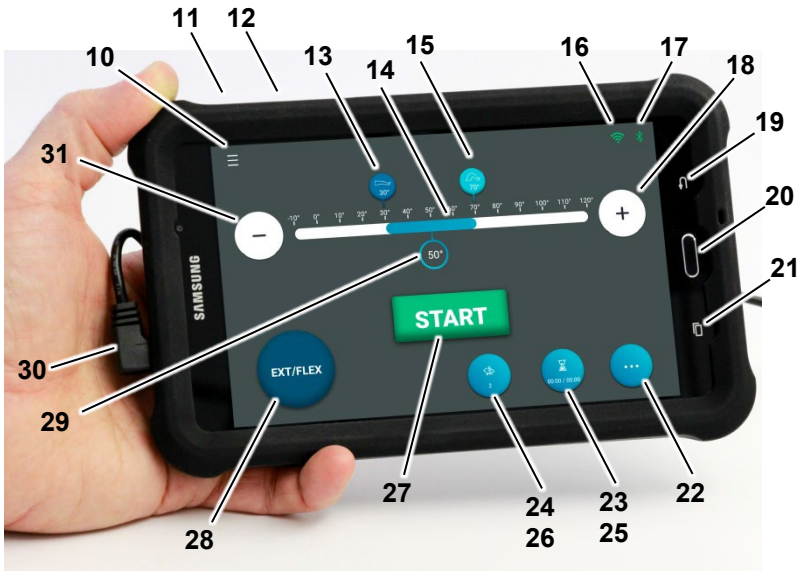
WARNING: Portable radio-frequency devices should not be used (including peripherals such as coil cables and external coils) within 30 cm (12 inches) of any part of the Kinetec Spectra Kompanion™ device including cables specified by Kinetec. Should the opposite occur, the performance of these devices could be altered.

3. Description of the device

The Kinetec Spectra Kompanion™ device is composed of the following parts:



1 Articulated foot plate, with housing for tablet during transport
2 Lower limb support adjustment buttons
3 Lower limb support
4 Thigh support
5 Thigh support adjustment buttons
6 Transport handle
7 Remote control (touch tablet)
8 ON/OFF switch, fuses and connector for power supply lead
9 Foot plate adjustment buttons



10 Menu access key
11 ON/OFF key
12 Volume key
13 Extension limit adjustment key
14 Extension and flexion limit adjustment touch zone
15 Flexion limit adjustment key
16 Wi-Fi connection status icon
17 Bluetooth connection status icon
18 Keys to change operating values (positive direction)
19 Back Key
20 Home Key
21 Multiwindow Key
22 Key to access functions 25 and 26
23 Pause Key
24 Speed Key
25 Session time key
26 Force Key
27 Movement START/STOP key
28 Movement selection key
29 Display of instantaneous position
30 Tablet power supply lead
31 Keys to change operating values (negative direction)

4. Unpacking and packing

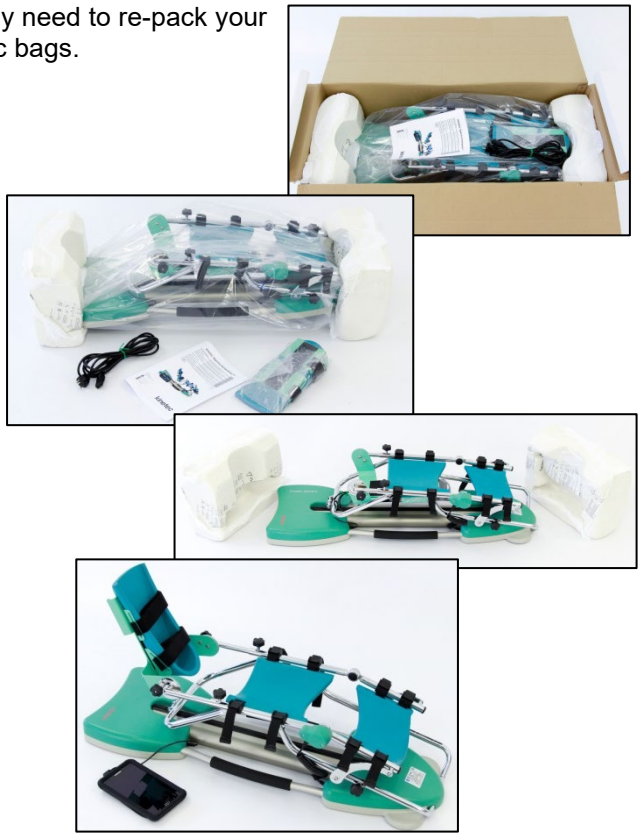
4.1. Unpacking

WARNING:	**Risk associated with plastic bags** **Plastic bags should be kept out of reach of babies and children. For them, a plastic bag can become a toy and attract their curiosity. The risk of suffocation is therefore significant and must be avoided as much as possible to avoid serious brain injury or death.**

WARNING:	**Risk associated with small objects.** **Keep children away, risk of suffocation or asphyxia by inhalation or accidental ingestion of small objects that could cause serious injury or death.**

WARNING:	**Risk associated with leads and cables.** **Keep children away, risk of strangulation that could cause serious brain injury or death.**

When unpacking, we draw your attention to the fact that you may need to re-pack your device. We recommend you keep the wedges, boxes and plastic bags.



① Open the box.

② Remove the splint from the box and place it on the floor.

③ Remove the wedges and then the plastic bag.

④ Return the *articulated foot plate (1)*.

⑤ To install the device: *see page 6*.

⑥ To install comfort shells or hygienic casing: *see page 6*.

⑦ To install a patient on the device: *see page 7*.

⑧ To connect the device: *see page 7*.

4.2. Packaging

To avoid any problems when transporting the splint, only pack it in its original packaging.

① Set the leg support to 42 cm using the *Thigh support adjustment buttons (5)*.

② Stop the splint at 5° Flexion.

③ Return the *articulated foot plate (1)*.

④ Put the plastic bag and fit the wedges together.

⑤ Put the splint in the packaging box.

5. Installing the device

The Kinetec Spectra Kompanion™ device is designed to be used in hospitals, clinics, medical clinics or by a private individual (rental). It can be used by the patient himself or by the practitioner.

The device must be installed on a flat surface wide enough for the entire splint and the opposite leg.

It is not recommended using an inflatable mattress.

The Kinetec Spectra Kompanion™ device is ready to use. It does not require any additional external hardware and software resources to operate, nor the use of IT infrastructure.
The tablet is supplied with the software to control the splint pre-installed at the factory. After switching on the splint and then the tablet, the software starts automatically and automatically connects to the splint.

6. Use of the Plastic Comfort Shell kit

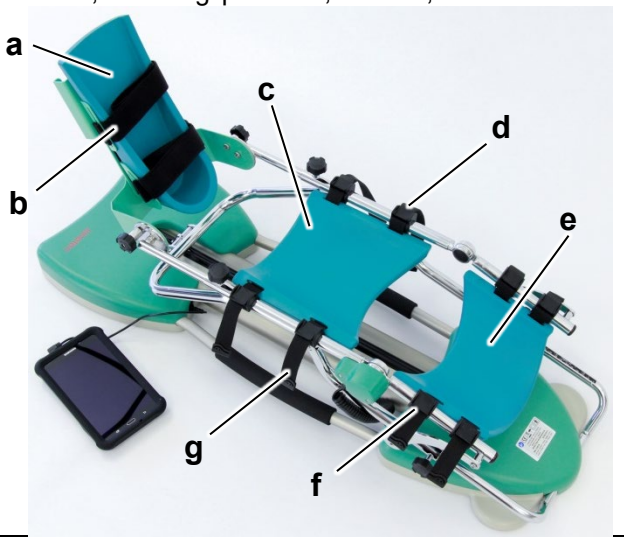
Especially designed to improve a patient's comfort and hygiene, the Plastic Comfort Shells are fitted with clips, directly attached to the tubes of the leg and crural segment of the device, and with straps with a safety stop for accurate and rapid adjustment of the leg size of the patient.

Cleaning

It is recommended cleaning the device and shells between each patient.

Cleaning protocol of the health care facility shall be followed. However, cleaning products, if used, shall either be alcohol-free or contain <5% alcohol.

It is advised replacing the shells every 500h of operation.



Spare parts

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

Reference for ordering a complete kit:

- attachment with clips: 4670024345
- attachment without clips: 4670023701 (when your device is not fitted with clips).

7. Use of the Kinetec® hygienic casing

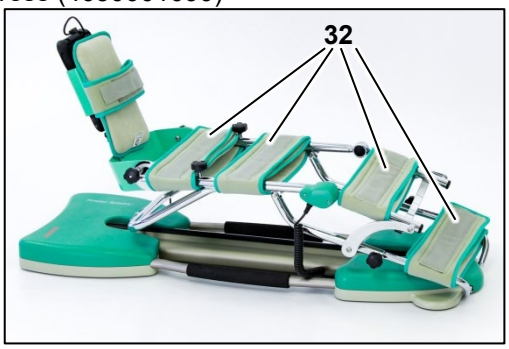
The Kinetec® hygienic casing was especially designed for rapid installation, total hygiene and maximum patient comfort.
- Position the straps as shown below; ensure that the self-adhesive parts (32) are visible.
- Position the mattress sponge side facing up.

TO ENSURE OPTIMUM HYGIENE, FOLLOW THE RULE: 1 PATIENT = 1 MATTRESS.
(A label can be used to record the patient's name.)

Cleaning

- Disinfecting straps: Wash at 30°C using a disinfectant during the rinse cycle. Example of disinfection products: Bac linge solution 0.125% or Souplanios 0.125% from ANIOS Laboratories. Contact us for the list of distributors in your country.

The complete hygienic casing kit is composed of:
- 4 straps (4650001107)
- 1 foot support (4650001420)
- 1 mattress (4650001090)



8. Patient installation

See "5. Installing the device", page 6, for conditions of use for the device.
Stop the device in an analgesic position for the patient (or use the *Patient installation* function: *see page 18*).

① Measure the crural length (L) of the patient (in cm or inches) and adjust the Thigh support to this measurement using the *adjustment buttons (5)*.

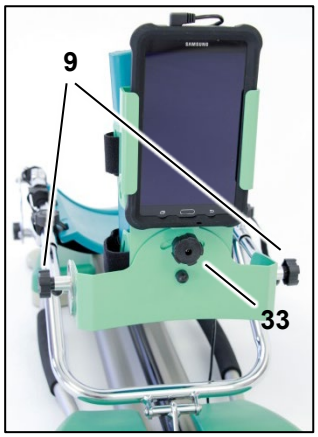
② Install the patient on the device.

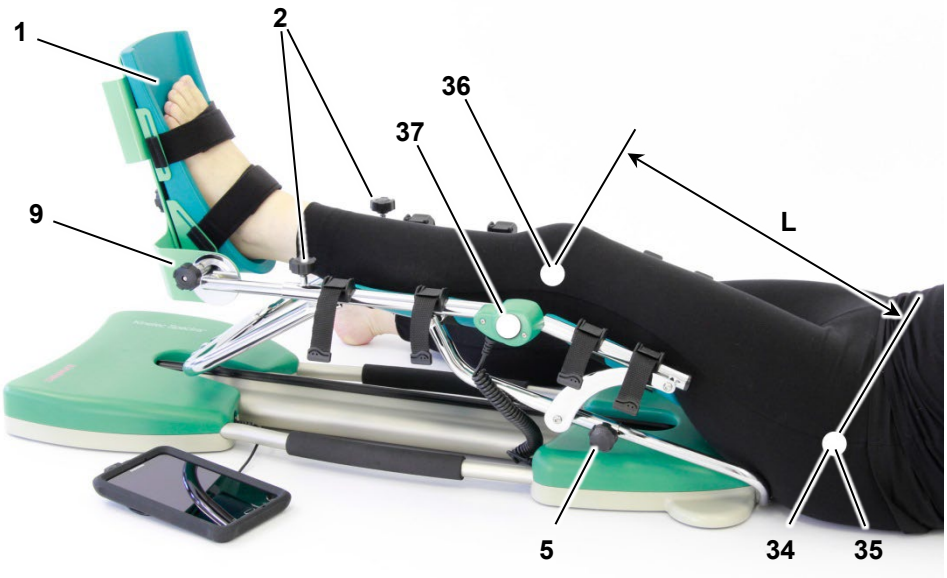
③ Put the *articulated foot plate (1)* in contact with the patient's foot; tighten the *Lower limb support adjustment buttons (2)*.

④ Adjust the plantar flexion position (40°) or dorsal position (30°) of the foot, using the *Foot plate adjustment buttons (9)*.

⑤ Adjust the internal (30°) or external rotation position (30°) of the foot, using *button (33)*.

IMPORTANT
Adjust the articulation axis as accurately as possible (34) for the hip with the "THEORETICAL" rotation axis (35) for the device, as well as the articulation axis (36) for the knee with the articulation axis (37) for the device.



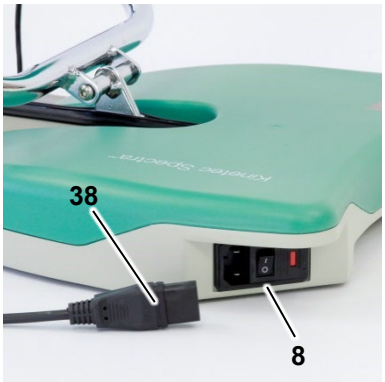


9. Electrical connection: safety first

WARNING:	**Only use the original lead supplied with your device.**
	Ensure that leads are clear of the device to avoid damaging them.
	Check that the device is not damaged, particularly the protective casings.

Before connecting the device, check if the mains voltage corresponds to the setting on the marking plate (100-240V~ 50/60Hz).

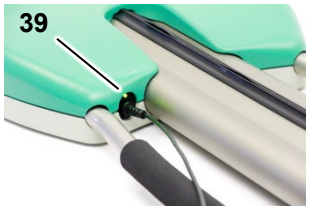
Connect the *mains cable (38)*.



10. Procedure for starting up the device

Warning:	**When the ambient temperature is 20°C, the warm-up time needed for the Kinetec Spectra Kompanion™ device from the minimum storage temperature between uses until it is ready for use is 4 hours.**

Warning:	**When the ambient temperature is 20°C, the cooling time needed for the Kinetec Spectra Kompanion™ device from the maximum storage temperature between uses until it is ready for use is 4 hours.**



To switch the splint on, *toggle the ON/OFF switch (8)* on "**I**". The *power indicator (39)* comes on or flashes depending on the Bluetooth connection status.

When the Kinetec Spectra Kompanion™ device is dispatched, the tablet is switched off to preserve the life span of the battery.
Consequently, when first used or when you have not used it for a while, if the tablet does not switch on, hold the *Stop/Start key (11)* down for a few seconds until the welcome message appears. Wait a few seconds before the main screen appears (*see page 4*).

WARNING:	**Always check the movement settings displayed on the tablet before starting the machine.**

11. Procedure for shutting down the device

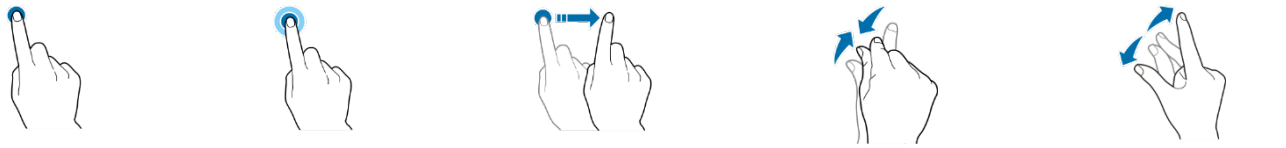
To stop device movement: press key **STOP**

To switch the device off: set the *ON/OFF switch (8)* to "**0**" then keep the *ON/OFF key (11)* pressed for a few seconds and follow the instructions on the screen.

12. Using the tablet

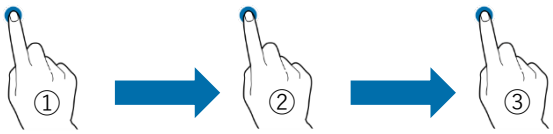
12.1. Touch screen

Pictograms used in this manual to use the touch screen:



Press | Keep pressed | Move | Bring fingers together | Move fingers apart

When a number is written in the pictogram, this means the order of steps to be followed.



ATTENTION: situations likely to damage your device or other equipment

- Avoid the touch screen coming into contact with other electrical equipment. Electrostatic discharge can cause the touch screen to malfunction.
- To avoid damaging the touch screen, do not press on it with a sharp object and do not apply excessive pressure with fingers.
- It is recommended using the touch screen with fingers (no gloves, no plaster on fingers).

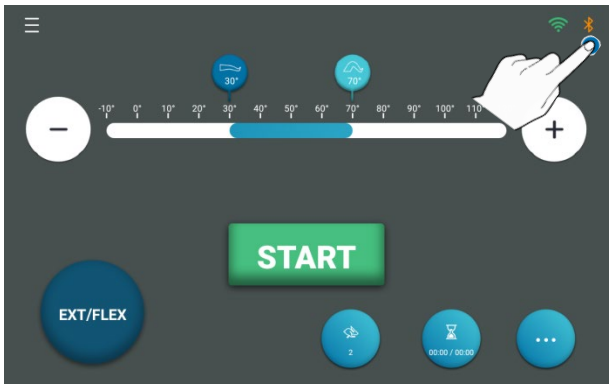
12.2. Changing the display language

When your Kinetec Spectra Kompanion™ device is dispatched, the tablet is configured for display in the language of your country.
However, should you wish to change the display language, press the *menu access key (10)* and then press the *Settings* option and select the desired display language in the S*ettings* section.

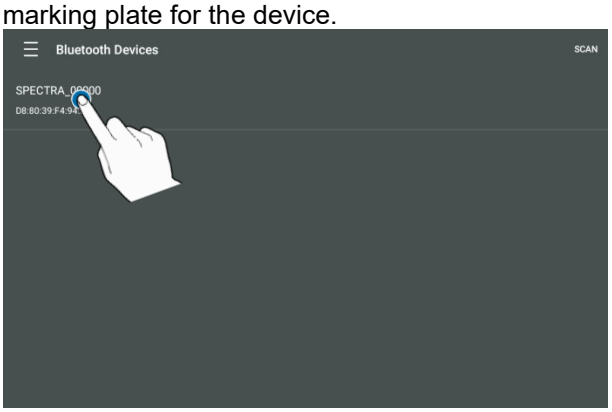
12.3. Bluetooth connection between the splint and the tablet

When your Kinetec Spectra Kompanion™ device is dispatched, the Bluetooth pairing between the tablet and the splint is already done. When the main screen is displayed, wait a few seconds until the *Bluetooth connection status icon* goes green (17).

① However, if the message “Impossible to connect to the device” appears on the bottom of the screen, press the *Bluetooth connection status icon* (17).



② Select the Kinetec Spectra Kompanion™ device corresponding to the serial number shown on the marking plate for the device.



③ Go back to the main screen: *the Bluetooth connection status icon (17)* goes green and the *power indicator (39)* is on.

If the problem persists, see *“14.9.* Troubleshooting guide*“, page 24.*

12.4. Connection to Wi-Fi network

To avail of all the functionalities of your Kinetec Spectra Kompanion™ device, such as for example receiving programmes sent by your practitioner or sending your rehabilitation report by email to your practitioner, a Wi-Fi connection is needed.
However, you can use your Kinetec Spectra Kompanion™ device without this functionality.

Note:

- **Functionalities requiring an active Wi-Fi connection are indicated in this user manual with the logo**

12.5. STOP / START / REVERSE function

The Kinetec Spectra Kompanion™ device has, like all Kinetec® devices, the STOP/START/REVERSE function.

Pressing on the key **STOP** stops movement,

Pressing on the key **START** starts movement again in the inverse direction.

WARNING:	**For maximum safety, the tablet must always be given to the patient.** **Check that the patient has understood the stop/start/reverse function of the tablet.**

12.6. Locking - unlocking the tablet

This function enables a practitioner to authorize or not authorize access to changing the movement settings.

Press simultaneously on keys − and + for a few seconds to activate or de-activate locking.

When locking is active, only the keys START and STOP can be used.

It is recommended locking the tablet when you give it to a patient.

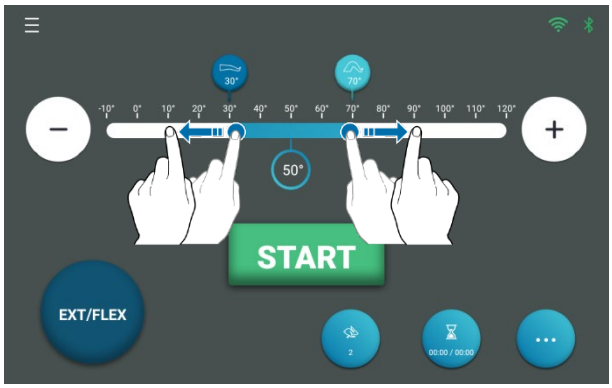
12.7. Adjusting the base movement settings

12.7.1. Ranges

The movement ranges can be adjusted in 3 different ways:

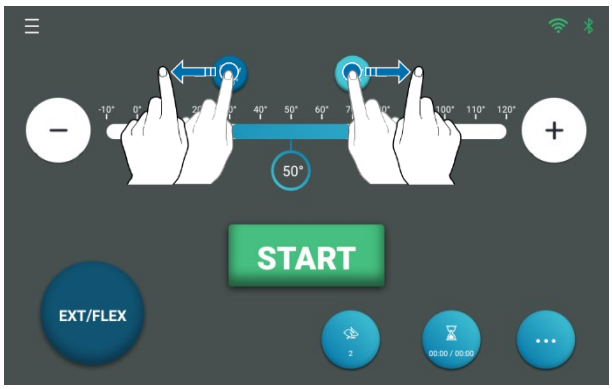
- **Method 1:** moves the edges of the *adjustment zone (14)* until the desired position is reached, then release.

  Tip: once released, to refine the setting to the nearest degree, press on keys − or +

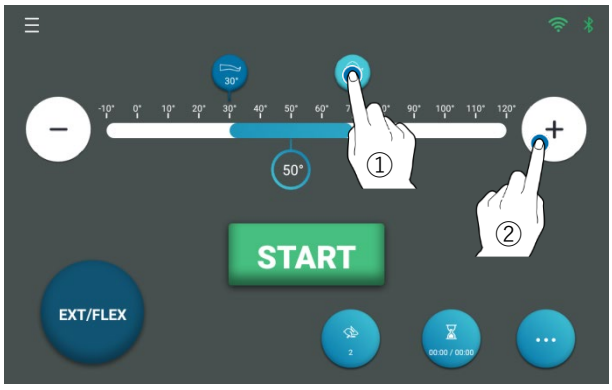


- **Method 2:** move the *extension (13) or flexion limit adjustment key (15)* until the desired position is reached, then release.

  Tip: once released, to refine the setting to the nearest degree, press on keys − or +



- **Method 3:** press on the extension (13) or flexion extension limit adjustment key (15) then press on keys − or +



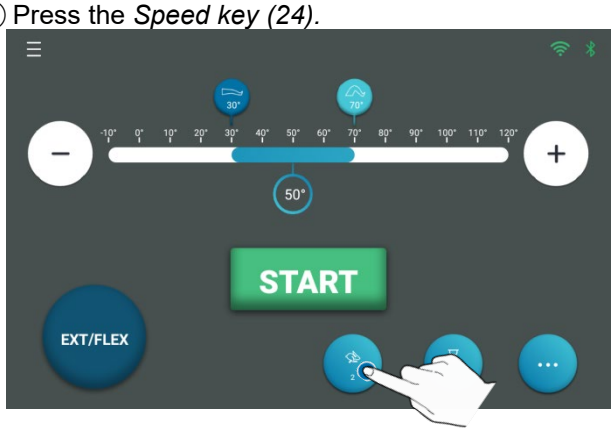
Notes:

- **The maximum range that can be set is -10° to 120° flexion.**
- **The difference between the extension limit and the flexion limit cannot be less than 5°.**
- **These settings can be changed during operation.**

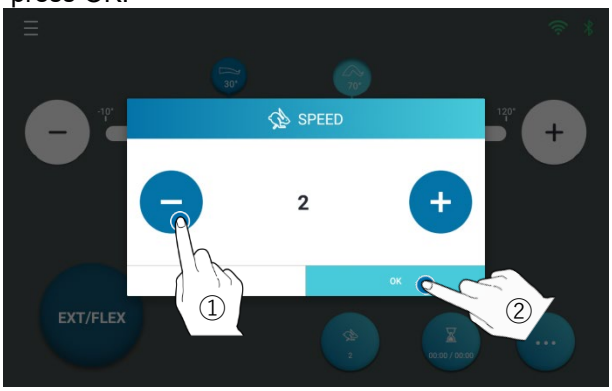
12.7.2. Speed

The Kinetec Spectra Kompanion™ device has a speed range spreading from level 1 to level 5.

① Press the *Speed key (24).*

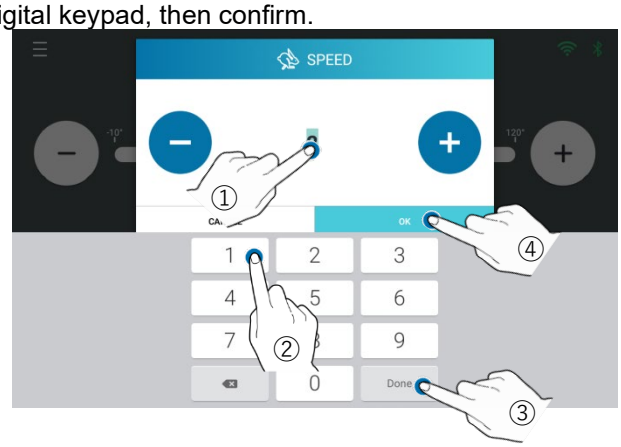


② Adjust speed by pressing on keys − or + then press OK.



OR

Press the digital value, enter the new value using the digital keypad, then confirm.



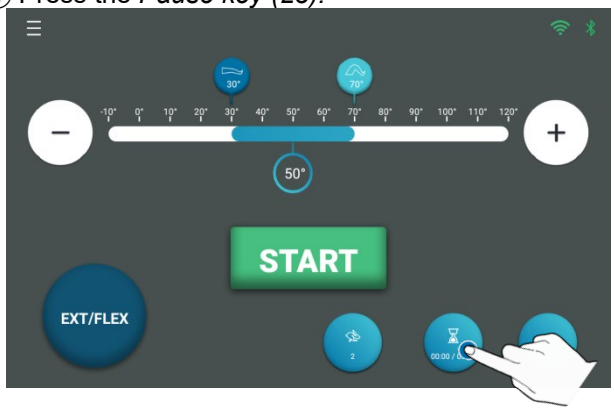
Notes:

- **See "14.6. Technical characteristics", page 23 for more information about operating speeds in degrees per minute.**
- **This setting can be modified during operation.**

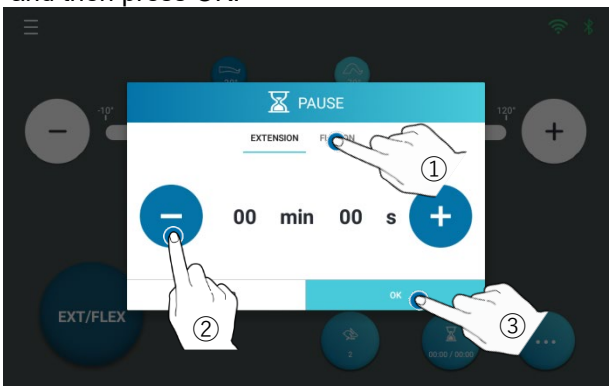
12.7.3. Pauses at extremities

The Kinetec Spectra Kompanion™ device enables pauses at extension and flexion extremities.

① Press the *Pause key (23).*

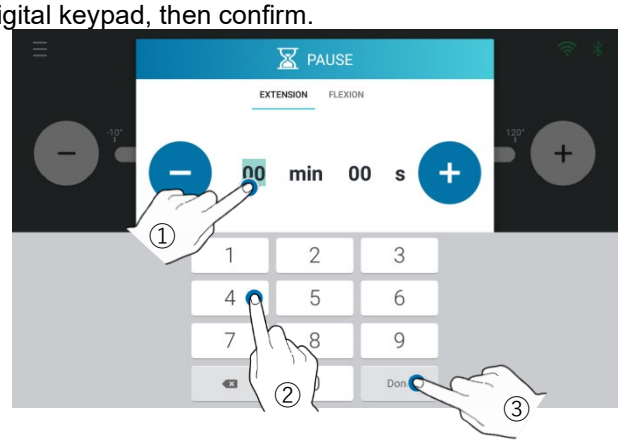


② Select the extremity where the pause is to occur and then set the pause duration by pressing on − or + and then press OK.



OR

Press the digital value, enter the new value using the digital keypad, then confirm.



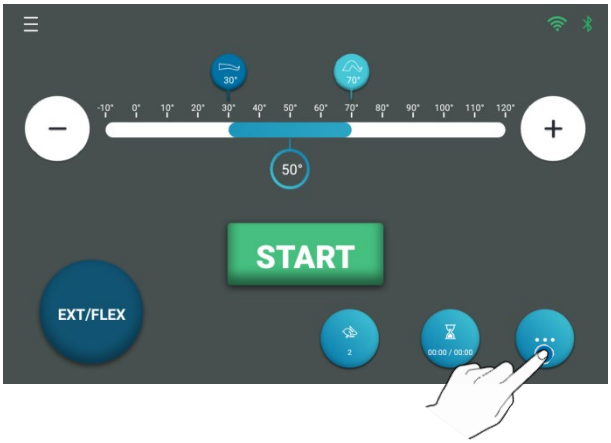
Notes:

- **Pause durations can be adjusted from 0 to 15 minutes.**
- ***See "14.6. Technical characteristics", page 23* for more information.**
- **These settings can be changed during operation.**

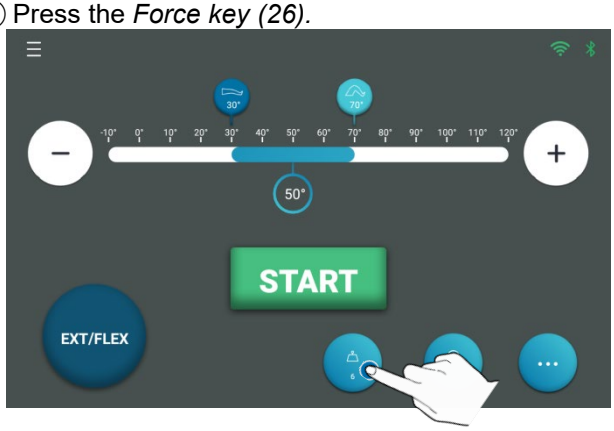
12.7.4. Inversion strength

The Kinetec Spectra Kompanion™ device has, like all Kinetec® devices, the automatic inversion function in the event of patient joint stiffness. Inversion in the event of overload protects a patient when excessive force is applied to the joint.

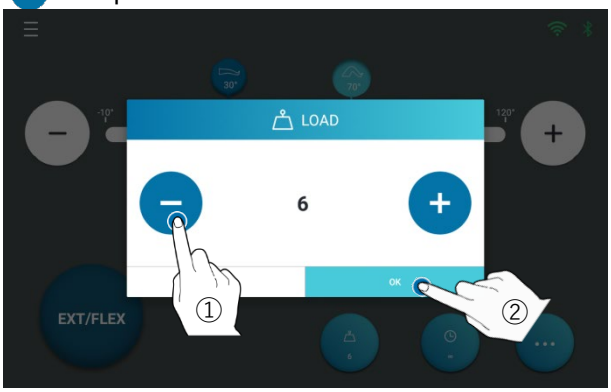
① If necessary press *key (22)* to access the Force and Session Time functions.



② Press the *Force key (26).*

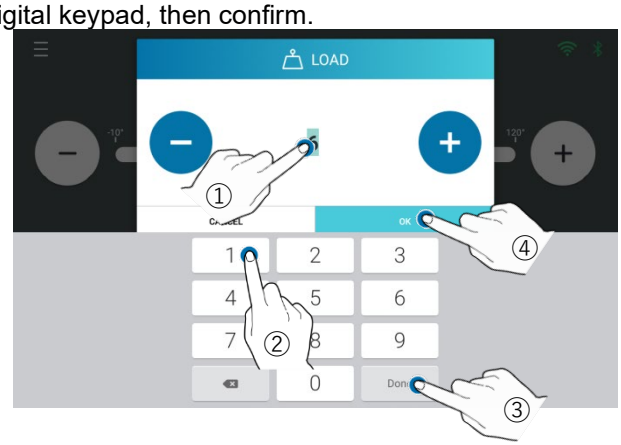


③ Set the inversion force by pressing on keys − or + then press OK.



OR

Press the digital value, enter the new value using the digital keypad, then confirm.



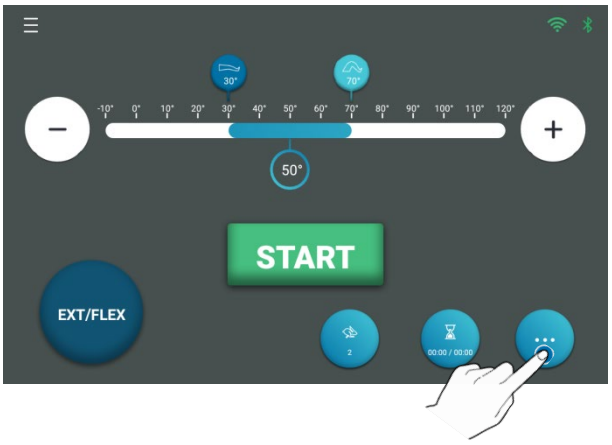
Notes:

- **The inversion force can be adjusted from level 1 to level 6.**
- ***See "14.6.* Technical characteristics*", page 23* for more information.**
- **This setting can be modified during operation.**

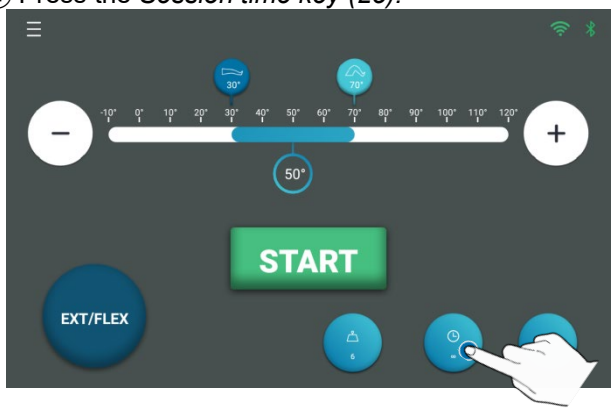
12.7.5. Session time

The Kinetec Spectra Kompanion™ device enables a session time to be programmed. Once the time has elapsed, the Kinetec Spectra Kompanion™ device stops, signifying the end of the rehabilitation session.

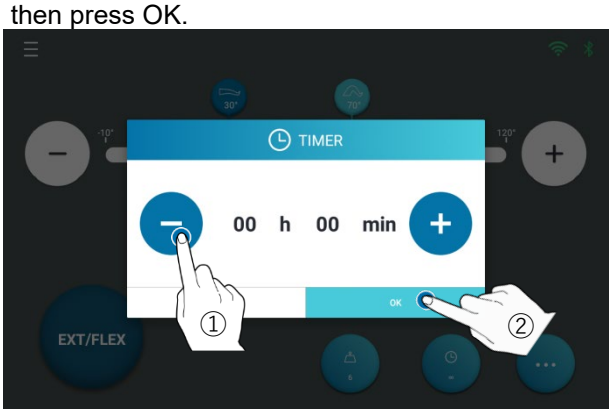
① If necessary press *key (22)* to access the Force and Session Time functions.



② Press the *Session time key (25).*



③ Set the Session Time by pressing on keys − or + then press OK.



OR

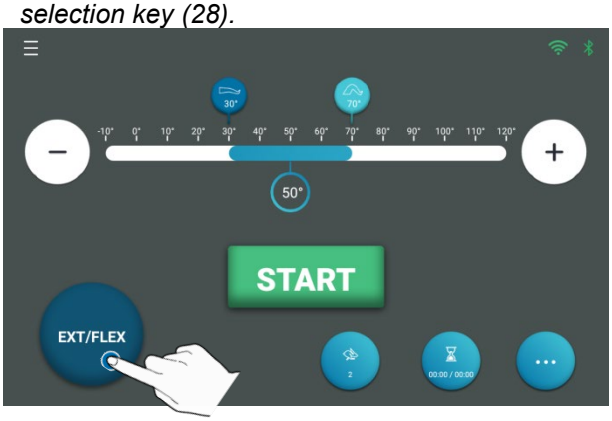
Press the digital value, enter the new value using the digital keypad, then confirm.

Notes:

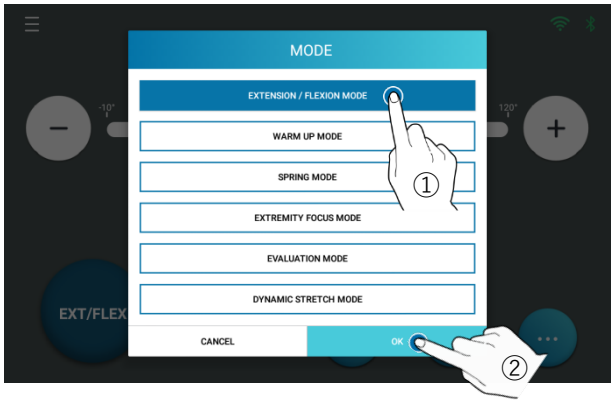
- **The session time can be adjusted from 1 minute to 24 hours or as continuous (symbol ∞).**
- **The session time is sometimes longer than the value initially defined. It is dependent on the angular range programmed and the selected speed level.**
- **Once the time has elapsed, the Kinetec Spectra Kompanion™ device stops at the middle of the programmed angular range (±3°).**
- **This setting can be modified during operation.**

12.8. Operating modes

① To change operating mode, press the *Movement selection key (28).*



② Press the desired operating mode then press OK to confirm.



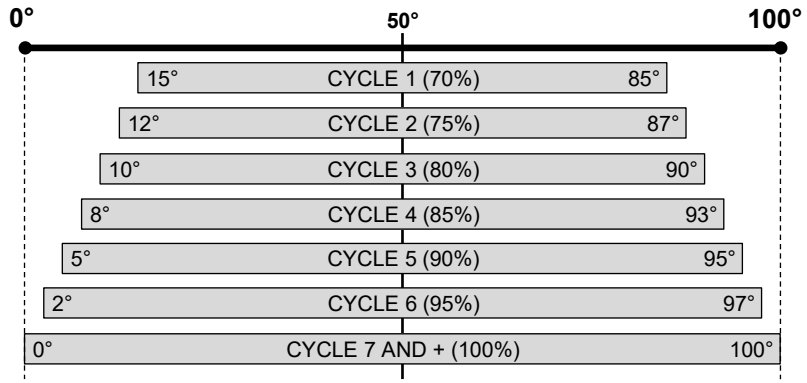
12.8.1. EXTENSION / FLEXION mode

This operating mode enables extension and flexion movement for the knee over the entire angular range programmed according to the pre-selected speed, pause, inversion force and session time settings (*see "12.7. Adjusting the base movement settings", page 10*).

12.8.2. WARM UP mode

The WARM UP enables the rehabilitation session to be started gradually. It enables the first extension and flexion cycle to be started over approximately 70% of the programmed angular range. The following cycles increase by approximately 5% at each complete cycle until the maximum angular range programmed is reached according to the pre-selected speed, pause, inversion force and session time settings (*see "12.7. Adjusting the base movement settings", page 10*).

Example: For warm up with an angular range programmed from 0° to 100°, cycle 1 starts from 15° to 85° and progresses by about 5% at each cycle.



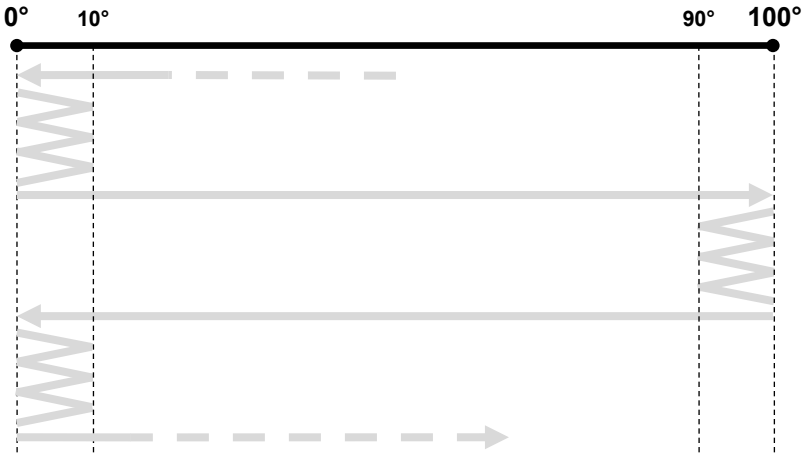
Notes:

- **Pauses are not active in warm up cycles.**
- **The calculation mode used represents a progression of the range over an average of 7 complete cycles.**
- **The warm up cycles only occur when movement is first switched on. To perform a new warm up cycle, press the *Movement selection key (28)* then select the WARM UP mode again.**
- **Changing the movement values must always be done when the splint is off.**

12.8.3. SPRING mode

The SPRING mode enables working on maximum ranges in particular. This operating mode enables repeating several extension-flexion movements over the last degrees of the working range set by the practitioner and according to the pre-selected speed, pause, inversion force and session time settings (*see "12.7. Adjusting the base movement settings", page 10*).

Example: For an angular range programmed from 0° to 100°, once the extension position is reached, the splint will repeat 3 to and fro movements over the last 10 degrees before regaining the flexion position then repeating the to and fro movements in the same way.



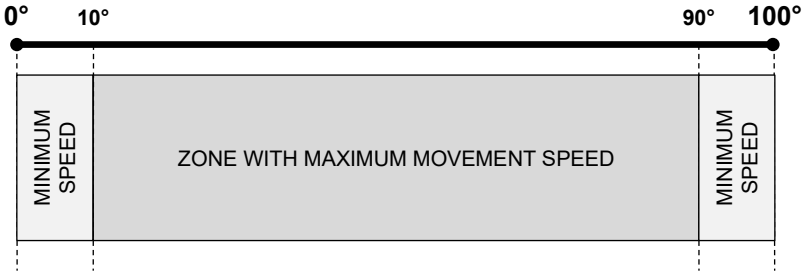
Note:

- **The number of to and fro movements as well as the track to be repeated can be configured in the "Settings" menu.**

12.8.4. EXTREMITY FOCUS mode

The EXTREMITY FOCUS mode enables the extremities of the programmed angular range to be reached by slowing the movement speed close to the last degrees of the working range set by the practitioner and according to the pre-selected pause, inversion force and session time settings (*see "12.7. Adjusting the base movement settings", page 10*).

Example: For an angular range programmed from 0° to 100°, the movement speed is maximum in the middle of the range and it is minimal over the last 10 degrees.



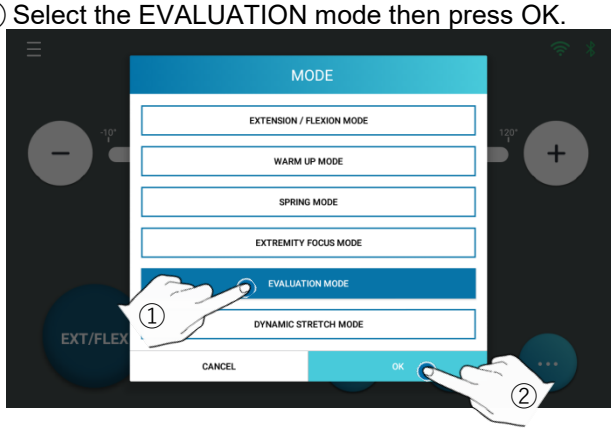
Notes:

- **The movement speed as well as the track can be configured in the "Settings" menu.**
- **The *Speed key (24)* is de-activated when the EXTREMITY FOCUS mode is activated.**

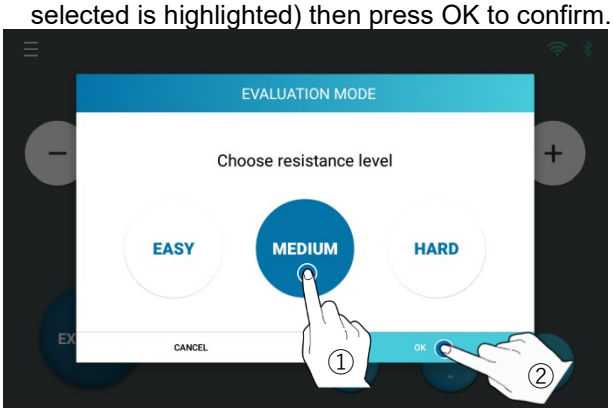
12.8.5. EVALUATION mode

The EVALUATION mode enables a patient to work in counter-reaction to the device so that the practitioner can estimate the progression of the rehabilitation phase. When this mode is activated, the Kinetec Spectra Kompanion™ device triggers a flexion movement and indicates to the patient to strain to invert the movement. Once all the trials are completed, a message summarizes the number of successful or missed trials.

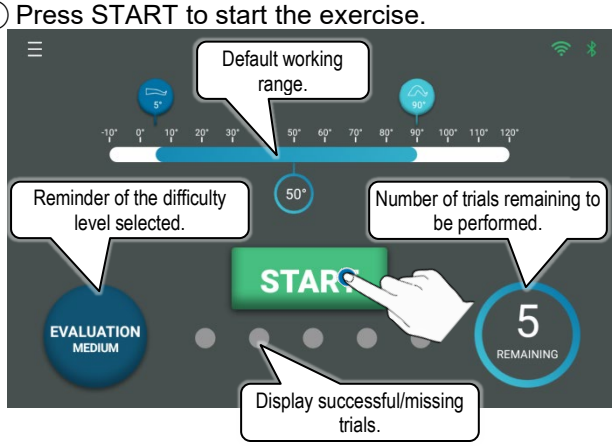
① Select the EVALUATION mode then press OK.



② Select the exercise difficulty level (the level selected is highlighted) then press OK to confirm.



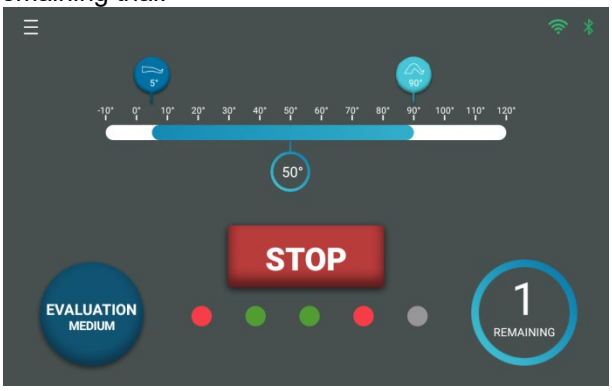
③ Press START to start the exercise.



④ The device starts by regaining the maximum extension angle. A message invites the patient to be ready to strain.

⑤ To pass a trial, the patient must be able to invert the movement before reaching the maximum flexion angle.

Example of display for 2 successful, 2 failed and 1 remaining trial.



Notes:

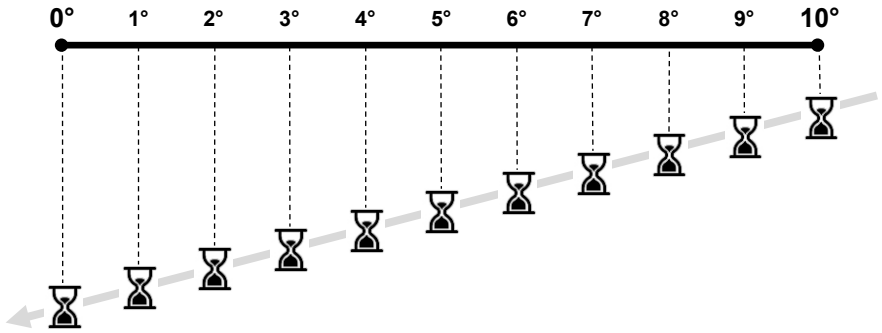
- **The speed, pause, inversion force and session time settings are not accessible when the EVALUATION mode is activated.**
- **The number of trials, the working angular range as well as the default difficulty level can be configured in the "Settings" menu.**

The EASY level corresponds to an inversion force of approximately 20daN ±20%.
The MEDIUM level corresponds to an inversion force of approximately 30daN ±20%.
The DIFFICULT level corresponds to an inversion force of approximately 40daN ±20%.

12.8.6. DYNAMIC STRETCH mode

When the DYNAMIC STRETCH mode is activated, the Kinetec Spectra Kompanion™ device starts at 15° flexion and reduces by 1° every 10 minutes until complete extension is reached. The angular range can be modified before starting the exercise. The default pause time can be configured in the “Settings” menu.

Example: For an angular range programmed from 0° to 10°.

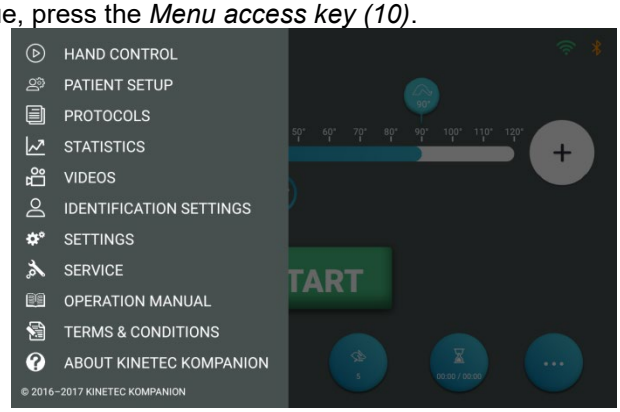


Note:

- **The default pause time can be configured in the “Settings” menu.**

12.9. System menu

To access the functions catalogue, press the *Menu access key (10)*.



12.9.1. Hand control

This option goes back to the main screen to control the Kinetec Spectra Kompanion™ device.

12.9.2. Patient setup

This option positions the Kinetec Spectra Kompanion™ device in an analgesic position for the patient thereby facilitating his/her installation on the device. *See “8. Patient installation”, page 7*.

Note:

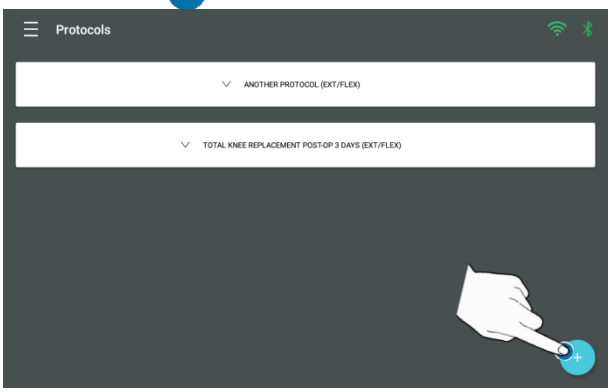
- **The default stop position can be configured in the “Settings” menu.**

12.9.3. Protocols

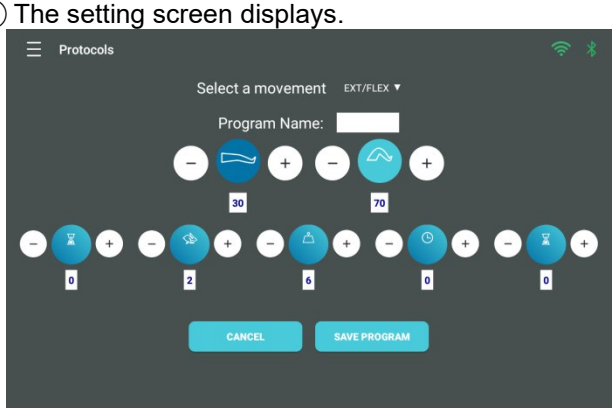
This option creates individual rehabilitation programmes and accesses pre-recorded programmes.
A programme includes the treatment mode with its ranges, speed, force, pauses and session time.

Creating a programme:

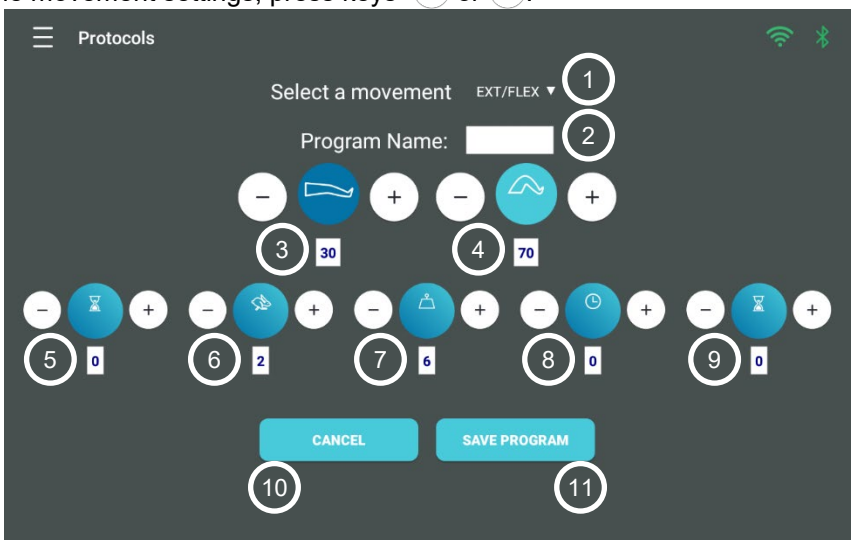
① Press button +.



② The setting screen displays.



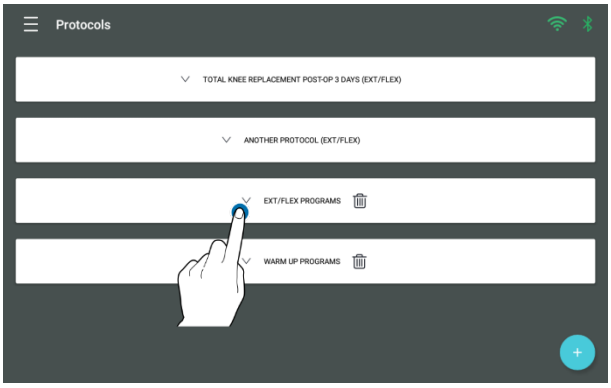
To adjust the movement settings, press keys − or +.



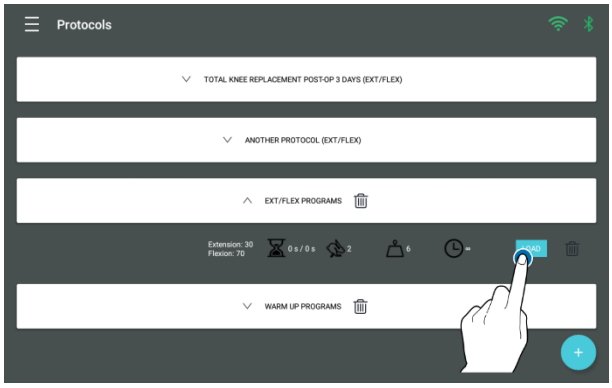
1. Select an operating mode
2. Name of programme (optional)
3. Extension limit
4. Flexion limit
5. Extension pause
6. Speed
7. Inversion force
8. Session time
9. Flexion pause
10. Cancel
11. Record the programme

Selecting a programme:

① Scroll the list where the programme to be selected is found.



② Press the LOAD button.



③ The values for the selected programme display on the main screen.

Note:

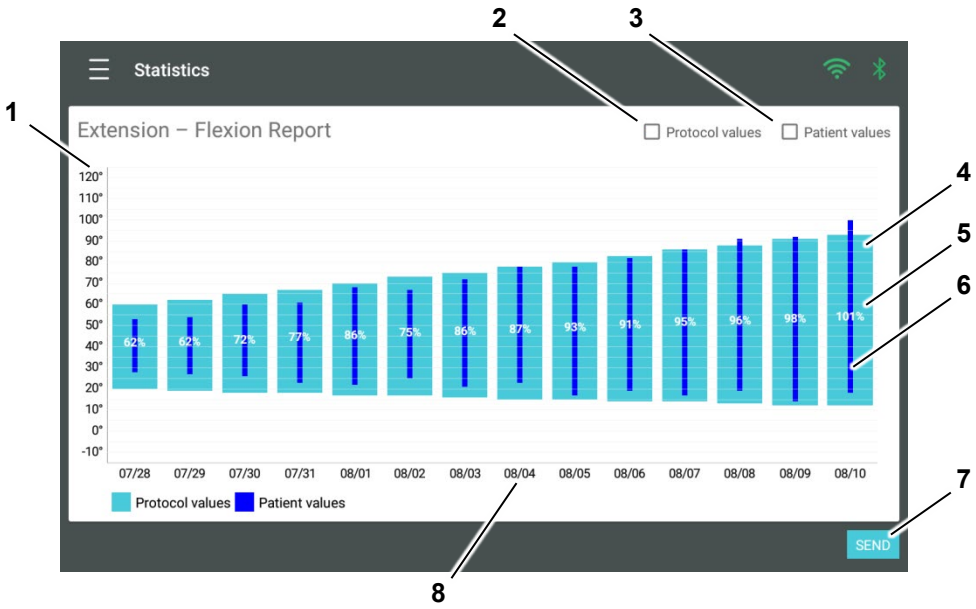
- **These values can be changed before pressing the key START.**

WARNING: **Always check the movement settings displayed on the tablet before starting the device.**

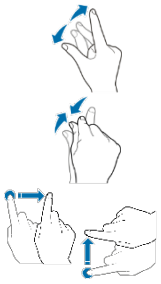
12.9.4. Statistics

This option displays the patient's rehabilitation report in the form of a graph.

1. Range of movement in degrees.
2. Tick this box to display the values for the planned programme.
3. Tick this box to display the values reached by the patient.
4. Range for selected programme.
5. Success percentage in relation to the planned programme.
6. Range reached by the patient
7. Send the report by email Wi-Fi connection required)
8. Date of rehabilitation session.



Notes:



Moving fingers apart on the graph zooms in.

Bringing fingers together on the graph zooms out.

Move the graph horizontally or vertically.

12.9.5. Videos

This option accesses the various tutorials for the Kinetec Spectra Kompanion™ device (Wi-Fi connection required).

12.9.6. Identification settings

This option:

- enables patient information to be viewed,
- enables practitioner information to be viewed,
- enables rental company information to be viewed,

Changing this information is secured by a password and is therefore only accessible for qualified staff in the company renting the Kinetec Spectra Kompanion™ device.

12.9.7. Settings

This option:

- modifies the display language,
- modifies the display format for the date,
- modifies the various default values for operating modes.

12.9.8. Service

Access to this option is secured by a password and is therefore only accessible for qualified Kinetec staff.
This option:

- enables technical data for the Kinetec Spectra Kompanion™ device to be viewed,
- enables maintenance operations to be performed.

12.9.9. Operation manual

This option enables viewing of the user manual.

12.9.10. Terms & Conditions

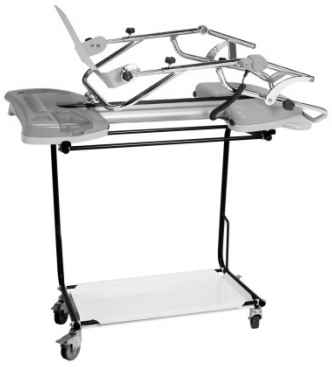
This option enables the general conditions of use to be viewed.

12.9.11. About Kinetec Kompanion

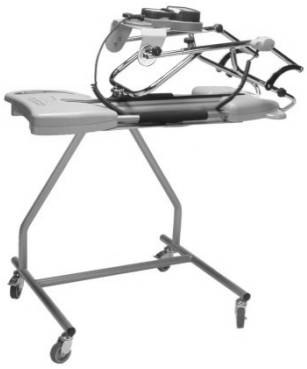
This option contains information about:

- the contact details of the manufacturer of the Kinetec Spectra Kompanion™ device,
- the application version,
- copyright.

13. Options



Splint storage trolley
Reference: 4655001053



Trolley for bedside use
Reference: 4665003297

Base for armchair use
Reference: 4670024098

Transport case
Reference: 4640001927

Paediatric Foot plate
Reference: 4670023777

14. Product information

14.1. Regulatory compliance

The Kinetec Spectra Kompanion™ device was designed, manufactured and distributed in accordance with the requirements of Directive 93/42/CEE applicable to medical devices. In this respect, the Kinetec Spectra Kompanion™ device is CE marked.

The Kinetec Spectra Kompanion™ device complies with the following standards:

- IEC 60601-1 relating to requirements and tests in terms of electrical safety,
- IEC 60601-1-2 relating to electromagnetic compatibility,
- IEC 60601-1-11 which defines requirements for electro-medical devices used in the home care environment.

The Kinetec Spectra Kompanion™ device also complies with:

- the essential requirements of Directive Machine n°2006/42/CE,
- directive 2011/65/UE relating to the limitation of the use of certain hazardous substances in electrical and electronic equipment,
- directive 2002/96/CEE relating to electrical and electronic equipment waste (DEEE).

14.2. Conditions of guarantee

The Kinetec® guarantee is strictly limited to the free replacement or factory repair of the part or parts that are recognized to be defective.
KINETEC SAS guarantees its passive articular mobility devices for 2 years against any manufacturing defect, from the date of purchase by the consumer.
KINETEC SAS is solely accredited to judge the application of the guarantee for its devices.
The guarantee cannot be applied if the device has been used abnormally or was used in conditions of use other than those contained in our user manual.
The guarantee shall also not apply in the event of deterioration or accident resulting from negligence, compliance or maintenance fault resulting from a transformation of the equipment or an attempt to repair equipment.

14.3. Cleaning

WARNING:	**Above all, switch the device OFF by disconnecting the mains lead.**

Please clean the device after use to ensure visual cleanliness prior to the next use.

Cleaning is performed under the environmental conditions outlined in paragraph "14.6. Technical characteristics", page 23.

Cleaning protocol of the health care facility shall be followed. However, cleaning products, if used, shall either be alcohol-free or contain <5% alcohol.

When cleaning the tablet, do not let fluid get on to the *Welcome key (20) or* into the openings (power supply connector for the tablet, headset socket, etc.).

All consumables of the device can be disposed of without risk.

14.4. Maintenance

After 2,000 hours of operation or every year, the Kinetec Spectra Kompanion™ device requires some lubrication and maintenance (lubrication of joints, needle stops and ballscrews, verification of angulations, etc.).

This maintenance operation is indicated by the message **SERVICE TIME**. Despite this indication, you can continue to use your device but you should contact your closest Kinetec® specialist to carry out this maintenance.

An after-sales check sheet as well as the technical catalogue are available to you upon request from your Kinetec® distributor.

WARNING:	**Before use, check that the power socket is in good condition and can accommodate the power supply lead for the device. Only use the lead supplied with the device. Ensure that leads are clear of the device to avoid damaging them.**
WARNING:	**Before use, check that the device is not damaged, particularly the protective casings.**

When the device is no longer functioning, please return it to us along with its accessories for destruction.

14.5. Disposal and recycling

- **Packaging:** The packaging must be separated from plastic and paper/cardboard components and placed in specific recycling locations.
- **Kinetec® hygienic casing:** Clean with a disinfection product and then put it in specific recycling locations.
- **Device:** It contains electronic components, cables, plastic, steel and aluminium parts. When the device is no longer functional, dismantle and separate into groups of materials and place them in approved recycling units or return the device to KINETEC SAS for destruction. Or contact local authorities to establish the appropriate method of disposing of parts and accessories that are potentially dangerous to the environment.

14.6. Technical characteristics

Product:

Lifespan of the device:	8 years	
Lifespan of accessories:	8 years	
Weight:	12.5 kg (27.5 lbs)	
Dimensions of the device:	Length 95 cm, Width 37 cm, Height 33 cm	
Angular limits:	-10° to 120°	
Speeds:	From 45° to 155° per minute ±20%	
Inversion forces:	From 20 to 45 daN ±20% (dependent on levels of force and speed)	
Height of patients:	Complete leg:	71 to 99 cm
	Tibia:	38 to 53 cm
	Femur:	33 to 46 cm
Maximum user weight:	135 kg (297 lbs)	
Acoustic pressure:	<70dB	
Applied parts:	Hygienic casing and/or comfort shells	

Electricity:

Power supply voltage:	100-240V~	
Frequency:	50/60Hz	
Absorbed power:	50VA	
Class:	Class II BF type device	
Protection class (splint):	IP20 (protected against solid objects greater than 12.5 mm, but not protected against liquids)	
Protection class (carrying case):	IP01 (non-protected against solid foreign objects, protected against vertically falling water drops)	
Fuse:	T 750mA 250V 6,3x32mm (Kinetec® ref: 4610007434)	

Environment:

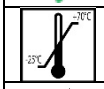
Storage / transport conditions:	Ambient temperature:	-25°C to +70°C.
	Relative humidity:	up to 93%.
Conditions of use:	Ambient temperature:	+5°C to +40°C.
	Relative humidity:	from 15% to 93% without condensation.
	Atmospheric pressure:	from 700 hPa to 1060 hPa.

14.7. Possible values for each of the settings

Treatment mode	Extension/Flexion Warm Up Spring Extremity Focus Evaluation Dynamic Stretch
Extension limit	-10° to 115°
Flexion limit	-5° to 120°
Speed	1 to 5 *(from 45° to 155° per minute)*
Inversion force	1 to 6 *(from 20 to 45 daN ±20%)*
Extension and flexion pauses	0 to 900 seconds (15 minutes) *From 1s in 1s up to 60 seconds* *From 30s in 30s from 1min to 5min* *From 1min in 1min from 5min to 15min*
Session time	Continuous (∞) or from 1min to 24h00

14.8. Symbols used

	Follow the instructions for use
START	Start of movement
	“Flexion limit” key
	“Speed” key
	“Force” key
	Status of Wi-Fi connection
	Direction of storage of box
IP20 IP01	Technical characteristics / Water-tightness, see page 23
~	Alternative current
	Class II device

	STOP (switch off)
STOP	Stop of movement
	“Less” key
	“Pause” key
	“Session time” key
	Status of Bluetooth connection
	Temperature limits outside of storage and transport
	Keep dry
	General safety sign
	BF type device (protection against electrical shock)

	START (switch on)
	“Extension limit” key
	“Plus” key
	Access to other settings key
	Fragile
	Humidity limits outside of storage and transport
	Contains electrical and electronic components: do not discard in household waste bins.

14.9. Troubleshooting guide

A “replacement parts” leaflet and/or technical catalogue are available to you upon request from your Kinetec® distributor.

After connection of the mains lead to a power socket and after the device is switched on:

- The *power indicator (39)* is not on:
  - Check the voltage in the mains socket using another electrical device or voltmeter.
  - Replace the fuse(s) for the power supply connector with fuses of the same type and grade: 2 fuses T750mA 250V (6,3x32mm) (Kinetec® ref: 4610007434).
  - Contact the closest Kinetec® specialist.
- No display on the tablet:
  - Check that the tablet is on. See “ 10. Procedure for starting up the device “, page 8.
  - The tablet is probably completely discharged. Leave the tablet charging for approximately 10 minutes before trying to switch it on (see previous step).
  - Contact the closest Kinetec® specialist.
- The *power indicator (39)* and the tablet are on but the device is not working. The following error message appears:
  - “SERVICE D1”: anomaly for the angle measurement function,
  - “SERVICE D2”: no movement,
  - “SERVICE D3”: abnormal electrical consumption for the motor,
  - “PUSH STOP/START”: motor power supply anomaly or motor disconnected.
- The *power indicator (39)* is on solid or flashing and the *Bluetooth connection status icon (17)* is green but the device is not working:
  - Switch off the device and the tablet (see "Procedure for shutting down the device", page 8),
  - Wait about 10 seconds,
  - Switch the *On/Off switch (8)* to **"I"**,
  - Keep the *On/Off key (11)* pressed for a few seconds until the welcome message appears,
  - Wait a few seconds before the main screen appears,
  - Wait about 30 seconds then follow "Bluetooth connection between the splint and the tablet", page 9
  - If the problem persists, contact your nearest Kinetec® specialist.

14.10. Information about electromagnetic compatibility (CEM)

All the information shown below is from requirements which the manufacturers of electro-medical devices are subject to, in the context of standard IEC60601-1-2.

Radio-frequency emissions from the Kinetec Spectra Kompanion™ device are very low and is therefore not likely to cause interference with electronic equipment installed close by (radios, computers, telephones, etc.). Nevertheless, the user shall ensure that any electromagnetic interference does not pose an additional risk, such as radio-frequency emitters or other electronic devices.

The Kinetec Spectra Kompanion™ device is designed to tolerate foreseeable disturbances resulting from electrostatic discharges, magnetic fields of the mains power supply or radio-frequency emitters. Nevertheless, certain types of mobile telecommunication devices such as mobile phones are likely to interfere with the medical device. The separation distances recommended in this chapter must therefore be scrupulously followed.

In this chapter you will find information about installing and using your medical device under the best conditions in terms of electromagnetic compatibility.

WARNING: **In the event of reciprocal, electromagnetic or other interference with other devices, move the device away.**

WARNING: **The Kinetec Spectra Kompanion™ device must not be used next to other devices or stored with the latter because this can cause incorrect operation. If such use is necessary, the device and other machines should be monitored to ensure normal operation.**

14.11. List of cables

WARNING: **The use of accessories and cables other than those specified or provided by KINETEC SAS can increase electromagnetic emissions or reduce immunity of the device and cause inappropriate operation.**

List of cables likely to alter the compliance of the Kinetec Spectra Kompanion™ device in relation to emission requirements and electromagnetic immunity:

Designation	Kinetec reference	Maximum length
Europe mains lead	4610009092	3.5m
US/Japan mains lead	4610009109	4m
Brazil mains lead	4610009117	3.5m
UK mains lead	4610009125	3.5m
Australia mains lead	4610009133	3.5m
Swiss mains lead	4610009365	3.5m
Spiral cable	4610007913	2m
Tablet cable	4610009456	2m

14.12. Recommended separation distances

The Kinetec Spectra Kompanion™ device is anticipated to be used in an electromagnetic environment in which radiated radio-frequency disturbances are controlled.

WARNING: **Portable radio-frequency devices should not be used (including peripherals such as coil cables and external coils) within 30 cm (12 inches) of any part of the Kinetec Spectra Kompanion™ device including cables specified by Kinetec. Should the opposite occur, the performance of these devices could be altered.**

14.13. Electromagnetic emissions

The Kinetec Spectra Kompanion™ device is anticipated to be used in the electromagnetic environment described in the table below.
The user and the installer should ensure that the Kinetec Spectra Kompanion™ device is used in the environment described below.

Emission tests	Conformity	Electromagnetic environment - Notes
Disturbance from electromagnetic radiation (radiated emissions) CISPR 11	Group 1	The Kinetec Spectra Kompanion™ device uses radiofrequency energy only for its internal operation. Consequently, its radiofrequency emissions are very low and are not likely to create any interference with neighbouring equipment.
Disruptive voltage at power supply terminals (conducted emissions) CISPR 11	Class B	The Kinetec Spectra Kompanion™ device is suitable for use in the health care at home environment and in the environment of a professional health care institution.
Emissions from harmonic currents IEC 61000-3-2	Class A	
Variations of voltage, fluctuations of voltage and flickering IEC 61000-3-3	Compliant	

14.14. Magnetic and electromagnetic immunity

The Kinetec Spectra Kompanion™ device is anticipated to be used in the magnetic and electromagnetic environment described in the table below.
The user and the installer should ensure the conformity of the electromagnetic environment.

Immunity tests	Test level according to IEC60601	Level of conformity	Electromagnetic environment - Notes
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV in contact ±15kV to air	±8 kV in contact ±15kV to air	Suitable for use in the health at home care environment and in the environment of a professional health care institution.
Rapid / in salvo electrical transitionals IEC 61000-4-4	±2 kV for electrical power supply lines ±1 kV for signal ports	±2 kV for electrical power supply lines ±1 kV for signal ports	The quality of the electrical power supply network must be equivalent to that of a health at home care environment and of an environment of a professional health care institution.
Shock waves IEC 61000-4-5	±1 kV between phases ±2 kV between phase and earth	±1 kV between phases ±2 kV between phase and earth	The quality of the electrical power supply network must be equivalent to that of a health at home care environment and of an environment of a professional health care institution.
Magnetic field at the assigned industrial frequency IEC 61000-4-8	30A/m	30A/m	The intensity of the magnetic field must be of the level found in a health at home care environment and in an environment of a professional health care institution.
Voltage hollow IEC 61000-4-11	0% U_T for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle 70% U_T for 25 cycles at 50Hz for 30 cycles at 60Hz single phased at 0°	0% U_T for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle 70% U_T for 25 cycles at 50Hz for 30 cycles at 60Hz single phased at 0°	The quality of the electrical power supply network must be equivalent to that of a health at home care environment and of an environment of a professional health care institution. If the use of the device requires the continuation of operation during power cuts, it is recommended powering the medical device using a separate power source (UPS, etc.).
Voltage interruptions IEC 61000-4-11	0% U_T for 250 cycles at 50Hz for 300 cycles at 60Hz	0% U_T for 250 cycles at 50Hz for 300 cycles at 60Hz	
NOTE: U_T corresponds to the alternative network voltage before the application of the test level.			

14.15. Electromagnetic immunity, radio-frequency portable equipment

The Kinetec Spectra Kompanion™ device is anticipated to be used in the magnetic and electromagnetic environment described in the table below.
The user and the installer should ensure the conformity of the electromagnetic environment.

WARNING: **Portable radio-frequency devices should not be used (including peripherals such as coil cables and external coils) within 30 cm (12 inches) of any part of the Kinetec Spectra Kompanion™ device including cables specified by Kinetec. Should the opposite occur, the performance of these devices could be altered.**

Immunity tests	Test level	Level of conformity	Electromagnetic environment - Notes
Radiated radio-frequency electromagnetic fields IEC 61000-4-3	3 V/m from 80 MHz to 2.5 GHz 10 V/m from 80 MHz to 2.7 GHz 80% MA to 1kHz	3 V/m from 80 MHz to 2.5 GHz 10 V/m from 80 MHz to 2.7 GHz 80% MA to 1kHz	The Kinetec Spectra Kompanion™ device is suitable for use in the health care at home environment and in the environment of a professional health care institution.
Proximity fields emitted by radio-frequency wireless communication devices IEC 61000-4-3	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	The Kinetec Spectra Kompanion™ device is suitable for use in the health care at home environment and in the environment of a professional health care institution.
Disturbances conducted, induced by radio-frequency fields IEC 61000-4-6	3 V from 150 kHz to 80 MHz 6 V in ISM band and band between 0.15 MHZ and 80 MHZ, amateur radio band included 80% MA to 1 KHz	3 V from 150 kHz to 80 MHz 6 V in ISM band and band between 0.15 MHZ and 80 MHZ, amateur radio band included 80% MA to 1 KHz	The Kinetec Spectra Kompanion™ device is suitable for use in the health care at home environment and in the environment of a professional health care institution.

The intensities of electromagnetic fields for fixed radio-frequency emitters, as determined by an electromagnetic environment measurement (a) must be less than the conformity level for each range of frequency.

Interference can occur close to equipment identified by the following symbol: 

NOTE: These specifications may not apply in all situations. Electromagnetic propagation is affected by the absorption and by the reflection of structures, objects and people.

(a) The intensities of electromagnetic fields for fixed radio-frequency emitters such as base stations for mobile phones (cell/wireless), mobile radios, amateur radios, AM/FM radio emissions and TV emissions cannot be determined accurately by theory.
To evaluate the electromagnetic environment due to fixed radio-frequency emitters, an electromagnetic environment measurement must be made. If the intensity measured of the radio-frequency field in the immediate environment of use of the product exceeds the level of radio-frequency conformity specified above, it is necessary to test the performance of the product to check that it is compliant with the specifications. If abnormal performance is noticed, additional measurements may be necessary, such as re-directing or moving the product.

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