





Kinetec Kinevia™ Kinetec Kinevia Duo™

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1. Information about this user manual

Read this user manual carefully and entirely before using the device for the first time.



Users must have access to this user manual at all times. It must be kept for future use.

1.1. Danger and warning indications

This user manual contains safety information allowing users to recognise and avoid potential hazards. In this manual, potential hazards are indicated using three warning words:

- DANGER: indicates immediate danger situations that can result in death or serious injury if not avoided.
- WARNING: indicates potential danger situations that can result in injury if not avoided.
- CAUTION: indicates potential danger situations that can result in minor or moderate injury if not avoided. This
 warning word can also be used to draw attention to unsafe practises or potential damage to the device or its
 accessories.

1.2. Danger and warning symbols

Potential hazards, mandatory measures, prohibitions and information are indicated consistently using the same symbols throughout this user manual.



Hazard indication

Symbol used to warn of hazards, independently of the danger level. The danger level is indicated by the corresponding warning word, as described in section 1.1



Prohibition

Symbol used to indicate prohibitions.



Information

Symbol used to indicate advice or additional useful information.

1.3. User manual photos

The product and display screen presentation may vary slightly from the illustrations in this user manual.

2. General information about the Kinetec Kinevia™ device

2.1. Field of use

The Kinetec Kinevia™ motorised therapy trainer is designed to exercise the lower or upper limbs of patients who have limited movement capacity caused by neurological or neuromuscular pathologies.

Kinevia is to be used as a:

- Leg trainer (Kinetec Kinevia™)
- Combined leg and upper body trainer (Kinetec Kinevia Duo™)



It is not possible to use the arm and leg trainer at the same time.

Kinevia can be used for the following types of exercise:

- Passive mobilisation: the arm or leg movements are initiated by the motors.
- Active mobilisation: patients move their arms and legs using their own muscular force.
- Active mobilisation with motor support (soft training or assisted active training): patients move their arms
 and legs using their own muscular force while the motor is operated in a targeted manner.

2.2. Indications

The use of Kinevia is indicated in cases of:

- Paralysis or neuromuscular pathologies with reduced arm / leg mobility, for example following paraplegic lesions, multiple sclerosis, muscular dystrophy, Parkinson's disease, brain damage or neuromuscular pathologies with comparable symptoms.
- · Cardiac / circulatory problems
- Metabolic pathologies
- Rheumatoid pathologies
- Vascularization problems
- · Lack of movement

2.3. Contraindications

Motor-assisted rehabilitation therapy is a form of treatment with support. However, there are situations in which it should not be used.

These contraindications cover:

- Significant pain experienced during movements
- Diseases or injuries for which movement is not recommended, such as recent fractures for example
- Significant nerve compression (excess pressure damage)
- Fever generating infections
- Brittle bones
- · Unstable circulation

2.4. Side effects

The therapy should be discussed with the attending physician, the therapist or the kinesitherapist concerning its extent and duration in order to avoid excess activity and side effects.

Risks may appear if patients are pushed beyond their personal limits or capacity.

In rare cases, certain adverse effects can appear, such as:

- Muscular or articular pain,
- A significant reduction in muscle tone,
- Skin injuries.

2.5. Intended user profile

The user can be:

- A patient,
- · A health and rehabilitation professional,
- · A cleaning agent,
- · A maintenance, servicing or repair agent,
- · A carrier,
- · A recycling officer.

The user must have the following knowledge and skills:

- Know how to read and understand "westernized Arabic" numerals and at least 5 years of reading experience.
- $\,{}^{\circ}$ Know how to distinguish arms, legs and feet.
- Understand the hygienic aspect.
- Have a visual acuity ≥ 8/10th, with or without correction.
- $\,{}^{\circ}$ Have a tactile sensitivity in order to use the touch panel.
- Have sufficient grip capability to hold the arm trainer handles.

2.6. Intended use environment

- Kinevia is designed for use in a professional healthcare establishment (hospital, clinic, medical practice) and in a home healthcare environment (residential establishment, medical care centre).
- Indoor use only.
- Do not use in wet rooms (i.e. bathroom)
- Viewing distance: 50cm to 100cm from the display
- Viewing angle: perpendicular to the display ± 30 °.

2.7. Important information before starting a training session

- It is essential to consult with your doctor or therapist before starting training.
- Please discuss the suitability of rehabilitation using Kinevia, the appropriate forms and duration of rehabilitation, as well as the device settings with your attending physician or therapist.
- Especially following recent surgery such as: knee or hip surgery, articular injuries, amputation/fitting of prostheses, partial or completely torn cruciate ligaments, thrombosis, osteoporosis, decubitus, stiff articulations, risk of shoulder or hip dislocation.
- In cases of heart failure or circulatory deficit, you should consult your doctor before starting training. In that case it is preferable to train under the supervision of an adult.
- Kinevia is designed for humans with a body weight of up to 135 kg.
- The arm trainer must not be loaded with more than 15 kg on each side.
- The leg trainer must not be loaded with more than 25 kg on each side.
- Proper use of the Kinevia is only possible using accessories authorised by Kinevia.



Kinevia is a medical device reserved for therapeutic uses. Kinevia is not designed for diagnostic, monitoring or measurement purposes.

2.8. Training prerequisites

- No training is required in the context of use in a professional healthcare establishment.
- In the context of use in a home healthcare environment, the user manual must be fully read or training in the use
 of the device must be given by qualified personnel.
- Users must be able to sit up straight.
- Users can only use the device without supervision if they are capable of operating the device on their own.
 Otherwise, training should only occur under the supervision of assistance staff.

2.9. Non-liability clause

Kinetec SAS declines all liability for damage, losses or costs resulting from or associated with:

- · Incorrect installation, repair or maintenance carried out by persons not authorised by Kinetec.
- The use of accessories, spare parts or supplies not authorised by Kinetec SAS.
- Incorrect use.
- Use without consulting the attending physician or therapist.
- Failure to comply with the user manual.
- · Negligence.

3. Therapy using Kinevia

3.1. Therapy forms

The following forms of therapy are possible using Kinevia:

Passive mobilisation using a motor drive

The limbs are put into movement by the force provided by the motor. Pedal acceleration and stoppage is gentle and gradual.

The final rotation speed is reached at the earliest after 10 seconds.

The maximum rotation speed for passive training is 60 rpm.

Active movement using the patient's muscular strength

This type of movement can be carried out with more or less active muscle movement.

Two forms are available:

Assisted training: active movement with passive motor support

The active movements are supported by the passive motor force.

Active training: active movement with motor resistance

The muscles are subjected to a resistance which favours muscular development.

Resistance can be set to 20 different levels, comparable to changing gears on a bicycle. The higher the level, the harder it is to pedal. This function is used to develop the muscles.

The device can be used in forward or reverse mode. An automatic change of rotation direction can also be configured using the automatic rotation direction.

3.2. Antispastic and relaxation control

Kinevia is fitted with an antispastic control system which, if spasms are identified during passive mobilisation, is used to stop the movement and then resume after a short pause.

When a spasm is identified, it is possible to configure whether the pedals should carry on turning in forward or reverse or in the opposite direction. By default, the Kinevia will reverse the direction of rotation when a spasm is identified.

The relaxation program eliminates cramps and relaxes the muscles in the event of spasms. Depending on needs, the antispastic control sensitivity can be adjusted to six level settings.



4. Warnings and safety instructions



Please read the following safety instructions carefully. Failure to follow these instructions can endanger patients, operators or auxiliary staff.

When assembling or installing the device:

- If assistance is needed when assembling, using or maintaining the device, contact your Kinetec® dealer.
- The device must be installed and commissioned in compliance with the information contained in this manual.
- The device must be installed by an adult.
- Please leave sufficient space around the device to allow use without interaction.
- Place the device so that the power plug is easy to access and can be quickly disconnected from the power outlet in an emergency.
- Place the device on a firm, flat and non-slippery floor with the four support stands firmly in contact with the floor.
- When installed on a mat or carpeting, make sure it is installed in a way that prevents sliding.
- Make sure that the ventilation outlets located under the support stands (7) are not obstructed.
- Do not use the device with anaesthetic gas or in an oxygen-rich environment. Risk of explosion.
- The device is fitted with an external power supply (PMP220F-14-HI). The device should only be started up using the supplied power supply block. Please make sure that the power supply block and the electric cables are in good condition. Only use the original power cord supplied with the device.
- Do not use accessories, spare parts or supplies other than those described in this manual.
- Do not connect the Kinevia to other devices not described in this manual.
- Only equipment authorised by Kinetec should be connected to the USB port (12) and jack socket (13).
- Do expose the device to direct sunlight, or heating elements or other heat sources, in order to avoid the dangerous heating of the guard surface.
- The time required for the device to warm up from the minimum storage temperature between uses until it is ready for use when the room temperature is 20°C is 2 hours.
- The time required for the device to cool down from the maximum storage temperature between uses until it is ready for use when the room temperature is 20°C is 2 hours.

DANGER

DANGER OF DEATH FROM PLASTIC BAGS, SMALL OBJECTS AND CABLES AND CORDS



Plastic packaging must be kept out of the reach of infants and children. For them, plastic bags can become a toy and attract their attention. In those cases there is a major risk of suffocation which must be avoided as much as possible to avoid serious brain damage or death.

Keep children at a distance, risk of suffocation or asphyxia from the accidental inhaling or swallowing of small objects that can cause serious lesions or death.

Keep children at a distance, risk of strangling leading to serious brain damage or death.



Before each training session:

- Check that the device is not damaged.
- Please make sure that the power supply block and the electric cables are in good condition. Only use the original power cord delivered with the device.
- Check that the power outlet is in good condition and is suitable to connect the device power cord plug.
- Check that the cords are always free around the device to avoid damaging them.
- Always make sure it is not possible for the arms to become caught up in moving parts such as leg fixings, arm handles or protective plates during use.
- · Make sure that the foot pedals (5) and the arm trainer grips (9) rotate freely during training.
- · Make sure that the indexing button (3) for height adjustments is firmly anchored in one of the holes and tightened.
- Make sure that the two indexing buttons (14) used to adjust pedal distances are firmly anchored in one of the holes and tightened.
- The doctor or therapist defines the training protocol and duration and makes sure it is properly carried out (settings, session duration and frequency of use).
- Always check the displayed movement parameters before starting the device.
- Make sure that the posture, the device height setting, the pedalling radius, the distance to the pedals and all training
 parameters are set to match your physical capacities.
- Make sure that the legs or arms are properly fixed before starting the therapy.

During the training session:

- Do not touch the static or moving parts of the device when it is in use. There is a risk of pinching or crushing by the arm trainer grips or foot pedals.
- Keep children and pets away from the device. There is a risk of pinching or crushing by the arm trainer grips or foot
 pedals.
- Children under the age of 15 should only train using the Kinevia under permanent supervision.
- Only use the leg trainer wearing suitable footwear and check that shoe laces will not get caught up in moving parts.
 Risk of injury by laces being caught up.
- Only use the leg trainer with both foot fixings attached and tightened.
- Always make sure the arms are securely attached to the arm attachments and that there is a good grip on the handles when using the arm trainer.
- The device must only be used on healthy and unbroken skin.
- When using the arm trainer, your feet must not be attached to the foot pedals (5).
- Make sure there is a correct distance between your seated position and the device position. Avoid stretching your articulations too much (see section 7.1 on page 19)
- We recommend starting training slowly and avoiding overloads.
- Not smoking is recommended during training.



During cleaning and care:

- Clean the device between each patient, especially the parts in contact with patients such as the arm trainer grips (9) and the support and/or transport bar (2).
- Do not use cleaning products containing solvents, acids or abrasives.
- It cannot be excluded that carpeting, wood flooring or tiling cleaning products contain substances that are corrosive to the Kinevia support stand (7) plastic coatings. This could lead to deposits on the floor. Kinetec is not liable for this damage.
- Regularly check that the screws are properly tightened.

During the entire device service life:

- Only the manufacturer or staff authorised by Kinetec are authorised to alter the device.
- Disconnect the power supply before any work on the device.
- Extensions, re-installations, alterations or repairs should only be carried out by staff authorised and approved by Kinetec.
- If unexpected operation or events, strange noises, a smell of burning occur, immediately power off the device by disconnecting the power cord and contact your Kinetec® dealer.
- All serious incidents related to the system must be the subject of a notification to the manufacturer and the competent authority in the member state in which the user and/or patient are located.
- · Avoid allowing liquids to penetrate inside the device or the touch screen.
- Kinevia is designed for use in the seated position. Do not climb onto the foot fixings with your whole weight and do not hang from the arm trainer.
- The leg trainer must not be loaded with more than 25 kg on each side.
- The arm trainer must not be loaded with more than 15 kg on each side.
- If there is electromagnetic or other interference with other devices, more the system away from them.
- Kinevia must not be used next to other devices or stacked with them as this could lead to malfunctions. If this use is required, observe this and the other devices to check that they are still in working order.
- The use of accessories and cables other than those indicated or supplied by Kinetec can cause increased electromagnetic emissions or reduce device immunity and cause malfunctions.
- Portable radio-frequency communication devices (including peripherals such as aerial cables and external aerials) should not be used closer than 30 cm (12 inches) from any part of the Kinevia, including the cables specified by Kinetec. If this is not the case, the performances of those devices could be altered.



DANGER



DANGER OF DEATH DUE TO A PACEMAKER

If you have a pacemaker, consult a doctor before your first training session and enquire about possible complications.

Beware of possible interference and contact an expert dealer if this occurs.

WARNING

DANGER DUE TO PHYSICAL DEFICIENCIES



Determine whether an assistant needs to be present during training with help from your doctor, therapist or your expert dealer.

If assistance is needed for safe training, make sure the assistant is in the immediate vicinity during training so that they can stop the Kinevia at all times.



WARNING

DANGER DUE TO PHYSICAL DEFICIENCIES

If training using the Kinevia gives you pain or causes you to feel unwell, contact your doctor or therapist immediately.

WARNING

RISK OF INJURY DUE TO A LACK OF PREPARATION



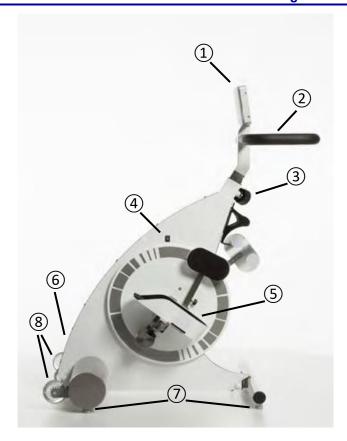
Before each use, visually inspect the Kinevia to check for possible damage, especially on the power socket (6), power supply and cables.

The device must be disinfected before training sessions.

Make sure that the foot pedals (5) and the arm trainer grips (9) rotate freely during training.



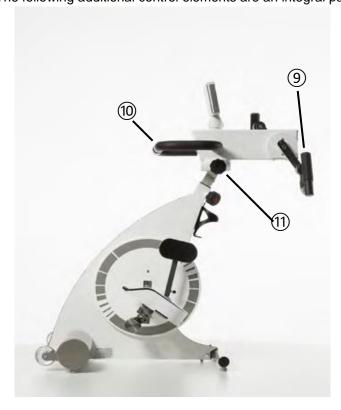
5.1. General view of the Kinetec Kinevia™ leg trainer



- ① Control touch screen
- ② Support and/or transport bar
- ③ Grip height indexing button
- 4 On/Off switch
- (5) Foot pedal
- 6 Power supply plug
- Support stands
- Transport castors

5.2. General view of the Kinetec Kinevia Duo™ upper and lower limb trainer

The following additional control elements are an integral part of the arm trainer system:



- Arm trainer grip
- Support and/or transport bar
- 1 Pivoting arm locking screw





- (2) USB port
- (13) Jack connector

5.4. Accessories

5.4.1. Calf support

The leg guides with calf supports are height adjustable. They provide additional stabilisation and guidance to the lower leg during training and prevent unintentional sideways leg movements.

Order reference: 4665009477



5.4.2. Self-handling foot attachment

The self-handling foot attachments are used to hold the feet in place in the supports. Locking and unlocking are easy to access, thereby facilitating patient autonomy when they install themselves on the device.

Order reference: 4665010870



5.4.3. Tilt protection hooks

The tilt protection hooks are fixed to the Kinevia front support stand and are attached to the wheelchair to prevent tipping over during training.

Order reference: 4665009500





5.4.4. Heart rate kit

The Kinevia heart rate kit provides monitoring and the display of the heart rate as part of training. The kit is composed of a training belt (emitter) and a receiver connected to the touch screen using the jack socket (13).

Use of the kit is described in section 6.9 on page 19.

Order reference: 4665009469





5.4.5. Ergonomic handle

The perfectly curved ergonomic handles allow comfortable upper limb training.

Order reference: 4665010515



5.4.6. Support glove

The fixture for a Handfix wrist is used to attach the hands to the arm trainer grips. It is recommended in cases of spasms, hand paralysis and all hand motor pathologies which prevent a proper grip.

Available in 4 sizes: 0 (children), 1 (women/teenagers), 2 (men), 3 (large hands)

Order references: 4665009972 (size 0)

4665009964 (size 1) 4665009956 (size 2) 4665011026 (size 3)



5.4.7. Hand support with forearm guide

The length and pitch adjustable hand support with forearm guide is used to support the arm in cases of paresis. The arms are fixed using hook and loop bands.

The hand support with forearm guide should only be used when auxiliary staff is present.

Order reference: 4665010119





5.4.8. Paediatric foot support

The paediatric foot supports make it possible for children to use the therapeutic leg trainer safely and comfortably.

Order reference: 4665040001



5.4.9. Kinetec Kinevia Cockpit™

Kinetec Kinevia Cockpit™ software is for use by healthcare professionals.

It can be used to:

- analyse and archive the training sessions for up to 100 users
- print training data or export it to a PDF file.

Training data is transferred using a USB thumb drive

Order reference: 4665040002



6. Commissioning, transport and settings

6.1. Unpacking and installation

Please follow the safety instructions on page 7.

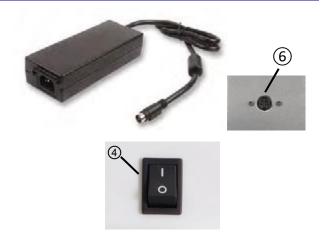
Before starting up, remove all packaging and transport protection.

Check that the device is complete and identify possible damage that may have been caused during transport.

If there are missing parts or if there is visible damage, immediately contact your Kinetec® dealer.

6.2. Electric connection

- a) Connect the external power supply connector to the power supply socket (6) at the back of the Kinevia.
- b) Connect the power supply cable to the external power supply.
- Connect the power supply cable to the mains power outlet.
- d) Turn the Kinevia on by pressing the on/off switch (4).
- e) The screen comes on and displays the home page (see section 8.1 on page 21).





6.3. Transport

- a) Before moving the device, make sure it is powered off and that the power supply cable is disconnected.
- b) Remove the connector from the power supply socket (6).
- c) Pivot the arm trainer so that the support bar is directed to the transport castor side.
- d) Tip the device over the transport castors until the Kinevia can safely be pushed or pulled.
- e) When moving it, firmly hold the device using the transport grips with both hands.
- f) If rolling the Kinevia to the required spot is not possible (for example due to thresholds or stairs), two people should carry it by lifting the lower part of the frame.



The castors are not designed for transport over long distances or on floors that are not flat.



WARNING

RISK OF INJURY DURING UNSUITABLE TRANSPORT



When being transported on stairs or uneven surfaces, the device must be carried by at least two people.

Only use the device transport castors on hard, flat flooring.

The external power supply must be fully removed from the device for transport.



6.4. Foot support spacing setting

The foot support spacing can be set to 4 different positions using the indexing button (14).

- a) Please power off the device before setting the pedal spacing.
- b) Unscrew the indexing button (14) by about a ½ turn and pull the anchoring pin out of the hole.
- c) Move the foot support to the required position until the anchoring pin returns to the hole.
- d) Screw back the indexing button (14).
- e) Repeat steps b and c for the second foot support.
- **(i)**

Make sure the two foot supports are set to the same distance.





WARNING

RISK OF INJURY CAUSED BY UNTIGHTENED SUPPORTS

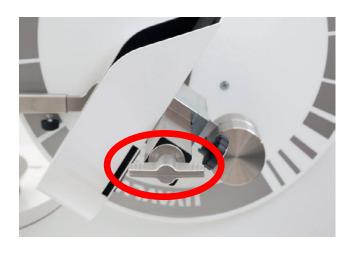
Make sure the white anchoring bolt is always properly tightened.

6.5. Pedal radius setting

The radius can be continuously set between 50 and 125 mm.

- Please power off the device before setting the pedal radius.
- b) Slightly unscrew the wing nuts located at the outside end of the pedal arms (photo).
- Guide the foot support to the required position using both hands.
- d) Tighten the wing nuts (only tighten by hand).
- e) Repeat steps b and c for the second foot support.
- **(i)**

Make sure the pedal radius is set to an identical position on both sides, otherwise the device will not run in a circle.





Your knee joints should always be slightly flexed to protect your joints. Correct the distance to the device or the pedal radius if necessary.

À

WARNING

RISK OF INJURY CAUSED BY UNTIGHTENED PEDAL ARMS

When making the settings, make sure the pedal arm is properly fixed.

Check that the wing nut is properly tightened before each training session.

If you experience difficulty unscrewing the wing nuts, use the loosening tool supplied below.









6.6. Grip height setting

The arm trainer support/transport grip height can be set to 6 different positions using the indexing button (3)

- Unscrew the indexing button (3) by about a ½ turn and pull the anchoring pin out of the hole.
- Raise or lower the grips to the required position until the anchoring pin returns to the hole
- c) Screw the indexing button (3).



The red safety button indicates whether the anchoring pin is properly anchored in one of the

The indexing button (3) can only be tightened if the red safety button is not deployed.







RISK OF INJURY CAUSED BY UNTIGHTENED INDEXING BUTTON

Before each training session, check that the indexing button is anchored and tightened.

Make sure the grips do not collide with the legs when setting their height.

6.7. Calf support height setting

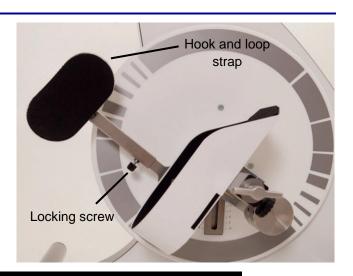
- a) Unscrew the locking screw by about a ½ turn.
- b) Raise or lower the calf support to the required height.
- Re-tighten the locking screw. c)
- Before starting to train, pass the leg hook and loop strap and attach it to the calf support.



Make sure the calf support fixings are attached at the most at a hand's width below your knee.



Make sure that the hook and loop band is not too tight so that it does not cut off your blood flow.





WARNING

DANGER DUE TO A LACK OF AUTONOMY

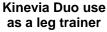
Patients who are unable to remove the calf fixing themselves must not train without supervision.

6.8. Starting the Kinevia duo arm trainer

To use the Kinevia as an arm trainer:

- a) Unscrew the 2 pivoting arm locking screws (11).
- b) Pivot the arm trainer 180 degrees to the right.
- c) Re-tighten the 2 pivoting arm locking screws (11).
- d) You can now activate the arm trainer from the touch screen (see section 8.3.2 on page 23)







Kinevia Duo use as an arm trainer



It is not possible to use the arm and leg trainer at the same time.



WARNING

RISK OF INJURY DUE TO LEG POSITION WHEN USING THE ARM TRAINER

The user's feet must not be placed in the foot pedals when using the device as an arm trainer.



6.9. Cardio kit settings

- a) To use the Kinevia cardio kit, connect the heart rate receiver to the jack socket (13) at the top of the touch screen (the POLAR logo on the receiver should be towards you).
- b) Place the emitter centred on the chest (slightly dampen the emitter for better conductivity).
- c) Attach the thoracic belt clip closure.



The belt length is adjustable. Make sure the thoracic belt is not too tight.



Make sure the thoracic belt cannot slip.

d) Once the thoracic belt is properly attached and the receiver connected, the Kinevia displays your heart rate on the screen during training (see section 8.3.3 on page 24).



Receiver



Emitter



6.10. Standby mode

· Activating standby mode:

Standby mode is activated by pressing anywhere on the screen for about 5 seconds.

• Exiting standby mode:

Standby mode is disabled by pressing anywhere on the screen for about 5 seconds unit the home page is displayed.

7. Instructions for the proper use of the Kinevia

7.1. Installing the patient

The success of your therapy mainly depends on a correct seated position.

Follow the following instructions:

- If you are training from a wheelchair:
 - Make sure you use a suitable wheelchair.
 - The wheelchair must not tip backwards.
 - Make sure the wheelchair is properly attached.
 - If spasms were to appear, we especially recommend the use of the tipping prevention hooks (see section 5.4.3 on page 12).
- If you are training from a chair:
 - Make sure the chair is stable and has a wide, flat back.
 - The chair must not tip backwards.
 - Do not use chairs fitted with castors (office chairs, for example).
- Sit straight and in a centred position. The chair or wheelchair must be centred facing the device.



7.2. Using the leg trainer

- Make sure the chair or wheelchair are at a proper distance from the Kinevia: your legs must be lightly sloped and not stretched in order to prevent injuries to the joints, muscles and ligaments.
- If you are a beginner, choose a slightly shorter distance from the device.
- Set the support bar height depending on your height (see section 6.6 on page 17): your arms should not be stretched
 and your knees must not collide with the support bar during the movements.
- Make sure your feet are properly attached to the foot supports using the hook and loop straps.
- If you suffer from signs of paralysis, we recommend using the leg guiding system (see sections 5.4.1 on page 12 and 6.7 on page 17).

7.3. Using the arm trainer

- The user's feet must not be placed in the foot pedals
- Set the arm trainer grip height depending on your height (see section 6.6 on page 17).
- Make sure there is a sufficient distance between the chair or wheelchair and the Kinevia: your elbow joints must not be too strained.
- If your arm muscles are weak or partially paralysed, we recommend using the support gloves (see section 5.4.6 on page 13) or the hand supports with forearm guide (see section 5.4.7 on page 13).



WARNING

RISK OF INJURY DUE TO AN INCORRECT SEATED POSITION

Before training for the first time, ask your doctor or therapist show you the correct seated position.

7.4. General training advice

Training using Kinevia has positive effects on the body and mind.

Regular training can contribute to muscle growth, joint release, improved blood circulation and even good digestion.

Kinevia is indicated both to prevent lack of movements and for therapeutic uses. However, successful training requires a suitable training plan adapted to your personal needs.



WARNING

RISK OF INJURY THROUGH EXCESSIVE TRAINING

Discuss your personal training plan to reach your training target with your doctor or therapist.

The following recommendations are valid for correct training:

- Adapt training sessions to your physical capacities and your state of health.
- Prefer several short training sessions rather than long ones during which you overexert yourself.
- If possible, schedule your training sessions at fixed times in your schedule. Regular training will be more likely to give the hoped for training results than sporadic training.
- Start your training sessions in passive mode in order to warm up your joints and avoid spasms.
- At the start of training, select a lower rotation speed and pedalling resistance. When in doubt, set a lower pedal radius.
- When in doubt, start your training sessions using the "soft" option in the "Guided training" menu.

Training should be pleasant in order to maintain your long term motivation. After 4 to 6 weeks of daily training, the first positive effects are usually visible.

You will see the success of your training because your muscles become increasingly relaxed and the motor contributes less power than before for continuous pedal rotation.

You can adapt your training gradually depending on your physical condition and your progress.

8. Using the touch screen

The touch screen has a high quality 7 inch display. All the functions are triggered by pressing the corresponding zones with the fingertips. The screen is adjusted to only react to light pressure to avoid unintentional actions. Use the index finger, the middle finger or the thumb to press the screen.

8.1. Main menu

The main menu is displayed a few seconds after powering on.



You can select from the following options:

Quick start: used to directly access the start of training using the previously set standard training (see section 9.1 on page 29).

Guided training: accesses the pre-programmed training selection screen for various pathologies (see section 9.2 on page 29).

Individual training: accesses the selection of other training without pre-settings (see section 0 on page 32).

Training analysis: displays the training synthesis after a session has been completed (see section 10 on page 32).

Statistics: displays the overall assessment of all your completed training sessions using a long term view (total and mean values) (see section 0 on page 34).

Settings: accesses the menu to update preset parameters and device parameters (see section 0 on page 34).

Service: this key is locked by a 4-digit code and can only be accessed by maintenance technicians. The service menu can be used to apply updates, for example.

Standby: activates standby mode. This key must be pressed for 5 seconds to avoid any unintentional activation of standby mode. The screen turns off as soon as standby mode is activated. To reactivate the device from standby mode, press anywhere on the screen for about 5 seconds (see section 6.10 on page 19).



8.2. Main key functions

8.2.1. "Minus" and "plus" keys

These keys are used to increment or decrement values such as resistance, rotation speed, date, etc.



8.2.2. "Horizontal arrow" keys

These keys are used to scroll through the different parameter fields or from one screen to the next.



8.2.3. "Home" key

This key is used to go back to the home page. The key is disabled during an ongoing training session.



8.2.4. "Back" key

This key is used to go back to your last setting or to the previous screen



8.2.5. "Validate" key

This key is used to confirm a menu selection.



8.2.6. "Cancel" key

This key is used to cancel a menu selection.



8.2.7. "Start" key

Pressing this key starts the therapy program. The rotation speed gradually increases until it reaches the preset value (the target rotation speed is reached after minimum 10 seconds).



8.2.8. "Stop" key

Pressing this key stops the therapy programme. The rotation speed drops gradually until it comes to a complete stop.

To carry on the training session, press the "start" button again.

To display the training analysis, press the "back" button To exit the therapy programme, press the "home "button."



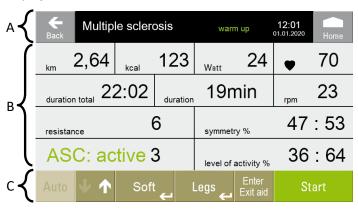


8.3. Training menu

When you select a therapy programme, a training screen is displayed:

The training screen is organised as follows:

- A Upper command panel
- B Training command panel
- C Lower command panel



8.3.1. Upper command panel displays and keys



1 Back key:

Used to go back to the last setting or to the previous screen.

② Display panel:

Displays the current therapy programme, the training phase and the date and time. The different training phases are: warm up, training, recovery.

3 Home key:

Used to go back to the home page.

8.3.2. Lower command panel displays and keys



4 Automatic change of rotation direction key:

This key is used to enable or disable the automatic change of pedal rotation direction.



Using the "settings" menu (see section 12.7 on page 36), you can adapt the time between each automatic change of direction (the factory setting is 3 minutes).

A few seconds before the change of direction, the rotation speed drops gradually until it comes to a complete stop. The direction changes. Then the rotation speed increases gradually until it reaches the preset value.



Manual change of rotation direction key:

This key is used to reverse the pedal rotation direction.





When this key is pressed, the rotation speed drops gradually until it comes to a complete stop. The direction changes. Then the rotation speed increases gradually until it reaches the preset value.

6 Active / passive / soft mode selection key:

This key is used to select the following training modes:

- o Active: training using your own muscular force
- Passive: training using the motor
- Soft or assisted active: training using your own muscular force assisted by the motor in a targeted manner

O Arm trainer / Leg trainer mode selection key:

This key is used to select the leg trainer or arm trainer operating modes. The key is enabled if, and only if, the arm trainer is properly installed and leg training has been completed.



It is not possible to use the arm and leg trainer at the same time.

8 Enter exit aid key:

This key is used to move the pedals to a comfortable position allowing the patient to place or remove their feet from the foot supports (also see section 8.4 on page 26).

Start/stop key:

This key is used to start or stop the training (also see sections 8.2.7 on page 22 and 8.2.8 on page 22).

8.3.3. Training command panel displays and keys



10 Distance covered:

This field indicates the distance covered during the training session in km.

11 Calories:

This field indicates the energy burned by your muscular work displayed in kcal.

2 Active power:

This field indicates your active pedalling power displayed in Watts.



(3) Heart rate:

This field indicates your current heart rate if you have connected the Kinevia cardio kit displayed in beats per minute.

(4) Duration:

This field displays the remaining training time displayed in minutes and seconds.

(15) Timer:

This field indicates the set duration for the current training phase (warm up, training, recovery) displayed in minutes. The duration can be changed by pressing this key (see section 8.6.1 on page 28).

® Rotation speed:

This field indicates the pedal rotation speed displayed in rotations per minute. In passive mode, pressing this key modifies the target speed (see section 8.6.2 on page 28).

® Resistance:

This field indicates the motor braking resistance level. Pressing this key modifies the resistance during active training (see section 8.6.3 on page 29). This key is disabled for passive training.

® Symmetry:

This field respectively indicates the load level for the left and right sides of your body during active training. The indication is displayed as a percentage for the left and right sides. The total will always be 100%. Pressing this key displays a graphic symmetry display in the form of a bar chart.

Antispastic control (ASC):

This field indicates the sensitivity level for automatic spasm detection during passive training. Pressing this key modifies the sensitivity level (see section 8.5 on page 27).

20 Level of activity:

This field indicates the share of the distance covered using your active muscular work (on the left) and the distance covered using the motor (on the right).



All fields marked by a blue arrow can be updated during training:

- Training session duration
- Rotation speed
- Resistance
- Spasm control level
- Symmetry display (in active mode, displayed in graphic form)
- Heart rate (in cardio training mode)

Examples:







8.4.1. Entry aid

Before starting the training, you can use the entry/exit aid to move the foot supports to a comfortable and easy to access entry position.

- a) Press the "Entry/Exit aid" key and keep it pressed until one of the foot supports is in an easy to access position for the foot. A green light is displayed in the upper right corner of the key.
- b) Release the "entry/exit aid" key. A red light is displayed in the upper right corner of the key. The motor brake is activated.
- c) Place the foot in the foot support and attach it using the hook and loop strap.
- d) Press the "Entry/Exit aid" key again and keep it pressed until the second foot support is in an easy to access position for the foot. A green light is displayed in the upper right corner of the key.
- e) Release the "entry/exit aid" key. A red light is displayed in the upper right corner of the key. The motor brake is activated.
 - Place the second foot in the foot support and attach it using the hook and loop strap.



To change the direction of rotation, press the key



To disable the motor brake, press the Start ke







8.4.2. Exit aid

To remove your feet once training is complete, repeat the same operations as for entry aid.

WARNING

RISK OF INJURY WHEN GETTING IN POSITION



Always place your feet in front of the device forward support when they are not fixed in the foot supports.

Make sure your feet or legs will not be touched by the foot supports during rotation.



8.5. ASC - Antispastic control

Automatic spasm detection (ASC) protects you from sudden muscular contractions cause by spasms during passive training.

As soon as a spasm is detected, a red square is displayed in the command field and pedal rotation stops. The pedals remain at a standstill for about 4 seconds before resuming rotation.

By default, the device resumes pedal rotation in the opposite direction. You can change the restart direction (forward, reverse, opposite direction, stop) using the "Settings / ASC" menu (see section 0 on page 36).

Spasm severity varies from one patient to the next: as a result, the antispastic control sensitivity can be set as follows:

- a) Press the ASC key to access the settings screen (accessible when the motor is stopped or running).
- b) Press the plus/minus keys to set the spasm detection sensitivity:

0 = spasm detection disabled

1 = weak spasm detection

6 = very strong spasm detection

c) Press the "back" key or wait for a few seconds to go back to the previous screen.

When spasm detection is disabled, the screen displays the text opposite.





Automatic spasm detection can also be disabled using the "Settings / ASC" menu (see section 0 on page 36).

WARNING

RISK OF INJURY DUE TO INACTIVE OR INCORRECTLY SET SAFETY FUNCTIONS



Check the status of the ASC function before each training session.

We recommend always leaving the ASC function active.

Adapt the level of ASC sensitivity according to the physical capacities and state of health of the person who is training.

The ASC function should only be disabled after having consulted your doctor or therapist.



8.6.1. Timer

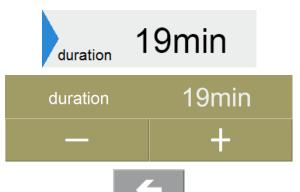
Pressing the "Duration" key accesses the current training phase duration settings menu (warm up, training, recovery).

a) Press the "Duration" key to access the settings screen.

b) Press the plus/minus keys to set the training duration.

Warm up phase: from 1 minute to 60 minutes
Training phase: from 1 minute to 180 minutes
Recovery phase: from 1 minute to 60 minutes

c) Press the "back" key or wait for a few seconds to go back to the previous screen.





WARNING

RISK OF INJURY DUE TO EXCESSIVE TRAINING TIME

Adapt the training duration to the physical capacities and state of health of the person who is training.

Short but regular training sessions should be preferred.

8.6.2. Rotation speed

Pressing the "rpm" key accesses the rotation speed setting menu for passive training.

a) Press the "rpm" key to access the settings screen.

_{rpm} 23

- b) Press the plus/minus keys to set the target rotation speed (from 5 to 60 rotations per minute).
- c) Press the "back" key or wait for a few seconds to go back to the previous screen.





Acceleration and stoppage are gradual.

The target rotation speed is reached at the earliest after 10 seconds.



WARNING

RISK OF INJURY THROUGH OVERLOADING

It is preferable to start training sessions at low speed and then gradually increase depending on the physical capacities and state of health of the person who is training.

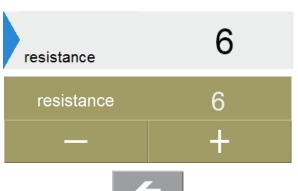
8.6.3. Resistance

Pressing the "Resistance" key accesses the motor resistance setting menu for active training. The higher the motor resistance, the more force will be needed to work the pedals.

- a) Press the "Resistance" key to access the settings screen.
- b) Press the plus/minus keys to set the motor resistance.

0 = very low motor resistance 20 = very high motor resistance

c) Press the "back" key or wait for a few seconds to go back to the previous screen.





WARNING

RISK OF INJURY THROUGH OVERLOADING

It is preferable to start training sessions with a low motor resistance and then gradually increase it depending on the physical capacities and state of health of the person who is training.

9. Description of training possible using Kinevia

9.1. Quick start

quick start

Using this option, you directly access the training menu (see section 8.3 on page 23) and you can compose your own therapy programme by selecting the passive / soft / active modes and then setting the different fields indicated by a blue arrow.

9.2. Guided training (therapy programs)

guided training



This menu features the different therapy programs developed jointly with therapists depending on the indications and therapy targets.

The therapy programs are designed to simplify configuring training settings by proposing preset values for the warm up, training and recovery phases.

The preset values can be adapted either during training, or from the training settings menu.

WARNING



RISK OF INJURY THROUGH INCORRECT TRAINING SETTINGS

The preset values in guided training represent general training advice.

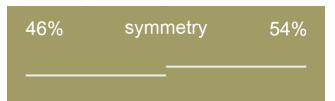
It is essential that you define your training with your doctor or therapist and adapt these values to your personal needs.



therapy programs	Home	
standard training	multiple sclerosis	
symmetry	parkinson's disease	
endurance	post op	
cardio	stroke	

Standard [assisted active]: this program is used for training with a braking resistance that you can adapt to your personal needs. Standard training (medium training level) can also be called using the quick start key on the home page.

Symmetrical training [active]: this programme helps correct movement symmetry by displaying the force you exert on the left and right sides of your body. Deficiencies can be corrected in this way.



The horizontal lines and the values indicate the levels you use your left and right halves respectively. The total of the values will always be 100%.

The objective is for the two horizontal lines to be at the same level forming an unbroken line.



The values can be false if different pedal radiuses are set on each side or if you are not seated in a central position on your chair or in your wheelchair.

Endurance [active]: depending on the training level, this program uses a target Watt value given for active training. The motor resistance automatically adapts to the rotation speed in order to maintain your power (measured in Watts) constant. You can adapt the Watt set point during training by pressing the "Watt" key.

Cardio [assisted active]: (only available with the Kinevia cardio kit, reference 4665009469) this uses a target heart rate. The motor resistance is automatically reduced once the heart rate has been reached. You can adapt the target heart rate by pressing the "heart rate" key.



Multiple sclerosis [assisted active]: this program provides training against a braking resistance that depends on the selected training level. Assisted training is enabled during the active training to support you during your movement.

Parkinson's disease [assisted active]: this program provides training against a braking resistance that depends on the selected training level. Assisted training is enabled during the active training to support you during your movement. Rotation speed and motor resistance are set to higher values than the "multiple sclerosis" program because, from experience, a higher pedalling radius is required for this pathology.

Post-OP [assisted active]: in this program, assisted training is enabled during active training to support you during your movement..

Stroke [assisted active]: in this program, assisted training is enabled during the active training to support you during your movement.



You can change the default values for each program using the "Settings" menu (see section 12.2 on page 35).

9.2.1. Training phases

Each training session is split into three phases:

Warm up: this phase is used to warm up the muscles, loosen the joints and relax spasms and cramps. By default, low speed passive training is preset for the warm up phase.

Training: in this phase, individual training begins depending on the selected therapy program and your physical condition. Depending on the selected program and the required level of active muscular participation, several forms of motor support are possible:

- Active training without motor support: training relying entirely on your own muscular work. Pedalling resistance can be changed at all times. Starting with reduced pedalling resistance is recommended.
- Active training with motor support (soft training or assisted active): training using your own muscular work and soft motor support.
- Passive training: training entirely using the motor drive force. Rotation speed can be changed at all times.

Recovery: at the end of the training phase, a short recovery phase for passive training and at a reduced rotation speed starts to complete the training gently.



The active training phase is displayed in the upper command panel (see section 8.3.1 on page 23).

You can change the duration of the active training phase at all times by pressing the "duration" key (see section 8.6.1 on page 28).

9.2.2. Training levels

Depending on the selected program, you can choose from three training levels to adapt your training to your progress and your physical condition.

Soft: short training durations and reduced rotation speeds.

Medium: medium length training durations and medium rotation speeds.

Advanced: long training durations and high rotation speeds.



WARNING

RISK OF INJURY DUE TO EXCESSIVE TRAINING TIME



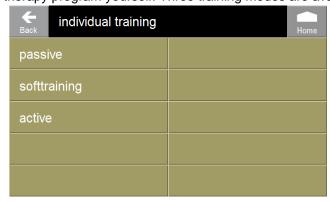
Define training durations with your doctor or therapist and adapt the values if necessary.

For the first training session, or after extended pauses in training, select an easy training level.





This menu lets you define your therapy program yourself. Three training modes are available.



Passive training: the motor drives your movements. The rotation speed can be set at all times up to the maximum rotation speed of 60 rpm.

Soft or assisted active training: your muscular work is supported by the motor. This especially helps you if your muscular force is weak.

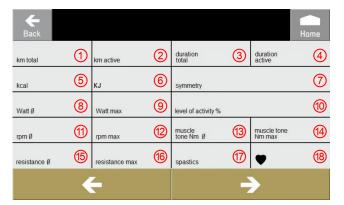
Active training: you pedal against motor braking resistance. You can adapt the resistance using 20 levels from 1 = very weak resistance to 20 = very high resistance depending on your personal needs. Starting training using a low resistance is recommended.

10. Training analysis

training analysis



At the end of the training session, you can view your results by pressing the "Training analysis" key. The following screen is displayed:



1 Km total:

This field indicates the total distance covered all training modes included (in kilometres).

2 Km active:

This field indicates distance covered during active training modes (in kilometres).

③ Duration total:

This field indicates the total training duration (in hours, minutes and seconds).

4 Duration active:

This field indicates the proportion of training duration in active mode (in hours, minutes and seconds).

⑤ Kcal:

This field indicates the expended energy (in kilocalories).



6 KJ:

This field indicates the expended energy (in kilojoules).

O Symmetry:

This field indicates the average distribution of the force exerted on the left and right halves (in percentage).

8 Watt Ø:

This field indicates the mean exerted power (in Watts).

Watt max:

This field indicates the maximum exerted power during training (in Watts).

① Level of activity %:

This field indicates the ratio of the distance covered during active training (in percentage).

11 Rpm Ø:

This field indicates the average rotation speed during active training (in pedal rotations per minute).

® Rpm max:

This field indicates the maximum rotation speed during active training (in pedal rotations per minute).

Muscle tone Nm Ø:

This field indicates the average motor resistance value (in Newton-metres).

(4) Muscle tone Nm max:

This field indicates the maximum motor resistance value (in Newton-metres).

® Resistance Ø:

This field indicates the average motor braking resistance during active training.

16 Resistance max:

This field indicates the maximum motor braking resistance during active training.

7 Spastics:

This field indicates the number of spasms detected during training.

① Heart rate:

This field indicates the average heart rate during training (in beats per minute). Only available with the Kinevia cardio kit accessory, reference 4665009469.

The values for the last ten training sessions are saved.

To view the saved training sessions, you can scroll forward and backwards through the displayed pages using the arrow keys. The respective training dates and times are displayed in the upper display bar.

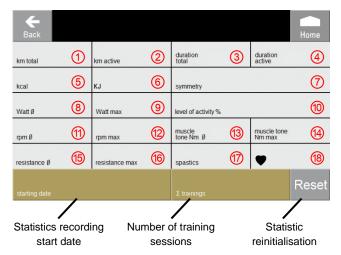


All the training values are approximate values.

Kinevia is not designed for diagnostic, monitoring or measurement purposes.



You can view the total, average and maximum values for all training sessions since the last reinitialisation from the "Statistics" menu. See section 10 on page 32 for a description of the fields.



Values displayed as total for the analysis duration: ①②③④⑤⑥⑦

Values displayed as average values for the analysis duration: ⑦⑧⑩⑪⑬⑮

Values displayed as maximum values for the analysis duration: 9@468



All the training values are approximate values.

Kinevia is not designed for diagnostic, monitoring or measurement purposes.

12. Settings settings

This menu is used to configure different Kinevia and training settings.

settings	Home	
training duration	ASC	
training settings	change of direction	
time / date	adjustment of velocity	
user data	language	
technical settings		



You can set the durations for the different training phases for each training level using this menu. The following values are set by default.

Level	Warm up (min 2 / max 60)	Training (min 2 / max 60)	Recovery (min 2 / max 60)
soft	2 minutes	6 minutes	2 minutes
medium • •	2 minutes	10 minutes	3 minutes
advanced • • •	2 minutes	19 minutes	4 minutes

12.2. Training settings

training settings

You can set the default training parameters for each program, each training level and each training phase using this menu.

12.3. Date and time

time / date

You can set the date and time on this menu using the arrows to move from field to field and the plus/minus keys to change the values.

The date and time are saved when the Kinevia switches to standby mode.

The date and time must be reset if the Kinevia has been powered off.

12.4. User data user dat

This menu is used to set patient data using the arrows to move from field to field and the plus/minus keys to change values such as age, height, weight and gender.

This data is required to calculate the exerted power (Watts) and energy burned (calories).

12.5. Technical settings

technical settings

Different Kinevia settings can be adjusted using this menu.

- Rpm limit: is used to define a pedalling rotation speed not to be exceeded (min 10 / max 60).
- Lock changes: when this option is enabled, all the keys are locked during training except the "stop" key. The symbol is displayed at the top right of the screen.
- Allow changes: when this option is enabled, you can choose to save the settings used as default settings for the next training sessions.
- Factory settings: is used to reset all the Kinevia settings to their default values, such as duration and training settings (see sections 0 and 12.2), statistics (see section 0), ...



You can set the automatic spasm detection (ASC) sensitivity level during training using this menu. You can set automatic spasm recognition from 1 = detection of weak spasms and 6 = detection of major spasms (see also section 8.5 on page 27) or disable ASC by setting it to "stop".

WARNING

RISK OF INJURY DUE TO INACTIVE OR INCORRECTLY SET SAFETY FUNCTIONS



Check the status of the ASC function before each training session.

We recommend always leaving the ASC function active.

Adapt the level of ASC sensitivity according to the physical capacities and state of health of the person who is training.

The ASC function should only be disabled after having consulted your doctor or therapist.

You can also define the Kinevia's reaction once a spasm has been detected.

There are four available options:

- Opposite direction: pedal rotation resumes in the opposite direction.
- Forward: pedal rotation resumes in the forward direction.
- Back: pedal rotation resumes in the reverse direction.
- Stop: pedal rotation stops.

12.7. Change of direction

change of direction

This option is used to set the time after which the rotation direction changes automatically during passive training if you activated the AUTO change of direction key (see key 4), section 8.3.2 on page 23).

The time can be set from 1 to 10 minutes, the factory setting being 3 minutes.

12.8. Adjustment of velocity

adjustment of velocity

This option is used to enable or disable the automatic rotation speed.

If automatic rotation speed is enabled, you will automatically be supported by the motor during active training as soon as you stop pedalling. In that situation, the motor adapts to the last rotation speed you reached and takes over at a slightly slower speed (55 rpm maximum).

12.9. Language language

You can choose the screen display language settings using this menu.

Scroll through the list of available languages using the arrows and press the required language. A beep indicates a successful language change.



13.1. Regulatory compliance

The device has been designed, manufactured and distributed in compliance with the requirements of the (EU) 2017/745 regulations on medical devices. As such, the device bears a CE marking.

The device is compliant with the following standards:

- IEC 60601-1 covering electrical safety requirements and tests,
- IEC 60601-1-2 covering electromagnetic compatibility,
- IEC 60601-1-11 defining requirements for electro-medical devices used in the home healthcare environment.

The device is also compliant with:

- The requirements of the Machinery Directive n°2006/42/EC,
- The 2011/65/EU directive on the limitation of the use of certain hazardous substances in electric and electronic equipment,
- The 2002/96/EEC directive on waste electric and electronic equipment (WEEE).

13.2. Warranty terms and conditions

The warranty for manufacturing defects is 2 years from the date the product was delivered to the consumer. Kinetec is convinced of the high quality and long service life of the Kinevia and Kinevia Duo therapeutic trainers and therefore grants a voluntary warranty extension to 5 years for the operation and performances of its devices. The warranty extension is valid under the following conditions:

Subject of the warranty extension: Kinetec grants a voluntary 5 year warranty for mechanical parts. The warranty begins on the date the product is delivered to the consumer.

Scope of the warranty extension: the warranty includes all defects of, and damage to, mechanical parts resulting from construction, manufacturing or material errors. In those cases, Kinetec will cover the equipment, repair and transport costs required to return the device to service. The warranty only applies to defects or actual damage resulting from construction, manufacturing or material errors. If a defect or damage cannot be repaired, or if the repair costs exceed the current value of the device, compensation limited to the current value of the device will be paid.

Exclusions from the warranty extension: the warranty extension does not apply to electronic components, the touch screen, the electric motors, to wear parts (for example belts, grips, hook and loop straps and bands, etc.) or to consumables such as accessories and components not manufactured by Kinetec SAS. The warranty does not apply to personal injury, indirect damage and damage external to the device.

Warranty extension cancellation: the warranty is voided in cases of insufficient maintenance or failure to follow the prescribed maintenance frequencies. The warranty is also voided if the device is opened by persons not authorised by Kinetec, if repairs or work is carried out by persons not authorised by Kinetec or if the device has been fitted with accessories not authorised by Kinetec.

The following defects and damage are also excluded from the warranty:

- Damage resulting from use for purposes other than those the device was designed for.
- Damage resulting from incorrect use or incorrect installation.
- Damage resulting from failure to comply with the user manual.
- Damage caused by external factors, for example damage during transport, damage due to shocks or impacts.
- Damage resulting from force majeure events.

Warranty application: the repair of damage is exclusively carried out by Kinetec or by staff authorised by Kinetec. Kinetec authorises the processing of the warranty application with the authorised customer department. If damage leading to the application of the warranty is observed, it must be notified to Kinetec as quickly as possible. It is essential to at least provide a detailed description of the damage as well as the device serial number. Kinetec reserves the right to recover defective parts. You therefore have a duty to keep the exchanged parts until the warranty application case is closed and Kinetec has provided a written validation. Exchanged parts become the property of Kinetec.



DANGER

DANGER OF DEATH BY ELECTROCUTION



Before cleaning the device, it is essential to switch off the device and unplug the power cord.

Make sure that no cleaning or disinfection liquids penetrate inside the device.

If electric components or cables are damaged, contact your Kinetec dealer.



WARNING

HEALTH RISK FROM A CONTAMINATED DEVICE

Wear suitable protective gloves to clean and disinfect the device.

- · Clean the device between each patient.
- Before each cleaning or disinfection, switch off the device and unplug the power supply.
- Clean the surface of the Kinevia by wiping using a soft and damp cloth.
- Disinfect the surfaces of the Kinevia (especially those in contact with the patient) using a surface disinfectant such as Bactinyl® from Laboratoire Garcin-bactinyl® (Kinetec order references: 4665005483 for a spray or 4665005491 for wipes).
- Do not spray cleaning or disinfection products directly on the device or its accessories.
- $\,{}^{\circ}$ Make sure that no cleaning or disinfection liquids penetrate inside the device.
- When cleaning the touch screen, only use specifically adapted cleaning products.
- During cleaning and disinfection, make sure no stickers or protective films are damaged.
- Only use cleaning and disinfection products compliant with regulations and specific standards in the country of use.
- · Only use cleaning and disinfection products that are not aggressive and are harmless to the environment.
- Let the disinfectant solution dry sufficiently before returning the device to service.

WARNING



RISK OF DAMAGE TO THE DEVICE THROUGH INCORRECT CLEANING OR DISINFECTION

Do not use cleaning products that contain solvents, acids or abrasives as they could attack the plastic parts of the screen.

Follow the safety instructions provided by the manufacturers of the cleaning and disinfection products.



When in doubt, contact the cleaning or disinfection product manufacturer.

13.4. Maintenance and safety inspections

Kinetec recommends carrying out a visual inspection of the device before each training session.

Kinetec recommends subjecting the device to annual maintenance in order to check the condition of the belt as well as different device elements. Please contact your Kinetec® dealer to carry out this operation.

13.5. Elimination and recycling

Packaging: the packaging must be separated from plastic components and paper/cardboard and placed in the specific recycling locations.

Device: it contains metal, plastics, electronic components and cables. When the device is no longer operational, dismantle it and separate the parts into groups of materials and deliver them to authorised recycling units or return the device to KINETEC SAS for destruction. Or contact the local authorities to determine the suitable method to dispose of the parts and accessories that are potentially hazardous to the environment.

13.6. Technical specifications

Device dimensions:	Kinevia: Height: from 102 to 112 cm Length: from 87 to 92 cm Width: 68 cm
	Kinevia Duo: Height: from 112 to 122 cm Length: from 88 to 110 cm Width: 68 cm
Weight	Kinevia 36 kg
	Kinevia Duo: 52 kg
Maximum user weight	135 kg
Acoustic pressure	<70dBA
Rotation speed (arms and legs)	from 5 to 60 rotations per minute for passive training from 5 to 90 rotations per minute for active training
Distance between foot rests	from 13.5 to 25.5 cm (measured on the inner sides)
Distance between arm grips	12 cm (measured on the inner sides)
Pedal radius	Leg trainer: from 50 to 125 mm Arm trainer: 100 mm
Device service life	8 years
Accessory service life	8 years
Applied parts	Support/transport bar, arm trainer grips
Essential performance	Rotation speed ≤60 rotations per minute for passive training
Device leak tightness	IP21 (Protected from solid bodies larger than 12.5 mm, protected from the penetration of vertical drops of water)
Transport box leak tightness	IP01 (no protection from the penetration of solid foreign bodies, protected from the penetration of vertical drops of water)
External power supply	PMP220F-14-HI
Power supply voltage	Input 100-240V 47-63Hz Output 24V == 9.17A
Electric type and class	BF Type Class II device
Fuse	T 6.3A 250V 5x20mm (ref. Kinetec®: 4610007434)
Use conditions	Ambient temperature: +5°C to +40°C Relative humidity: from 15% to 90% without condensation Atmospheric pressure: from 700 hPa to 1060 hPa
Storage / transport conditions	Ambient temperature: -25°C to +70°C Relative humidity: from 20% to 90% without condensation Atmospheric pressure: from 700 hPa to 1060 hPa



13.7. Symbols used



Follow the instructions for use



Do not push the device



No not walk on the device



Do not sit on the device



Keep hands away: moving parts



Safety sign



Do not stack



Keep dry



Temperature limits during storage and transport



Medical CE device



Contains electric and electronic components; do not dispose of with household waste.



Class II device (double insulation)



BF TYPE device (protection from electric shocks)



Alternating current



Direct current



Box storage direction



Atmospheric pressure limits during storage and transport



OFF (power off)



Manufacturer



Medical device



Device reference



Device serial number



Manufacture batch number



Manufacture date



Fragile



Humidity limits during storage and transport



ON (power on)



13.8. Troubleshooting guide

Defect	Possible cause	Action	See section
	The power cord is not plugged in	Plug the power cord into a mains power outlet and to the power supply box. Plug the power supply box cable into the Kinevia connector.	6.2
The Kinevia will not start	The device is not switched on	Turn the on/off switch to "I".	6.2
	Standby mode has been activated	Press anywhere on the screen for about 5 seconds.	6.10
	Defective fuse	Contact the maintenance technician	
The movements are not fluid	Pedal radius setting different on each side	Set the pedal radius to the same value on both sides	6.5
	Incorrect seated position	Correct the seated position	7.1
Too high resistance during pedalling	The braking resistance in active mode is too high	Reduce the braking resistance. Activate soft training if necessary	8.6.3
Spasm detection triggers too quickly or too often	The spasm detection level setting is too sensitive	Set the spasm detection (ASC) level to a higher value	8.5
The arm trainer will not start	Arm trainer not activated on the training menu	Press the arm trainer selection key	8.3.2
	Leg training not complete	Stop leg training by pressing the Stop key before selecting the arm trainer	8.3.2
The heart rate display is not working	The Kinevia cardio kit is not installed or is not properly installed	Connect the receiver properly to the jack socket. The logo should point towards the front. Check and correct the thoracic belt position.	6.9

If you need to return the device or its accessories, first discuss the return and packaging specifications with Kinetec.



13.9. Information about electromagnetic compatibility

All the information given below comes from standard requirements to which electromedical devices are subject as defined by the IEC60601-1-2 standard.

The device radio-frequency emissions are very low and are not therefore likely to cause interference with electronic equipment installed nearby (radios, computers, phones, etc.). Nevertheless, users will make sure that possible electromagnetic interferences do not create an additional risk, such as from radio-frequency emitters or other electronic devices.

The device is designed to withstand foreseeable interferences from electrostatic discharges, magnetic fields from mains power supplies or radio-frequency emitters. Nevertheless, some types of mobile telecommunications devices such as mobile phones may interfere with the medical device. The separation distances recommended in this section must therefore imperatively be respected.

In this section, you will find the information required to guarantee the installation and commissioning of your medical device in the best conditions in terms of electromagnetic compatibility.

WARNING MALFUNCTION RISK



If there is mutual electromagnetic or other interference with other devices, move the device away from them.

The device must not be used next to other devices or stacked with them as this could lead to malfunctions. If this use is required, observe this and the other devices to check that they are still in working order.

Cable list

List of cables likely to alter device compliance with electromagnetic emissions and immunity:

Description	Kinetec reference	Maximum length
Europe mains cord	4610009092	3.50m
US/Japan mains cord	4610009109	4.00m
Brazil mains cord	4610009117	3.50m
UK mains cord	4610009125	3.50m
Australia mains cord	4610009133	3.50m
Swiss mains cord	4610009365	3.50m



WARNING

MALFUNCTION RISK

The use of accessories and cables other than those indicated or supplied by KINETEC SAS can cause increased electromagnetic emissions or reduce device immunity and cause malfunctions.

Recommended separation distances

The device is designed for use in an electromagnetic environment in which radiated radiofrequency interference is controlled.

WARNING MALFUNCTION RISK



Portable radio-frequency communications devices (including peripherals such as aerial cables and external aerials) should not be used closer than 30 cm (12 inches) from any part of the device, including the cables specified by Kinetec. If this is not the case, the performances of those devices could be altered.

• Electromagnetic emissions

The device is designed for use in the electromagnetic environment described in the table below.

The user and installer must make sure the device is used in the environment described below.

Emissions tests	Compliance	Electromagnetic environment - Remarks
Electromagnetic radiation interference (radiated emissions) CISPR 11	Group 1	The device only uses radio-frequency energy for its internal operation. As a result, its radio-frequency emissions are very low and are not likely to create any interference with neighbouring equipment.
Interference voltage at the supply terminals (conducted emissions) CISPR 11	Class B	The device is suitable for use in a home healthcare environment and
Harmonic current emissions IEC 61000-3-2	Class A	in a professional healthcare establishment environment.
Voltage variations, voltage fluctuations and flicker IEC 61000-3-3	Compliant	

• Magnetic and electromagnetic immunity

The device is designed for use in the magnetic and electromagnetic environment described in the table below.

Users and installers must guarantee the compliance of the electromagnetic environment.

Immunity tests	Test level as per IEC60601	Compliance level	Electromagnetic environment - Remarks
Electrostatic	±8 kV in contact	±8 kV in contact	The device is suitable for use in a home
discharges (ESD)			healthcare environment and in a professional
IEC 61000-4-2	± 2, 4, 8, 15 kV in the air	± 2, 4, 8, 15 kV in the air	healthcare establishment environment.
Fast electric transients / bursts IEC 61000-4-4	lines	±2 kV for electricity supply lines	The quality of the electricity supply grid must be equivalent to that of a home healthcare environment and a professional healthcare establishment environment.
Shock waves	±0.5, 1 kV in differential mode	±0.5, 1 kV in differential mode	The quality of the electricity supply grid must be equivalent to that of a home healthcare
IEC 61000-4-5	±0.5, 1, 2 kV in common mode	±0.5, 1, 2 kV in common mode	environment and a professional healthcare establishment environment.
Magnetic field at the assigned industrial frequency IEC 61000-4-8	30A/m	30A/m	The magnetic field intensity must be of the same level as that of a home healthcare environment and a professional healthcare establishment environment.
	0% <i>U</i> ₇ for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% <i>U</i> _T for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The quality of the electricity supply grid must be
Voltage dips, short power cuts and voltage variations	0% <i>U</i> ₇ for 1 cycle	0% <i>U</i> ₇ for 1 cycle	equivalent to that of a home healthcare environment and a professional healthcare establishment environment.
IEC 61000-4-11	70% <i>U</i> ⊤	70% <i>U</i> ⊤	
	for 25 cycles at 50Hz	for 25 cycles at 50Hz	If the use of the device requires continued use
	for 30 cycles at 60Hz	for 30 cycles at 60Hz	during mains power outages, it is recommended
	single phased at 0°	single phased at 0°	to supply the medical system using a separate
Voltage	0% <i>U</i> _T	0% <i>U</i> _T	power source (UPS, etc.)
interruptions	for 250 cycles at 50Hz	for 250 cycles at 50Hz	
IEC 61000-4-11	for 300 cycles at 60Hz	for 300 cycles at 60Hz vork voltage before applicat	



Electromagnetic immunity, portable radio-frequency equipment

The device is designed for use in the magnetic and electromagnetic environment described in the table below.

Users and installers must guarantee the compliance of the electromagnetic environment.



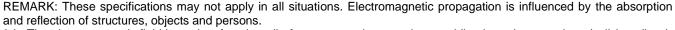


Portable radio-frequency communications devices (including peripherals such as aerial cables and external aerials) should not be used closer than 30 cm (12 inches) from any part of the device, including the cables specified by Kinetec. If this is not the case, the performances of those devices could be altered.

Immunity tests	Test level	Compliance level	Electromagnetic environment - Remarks
	3 V/m	3 V/m	
Radiated radio-	from 80 MHz to 2.7 GHz	from 80 MHz to 2.7 GHz	
frequency	80% MA at 1kHz	80% MA at 1kHz	The device is suitable for use in a home
electromagnetic fields			healthcare environment and in a professional
IEC 61000-4-3	10 V/m	10 V/m	healthcare establishment environment.
120 01000-4-3	from 80 MHz to 2.7 GHz	from 80 MHz to 2.7 GHz	
	80% MA at 1kHz	80% MA at 1kHz	
	9 V/m	9 V/m	
	710 MHz, 745 MHz,	710 MHz, 745 MHz,	
	780 MHZ, 5240 MHz,	780 MHZ, 5240 MHz,	
Proximity fields	5550 MHz, 5785 MHz	5550 MHz, 5785 MHz	
emitted by wireless			
radio-frequency	27 V/m	27 V/m	The device is suitable for use in a home
communications	385 MHz	385 MHz	healthcare environment and in a professional
devices	00.14	00.14	healthcare establishment environment.
IEC 61000-4-3	28 V/m	28 V/m	
	450 MHz, 810 MHz,	450 MHz, 810 MHz,	
	870 MHz, 930 MHz,	870 MHz, 930 MHz,	
	1720 MHz, 1845 MHz,	1720 MHz, 1845 MHz,	
	1970 MHz, 2450 MHz	1970 MHz, 2450 MHz	
	3 V from 150 kHz to 80 MHz	3 V from 150 kHz to 80 MHz	
Conducted	110111 150 KHZ 10 80 WHZ	ITOTTI 150 KHZ tO 80 MHZ	
interference induced	6 V in the ISM band and	6 V in the ISM band and	The device is suitable for use in a home
by radio-frequency	band included between	band included between	healthcare environment and in a professional
fields	0.15 MHz and 80 MHz,	0.15 MHz and 80 MHz,	healthcare establishment environment.
IEC 61000-4-6	including the amateur	including the amateur	neamicate establishment environment.
120 01000-4-0	radio band	radio band	
	80% MA at 1 kHz	80% MA at 1 kHz	

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

Interference can occur near equipment identified by the following symbol.



(a) The electromagnetic field intensity of static radio-frequency emitters such as mobile phone base stations (cell / cordless), mobile radios, amateur radios, AF/FM radio emissions and TV emissions cannot be accurately determined by the theory. To assess the electromagnetic environment due to the static radio-frequency emitters, an electromagnetic environment measurement must be carried out. If the measured intensity of the radio-frequency field in the immediate product use environment exceeds the radio-frequency conformity level specified above, the product performances must be tested to check that they are compliant with specifications. If abnormal performances are found, additional measurements may be needed, such as reorienting or moving the product.







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