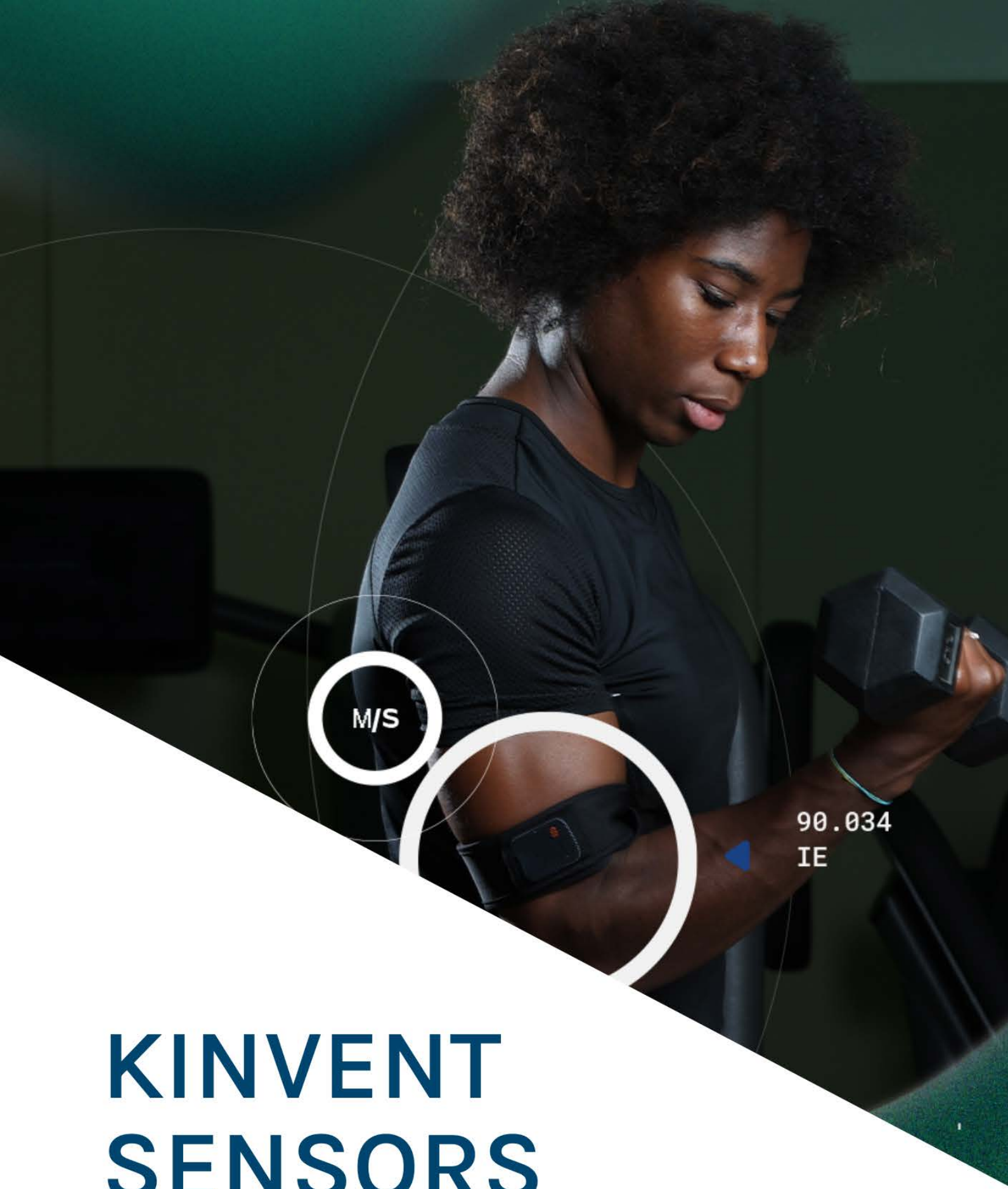


KINVENT SENSORS

User manual

KINVENT

K-Sensors User Manual

K-Grip

K-Bubble

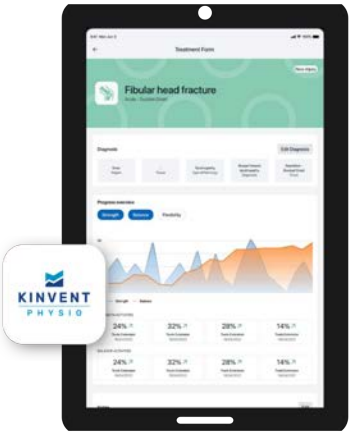
K-Push

K-Pull

K-Force Plates

K-Deltas

K-Move



K-Deltas XL

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NOTICE

This manual concerns K-SENSORS products. The information content of this manual belongs to KINVENT, and is provided only for the purpose of operating K-SENSORS and software. This manual is subject to modifications. The latest version is available on https://quickstart.k-invent.com/

NOTICE

The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country

Manufacturer

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Trademarks
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This product is protected by granted patents, pending patent applications and their corresponding national rights.

Revision: 15
Last revision: 2023-06-27 , Printed in France

CE

Medical Device Name	Trade Name
KForce Grip	K Grip
KForce Muscle Controller	K Push
KForce Plates	K Force Plates
KForce Bubble	K Bubble
KForce Sens	K Move
KForce Link	K Pull
KForce Deltas	K Deltas
KForce Deltas XL	K Deltas XL

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Graphic Symbol

The sensors comply with electromagnetic regulations as laid out by the Federal Communications Commission.

European Conformity
MDR 2017/ 745

IEC 60878
Direct Current IN

Recyclable Packaging Box

Keep Dry. Indicates a medical device that needs to be protected from moisture.

Sensor is provided nonsterile

Attention, See Instructions for use

Type BF applied part - External Body only , Floating- No earth connection

Indicates the manufacturer's **serial number** so that a specific medical device can be identified

Indicates the **medical device legal manufacturer**, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC

Sensor will not work when connected to AC outlet

Class II Electrical Equipment

An ISO 15223 symbol Indicating upper & lower temperature limits for operation, transport, and storage

Humidity limitation. Indicates the range of humidity to which the medical device can be safely exposed.

Atmospheric pressure limitation. Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Non Ionizing radiation

Do not dispose of the units in normal household waste. Dispose products in accordance with local regulations
Waste Electrical and Electronic Equipment (WEEE) logo

WARNING General warning

NOTICE General Notice

Bluetooth logo. The utilizes a Bluetooth LE radio for wireless communications

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Contents

K-Sensors User Manual 2
Graphic Symbol 4
Contents 5
Introduction 7
About us 8
Safety Information 8
Photosensitive seizure warning 8
K-Physio application 1.19 9
Installation the Application on the Host Device 10
First Login 10
Intended use 12
Contraindications 12
Safety precautions 13
Replaceable Parts 15
General Operating Conditions 16
Operating Environment 16
Storage, Packaging and Transportation 16
Calibration 16
Cleaning 17
Interface 17
LED States 18
K-Grip 19
Description 19
Benefits 19
Usability Data 19
Technical Features 20
Content of the Commercial Package 21
Accessories 21
Get Started 21
K-Push 21
Description 22
Benefits 22
Usability Data 22
Technical Features 23
Content of the Commercial Package 24
Accessories 24
Get Started 24
K-Force Plates 26
Benefits 26
Usability Data 26
Technical Features 27
Content of the Commercial Package 28
Accessories 28
Installation 28
On the floor 28
On vertical surface 28
Get started 29
K-Bubble 30
Description 30
Benefits 30
Usability Data 30
Technical Features 31
Content of the Commercial Package 31
Accessories 32
Get Started 32
K-Move 33
Description 33
Benefits 33
Usability Data 33
Content of the Commercial Package 33
Accessories : 34
Technical Features 34
Get Started 35
K-Pull 36
Description 36
Usability Data 36
Content of the Commercial Package 36
Accessories : 37
Technical Features 37
Get Started 38
K-Deltas 39
Description 39
Benefits 39
Usability Data 39
Content of the Commercial Package 39
Accessories 40
Technical Features 40
Installation 41
On the floor 41
Get started 41
K-Deltas XL 43
Description 43
Benefits 43

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Usability Data 43
Technical Features 44
Content of the Commercial Package 44
Installation 45
On the floor 45
Get started 45
Troubleshooting 46
Sensor difficulties 46
Connectivity difficulties 47
Legal information 48
Warranty Terms 48
European Union 48
Other countries 48
Obligations of the User 48
Service policy 49
Waste Electrical and Electronic Equipment (WEEE) Policy 49
Declaration of Conformity 50
FCC information 55
Canada 55
Japan 55
Switzerland 56
United Kingdom 56
Contact Information 56

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Introduction

Thank you for purchasing a K-Sensor.
K-SENSORS is the product line developed by KINVENT to objectively quantify rehabilitation. The product line of K-SENSORS is the complete tool designed for assessing, monitoring and exercising balance, strength, and joint motion. It consists of 7 sensors, all of them equipped with high precision measuring systems and with the KINVENT's excellence in interface development, mechanics and electronics.
K-Sensors series is composed of:

K-Grip

for the measurement of hand grip strength

K-Bubble

for the rehabilitation with biofeedback by the way of inflatable tools

K-Push

the handheld muscle dynamometer

K-Pull

for the strength measurement regardless of the operator

K-Force Plates

for the measurement of lower limb strength as well as balance

K-Deltas

for high speed jump analysis and lower limb strength and balance

K-Move

the connected goniometer for the measurement of joint amplitudes

K-Deltas XL

for high speed jump analysis and lower limb strength and balance

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About us

KINVENT is specialized in the design and manufacturing of biomechanics equipment. Our strength is that we can conceive and implement solutions to any challenge in sports biomechanics and physical rehabilitation. Our products include ready-to-use force plates, inertial wireless sensors, dynamometers, simulators and various custom-made applications.
Find more information on our products at www.k-invent.com.

Safety Information

The instructions and safety information in this user manual must be followed to ensure safe operation of the K SENSORS . Please note that if the equipment is used in a manner not specified by KINVENT, the protection provided by the equipment may be impaired.
The following types of safety information appear throughout the Manual. Details are given in the format as shown below:

⚠ WARNING The term WARNING is used to inform you about situations that could result in serious damage to the device or other part of the System and to the environment.

⚠ CAUTION The term CAUTION is used to inform you about situations that could result in damage to the device that affect the measurement results or pose a risk to the safety of the patient/user or the operator.

NOTICE The term NOTICE is used to indicate information considered important but not hazard related (e.g., security messages, maintenance and cleaning guidelines)

Photosensitive seizure warning

⚠ WARNING

A very small percentage of people may experience a seizure when exposed to certain visual images, including flashing lights or patterns that may appear in video games. Even people who have no history of seizures or epilepsy may have an undiagnosed condition that can cause these “photosensitive epileptic seizures” while watching video games. These seizures may have a variety of symptoms, including altered vision, eye or face twitching, jerking or shaking of arms or legs, disorientation, confusion, or momentary loss of awareness. Seizures may also cause loss of consciousness or convulsions that can lead to injury.
Immediately discontinue playing and consult a doctor if you experience any of these symptoms. Parents should watch for or ask their children about the above symptoms.

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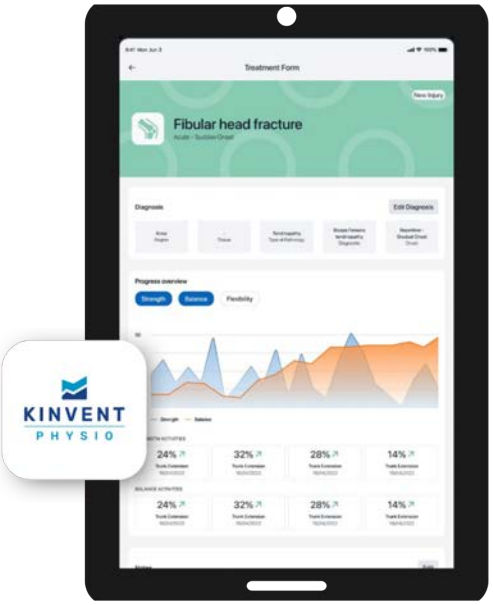
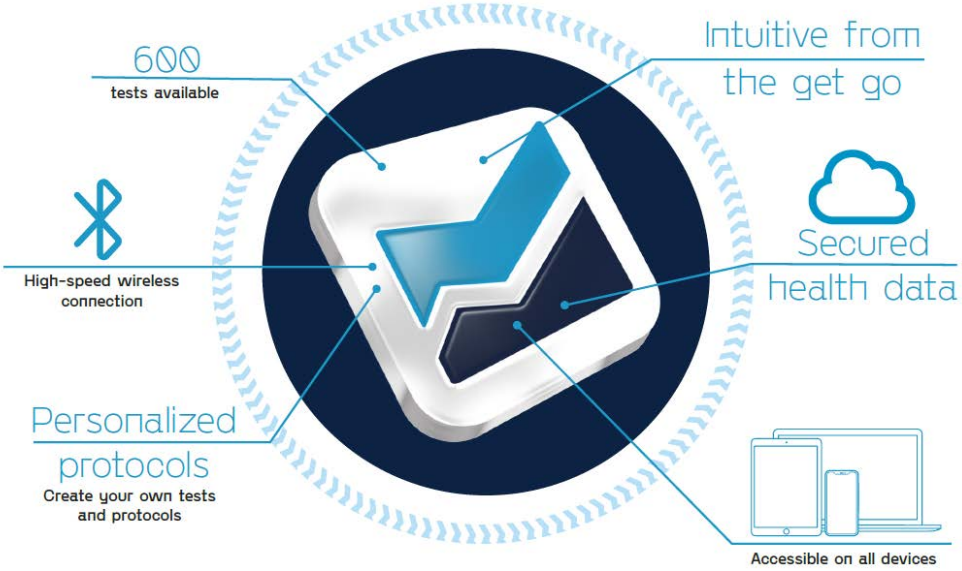
K-Physio application 1.19[1]

Kinvent Physio is the only app you will need for all your Kinvent Sensors. All tutorials for the Kinvent Physio app are available online at: Kinvent.link/quickstart

Minimum Requirements: Android 6.0+ or iOS 11.0+, 2GB of RAM, Bluetooth Low Energy 4.2+, 5'' (12.7cm) Screen diagonal
Recommended: Android 8.0+ or iOS 16.0+, 4GB of RAM, Bluetooth Low Energy 5.0+, 6.5'' (16.5 cm) Screen diagonal





[1] Latest version may differ on the store

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Installation the Application on the Host Device

Download the App from Google Play for Android Devices or App Store for iOS devices

Follow the Instruction registration on the App

Connect the Device with the App Via BLE

First Login

The K Physio App will require an initial registration and some information regarding the operator's specialty and profile to help ensure proper use.

You need to connect the K SENSORS with compatible Bluetooth® Low Energy (BLE) devices to store, analyze and view the measurement data. These host devices HD can be, for example mobile devices running respective host applications (K Physio) for data visualization.

The sensors can be registered in the K Physio App in order to be easily identified when starting an exercise.

You can register the devices with multiple host devices, but only one connection can be active at a time.

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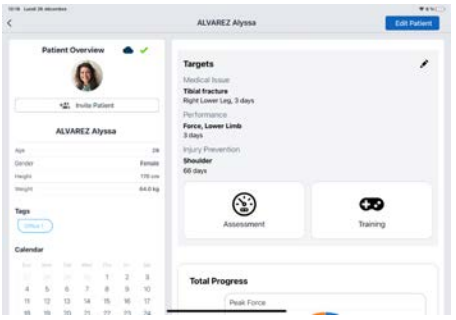
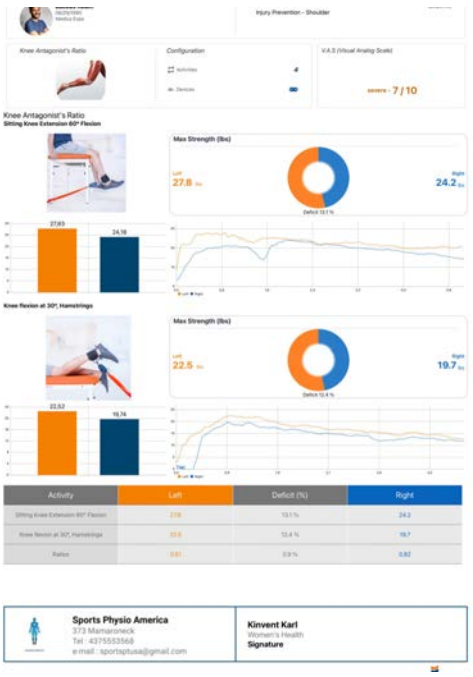
Full patient file
Fill in the patient's pathology information to guide care and make their file available to all healthcare professionals in your office.



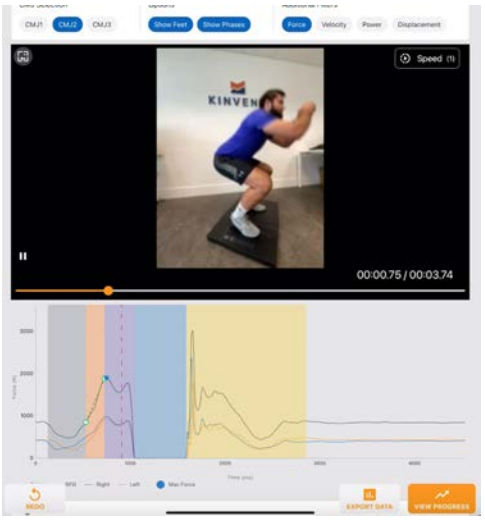
Personalized reports
Synthesize your rehabilitation results with the multiple export module.



K-apture
Film your patient's movement and synchronize it with every Kinvent Physio evaluations. Carry out qualitative analysis to integrate in your reports.

MyKinvent
Give your patient agency in their rehabilitation by giving them access to their own data.

Kinvent Connect
Centralize all your data in one place and access it from any device: smartphone, tablet, computer, etc.



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Intended use

The K-Sensors are intended to be used by trained professionals to assist with objective assessment of a person's physical strength, balance and range of motion.
The K Sensors may be used by medical professionals at healthcare facilities or at patient homes. The K SENSORS by KINVENT must be operated by personnel familiar with K SENSORS and have the appropriate training

K SENSORS are

- Medical Electrical Equipment
- Internally Powered Equipment (Battery operated)
- With Type BF Applied Part
- Continuous operation
- Not suitable for operation in an oxygen rich environment

The expected service life in normal use is 5 years

⚠ CAUTION

Replace the device after ending the expected service life or earlier if one of the follows occur:

- otherwise instructed or
- the harsher than normal operating conditions have caused deterioration of the essential features or
- if any damage to the device is observed (e.g., any cracks or structural damage).
- See paragraph for recycling guidance.

Contraindications

The K-Sensors are contraindicated under the following:
- On or near open wounds
- Patients having severe osteoporosis
- On or near burned tissue
- On or near the eye
- On or near fractures
- Not to be used for any purpose other than indicated

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Safety precautions

The safety information must be read thoroughly and understood before starting the work with K-SENSORS

⚠ WARNING

- Take care of the strong attachment or hold of each sensor.
- Do not dispose of the K-Sensors sensor in fire.
- K-Sensors contain lithium-polymer batteries. *Do not dispose of the* batteries with household waste
- The K-Sensors are not protected against ingress of liquids. Keep sensors dry. Do not immerse the K-Sensors or their accessories in water.
- The K-Sensors and accessories are provided non-sterile and are not compatible with autoclave or other sterilization techniques. Do not autoclave.
- Use only a factory supplied wall pack power supply, charger. Use of another charger may result in electrical shock or equipment damage.
- K-Sensors are not intended for use while attached to wall pack power supply or a charger. Never attempt to operate the instrument while it is connected to the charger as electrical shock or damage to the instrument may occur.

⚠ CAUTION

- Only use the device in your existing environment during your daily routine activities. Do not use the device during enhanced or irregular activities or outside your natural environment, unless specifically instructed otherwise by your doctor or physical therapist.
- Do not drive or operate heavy machinery while wearing the device.
- Users with disabilities (e.g neurological disorders, osteoporosis), which may cause contraindications, or users for whom exercise may be extremely dangerous, must take precaution to ensure their safety when using the device (e.g., supervision, etc.).
- Do not use the device if you suspect that it is faulty or has been damaged. Do not try to repair the device on your own.
- Report any change in your medical condition that is related to the diagnosis or treatment to your doctor or physical therapist.
- Do not give, sell, rent or allow the use of your device to or by another person.
- Stop the use of the system immediately if parts are damaged or if a change in the performance is observed.
- Stop the use of the system immediately if an allergic reaction is observed.
- Do not modify this system without prior written authorization of the manufacturer. If this system is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the system.

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- Always consult your doctor if you have a medical condition and before beginning a program.
- Always consult your doctor before using the device if you have a pacemaker or other implanted device. Although several implanted pacemaker manufacturers state the risk associated with the simultaneous use is low, it is essential to consult a doctor who knows the exact type and model of the implanted device in question before using the system. In any case keep the device at least 15cm (6") away from the implanted device.
- Do not use the device during magnetic resonance imaging (MRI), unless specifically approved by the personnel operating the MRI equipment. The battery inside the device is sensitive to magnetic fields.
- The device is not for multiple users if consequences from possible cross contamination may be severe. Careful cleaning and disinfection are recommended to prevent cross infection if used by multiple users.
- The conductive parts of the device must not be allowed to contact any conductive parts, including protective earth connection.
- Keep the device and any part of the system away from the reach of children, pets or pests when not in use.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system. Otherwise, degradation of the performance of this system could result.
- Use of this system adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this system and the other equipment should be observed to verify that they are operating normally.
- If the storage temperature is below 0°C , allow the parts of the system internal temperature to stabilize for at least 30 min before use. Be aware of condensation
- If the part of the system is to be used in an environment prone to dirt build-up, clean the device regularly. For cleaning, please follow the instructions provided in paragraph " Cleaning".
- Use the system at least 30 cm (12") away from the sources of power line frequency magnetic fields, radio frequency communications equipment and other sources of radio frequency signals (such as radars or microwave ovens).
- If the measurement results are fluctuated by a strong nearby radio frequency disturbance source, move further away from the source of the radio frequency disturbances.
- Avoid using the system in the proximity of electrostatic disturbance sources. Do not use close to a 2.4GHz signal source, as strong signals may negatively affect the performance of the radio link.
- Prior to each use of the device you may want to re-check and confirm that parts are properly attached.
- Should any problem occur as a result of the device, you are advised to discontinue use immediately and contact your doctor or physician immediately

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- Contact the manufacturer in case assistance is needed in setting up, using or maintaining the device or to report unexpected operation or events.
- The K-Sensors should only be used by trained professionals.
- The K-Sensors are precision medical sensors. The sensors should be treated with care. Do not drop, bang, hit or subject the sensors to strong shock . Be careful to have a firm grip when holding sensors in order to avoid accidental fall of the system which may cause damage to the sensor or injury to the patient/operator.
- Not recommended for use in extreme temperatures, high humidity, or direct sunlight
- Ensure your patient is able to keep his balance while watching the screen to avoid fall
- Sensors are not known to contain any hazardous materials. For proper disposal instructions, consult your local waste management facility. E-waste recycling should be used where available.
- Do not service the battery while in use with a patient.
- Never disassemble or modify the system using any accessories not specifically approved by KINVENT Biomécanique, LLC, this will void the warranty as well as reduce immunity to electromagnetic interference, or increase electromagnetic emissions, and result in improper operation.
- Don't place any K-Sensors components on unstable surfaces, or surfaces subject to vibration.
- Medical Electrical Equipment needs special precautions regarding EMC. K-Sensors need to be installed and put into service according to the information provided in this manual.

Replaceable Parts

- Straps
- Belts
- Handles
- Cushions
- Rubber attachments

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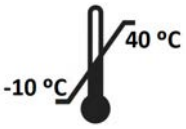
General Operating Conditions

Operating Environment

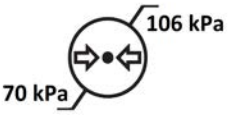
K-Sensors must be used indoors. K-Sensors must be used only in clean, dry rooms with leveled floors. Make sure you have plenty of space around you when you use it.

Storage, Packaging and Transportation

Temperature:
-10 °C to 40 °C
(14 °F to 104 °F)



Pressure :
70kPa to 106kPa



Air Humidity:
30 % to 75 %

When not in use, please store them in the protective carrying pouch.

If the K Sensors are stored for longer than 30 days, check battery level and recharge if necessary before using.

⚠ CAUTION

Please observe the storage conditions and never store them in an automobile except when transporting them.

Calibration

K-Sensors gives you metrics on the human muscular force. K-Sensors are sold already calibrated, to make them ready for use out of the box.
We recommend that the product be tested for calibration at least once a year under normal use or sooner under severe conditions and usage.
K-Sensors are not user serviceable and do not include a service manual. For more information on calibration as well as special requirements, please contact your K-Sensors dealer.

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Cleaning

NOTICE

The cleaning paragraph must be read thoroughly and understood before starting the cleaning work.

K Sensors should be cleaned after each use. Cleaning and disinfection of the K Sensors can be performed by the system operator or the patient/user.
In order to clean the K SENSOR's housing, use a damp cloth moistened with water or a mild detergent. If the dirt is persistent, rub the surface of the K SENSOR with a cloth moistened with ethanol-based disinfectant or with 70% alcohol solvent. Do not use aggressive cleaning agents such as acetone.
For more persistent stains and for disinfecting the K SENSOR **Low level or intermediate level disinfectants should be used (e.g. alcohol wipes). Do not use bleach to clean the plastic parts, prefer alcohol blends**

Do not use objects that could damage or scratch the surface.
If the inside of the K SENSOR is contaminated, contact your local distributor or KINVENT support directly.

⚠ WARNING

Careful cleaning and disinfection by the operator are recommended between uses to prevent cross infection if worn by multiple users or patients. Disinfect before and after each use. Allow disinfectants to dry before taking into use. Not to be worn by multiple users if consequences of cross contamination may be severe.

NOTICE

Repetitive disinfection with ethanol-based disinfectant may in the long run cause aging and discoloration of the case used. Discoloration does not affect safe use. If any cracks or structural damage is observed, replace the device .

Interface

All K-Sensors share the same interface

1- Multi color LED
2- USB-C charge port
3- Power on/ Command orange button

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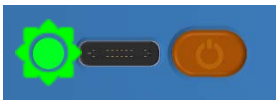
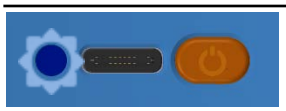
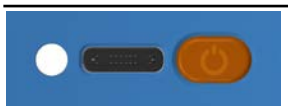
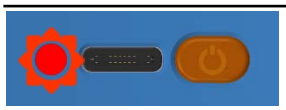
LED States

- When the sensor is connected via USB, the sensor will turn on (**GREEN** flashing LED) and begin to charge the internal battery.
- After 10 min, if not connected to the application, it will automatically power off . The battery will continue to charge indicated by a pulsing **ORANGE** light.
- Once the battery reaches full charge the sensor will indicate this by switching to permanent **WHITE** light. If power is removed the sensor will power on again.
- The sensor can wake by plugging in the USB cable or pushing the orange button.The **GREEN** led starts blinking.
- When a successful connection over Bluetooth is attained then the light begins flashing **BLUE**
- If the battery is low, then a **RED** light will flash intermittently three times and every 5 seconds. Wireless range may be affected if operating under this condition.
- The sensor will switch off if the battery voltage is lower than 1%.
- A single push on the button will display the battery status via bright ***red***, ***yellow,*** or ***green*** light depending on charge level.

Visual	LED Functionality	Explanation	Action requested
	LED is **OFF**	Sensor is **OFF**	Press the button to power on the sensor
	***GREEN*** LED is Blinking	Sensor is **ON**	Normal operation - Sensor is ready to connect
	***BLUE*** LED is Blinking	Sensor **Connected**	Sensor is connected to the app (tablet/phone)
	**ORANGE** LED Slow blink	Sensor is **OFF and charging**	None- the sensor will continue charge until full
	**WHITE** LED is lit steady	Sensor has reached **End of charge**	Internal battery is 100%, please remove charging cable
	**RED** LED is blinking **(three blinks intermittently)**	Sensor has **low battery (<10%)**	Please charge the sensor

Action	LED behavior	Explanation
Button pressed once during ready or connected state	Steady lit LED color **Green, Yellow or Red**	Battery state of charge **Green : 71 to 100%** **Yellow : 31 to 70%** **Red : <30%**
Button pressed once during a "Start screen" in the app	Steady lit LED color **Green, Yellow or Red**	**Will also start the training/exercise selected or switch sides depending on the app message**

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K-Grip

Description

K-Grip is used for the evaluation of hand grip strength. You can assess isometric strength by the way of the peak force as well as of the average force.
The Grip dynamometer quantitatively measures the grip weakness caused by injury compared to the strength of the healthy hand.

Benefits

K-Grip is equipped with electronic force transducers and gives you real-time biofeedback on your tablet or smartphone through the Kinvent Physio app. Therefore, you can set strength objectives for your patient and motivate him through the process of rehabilitation. You will, then, follow-up your patient's progress through the Kinvent Physio interactive database.

Usability Data

Intended medical indication:
For the strength evaluation of hand grip strength

Intended patient population
Teenagers to geriatric, with normal health or pre/post operation only on doctor's approval for rehabilitation.

Intended part of the body or type of tissue to or interacted with:
Site: External areas , typically arms, hands, torso, head, legs, feet
Condition: Normal, no abscesses nor wounds.
Direct contact not required , contact over clothing or through silicone cushions

Intended User Profile:
The K-Grip must be used by a trained health professional. The user must have received sufficient training in clinical procedures to get reliable measurements.

Intended use environment :
Hospital or other medical practice environment.

Operating Principle:
K Grip is equipped with an electronic force transducer that converts the applied forces to electrical signals which are then converted to digital calibrated outputs.

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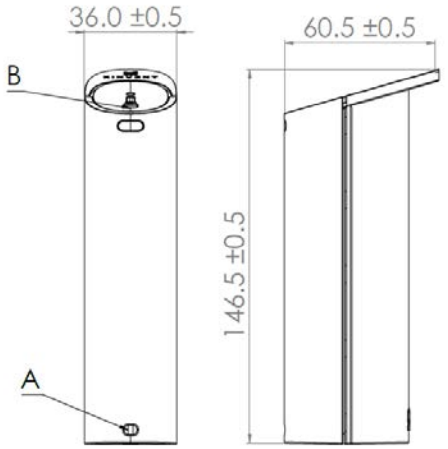
Technical Features

Dimensions and Weight

Weight	170 g / 6 oz
Dimensions (H x W x L) **A- Ribbon attachment point.** **B- Button**	Metric : 146.5 x 36 x 60.5 mm US : 5.77 x 1.42 x 2.38 “ 
Max force	90 kg / 198 lbs
Accuracy	< 0.2%, +-0.1kg / +-0.22lbs
Acquisition frequency	1000 Hz
Adjustable handle size	Silicon pillow with soft center
Eco features	Self-activated “sleep” mode after 10 minutes.
Units	Selectable in application KgF, N, lbs

Electrical and Communication Data

Radio Technology	Bluetooth Low Energy 5.1
Power supply	1 cell 3.7V Li-Po Battery 280mAh
Radiated output power	Max.10 mW
Wireless transmission Frequency	2.4 GHz band 2402- 2480 MHz
Modulation	GFSK
Channel Bandwidth	2 MHz
ERP	8.6dbm
Wireless range	Up to 40 meters / 44 yd
Contains FCC ID	2AAQS-ISP1807
Battery	12h of autonomy, 2h charging
Minimum requirements	Android 6.0+ or iOS 11.0+, Bluetooth Low Energy

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Content of the Commercial Package

The User will receive:

- K-Grip
- Attachment Cord
- Medical grade power adapter with USB-A for charging
- USB-C to USB-A charging/data cable
- Quick start cards in EN/ FR /ES
- User manual

The battery is not removable, it is already installed in the device

Accessories

The K-Grip is provided with an attaching cord (removable) at the rear of the sensor. Use this cord to secure the sensor at the patient's arm

The K-Grip has optional changeable grip sizes that allow it to fit different sizes of hands. They are easily attached magnetically and removed by simply pulling them with about 1 kg /2 lbs of force straight forward. The sensor is supplied with the regular size bumper accessory. For further sizes please consult the catalog

Get Started

On the top surface of the sensor there are : one USB-C port used for charging, one LED indicator for the working state/charging state and one push-button.

You can charge your K-Grip sensor through the USB A to USB C cable provided or with any USB-C charging cable. The sensor is supplied with the appropriate IEC 60601 medical USB power supply. If a different charger is used, ensure that it meets the minimum medical safety requirements and if unsure please do not use the sensor while plugged in/charging.

⚠ WARNING

Disinfect K-Grip prior to use. Low level or intermediate level disinfectants should be used (e.g. alcohol wipes). Do not use bleach to clean the plastic parts, prefer alcohol blends

Press the orange power on button on K-Grip. The indicator begins flashing green. Your sensor is ON! Your sensor will turn off after 10 minutes of no Bluetooth connection or no application connection.
Once the sensor is turned on, select the K-Grip sensor activity in the Home Page. At this step, the K-Grip is connected and the LED starts flashing Blue.

NOTICE

While your K-Grip is connecting, don't apply force on the sensor, don't step on the sensor, don't move the sensor, keep it vertical on a flat surface.

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K-Push

Description

K-Push is a handheld dynamometer used for the strength evaluation of different muscles. You can assess isometric strength through the peak force as well as the average force for a specific muscle or muscle groups.
The K-Push allows to quantitatively measure the muscle strength and the deficit percentage caused by injury compared to the strength of the healthy side.

Benefits

K-Push is equipped with electronic force transducers and gives real-time acoustic and optic Biofeedback on your Smartphone or Tablet through the Kinvent Physio app. Through its Target oriented exercises, you can set objectives to your patient and encourage him to surpass himself. The app saves your participant's results. You can then follow-up his progress on Maximal Force, Endurance, and muscular Symmetry on the app's database.

Usability Data

Intended medical indication:
For the strength evaluation of different muscles

Intended patient population
Teenagers to geriatric, with normal health or pre/post operation only on doctor’s approval for rehabilitation.

Intended part of the body or type of tissue to or interacted with:
Site: External areas , typically arms, hands, torso, head, legs, feet
Condition: Normal, no abscesses nor wounds.
Direct contact not required , contact over clothing or through silicone cushions

Intended User Profile:
The K-Push must be used by a trained health professional. The user must have received sufficient training in clinical procedures to get reliable measurements.

Intended use environment :
Hospital or other medical practice environment.

Operating Principle:
K Push is equipped with an electronic force transducer that converts the applied forces to electrical signals which are then converted to digital calibrated outputs.

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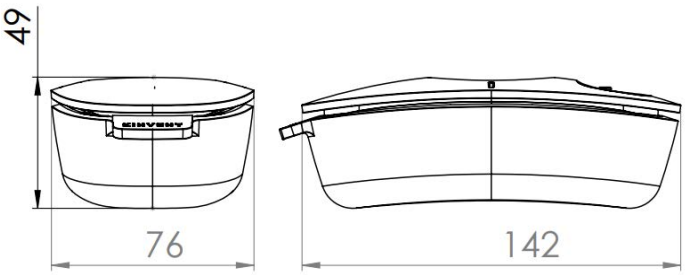
Technical Features

Dimensions and Weight

Weight	370 g / 13 oz (including the starter pillow)
Dimensions (H x W x L)	Metric 49 x 142 x 76 mm; US : 1.93 x 5.6 x 3” 
Max force	90 kg / 198 lbs
Accuracy	< 0.1%, +-0.1kg / +-0.22lbs
Acquisition frequency	1000 Hz
Adjustable handle size	Silicon pillow with soft center
Eco features	Self-activated “sleep” mode after 10 minutes.
Units	Selectable in application KgF, N, lbs

Electrical and Communication Data

Radio Technology	Bluetooth Low Energy 5.1
Power supply	1 cell 3.7V Li-Po Battery 280mAh
Radiated output power	Max.10 mW
Wireless transmission Frequency	2.4 GHz band 2402- 2480 MHz
Modulation	GFSK
Channel Bandwidth	2 MHz
ERP	8.6dbm
Wireless range	Up to 40 meters / 44 yd
Contains FCC ID	2AAQS-ISP1807
Battery	12h of autonomy, 2h charging
Minimum requirements	Android 6.0+ or iOS 11.0+, Bluetooth Low Energy

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Content of the Commercial Package

The User will receive:

- K-Push
- Twin Handle
- Medical grade power adapter with USB-A for charging
- One hand holder with belt
- USB-C to USB-A charging/data cable
- Quick start cards in EN/ FR /ES
- User manual

The battery is not removable, it is already installed in the device

Accessories

The sensor has an option to fit accessories through the top magnetic coupling.
The Twin Handle is an accessory that makes the K-Push easier to handle at greater forces. It is suitable for measures that require a stable and controlled two-handed grip. The use of a hand-held dynamometer has never been so comfortable
The Nordic assessment set, allows secure mounting of the K Push on gym bars or iso-box to use for the nordic hamstring assessment protocol.

Get Started

The sensor comes with the cushion preinstalled on the sensor. The cushion can be very easily installed as it snaps in place
Next, configure the strap length according to your hand and place it over it. Otherwise, you can replace the default handle by the Nordic or the Twin Handle accessory.

⚠ WARNING

The cushion can be removed for cleaning. Use antiseptic alcohol wipes to **disinfect the cushion prior to use.**

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To change the handle twist clockwise 45 degrees (diagonal position). The handle will lift on its own, so you can then easily pull and remove

On the top surface of the sensor there are: one USB-C port used for charging, one LED indicator for the working state/charging state and one push-button.

You can charge your K-Push sensor through the USB-A to USB-C cable provided or with any USB-C charging cable. The sensor is supplied with the appropriate IEC 60601 medical USB power supply. If a different charger is used, ensure that it meets the minimum medical safety requirements and if unsure please do not use the sensor while plugged in/charging sensor.

Press the orange power on button on K Push. The indicator begins flashing green. Your sensor is ON! Your sensor will turn off after 10 minutes of no Bluetooth connection or no application connection.
Once the sensor is turned on, select the K Push sensor in the Home Page. Select the body part you want to measure and then select one of the proposed exercises. Once the K Push is connected, the LED turns Blue.

NOTICE

While your sensor is connecting, do not load the sensor, do not step on the sensor, do not move the sensor, and do not apply force on the sensor.

NOTICE

For a better reliability of the isometric strength measurement, the attachment position should always be the same and should be perpendicular to the exerted force direction

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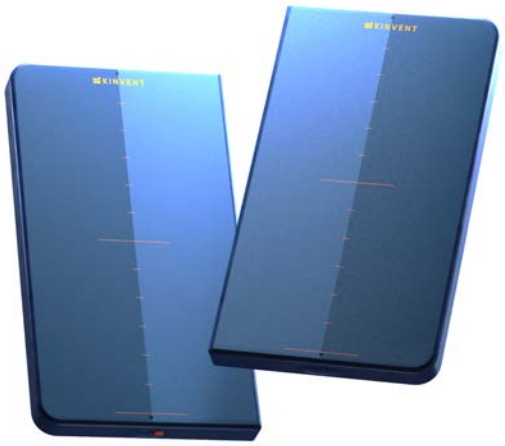
K-Force Plates



Description
K-Force Plates are two independent force platforms for rehabilitating balance and assessing lower limb muscular symmetry and strength.

Benefits

K Plates are equipped with electronic force transducers and give real-time acoustic and optic biofeedback on your Smartphone or Tablet through the Kinvent Physio app. Each platform has 4 independent sensors on the corners, allowing measurement of the center of pressure. Each foot comes with a mounting thread so that the sensor can be fixed on a surface.

Usability Data

Intended medical indication:
Rehabilitating balance and assessing lower limb muscular symmetry and strength.

Intended patient population
Teenagers to geriatric, with normal health or pre/post operation only on doctor's approval for rehabilitation.

Intended part of the body or type of tissue to or interacted with:
Site: External areas , typically arms, hands, torso, head, legs, feet
Condition: Normal, no abscesses nor wounds.
Direct contact not required , contact over clothing or through silicone cushions

Intended User Profile:
The K Force Plates must be used by a trained health professional. The user must have received sufficient training in clinical procedures to get reliable measurements.

Intended use environment :
Hospital or other medical practice environment.

Operating Principle:
K Force Plates are equipped with 4 electronic force transducers per platform that convert the applied forces to electrical signals which are then converted to digital calibrated outputs.

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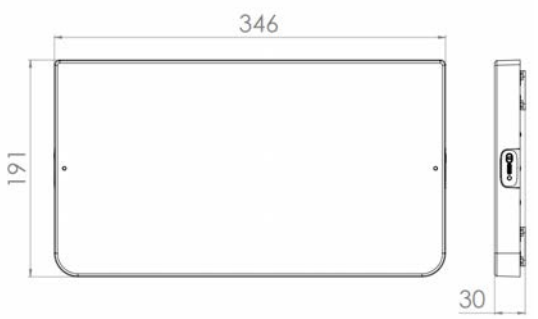
Technical Features

Dimensions and Weight

Weight	2000 grams / 4.4 lbs per platform
Dimensions (H x W x L) *5 mm/ 0.2" ground clearance*	Metric 30 x 346 x 191mm US : 1.18x13.62x7.52" 
Max force	600 kg / 1322 lbs per platform
Accuracy	< 0.1%, +-0.1kg / +-0.22lbs
Acquisition frequency	1000 Hz Full CoP
Cover	Anti-slip R11 film
Eco features	Self-activated "sleep" mode after 10 minutes.
Units	Selectable in application KgF, N, lbs

Electrical and Communication Data

Radio Technology	Bluetooth Low Energy 5.1
Power supply	1 cell 3.7V Li-Po Battery 800 mAh / platform
Radiated output power	Max.10 mW
Wireless transmission Frequency	2.4 GHz band 2402- 2480 MHz
Modulation	GFSK
Channel Bandwidth	2 MHz
ERP	8.6dbm
Wireless range	Up to 20 meters / 21 yd
Contains FCC ID	2AAQS-ISP1807 or X8WBM833
Battery	20h of autonomy, 2h charging
Minimum requirements	Android 6.0+ or iOS 11.0+, Bluetooth Low Energy

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Content of the Commercial Package

The User will receive:

- K Force Plates (2 x plates)
- Medical grade power adapter with USB-A for charging
- 2x USB-C to USB-A charging/data cable
- Quick start cards in EN/ FR /ES
- User manual

The battery is not removable, it is already installed in the device

Accessories

The Jump Frame is an accessory for the K-Force Plates that allows it to stabilize the platforms and to obtain a larger surface at equal height to perform jumps in complete safety. It also allows you to adjust the distance between the plates to easily adapt it to the patient's comfort. In addition, it ensures reproducibility of measurements under similar conditions. The Jump Frame is made of rigid foam. Lightweight and transportable, it will ensure the safety of your patients.

Installation

Install K-FORCE PLATES according to the measurement selected.

On the floor

This configuration is ideal for balance exercises. You can place the K-FORCE PLATES on the ground either side by side or spaced apart. This increases the difficulty level of balance exercises, as you can work on your lower limbs muscular force at the same time.




On vertical surface

K-FORCE PLATES can be attached on a vertical surface (Wall) to measure upper limbs muscular strength, or even on weightlifting machinery such as a Leg Press Machine. To this end, use Velcro sticks with at least 200 cm^2 / 31 in^2 surface.

⚠ WARNING

For your safety, please make sure that K-FORCE PLATES are well fixed on vertical surfaces before using.

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Get started

On the side surface of the sensor there are:
One USB-C port used for charging, one LED indicator for the working state/charging state and one push-button. On the top surface a second LED indicator is present that works together with the first on the side.
You can charge your K-Force Plates sensors through the USB-A to USB-C cable provided or with any USB-C charging cable. The sensor is supplied with the appropriate IEC 60601 medical USB power supply. If a different charger is used, ensure that it meets the minimum medical safety requirements and if unsure please do not use the sensor while plugged in/charging

⚠ WARNING

Disinfect K-FORCE PLATES prior to use, using antiseptic alcohol wipes.

Press the orange power on button on both K-Force Plates. The indicators begin flashing green. Your sensor is ON! Your sensor will turn off after 10 minutes of no Bluetooth connection or no application connection. Turn on both platforms. Once the sensor is switched on, go to the homepage, and select Plates sensor and an activity. Once the K Plates are connected, the LED turns Blue.

NOTICE

While your sensor is connecting, do not load the sensor, do not step on the sensor, do not move the sensor, do not apply force on the sensor.

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K-Bubble

Description

K-Bubble is a pneumatic sensor allowing you to work your strength with convenient inflatable tools.

Benefits

K-Bubble is equipped with a pneumatic (pressure) sensor and gives you real-time biofeedback based on the pressure applied on the inflatable cushion used.

Usability Data

Intended medical indication:
Training with medical inflatable accessories for rehabilitation

Intended patient population
Teenagers to geriatric, with normal health or pre/post operation only on doctor's approval for rehabilitation.

Intended part of the body or type of tissue to or interacted with:
Site: External areas , typically arms, hands, torso, head, legs, feet
Condition: Normal, no abscesses nor wounds.
Direct contact not required , contact over clothing or through silicone cushions

Intended User Profile:
The K Bubble must be used by a trained health professional. The user must have received sufficient training in clinical procedures to get reliable measurements.

Intended use environment :
Hospital or other medical practice environment.

Operating Principle:
K-Bubble is equipped with a pneumatic (pressure) sensor that measures the air pressure of the connected inflatable accessory.

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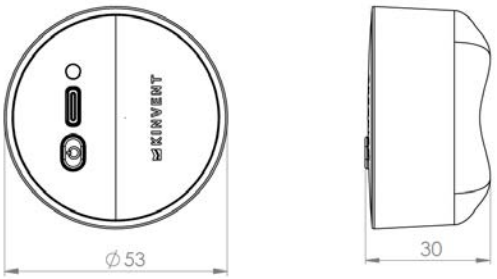
Technical Features

Dimensions and Weight

Weight	36 g / 1.27 oz
Dimensions (D x H)	Metric Ø53 x30 mm ; US Ø2.09 x 1.18 “ 
Max Pressure	0.4 Bar / 5.8 PSI
Accuracy	< 1.5%
Acquisition frequency	125 Hz
Eco features	Self-activated “sleep” mode after 10 minutes.
Units	Selectable in application KgF, N, lbs

Electrical and Communication Data

Radio Technology	Bluetooth Low Energy 5.1
Power supply	1 cell 3.7V Li-Po Battery 160mAh
Radiated output power	Max.10 mW
Wireless transmission Frequency	2.4 GHz band 2402- 2480 MHz
Modulation	GFSK
Channel Bandwidth	2 MHz
ERP	8.6dbm
Wireless range	Up to 50 meters / 54 yd
Contains FCC ID	2AAQS-ISP1807 or X8WBM833
Battery	12h of autonomy, 1.5h for charging
Minimum requirements	Android 6.0+ or iOS 11.0+, Bluetooth Low Energy

Content of the Commercial Package

The User will receive:

- K-Bubble
- Medical grade power adapter with USB-A for charging
- USB-C to USB-A charging/data cable
- Quick start cards in EN/ FR /ES
- User manual
- Accessory pack with 1x Body Roll, 1 Senso Ball 18cm, 1 x Air Grip, 1x Needle valve, 1 x connecting tube

The battery is not removable, it is already installed in the device

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Accessories

The K-Bubble accessory pack contains the following inflatable tools

Body Roll

Senso ball 18 cm

Air Grip

Get Started

The sensor is equipped with a USB-C port used for charging, 1 LED for the working/charging state and one push-button.
You can charge your K-Bubble sensor through the USB A to USB C cable provided or with any USB-C charging cable. The sensor is supplied with the appropriate IEC 60601 medical USB power supply. If a different charger is used, ensure that it meets the minimum medical safety requirements and if unsure please do not use the sensor while plugged in / charging sensor.
Press the orange power on button on K Bubble. The indicator begins flashing green. Your sensor is ON! Your sensor will turn off after 10 minutes of no Bluetooth connection or no application connection.
Put the needle in the valve of your inflatable tool, then go to the homepage and select the corresponding inflatable tool and begin to work following the onscreen instructions.
Important

- **Moisten the needle before inserting in the inflatable accessories to prevent damage and improve the seal.**
- **Carefully insert the needle straight into the needle valve of the accessory.**
- **The needle must fit tight, without touching the internal opposite side of the inflatable accessory**

NOTICE

Zeroing of the pressure
The test result comparability is influenced by the pressure inside the inflatable accessory.

After inserting the needle in the valve, unscrew about half a turn the needle from the socket to allow the pressure to equalize for about 5 sec. Then tighten the needle again. Please make sure that everything is tight and when squeezing and no air leak is heard or air bubbles are formed on the valve. Although the sensor is working in absolute terms and is thus unaffected by the external/internal pressure difference the inflatable accessory will behave differently if over- or under- inflated.
In order to change accessories the above process will have to be repeated.

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K-Move

Description

K-Move is an inertial sensor to measure the range of motion and to compare the symmetry between the injured limb's amplitude and the healthy limb.

Benefits

K-Move is equipped with an IMU sensor and gives you real-time biofeedback based on the evolving range of motion compared to the initial movement position.

Usability Data

Intended medical indication:
Evaluation of range of motion

Intended patient population
Teenagers to geriatric, with normal health or pre/post operation only on doctor's approval for rehabilitation.

Intended part of the body or type of tissue to or interacted with:
Site: External areas , typically arms, hands, torso, head, legs, feet
Condition: Normal, no abscesses nor wounds.
Direct contact not required , contact over clothing or through silicone cushions

Intended User Profile:
The K Move must be used by a trained health professional. The user must have received sufficient training in clinical procedures to get reliable measurements.

Intended use environment :
Hospital or other medical practice environment.

Operating Principle:
K-Move is equipped with a 9axis inertia sensor that measures the angle, acceleration and rotation of the device.

Content of the Commercial Package

The User will receive:

- K-Move
- Medical grade power adapter with USB-A for charging
- USB-C to USB-A charging/data cable
- Quick start cards in EN/ FR /ES
- User manual
- Accessory pack with belts

The battery is not removable, it is already installed in the device

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Accessories :

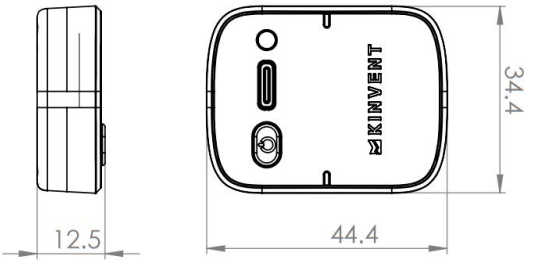
K-Move is provided with accessories for a turnkey operation:

Different size belts:

- 57cm / 22.4” thighs/triceps
- 77cm / 30.3” torso/head

Technical Features

Dimensions and Weight

Weight	18 g / 0.63 oz
Dimensions (H x W x L)	Metric 12.5 x 34.5 x 44.5 mm ; US : 0.49 x 1.36 x 1.75 “ 
Max Accelerations	+-16g
Static Accuracy	2°
Dynamic accuracy (head., pitch, roll)	7°, 2°,2°
Acquisition frequency	400 Hz
Eco features	Self-activated “sleep” mode after 10 minutes.
Units	Selectable in application degrees

Electrical and Communication Data

Radio Technology	Bluetooth Low Energy 5.1
Power supply	1 cell 3.7V Li-Po Battery 160mAh
Radiated output power	Max.10 mW
Wireless transmission Frequency	2.4 GHz band 2402- 2480 MHz
Modulation	GFSK
Channel Bandwidth	2 MHz
ERP	8.6dbm
Wireless range	Up to 50 meters / 54 yd
Contains FCC ID	2AAQS-ISP1807 or X8WBM833
Battery	12h of autonomy, 1.5h for charging
Minimum requirements	Android 6.0+ or iOS 11.0+, Bluetooth Low Energy

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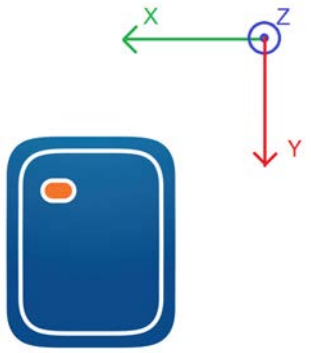
Get Started

The sensor is equipped with a USB C port used for charging, 1 LED for the working/charging state and one push-button.
You can charge your K-Move sensor through the USB A to USB C cable provided or with any USB-C charging cable. The sensor is supplied with the appropriate IEC 60601 medical USB power supply. If a different charger is used, ensure that it meets the minimum medical safety requirements and if unsure please do not use the sensor while plugged in/charging
Press the orange power on button on K-Move. The indicator begins flashing green. Your sensor is ON! Your sensor will turn off after 10 minutes of no Bluetooth connection or no application connection.
Once the sensor is switched on, choose the joint's amplitude and the movement you want to assess. Attach the K-Move on the limb of your patient. Ask him to stay in a neutral position to initialize the reference position. When you click on START your patient can start moving. The range of motion is measured in degrees. Ensure the patient is not using compensation movement.
To assess a joint's amplitude of a movement not available in the list, create your own assessment.



Axis definition on the device

NOTICE

For better reliability of the range of motion measurement, the initial position should be set as the zero-amplitude angle and the start should be pressed at this time. Take care to avoid compensation of other limbs.

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K-Pull

Description

Traction dynamometer for the measurement of isometric strength and biofeedback training.
K-Pull enables independent measurements. It can be fixed on a physiotherapists table, on the espalier or on pulley machines.

Usability Data

Intended medical indication:
Adjusting the distribution of weight/force(s) that is being applied to a lower or upper limb.

Intended patient population
Teenagers to geriatric, with normal health or pre/post operation only on doctor's approval for rehabilitation.

Intended part of the body or type of tissue to or interacted with:
Site: External areas , typically arms, hands, torso, head, legs, feet
Condition: Normal, no abscesses nor wounds.
Direct contact not required , contact over clothing or through silicone cushions

Intended User Profile:
The K Pull must be used by a trained health professional. The user must have received sufficient training in clinical procedures to get reliable measurements.

Intended use environment :
Hospital or other medical practice environment.

Operating Principle:
K-Pull is equipped with 1 extension electronic force transducer that converts the applied force to electrical signal which is then converted to a digital calibrated output.

Content of the Commercial Package

The User will receive:

- K-Pull
- Medical grade power adapter with USB-A for charging
- USB-C to USB-A charging/data cable
- Quick start cards in EN/ FR /ES
- User manual
- Accessory pack with 2x Carabiners, 2x Loop fasteting accessories, 2 x resistance bands, 1 rigid strap

The battery is not removable, it is already installed in the device

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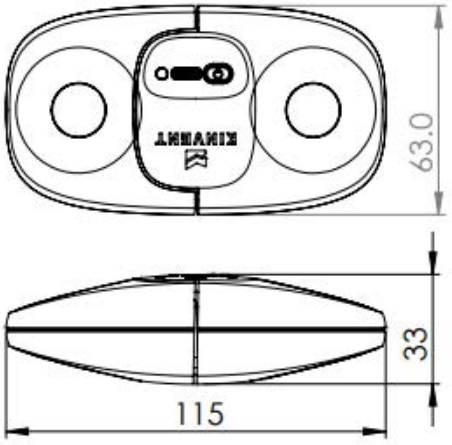
Accessories :

K-Pull is provided with accessories for a turnkey operation:

- 2 carabiners (rated for max 600 kg / 1322 lbs)
- 2 loop fastening accessories allowing attachment to a physiotherapy table or to a wall bar and to the desired limb with maximum force of 180 kg /396 lbs
- 2 different resistance elastics for exercise with resistance.
  - Blue Resistance Band 0.5-4 kg / 1.1 to 8.8lbs of resistance (lightest) used for Shoulders and shins
  - Orange Resistance Band - 1-8 kg / 2.2 to 17.6 lbs of
  - resistance (light) used for Biceps and triceps
- 1 adjustable rigid strap for the measurement of the maximum isometric force rated for max 600 daN / 611 kg / 1347 lbs .

Technical Features

Dimensions and Weight

Weight	150 g / 5.29 oz
Dimensions (H x W x L)	Metric: 115 x 63 x 33 mm ; US : 4.53 x 2.48 x 1.3 “ 
Max force	300 Kg / 661 lbs
Accuracy	< 0.1% , C3 Class
Acquisition frequency	1000 Hz
Connecting loop diameter	14 mm
Eco features	Self-activated “sleep” mode after 10 minutes.
Units	Selectable in application KgF, N, lbs

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Electrical and Communication Data

Radio Technology	Bluetooth Low Energy 5.1
Power supply	1 cell 3.7V Li-Po battery 280 mAh
Radiated output power	Max.10 mW
Wireless transmission Frequency	2.4 GHz band 2402- 2480 MHz
Modulation	GFSK
Channel Bandwidth	2 MHz
ERP	8.6dbm
Wireless range	Up to 40 meters / 44 yd
Contains FCC ID	2AAQS-ISP1807
Battery	12h of autonomy, 2h charging
Minimum requirements	Android 6.0+ or iOS 11.0+, Bluetooth Low Energy

Get Started

The sensor is equipped with a USB C port used for charging, 1 LED for the working/charging state and one push-button.
You can charge your K Pull sensor through the USB A to USB C cable provided or with any USB-C charging cable. The sensor is supplied with the appropriate IEC 60601 medical USB power supply. If a different charger is used, ensure that it meets the minimum medical safety requirements and if unsure please do not use the sensor while plugged in/charging
Press the orange power on button on K-Pull. The indicator begins flashing green. Your sensor is ON! Your sensor will turn off after 10 minutes of no Bluetooth connection or no application connection.
Once the sensor is turned on, select the K-Pull sensor in the Home Page. Select the body part you want to measure and then select one of the proposed exercises. Once the K-Pull is connected, the LED turns Blue.

NOTICE

While your sensor is connecting, do not load the sensor, do not step on the sensor, do not move the sensor, and do not apply force on the sensor.

⚠ WARNING

This is a high traction force sensor so extra care must be taken when selecting the anchoring point on the sensor or the included accessories. The strap and carabiner are rated for 600 daN /611 kg / 1347 lbs of maximum force while the elastics should not exceed an extension of 2.5 times their length.

NOTICE

For a better reliability of the isometric strength measurement, the attachment position should always be the same and should be perpendicular to the exerted force direction

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K-Deltas

Description

K-Deltas are two independent force platforms for rehabilitating balance and assessing lower limb muscular symmetry and strength.

Benefits

K-Deltas are equipped with electronic force transducers and give real-time acoustic and optic biofeedback on your Smartphone or Tablet through the Kinvent Physio app.

Usability Data

Intended medical indication:
Adjusting the distribution of weight/force(s) that is being applied to a lower or upper limb.

Intended patient population
Teenagers to geriatric, with normal health or pre/post operation only on doctor's approval for rehabilitation.

Intended part of the body or type of tissue to or interacted with:
Site: External areas , typically arms, hands, torso, head, legs, feet
Condition: Normal, no abscesses nor wounds.
Direct contact not required , contact over clothing or through silicone cushions

Intended User Profile:
The K-Deltas must be used by a trained health professional. The user must have received sufficient training in clinical procedures to get reliable measurements.

Intended use environment :
Hospital or other medical practice environment.

Operating Principle:
K-Deltas are equipped with 4 electronic force transducers per platform that convert the applied forces to electrical signals which are then converted to digital calibrated outputs.

Content of the Commercial Package

The User will receive:

- K-Deltas (2 platforms)
- Medical grade power adapter with USB A for charging
- 2x USB-C to USB-A charging/data cable
- Quick start cards in EN/ FR /ES
- User manual

The battery is not removable, it is already installed in the device

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Accessories

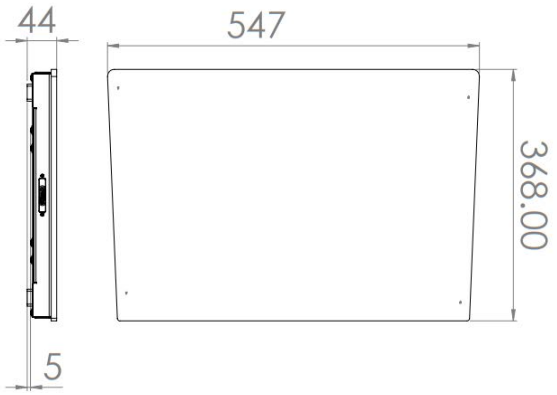
K-Deltas can be used with the following accessories

Deltas Frame is an accessory for the K-Force Deltas that allows it to stabilize the platforms and to obtain a larger surface at equal height to perform jumps in complete safety. In addition, it ensures reproducibility of measurements under similar conditions. The Deltas Frame is made of rigid foam. Lightweight and transportable, it will ensure the safety of your patients, it comes in a jigsaw format and can be easily dismantled for storage and transport

IMTP - Isometric Mid-Thigh pull accessory. This is a specialized , transportable tool for doing on field assessments. The accessory consists of a platform, a middle bar and a hand grip bar. The accessory along with the K-Deltas can be stored inside the same flight case.

Technical Features

Dimensions and Weight

Weight	8.8 kg/ 19.4 lbs per platform
Dimensions (H x W x L) *5 mm/ 0.2" ground clearance*	Metric 44 x 547 x368 mm US: 1.73 x 21.53 x 14.48 " 
Max force	2000 kg per platform (500kg/ sensor) 4410 lbs per platform (1103 lbs/sensor)
Accuracy	0.1%
Acquisition frequency	1000 Hz / 2000 Hz Full CoP
Cover	Anti-slip R11 film
Eco features	Self-activated "sleep" mode after 10 minutes.
Units	Selectable in application KgF, N, lbs

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Electrical and Communication Data

Radio Technology	Bluetooth Low Energy 5.1
Power supply	1 cell 3.7V Li-Po Battery 800 mAh / platform
Radiated output power	Max.10 mW
Wireless transmission Frequency	2.4 GHz band 2402- 2480 MHz
Modulation	GFSK
Channel Bandwidth	2 MHz
ERP	8.6dbm
Wireless range	Up to 20 meters / 21 yd
Contains FCC ID	2AAQS-ISP1807 or X8WBM833
Battery	20h of autonomy, 2h charging
Minimum requirements	Android 6.0+ or iOS 11.0+, Bluetooth Low Energy

Installation

Install K Deltas according to the measurement programme selected according to the on-screen instructions.

On the floor

This configuration is ideal for balance exercises. You can place K Deltas on the ground either side by side or spaced apart. This increases the difficulty level of balance exercises, as you can work on your lower limbs muscular force at the same time.

Get started

Each Deltas platform is fitted with a USB C port used for charging, 1 LED for the working/charging state and one push-button.
You can charge K- Deltas sensors through the USB A to USB C cable provided or with any USB-C charging cable. The sensor is supplied with the appropriate IEC 60601 medical USB power supply. If a different charger is used, ensure that it meets the minimum medical safety requirements and if unsure please do not use the sensor while plugged in/charging

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⚠ WARNING

Disinfect K- Deltas prior to use, using antiseptic alcohol wipes.

To switch on K-Deltas, press the on-off button on each platform . You will notice a green flashing LED. Your K-Deltas are on! Your K-Deltas will switch off after 10 minutes of inactivity.
Once the sensor is switched on, go to the homepage, and select K-Deltas sensor and an activity. When the K–Deltas are connected, the LED turns Blue.

NOTICE

While your sensor is connecting, do not load the sensor, do not step on the sensor, do not move the sensor, do not apply force on the sensor.

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K-Deltas XL

Description

K-Deltas XL are two independent force platforms for rehabilitating balance and assessing lower limb muscular symmetry and strength.

Benefits

K-Deltas XL are equipped with electronic force transducers and give real-time acoustic and optic biofeedback on your Smartphone or Tablet through the Kinvent Physio app.

Usability Data

Intended medical indication:
adjusting the distribution of weight/force(s) that is being applied to a lower or upper limb.

Intended patient population
Teenagers to geriatric, with normal health or pre/post operation only on doctor's approval for rehabilitation.

Intended part of the body or type of tissue to or interacted with:
Site: External areas , typically arms, hands, torso, head, legs, feet
Condition: Normal, no abscesses nor wounds.
Direct contact not required , contact over clothing or through silicone cushions

Intended User Profile:
The K-Deltas XL must be used by a trained health professional. The user must have received sufficient training in clinical procedures to get reliable measurements.

Intended use environment :
Hospital or other medical practice environment.

Operating Principle:
K-Deltas XL are equipped with 4 electronic force transducers per platform that convert the applied forces to electrical signals which are then converted to digital calibrated outputs.

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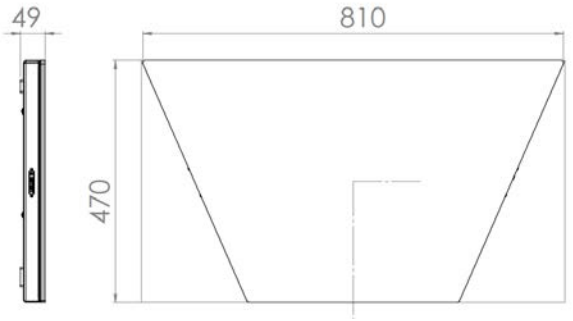
Technical Features

Dimensions and Weight

Weight	13.3 kg/ 29.3 lbs per platform
Dimensions (H x W x L) *5 mm/ 0.2" ground clearance*	Metric: 49x 810 x 470 mm US: 1.93 x 31.89 x 18.5 " 
Max force	2400 kg per platform (600kg/ sensor) 5291 lbs per platform (1323 lbs / sensor)
Accuracy	0.1%
Acquisition frequency	4000 Hz Full CoP
Cover	Anti-slip R11 film
Eco features	Self-activated "sleep" mode after 10 minutes.
Units	Selectable in application KgF, N, lbs

Electrical and Communication Data

Radio Technology	Bluetooth Low Energy 5.1
Power supply	1 cell 3.7V Li-Po Battery 800 mAh / platform
Radiated output power	Max.10 mW
Wireless transmission Frequency	2.4 GHz band 2402- 2480 MHz
Modulation	GFSK
Channel Bandwidth	2 MHz
ERP	8.6dbm
Wireless range	Up to 20 meters / 21 yd
Contains FCC ID	2AAQS-ISP1807 or X8WBM833
Battery	20h of autonomy, 2h charging
Minimum requirements	Android 6.0+ or iOS 11.0+, Bluetooth Low Energy

Content of the Commercial Package

The User will receive:

- K-Deltas XL (2 platforms)
- Medical Adapter with USB-A for charging
- 2x USB-C to USB-A charging/data cable
- Quick start cards in EN/ FR /ES
- User manual

The battery is not removable, it is already installed in the device

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Installation

Install K Deltas XL according to the measurement programme selected according to the on -screen instructions.

On the floor

This configuration is ideal for balance exercises. You can place K Deltas XL on the ground either side by side or spaced apart. This increases the difficulty level of balance exercises, as you can work on your lower limbs muscular force at the same time.

Get started

Each Deltas XL platform is fitted with a USB C port used for charging, 1 LED for the working/charging state and one push-button.
You can charge K-Deltas XL sensors through the USB A to USB C cable provided or with any USB-C charging cable. The sensor is supplied with the appropriate IEC 60601 medical USB power supply. If a different charger is used, ensure that it meets the minimum medical safety requirements and if unsure please do not use the sensor while plugged in/charging

⚠ WARNING

Disinfect K-Deltas XL prior to use, using antiseptic alcohol wipes.

To switch on K-Deltas XL press the on-off button on each platform . You will notice a green flashing LED. Your K-Deltas XL are on! Your K-Deltas XL will switch off after 10 minutes of inactivity.
Once the sensor is switched on, go to the homepage, and select K-Deltas sensor and an activity. Once the K-Deltas XL are connected, the LED turns Blue.

NOTICE

While your sensor is connecting, do not load the sensor, do not step on the sensor, do not move the sensor, do not apply force on the sensor.

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Troubleshooting

If any difficulties occur while using the system check if the symptoms appear in the following list. For further assistance please visit KINVENT's Help Center at Kinvent.link/quickstart or use the Kinvent Physio app assistance menu: “support”.

Sensor difficulties

Symptom	Actions
The sensor isn't turning on	1. Connect a known working charger with a known working USB cable and charge the sensor for a minimum of 30 min. Plug and unplug the usb cable, an orange or green light should come on after a short while. 2. Press the On/Off button until an audible click is heard and felt. 3. If you suspect failure, contact your distributor or check our website for the replacement scheme or contact directly using the K PHYSIO assistance menu
While having closed the app, the sensors keeps the Blue LED on	1. Make sure the app is closed. On Android **hold the "Home" button or press the "Recently Used Apps" button to view the list of running apps**. To close the app, swipe it to the left or to the right 2. Turn off the Bluetooth on the tablet or smartphone sensor. 3. Press the on/off push button for 5 sec to force it to turn off
The sensor isn't shutting down after 10 minutes of inactivity	1. Check if an active connection is on (indicated by blue light) and close the application/bluetooth. Press optionally the on/off push button for > 5 sec to force shut down the sensor. 2. Make sure that no load is applied on the sensor. 3. If the issue persists, you can use the on-screen instruction on the app for resetting the baseline.
A calibration error message is shown.	1. Close the app and try again while making sure that no load is applied on the sensors. For K-Force Plates / K-Deltas make sure the surface is flat and all feet are in contact with the ground and the platform does not wobble. For K-Move please do not move/bump the sensor while calibrating. 2. Contact KINVENT for scheduling a calibration. Calibration should be performed annually or sooner if special conditions apply.
A part is damaged/ lost	1. Please contact KINVENT to arrange a replacement spare part.

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Connectivity difficulties

Symptom	Actions
The sensor is turned on but isn't connecting.	1. Make sure your smartphone or tablet is compatible with K Physio. 2. Check if Bluetooth and location services are enabled, on your tablet or smartphone 3. Check if the sensors are properly charged - pressing the button should light up the LED indicator and pressing a second time will bring a steady light indicating the battery charge level, make sure that it is green or orange. 4. Restart the app. On Android **hold the "Home" button or press the "Recently Used Apps" button to view the list of running apps**. To close the app, swipe it to the left or to the right 5. Restart your tablet or smartphone. 6. Make sure your sensor is close to your tablet or smartphone ideally no more than 5 meters/ 5.5 yd . 7. Don't pair manually the K-sensor in the Bluetooth settings of the tablet, otherwise please unpair immediately
The sensor lost connection during training	1. Do not plug the USB C from the sensor to a computer or smartphone for charging during training. Only use the supplied or equivalent USB charger.
While connecting the app is showing a gray or red circle on the sensor	1. Please turn off the sensor and try again. 2. Make sure that you are within range while using of the sensors 3. The official Bluetooth specifications state seven is the maximum number of Bluetooth sensors that can be connected at once. However, **three to four sensors** is a practical limit, depending on the sensor. Make sure that no other Bluetooth sensors (headphones/speakers etc.) are connected.
After connection , Green led is still flashing.	1. Use the sensor registration menu in the application to identify using the serial number of the sensor the correct sensor. Another sensor is possibly nearby. 2. Check if other sensors are in the near area and either allow them to turn off or manually power them off. 3. In case of K Plates/ K- Deltas please verify that both a left and right sensor is present and powered on.

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Legal information

Warranty Terms

This warranty shall not apply if the product

- is used with non-compatible products
- is used for commercial purposes such as rental
- is modified
- is damaged by accident, misuse, wear, or any other cause not related to defectiveness of materials or fabrication.

A valid proof of purchase in the form of a bill of sale or receipt must be provided to obtain warranty services.
KINVENT excludes all liability for any data loss, loss of profit or any other loss or damage suffered by the end customer.

European Union

K-Sensors is warranted for its electronics and all mechanical components for a period of 2 (two) years from the purchase date when used in accordance with the present manual. KINVENT can proceed to replace a K-Sensor covered by the warranty free of charge. The warranty is invalid in case of modification or replacement of any component in a K-Sensor, made without the KINVENT's authorization or the authorized K-Sensors dealer's authorization. KINVENT doesn't guarantee any therapeutic result when using K-Sensors. You must contact KINVENT or your authorized dealer to receive a return authorization and shipping instructions.

Other countries

K-Sensors is warranted for its electronics and all mechanical components for a period of 1 (one) year from the purchase date when used in accordance with the present user's manual. KINVENT can proceed to replace a K-Sensor covered by the warranty free of charge. The warranty is invalid in case of modification or replacement of any component in a K-Sensor, made without the authorization of KINVENT or the authorized K-Sensors' dealer. KINVENT doesn't guarantee any therapeutic result when using K-Sensors. You must contact KINVENT or your authorized distributor to receive a return authorization and shipping instructions.

Obligations of the User

Except in case of damage or defect attributable to KINVENT Biomecanique, the user shall not make any claims against KINVENT or their subsidiaries for any damaged or defective products or components. The user shall carefully examine the condition of the products immediately upon receipt.

If instructions given by KINVENT Biomecanique with respect to storage, installation and handling of the products are not observed or if changes are made to the product, if components are replaced or if consumable items are used which do not comply with the original specifications, any warranty rights are forfeited unless the user is able to refute any assertion that only any of these circumstances has caused the deficiency.

Defects, incorrect deliveries, quantities, or transport damage are to be notified without delay by the user in writing, by fax, or by email (in case of defects which can be identified immediately) to the KINVENT Biomecanique's distributors or to KINVENT Biomecanique directly, otherwise within two weeks of receipt of the products at the place of destination,

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by clearly describing the defect; in this respect, it is necessary that the user properly fulfills his obligations of investigation and notification.

In case you need to return one or multiple K-SENSORs, the sensors and accessories must be decontaminated and free of infectious material in order to be handled safely in a non-biological safety laboratory (see Cleaning instructions on each sensor).

The K Sensors must be returned in the original packaging. If not available anymore please inform the support or authorized distributor.

How to repackage for a return

- Pack the sensor in the original packaging (or bubble wrap if original packaging not available)
- Print and fill the after-sales service form
- Pack the sensor + form in a package
- Stick the return voucher on the package and ship

Are considered as signs of material degradation

- Scratches
- Broken parts due to drops or inappropriate uses
- Modification or replacement of any component
- Wet environment exposition
- Underwater immersion
- Extreme temperature exposition

Service policy

You acknowledge that any time your K-Sensors product is serviced, this service may change your settings or cause loss of data or of some functionalities. Backup your data (stored on your tablet or smartphone) on a regular basis.

⚠ WARNING

K-Sensors is a medical sensor. K-Sensors must be used according to the present User's Manual and its recommendations. Failure to do so may result in personal injury.
Users are responsible for their exercise manner and the manner in which they use K-Sensors. Movement promoted by K-Sensors can be associated with risks of injury.
Consult on a regular basis KINVENT's website for available information on contraindications, risks or side effects concerning K-Sensors. Kinvent doesn't offer treatment advice or any medical diagnosis.
In case you are currently under medication, injured or in delicate medical condition, consult a qualified professional prior to the use of any K-Sensors product. .
KINVENT doesn't guarantee any therapeutic result when using K-Sensors.

Waste Electrical and Electronic Equipment (WEEE) Policy

This section provides information about disposal of waste electrical and electronic equipment by users in the European Union.
The European Directive 2012/19/EC on WEEE requires proper disposal of electrical and electronic equipment when it reaches its end of life. The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local legislation. The separate collection and recycling of waste electronic

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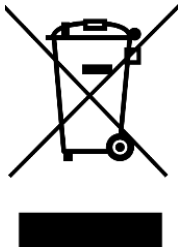
equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment



KINVENT accepts its responsibility in accordance with the specific WEEE recycling requirements and, where a replacement product is being supplied by KINVENT, provides free recycling of its WEEE-marked electronic equipment in Europe. If a replacement product is not being purchased from KINVENT recycling can be provided upon request at additional cost. To recycle electronic equipment, contact your local distributor for the required return form. Once the form is submitted, you will be contacted by the distributor either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

Declaration of Conformity

KINVENT Sensors are:
Class I measuring medical devices per Annex IX of Council Directive 93/42/EEC

K Plates, K Deltas are
Class I medical devices per CFR Title 21 Part 890 Subpart B, Sec. 890.1575

K Push, K Pull, K Grip, K Bubble are
Class II medical devices per CFR Title 21 Part 890 Subpart B, Sec. 890.1925

K Sens is
Class I medical devices per CFR Title 21 Part 888 Subpart B, Sec. 888.1500

KINVENT Sensors are:
Class II medical devices per Rule 10 of the Canadian Medical Devices Regulations

KINVENT Sensors also meet the following Technical Standards, to which Conformity is declared:

IEC 60601-1:2005, + AMD1:2012 +AMD2:2020	Medical electrical equipment - part 1: General requirements for basic safety and essential performance
IEC 60601-1-11:2015 + AMD1:2020	Medical Electrical Equipment - part 1-11: General requirements for basic safety and essential performance. Collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home health care environment
60601-1-2:2014+A1:2020	Medical electrical equipment - part 1-2: General requirements for basic safety and essential performance. Collateral standard: electromagnetic disturbances. requirements and tests
CISPR 11:2015+ A1:2016+A2:2019	Radiated emissions Group 1, class B
IEC 61000-3-2: 2019+A1:2021,	Harmonic Current Emissions

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EN 61000-3-3:2013 +A2:2021,	Voltage Fluctuations and Flicker
IEC 61000-4-2:2008	ESD immunity, ±8kV contact, ±2, ±4, ±8, ±15kV air
IEC 61000-4-3:2006 +A1:2007+A2:2010,	Radiated field immunity 80 MHz - 2.7 GHz, 10 V/m
IEC 61000-4-4:2012,	EFT/B Immunity
IEC 61000-4-5:2014 +A1:2017	Surge Immunity
IEC 61000-4-6:2013,	Conducted RF Immunity
IEC 61000-4-8:2009,	Power Frequency Magnetic Field Immunity: 30A/m 50 and 60 Hz
IEC 61000-4-11:2004 +A1:2017	Voltage Dips

KINVENT Sensors are designed and manufactured in a facility certified to the following international standards:
EN ISO 9001:2015

KINVENT products are subject to the quality standards within the quality management system according to ISO 13485::2016

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The K-SENSORS are intended for use in the electromagnetic environment specified below. The customer or user of the K-SENSORS should assure that they are used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment- guidance**
RF emissions CISPR 11	Group 2	The K SENSORS devices uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The K-SENSORS are intended for use in the electromagnetic environment specified below. The customer or user of the K-SENSORS should assure that they are used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC-61000-4-2	± 8 kV contact 2, 4, 8 , 15 kV air	± 8 kV contact 2, 4, 8 , 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

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Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a domestic environment.
NOTE UT is the AC mains voltage prior to application of the test level			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The K-SENSORS are intended for use in the electromagnetic environment specified below. The customer or user of the K-SENSORS should assure that they are used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment- guidance**
Radiated RF IEC 61000-4-3	3V/m 0.15 to 80MHz 6V/m 0.15 to 80MHz and 80% AM@ 1kHz 10V/m from 80MHz to 2.7GHz	3V/m 0.15 to 80MHz 6V/m 0.15 to 80MHz and 80% AM@ 1kHz 10V/m from 80MHz to 2.7GHz	Portable and mobile RF communications equipment should be used no closer to any part of the K SENSORS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \frac{3.5}{V_1}\sqrt{P}$ $d = \frac{12}{V_2}\sqrt{P}$ $d = \frac{12}{E_1}\sqrt{P}$ 80MHz to 800MHz $d = \frac{23}{E_1}\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b].

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			Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the K SENSORS are used exceeds the applicable RF compliance level above, the K SENSORS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the K SENSORS.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than V_1 V/m.

Recommended separation distances (in m) between portable and mobile RF communications equipment and the K SENSORS

The K SENSORS are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the K SENSORS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the K SENSORS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter Watt	**Separation distance according to frequency of transmitter**			
	150 kHz to 80 MHz outside ISM bands	**150 kHz to 80 MHz outside ISM bands** $d = \frac{12}{V_2}\sqrt{P}$	**80 MHz to 800MHz** $d = \frac{12}{E_1}\sqrt{P}$	**800 MHz to 2.5GHz** $d = \frac{23}{E_1}\sqrt{P}$
0.01	**0.12**	**0.2**	**0.4**	**1**
0.1	**0.37**	**0.64**	**1.3**	**2.6**
1	**1.17**	**2**	**4**	**8**
10	**3.7**	**6.4**	**13**	**26**
100	**11.7**	**20**	**40**	**80**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**	**Compliance level (V/m)**
385	380-390		Pulse Modulation 18 Hz	1.8	0.3	27	27
450	430-470		FM +-5 KHz deviation	2	0.3	28	28
710	704-787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
745							
780							
810	800-960	LTE band 5	Pulse modulation 18 Hz	2	0.3	28	28
870							
930							
1720	1700-1990	LTE band 1, 3, 4, 25	Pulse Modulation 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n RFID 2450 LTE band 7	Pulse modulation 217 Hz	2	0.3	28	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse Modulation	0.2	0.3	9	9
5500							
5785							

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FCC information

K-Sensors is a product using certain radio-frequencies during functioning. All K-Sensors equipment has been tested and found to comply with the limits for a Class B digital sensor, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Canada

This sensor contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

1.This sensor may not cause interference.

2.This sensor must accept any interference, including interference that may cause undesired operation of the sensor.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1.L'appareil ne doit pas produire de brouillage.

2.L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This radio transmitter has been approved by Innovation, Science and Economic Development Canada to operate with the antenna types listed below, with the maximum permissible gain indicated. Antenna types not included in this list that have a gain greater than the maximum gain indicated for any type listed are strictly prohibited for use with this sensor.

Le présent émetteur radio a été approuvé par Innovation, Sciences et Développement économique Canada pour fonctionner avec les types d'antennes énumérés ci-dessous et ayant un gain admissible maximal. Les types d'antenne non inclus dans cette liste, et dont le gain est supérieur au gain maximal indiqué pour tout type figurant sur la liste, sont strictement interdits pour l'exploitation de l'émetteur.

Japan

The Bluetooth module has received type certification, and is labeled with its own technical conformity mark and certification number, as required, to conform to the technical standards regulated by the Ministry of Internal Affairs and Communications (MIC) of Japan pursuant to the Radio Act of Japan.

Certificate number 020-200037, 201-190838/00

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Switzerland

For the Swiss market, our product range is registered with swissmedic and our authorised representative for Switzerland (CH-REP) is Freyr Life Sciences GmbH.

United Kingdom

For the UK market, our product range is registered with the MHRA and our authorised representative for the UK (UKRP) is I3CGLOBAL(UK) (Office 54, No.58 Peregrine Road, Hainault, IG63SZ, England).

Contact Information

For any information or Assistance, please contact:

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Release changes

E2023A_EN	2022-09-07	Initial version
E2023B_EN	2022-11-29	Added diagrams with dimensions for all devices, updated photos of K Plates exercises.
E2023C_EN	2022-12-19	K Deltas XL added
E2023D_EN	2023-02-23	K Bubble accessories updated images.
E2023E_EN	2023-06-01	Trade Name and Medical name table, changes table, K Physio version and functionally table. IEC 60601-1-11 addition, addition of FCC IDs, altitude specifications.
E2023F_EN	2023-06-26	Warning and Notice Icons, BLE icon, Cleaning section, Immunity and Emissions Declarations, User Obligations, DeltasXL images, axis of K Move

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