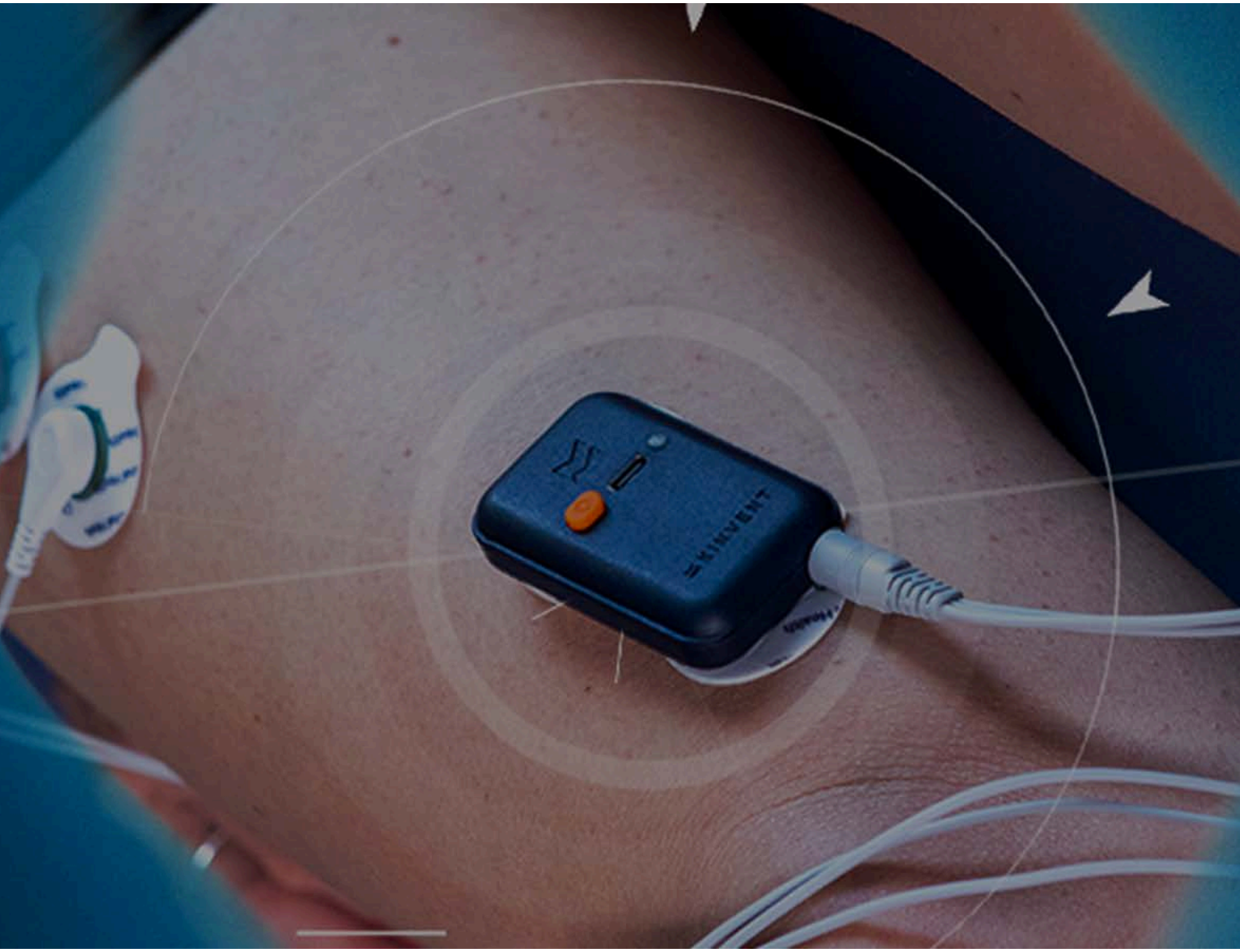


K-Myo Electromyograph
User Guide

KINVENT

Contents

NOTICE

This manual concerns the K-Myo product. The information content of this manual belongs to KINVENT, and is provided only for the purpose of operating K-Myo 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

KINVENT Biomécanique SAS
Zac Eureka Bâtiment Apollo A,
6 Rue de Pommessargues,
34000 Montpellier, FRANCE
+33 4 11 28 06 95
info@k-invent.com,
www.k-invent.com

Revision: 5
Last revision: 2024-10-11, printed in France

CE

Graphic Symbol

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

European Conformity
MDR 2017/ 745

Range of humidity to which the medical device can be safely exposed.

Keep Dry.

Sensor is provided **nonsterile**

Attention, See Instructions for use before use.

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

Manufacturer's **serial number**

Manufacturer's **lot code**

Recyclable Packaging Box

Consult electronic instruction for use

Indicates a carrier that contains **unique device information**

Recycling instruction for specific countries

Importer

Environmental Protection indicator,

Use-by date

Sensor will not work when connected to AC outlet

Class II Electrical Equipment

Upper & lower temperature limits for operation, transport, and storage

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

The devices utilize a **Bluetooth LE** radio for wireless communications

Medical device legal manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC

Manufacturing Date

Direct Current IN

Manufacturer's **catalog number**

Indicates a Medical Device

Plastic Resin codes of materials used (eg. Polypropylene)

Distributor

Medical Representative in Switzerland

Introduction

Thank you for purchasing the K-Myo.
K-Myo is part of the product line developed by KINVENT to objectively quantify rehabilitation.

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, 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-Myo. 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.

KINVENT Physio application 2.14[1]

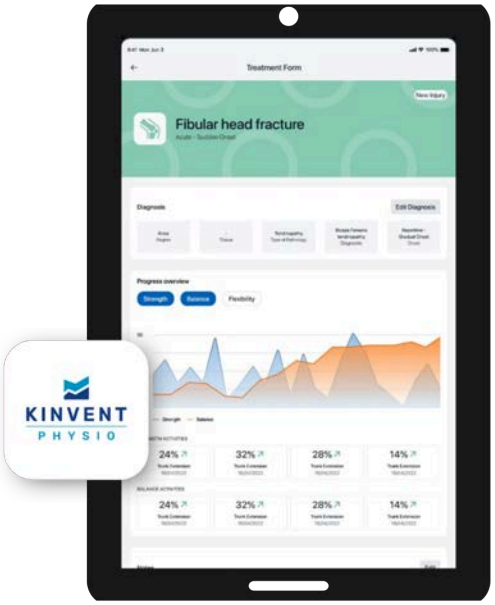
KINVENT Physio is the only app you will need for all your KINVENT Sensors.
All tutorials for the KINVENT Physio app are available online at: Kinvent.link/quickstart

The app is a smartphone/tablet application that supports the K-SENSORS/ K-Myo and other KINVENT sensors. The KINVENT Physio app records the measurement data from all compatible sensors and provides instant analysis and advanced parameter calculations replacing manual calculations.

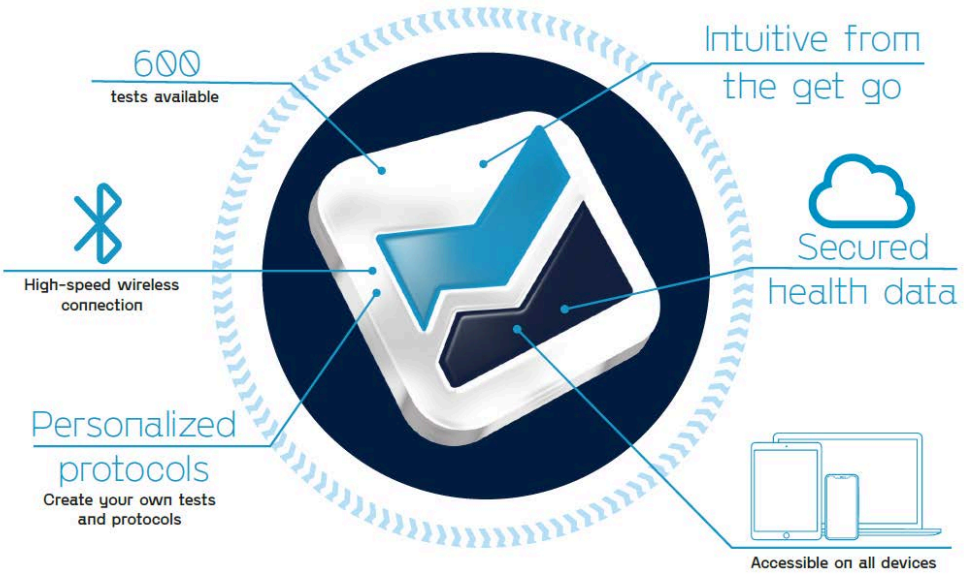
The KINVENT Physio app allows users to select the duration of recording, the rest time, repetitions, initial pause, detection threshold, sampling frequency, measurement units, enable video capture, as well as get detailed information on the measurement protocols via images and on-screen help. Further information such as white-papers are available for reference. The KINVENT Physio app can take unlimited number of recordings (limited by the available smartphone/tablet storage) which are also stored in the cloud and can be shared with the patients via the MyKinvent cloud platform

The KINVENT Physio app enables users to:

- Create patient profiles and assign tags / filters by pathology
- Collect and store multiple measurements from all compatible sensors for any of the patient profiles.
- Transmit the data to the KINVENT Health data servers in an encrypted format
- Create PDF reports
- Export measurements in CSV format (Excellence Tier feature)
- Use validated protocols (Different protocols available depending on License Tier)
- Train using games (Starter Tier feature)



[1] Latest version may differ on the **App Store** / **Google Play**



#

Installation the Application on the Host Device

Minimum Requirements: Android 10.0+ or iOS 12.0+, 2GB of RAM, Bluetooth Low Energy 4.2+, 5'' (12.7cm) Screen diagonal. For Mac OS a minimum of M1 processor is required
Recommended: Android 15.0+ or iOS 18.0+, 4GB of RAM, Bluetooth Low Energy 5.0+, 6.5'' (16.5 cm) Screen diagonal. For Mac OS M2 and M3 processors are recommended.

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

Security
It is highly recommended to keep the app unlock pattern enabled to guard the sensitive information stored and use a complex pattern. It is important to also secure your smartphone/tablet since you will be storing personal health information via the use of passcode, 6 digit or higher PIN, Touch ID or Face ID (availability depends on the smartphone abilities). Review your smartphone for information on how to add a layer of security.

The KINVENT Physio App does not require an active internet connection for the recording and analysis of the data. All data will be stored in the local memory of the smartphone/tablet. However for cybersecurity purposes, the user is required to periodically re-login so that the account is verified and internet connection is

required during the log-in. Additionally, the locally stored data will be synced when the internet connection is again available.

You need to connect the K-SENSORS / K-Myo 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 (KINVENT Physio) for data visualization.

Registering sensors

The K-SENSORS / K-Myo can be registered in the KINVENT 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.

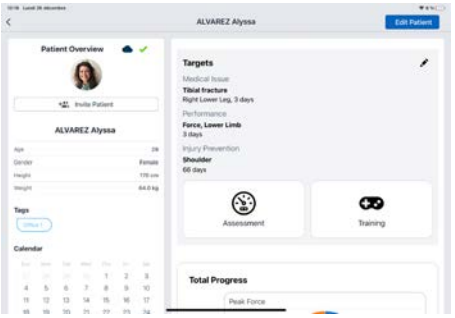
To register a sensor

- Launch the app
- Log-in using your password and unlock pattern
- Tap the sensors " " icon
- The app will ask to enable the Bluetooth connection, tap on enable
- Make sure you have turned on the K-Myo you wish to register
- Tap on "**Register Sensor**"
- The app will start to search for devices, and will prompt you to select the type of K-Sensor you wish to register
- Select the K-Myo you want to register from the list
- If no K-SENSORS or K-Myo are found you will be prompted to retry making sure that their LED is on and flashing Green

Adding a patient

To create a new patient profile:

- From the Home screen tap "**Patient List**" or tap on the icon " " on the bottom
- Tap "**(+) Add patient**"
- There it is necessary to fill in the Last Name/ First Name and the Date of Birth of the patient. You can scroll and add other information such as weight/height contact info etc. or add a photo.
- Once you have completed all the information, tap on "**Complete**"



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.

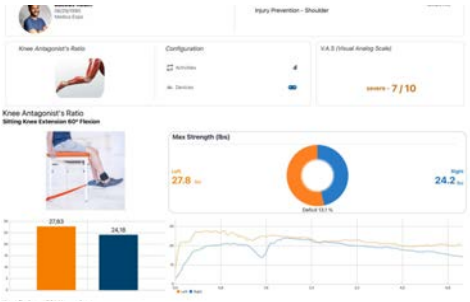
Starting a measurement

To start a measurement:

- From the Home screen tap"**Patient List**" or tap on the icon " " on the bottom
- Scroll or search for the patient that will be performing the assessment

- Tap on the name of the patient
- Scroll downwards and tap either on **“Assessment”** (or **“Training”** if available)
- A list of exercises/protocols is shown. A series of filters are shown on the right depending on the K-Sensor to be used and the body part that will be assessed
- Make a selection of the appropriate assessment type.
- Single type assessments have one type of assessment, while protocols have multiple steps and in-between rest recommendations or other steps.
- Once you tap on the selected assessment, the configuration screen will show up
- Select the Left/Right or the side that will begin with, select the preparation time, the duration and rest times, choose the number of repetitions as well any other specific to the assessment setting (threshold/segment length/video capture)
- On the top right, the list of the required K-SENSORS/ K-Myo will be displayed along with a flashing orb.
- The orb color and flashing indicates the status of the connection.
    - Grey orb slow flash: Searching
    - Circle rotating: Connection in progress
    - Blue tick: Connection established and ready for exercise
    - Red orb: Error on the device or connection failed
- Once all devices have a blue tick shown , tap on “Start” and follow the on-screen instruction.

Standard premium evaluations
Take a scientific approach to validated standard protocols: CMJ, Drop jump, Squat jump, McCall test, ASH test, squat analysis, Romberg, test profile strength, DSI, EVA, max strength, IMPT, antagonist ratio, posture analysis.



Accessing the Library

In the KINVENT Physio app, a variety of scientific and academic documents are available for in-depth study. Additionally Tutorials and helpful videos are available

- From the Home screen tap the “ ” icon at the bottom
- A list of features is available
    - **K-Pedia:** A database with explanation of terminology for all parameters and metrics available and calculated in the app
    - **Test Bank:** A list of all available protocols and assessments. Tap on any one of them to view instructions on how to perform, definitions, purpose of the assessment, K-Sensors/ K-Myo and tools required, suggested configurations and instructions for the patient as well as key results obtained and any references regarding the validity of the assessment.
    - **Bookshelf :** A list of ebooks , white papers and publications
    - **K-Start:** A link to the online quick start videos to help users familiarize with the application
    - **Tutorials:** A list of video tutorials for a number of exercises and assessments with live demonstrations and guidance
    - **Help Center:** A link to the list of short help articles of more advanced features of the app.

Settings and Account management

- From the Home tap on the icon " " on the bottom
- In the menu, you can adjust your personal info and other app settings
  - Tap on **"Profile"** to edit personal details and change your password
  - Tap on **"Organization"** to add a logo and set the name/address and other info to be shown in your personalized reports
  - Tap on **"Users"** to add other physician/medical personnel that will be using this account (Number of users depends on the license tier)
  - Tap on **"Settings"** to choose the language, measurement units, set the sampling frequency, enable/disable sound effects.
  - Tap on **"Addons"** to enable or connect any one of the additional app extensions. To use these features a separate account with these providers may be necessary
  - Tap on **"Pattern"** to enable or change your unlock pattern
  - Tap on **"Cloud"** to check the current connection status and/or upload manually the local measurements
  - Tap on **"Subscription Plan"** to view your current subscription level, and review the privacy policy and General Terms & Conditions
  - Tap on **"Contact us"** to connect with customer support
  - Tap on **"Privacy Information"** to review legal documents and check the app version.

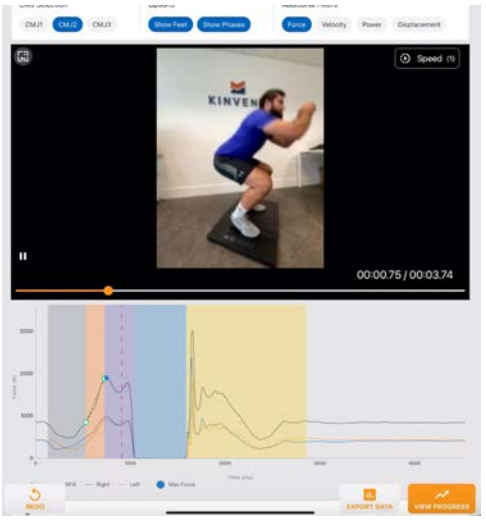
Supplemental App Features

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.



KINVENT Physio App Version History

Newly introduced features are in **bold**

ID	Date	Changes
2.14.2	9 Oct. 2024	**- Fixed an issue affecting games**
2.14.1	7 Oct. 2024	- Fixed an issue causing the application to crash when viewing the results of certain activities
2.14.0	4 Oct. 2024	**Introducing Smart Mode. An advanced feature automatic recognition of isometric activities and jumps** **- Introduced the K-Session. An complete rehab guide for assessment and training for many pathologies** - New report interface for advanced squat assessment - Introduced new advanced assessments - Fixed a visual issue in some reports - Overall app performance and stability enhancements
2.13.0	1 Oct. 2024	- Implement SSO support - Improvements in the reporting of various activities - Overall app performance and stability enhancements
2.12.0	24 Aug 2024	**- Greatly improved the protocol execution User Interface** **- Greatly improved the game with Karl in the desert** - CSV export now respects the preferred units - Overall app performance and stability enhancements
2.11.2	9 Aug 2024	- Overall app stability enhancements
2.11.1	7 Aug 2024	**- Add support for creating a custom activity using 2 K-Myo sensors** - Fix an issue with CoP display when using deltas sensors - Fix an issue with display of angles in line chart of advanced squats activity - Overall app stability improvements
2.11.0	23 July 2024	**Introduced the Flex mode activity. Performed with the K-Deltas sensors, you can now start recording and the system will automatically detect jump events** **Introduced the ability to customize test reports with the preferred statistics** Greatly enhanced the execution experience of a Protocol or Program Greatly improved the performance of the patients list screen Fixed an issue causing games to crash while running on a MacBook Raised the limit of the favorite activities Overall app performance and stability improvements
2.10.1	12 July 2024	Fixed an issue concerning relative values in jump reports Fixed the KPIs in summary per phase on jump reports, to display the selected rep's data and not average.

2.10.0	6 July 2024	**The MyKinvent feature is now free!** **Enhanced the protocol sharing capabilities. It is now easier to accept the shared assets** **Introduced new activities** not audible option Enhanced the User Interface of several screens Fixed issues regarding the PDF export of multiple activities Fixed the issue where the sound upon reaching a target was Several improvements and app performance optimisations
2.9.0	15 June 2024	**Greatly enhanced the Jump analysis algorithms** **Introduced the S-Starts protocol** Fixed an issue with multiple export and exercise titles
2.8.1	8 June 2024	**Introduced settings for different frequency acquisition with sensors** Fixed an issue with the PDF export of Jump assessments Fixed an issue when sharing a protocol Fixed an issue with the K-Starts result calculation Overall app performance improvements and optimizations
2.8.0	2 June 2024	**Introduced the VISA forms** Improved the handling of events in the calendar screen **Introduced rest time between asymmetry game sessions** Fixed an issue when duplicating protocols or activities Overall app improvements and performance optimisations
2.7.1	29 April 2024	Fixed an issue with games and certain iOS versions
2.7.0	23 April 2024	**Added total COP in the CSV export** Fixed an issue with the keyboard appearing in large scrollable areas Fixed an issue with games and the K-Myo sensor Fixed several UI issues with reports Overall bug fixes and app performance changes
2.6.2	18 April 2024	Fixed an interface issue with K-Myo during running an activity.
2.6.1	8 April 2024	**Introduced a new list of Forms, the Functional Assessment Scale for Acute Hamstring Injuries** **Enhanced the Protocol Sharing functionality to support build in activities** Fixed an issue with the Repetition Count test and the PDF export Fixed an issue with the K-Myo reports
2.6.0	29 Mar 2024	**Greatly enhanced the sharing of custom activities and protocols** Fixed an issue with the group exports Fixed an issue with the CSV export of various activities- Overall UI enhances Overall performance and stability improvements
2.5.2	17 March	Fix an issue causing the application to crash

	2024	
2.5.1	15 March 2024	**The Sharing feature has been enhanced. You can now share custom Activities!** Fixed an issue where the images from a shared protocol would not show Fixed an issue with different units in the report of Nordic Hamstrings Fixed an issue with the CSV export
2.5.0	8 March 2024	**Introduced the Force at 100ms index in the IMTP report** **Added better compatibility support with the K-Myo sensor** **Enhanced the K-Starts protocol reports** Overall app stability and performance changes
2.4.3	27 February 2024	Fixed a performance issue with the K-Myo reports
2.4.2	21 February 2024	Fixed an issue in account management screen Fixed an issue in the reporting of the Grip strength assessment
2.4.1	15 Feb 2024	**Introduced protocol sharing! You can now share protocols via a number of different applications!** Optimisation fixes for games Improved the French translation
2.4.0	12 February 2024	**Introduced new gaming tests! You can now train isometric, rep count and tempo training with all of your favorite game cases** Fixed issues with the custom protocol creation Fixed an issue with the K-Move sensor Overall app performance and stability changes
2.3.1	29 January 2024	Fix an issue when exporting group results in CSV format Fix an issue with the K-Myo sensor
2.3.0	22 January 2024	**Introduced the K-Starts forms, made by Reathletik** **Introduced a new integration support with Smartabase** **Introduced Leaderboard export with PDF and CSV formats available** **Enhanced the Jumps reporting** You can now delete a profile photo **Introduced a new Study in the Library** **You can now add and remove patients from the multiple patients session** Fixed an issue with the camera orientation Overall app performance and stability changes
2.2.1	22 December 2023	- Fix an issue with Asymmetry configuration in several tests
2.2.0	21 December 2023	**Greatly enhance the Program creation workflow** Fixed an issue with the Single Leg Static distribution test Fixed an issue with the login process

2.1.0	9 December 2023	Greatly enhanced the experience with certain games **Improved the reports of the distribution training** Fixed an issue with the camera and certain device models Overall app performance and stability changes
2.0.0	15 November 2023	**Improved the analysis of Jumps tests** **The Surf, Rugby and Breakout games have been upgraded** **Improved the leaderboard functionality** **You can now perform torque evaluations** **Improved the Bluetooth connectivity for latest iOS updates** Overall app stability and performance enhancements Improved the overall speed of the app
1.19.1	31 October 2023	Fix an issue regarding the registration process

Intended use

The K-Myo is intended to be used by trained professionals to assist with qualitative evaluating the muscle activity
The K-Myo may be used by medical professionals at healthcare facilities or at patient homes. The K-Myo by KINVENT must be operated by personnel familiar with electromyography and have the appropriate training

K-Myo is

- 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-Myo is 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

Safety precautions

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

⚠ WARNING

- **Take care of the strong attachment or hold of each sensor.**
- **Do not dispose of the K-Myo sensor in fire.**
- **K-Myo contains lithium-polymer batteries. Do not dispose the batteries with household waste.**
- **The K-Myo is not protected against ingress of liquids. Keep sensors dry. Do not immerse the K-Myo or their accessories in water.**
- **The K-Myo 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-Myo is not intended for use while attached to a 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.**

⚠ WARNING **DO NOT USE ON Patients with Silver allergies.**

⚠ WARNING **DO NOT USE on irritated skin or open wounds.**

⚠ WARNING **Immediately discontinue device use if skin irritation or discomfort occurs.**

⚠ 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.
- 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
- 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-Myo should only be used by trained professionals.

- The K-Myo is a medical sensor. 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-Myo components on unstable surfaces, or surfaces subject to vibration.
- Medical Electrical Equipment needs special precautions regarding EMC. K-Myo needs to be installed and put into service according to the information provided in this manual.

Replaceable Parts

- Device holder
- Straps
- Accessories

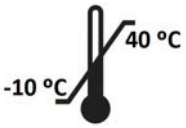
General Operating Conditions

Operating Environment

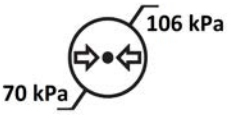
K-Myo must be used indoors. K-Myo must be used only in clean, dry rooms with leveled floors. Make sure you have plenty of space around you when you use it.

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 it in the protective carrying pouch.

If the K Myo is 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-Myo gives you measurements of muscle activity. K-Myo is already calibrated, to make it 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-Myo 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-Myo dealer.

Cleaning

NOTICE

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

K-Myo should be cleaned after each use. Cleaning and disinfection of the K-Myo can be performed by the system operator or the patient/user.
In order to clean the K-Myo's housing, use a damp cloth moistened with water or a mild detergent. If the dirt is persistent, rub the surface of the K-Myo 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-Myo **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-Myo is contaminated, contact your local distributor or KINVENT support directly.

⚠ WARNING

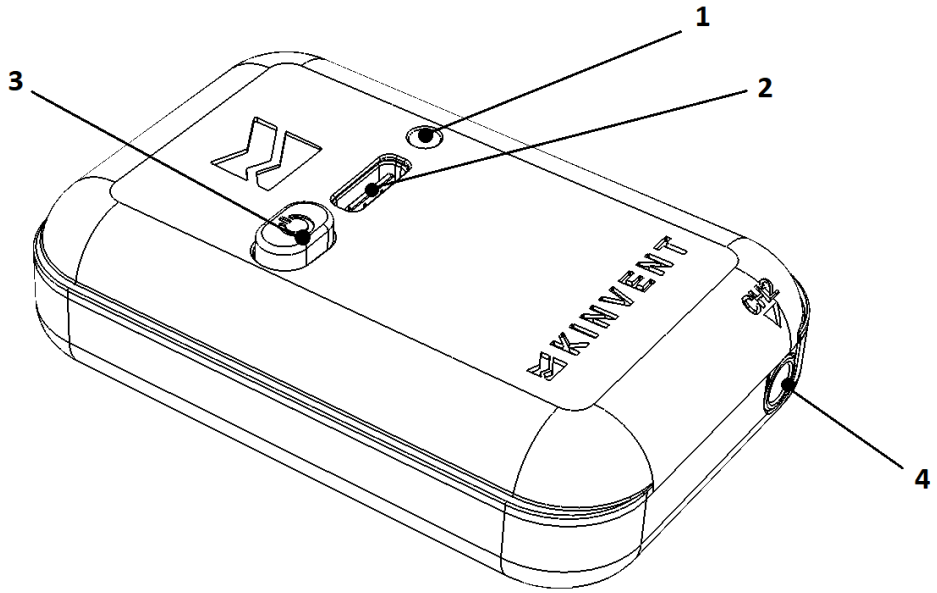
Careful cleaning and disinfection by the operator are recommended between uses to prevent cross infection if worn by multiple users or patients. Disinfect before and after each use. Allow disinfectants to dry before taking into use. Not to be worn by multiple users if consequences of cross contamination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

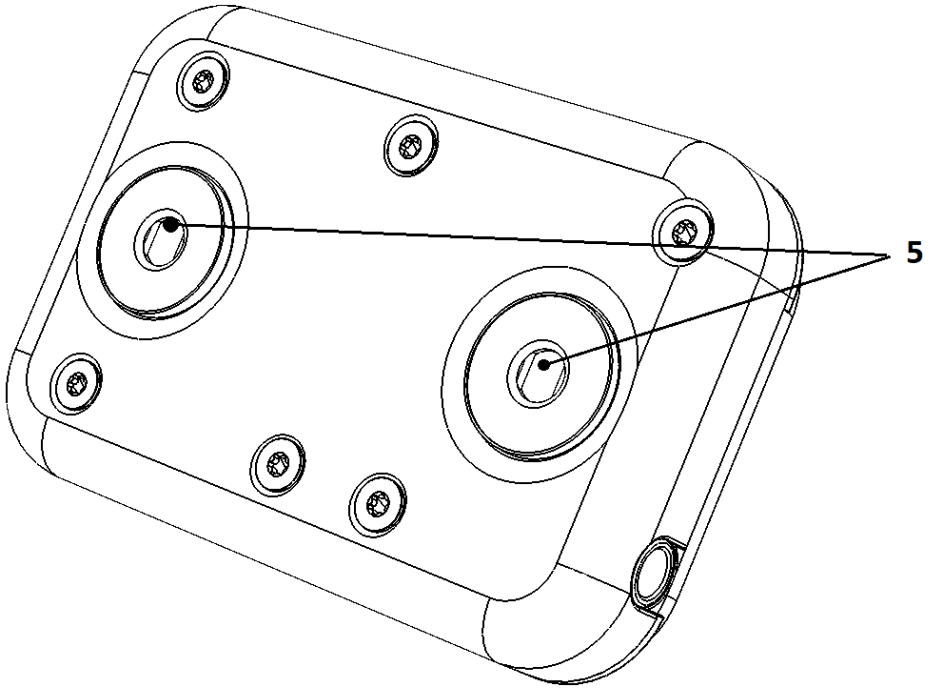
NOTICE

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

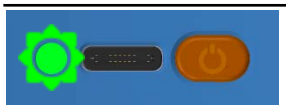
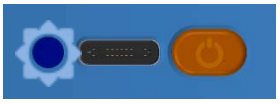
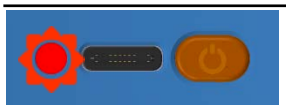
1- Multi color LED
2- USB-C charge port
3- Power on/ Command orange button
4- 3.5mm jack for connecting to external leads to Channel 2
5- Snap in connector for electrodes of Channel 1





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**

K-Myo

Description

K-Myo is used for the evaluation of the activation of a muscle during training. K-Myo qualitative measures the muscle effort caused during training

Benefits

K-Myo is an electromyography tool that measures the biopotential 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 evaluation of different muscle activation levels

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 via metallic pads (silver) or gel type pads

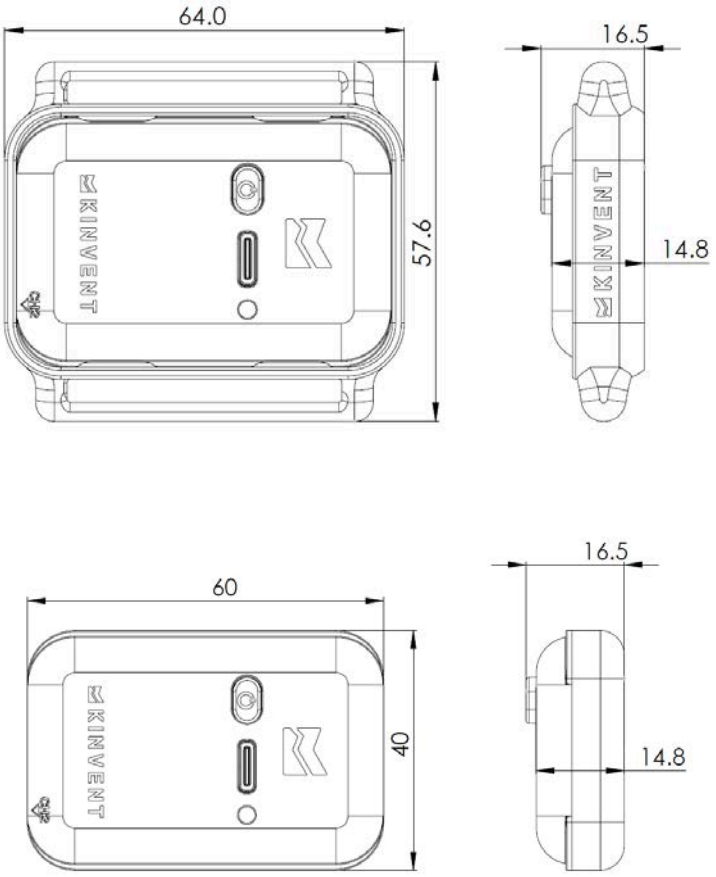
Intended User Profile:
The K-Myo must be used by a trained health professional. The user must have received sufficient training in clinical procedures to get reliable measurements.

Intended use environment :
Hospital or other medical practice environment.

Operating Principle:
K-Myo is equipped with an electronic converter that measures the muscle activation signals in the mV range and amplifies them for them to be measured.

Technical Features

Dimensions and Weight

Weight	37 g / 1.30 oz with holder 30 g / 1.05 oz device only
Dimensions (H x W x L)	Metric : 60 x 40 x 16.5 mm With holder 64 x 57 x 16.5 mm 
Channels	2 (1 internal, 1 external via 3.5mm jack) External channel contains a bias channel
Gain	Software selectable 6,8,12,24
Acquisition frequency	1000Hz
Eco features	Self-activated “sleep” mode after 10 minutes.

Electrical and Communication Data

Radio Technology	Bluetooth Low Energy 5.1
Power supply	1 cell 3.7V Li-Po Battery 200mAh
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
Contains IC ID	11306A-ISP1807
Input Differential range	750mV (at 6 Gain) , 187mV (24 Gain)
Input Protection	ESD 12kV, Current limiting
ADC, sampling and bandwidth	24 bit ADC, up to 2000 Hz , Bandwidth 10-1061 Hz Channel 1 Bandwidth 0-1061 Hz Channel 2 (use of external Bias lead)
Battery	12h of autonomy, 2h for charging
Minimum requirements	Android 10.0+ or iOS 12.0+, Bluetooth Low Energy

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-Myo 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-Myo 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-Myo. 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-Myo sensor activity in the Home Page. At this step, the K-Myo is connected and the LED starts flashing Blue.

NOTICE

While your K-Myo is connecting, don't touch the EMG leads.

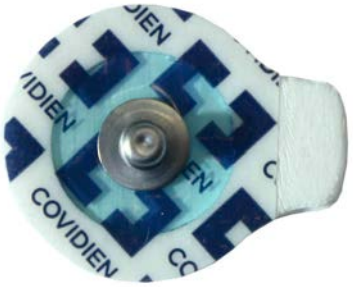
Accessories

The following accessories are available

- Strap and holder

- Single use patches with snap connector Ø 35 mm

  Kendall EKG adhesive electrode H135SG - diameter of the electrode 24 mm
  50 electrodes per bag
  Ag / AgCl sensor - embedded in an adhesive and conductive liquid hydrogel
  The carrier material is foam (adhesive) - suitable for sweaty patients
  Good long-term adhesive strength - experience has shown that it is very suitable for use in the sleep laboratory for EKG, EOG and EMG.
  REF: 31.1355.21



- Multi-use AgCL snap pads

- Reusable triple strap with leads and a 3.5mm jack for use with the secondary channel (CH2)
  - Left, Right, and Bias channels

- EMG leads with 3 snap-on connectors and a 3.5mm jack for use with the secondary channel (CH2)
  - Silicone rubber
  - Shielded
  - 3.5mm phone jack connector
  - Length: 80 cm or 60 cm
  - Left, Right, and Bias channels

Content of the Commercial Package

The User will receive:

- K-Myo
- 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.

Sold separately

- Accessory pack with 1x holder, 50 patches, 1 reusable strap, 1x set of EMG leads, 2x reusable snap pads

Preparation for measurement and best practices

- Ensure a good electrode/skin contact. Using the gel electrodes provides a higher quality signal and reduces unwanted noise sources and position changes or sporadic contact due to debris, hair or dirt. If an enhanced signal is needed, the area must be shaved off and the skin cleaned and sanitized to remove oil sweat and dirt.

- Sampling rate of 1000 Hz is recommended

- External wire length should be minimized (in case of use of Ch2) since the EMG voltage is very low. Motor or power lines will cause interference (50/60Hz). Mains notch filtering is applied by default on the signal to reduce the effect, but it is recommended to stay at least a few meters away from such sources.

- Wires need to be secured to reduce noise due to movement as well as reduce the risk of falls /tripping during movement

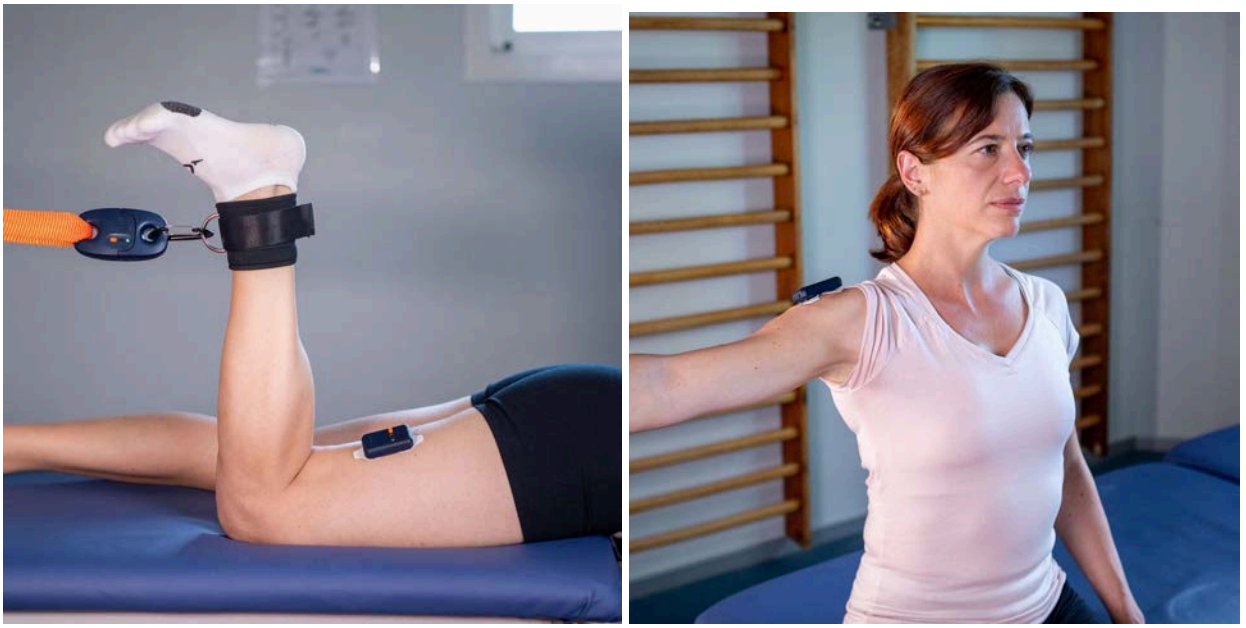


Figure 1 (left) use with K-Link on hamstrings, (right) use with belts on shoulder

Available assessments	Muscle	Device
Leg Extension / Isometric contraction	Quads assessment	K-Myo
Leg Flexion / Isometric contraction	Hamstrings assessment	K-Myo
Grip	Flexors assessment	K-Myo
Shoulder Abduction	Deltoids assessment	K-Myo
Leg Extension	Quads assessment	K-Myo + K-Pull
Leg Flexion	Hamstrings assessment	K-Myo + K-Push
Shoulder Abduction	Shoulder assessment	K-Myo + K-Push
Grip	Brachioradialis assessment	K-Myo + K-Grip

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.

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.

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

Other countries

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

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-Myo, 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-Myo 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

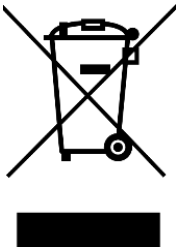
You acknowledge that any time your K-Myo product is serviced, this service may change your settings or cause loss of data or of some functionalities. Backup your data (stored on your tablet or smartphone) on a regular basis.

⚠ WARNING

K-Myo is a medical sensor. K-Myo 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-Myo. Movement promoted by K-Myo 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-Myo. 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-Myo product. .
KINVENT doesn't guarantee any therapeutic result when using K-Myo.

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 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

K-Myo is:
Class I medical devices per Annex VIII of MDR 2017/745 , Rules 1,9 and 13
K-Myo sensor is a Class II medical device per CFR Title 21 Part 882 Subpart F, Sec. 882.5050
K-Myo sensor is a Class II medical device per Rule 10 of the Canadian Medical Devices Regulations

K-Myo 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
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 K-Myo is 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-Myo is intended for use in the electromagnetic environment specified below. The customer or user of the K-Myo should assure that they are used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment- guidance**
RF emissions CISPR 11	Group 2	The K-Myo device 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-Myo is intended for use in the electromagnetic environment specified below. The customer or user of the K-Myo 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 %.
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-Myo is intended for use in the electromagnetic environment specified below. The customer or user of the K-Myo 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-Myo, 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]. 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-Myo is used exceeds the applicable RF compliance level above, the K-Myo 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-Myo.

[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-Myo

The K Myp is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the K-Myo can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the K-Myo 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.

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							

FCC information

K-Myo is a product using certain radio-frequencies during functioning. All K-Myo 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

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

KM2023A_EN	2023-05-31	Initial version
KM2023B_EN	2023-07-06	Warning and Notice Icons, BLE icon, Cleaning section, Immunity and Emissions Declarations, User Obligations
KM2023C_EN	2023-11-02	Warning and Caution re-arrange according to CER, USA Class and section added
KM2023D_EN	2024-09-23	Canada IC listing, App description and basic guides for measurements and usage and version history. Addition of cybersecurity recommendations. Addition of medical icon explanations. Company phone and address change, update App changelog, recommended app version, Mac version requirements. Added dimension sketches, updated minimum required android/iOS versions.
KM2023E_EN	2024-10-11	Software release notes up to 2.14 version

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