

Press release PKvitality / Diabetes / Innovation / Clinical trials

Diabetes:

PKvitality announces the results of its 3rd clinical trial on humans

Medtech startup at the forefront of innovation in the field of diabetes, PKvitality is developing K'Watch Glucose, the first Continuous Glucose Monitor (CGM) in the form of a smartwatch.



Paris, July 26, 2022 - The French startup PKvitality, focusing on health and sport biowearables, is developing K'Watch Glucose, the first Continuous Glucose Monitor (CGM) in the form of a smartwatch, designed to change the daily lives of millions of diabetic patients. After two first phases of testing which brought a significant step forward on the initial roadmap, the company champion of innovation against diabetes announces the results of its third phase of clinical trials on humans (First-in-human).

PKvitality's mission is to enable everyone to contribute actively to their well-being and health through products that are simple and comfortable to use. Thus, its K'Watch Glucose smartwatch will be the world's first CGM device that will track glucose levels discreetly and continuously at the wrist. This system, currently at the stage of clinical studies, will measure the level of glucose in the interstitial fluid through micro-tips. It will thus offer a painless and non-stigmatizing experience to the user.



The 3rd clinical trial on humans that announces the success of K'Watch

After two conclusive clinical trials, the results of the 3rd study suggest a promising future for the development of K'Watch. Indeed, the measurement of glucose levels for patients with type 1 and type 2 diabetes is commonly a demanding process whether in terms of accuracy, tolerance, or pain. Based on these criteria, the objective has been more than achieved since K'Watch obtains a 16% margin of error on the accuracy (MARD) for continuous glucose measurement against the 17-18% initially desired. This efficiency is the result of in-depth improvements in the patch and the algorithm.



The % representing the MARD ("Mean absolute relative Difference")

Two previous conclusive clinical trials to monitor diabetes

In the past few months, PKvitality has also unveiled the results of its 1st and 2nd clinical studies on humans. The results of these studies were a real success and showed 19% accuracy in continuous glucose analysis. In addition, studies conducted by PKvitality reveal an excellent user experience with very good tolerance for patients with no adverse effects, pain, or irritation during use.

The trials took place at the AMCR Institute, a clinical research center focused on diabetes and obesity with worldwide renowned expertise in medical devices related to metabolism.



According to Luc Pierart, founder of PKvitality, "With K'Watch, we seek to offer people with diabetes a technological innovation that will accompany them in their daily lives. Although we started clinical trials at the end of 2021, we are making rapid and very conclusive progress. This tremendous acceleration towards the precision required in our clinical trials makes us confident in the development of our product. We are a few months away from validating our project and offering a CGM that meets the expectations of diabetes patients: painless, without adhesive issues, discreet and ultra-practical."

K'Watch

K'Watch for diabetics

PKvitality develops K'Watch, the world's first Continuous Glucose Monitor (CGM) in a form of a smartwatch, able to measure and display glucose levels continuously and

discreetly, for patients with diabetes. His system measures glucose levels by analyzing interstitial fluid through micro-tips. It provides a painless, non-stigmatizing experience and solves the adhesive problem. In addition, PKvitality has also joined the largest e-health accelerator in Europe, Future4Care.

Check the video of the watch <u>here</u>

About PKvitality

PKvitality is a health & sport bio-wearable start-up currently working on the K'Watch Glucose, a Continuous Glucose Monitoring (CGM) device in the form of a smartwatch currently in clinical trials. It will enable a painless, discreet and precise monitoring of systemic glucose level anytime and anywhere. Using the same technology, PKvitality is also working on K'Watch Athlete, a smartwatch which will provide real-time monitoring of lactic acid – an indicator of muscle fatigue – to significantly improve training and performance among athletes.

More information: www.pkvitality.com

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