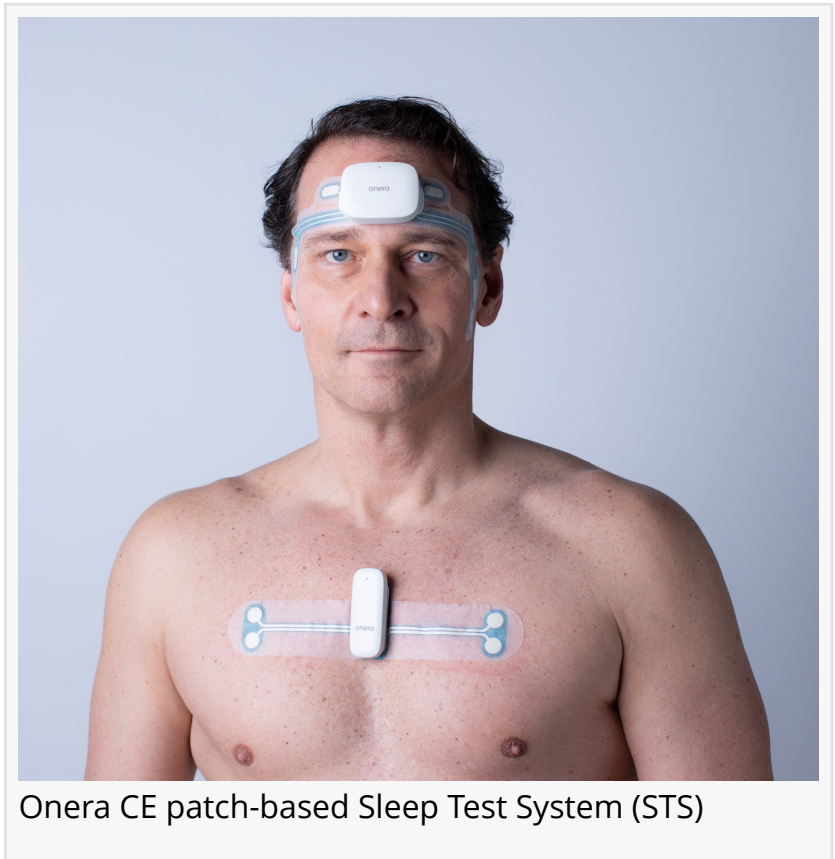


Onera receives CE mark for innovative sleep PSG system

Company announces the launch of its Polysomnography (PSG) device in Europe.

EINDHOVEN, NETHERLANDS, June 9, 2021 /EINPresswire.com/ -- Onera Health, a privately held medical technology company, announced today that its wholly-owned subsidiary in the Netherlands, Onera B.V., has received a CE Certificate of Conformity for its patch-based Sleep Test System (STS) that brings the gold-standard quality of a hospital diagnostic system directly to a user's home. The CE mark allows the groundbreaking PSG device to be sold in the European market. As well as securing a CE mark in the EU, Onera is currently awaiting 510(k) clearance from the US Food and Drug Administration for its PSG system.

During the upcoming months, Onera will focus on strategic partnerships with exclusive European and American partners to evaluate the potential of the product and patched-based technology.



Onera CE patch-based Sleep Test System (STS)

“

I believe that our technology brings the quality, ease-of-use and ease-of-diagnosis to become the new gold standard PSG for sleep testing.”

Ruben de Francisco, Founder, CTO & interim CEO of Onera

Onera's medical-grade technology is a huge step forward in transforming the outdated, cumbersome, and expensive process of traditional sleep testing, which is partly responsible for the underdiagnosis of sleep disorders, which are estimated to occur in one in five people worldwide. Different configurations of Onera's non-invasive, compact, and portable medical device offer comprehensive data to support the diagnosis of various sleep disorders and enable clinicians to remotely monitor and optimize patients' treatment. Onera's innovative and

convenient patch-based device can reduce procedural delays in sleep testing due to the space crisis and challenges in accessing healthcare professionals. The user-centric technology enables not only at-home diagnostics but also offers opportunities for hospitals that have limited or no access to a sleep clinic to implement sleep diagnostic testing within their institution.



"By obtaining the CE mark Onera has achieved a critical regulatory milestone which is an important step toward delivering on our promise to make sleep testing more convenient, easy-to-use and accessible to everyone, anywhere - even in the patient's home! We are now in a position to introduce Onera's technology in various configurations to the European market, working closely with doctors from different areas in medicine, beginning with exclusive partnerships in The Netherlands, Germany, and Italy while we continue to explore other geographies. Simultaneously are we awaiting the pending FDA approval for authorization in the US.", said Ruben de Francisco, Founder, CTO & interim CEO of Onera.

"We are eager to offer physicians an innovation that extends their diagnostic repertoire in their day-to-day operations. Being able to order and obtain results of a sleep study, as easily as ordering blood work or a CT, will improve the care of all patients, whether they are in the hospital or at home." said Hartmut Schneider, M.D., PhD, Founder & Chief Medical Officer of Onera.

"Receiving the CE mark for our first generation is a significant achievement for the Onera team and represents a multi-year investment in innovative product development and high-quality clinical research. I believe that our technology brings the quality, ease-of-use and ease-of-diagnosis to become the new gold standard PSG for sleep testing.", said de Francisco when asked about the impact Onera's PSG system could have in the field of sleep medicine. Onera will exhibit and share their research work at the largest gathering of professionals and world-renown experts at SLEEP 2021, June 10-13.

About Onera Health

Onera Health is a leader in transforming sleep medicine and remote monitoring. Their breakthrough diagnostic solutions and services are poised to help millions of people struggling with sleep-related ailments, while also impacting other medical fields by monitoring a variety of chronic conditions, ultimately improving the health and quality of life for patients around the world. Onera is headquartered in California's Silicon Valley and has R&D offices in the Netherlands. For more information, please visit www.onerahealth.com

Soukaina Adnane

Onera Health
+31 655 253 424
soukaina@onerahealth.com

This press release can be viewed online at: <https://www.einpresswire.com/article/543295841>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2021 IPD Group, Inc. All Right Reserved.