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The first 1.5 Tesla point-of-care system for pediatric MRI becomes available in Europe.

Neoscan Solutions announced today that its pediatric MRI system neo315 has received CE-certification and is hence available for diagnostic use in Europe.

- The young MedTech company Neoscan Solutions GmbH from Magdeburg, Germany, receives the European Certification (CE) for the first 1.5 Tesla MRI system for infants up to an age of six years.
- Key innovation: the first clinical MRI magnet based on a high temperature superconductor (HTS)
- HTS technology allows for compact system size, low weight, cooling without using liquid Helium, and low service costs; HTS technology has the potential to replace the conventional MRI magnet technology based on low temperature superconductors; the system can be installed at places not foreseen for MRI.
- For the first time, non-invasive MR resonance imaging becomes readily available for the most vulnerable patients.
- Status of the premarket submission made to the FDA in the U.S.: 510(k) pending.

Magdeburg, 16th of August 2023 – Neoscan Solutions GmbH, a medical device manufacturer specializing in magnetic resonance imaging (MRI), releases its 1.5T pediatric MRI system neo315 for the European market. Prior to that, the system received its CE-certification according to the new European Medical Device Regulation (MDR). Major aspects of the release process are verifications of patient safety, safety of the user and image quality. The product name “neo315” is derived from its 30 cm patient bore and its 1.5 Tesla field strength.

While for adults non-invasive diagnostic MRI, providing excellent soft tissue contrast, has become a standard of care which is taken for granted, such exams are too often not available for newborns and infants. In the case of the most vulnerable patients, their risky and laborious transports to an MRI system, which is often located far away from these patients, are avoided. Further, many existing MRIs are overloaded by the adult population.

neo315 addresses the clinical need of MRI availability close to the patients by certain key-innovations: This is the world's first clinical 1.5 Tesla MR magnet using a high temperature superconductor (HTS); i.e., there is no compromise in image quality, but – due to its higher current density – HTS technology allows for a lighter system with a reduced footprint, as compared to a conventional magnet. The magnet uses no liquid Helium, shows lower running and service costs, and is also the first reversibly engineered magnet. Its expensive

superconductor can be salvaged at the end of product life. Further, neo315 is the only high field system requiring no RF cabin with its effortful installation. Due to its compact size, neo315 fits into almost any room in or next to a NICU or pediatric ward, and due to its low infrastructural requirements, it can be installed at locations which were never foreseen to host an MRI system. Its control system supports remote scanning, freeing the person who is accompanying the patient during the scan to focus on the patient. Further, the system “understands” the modelling language MR#, which allows scientists and users to describe and control the data acquisition process without programming. In MR# they can develop new MR acquisition techniques, adapt those to the patients and share those with each other.

Dr. Röhl, executive director of Neoscan Solutions, sees the certification as an important achievement of the young company; however, this is also the beginning of a new phase with new challenges ahead: “We are now entering the phase of clinical introduction, working together with radiologists and pediatricians, who share the vision that by collaborating in MRI, both subspecialties together can reach a better outcome for the patients. Everyone involved is very excited doing the first cases, and we will keep you posted!”

Eventually it remains to be said that the procedure chosen, i.e. to first complete the certification before conducting case studies on the young patients, is being suggested by the new MDR.

About Neoscan Solutions:

Neoscan Solutions is a young MedTech company focused on developing, manufacturing, distributing, and servicing breakthrough innovations in the field of MRI. The company has recently been certified as a medical device manufacturer according to ISO 13485. In addition to a clinical pediatric MRI system, it offers preclinical MRI solutions, as well as components such as HTS MRI magnets, digital consoles, and MRI Software.

Professor Rose, the director of the Research Campus STIMULATE, and Dr. Gerhold, the founder of the GETEC group of companies, took the initiative that Neoscan Solutions was established in 2017: Karl Gerhold has provided a frame of funding and won Klemens Gutman, shareholder of regiocom, to invest as well, thus enabling Stefan Röhl to found and build Neoscan Solutions in Magdeburg, Saxony-Anhalt. The Otto-von-Guericke University and the Research Campus STIMULATE who are engaging in joint research projects have been key for the vibrant development of the company. Neoscan Solutions is grateful for support by the state of Saxony-Anhalt, and for support of the program “KMU innovativ Medizintechnik” by the Federal Ministry of Education and Research.

Neoscan Solutions strongly believes in collaborating with non-academic and academic partners. Together we can reach so much more than each party on its own, and we keep looking for partners who share our vision and are going to revolutionize the field of MRI together with us.

For further information, please visit our website:

<https://www.neoscan-solutions.com/>

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A faithful model of neo315



A typical product label of neo315

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