



The development of the NanoEcho imaging device completed and ready for clinical studies

The development of NanoEcho's commercial imaging device is now completed and ready to be used on patients, in clinical studies. The formal verification has today been successfully finalised without any remarks, which is the last step in the product development. This means that the device meets the customers' and the authorities' requirements for medical technology equipment. This represents a significant milestone towards a market launch.

NanoEcho has now completed the product development as the formal verification is finalised, without any remarks. During verification, the device has undergone extensive internal testing and external certification tests to ensure that it meets all requirements, including the strict requirements of the EU Medical Device Regulation (MDR). The result of this process confirms that NanoEcho's imaging device meets all requirements and is safe, reliable and approved for use on patients.

Among other things, the reputable testing institute Nemko in Norway has carried out EMC testing, which ensures that the equipment is not disturbed by or interferes with other electronics, which is critical for safety and efficiency in clinical environments. In addition, the device has also undergone external testing at TÜV Süd in Germany, which for example included electrical and mechanical safety testing, as well as performance testing according to strict international product standards.

"This is a fantastic achievement by our team who successfully developed our innovative device, completely according to plan. The journey started in the research laboratory at Lund University and has now led to a commercial imaging device, that is ready to be used on patients in clinical studies. NanoEcho is thus making a clear positional shift and we are now directing all our focus on the clinical phase," says Linda Persson, CEO of NanoEcho.

The application to the Swedish Medicines Agency to start the clinical trials is now being completed. The objective of the clinical trials is to prove the clinical benefit of the device - to improve the diagnosis of rectal cancer and create significant health economic benefits for society.

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NANO ECHO
next level diagnostics

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NanoEcho develops a new technology for clearer diagnostics of, in the first indication, rectal cancer. The imaging technology is based on a new medical approach where nanotechnology is used in combination with modern patented ultrasound technology. The images that are generated are intended to facilitate differentiation between healthy and diseased tissue and at the same time determine the location of the cancer tissue more precisely. The goal is to provide a more reliable diagnosis of, for example cancer diseases, that has the potential to contribute to cost-effectiveness in health care. www.nanoecho.se