

Norwegian study confirms the potential health benefits of pressure based compression in accordance with Sigmascreening's Sensitive Paddle concept for mammography equipment

Fewer false positives, fewer false negatives and reduced unnecessary pain

Amsterdam, The Netherlands, May 22, 2017 – Sigmascreening, a Dutch MedTech developer and world leader in the field of pressure based digital mammography and breast cancer screening, announces that a large independent Norwegian study¹ further confirms Sigma's hypothesis that pressure has a clear relation with the most optimal results in mammography. The study confirms the importance of pressure in accordance with Sigmascreening's concept of the Sensitive Sigma Paddle, which applies pressure guidance during mammography. The combination of results of an earlier Dutch and this new Norwegian study shows an optimal pressure in the range of 10 kPa. This pressure clearly correlates very well with the proposed pressure by Sigmascreening.

The data show that high breast volume and low compression pressure are associated with positive performance measures such as lower recall rate and higher specificity (true positive) of tumor detection. Procedures with too low pressures result in unnecessary recalls due to false positives. Flattening of the breast on the basis of pressure, also prevents unnecessary discomfort and pain, which may contribute to a higher breast cancer screening compliance of women. The Sigma pressure technology aims to optimize these three elements.

Sigmascreening's Sensitive Sigma Paddle is the first pressure based compression paddle providing real-time and reproducible information on mammographic pressure, which can considerably reduce frequently experienced pain for women during screening. It optimizes compression for every individual breast, taking into account breast size and tissue stiffness, which leads to an optimal mean contact pressure per woman thereby optimizing both specificity (true negative) and sensitivity (true positive) for the most optimal screening result.

“The data from this Norwegian study clearly show the huge potential of our pressure based paddle for women's health. We strongly believe that our less painful solution will increase the compliance of breast cancer screening programs, while at the same time significantly improves the diagnostic performance,” says Ivo Aarninkhof, Sigmascreening CEO. “Our Sensitive Sigma Paddle can measure and visualize a – previously not available – parameter, PRESSURE, which allows hospitals and breast screening centers to take breast size and tissue stiffness into account. This avoids the currently experienced negative consequences of under- or over compression of the breast and enables a highly reproducible procedure, year after year. But foremost leads to more precise tumor detection.”

Norwegian study

The data of the Norwegian retrospective study of 261,000 mammography exams, show that high breast volume and low compression pressure are associated with positive performance measures such as lower recall rate and higher specificity (true positive) of tumor detection. Especially the findings on the applied pressure are in line with earlier data generated in a Dutch study by the research group of Professor Nico Karssemeijer et al² in 54,137, showing that the performance of breast cancer screening also depends on mammographic compression. These studies confirm the philosophy behind Sigmascreening's Sensitive Sigma Paddle for breast cancer screening devices.

The Norwegian researchers, led by Dr. Nataliia Moshina, a doctoral research fellow at the Cancer Registry of Norway in Oslo¹ categorized compression force and pressure to determine performance outcome measures such as recall rate, sensitivity, specificity, and positive predictive value (PPV). "Based on our findings, low compression pressure and high breast volume are associated with favorable early performance measures, including lower recall rate, higher rate of screen-detected cancer, and lower rate of interval breast cancer, compared with high compression pressure and low breast volume," the study authors wrote.

But apart from the screened and diagnosed women, also radiographers and radiologists benefit from pressure based compression. The real-time visualization of the applied pressure gives more insights into the compression practice, which leads to a faster more pleasant and much more accurate procedure.

Rapid market acceptance in Europe

Sigmascreening's pressure-standardized breast compression is expanding rapidly in screening centers and hospitals throughout Europe. In Europe, over 10,000 patients already experienced the more woman-friendly way of making mammograms while clinicians are starting to recognize the improved sensitivity and specificity of our technology. The Sensitive Sigma Paddle with CE marking is already being used in the United Kingdom, Norway, France, Germany, Sweden, The Netherlands, Belgium and Switzerland.

About Sigmascreening

Sigmascreening, founded in 2009, is an Amsterdam based MedTech company focusing on the development of new innovative products in the area of digital mammography and breast cancer screening. The Sensitive Sigma Paddle is the first product with CE marking, based on patented technology. Sigmascreening aims to further introduce new products that will improve mammography and contribute to the early detection of cancer which ultimately can save lives.

For more information please contact:

Sigmascreening, Amsterdam

Ivo Aarninkhof

Tel: +31 6 12 04 17 14

E-mail: ivo.aarninkhof@sigmascreening.com

LifeSpring LifeSciences Communication, Amsterdam

Leon Melens

Tel: +31 6 538 16 427

E-mail: lmelens@lifespring.nl

¹Nataliia Moshina, Sofie Sebuødegård, Solveig Hofvind; Is breast compression associated with breast cancer detection and other early performance measures in a population-based breast cancer screening program? - Breast Cancer Research and Treatment, 29 March 2017.

²Katharina Holland, Ioannis Sechopoulos, Gerard den Heeten, Ritse M. Mann, Nico Karssemeijer; Performance of Breast Cancer Screening Depends on Mammographic Compression. – Breast Imaging, 17 June, 2016