

# Proposal for assessment of new health technologies

## Important information – read this first!

- Submitted proposals for national health technologies (HTAs) will be published in full. If the proposer thinks there is information necessary for filling out the form, that should not be made public, please contact the secretariat (Nye Metoder) before submission.  
The proposer is aware that the form will be published in its entirety (tick):
- Proposer has filled out point 19 below «Interests and, if any, conflicts of interest» (tick):
- This form serves the purpose to submit proposals for health technology assessment (HTA) at the national level in Nye Metoder - the national system for managed introduction of new health technologies within the specialist health service in Norway. The form does not apply to proposals for research projects. A health technology assessment is a type of evidence review, and for this to be possible, documentation is required, e.g. from completed clinical trials. Lack of documentation may be one of the reasons why the Commissioning Forum (Bestillerforum RHF) does not assign a health technology assessment.
- If the proposal concerns a medical device, the proposer is familiar with the document [«Guidance criteria for management of medical devices in the National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway»](#) (link) (tick):

## Contact information:

**Name of the proposer** (organization / institution / company / manufacturer):

Sigmascreening B.V. (Company)

**Name of proposal contact:**

Monique van Lier

**Telephone number:**

+31205665388 / +31653848630

**E-mail address:**

monique.van.lier@sigmascreening.com

**Date and locality:**

11-12-2018, Amsterdam, The Netherlands

1. Proposer's title on the proposal: \*

\*This may be changed during the course of the process"

Sensitive Sigma Paddle

2. Brief description of the health technology proposed to be considered:

The Sensitive Sigma Paddle is a compression paddle used for mammography. In mammography, a C-arm of the X-ray source and an X-ray detector is used to acquire mammograms. A plastic paddle is used for compression of the breast tissue during exposure to immobilize and flatten the breast to produce an optimal image and a minimal dose. The compression force is automatically measured in the C-arm of the mammography machine and is displayed, together with other parameters including the thickness of the breast tissue between the paddle and the detector cover.

The new Sensitive Sigma Paddle uses multiple sensors to enable optimal breast compression for every breast individually. To calculate the mean pressure — which is the basis of the new system—, the ratio of the force and the contact area with the breast is needed. Thus, a method is needed to measure the contact area in real time. The Sensitive Sigma Paddle system uses a capacitance-based method to measure the contact area, for which a conductive layer is needed in the paddle. This layer is transparent for light and X-rays. For this, an innovative plastic foil covered with a layer with very thin (~ 30 nanometers diameter) silver nanowires is used. This foil is fairly similar to those widely used in touch screens. The homogeneous foil (0.1- 0.2 mm) adds only approximately 4 – 8 % to the absorption and scattering of X-rays, already occurring from the approx. 2.5 mm thick paddle material. Repercussions on the image quality have been shown to be minimal.

The retrofittable paddle contains proprietary load cells and electronics to measure the force and the contact area. The ratio of the force and contact area is then automatically computed and visually presented on the rear of the paddle by LEDs, with each LED representing a mean pressure of 2 kilopascals (15 mmHg).

In practice, the operation of the system is carried out in a few simple steps:

- The mammography technologist positions the breast and starts the compression (Similar to the current standard of care);
- During compression, the real time pressure value is calculated automatically by the Sensitive Sigma Paddle system and visualized from the built-in LED ribbon of lights (This is in conventional paddles not available);
- At the start of the procedure, i.e., with no breast compression, only the first LED is lit;
- As the pressure increases, additional LED's will light up;
- When the target pressure of 75 mmHg is reached the sixth LED will light up;
- The target pressure is chosen as being the optimal compression for this particular breast in this position;



*Picture of the Sensitive Sigma Paddle, when the target pressure (sixth LED) is reached.*

3. Brief description of current standard of care (SOC) (Which health technology (ies) are currently used. What is the status of the technology (ies)? Whether it provides curative treatment, life extension, etc.)

Will the proposed technology replace or be a supplement to today's SOC?

In current SOC, a conventional plastic compression paddle, an accessory to every mammography system, is used to compress the breast tissue. The amount of compression in the current SOC is determined by the *force* as indicated on the mammography system, local guidelines and personal judgment of the radiographer. Current conventional mammography systems cannot determine the pressure creating a large variation in compression practice within and between institutes.

- | 4. This proposal concerns:                                       | Yes                                 | No                                  |
|--|-------------------------------------|-------------------------------------|
| A brand new and innovative health technology                     | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| A new application, or a new indication for an established method | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| A comparison between several methods                             | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| A technology that is already in use                              | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| If yes – technology used in clinical practice                    | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| If yes – technology used in research/clinical trials             | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| A re-evaluation of technology used in clinical practice          | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| The technology is relevant for disinvestment                     | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |

Details about any use of the technology:

- Clinical studies:
  - o de Groot, J. E., W. Branderhorst, C. A. Grimbergen, G. J. den Heeten and M. J. M. Broeders (2015). "Towards personalized compression in mammography: a comparison study between pressure- and force-standardization." *Eur J Radiol* **84**(3): 384-391.
  - o den Boer, D., L. A. J. Dam-Vervloet, M. F. Boomsma, E. de Boer, J. A. van Dalen and L. Poot (2018). "Clinical validation of a pressure-standardized compression mammography system." *Eur J Radiol* **105**: 251-254.
  - o de Groot, J. E., I. G. M. Hopman, M. G. J. T. B. van Lier, W. Branderhorst, C. A. Grimbergen and G. J. den Heeten (2017). "Pressure-standardised mammography does not affect visibility, contrast and sharpness of stable lesions." *Eur J Radiol* **86**: 289-295.
- The Sensitive Sigma Paddles are approved for use in the Belgian breast cancer screening program: (in Dutch) <https://www.zorg-en-gezondheid.be/overzicht-typetoelating-voor-toestellen-voor-digitale-beeldverwerving>
- The technology is used as SOC in 20 institutes in The Netherlands, Germany, Belgium, France and Sweden
- The technology is used within the Norwegian screening (under Medical Ethical Approval) by prof. Hofvind.

5. This health technology involves (Multiple ticks are possible)

- |  |                                     |
|--|-------------------------------------|
| Pharmaceutical                                       | <input type="checkbox"/>            |
| Medical device/IVD medical device that is CE-marked* | <input checked="" type="checkbox"/> |

“What is it CE- marked as and for which indication?”

The paddles are intended to be used as routine tool in screening and in clinical mammography.

Class IIb

- Medical device/IVD medical device that is not CE-marked
- Procedure
- Screening
- Highly specialized services / national offers
- Organization of the health services
- Other (describe)

“If relevant, please include who should be responsible for developing the technology.”

N/A

6. Application of the technology:

- Prevention
- Assessment and diagnostics
- Treatment
- Rehabilitation
- Specialist health care
- Primary health care

The Sensitive Sigma Paddles paddles are used on a mammography system for (early) detection of breast cancer.

7. Responsibility for funding Yes      No

- Is the specialized health service responsible for financing the technology today?
- May the specialized health service become responsible for funding the health technology?

“Description of responsibility for funding”  
The Sensitive Sigma Paddle is commercially available

8. Is the technology mentioned in the national guidelines or action programs prepared by the Norwegian Directorate of Health? Yes      No

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N/A

9. Does the technology involve the use of radiation (ionizing/ non- ionizing)? Yes      No

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“Short description of type of radiation source, device and degree of radiation exposure.”  
The Sensitive Sigma Paddles are used on currently available mammography systems with X-ray radiation. The introduction of a homogeneous foil (0.1- 0.2 mm) in the paddle tray adds only approximately 4 – 8 % to the absorption and scatter of X-rays, already occurring from the approx. 2.5 mm thick paddle material.

10. Which discipline(s) does the health technology apply to, and which patients are affected? (Could the health technology also affect other groups (e.g. health personnel or relatives)?)

Field of Radiology within hospital care and the breast cancer screening program.  
 Affected area; clients of the national breast cancer screening program, patients with suspicion for a tumor, or follow-up after breast cancer.

11. Which aspects are relevant to the assessment? (Multiple ticks are possible)

- Clinical efficacy
- Safety/adverse effects
- Costs/resource use
- Cost-effectiveness
- Organizational consequences
- Ethical
- Legal

12. Please suggest the main scope/objective for the health technology assessment, as well as secondary scopes/objectives (in compliance with question 10). For those familiar with “PICO” (Patient, Intervention, Comparator, Outcome) – please include tentative suggestions for PICO.

The suggested main scope of the health technology assessment would be the use of the Sensitive Sigma Paddle within the Norwegian Screening. The objective should be a “physical and technical type testing” of the technology.

13. Please give a brief explanation of why it is important that the health technology assessment proposed should be conducted.

Physical and technical testing of new technologies for the use in screening programs is generally necessary due to the use of the technology on healthy women. Lack of standardization can lead to variability in compression. Under-compression can lead to blurred images, more retakes and a higher average glandular dose (AGD), while over-compression causes discomfort and unnecessary pain for the patient. Based on breast-size and tissue-stiffness, the Sensitive Sigma Paddle calculates the pressure to achieve an optimal compression range and allows for a highly reproducible procedure. A real-time pressure indicator provides women more control over the compression of their breasts and enhances interaction between the technologist and the patient about the progress of the compression procedure. This makes communication easier because the patient is more involved, making the examination less stressful, with overall better image quality, lower radiation dose, and a faster workflow.

14. Please comment on the technology that is proposed to be assessed with regard to the following points:

The severity of the disease/condition the health technology targets

The technology is used in combination with mammography, a tool for early breast cancer detection.

Expected effect

It gives the possibility to improve further and standardize the mammographic procedure based on a more predictable and individualized compression of the breasts resulting in optimal image quality.

Better possibilities for quality control due to the reduction in compression variability within and between institutes, improving the efficacy of mammography.

Potential reduction of interval carcinomas (tumors that occur between two consecutive screening rounds) and, because of that, improved screening sensitivity.

Safety

There is no additional risk when compared to the current way of working (using a conventional compression paddle). This technology reduces risks of over- compression (too much compression causing pain and a potential reduction in screening performance) or under-compression (too low compression causing an increased radiation dose and image blurring due to motion).

Total number of patients in Norway the health technology is applicable to

Every woman in Norway between 50 and 69 years of age is invited for mammographic screening every two years. These are approximately 300.000 women every year for breast cancer screening only.

Consequences for resource use in the public health service

Current experiences with the Sigma technology are that the workflow will be easier, due to better communication between patient and technician, which is communicated via customer testimonials.

Need for revision of existing national guidelines or preparation of new guidelines

To our knowledge, there is no need for revision of existing guidelines or the preparation of new guidelines before the paddle can be used.

15. Please provide references to documentation of the health technology's effect and safety (i.e. previous technology assessments). (Up to 10 key references can be provided, please do not send attachments in this step of the process):

Current compression practice; substantial variation:

Norwegian screening:

1. Waade, G. G., A. Sanderud and S. Hofvind (2017). "Compression force and radiation dose in the Norwegian Breast Cancer Screening Program." Eur J Radiol **88**: 41-46.

Dutch and United States sites:

2. Branderhorst, W., J. E. de Groot, R. Highnam, A. Chan, M. Bohm-Velez, M. J. Broeders, G. J. den Heeten and C. A. Grimbergen (2015). "Mammographic compression--a need for mechanical standardization." Eur J Radiol **84**(4): 596-602.

Current compression practice; impact on screening performance:

Norwegian screening population:

3. Moshina, N., S. Sebuodegard and S. Hofvind (2017). "Is breast compression associated with breast cancer detection and other early performance measures in a population-based breast cancer screening program?" Breast Cancer Res Treat **163**(3): 605-613.

Dutch screening population:

4. Holland, K., I. Sechopoulos, R. M. Mann, G. J. den Heeten, C. H. van Gils and N. Karssemeijer (2017). "Influence of breast compression pressure on the performance of population-based mammography screening." Breast Cancer Res **19**(1): 126.

Current practice, observation studies:

5. de Groot, J. E., M. J. Broeders, W. Branderhorst, G. J. den Heeten and C. A. Grimbergen (2013). "A novel approach to mammographic breast compression: Improved standardization and reduced discomfort by controlling pressure instead of force." Med Phys **40**(8): 081901.
6. de Groot, J. E., M. J. Broeders, C. A. Grimbergen and G. J. den Heeten (2015). "Pain-preventing strategies in mammography: an observational study of simultaneously recorded pain and breast mechanics throughout the entire breast compression cycle." BMC Womens Health **15**(1): 26.
7. Feder, K. and J. H. Grunert (2017). "Is Individualizing Breast Compression during Mammography useful? - Investigations of pain indications during mammography relating to compression force and surface area of the compressed breast." Fortschr Röntgenstr **189**(1): 39-48.

Validation studies of the technology:

8. de Groot, J. E., W. Branderhorst, C. A. Grimbergen, G. J. den Heeten and M. J. M. Broeders (2015). "Towards personalized compression in mammography: a comparison study between pressure- and force-standardization." Eur J Radiol **84**(3): 384-391.
9. den Boer, D., L. A. J. Dam-Vervloet, M. F. Boomsma, E. de Boer, J. A. van Dalen and L. Poot (2018). "Clinical validation of a pressure-standardized compression mammography system." Eur J Radiol **105**: 251-254.
10. de Groot, J. E., I. G. M. Hopman, M. G. J. T. B. van Lier, W. Branderhorst, C. A. Grimbergen and G. J. den Heeten (2017). "Pressure-standardised mammography does not affect visibility, contrast and sharpness of stable lesions." Eur J Radiol **86**: 289-295.

16. Please provide the name of the marketing authorization holder/manufacturer/supplier of the health technology (if applicable/available):

Legal Manufacturer: Claymount Assemblies B.V. – A Varex Imaging Company –



17. Marketing Authorization Status (MA) or CE-marking: When is MA or CE- marking expected? If possible, provide the time of planned marketing:

CE- marking available

18. Additional relevant information (up to 300 words.)

The Sensitive Sigma Paddle technology was used in the Norwegian Screening by prof. Solveig Hofvind (Head of section, Breast Cancer Screening Programme of the Cancer Registry of Norway) within a clinical study, approved by the local medical ethical committee, comparing the conventional paddle with the Sensitive Sigma Paddle.

19. Interests and potential conflicts of interests

Please describe the proposer’s relationships or activities that may affect, be influenced by, or be perceived by others to be important for further management of the health technology that is proposed assessed. (E.g. proposer has financial interests in the matter. Proposer has or has had assignments in connection with the technology or to other actors with interest in the technology)

Sigmascreening is patentholder of the Sensitive Sigma Paddle technology.