Reprinted from DI EUROPE October 2019

Standardizing compression in mammography

Belgian hospital implements pressure-based mammography compression system which avoids both over- and under-compression, increases reproducibility and minimizes patient discomfort

The Breast Clinic in the Sint Lucas hospital in Bruges, Belgium has recently retro-fitted one of its mammography machines with a new breast compression system from the Dutch company Sigmascreening. Based on measuring the pressure applied during breast compression rather than an arbitrary force applied by the radiographer, the new system allows a standardised pressure to be applied during the compression phase of mammography. We wanted to find out more about Sint Lucas' experience with the system so we spoke to Dr. Hilde Goris, specialised breast radiologist.

Dr. Hilde Goris,
Breast radiologist, Sint Lucas Hospital, Bruges, Belgium
email: hilde.goris@stlucas.be

Q *Before we get on to the new compression system, please give us a brief introduction to your hospital and facilities.*

Sint Lucas is a medium-sized hospital with more than 400 beds. We're located just outside Bruges, so our patients are referred to us from the city itself and also the surrounding area in the Belgian province of West Flanders. To add to our in-patients we handle more than 25 000 out-patients per year.

In addition to our general radiology capabilities, we have always been specially focussed on breast imaging, and are proud to say that we were actually the first hospital in Belgium to set up a dedicated Breast Clinic, which was inaugurated as far back as 1999.

The idea behind the Breast Clinic is to gather together all the disciplines needed for the optimal treatment of women being examined for, or diagnosed with, breast cancer, Thus, in addition to radiologists, our multi-disciplinary team includes pathologists, oncologists, surgeons, and a psychologist for the optimal treatment of our breast cancer patients.

Q *What imaging modalities do you have in the Breast Clinic?*

We are relatively well equipped to handle the number of patients we see, which is approximately 4000 women, per year. Of these roughly half are referred to us for diagnostic mammography and the rest are women undergoing screening examinations., The majority of women who come to us for screening mammography do so in the context of the Flemish Health ministry's organized breast screening program while the remainder come after referral by a general practitioner or gynecologist .

As regards equipment, we have one mammography unit (GE Essential) and a brand-new tomosynthesis system (GE Pristina) which can also carry out Contrast Enhanced Spectral Mammography (CESM). We intend to use CESM for our high-risk, more elderly patients, but we also have a GE MRI machine for high-risk patients such as women with BRCA mutations. We have Aplio hand-held ultrasound systems from Canon.

Q *Let's turn to the Sensitive Sigma paddle*

We have had this now for more than two years. The basic principle behind the system is actually quite simple: rather than measuring the force applied to the breast during the compression phase of the mammography procedure, the Sensitive Sigma system calculates the actual pressure, i.e. the force applied divided by the area of the breast on which this force is exerted. If the same compression force is applied to a small breast as to a large breast, it is clear that the pressure applied to the small breast is greater than that for a large breast. The result is that women with small breasts can experience unnecessary discomfort.

The Sensitive Sigma paddle from Sigmascreening measures the pressure applied to the breast during the compression process as opposed to the usual force. A system of LED lights indicates when the optimal compression is reached.

In practice, in the Sensitive Sigma Paddle, the measurement of the area of the breast in contact with the paddle is made automatically through use of a special, X-ray transparent conductive coating on the paddle.

The mammography procedure is initiated as usual by the mammography technologist positioning the breast on the bucky cover and compressed by the paddle. During compression, the real time pressure value is calculated and displayed using a series of LED lights which are built into the system. At the start of the procedure, when there is no applied breast compression, only the first LED is lit up. As pressure increases, additional LED's light up sequentially. When the optimal target pressure is reached, which has been determined to be the equivalent of 75 mmHg, the sixth LED is lit up. These LED lights are clearly visible, not just by the technologist but also by the patients. The time taken for the mammography examination is not affected by the use of the new paddle systems.

The actual retrofitting of the new paddles system to the mammography unit does not involve significant modification.

Q And how has the new system performed in practice ?

In short, very well. Of course different members of the mammography team have different criteria for evaluating the system.

Thus, as a radiologist, one of my priorities is to be sure that the quality of images isn't in any way affected by the use of the new paddles. (In fact this was one of the aspects that was evaluated in the independent "Type" assessment which is required by the authorities before any new imaging system is introduced to the market in the Flemish region of Belgium. See Side Panel). In addition, the use of consistent and optimal breast compression not only enables high-quality images, but also means that the images are acquired at low doses of radiation. The radiation dose in the GE Essential mammography system is already quite low, but optimal compression enables the dose to be slightly lowered even further, which is important, especially when we are dealing with healthy women in the screening process.

As for the radiographers/technologists, after an initial period during which they wondered about the impact the new system would have regarding their work practices, they are now very positive. Technologists are aware of the importance of good compression in mammography, but are of course reluctant to increase any discomfort that the woman may be undergoing during the process by increasing the compression. These two aspects can be mutually contradictory. By providing a visual indication of when the 75 mm Hg optimal compression is attained, the new paddle system provides an objective way of resolving these potentially conflicting aspects.

As for the patients, the feed-back is overwhelmingly in favor of the new system, mostly because they can see when the maximum compression will be reached. They also like the assurance given by the LED light system that the optimal compression has been used during the examination and that the quality of their mammogram is therefore likely to be optimal.

An indication of our overall positive opinion is that we have insisted that our new tomosynthesis system (the GE Pristina) be also fitted with the Sensitive Sigma Paddle system.

Pre-Market quality evaluation of Sensitive Sigma system

The regulatory authorities of the Flemish region in Belgium require that all breast imaging systems be subject to regular quality control and that the first model of any new imaging system introduced into the region undergoes a one-off "Type Testing". The Department of Medical Physics & Quality Assessment at UZ Leuven, headed by Prof H. Bosmans is mandated by the authorities to carry out such tests in accordance with the appropriate European guidelines. We spoke to Prof. Bosmans.

Prof Hilde Bosmans
Department of Medical Physics & Quality Assessment, University Hospital, Leuven, Belgium
email: hilde.bosmans@uzleuven.be

Q What kind of quality assurance testing does your department carry out?

The majority of the tests we carry out for breast imaging systems are regular quality control evaluations which are carried out at various levels. These include daily evaluation of standard phantoms whose images are sent automatically to our lab every day. These are backed up by six monthly visits by a team of physicists from our lab to each installation where a complete QC protocol is carried out to monitor compliance with the European Guidelines. In addition to these routine tests, the authorities require that "Type" testing be carried out on each new type of imaging equipment introduced into the region. This involves several teams of independent physicists who develop a unique testing protocol appropriate for the system being introduced to the market. Our lab was assigned this task for the Sigmascreening Sensitive Sigma system

Q What type of tests did you decide on?

In addition to the routine QC, several specific tests were carried out :
1) To verify that the display system accurately and reproducibly indicated the true pressure.
2) To verify whether the compression paddle produces a constant and left-right, anterio-posterior symmetrical compression.
3) To verify that the new paddle does not show abnormal absorption of radiation.
4) To verify that the operation of the Automatic Exposure Control (AEC) system is not affected by the new paddles.
5) To verify that the compression paddle does not induce any extra noise in the images as measured from the noise power in a standard test block.
6) In addition we carried out a comparative study of 100 women imaged both with the new paddles and standard paddles.

Q And the results ?

All test results were acceptable and a full report was submitted to the Flemish authorities. Although the type test protocol was carried out on the GE Essential mammography system at Sint Lucas in Bruges, it was judged that the results of the acceptability of the Sensitive Sigma paddles could be applied also to mammography systems from other manufacturers, which would therefore not require any further type testing.