With every woman, with you

MAMMI breast PET

www.oncovision.es

THE NEXT NATURAL PRONE POSITION GENERATION IN PEM

ONCOVISION GEM-IMAGING SA
Overcoming breast cancer with Technology and personal Care

Every 2.5 minutes a woman is diagnosed with breast cancer. Every 7.5 minutes a woman dies from the disease. Complete cure is possible for more and more women, with earlier diagnosis and improved, less aggressive treatments. Cross Specialty teams, with surgeons, gynecologists, nuclear medicine physicians, radiologists, pathologists, oncologists, nurses and researchers are making it possible. Victory is at hand for many women and their families, but not yet for everyone, as there is still significant mortality. Not every treatment is definitive, and there are still some recurrences, both local and at a distance, in up to 25% of patients. Improving survival and care is the objective, and technology can help the professionals who are taking care of every woman at screening, diagnosis or treatment.

One challenge, many clinical options

Breast cancer, the most frequent malignant tumor in women, is receiving growing health focus around the world, still with many inequalities. Its treatment is supported by a host of technological and clinical options. From the basic self-exploration or X-Ray screening to the sophisticated stereotactic prone tables or the MRI programs for early detection in groups of women at increased risk, there are several options, each with clinical and economic pros and cons, and classified as either morphological (detect abnormal anatomy) and functional (detect abnormal metabolic activity, often BEFORE anatomical change). Some technologies, however, are more commonly used in different phases of disease progression and continuum of care.
Functional Vision and the expanding role of PET

Whole-body PET has been confirmed, after some early conflicting reports about its sensitivity and poor resolution, as “very valuable” at multiple stages in breast cancer assessment, and a key element, complementary and often superior to others, in diagnosing palpable masses, staging of tumors and lymph nodes, tumor characterization, long term follow up, assessment of results of chemotherapy, identification of distant metastases. A major exclusive advantage is its quantification of metabolism and tumor activity, avoiding many false positives vs MRI. Its major limitation is its low resolution, often above 5 mm.

STRONG POSITIVE REPORTS...
PET’s sensitivity, specificity, positive predictive value and negative predictive value in detecting primary breast cancer are all well above 90%.

...AND STILL SOME DOUBTS...
Multiple investigators report a reduced ability of whole-body PET to detect small, well-differentiated in situ breast carcinoma (<1 cm).

...LED TO THE POSITION OF MANY PROTOCOLS
As primary breast cancer detection requires the ability to depict occult, non palpable, small (<1 cm) invasive and in situ malignant lesions, Whole-body PET is not often used today in primary breast cancer detection.

The option of dedicated PET (PEM, Positron Emission Mammography) in Breast cancer assessment

Whole-body PET can detect distant metastasis and assess the axilla, PEM are offering unprecedented resolution, specificity and convenience, both for diagnosis, characterization and follow up of both invasive and in situ, ductal or lobular carcinomas:

Early studies demonstrated that PEM is capable of imaging smaller breast cancers than standard Whole-body PET.

The classical mammography position can be less effective (due to breast compression) in small breasts, lesions near thoracic wall, and located in superior external quadrant, as well as very low cationation tumors.
MAMMI breast PET

Ergonomic curved handle for easy and safe movement of - and around - the unit

Wide space and easy access to every component and future expansion module. Upgradable data storage capability

24" Full HD LED screen for optimum visualization

Perfect fitting ring-prone table for simple, safe, accurate connection and maximum clinical efficacy

Ergonomic handles for easy, comfortable patient positioning

Solid, strong design with controlled elevation for easy patient access

Reinforced, big wheels, for easy movement

Easy, safe wheel blocking mechanism

Ergonomic, automatic ring, optimizing access and safety

Full, automated control of table elevators, including safety systems

Broad, 17 cm diameter, demonstrated to fit 99%+ of breasts

Very comfortable prone positioning, maximizing also access to difficult breast areas, and in small breasts

Long table, accommodating patient lying with her head to either left or right side for optimum access to either breast

Safe, ergonomic table handle, completely separating patient from PEM ring
Designed with women in mind

The seven clinical advantages of MAMMI

**ADVANTAGE** Unprecedented high spatial resolution: 1.4 mm
For detection of early tumors and unprecedented accuracy
Demonstrated performance at least equal to whole body PET

**ADVANTAGE** Natural, no compression prone position for improved sensitivity and
detection of difficult lesions
Near thoracic wall. Multicentric…

**ADVANTAGE** Whole breast TRUE 3D reconstruction with quantification of tumor activity
Decisive for measuring QT /RT efficacy

**ADVANTAGE** Very fast: acquisition total time varying from 5 (standard) to 15 minutes

**ADVANTAGE** Exclusive, proprietary single continuous crystal technology and software: safe and effective with VERY low tracer dosage
Clear lesion differentiation in dense, small, breast with prosthesis

**ADVANTAGE** Remarkably easy to use and fully reliable, even with intensive use

**ADVANTAGE** Very comfortable exploration bed, adaptable to any practice

Expanding possible indications for MAMMI

Very early diagnosis of breast cancer in women from high risk groups
Familiar incidence, alternative risk factors
Based on resolution, sensitivity, quantification, 3D vision

Assessment of QT /HT/RT/other treatment efficacy
Keys are high resolution and accurate quantification of tumor activity

Patient stratification in suspicious lesions identified in screening
Avoids unnecessary biopsies. Based on very low radiation dosage

Follow up post surgery, differentiating scar tissue from active lesions
Keys are resolution, sensitivity, 3D vision, quantification
EXCLUSIVE
CLINICALLY PROVEN
PEM TECHNOLOGY

When maximum accuracy is decisive
Precise breast cancer diagnosis depends on the accuracy to detect abnormal tracer uptakes. With FDG as the most common PET tracer, consumption of sugar is indicating metabolic intensity. The more advanced the detector, the lower the dosage needed to obtain relevant, reliable clinical results. MAMMI provides physicians with the best in class spatial resolution and sensitivity detection system.

MAMMI’s breakthrough technology has been developed and fully tested in the OR in thousands of cancer patients with Sentinella, Oncovision’s integrated gammacamera, gammaprobes, pointers and software, and refined with the preclinical PET+SPECT+CT Albira, the Award winning multimodal platform with unprecedented sensitivity and resolution for small animal research. All these years of learnings and expertise are at the base of MAMMI’s performance.

Parallax error becomes crucial in PETs with small distance between detectors, as in breast dedicated PET systems. MAMMI’s technology specifically addresses this issue. Unlike conventional systems, MAMMI is using single, continuous LYSO crystals without dead zones. These crystals, together with their associated position sensitive photomultipliers (PSPMT) and proprietary electronics are making feasible an accurate measurement of the impinging position and the depth of interaction DOI; correcting the parallax error without sacrificing sensitivity.

A major innovation in attenuation correction significantly improves image quality and quantitative accuracy with an important dose reduction.
MAMMI Software Suite, a comprehensive solution

MAMMI comes complete with an integrated software suite, optimizing clinical workflow. The MAMMI software suite consists of three dedicated modules, Acquirer, for data acquisition, Reconstructor, for 3D image reconstruction and base visualization, and Visualization, including the most advanced image processing and rendering tools.

User’s interface is designed for simplicity and ease of use, responding to physician requirements with a single sight and click. Robust and rapid algorithms provide fast and accurate image reconstructions. A dedicated multi-core reconstruction computer with an upgradable data storage capability for more than 4.000 studies, as well as a 24" full HD LED technology screen are providing optimum visualization.

**Acquirer Module**

Easy to use, friendly software
Easy patient file creation and case information
Study parameters (injected activity, image type...)
Exploration configuration
Very fast acquisition, with process monitoring
Programmable, automatic ring movement when needed

**Reconstructor Module**

User friendly interface
Customizable for DYNAMIC studies
Scatter, random and attenuation corrections
Study reconstruction progress bar
Reconstructed image visualization
DICOM images export

**Visualization Software**

MAMMI Visualization software
Fast and easy visualization of patient images
Volview, for high quality rendering
Powerful tool to produce high impact 3D images for presentations and publications

Courtesy of Dr. R. Valdés Olmos, Netherlands Cancer Institute, Amsterdam

Kitware
MAMMI: More accurate than Whole-body PET in advanced tumors

MAMMI has been directly evaluated, during its clinical development, against prestigious and state-of-the-art Whole-body PET, with excellent comparative results in sensitivity and, specially, significantly improved resolution, speed and ease of use, as well as excellent performance significantly reducing (often lower than 50%) tracer dosage.

MAMMI is not defined as a substitute for Whole-body PET units, useful for multiple other Whole-body applications. MAMMI’s superior performance in breast pathologies is complementary of standard Whole-body PET at major Institutions, and can be of definitive independent value in Centers with access to Whole-body PET explorations when needed during patient evolution.

Supine vs Prone position: a major clinical difference

Supine vs Prone position: a major clinical difference

Prone position does not only bring significantly improved comfort to every woman, by avoiding any breast compression, this being important. The MAIN difference is the greatly improved clinical localization and clear topographic identification of lesions, which can impact treatment, as well as the more correct anatomical correlation of images with actual anatomy, specially valuable for surgery. For this same reason, the prone position has been also adopted by MRI and stereotactic digital X-Ray tables, often requiring, however, breast compresion, which MAMMI does not need.

Images Courtesy of Dr. R. Valdés Olmos, Netherlands Cancer Institute, Amsterdam
PROVEN results in assessment of the results of chemotherapy and other treatments

Fused MAMMI and Whole-body PET images

September, 4th

October, 9th

Treatment follow up with MAMMI
A. Image taken before chemotherapy
B. One month later and after one treatment session

The fast and accurate evaluation of the results of therapies applied to breast cancer patients is decisive for their clinical evolution. Continuing or not with a treatment, often aggressive and always expensive, when it does not help the patient (or, on the other hand, confirming a good evolution) is a strong advantage of PEM vs other less specific alternatives.

MAMMI has demonstrated strong performance in this indication, due to its best in class resolution and powerful quantification tools, allowing an objective measurement of tumor activity. Its sensitivity and low tracer dosage are also factors to be considered for repeated explorations, specially in younger women and dense breasts.

Best in class resolution and powerful quantification tools

Images Courtesy of Dr. R. Valdés Olmos, Netherlands Cancer Institute, Amsterdam
Adding it all together: a role for MAMMI Breast PET

Several clinically proven options are available today to help women in the more advanced breast cancer centers around the World.

The Innovate PET MAMMI is now one more, with some significant differences vs former options:

**PEM or MRI...**
MRI is an excellent morphological (anatomical) exploration. It has high sensitivity and excellent resolution, and it is used today in the assessment of younger women from groups of risk. It does generate, however, a significant number of false positives. PEM has good, comparable sensitivity and higher specificity, reducing the number of false positives. Quantification of tumor activity, related to the physiological imaging capability of PEM, having fewer patient restrictions than MRI (obesity, implants...) and fast speed, together with freeing MRI time for other explorations are also factors to be considered.

**PEM or whole body PET...**
Both types are complementary. The improved resolution and the lower radiation dosage of PEM vs Whole-body PET, the flexibility of having a dedicated unit in high volume centers vs the pressure by multiple specialties in using PET and, specially, the fast and clear assessment of results of chemotherapy and other treatments, and the study of younger women or women with dense breasts with reduced radiation dosage are fields of indication.

**PEM vs BSGI**
BSGI is also a valuable breast exploration, with good resolution, used as complementary to X-Ray mammography in some centers. PEM’s accurate quantification, excellent resolution, MAMMI’s prone position and no breast compression for improved patient comfort, access to difficult lesions and in small breasts, very fast explorations and reduced radiation dosage are points to be possibly considered.

**MAMMI vs other PEM**
MAMMI’s exclusive continuous crystal technology, with related improved resolution, excellent sensitivity, very fast explorations and reconstructions, prone position and no breast compression for improved patient comfort, access to difficult lesions and in small breasts, very fast explorations and reduced radiation dosage are possible relevant differences.
Exclusive PET Ring Architecture

Exclusive single continuous crystal per module, for maximum sensitivity and resolution

Exclusive integrated PSPMT and electronics

Full 3D capabilities, without altering natural shape of breast, for optimum localization and quantification, even in small, difficult lesions

Exclusive wide ring architecture, guaranteed to fit 99%+ of breasts

Fully validated ring technology, proven in in-vivo preclinical research, where maximum near 1 millimeter accuracy is a must
The seven clinical advantages of MAMMI

- Unprecedented high spatial resolution: 1.4 mm
- Natural, no compression prone position for improved sensitivity and detection of difficult lesions
- Whole breast 3D reconstruction with quantification of tumor activity
- Very fast: acquisition total time varying from 5 (standard) to 15 minutes
- Exclusive, proprietary single continuous crystal technology and software: safe and effective with VERY low tracer dosage
- Remarkably easy to use and fully reliable, even with intensive use
- Very comfortable exploration bed, adaptable to any practice