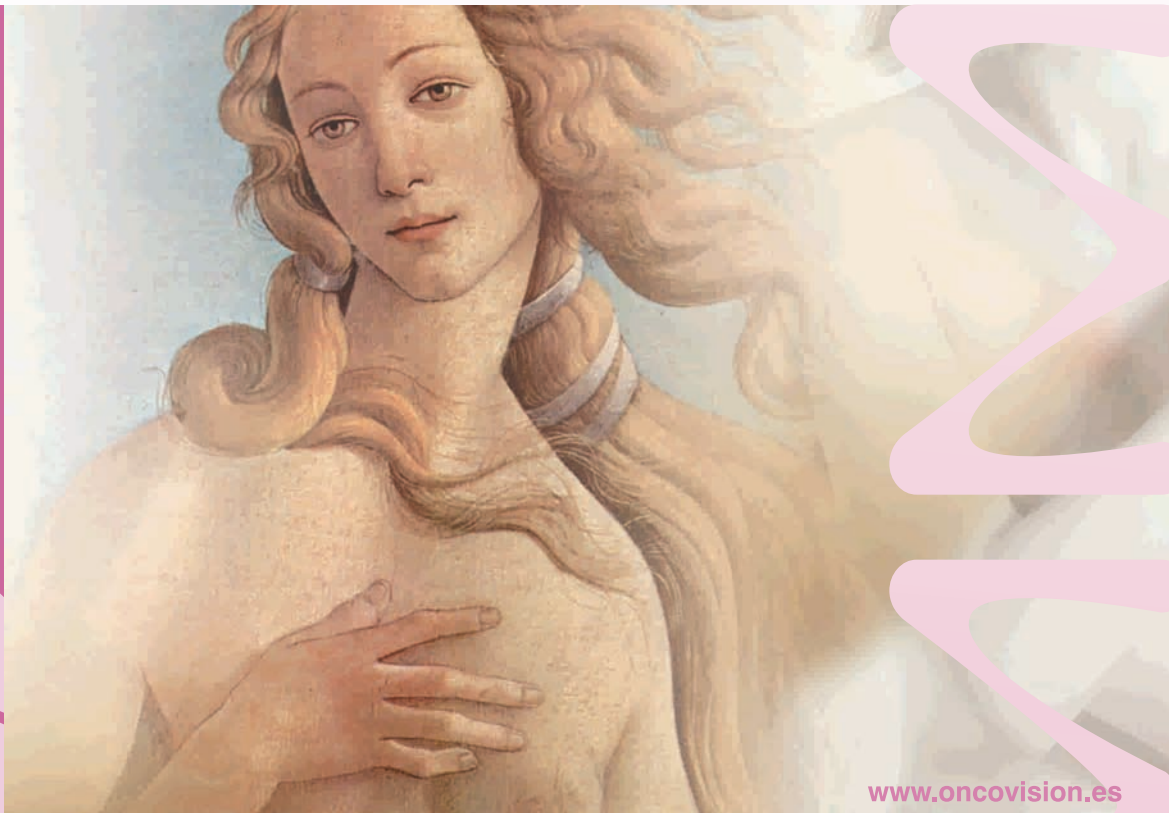


With every  
woman,  
with you



[www.oncovision.es](http://www.oncovision.es)

# MAMMI

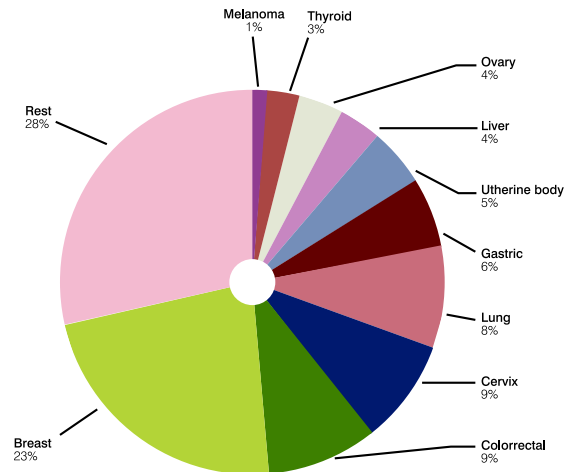
## breast PET



## 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.

**New Cancer cases worldwide, women, 2008**  
Source: Globocan 2008, FCAECC, internal assessment



## 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.

PRIMARY DETECTION	DIAGNOSIS	STAGING	ASSESSING TREATMENT	CHARACTERIZATION
X-Ray Mammography and screening	X-Ray and digital Mammography	SNL Sentinel lymph node	X-Ray and digital Mammography	Hystopathology H&E, IHQ...
Breast MRI screening in high risk women	Breast ultrasound	Axillary ultrasound	Breast ultrasound	PET
PEM	Breast MRI	PET & PET-CT	MRI, CT	Tumoral markers
	PEM	Bone scintigraphy	PET & PET-CT	
	Breast specific gamma Imaging BSGI	PEM local	PEM local pre and post surgery	

# 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...**

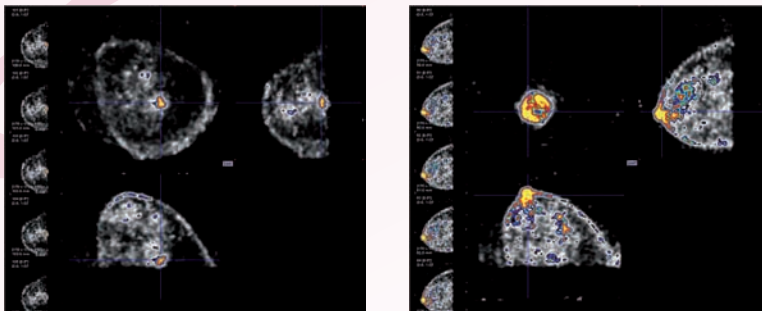
**PET’s sensitivity, specificity, positive predictive value and negative predictive value in detecting primary breast cancer are all well above 90%.**

## **...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.**



Courtesy of Dr. Valdés Olmos  
NKI Amsterdam

## 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 lobullar carcinomas:

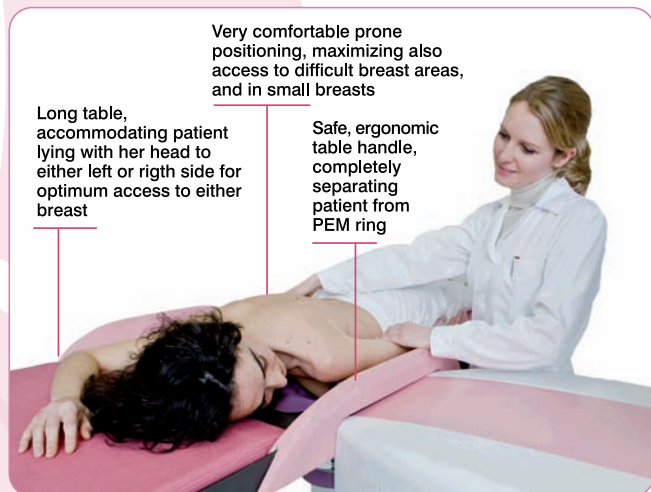
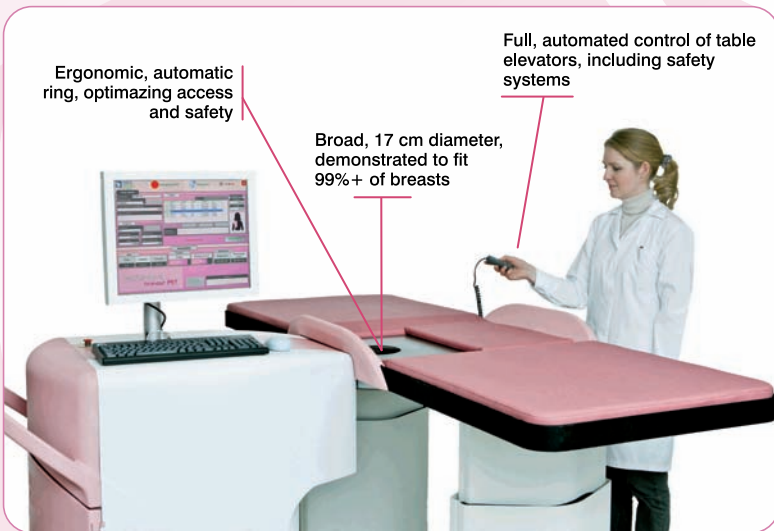
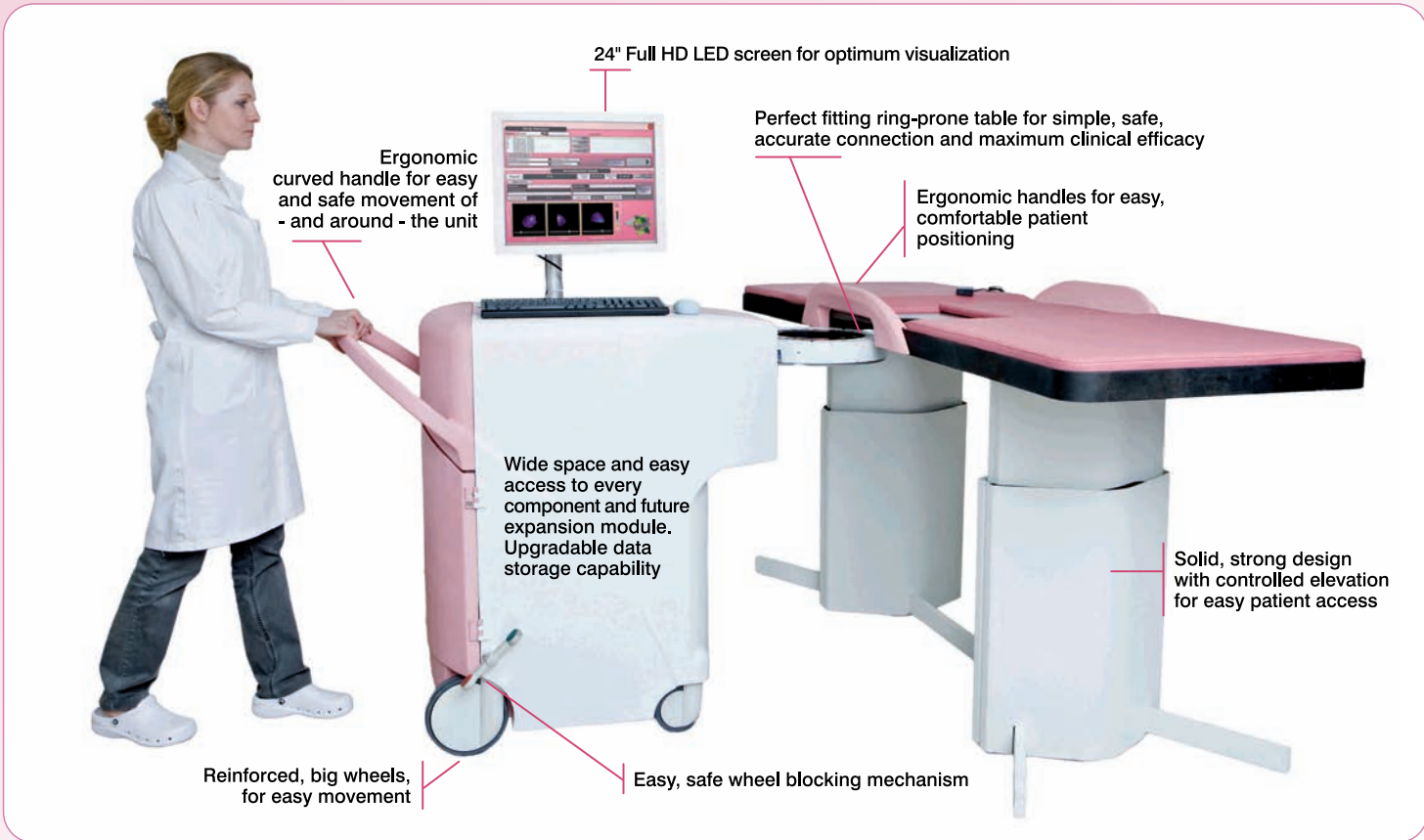
Early studies demonstrated that PEM is capable of imaging smaller breast cancers than standard Whole-body PET.

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 captation tumors.



# MAMMI

breast PET



# MAMMI

## Designed with women in mind

### The seven clinical advantages of MAMMI

- A 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
- A ADVANTAGE Natural, no compression prone position for improved sensitivity and detection of difficult lesions**  
Near thoracic wall. Multicentric...
- A ADVANTAGE Whole breast TRUE 3D reconstruction with quantification of tumor activity**  
Decisive for measuring QT /RT efficacy
- A ADVANTAGE Very fast: acquisition total time varying from 5 (standard) to 15 minutes**
- A 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
- A ADVANTAGE Remarkably easy to use and fully reliable, even with intensive use**
- A 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

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#### **Assessment of QT /HT/RT/other treatment efficacy**

Keys are high resolution and accurate quantification of tumor activity

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#### **Patient stratification in suspicious lesions identified in screening**

Avoids unnecessary biopsies. Based on very low radiation dosage

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#### **Follow up post surgery, differentiating scar tissue from active lesions**

Keys are resolution, sensitivity, 3D vision, quantification

# F

## 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.

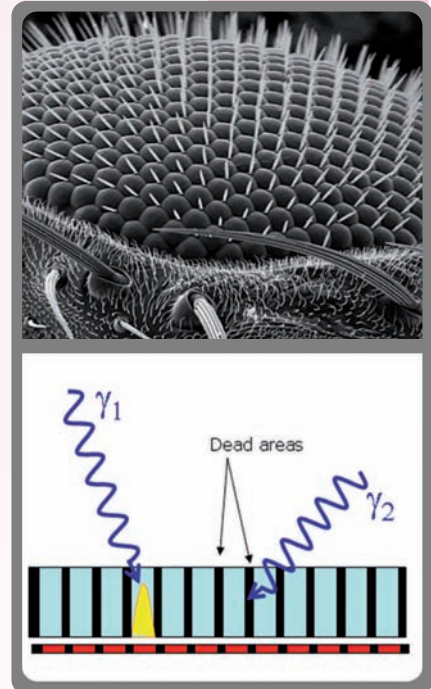
MAMMI's breakthrough technology has been developed and fully tested in the OR in thousands of cancer patients with Sentinella, Oncovision's integrated gammacamera, gammaprobes, pointers and software, and refined with the preclinical PET+SPECT+CT Albira, the Award winning multimodal platform with unprecedented 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.

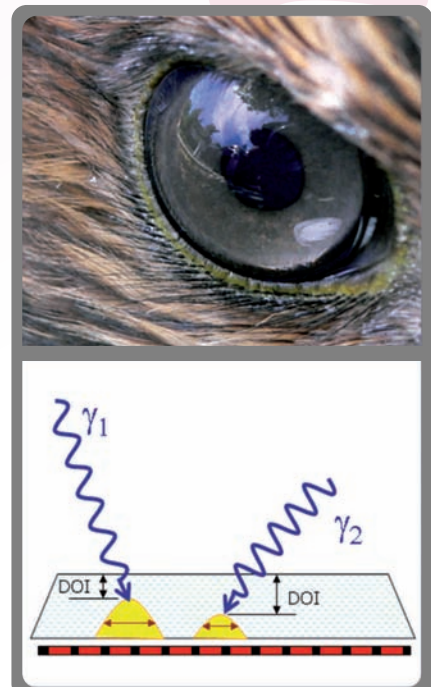
MAMMI  
breast PET

### Conventional Technology



Pixelated crystals with dead zones

### MAMMI Technology



Simultaneous detection of position and Depth Of Interaction DOI measurement. NO dead areas

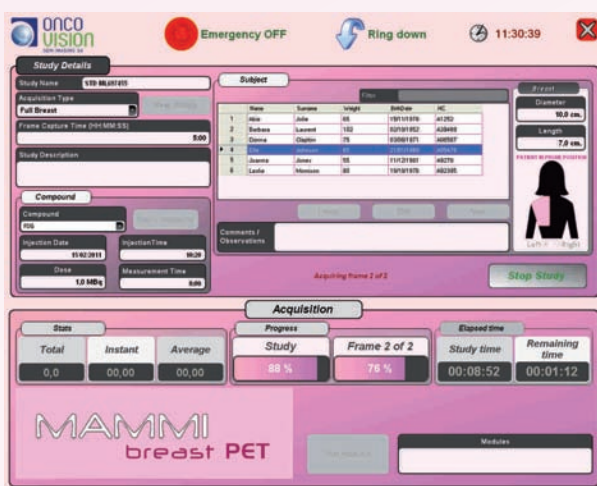
## MAMMI Software Suite, a comprehensive solution

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

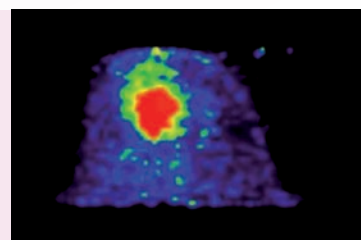
- User friendly interface
- Customizable for DYNAMIC studies
- Scatter, random and attenuation corrections
- Study reconstruction progress bar
- Reconstructed image visualization
- DICOM images export



## 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



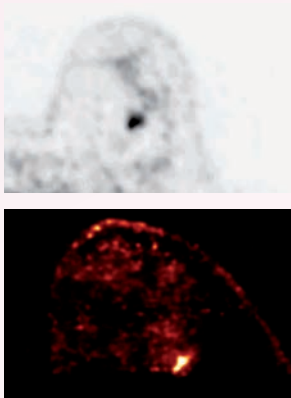
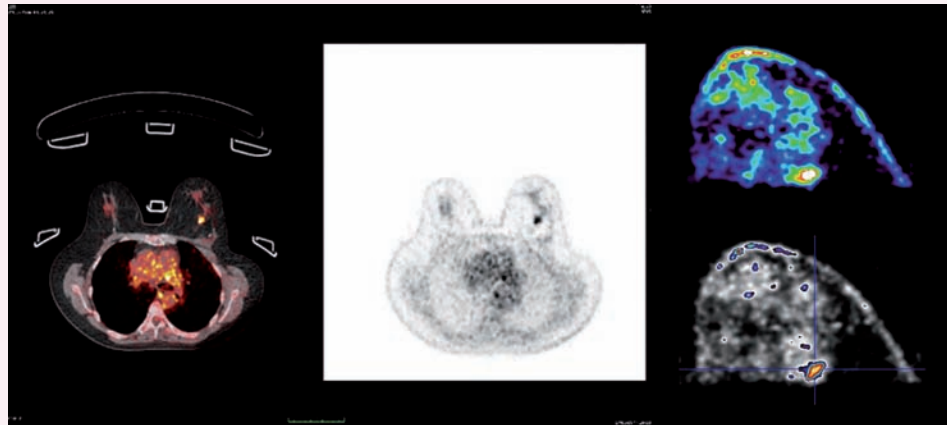
Courtesy of Dr. R. Valdés Olmos, Netherlands Cancer Institute, Amsterdam



# MAMMI: Performance Delivered

# MAMMI breast PET

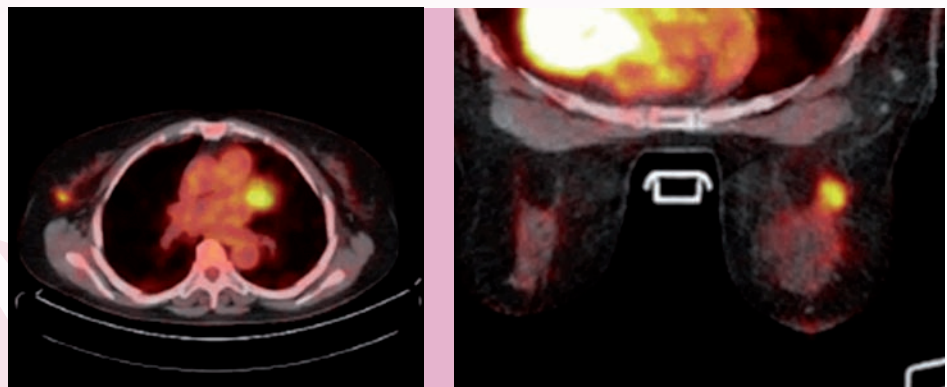
MAMMI:  
More accurate  
than Whole-  
body PET in  
advanced  
tumors



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.

Prone  
position for  
optimum  
tumor  
(and other  
pathologies)  
identification

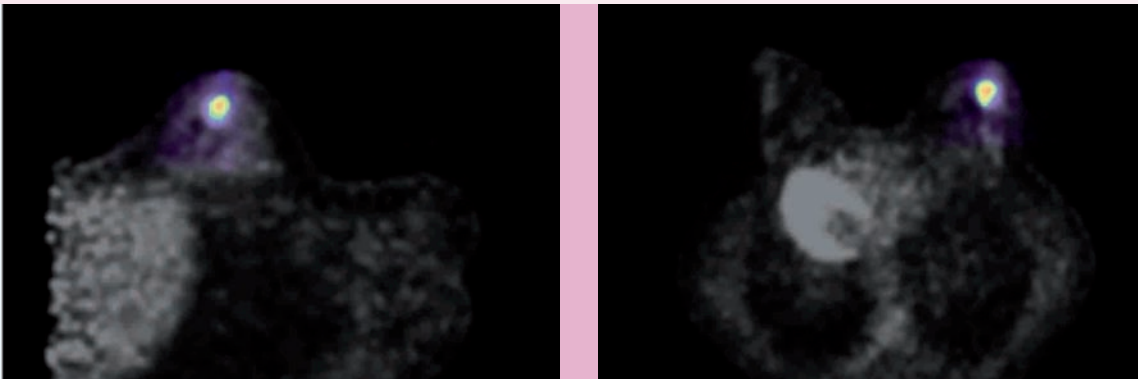


## Supine vs Prone position: a major clinical difference

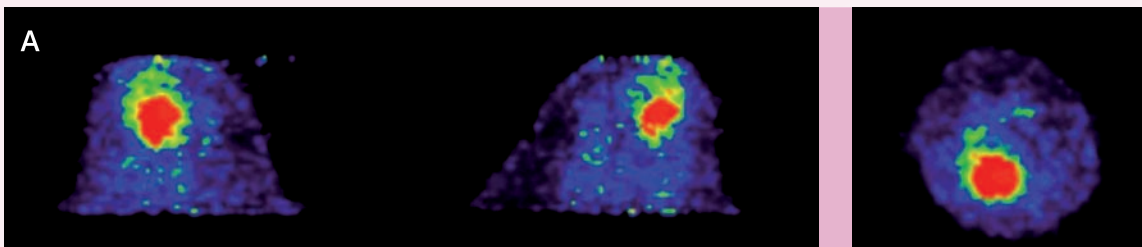
Prone position does not only bring significantly improved comfort to every woman, by avoiding any breast compression, this being important. The MAIN difference is the greatly **improved clinical localization and clear topographic identification of lesions**, which can impact treatment, as well as the 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 compression, which MAMMI does not need.



# PROVEN results in assessment of the results of chemotherapy and other treatments

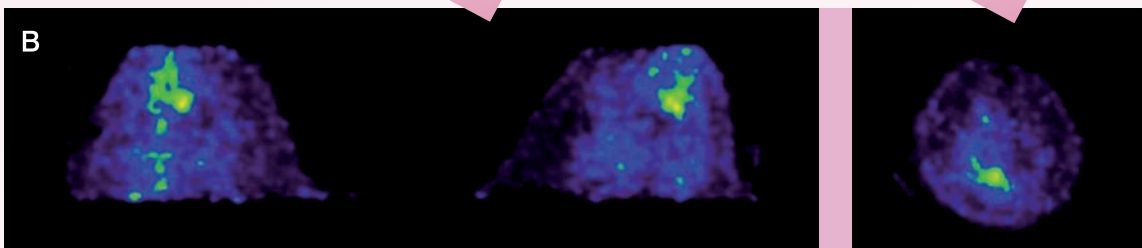


Fused MAMMI and Whole-body PET images



September, 4<sup>th</sup>

a visible  
DIFFERENCE



October, 9<sup>th</sup>

## 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.

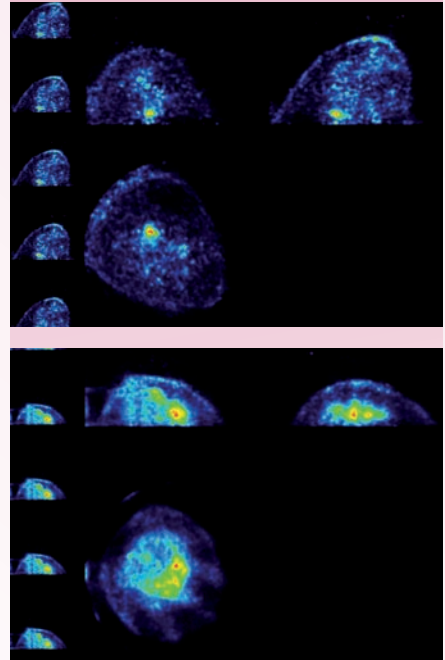
MAMMI has demonstrated strong performance in this indication, due to its best in class resolution and powerful quantification tools, allowing an objective measurement of tumor activity. Its sensitivity and low tracer dosage are also factors to be considered for repeated explorations, specially in younger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

**Best in class  
resolution  
and powerful  
quantification  
tools**

## 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:



Clinical Images 3D View  
Courtesy of Dr. R. Valdés Olmos,  
Netherlands Cancer Institute, Amsterdam

### 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.

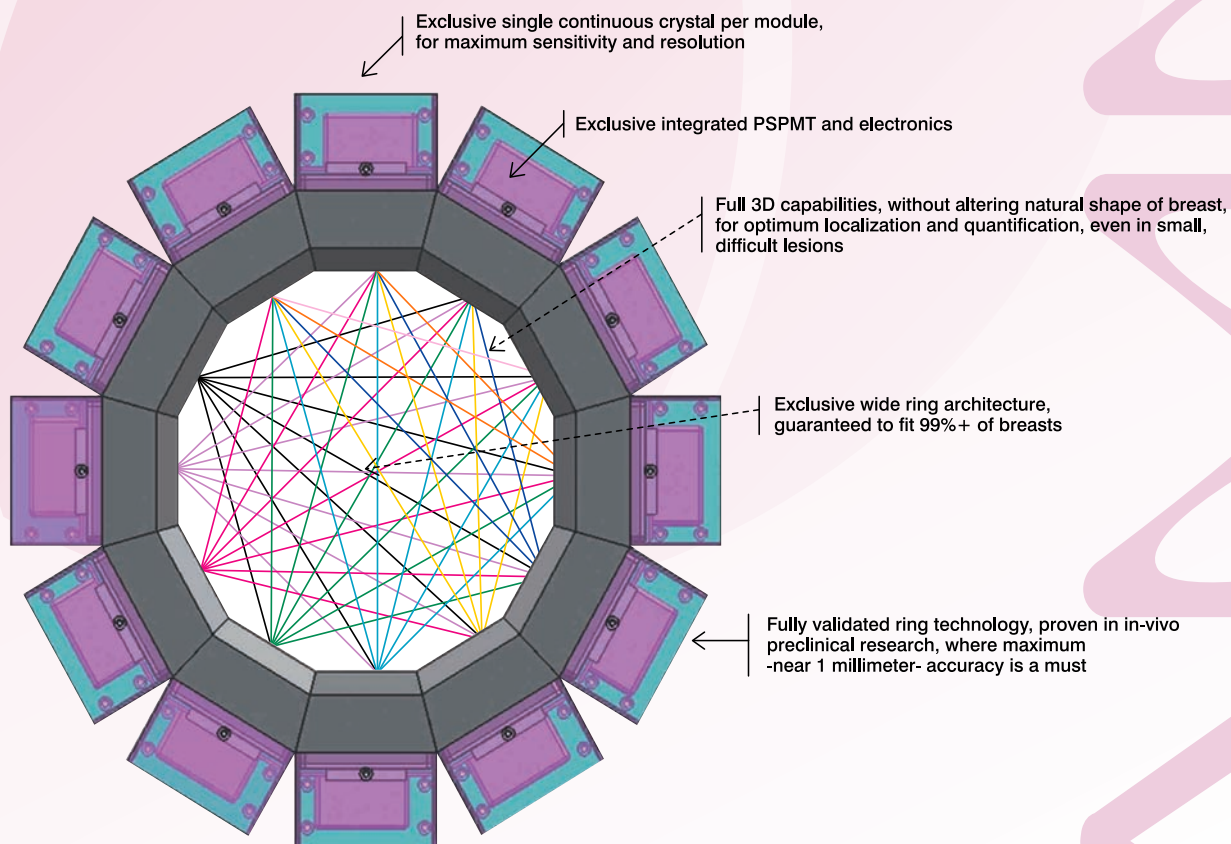
### MAMMI vs other PEM

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.

# MAMMI

breast PET

## Exclusive PET Ring Architecture



# MAMMI

## breast PET

### The seven clinical advantages of MAMMI

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



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