High-Resolution Breast PET
Naviscan PET Scanner

- High (1.6 mm) intrinsic resolution
- Short 4-10 minute scan time
- Compact, portable, easy to use
- High value 3-D tomographic PET images
- Gentle immobilization vs. compression
- Only FDA cleared and CE Mark certified scanner with breast biopsy guidance
- Breast application is Positron Emission Mammography (PEM)
PEM Provided Limited-angle Tomographic Images

Grade III IDC, multifocal
Lesions < 5mm … PEM & relevance of early detection

Tumor Growth & Angiogenesis

Early detection of lesion with PEM (molecular)

Earliest detection of lesion with MRI (vascular)

Early Disease Identification

Late Disease Stage Development

PEM  MRI  Mammography
Diagnostic Value – The Power of PEM

- Sensitivity and specificity are key to early detection of breast cancer lesions
- A prospective multicenter PEM performance study showed >90% sensitivity and specificity, 88% NPV and 92% accuracy. PEM identified 91% of pre-operative DCIS
- MRI false positive rate is an issue in diagnosis and accurate image reads

<table>
<thead>
<tr>
<th>Parameter</th>
<th>PEM (3D MBI)</th>
<th>Whole-Body PET/CT</th>
<th>Breast MRI</th>
<th>BSGI (2D MBI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity – Index Lesions</td>
<td>93% (88%&lt; 5 mm)²</td>
<td>80%³</td>
<td>91%</td>
<td>93% (29%&lt;5 mm)⁶</td>
</tr>
<tr>
<td>Specificity – Index Lesions</td>
<td>93%¹</td>
<td>76%³</td>
<td>20-90%⁴</td>
<td>59.5%⁵</td>
</tr>
</tbody>
</table>

*For secondary disease, PEM demonstrated 6% greater specificity and 26% higher PPV than MRI at comparably high sensitivity

The Value of PEM Across the Continuum of Care

Studies have shown that both the sensitivity and specificity of images from the Naviscan PET scanner exceeds 90%. As a result, surgeons can more accurately stage lesions and plan surgeries, resulting in optimal clinical results.

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The Naviscan PET scanner helps medical oncologists monitor patient responses to radiation and chemotherapy treatment. As a result, clinicians are in a stronger position to deploy the most effective treatment plans leading to optimal results.

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The Naviscan PET scanner complements ultrasound, mammography, and breast MR scans to detect local recurrent disease. Early detection is the key to successful treatment. The five-year survival rate for localized disease is 99%*

*American Cancer Society 2012 statistics
40 year-old female with area of increased density in the left inferior breast.

Ultrasound biopsy found IDC and MRI confirmed single index cancer in left breast

Mammogram (X-ray – Anatomic Imaging)

...However, PEM found bilateral cancer:
- Left index cancer plus 2 small satellite cancers
- Right cancer - hidden in the upper outer quadrant

Additional cancer lesions
How does PEM differ from PET?

Both

Provide “functional” imaging and use FDG (fluorodeoxyglucose)

PEM

- Optimized for small body parts
- Gentle immobilization
- Designed for patient comfort
- Biopsy capability

PET

- Whole Body Imaging
How PEM Differs from PET-CT

37 year-old with palpable mass, final pathology found grade III IDC+DCIS (3.2 cm)

Fused PET-CT
single tumor

PET
single tumor

PEM
index tumor+ DCIS x 2
PEM Comparison to WBPET Study

**Purpose:** To compare the sensitivity of PEM to MRI and whole body PET.

**Methods:** Single site (BRCH), prospective, blinded clinical trial for women who qualified for BCT.

**Results:** 182 women newly-diagnosed cancer enrolled.
- 167 with residual tumor had PEM+MRI, 159 had PEM+WBPET
  - 155/167 (92.8% sensitivity) for PEM (equal to MRI)
  - 108/159 (67.9% sensitivity) for WBPET (p<.001)

**Conclusions:** PEM is as sensitive as MRI. PEM is significantly more sensitive than whole body PET imaging.

Pre-Surgical Planning and
Comparing to Breast MRI
The Power of Specificity for Pre-surgical Planning

Finding: MRI found Bilateral masses suspicious for malignancy seen. PEM found R irregular mass suspicious for malignancy, left breast normal.

Pathology: R breast IDC; L breast benign fibrocystic change.

Images courtesy James Rogers, MD, Swedish Medical Center, Seattle, WA
Right breast FDG uptake in known multifocal IDC
Left FDG uptake in axillary tail matches MRI finding….but

Images courtesy James Rogers, MD, Swedish Cancer Institute, Seattle, WA
Delayed PEM imaging showed loss of FDG uptake consistent with it being a benign process.

Biopsy showed chronic inflammatory cells, periductal & perilobular.

Images courtesy James Rogers, MD, Swedish Cancer Institute, Seattle, WA
Right breast with 10 mm round mass in lower, outer quadrant, 8 cm from nipple. Lesion PUVmax is 6.6, Bkg PUVmean is 0.3, with a LTB ratio of 22.0. Assessment 5, highly suggestive of malignancy. IDC grade III.
Pre-surgical Planning

Excisional biopsy inflammation with seroma (PUVmax = 1.38)

Tumor (PUVmax = 5.48)

Skin biopsy site (PUVmax = 1.5)
Pathological Confirmation of IDC and DCIS

History: 40 year-old dense-breasted female presenting with palpable abnormality on right breast.

Findings: Ultrasound-guided biopsy showed expected IDC from mammogram but with unexpected DCIS intertwined in lesion. MRI and PEM found expected IDC lesion and greater than expected extensive DCIS.

*Images courtesy James Rogers, MD, Swedish Cancer Institute, Seattle, WA*
Multifocal IDC

Images courtesy James Rogers, MD, Swedish Cancer Institute, Seattle, WA
Pathological Confirmation of Two IDC Lesions

**Technique:** MRI acquired at 0.6 mm slice thickness; PEM presented in 12 slice view. PEM interpretation time was significantly faster than MRI.

**Imaging Findings:** MRI and PEM found 2 IDC lesions not seen by mammography. Ultrasound identified only one lesion at 10 o’clock.

**Pathology size:** PEM more accurate estimate of lesion size.

*Images courtesy James Rogers, MD, Swedish Cancer Institute, Seattle, WA*
**History:** 63 year-old woman with DCIS in left breast identified on mammogram with no apparent disease in contralateral breast. Pathology of left breast showed Stage 0 disease. Underwent PEM for staging.

**Findings:** PEM found 1.9 cm IDC in the left breast not initially seen on routine imaging. Patient was re-staged as Stage 1 and Oncotype DX assay results determined tumor to be aggressive. Without PEM she would not have had necessary chemotherapy regimen and lesion would have remained undetected in her breast.

*Images courtesy Michael Kinney, MD, The Center for Advanced Breast Care, Arlington Heights, IL*
Pre-surgical Planning: Finding the Unsuspected

**History:** 72 year-old woman with a bi-lobed lesion in the upper outer quadrant of right breast

*Images provided courtesy of Orkun Falay, MD, Medica, Istanbul, Turkey*
Ultrasound validated mammogram findings and provided size estimates of:
Lesion #1: 25.8 x 15.5 mm.
Lesion #2: 8.0 x 7.7 mm.
**Conclusion:** multifocal cancer.
Pre-surgical Planning: PEM Found the Unsuspected

**PEM:** changed classification from multifocal to multicentric disease

**Pathology:** Multicentric Invasive Lobular Carcinoma, histologic Grade II, nuclear Grade 2, SLN (-), ER(+), PR(+), HER-2/neu 4B5(-), Ki-67(+)

*Images provided courtesy of Orkun Falay, MD, Medica, Istanbul, Turkey*
Benefits of PEM – Supporting Pre-surgical Planning
The Research Speaks for Itself…
Body of Knowledge Published on PEM

Peer-reviewed Manuscripts


Tatro L. Positron emission tomography (PET) and mammography (PEM) for breast cancer importance to surgeons. Annals of Surgical Oncology 14 (3): 383-388 (2006)


Posters and Presentations


Heinmuller M, Radiopharmaceuticals, Horizons, and Clinical Experience with Navicent PEM. 5th International Workshop on the Molecular Radiology of Breast Cancer, Valencia, Spain (2011)


MacDonald L, et al. Low dose lesion contrast on the PEM Flex Solo II. The American Association of Physicists in Medicine (2010)

Paschir R, Hayes M. Integration of positron emission mammography (PEM) is a clinical breast center. National Coalition of Breast Centers (2010)


Hax, M. Software tools for breast cancer detection in positron emission mammography images. Informatik im Fokus der Zukunft (2009)


Multicenter PEM vs. MRI Comparison Trial

- NIH Sponsored (Grant #5R44CA103102)
- Randomized …both PEM & MRI
- Prospective …388 patients
- Secondary lesions
- Gold Standard = Pathology

Study Goals:

- Document the Performance Characteristics of PEM vs. Breast MRI
- Define the Role of PEM in Pre-Surgical Planning & Patient Management
NIH-sponsored PEM-MRI Comparison Study

Objective
To determine performance of PEM compared to MRI

Methods
• NIH funded*, multi-center, prospective clinical trial of 388 women with recent biopsy-confirmed in situ or invasive breast cancer
• Positive truth was histopathology or diagnosis of malignancy within one year of imaging

Results
• 404 index tumors in 388 breasts, median size 1.5 cm

<table>
<thead>
<tr>
<th>Index Lesions</th>
<th>MRI</th>
<th>PEM</th>
<th>MRI vs. PEM p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>89.1%</td>
<td>92.5%</td>
<td>0.079</td>
</tr>
</tbody>
</table>

* NIH Grant 5R44CA103102
<table>
<thead>
<tr>
<th>Breast with Ipsilateral Cancer</th>
<th>MRI (95% CI)</th>
<th>PEM (95% CI)</th>
<th>PEM vs MRI p-value</th>
<th>PEM + MRI (95% CI)</th>
<th>PEM+MRI vs MRI alone p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity</strong></td>
<td>60.0% (48.0 – 70.0)</td>
<td>51.0% (40.0 – 62.0)</td>
<td>0.24</td>
<td>74.0% (63.0 – 83.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td>86.3% (81.8 – 89.8)</td>
<td>91.2% (87.3 – 93.9)</td>
<td><strong>0.032</strong></td>
<td>83.6% (78.6 – 87.2)</td>
<td>0.020</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>80.7% (76.3 – 84.4)</td>
<td>82.7% (78.5 – 86.3)</td>
<td>0.36</td>
<td>81.4% (77.1 – 85.1)</td>
<td>0.56</td>
</tr>
</tbody>
</table>

- Medial ipsilateral tumor size, 0.7 cm
- **PPV of PEM-prompted biopsies (66%) versus MRI (53%), p=0.016**
- 2.8% women had unnecessary mastectomies:
  - MRI prompted 5 unnecessary mastectomies
  - PEM prompted 1 unnecessary mastectomy
- 8.5% (33) of women required wider excision: MRI identified 24 & PEM identified 22

1. PEM had 5% points greater specificity than Breast MRI, reducing false positives

2. PEM had comparable high MRI sensitivity

3. PEM had 14% points higher PPV than MRI, potentially reducing unnecessary biopsies

4. PEM was unaffected by Breast Density, Tumor Type, Menopausal or Hormonal Status providing significantly more precise Personalized Imaging than MRI.

“We looked very carefully for additional cancers and were surprised that barely half of these were shown on MR. PEM significantly improved detection of additional disease over MR alone”

Wendie Berg, M.D., Ph.D. and Principal Investigator

15% of Women Cannot Tolerate a Breast MRI*

Study Summary: 1215 women offered free screening breast MRI as part of ACRIN 6666 protocol MRI sub-study

Results:

15% of eligible women not enrolled in study due to inability to tolerate breast MRI

- 11% due to claustrophobia
- 3% were medically intolerant to MRI
- 1% due to gadolinium-related risks

Monitoring Response to Neoadjuvant Chemotherapy
Neoadjuvant Chemotherapy Monitoring

PEM can detect whether therapies are having an effect on patients EARLY…within the first cycle of treatment!

PEM is indicated as a biomarker to gauge progression of disease.

Images courtesy of Mary K. Hayes, MD, Memorial Healthcare System, Hollywood, FL
Response to Neoadjuvant Chemotherapy

Not all tumors respond the same

Before Chemo

After Chemo
Monitoring for Cancer Recurrence
73 year-old with history of left papillary cancer treated with lumpectomy 12 yrs ago.

Presented with abnormal right mammogram, biopsy found IDC.

PEM for pre-surgical planning confirms index cancer in right breast and finds recurrent papillary cancer in left breast (both path proven).

Images courtesy of Kathy Schilling, MD, Boca Raton Regional Hospital, Boca Raton, FL
Local Regional Staging
Lymph Node/Axilla Evaluation

Invasive ductal carcinoma at 2:00 o’clock right breast. Level I lymph node seen, and suspicious for metastatic disease.

Axillary imaging shows numerous lymph nodes with FDG uptake consistent with metastatic disease. Seven of 7 nodes were positive for cancer.
Evaluation for Loco-regional Staging

Index cancer

Axillary Mets

5/12
3.01 cm

6/12
3.64 cm

7/12
4.27 cm

9/12
5.54 cm

10/12
6.17 cm

11/12
6.81 cm
Assessment of Axillary Lymph Node Status

Purpose: Evaluation of metabolic imaging for identification of breast cancer metastatic disease in lymph nodes.

Methods: 14 newly diagnosed breast cancer patients (13 IDC, 1 DCIS) underwent PEM axillary imaging. Biopsy of PEM suspicious nodes or sentinel lymph node biopsy with pathological analysis.

Results: 5/14 pathology proven cancer metastasis in nodes. PEM identified 4/5 true positive (80% sensitivity), 0/9 false positive (100% specificity), PPV 100%, NPV 90%.

Conclusion: PEM pilot study shows promising results for accurate lymph node assessment in breast cancer.

Kulkarni, Appelbaum, Sennett, Pu, Newstead; Univ of Chicago, ECR, March 2011
PET-guided Biopsy
The Only FDA Cleared, CE Mark Certified, Commercially-available Breast PET-guided Biopsy
Peripheral Tumors
Peripheral Tumors

PET-CT

Organ-specific PET
Utilization of Organ-specific PET ...Beyond Breast

PEM scan provides additional localization to known anatomical structures due to the close proximity of the detectors and the 2 mm spatial resolution.
Note the anatomical detail in the PEM image showing the photopenic center from the dead cancer with only mild post-radiation inflammation.
High-grade sarcoma of the cuboid bone, s/p adjuvant chemotherapy. Wouldn’t PEM imaging be helpful in monitoring response for peripheral sarcomas due to its better spatial resolution?

Utilization of Organ-specific PET …Beyond Breast
**History**: 85 year-old with history of melanoma now presents with right toe lesion and question of reoccurrence.
Reducing FDG to 5 mCi or Less
The Risk-to-Benefit Ratio

### THE LOW RISK OF PROPER TREATMENT

<table>
<thead>
<tr>
<th>Dose Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mSv/year</td>
<td>U.S.A. Federal agencies annual limit for occupational workers</td>
</tr>
<tr>
<td>11 mSv²</td>
<td>CT scan of head and body</td>
</tr>
<tr>
<td>8.3 mSv⁶</td>
<td>25 mCi Tc-Sestamibi Gamma Imaging</td>
</tr>
<tr>
<td>7 mSv³</td>
<td>10 mCi FDG PEM scan</td>
</tr>
<tr>
<td>6.2 mSv²</td>
<td>Average U.S.A. yearly exposure</td>
</tr>
<tr>
<td>3.5 mSv³</td>
<td>5 mCi FDG PEM scan</td>
</tr>
<tr>
<td>1 mSv⁴</td>
<td>Tomosynthesis &amp; Mammogram</td>
</tr>
<tr>
<td>0.42 mSv⁷</td>
<td>Mammogram (Bilateral exam – 4 views)</td>
</tr>
</tbody>
</table>

**Effective Dose (mSv)**

```
10  20  30  40  50
```

**INTERESTING FACTS**

- Watching TV or computer using CRT technology: **0.01 mSv (1 mrem)/year**
- Eating 1 banana per day: **0.036 mSv (3.6 mrem)/year**
- Flying coast-to-coast across the U.S.A.: **0.05 mSv (5 mrem)**
- Sleeping next to another person for 3 hours/day: **0.02 mSv (2 mrem)/year**
- Natural background radiation (i.e. cosmic rays): **3.1 mSv (310 mrem)/year**
- Living in a brick house: **0.07 mSv (7 mrem)/year**
- Living in Breckenridge, CO compared to sea level: **0.7 mSv (70 mrem)/year**

*The benefit of proper treatment exceeds the low risk from PEM.*

Wendie Berg, M.D., Ph.D.
Proactive Steps to Reduce FDG Dose for PEM

- 50% coincident count reduction study showed no change in sensitivity for cancer detection, suggesting 5 mCi dose is adequate. *(SNM 2010 Annual Meeting)*

- Dr. MacDonald showed that FDG dose may be reduced down to 2 mCi without loss of sensitivity *(AAPM 2010)*.

- Swedish Cancer Institute’s clinical trial showed same sensitivity with 5 mCi dose in patients, now testing 2.5 mCi *(SNM 2011 Annual Meeting)*

- Clinical sites across the United States and Europe have reduced the FDG dose for PEM imaging to 5 mCi based on their own clinical experience and are supported by current FDA recommendations.
LC is a 37 year-old woman who had a non-diagnostic breast MRI due to cystic breast disease.

PEM scan was performed with 5.3 mCi imaged 60 min post injection with 10 min scan.

Note the FDG uptake in lower, outer quadrant Bx found ALH. Surgery found LCIS+ADH+DCIS
GW is a 69 year-old, received 6.2 mCi; 288 lbs; imaged 60 min post injection; 10 min scan

SR is a 78 year-old, received 4.7 mCi; 174 lbs; imaged 60 min post injection; 10 min scan

Images courtesy Kathy Schilling, MD, Boca Raton Community Hospital, Boca Raton, FL
Two Doses – Same Patient

**History:** 76 year-old, 244 lb woman with a recent diagnosis of intraductal carcinoma intermediate grade with necrosis and calcifications in the inferior medial right breast. Patient underwent an initial PEM scan for preoperative staging.

**Findings:** Two areas of uptake were identified on the PEM imaged with **8.5 mCi of $^{18}$F-FDG**, the known malignancy already identified as DCIS, and a second **unknown 8 mm area located 6.5 cm from the nipple in the inferior lateral breast**. The patient was re-imaged 4 days later prior to biopsy using **3.2 mCi of $^{18}$F-FDG** with subsequent PET-guided biopsy. Final pathology results from PET-guided biopsy confirmed DCIS.

*Images courtesy of Kathy Schilling, MD, Boca Raton Regional Hospital, Boca Raton, FL*
Alternate PET Radiotracers
INCan Mexico’s Clinical Trials

**FES (16a-[18F] Fluoro-17β-Estradiol)**

Estrogen-receptor status of breast cancer is a known prognostic indicator of both disease-free survival and overall mortality. Measuring this in vivo in patients is a unique attempt to assess receptor status for both index and ipsilateral lesions.


**FLT (3′-Deoxy-3′-[18F] Fluorothymidine)**

The ability to image [18F]FLT incorporation into DNA provides an imaging marker of cell proliferation in vivo. This approach will be used in breast cancer patients to evaluate their response to chemotherapy and see if these results provide prognostic information.

History: 39 year-old female with HER-2+ invasive DCIS of the right breast.

Imaging: 3.9 mCi Cu-64-TP3805 injected, images obtained 2 hr later

Imaging: 12 mCi F-18-FDG injected, images obtained 1 hr later

(FDG imaging completed 8 days after Cu64)
PEM (3-D MBI)

vs.

Breast Specific Gamma Imaging
Core Technology (3-D vs. 2-D)

**PEM**

**Tomography** (3-D) with timing collimation.

**BSGI/MBI**

**Planar** (2-D) with collimator. As distance increases, **image quality decreases**.

---

Phantom at 2.5 cm from detector  
No Spatial Resolution Impact

Phantom at 4.0 cm from detector

Phantom at 2.5 cm from detector

Phantom at 4.0 cm from detector  
Spatial Resolution Impact
BSGI: 2-D Images vs. PEM: 3-D Images

BSGI produces one superimposed image per view providing only a 2-D perspective.

PEM generates 12 tomographic slices per view offering a 3-D perspective of the breast.
**Isotope Development**

**$^{18}$F-FDG**
Developed as a metabolism imaging agent as a tool to detect cancer.

---

**$^{99}$mTc-Sestimibi**
Developed as a cardiac imaging agent for evaluation of blood flow.

---
BSGI Reproducibility

Mammogram

Images courtesy Marie Tartar, MD, Scripps Institute, La Jolla, CA
PEM *Not* Impacted by Implants
## Image Quality Performance Characteristics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>PEM $^{18}$F-FDG</th>
<th>BSGI $^{99m}$Tc-Sestamibi</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Image Quality</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sensitivity</strong></td>
<td>93%</td>
<td>93%&lt;sup&gt;6&lt;/sup&gt;</td>
<td>PEM's higher sensitivity at a smaller lesion size (&lt;5 mm) can lead to early diagnosis.</td>
</tr>
<tr>
<td></td>
<td>(88% &lt;5 mm)&lt;sup&gt;5&lt;/sup&gt;</td>
<td>(29% &lt;5 mm)&lt;sup&gt;7&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td>93%&lt;sup&gt;8&lt;/sup&gt;</td>
<td>59.5%&lt;sup&gt;6&lt;/sup&gt;</td>
<td>PEM's higher specificity can lead to fewer false positives and less unnecessary biopsies.</td>
</tr>
</tbody>
</table>

Breast Specific Gamma Imaging

Gamma Camera Instrumentation

Lesion close to detector

Lesion farther from detector
Isotope Comparison

**PEM**

- Shorter half-life and higher energy of FDG generates lower whole-body radiation dose (350-700 mrem).¹
- FDG remains trapped in cells providing flexibility for dual time-point imaging and biopsy.

**BSGI**

- Sestamibi generates higher whole-body radiation dose (830 mrem).²
- Sestamibi washes out of cells, especially for aggressive or chemo-resistant tumors inhibiting delayed imaging.

---

1. International Commission on Radiological Protection (ICRP) Publication 80, p. 49.
## Isotope Comparison

<table>
<thead>
<tr>
<th>Parameter</th>
<th>PEM $^{18}$F-FDG</th>
<th>BSGI $^{99m}$Tc-Sestamibi</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose</strong></td>
<td>5-10 mCi</td>
<td>25 mCi</td>
<td>Whole body dose from FDG is 350-700 mrem.$^1$</td>
</tr>
<tr>
<td><strong>Energy</strong></td>
<td>511 keV</td>
<td>140 keV</td>
<td>Whole body dose from Sestamibi is 830 mrem.$^2$</td>
</tr>
<tr>
<td><strong>Half-Life</strong></td>
<td>110 min</td>
<td>360 min</td>
<td></td>
</tr>
<tr>
<td><strong>Transport</strong></td>
<td>Active transport into cell and trapped</td>
<td>Diffuses in and active transport out</td>
<td>Sestamibi has washout, highest in aggressive and chemo-resistant cancers. FDG is trapped</td>
</tr>
<tr>
<td><strong>Diabetic Patients</strong></td>
<td>No problem with proper preparation</td>
<td>No problem</td>
<td>Diabetic patients can be scanned on PEM or BSGI.</td>
</tr>
<tr>
<td><strong>Allergic Effects</strong></td>
<td>None</td>
<td>Headache, nausea, flushing, rash, tingling, seizures, angioedema, urticaria, metallic taste, abnormal smell, anaphylaxis</td>
<td>FDG for PEM can be used in all patients.</td>
</tr>
</tbody>
</table>

1. International Commission on Radiological Protection (ICRP) Publication 80, p. 49.
PEM for Pre-surgical Planning

Mammography

- Nipple
- Index Lesion
- Lymph node

PEM

- Secondary malignancy
PEM Reimbursement
Newly Diagnosed Breast Cancer Algorithm

Breast PET is reimbursed for:
- Pre-surgical planning or staging
- Monitoring response to treatment (i.e., neoadjuvant therapy)
- Restaging (i.e., staging for recurrence)
Note: Vacuum-assisted biopsy also reimbursed

Note blue boxes represent the reimbursed indications
Reimbursement may vary by payer, region and exam

Breast PET recommended when:
- Higher sensitivity and specificity is desired to optimize early-stage detection
- Striving for optimal results when outside 7-14 day menstrual cycle
- Obese patient is challenged to fit in other modalities
- Patient is claustrophobic
- Patient is kyphotic (curvature in upper spine)
- Metal implants limit use in MRI
- Patient has adverse gadolinium reaction
- Immediate confirmation of sample needed (when biopsying)
- Breast PET scan slots are available relative to other modalities
- Renal insufficiency when GFR < 30 milliliters/min
- Perimenopausal and unable to determine hormonal modulation of breast

Diagram:
- Staging I or II
  - MRI
  - Breast PET staging
- Staging III or IV
  - WB PET &/or MRI
  - Breast PET w/ same FDG injection
- Additional Researeh Disease?
  - Yes
  - Breast PET Biopsy
  - U/S Biopsy
  - MRI Biopsy
  - Nooadjuvant Therapy
  - Breast PET Monitoring Response
  - Surgery
  - Breast PET Restaging
- Other non-Breast Course of Treatment
Reimbursement for High-Resolution Breast PET

Reimbursable Clinical Indications:
- Surgical planning - extent of disease
- Neoadjuvant chemotherapy
  - monitoring response to therapy
- Suspicion of recurrence

Average break-even patient volume
- ~18 patients month ...less than 1 patient per day

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Health Assurance/Health America</th>
<th>Medicare</th>
<th>Aetna</th>
<th>Capital Blue Cross/Keystone</th>
<th>Highmark Blue Shield</th>
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</thead>
<tbody>
<tr>
<td>78811</td>
<td>$784.31</td>
<td>$834.06</td>
<td>$1,000.00</td>
<td>$1,834.77</td>
<td>$2,000.00</td>
</tr>
</tbody>
</table>
Global Footprint
50+ Installs in United States, Latin America, Asia, Middle East and Europe
High-Resolution Breast PET

MLO PEM
3-D PEM Imaging
3-D PEM Imaging
Images Are Formatted in 12 Slices

Detector Distance (cm) = 3.5
Dimensions (mm) = 200 X 136 X 12
Voxel Size (mm) = 1.2 X 1.2 X 2.9
PEM Visualization of Small (sub cm) Lesions by Cell Type

DCIS*
2 mm

IDC*
5 mm

ILC
7 mm

* Read as negative on MRI
Authorized PEM Service Providers may be the Right Solution for You

- Benefit from the revolutionary PEM technology while avoiding a capital outlay
- Grow the size, scope and referral reach of your practice without having to acquire the expertise in PEM and molecular imaging
Quiet Room with Hot Lab
Scanning Room