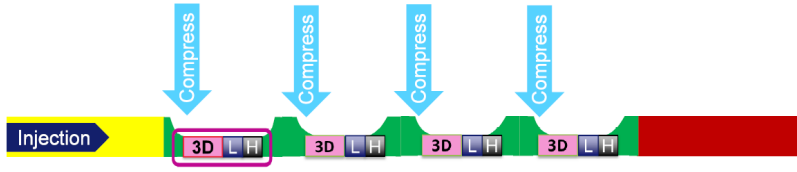


# I-View™ 2.0 Contrast Enhanced Mammography Imaging Implementation Guide

Protocol	Notes
Implementation: equipment and software required	<ul style="list-style-type: none"> <li>• I-View™ 2.0 software &amp; hardware (copper filter)</li> <li>• Selenia® Dimensions® or 3Dimensions™ mammography system with minimum 1.10/2.1 software</li> <li>• Computer minimum: CMP-01529/ CMP-01503</li> <li>• Power Injector: single or dual head</li> </ul>
Indications, uses	<p><b>Diagnostic pathway:</b></p> <ul style="list-style-type: none"> <li>• Recall from screening</li> <li>• Pre-op staging in the setting of cancer detected</li> <li>• Monitor effectiveness of drug therapy</li> <li>• Pre-biopsy work up: determine if biopsy is needed and if more sites are seen</li> <li>• Difficult mammography and ultrasound cases: to direct toward biopsy, return to screening or short term follow up</li> <li>• BIRADS 3 lesions: determine if shift to biopsy, routine follow up or short term follow up</li> <li>• Nodal metastasis with unknown site of cancer</li> <li>• Patient has contraindications for MRI (Claustrophobia, inability to lay prone, MRI unsafe devices in the body: pacemakers, stents, etc.)</li> </ul> <p><b>Screening:</b></p> <ul style="list-style-type: none"> <li>• High-risk: in women &gt;20% lifetime risk</li> <li>• Dense tissue: to improve sensitivity</li> <li>• History of high-risk lesions: leading to high risk state for patient</li> </ul>
Referral source	<ul style="list-style-type: none"> <li>• Surgeons</li> <li>• Radiologist</li> <li>• Medical oncologist</li> <li>• Radiation oncologist</li> <li>• OB/GYN or other qualified medical practitioner</li> </ul>

Protocol	Notes
<b>Scheduling patients &amp; Procedure room</b>	<ul style="list-style-type: none"> <li>• After completing patient file with patient's information per Centre's guidelines, explain the procedure to the patient verbally and in writing: risks, benefits and details of the exam including IV placement, contrast allergy and observation after the exam.</li> <li>• Room time: 30 minutes – 1 hour <ul style="list-style-type: none"> <li>- 1 hour is recommended at the start as staff experience a learning curve with the technology.</li> <li>- Can decrease to 30 mins after staff familiar with the procedures.</li> </ul> </li> </ul>
<b>Personnel</b>	<ul style="list-style-type: none"> <li>• Radiologist and technologist</li> <li>• If necessary, a nurse for IV and to monitor patient</li> </ul>
<b>Contrast injection</b>	<ul style="list-style-type: none"> <li>• CEM uses standard CT non-ionic iodine contrast media (Follow existing local or national guidelines on contrast media.)</li> </ul> <p>Primary Considerations:</p> <ul style="list-style-type: none"> <li>• Allergy information in detail</li> <li>• Perform pregnancy and renal function tests prior to injection (glomerular filtration rate &lt;30 mL/minutes/1.73 m<sup>2</sup>)</li> <li>• Contrast dose and rate of injection: patients received 1.5 mL/kg contrast media of choice at a rate of 3 mL/second in the seated position.</li> <li>• A single or dual head power injector is recommended.</li> </ul>
<b>Crash cart</b>	<ul style="list-style-type: none"> <li>• Required, training for nurses, radiologists, staff and/or relevant dedicated team if available</li> <li>• Local Emergency Number if outpatient center</li> </ul>
<b>Contra-Indications</b>	Contrast allergy, pregnancy, and renal insufficiency
<b>Pre-Exam workflow</b>	<ul style="list-style-type: none"> <li>• Radiologists – Determine if patient requires a 3-in-1 exam<sup>1</sup> (2D, Contrast and Tomosynthesis images in 1 compression) or just a contrast exam. Review images and determine added views.</li> <li>• Review indication for exam, allergy history, renal function, patient history.</li> <li>• Patient – Can eat a light meal on the day of CEM. Do not put on any deodorant, lotion, cream, powder, talc, oils, or perfume before CEM.</li> <li>• Nurse/Technologist – Prepare room and power injector. Place IV and test function.</li> </ul>

Protocol	Notes
<b>Images: timing, range of timing, views, diagnostic views</b>	<ul style="list-style-type: none"> <li>• Follow I-View™ user-interface</li> <li>• Approximately 2 minutes after contrast administration is complete, the breast is compressed and images are obtained.</li> <li>• The physician will decide the procedure views as desired (as well as which breast the examination begins with, the lesion breast or bi-lateral)</li> </ul> <p>The optimal imaging window is approximately 2 to 8 minutes post injection. The time may vary depending on lesion type and background parenchymal enhancement.</p>  <p style="text-align: center;">Figure 1: Example of the CEM + Tomosynthesis workflow</p>
<b>Compression amount</b>	<ul style="list-style-type: none"> <li>• Currently there are no standards for compression.</li> <li>• The breast should not be in compression, even light, during contrast administration as it could affect uptake.</li> </ul>
<b>Technologist training</b>	<ul style="list-style-type: none"> <li>• Will be conducted on-site by a local Hologic representative and supported by additional online educational options.</li> </ul>
<b>PACS/workstation, image storage and handling</b>	<p>Storage standard is similar to 2D and 3D images.</p>
<b>Post-Exam Workflow</b>	<ul style="list-style-type: none"> <li>• Radiologists – Interpret images and determine next steps which may include added mammographic images and/or ultrasound.</li> <li>• Nurse/Technologist – Prepare as usual for the next patient.</li> <li>• Patient – Drink enough water in the 24 hours after CEM to help eliminate the contrast from body.</li> </ul>

\*2D, Contrast and Tomosynthesis images in 1 compression

Protocol	Notes
<b>Interpretation (Radiologist training): education module</b>	<ul style="list-style-type: none"> <li>• Training <ul style="list-style-type: none"> <li>- a case set for readers will be provided and include common artifacts as well as normal, known benign cases and malignancies.</li> <li>- ICPME webinars available at <a href="http://www.HologicED.com">www.HologicED.com</a></li> </ul> </li> <li>• A total of 4 standard, low-energy (standard mammographic) views and 4 contrast-enhanced views are available, including bilateral CC and MLO projections at both settings (tomo images are available under 3-in-1 mode<sup>1</sup>). Interpretation will be performed on dedicated workstations and compared with prior examinations, if available.</li> </ul>
<b>Outcomes</b>	<ul style="list-style-type: none"> <li>• Normal</li> <li>• Benign appearing lesion recommended for short term follow up.</li> <li>• Biopsy for suspicious lesions for diagnosis</li> </ul>
<b>Maintenance, support needed, repairs</b>	Refer to Hologic's <sup>®</sup> user manuals

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#### References

<sup>1</sup> Chou C, Lewin J, Chiang C et al. "Clinical Evaluation of Contrast-Enhanced Digital Mammography and Contrast Enhanced Tomosynthesis-Comparison to Contrast-Enhanced Breast MRI" *Eur J Radiol.* 2015 Dec; 84(12):2501-8. [Epub 2015 Oct 1].

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