

MammaCare® Clinical Breast Exam (CBE) Simulator-Trainer

Breast cancer screening by physical examination is widely performed but the common practice of CBE is deficient and erratic leading to more advanced cancers than necessary.¹ MammaCare® scientists and engineers in cooperation with Mayo Clinic colleagues responded to this critical health care need with a new, intelligent palpation training technology that teaches and measures breast examination skills.

MammaCare's CBE simulator is a compact, self-administered, palpation-training platform that emulates the recognized [quality-standard examination protocols](#). Named the P.A.D, for Palpation Training and Assessment Device, a patented sensor array "observes" and builds CBE essential performance skills through a series of training modules presented and controlled by a laptop computer. As pictured below in fig 1, clinician's fingers examine tactually accurate breast models as the CBE simulator program captures and monitors performance on the computer.

The simulator/trainer advances the clinician's sensitivity and specificity with progressively more complex MammaCare breast models that are placed on its surface. A digital "clinical instructor" guides the learner through training modules, assessing progress and providing corrective feedback. In operation, palpation of the breast models is detected by highly sensitive tactile transducers, received by digital signal processors, and interpreted by a software program that directs the practice and performance sequences.

The simulator's tactile transducers locate and register every palpation at over 1000 levels of examination pressure in each square centimeter of breast tissue within 3mm of spatial resolution. The instructional software modules log and interpret the sensitivity and specificity of the trainee's performance as they shape and confirm palpation and search skills. An installed ftp link enables examination performance data to be transmitted for analysis of CBE proficiency and skill certification.

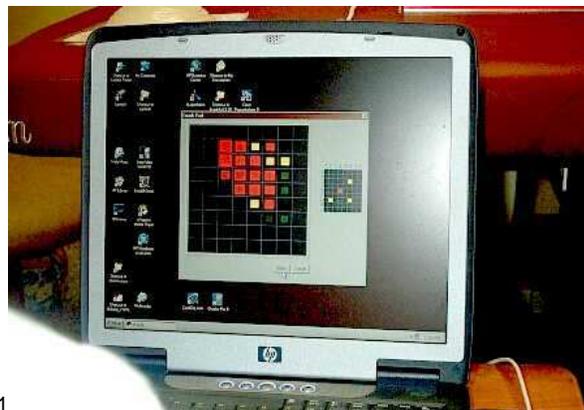


fig 1

The entire repertoire of essential examination skills including breast lesion detection, tissue coverage, search pattern completeness, and performance of the required range of palpation pressures is produced and recorded by the CBE simulator/trainer.

By quantifying human breast examination performance, we can conclude whether clinicians have (or have not) achieved required levels of breast palpation skill. Once the simulator/trainer confirms that foundation skills have been achieved, practice in vivo on patients or surrogates is vital to build further confidence and competence.

The MammaCare CBE simulator/trainer is the only known self-administered technology that quantifies and confirms acquisition of standardized breast examination palpation skills. The protocols embedded in the simulator/trainer's programs are acknowledged as the standards for clinical breast examination performance.²

1 "Weighted analysis indicated that physicians performed 198 million CBEs and made 110 million mammography recommendations over the study period (1996–2004)". *Breast cancer research and treatment*. Stephen, S., Venkatanaras, V., Electra, P., Rajesh, B., Volume 103, Number 1 / May, 2007, 53-59

2 Does this patient have breast cancer? The screening clinical breast examination: Should it be done? How? *Journal of the American Medical Association*, 283(13), 1270-1280. "MammaCare's standards for teaching and practicing effective CBE emerged from an extensive series of laboratory studies measuring lump detection and breast examination skills using tactually accurate breast models embedded with small simulated lesions" * Barton, M. B., Russell, H., Fletcher, S. W. (1999).

Recent evidence re: palpation:

Measuring performance in clinical breast examination. *Br J Surg*. 2010 [Aug;97\(8\):1246-52](#). Wishart G.C., Warwick J., Pitsinis V., Duffy S., Britton, P.D.. ("Performance measures ...could help to identify clinicians who have a lower sensitivity for CBE and who may therefore require feedback and further training." p1)

A significant number of women present with palpable breast cancer even with a normal mammogram within 1 year. [Am J. Surg 2010](#) Dec;200(6):712-7. Haakinson DJ, Stucky CC, Dueck A.C., Gray R.J., Wasif N, Apsey H.A., Pockaj B. ("Patients presenting with palpable masses on SBE or CBE even with a normal mammogram within 1 year tended to have more aggressive tumors... resulting in more aggressive therapy " abstract p1)

Palpable presentation of breast cancer persists in the era of screening mammography. [J Am Coll Surg. 2010](#) Mar;210(3):314-8. Mathis KL, Hoskin TL, Boughey JC, Crownhart BS, Brandt KR, Vachon CM, Grant CS, Degnim AAC. ("Patients with palpable presentation were younger than those with screen-detected cancer (mean age 57 versus 62 years..." abstract p1)

Discovery of breast cancers within 1 year of a normal screening mammogram: how are they found? [Ann Fam Med. 2006](#) Nov-Dec;4(6):512-8. Carney PA, Steiner E, Goodrich ME, Dietrich A.J., Kasales C.J., Weiss J.E., MacKenzie, T. ("Having a lump and both a personal and a family history of breast cancer was the most common reason why women initiated a health care visit." p1)

Self-Detection Remains a Key Method of Breast Cancer Detection for U.S. Women. [J Womens Health 2011](#) Jun 15. [Epub ahead of print] Roth M,Y., Elmore J.G., Yi-Frazier J.P., Reisch L.M., Oster N.V., Miglioretti D.L.. (*“Most women survivors (57%) reported a detection method other than mammographic examination.”* p1)

Tumor Characteristics Associated With Mammographic Detection of Breast Cancer in the Ontario Breast Screening Program. [J Natl Cancer Inst 2011](#).Jun 22;103(12):942-50. Epub 2011 May 3 Kirsh VA, Chiarelli AM, Edwards SA, O'Malley FP, Shumak RS , Yaffe MJ, Boyd, NF (*“...77% of these were true interval cancers, detected clinically in the 1–2 year interval between screening examinations...”* p4)

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