Framework for clinical validation of an AI-assisted portable breast cancer screening system

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Abstract

Background: Breast cancer remains one of the leading causes of cancer-related mortality among women worldwide. Early detection may substantially improve survival outcomes and support more equitable access to screening services. *Methods*: This study presents a framework for the clinical validation of an AI-assisted portable breast cancer screening system integrating artificial intelligence and standardized diagnostic features. *Results*: Initial validation demonstrated strong classification performance and supports the feasibility of integrating AI-assisted decision-support mechanisms into portable screening technologies. *Conclusion*: The proposed framework establishes a pathway toward responsible clinical translation of AI-assisted portable breast cancer screening technologies.

Background

Breast cancer remains one of the most frequently diagnosed cancers among women worldwide and continues to represent a major public health challenge. Early detection substantially improves survival outcomes and may reduce disparities in access to screening services.

Recent advances in artificial intelligence have highlighted the potential of AI-assisted diagnostic systems to support clinical decision-making and improve screening accessibility across diverse healthcare environments.

However, the clinical integration of AI-assisted technologies requires rigorous validation frameworks, methodological reproducibility, clinician supervision, and ethical oversight before real-world deployment.

Keywords

Translational Healthcare
AI Decision Support
Breast cancer screening
Equitable access

Purpose

- To develop a framework for the clinical validation of an AI-assisted portable breast cancer screening system.
- To evaluate initial classification performance using standardized diagnostic features and artificial intelligence.
- To support future clinician-supervised clinical translation in diverse healthcare settings.

Method

Component	Description
Dataset	Wisconsin Breast Cancer Diagnostic Dataset
Approach	Supervised machine learning classification
AI Model	Multi-layer perceptron neural network
Diagnostic Task	Benign vs malignant breast lesion classification
Preprocessing	Feature normalization and standardized data preparation
Validation Strategy	80/20 train-test split
Evaluation Metric	Classification accuracy

Clinical Validation Framework

Phase 1
Algorithmic Validation

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Phase 2
Portable Prototype Integration

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Phase 3
Clinician-Supervised Assessment

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Phase 4
Ethical Oversight and Evaluation

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Phase 5
Future Clinical Translation

Results & Translational Implications

98.25 % Initial Classification Accuracy

- Strong benign/malignant discrimination
- Stable classification performance
- Supports future clinician-supervised validation

Kelly et al. Lancet Digit Health, 2019
Erickson et al. Radiographics, 2017
Collins et al. BMJ, 2024
WHO Breast Cancer Fact Sheet, 2024