

## Online supplementary appendices

### Appendix 1 Search strategies

**Table 1. Summary of electronic database searches and dates**

Database	Platform	Searched on date	Date range of search	Update search
<b>MEDLINE, MEDLINE In-Process, MEDLINE Daily, Epub Ahead of Print</b>	Ovid SP	09 September 2020	2010 to Present	17 May 2021
<b>Embase</b>	Ovid SP	09 September 2020	2010 to 2020 Week 36	17 May 2021
<b>The Cochrane Library, including:</b> - <b>Cochrane Database of Systematic Reviews (CDSR)</b> - <b>Cochrane Central Register of Controlled Trials (CENTRAL)</b> - <b>Database of Abstracts of Reviews of Effects (DARE)</b>	Wiley Online	09 September 2020	January 2010 to September 2020	17 May 2021
<b>Web of Science</b>	Ovid SP	09 September 2020	2010 to 2020	17 May 2021

Database: Ovid MEDLINE(R) ALL <1946 to September 08, 2020>

Search Strategy:

- 
- 1 exp Breast Neoplasms/ (293428)
  - 2 (breast adj5 (cancer\* or neoplasm\* or tumor\* or tumour\* or carcino\* or malignan\* or disease\*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (394921)
  - 3 1 or 2 (395368)
  - 4 exp artificial intelligence/ or exp machine learning/ or exp deep learning/ or exp supervised machine learning/ or exp support vector machine/ or exp unsupervised machine learning/ (99304)
  - 5 ai.mp. (28888)
  - 6 ((artificial or machine or deep) adj5 (intelligence or learning or reasoning)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (70647)
  - 7 exp Neural Networks, Computer/ or exp Algorithms/ or neural network\*.mp. (354996)
  - 8 exp Diagnosis, Computer-Assisted/ (83632)
  - 9 4 or 5 or 6 or 7 or 8 (452038)
  - 10 3 and 9 (10492)
  - 11 exp Mammography/ (30025)
  - 12 mammogra\*.mp. (41086)
  - 13 screen\*.mp. or exp Mass Screening/ (844672)

14 exp "Early Detection of Cancer"/ or early detect\*.mp. (86182)  
15 11 or 12 or 13 or 14 (921015)  
16 10 and 15 (3324)  
17 exp "Sensitivity and Specificity"/ or sensitivity.mp. or specificity.mp. (1898406)  
18 exp "Predictive Value of Tests"/ (203774)  
19 exp roc curve/ or roc.mp. or receiver operating characteristic\*.mp. (119948)  
20 exp Area Under Curve/ or auc.mp. (96772)  
21 exp False Positive Reactions/ (27763)  
22 exp False Negative Reactions/ (17783)  
23 exp Observer Variation/ (42540)  
24 exp Diagnostic Errors/ (116740)  
25 (false adj4 (negativ\* or positiv\*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (100096)  
26 (true adj4 (positiv\* or negativ\*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (10701)  
27 likelihood ratio\*.mp. (15918)  
28 ((predict\* or test\*) adj1 (value\* or accura\* or error\*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (342222)  
29 exp Reproducibility of results/ (403133)  
30 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 (2397952)  
31 Randomized controlled trials as Topic/ (135939)  
32 Randomized controlled trial/ (512638)  
33 Random allocation/ (103549)  
34 Double blind method/ (159672)  
35 Single blind method/ (28987)  
36 Clinical trial/ (524613)  
37 exp Clinical Trials as Topic/ (345470)  
38 (clinic\$ adj trial\$1).tw. (373312)  
39 ((singl\$ or doubl\$ or treb\$ or tripl\$) adj (blind\$3 or mask\$3)).tw. (174345)  
40 Randomly allocated.tw. (29185)  
41 (allocated adj2 random).tw. (802)  
42 (test-treat trial\* or test treat trial\*).mp. (1)  
43 or/31-42 (1423959)  
44 30 or 43 (3676443)  
45 3 and 9 and 15 and 44 (2179)  
46 Case report.tw. (316143)  
47 Letter/ (1098543)  
48 Historical article/ (359991)  
49 Review of reported cases.pt. (0)  
50 Review, multicase.pt. (0)  
51 or/46-50 (1758549)  
52 45 not 51 (2164)  
53 30 or 52 (2398016)  
54 3 and 9 and 15 and 44 (2179)  
55 54 not 51 (2164)  
56 limit 55 to (english language and yr="2010 -Current") (1228)

Database: Embase <1980 to 2020 Week 36>

Search Strategy:

- 
- 1 exp breast tumor/ (522987)
  - 2 exp breast cancer/ (459643)
  - 3 (breast adj5 (neoplasm\* or cancer\* or tumor\* or tumour\* or malignanc\* or carcino\* or disease\*)).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (609633)
  - 4 or/1-3 (617527)
  - 5 exp artificial intelligence/ (41063)
  - 6 exp machine learning/ (215028)
  - 7 exp deep learning/ (9250)
  - 8 exp supervised machine learning/ (1511)
  - 9 exp support vector machine/ (22089)
  - 10 exp unsupervised machine learning/ (745)
  - 11 ai.mp. (37967)
  - 12 ((artificial or machine or deep) adj5 (intelliegence or learning or reasoning)).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (64514)
  - 13 exp artificial neural network/ or neural network\*.mp. (76598)
  - 14 exp algorithm/ (381894)
  - 15 exp computer assisted diagnosis/ (1123074)
  - 16 or/5-15 (1645988)
  - 17 exp mammography/ or mammogra\*.mp. (62455)
  - 18 screen\*.mp. (1308438)
  - 19 exp mass screening/ or exp screening/ (661930)
  - 20 exp early cancer diagnosis/ or early detect\*.mp. (97077)
  - 21 or/17-20 (1419229)
  - 22 exp "sensitivity and specificity"/ or sensitivity.mp. or specificity.mp. (1803827)
  - 23 exp reproducibility/ (217747)
  - 24 exp receiver operating characteristic/ or exp roc curve/ or roc.mp. (163201)
  - 25 exp predictive value/ or ((predict\* or test\*) adj1 (value\* or error\* or accura\*)).mp. (420596)
  - 26 auc.mp. or exp area under the curve/ (211311)
  - 27 exp false positive result/ (30242)
  - 28 exp false negative result/ (18705)
  - 29 exp observer variation/ (19992)
  - 30 exp diagnostic error/ (97269)
  - 31 (false adj4 (negativ\* or positiv\*)).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (120409)
  - 32 (true adj4 (positiv\* or negativ\*)).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (15519)
  - 33 likelihood ratio.mp. (16617)
  - 34 or/22-33 (2487428)
  - 35 clinical trial/ (971925)
  - 36 Randomized controlled trial/ (614311)
  - 37 Randomization/ (87593)
  - 38 Single blind procedure/ (40000)
  - 39 Double blind procedure/ (172538)
  - 40 Crossover procedure/ (64123)

41 Randomized controlled trial\$.tw. (236002)  
42 Rct.tw. (38207)  
43 Random allocation.tw. (2050)  
44 Randomly allocated.tw. (35853)  
45 Allocated randomly.tw. (2566)  
46 (allocated adj2 random).tw. (822)  
47 Single blind\$.tw. (25171)  
48 Double blind\$.tw. (204835)  
49 ((treble or triple) adj blind\$.tw. (1182)  
50 Prospective study/ (622435)  
51 (test-treat trial\* or test treat trial\*).mp. (2)  
52 or/35-51 (2076152)  
53 34 or 52 (4332240)  
54 Case study/ (71546)  
55 Case report.tw. (410369)  
56 Abstract report/ or letter/ (1114503)  
57 or/54-56 (1585513)  
58 53 not 57 (4229367)  
59 4 and 16 and 21 and 58 (5034)  
60 limit 59 to (english language and yr="2010 -Current") (3562)  
61 limit 60 to (article or article in press or "review") (2808)

Database: Web of Science (Ovid SP)

# 5	881	#4 AND #3 AND #2 AND #1 <i>Indexes=SCI-EXPANDED, SSCI Timespan=2010-2020</i>
# 4	1,576,497	TS=("sensitivity and specificity" or sensitivity or specificity or ((predict* or test*) NEAR/1 (value* or error* or accura* ) or roc or "receiver operating characteristic" or auc or "area under curve" or "observer variation" or "diagnostic error*") OR TS=(false NEAR/4 (negativ* or positiv* ) ) OR TS=(true NEAR/4 (negativ* or positiv* ) ) OR TS=("likelihood ratio*" or reproducibility) OR TS=(rct* or "randomi?ed controlled trial*" or "random allocat*" or "double blind*" or "single blind*" or "clinical trial*" or "test treat trial*" or "test-treat trial*") OR TS=((singl* or doubl* or treb* or tripl*) NEAR/1 (blind* or mask* ) ) OR TS=((random*) Near/2 (allocat* ) ) <i>Indexes=SCI-EXPANDED, SSCI Timespan=2010-2020</i>
# 3	538,555	TOPIC: (mammogra* or screen* or "early detect*") <i>Indexes=SCI-EXPANDED, SSCI Timespan=2010-2020</i>
# 2	895,801	TOPIC: ("artificial intelligence" or "machine learning" or "deep learning" or "support vector machine*" or ai) OR TOPIC: ((artificial or machine or deep) Near/5 (intelligence or learning or reasoning) ) OR TOPIC: ("neural network*" or algorithm*) OR TOPIC: (diagnosis NEAR/3 computer*) <i>Indexes=SCI-EXPANDED, SSCI Timespan=2010-2020</i>
# 1	306,059	TS=((breast) NEAR/5 (neoplasm* or cancer* or tumor* or tumour* or malignan* or carcino* or disease* ) ) <i>Indexes=SCI-EXPANDED, SSCI Timespan=2010-2020</i>

Database: Cochrane Library (CENTRAL) (Wiley online)

Search Name: AI and Breast Cancer

Last Saved: 09/09/2020 14:10:48

Comment: Numbers for individual search lines are not captured by the saved search strategy.

- ID Search
- #1 MeSH descriptor: [Breast Neoplasms] explode all trees
- #2 ((breast NEAR/5 (cancer\* or neoplasm\* or carcino\* or malignan\* or tumor\* or tumour\* or disease\*))) :ti,ab,kw
- #3 #1 or #2
- #4 MeSH descriptor: [Artificial Intelligence] explode all trees
- #5 MeSH descriptor: [Machine Learning] explode all trees
- #6 MeSH descriptor: [Deep Learning] explode all trees
- #7 MeSH descriptor: [Supervised Machine Learning] explode all trees
- #8 MeSH descriptor: [Support Vector Machine] explode all trees
- #9 MeSH descriptor: [Unsupervised Machine Learning] explode all trees
- #10 (ai):ti,ab,kw
- #11 ((artificial or machine or deep) NEAR/5 (intelligence or learning or reasoning)):ti,ab,kw
- #12 MeSH descriptor: [Neural Networks, Computer] explode all trees
- #13 MeSH descriptor: [Algorithms] explode all trees
- #14 (neural network\*):ti,ab,kw
- #15 MeSH descriptor: [Diagnosis, Computer-Assisted] explode all trees
- #16 #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15
- #17 MeSH descriptor: [Mammography] explode all trees
- #18 (mammogra\*):ti,ab,kw
- #19 MeSH descriptor: [Mass Screening] explode all trees
- #20 (screen\*):ti,ab,kw
- #21 MeSH descriptor: [Early Detection of Cancer] explode all trees
- #22 (early detect\*):ti,ab,kw
- #23 #17 or #18 or #19 or #20 or #21 or #22
- #24 #3 and #16 and #23
- #25 MeSH descriptor: [Sensitivity and Specificity] explode all trees
- #26 (sensitivity or specificity):ti,ab,kw
- #27 MeSH descriptor: [Predictive Value of Tests] explode all trees
- #28 MeSH descriptor: [ROC Curve] explode all trees
- #29 (roc or "receiver operating characteristic"):ti,ab,kw
- #30 MeSH descriptor: [Area Under Curve] explode all trees

#31 (auc):ti,ab,kw  
#32 MeSH descriptor: [False Positive Reactions] explode all trees  
#33 MeSH descriptor: [False Negative Reactions] explode all trees  
#34 MeSH descriptor: [Observer Variation] explode all trees  
#35 MeSH descriptor: [Diagnostic Errors] explode all trees  
#36 (false NEAR/4 (negativ\* or positiv\*)):ti,ab,kw  
#37 (true NEAR/4 (positiv\* or negativ\*)):ti,ab,kw  
#38 (likelihood ratio\*):ti,ab,kw  
#39 ((predict\* or test\*) NEAR/1 (value\* or accura\* or error\*)):ti,ab,kw  
#40 MeSH descriptor: [Reproducibility of Results] explode all trees  
#41 #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or  
#38 or #39 or #40  
#42 #24 and #41

## Appendix 2 QUADAS-2

Item	Response
<b>PARTICIPANT SELECTION - A. RISK OF BIAS</b>	
Was a consecutive or random sample of patients enrolled?	<p><b>Yes</b> - RCTs and cohort studies (prospective or retrospective) with unenriched (consecutive or random) sampling</p> <p><b>Unclear</b> - If not stated</p> <p><b>No</b> - other studies</p>
Did the study avoid inappropriate exclusions?	<p><b>Yes</b> – If inappropriate exclusions were avoided</p> <p><b>Unclear</b> – if not clearly reported</p> <p><b>No</b> - Exclusion of more than 10% of the samples for any reason, for example retrospective studies with missing data</p> <p><b>No</b> - Systematic exclusion of types of women / images (e.g. of dense breasts)</p> <p><b>No</b> - Exclusion based on outcomes (e.g. exclusion of cancer types, exclusion of interval cancers, exclusion/inclusion based on recall decision)</p>
Were the women and mammograms included in the study independent of those used to train the AI algorithm?	<p>For test set studies, this translates as has the test set been clearly described as an external (geographically) validation set?</p> <p><b>No</b> - Any internal validation (e.g. split sample, cross-validation) or temporal validation</p> <p><b>Unclear</b> - No details stated about the training set and tuning set</p> <p><b>Yes</b> - External geographical validation (Test set was sample from a different centre; can be in another country or the same country)</p> <p>For prospective applied studies in a clinical context:</p> <p><b>Yes</b> - If the study is located at different centre(s) to those who provided mammograms used to train and tune the AI algorithm</p> <p><b>Unclear</b> - If not stated</p> <p><b>No</b> - If there is any overlap</p>
<b>PARTICIPANT SELECTION - B. CONCERNS REGARDING APPLICABILITY</b>	
Is there concern that the included patients do not match the review question?	<p><b>High</b> - If 'yes' for any of the following statements</p> <p><b>Unclear</b> - If no details are provided</p> <p><b>Low</b> - If 'no' for all the following statements</p> <ul style="list-style-type: none"> <li>• Not a consecutive or random sample of women attending screening;</li> <li>• Enriched sample / cancer prevalence doesn't match screening context (&gt;3%);</li> <li>• Mammograms not from full-field digital mammography;</li> <li>• Mammograms not from screening (e.g. diagnostic or symptomatic) or only subset such as recalled cases or false-negatives included</li> </ul>

	<p>(cancer might be easier or more difficult to detect);</p> <ul style="list-style-type: none"> <li>• Women/women’s mammograms not representative of UK population (ethnicity, age)</li> </ul>
<b>INDEX TESTS – A. RISK OF BIAS</b>	
Were the index test results interpreted without knowledge of the results of the reference standard?	<p>For index tests where a human is involved (either human read comparator, AI as reader aid, or included otherwise on the AI testing pathway, e.g. arbitration):</p> <p><b>Yes</b> - Require clear statement of blinding, or clear temporal relationships where the human read occurred before the reference standard</p> <p><b>No</b> - Otherwise</p> <p>For index test where AI is used without any human element:</p> <p><b>Yes</b> - AI system has not previously been trained on these mammograms or learned from these mammograms or other mammograms from the same women</p> <p><b>No</b> - If any repeat use of the same cases then (unless explicit that the AI algorithm was pre-set and did not change upon repeat use, and the study did not select one of several AI systems based on use with the same cases)</p> <p><b>Unclear</b> - If not explicit that there has been no repeat within same or previous studies</p>
Were the index test results interpreted without knowledge of the results of any other index tests?	<p><b>No</b> - If human readers were not blinded to AI (unless that AI is specifically part of the same index test)</p> <p><b>No</b> - If AI systems are trained or calibrated using decisions from human readers in same cases</p> <p><b>Yes</b> - Otherwise</p>
If a threshold was used, was it pre-specified?	<p><b>Yes</b> - If using a commercially available AI system which gives a yes/no result, or threshold clearly pre-specified in methods</p> <p><b>Yes</b> - For systems giving a risk score and study explicitly states the pre-specified threshold</p> <p><b>No</b> - Using sensitivity / specificity of the reader as benchmark using the same dataset</p> <p><b>No</b> - Setting the threshold with the validation set without temporal evidence (e.g. published protocol) that threshold was truly pre-specified</p> <p><b>NA</b> - Human readers or human/AI combinations</p>
Where human readers are part of the test, were their decisions made in a clinical practice context? (i.e. avoidance of the laboratory effect)	<p><b>Yes</b> - If the readers made decisions in the clinical context, and those decisions were used to decide whether to recall women (either prospectively as part of a trial or test accuracy study or retrospective studies using the original decision)</p> <p><b>No</b> - If readers examined a test set (of any prevalence) outside clinical practice, or any other context likely to result in the laboratory effect<sup>1</sup></p>



<b>INDEX TESTS - B. CONCERNS REGARDING APPLICABILITY</b>	
Is there concern that the index test(s) or comparator, its conduct, or interpretation differ from the review question?	<p><b>High</b> - If 'yes' for any of the following</p> <p><b>Unclear</b> – If no details are provided</p> <p><b>Low</b> - If 'no' for all of the following</p> <ul style="list-style-type: none"> <li>• AI system not yet commercially available, e.g. in house systems;</li> <li>• Study did not use a pre-specified threshold for AI system;</li> <li>• Not a complete testing pathway applicable to clinical practice (for example AI accuracy for single read, but not integrated into screening centre decisions, e.g. arbitration);</li> <li>• Human comparator not a complete testing pathway applicable to clinical practice (human double reading with arbitration at clinical threshold);</li> <li>• AI system / reader had no access to prior mammograms / not 4 views available</li> </ul>
<b>REFERENCE STANDARD – A. RISK OF BIAS</b>	
Is the reference standard likely to correctly classify the target condition?	<p><b>Yes</b> - If the reference standard is histopathology results from biopsy (cancer present or absent) with at least 2 years follow up to interval cancers</p> <p><b>No</b> - If the reference standard is histopathology results from biopsy (cancer present or absent) with no follow up</p>
Were the reference standard results interpreted without knowledge of the results of the index test?	<p><b>Yes</b> - Retrospective studies where readers read mammograms prospectively (enriched test sets)</p> <p><b>No</b> - For retrospective studies (if we include the human reader comparator as an index test)</p> <p><b>No</b> - For prospective studies if the investigators did not blind the clinicians undertaking the follow up tests to which index test examined the mammograms, for example by putting location marks in the same format for AI and human readers</p>
<b>REFERENCE STANDARD - B. CONCERNS REGARDING APPLICABILITY</b>	
Is there concern that the target condition as defined by the reference standard does not match the review question?	<p><b>High</b> - If 'yes' for any of the following</p> <p><b>Unclear</b> - If no details are provided</p> <p><b>Low</b> - If 'no' for all of the following</p> <ul style="list-style-type: none"> <li>• Length of screening rounds &lt;2 years for follow-up / definition of interval cancers;</li> <li>• Classification not by biopsy/follow-up</li> </ul>
<b>FLOW AND TIMING – A. RISK OF BIAS</b>	
Did all patients receive a reference standard?	<p><b>No</b> - If there was significant (&gt;10%) loss to follow up for reference standards of interval cancers or subsequent screening results</p> <p><b>No</b> - If any women who should have received a biopsy or follow-up tests after index test positive results did not receive one or results were unavailable</p> <p><b>Yes</b> - otherwise</p>

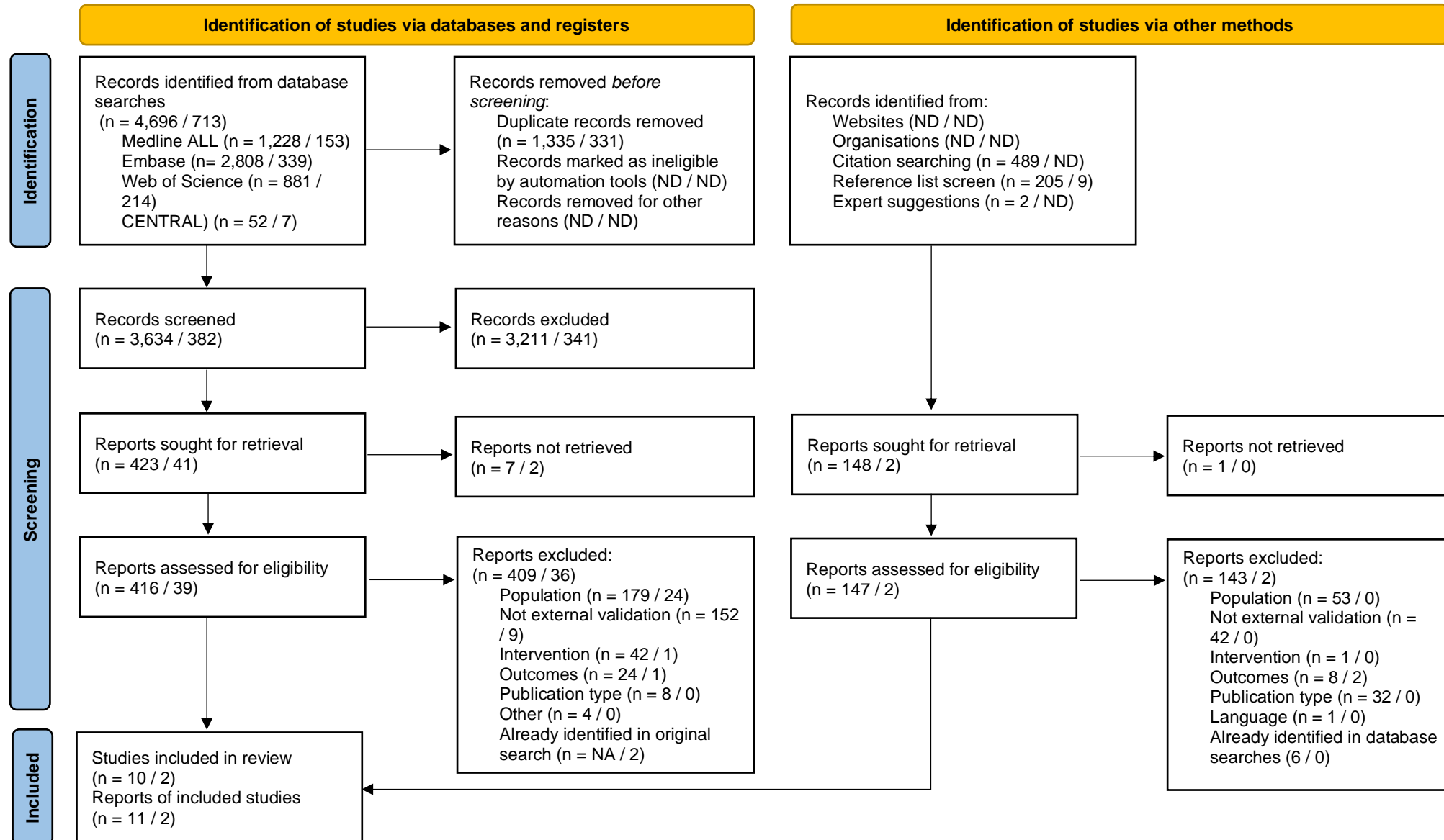
<p>Did the study avoid choosing which reference standard based on results of just one of the index tests? (All studies will necessarily have differential verification, because not all women can or should be biopsied. Here we are measuring whether deciding which reference standard is received based on results of just one of the index tests is avoided.)</p>	<p><b>Yes</b> - For test-treat RCTs randomizing to different test strategies and their associated recall decisions</p> <p><b>Yes</b> - If women testing positive in any of the included index tests (AI pathways or comparator human pathways) all receive follow up tests/biopsy in a prospective study</p> <p><b>No</b> - If women were recalled for further tests on the basis of one of the index tests, and not other(s) then this will cause bias because cancer, when present, is more likely to be found if the person receives follow-up tests after recall from screening</p> <p><b>No</b> - In retrospective studies, the decision whether to recall for follow-up tests/biopsy was made on the basis of the human readers' decision. We do not know whether AI positive, human reader negative women are false positive or true positive, and what type of true positive. Follow-up to development of interval cancers will detect some, but not all of these cancers, so reduces, but does not eliminate this bias</p> <p><b>No</b> - For prospective studies where decision to recall is informed by one index test but not all, or is more influenced by one index test than others</p> <p><b>Unclear</b> - Retrospective reader studies (enriched test set studies) in which readers prospectively read retrospective data, the reference standard is not based on any index test but the reference standard is based on the original human reader decision. The reviewers are unclear about the risk of bias.</p>
<p>Were all patients included in the analysis?</p>	<p><b>Yes</b> - If there were any exclusions after the point of selecting the cohort, for example intermediate or indeterminate results</p> <p><b>No</b> - Otherwise</p>

#### References for Appendix 4

1. Gur D, Bandos AI, Cohen CS, et al. The "laboratory" effect: comparing radiologists' performance and variability during prospective clinical and laboratory mammography interpretations. *Radiology* 2008;249(1):47-53. doi: 10.1148/radiol.2491072025 [published Online First: 2008/08/07]

**Supplementary Figure 1. PRISMA diagram. Summary of publications included and excluded at each stage of the review (original searches / update searches)**

FFDM, Full field digital mammogram; NA, Not applicable; ND, Not done



## **Appendix 3 Publications and sub-studies excluded after review of full-text articles**

### **Key to reasons for exclusions and justifications**

**Population – Image type:** Studies evaluating AI on image types other than full field digital mammography (FFDM) (mainly digitised film images). Screening mammography is typically undertaken using FFDM in women attending breast screening. Other imaging techniques not classed as mammography or not digital are not relevant. Results from imaging other than FFDM may not be applicable to FFDM in screening programmes.

**Population – Mammography type not reported:** Studies evaluating AI on image types which were not clearly identified as FFDM. Screening mammography is typically undertaken using full field digital mammography (FFDM) in women attending breast screening. Other imaging techniques not classed as mammography or not digital are not relevant. Results from imaging other than FFDM may not be applicable to FFDM in screening programmes.

**Population – Incomplete images:** Studies evaluating AI using regions of interest (ROIs) of images. Images of part of a mammogram do not represent the use case in the screening context, which requires recall or not decisions to be made on women's (craniocaudal and mediolateral oblique) screening mammograms for both breasts.

**Population – Subpopulation:** Studies only including images with cancer. These are not sufficient to estimate test accuracy of AI for screening mammograms, as it excludes specificity, and the trade-off between sensitivity and specificity. Studies on images of subpopulations by screening risk or screening outcome. They do not represent the screening population and no inference on the performance of the AI system in a screening population can be drawn (however, subpopulations by ethnicity or socioeconomic status are included as the impact of any change on equity is important). This does not apply to populations which represent a group of women at any stage within the screening pathway (e.g. recalled women without selection on final diagnosis) on the assumption that AI could be incorporated for this subgroup only.

**Population – <90% screening mammograms or unclear proportion:** Studies on images of diagnostic mammograms, with >10% diagnostic mammograms or an unclear proportion of diagnostic mammograms. These do not represent the use case in the screening context.

**Internal validation – Cross validation, Leave-one out, Split sample:** Studies using internal validation whereby the validation dataset used to assess a model uses data which were used to develop that model. Cross validation and leave-one out are resampling techniques which use the original data to assist with preliminary assessment and fine-tuning of the model during validation. The issue of using data on which an algorithm was trained with is that models can be prone to overfitting; whereby the model fits the trained data extremely well, but to the detriment of the model's ability to perform when presented with new data, which is known as poor generalization. The split-sample approach is generally an

inefficient form of internal validation because it does not accurately reflect a model's generalisability.

**Intervention – Detecting subtypes:** Studies using AI to detect cancer subtypes such as microcalcifications or architectural distortions only. The detection of cancer subtypes does not present the complete picture of cancer detection (e.g. microcalcifications are associated mainly with DCIS and not with cancer; detecting microcalcifications only will miss some types of cancers). On their own, these AI systems do not provide the information on cancer present/ not present to inform a decision whether to recall or not recall. Systems reporting single features could be combined to provide a more complete picture, however, studies would need to report an overall outcome of test accuracy of the combination of systems.

**Intervention – No detection/classification:** Studies using AI for lesion enhancement or segmentation of pectoral muscle regions. These studies do not report on the classification of images into recall or no recall and are uninformative in terms of test performance of AI.

**Intervention – Not AI:** Studies using traditional computer aided detection without machine learning features for the detection of lesions in images. In AI the layers of features are not designed by human expertise; instead they are learnt from the underlying data. Therefore, studies reporting the test accuracy and effectiveness of traditional CAD systems were considered significantly different from studies assessing machine learning AI systems.

**Intervention – Prediction of cancer:** Studies using AI for the prediction of future cancer risk including the detection of breast density and parenchymal patterns as risk factors. These studies did not consider the detection of cancer present on screening mammograms.

**No relevant outcomes:** Studies reporting accuracy without outcomes characterising the trade-off between false positive and false negative results including global measures such as the area under the curve (AUC). The trade-off between false positive and false negative results is critical to test accuracy.

**Study type – Systematic reviews with no relevant outcomes:** Studies reporting systematic reviews that were off topic and did not provide additional references for the review.

**Document Supply cancelled request: no location found:** Studies unavailable following internet searches, contacting authors and pursuing interlibrary requests.

## Publications excluded with reason – Original database searches

Reference	Main reason for exclusion
<b>Population – Image type (e.g. digitised film images; not FFDM images) (n=150)</b>	
1. Abbas Q, Fondo'n I, Celebi E. A Computerized System for Detection of Spiculated Margins based on Mammography. International Arab Journal of Information Technology. 2015;12(6):582-8.	Population – Image type
2. Agnes SA, Anitha J, Pandian SIA, Peter JD. Classification of Mammogram Images Using Multiscale all Convolutional Neural Network (MA-CNN). J Med Syst. 2019;44(1):30.	Population – Image type
3. Anitha J, Dinesh Peter J, Immanuel Alex Pandian S. A dual stage adaptive thresholding (DuSAT) for automatic mass detection in mammograms. Computer Methods and Programs in Biomedicine. 2017;138:93-104.	Population – Image type
4. Bartolotta TV, Orlando A, Cantisani V, Matranga D, Ienzi R, Cirino A, et al. Focal breast lesion characterization according to the BI-RADS US lexicon: role of a computer-aided decision-making support. La Radiologia medica. 2018;123(7):498-506.	Population – Image type
5. Beheshti SM, AhmadiNoubari H, Fatemizadeh E, Khalili M. An efficient fractal method for detection and diagnosis of breast masses in mammograms. J Digit Imaging. 2014;27(5):661-9.	Population – Image type
6. Chakraborty J, Midya A, Mukhopadhyay S, Rangayyan RM, Sadhu A, Singla V, et al. Computer-Aided Detection of Mammographic Masses Using Hybrid Region Growing Controlled by Multilevel Thresholding. Journal of Medical and Biological Engineering. 2019;39(3):352-66.	Population – Image type
7. Chithra Devi M, Audithan S. Analysis of different types of entropy measures for breast cancer diagnosis using ensemble classification. Biomedical Research (India). 2017;28(7):3182-6.	Population – Image type
8. Choi JY, Ro YM. Multiresolution local binary pattern texture analysis combined with variable selection for application to false-positive reduction in computer-aided detection of breast masses on mammograms. Phys Med Biol. 2012;57(21):7029-52.	Population – Image type
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Reference	Main reason for exclusion
10. Chowdhary CL, Mittal M, P K, Pattanaik PA, Marszalek Z. An Efficient Segmentation and Classification System in Medical Images Using Intuitionist Possibilistic Fuzzy C-Mean Clustering and Fuzzy SVM Algorithm. <i>Sensors (Basel)</i> . 2020;20(14):13.	Population – Image type
11. Cunningham CA, Drew T, Wolfe JM. Analog Computer-Aided Detection (CAD) information can be more effective than binary marks. <i>Atten Percept Psychophys</i> . 2017;79(2):679-90.	Population – Image type
12. de Oliveira Silva LC, Barros AK, Lopes MV. Detecting masses in dense breast using independent component analysis. <i>Artif Intell Med</i> . 2017;80:29-38.	Population – Image type
13. Dheeba J, Albert Singh N, Tamil Selvi S. Computer-aided detection of breast cancer on mammograms: a swarm intelligence optimized wavelet neural network approach. <i>J Biomed Inform</i> . 2014;49:45-52.	Population – Image type
14. Dheeba J, Jaya T, Singh NA. Breast cancer risk assessment and diagnosis model using fuzzy support vector machine based expert system. <i>Journal of Experimental &amp; Theoretical Artificial Intelligence</i> . 2017;29(5):1011-21.	Population – Image type
15. Dheeba J, Tamil Selvi S. An improved decision support system for detection of lesions in mammograms using Differential Evolution Optimized Wavelet Neural Network. <i>J Med Syst</i> . 2012;36(5):3223-32.	Population – Image type
16. Dubey AK, Gupta U, Jain S. Analysis of k-means clustering approach on the breast cancer Wisconsin dataset. <i>Int</i> . 2016;11(11):2033-47.	Population – Image type
17. El Fahssi K, Elmoufidi A, Abenaou A, Jai-Andaloussi S, Sekkaki A. Novel approach to classification of Abnormalities in the mammogram image. <i>International Journal of Biology and Biomedical Engineering</i> . 2016;10:72-9.	Population – Image type
18. El-Shazli AMA, Youssef SM, Elshennawy M. Computer-aided model for breast cancer detection in mammograms. <i>International Journal of Pharmacy and Pharmaceutical Sciences</i> . 2016;8(Supplement 2):31-4.	Population – Image type
19. Elmoufidi A, El Fahssi K, Jai-andaloussi S, Sekkaki A, Gwenole Q, Lamard M. Anomaly classification in digital mammography based on multiple-instance learning. <i>let Image Processing</i> . 2018;12(3):320-8.	Population – Image type
20. Eltoukhy MM, Faye I, Samir BB. Breast cancer diagnosis in digital mammogram using multiscale curvelet transform. <i>Comput Med Imaging Graph</i> . 2010;34(4):269-76.	Population – Image type

Reference	Main reason for exclusion
21. Ericeira DR, Silva AC, de Paiva AC, Gattass M. Detection of masses based on asymmetric regions of digital bilateral mammograms using spatial description with variogram and cross-variogram functions. <i>Comput Biol Med.</i> 2013;43(8):987-99.	Population – Image type
22. Ganesan K, Acharya RU, Chua CK, Min LC, Mathew B, Thomas AK. Decision support system for breast cancer detection using mammograms. <i>Proc Inst Mech Eng [H].</i> 2013;227(7):721-32.	Population – Image type
23. Garma FB, Hassan MA. Classification of breast tissue as normal or abnormal based on texture analysis of digital mammogram. <i>Journal of Medical Imaging and Health Informatics.</i> 2014;4(5):647-53.	Population – Image type
24. Gedik N. Breast cancer diagnosis system via contourlet transform with sharp frequency localization and least squares support vector machines. <i>Journal of Medical Imaging and Health Informatics.</i> 2015;5(3):497-505.	Population – Image type
25. Gedik N, Atasoy A. Performance evaluation of the wave atom algorithm to classify mammographic images. <i>Turkish Journal of Electrical Engineering and Computer Sciences.</i> 2014;22(4):957-69.	Population – Image type
26. Gedik N, Atasoy A, Sevim Y. Investigation of wave atom transform by using the classification of mammograms. <i>Applied Soft Computing.</i> 2016;43:546-52.	Population – Image type
27. Gorgel P, Sertbas A, Ucan ON. Mammographical mass detection and classification using Local Seed Region Growing-Spherical Wavelet Transform (LSRG-SWT) hybrid scheme. <i>Computers in Biology and Medicine.</i> 2013;43(6):765-74.	Population – Image type
28. Guan JS, Lin LY, Ji GL, Lin CM, Le TL, Rudas IJ. Breast Tumor Computer-aided Diagnosis using Self-Validating Cerebellar Model Neural Networks. <i>Acta Polytechnica Hungarica.</i> 2016;13(4):39-52.	Population – Image type
29. Hu K, Gao XP, Li F. Detection of Suspicious Lesions by Adaptive Thresholding Based on Multiresolution Analysis in Mammograms. <i>Ieee Transactions on Instrumentation and Measurement.</i> 2011;60(2):462-72.	Population – Image type
30. James JJ, Gilbert FJ, Wallis MG, Gillan MG, Astley SM, Boggis CR, et al. Mammographic features of breast cancers at single reading with computer-aided detection and at double reading in a large multicenter prospective trial of computer-aided detection: CADET II. <i>Radiology.</i> 2010;256(2):379-86.	Population – Image type



Reference	Main reason for exclusion
31. Jebamony J, Jacob D. Classification of Benign and Malignant Breast Masses on Mammograms for Large Datasets using Core Vector Machines. <i>Curr Med Imaging</i> . 2020;16(6):703-10.	Population – Image type
32. Kadam VJ, Jadhav SM, Vijayakumar K. Breast Cancer Diagnosis Using Feature Ensemble Learning Based on Stacked Sparse Autoencoders and Softmax Regression. <i>J Med Syst</i> . 2019;43(8):263.	Population – Image type
33. Kanadam KP, Cheretty SR. Mammogram classification using sparse-ROI: A novel representation to arbitrary shaped masses. <i>Expert Systems with Applications</i> . 2016;57:204-13.	Population – Image type
34. Kanchana M, Varalakshmi P. Computer aided system for breast cancer in digitized mammogram using shearlet band features with LS-SVM classifier. <i>International Journal of Wavelets Multiresolution and Information Processing</i> . 2016;14(3).	Population – Image type
35. Kanchanamani M, Perumal V. Performance evaluation and comparative analysis of various machine learning techniques for diagnosis of breast cancer. <i>Biomedical Research (India)</i> . 2016;27(3):623-31.	Population – Image type
36. Kashyap KL, Bajpai MK, Khanna P. Globally supported radial basis function based collocation method for evolution of level set in mass segmentation using mammograms. <i>Comput Biol Med</i> . 2017;87:22-37.	Population – Image type
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47. Lo CM, Moon WK, Huang CS, Chen JH, Yang MC, Chang RF. INTENSITY-INVARIANT TEXTURE ANALYSIS FOR CLASSIFICATION OF BI-RADS CATEGORY 3 BREAST MASSES. Ultrasound in Medicine and Biology. 2015;41(7):2039-48.	Population – Image type
48. Onan A. A stochastic gradient descent based SVM with fuzzy-rough feature selection and instance selection for breast cancer diagnosis. Journal of Medical Imaging and Health Informatics. 2015;5(6):1233-9.	Population – Image type
49. Singh WJ, Nagarajan B. Automatic diagnosis of mammographic abnormalities based on hybrid features with learning classifier. Comput Methods Biomech Biomed Engin. 2013;16(7):758-67.	Population – Image type
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51. Liu X, Zeng Z. A new automatic mass detection method for breast cancer with false positive reduction. Neurocomputing. 2015;152:388-402.	Population – Image type

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52. Liu XM, Tang JS. Mass Classification in Mammograms Using Selected Geometry and Texture Features, and a New SVM-Based Feature Selection Method. <i>Ieee Systems Journal</i> . 2014;8(3):910-20.	Population – Image type
53. Liu XM, Zhai LL, Zhu T, Liu J, Zhang K, Hu W. Multiple TBSVM-RFE for the detection of architectural distortion in mammographic images. <i>Multimedia Tools and Applications</i> . 2018;77(12):15773-802.	Population – Image type
54. Mahersia H, Boulehmi H, Hamrouni K. Development of intelligent systems based on Bayesian regularization network and neuro-fuzzy models for mass detection in mammograms: A comparative analysis. <i>Comput Methods Programs Biomed</i> . 2016;126:46-62.	Population – Image type
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58. Milosevic M, Jovanovic Z, Jankovic D. A comparison of methods for three-class mammograms classification. <i>Technol Health Care</i> . 2017;25(4):657-70.	Population – Image type
59. Mohammadi-Sardo S, Labibi F, Shafiei SA. A new approach for detecting abnormalities in mammograms using a computer-aided windowing system based on Otsu's method. <i>Radiol Phys Technol</i> . 2019;12(2):178-84.	Population – Image type
60. Mohammed SHA, Yousuf SEK. A computer-aided diagnosis system for the detection and classification of breast cancer. <i>Journal of Clinical Engineering</i> . 2016;41(2):97-100.	Population – Image type
61. Mohammed SHAA, Mustafa ZA. Breast Tumors Classification Using Adaptive Neuro-Fuzzy Inference System. <i>Journal of Clinical Engineering</i> . 2017;42(2):68-72.	Population – Image type
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Reference	Main reason for exclusion
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65. Mohanty F, Rup S, Dash B, Majhi B, Swamy MNS. An improved scheme for digital mammogram classification using weighted chaotic salp swarm algorithm-based kernel extreme learning machine. Applied Soft Computing. 2020;91.	Population – Image type
66. Mohanty F, Rup S, Dash B, Majhi B, Swamy MNS. Digital mammogram classification using 2D-BDWT and GLCM features with FOA-based feature selection approach. Neural Computing & Applications. 2020;32(11):7029-43.	Population – Image type
67. Moslemi H, Kazerouni IA, Hourali F. Breast cancer diagnosis in mammogram images using coordinate logic filters. Biomedical Research (India). 2017;28(22):10108-11.	Population – Image type
68. Muduli D, Dash R, Majhi B. Automated breast cancer detection in digital mammograms: A moth flame optimization based ELM approach. Biomedical Signal Processing and Control. 2020;59 (no pagination).	Population – Image type
69. Mughal B, Muhammad N, Sharif M. Adaptive hysteresis thresholding segmentation technique for localizing the breast masses in the curve stitching domain. Int J Med Inf. 2019;126:26-34.	Population – Image type
70. Nagarajan V, Britto EC, Veeraputhiran SM. Feature extraction based on empirical mode decomposition for automatic mass classification of mammogram images. Medicine in Novel Technology and Devices. 2019;1 (no pagination).	Population – Image type
71. Nagthane DK, Rajurkar AM. An improved diagnosis technique for breast cancer using LCFS and TreeHiCARE classifier model. Sensor Review. 2019;39(1):107-20.	Population – Image type
72. Nanni L, Brahnam S, Lumini A. A very high performing system to discriminate tissues in mammograms as benign and malignant. Expert Systems with Applications. 2012;39(2):1968-71.	Population – Image type
73. Narvaez F, Alvarez J, Garcia-Arteaga JD, Tarquino J, Romero E. Characterizing Architectural Distortion in Mammograms by Linear Saliency. J Med Syst. 2017;41(2):26.	Population – Image type

Reference	Main reason for exclusion
74. Naseem MT, Sulong GZB, Jaffar MA. MRT letter: Quantum noise removal and classification of breast mammogram images. <i>Microscopy Research and Technique</i> . 2012;75(12):1609-12.	Population – Image type
75. Naveed N, Jaffar MA, Choi TS. MRT Letter: Segmentation and Texture-Based Classification of Breast Mammogram Images. <i>Microscopy Research and Technique</i> . 2011;74(11):985-7.	Population – Image type
76. Neto OPS, Silva AC, Paiva AC, Gattass M. Automatic mass detection in mammography images using particle swarm optimization and functional diversity indexes. <i>Multimedia Tools and Applications</i> . 2017;76(18):19263-89.	Population – Image type
77. Nishikawa RM, Schmidt RA, Linver MN, Edwards AV, Papaioannou J, Stull MA. Clinically missed cancer: how effectively can radiologists use computer-aided detection? <i>AJR Am J Roentgenol</i> . 2012;198(3):708-16.	Population – Image type
78. Nugroho HA, Fajrin HR, Soesanti I, Budiani RL. Analysis of texture for classification of breast cancer on mammogram images. <i>International Journal of Medical Engineering and Informatics</i> . 2018;10(4):382-91.	Population – Image type
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80. Pak F, Kanan HR, Alikhassi A. Breast cancer detection and classification in digital mammography based on Non-Subsampled Contourlet Transform (NSCT) and Super Resolution. <i>Comput Methods Programs Biomed</i> . 2015;122(2):89-107.	Population – Image type
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82. Paquerault S, Hardy PT, Wersto N, Chen J, Smith RC. Investigation of optimal use of computer-aided detection systems: the role of the "machine" in decision making process. <i>Acad Radiol</i> . 2010;17(9):1112-21.	Population – Image type
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Reference	Main reason for exclusion
85. Patel BC, Sinha GR, Soni D. Detection of masses in mammographic breast cancer images using modified histogram based adaptive thresholding (MHAT) method. International Journal of Biomedical Engineering and Technology. 2019;29(2):134-54.	Population – Image type
86. Pawar MM, Talbar SN, Dudhane A. Local Binary Patterns Descriptor Based on Sparse Curvelet Coefficients for False-Positive Reduction in Mammograms. J. 2018;2018:5940436.	Population – Image type
87. Perre AC, Alexandre LA, Freire LC. Lesion classification in mammograms using convolutional neural networks and transfer learning. Computer Methods in Biomechanics and Biomedical Engineering: Imaging and Visualization. 2019;7(5-6):550-6.	Population – Image type
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92. Rabidas R, Arif W. Characterization of mammographic masses based on local photometric attributes. Multimedia Tools and Applications. 2020;79(29-30):21967-85.	Population – Image type
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94. Rabidas R, Midya A, Chakraborty J. Neighborhood Structural Similarity Mapping for the Classification of Masses in Mammograms. IEEE j. 2018;22(3):826-34.	Population – Image type
95. Rabottino G, Mencattini A, Salmeri M, Caselli F, Lojacono R. Performance evaluation of a region growing procedure for mammographic breast lesion identification. Computer Standards & Interfaces. 2011;33(2):128-35.	Population – Image type
96. Ragab DA, Sharkas M, Marshall S, Ren J. Breast cancer detection using deep convolutional neural networks and support vector machines. Peerj. 2019;7:e6201.	Population – Image type

Reference	Main reason for exclusion
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103. Rauch T, Rieger J, Pelzer G, Horn F, Erber R, Wunderle M, et al. Discrimination analysis of breast calcifications using x-ray dark-field radiography. <i>Med Phys</i> . 2020;47(4):1813-26.	Population – Image type
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Reference	Main reason for exclusion
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<b>Population – Mammography type not reported (n=8)</b>	
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<b>Reference</b>	<b>Main reason for exclusion</b>
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<b>Reference</b>	<b>Main reason for exclusion</b>
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Reference	Main reason for exclusion
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Reference	Main reason for exclusion
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<b>Reference</b>	<b>Main reason for exclusion</b>
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<b>Intervention – Not AI (“old” CAD) (n=16)</b>	
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364. Lehman CD, Wellman RD, Buist DS, Kerlikowske K, Tosteson AN, Miglioretti DL, et al. Diagnostic Accuracy of Digital Screening Mammography With and Without Computer-Aided Detection. JAMA Intern Med. 2015;175(11):1828-37.	Intervention – Not AI
365. Onega T, Aiello Bowles EJ, Miglioretti DL, Carney PA, Geller BM, Yankaskas BC, et al. Radiologists' perceptions of computer aided detection versus double reading for mammography interpretation. Acad Radiol. 2010;17(10):1217-26.	Intervention – Not AI
366. Romero C, Varela C, Munoz E, Almenar A, Pinto JM, Botella M. Impact on breast cancer diagnosis in a multidisciplinary unit after the incorporation of mammography digitalization and computer-aided detection systems. AJR Am J Roentgenol. 2011;197(6):1492-7.	Intervention – Not AI
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368. Singh S, Maxwell J, Baker JA, Nicholas JL, Lo JY. Computer-aided classification of breast masses: performance and interobserver variability of expert radiologists versus residents. Radiology. 2011;258(1):73-80.	Intervention – Not AI
369. Skaane P, Kshirsagar A, Hofvind S, Jahr G, Castellino RA. Mammography screening using independent double reading with consensus: is there a potential benefit for computer-aided detection? Acta Radiol. 2012;53(3):241-8.	Intervention – Not AI

<b>Reference</b>	<b>Main reason for exclusion</b>
370. Sohns C, Angic BC, Sossalla S, Konietschke F, Obenauer S. CAD in full-field digital mammography-influence of reader experience and application of CAD on interpretation of time. Clin Imaging. 2010;34(6):418-24.	Intervention – Not AI
371. Zheng B, Sumkin JH, Zuley ML, Lederman D, Wang X, Gur D. Computer-aided detection of breast masses depicted on full-field digital mammograms: a performance assessment. Br J Radiol. 2012;85(1014):e153-61.	Intervention – Not AI
<b>Intervention – Prediction of cancer (n=2)</b>	
372. Chen X, Moschidis E, Taylor C, Astley S. Breast cancer risk analysis based on a novel segmentation framework for digital mammograms. Med Image Comput Comput Assist Interv Int Conf Med Image Comput Comput Assist Interv. 2014;17(Pt 1):536-43.	Intervention – Prediction of cancer
373. Timmers JM, Verbeek AL, IntHout J, Pijnappel RM, Broeders MJ, den Heeten GJ. Breast cancer risk prediction model: a nomogram based on common mammographic screening findings. Eur Radiol. 2013;23(9):2413-9.	Intervention – Prediction of cancer
<b>Outcomes – No relevant outcomes (n=24)</b>	
374. Antropova N, Huynh BQ, Giger ML. A deep feature fusion methodology for breast cancer diagnosis demonstrated on three imaging modality datasets. Med Phys. 2017;44(10):5162-71.	No relevant outcomes
375. Benndorf M. Conditional non-independence of radiographic image features and the derivation of post-test probabilities - A mammography BI-RADS example. Radiography. 2012;18(3):201-5.	No relevant outcomes
376. Benndorf M, Burnside ES, Herda C, Langer M, Kotter E. External validation of a publicly available computer assisted diagnostic tool for mammographic mass lesions with two high prevalence research datasets. Med Phys. 2015;42(8):4987-96.	No relevant outcomes
377. Clancy K, Aboutalib S, Mohamed A, Sumkin J, Wu S. Deep Learning Pre-training Strategy for Mammogram Image Classification: an Evaluation Study. J Digit Imaging. 2020;30:30.	No relevant outcomes
378. Cole EB, Zhang Z, Marques HS, Nishikawa RM, Hendrick RE, Yaffe MJ, et al. Assessing the stand-alone sensitivity of computer-aided detection with cancer cases from the Digital Mammographic Imaging Screening Trial. AJR Am J Roentgenol. 2012;199(3):W392-401.	No relevant outcomes
379. Li Z, Yu L, Wang X, Yu H, Gao Y, Ren Y, et al. Diagnostic Performance of Mammographic Texture Analysis in the Differential Diagnosis of Benign and Malignant Breast Tumors. Clin Breast Cancer. 2018;18(4):e621-e7.	No relevant outcomes



Reference	Main reason for exclusion
380. Lobbes M, Smidt M, Keymeulen K, Girometti R, Zuiani C, Beets-Tan R, et al. Malignant lesions on mammography: accuracy of two different computer-aided detection systems. Clin Imaging. 2013;37(2):283-8.	No relevant outcomes
381. Mayo RC, Leung JWT. Impact of artificial intelligence on women's imaging: Cost-benefit analysis. American Journal of Roentgenology. 2019;212(5):1172-3.	No relevant outcomes
382. Mendel K, Li H, Sheth D, Giger M. Transfer Learning From Convolutional Neural Networks for Computer-Aided Diagnosis: A Comparison of Digital Breast Tomosynthesis and Full-Field Digital Mammography. Acad Radiol. 2019;26(6):735-43.	No relevant outcomes
383. Murakami R, Kumita S, Tani H, Yoshida T, Sugizaki K, Kuwako T, et al. Detection of breast cancer with a computer-aided detection applied to full-field digital mammography. J Digit Imaging. 2013;26(4):768-73.	No relevant outcomes
384. Oliver A, Llado X, Freixenet J, Marti R, Perez E, Pont J, et al. Influence of using manual or automatic breast density information in a mass detection CAD system. Acad Radiol. 2010;17(7):877-83.	No relevant outcomes
385. Park CS, Jung NY, Kim K, Jung HS, Sohn KM, Oh SJ. Detection of breast cancer in asymptomatic and symptomatic groups using computer-aided detection with full-field digital mammography. Journal of Breast Cancer. 2013;16(3):322-8.	No relevant outcomes
386. Punitha S, Ravi S, Devi MA, Vaishnavi J. Particle swarm optimized computer aided diagnosis system for classification of breast masses. Journal of Intelligent & Fuzzy Systems. 2017;32(4):2819-28.	No relevant outcomes
387. Sadaf A, Crystal P, Scaranelo A, Helbich T. Performance of computer-aided detection applied to full-field digital mammography in detection of breast cancers. Eur J Radiol. 2011;77(3):457-61.	No relevant outcomes
388. Sohns C, Angic B, Sossalla S, Konietschke F, Obenauer S. Computer-assisted diagnosis in full-field digital mammography--results in dependence of readers experiences. Breast J. 2010;16(5):490-7.	No relevant outcomes
389. Torrents-Barrena J, Puig D, Melendez J, Valls A. Computer-aided diagnosis of breast cancer via Gabor wavelet bank and binary-class SVM in mammographic images. Journal of Experimental & Theoretical Artificial Intelligence. 2016;28(1-2):295-311.	No relevant outcomes
390. van den Biggelaar FJ, Kessels AG, van Engelshoven JM, Boetes C, Flobbe K. Computer-aided detection in full-field digital mammography in a clinical population: performance of radiologist and technologists. Breast Cancer Res Treat. 2010;120(2):499-506.	No relevant outcomes

Reference	Main reason for exclusion
391. Vedanarayanan V, Nandhitha NM. Advanced image segmentation techniques for accurate isolation of abnormality to enhance breast cancer detection in digital mammographs. Biomedical Research (India). 2017;28(6):2753-7.	No relevant outcomes
392. Warren LM, Given-Wilson RM, Wallis MG, Cooke J, Halling-Brown MD, Mackenzie A, et al. The effect of image processing on the detection of cancers in digital mammography. AJR Am J Roentgenol. 2014;203(2):387-93.	No relevant outcomes
393. Warren LM, Halling-Brown MD, Looney PT, Dance DR, Wallis MG, Given-Wilson RM, et al. Image processing can cause some malignant soft-tissue lesions to be missed in digital mammography images. Clin Radiol. 2017;72(9):799.e1- .e8.	No relevant outcomes
394. Wu Y, Vanness DJ, Burnside ES. Using multidimensional mutual information to prioritize mammographic features for breast cancer diagnosis. AMIA Annu Symp Proc. 2013;2013:1534-43.	No relevant outcomes
395. Yang X, Cao A, Song Q, Schaefer G, Su Y. Vicinal support vector classifier using supervised kernel-based clustering. Artif Intell Med. 2014;60(3):189-96.	No relevant outcomes
396. Yu SD, Liu LL, Wang ZY, Dai GZ, Xie YQ. Transferring deep neural networks for the differentiation of mammographic breast lesions. Science China-Technological Sciences. 2019;62(3):441-7.	No relevant outcomes
397. Zheng K, Harris C, Bakic P, Makrogiannis S. Spatially localized sparse representations for breast lesion characterization. Computers in Biology and Medicine. 2020;123 (no pagination).	No relevant outcomes
<b>Study type – Systematic reviews (n=7)</b>	
398. Azavedo E, Zackrisson S, Mejare I, Heibert Arnlind M. Is single reading with computer-aided detection (CAD) as good as double reading in mammography screening? A systematic review. BMC med. 2012;12:22.	Study type – Systematic reviews with no relevant outcomes
399. Eadie LH, Taylor P, Gibson AP. A systematic review of computer-assisted diagnosis in diagnostic cancer imaging. Eur J Radiol. 2012;81(1):e70-6.	Study type – Systematic reviews with no relevant outcomes
400. Gruppo di studio G-S, Chersevani R, Ciatto S, Del Favero C, Frigerio A, Giordano L, et al. "CADEAT": considerations on the use of CAD (computer-aided diagnosis) in mammography. Radiol Med (Torino). 2010;115(4):563-70.	Study type – Systematic reviews with no relevant outcomes

Reference	Main reason for exclusion
401. Henriksen EL, Carlsen JF, Vejborg IM, Nielsen MB, Lauridsen CA. The efficacy of using computer-aided detection (CAD) for detection of breast cancer in mammography screening: a systematic review. <i>Acta Radiol.</i> 2019;60(1):13-8.	Study type – Systematic reviews with no relevant outcomes
402. Houssami N, Kirkpatrick-Jones G, Noguchi N, Lee CI. Artificial Intelligence (AI) for the early detection of breast cancer: a scoping review to assess AI's potential in breast screening practice. <i>Expert Rev Med Devices.</i> 2019;16(5):351-62.	Study type – Systematic reviews with no relevant outcomes
403. Sadoughi F, Kazemy Z, Hamedan F, Owji L, Rahmanikatiqari M, Azadboni TT. Artificial intelligence methods for the diagnosis of breast cancer by image processing: a review. <i>Breast Cancer (Dove Med Press).</i> 2018;10:219-30.	Study type – Systematic reviews with no relevant outcomes
404. Yassin NIR, Omran S, El Houbay EMF, Allam H. Machine learning techniques for breast cancer computer aided diagnosis using different image modalities: A systematic review. <i>Comput Methods Programs Biomed.</i> 2018;156:25-45.	Study type – Systematic reviews with no relevant outcomes
<b>Full text not available via Document Supply (n=7)</b>	
405. Bhavani SR, Chilambuchelvan A, Senthilkumar J, Manjula D, Krishnamoorthy R, Kannan A. A secure cloud-based multi-agent intelligent system for mammogram image diagnosis. <i>International Journal of Biomedical Engineering and Technology.</i> 2018;28(2):185-202.	Document Supply cancelled request: no location found.
406. Grout S, Dheeraj Suryaa SR, Hitesh, Venkatesan DH, Sumanth S, Vishnu Vardhan Reddy M. Anomaly detection in digital mammography using neural networks. <i>Journal of International Pharmaceutical Research.</i> 2019;46(3):750-4.	Document Supply cancelled request: no location found.
407. Saraswathi D, Srinivasan E. An ensemble approach to diagnose breast cancer using fully complex-valued relaxation neural network classifier. <i>International Journal of Biomedical Engineering and Technology.</i> 2014;15(3):243-60.	Document Supply cancelled request: no location found.
408. Selvan VP, Suganthi M. Clinical support system for classification of tumor in mammogram images using multiple features and neural network classifier. <i>Journal of Pure and Applied Microbiology.</i> 2015;9(Special Edition):253-61.	Document Supply cancelled request: no location found.
409. Singh B, Jain VK, Singh S. Mammogram mass classification using support vector machine with texture, shape features and hierarchical centroid method. <i>Journal of Medical Imaging and Health Informatics.</i> 2014;4(5):687-96.	Document Supply cancelled request: no location found.
410. Srivastava S, Sharma N, Singh SK, Srivastava R. Quantitative analysis of a general framework of a CAD tool for breast cancer detection from mammograms. <i>Journal of Medical Imaging and Health Informatics.</i> 2014;4(5):654-74.	Document Supply cancelled request: no location found.

Reference	Main reason for exclusion
411. Zhou L, Ding M, Xu L, Zhou Y, Zhang X. The automatic segmentation of mammographic mass using the end-to-end convolutional network based on dense-prediction. Journal of Medical Imaging and Health Informatics. 2019;9(7):1429-34.	Document Supply cancelled request: no location found.
<b>Other reasons (n=5)</b>	
412. Becker AS, Marcon M, Ghafoor S, et al. Deep Learning in Mammography: Diagnostic Accuracy of a Multipurpose Image Analysis Software in the Detection of Breast Cancer. Invest Radiol 2017;52(7):434-40. doi: <a href="https://dx.doi.org/10.1097/RLI.0000000000000358">https://dx.doi.org/10.1097/RLI.0000000000000358</a>	Study 1: BCDR database; unclear proportion of screening mammograms Study 2: Temporal validation
413. da Silva R, de Carvalho A. Automatic classification of breast lesions using Transfer Learning. IEEE Latin America Transactions. 2019;17(12):1964-9.	Language – Not available in English
414. Kim HE, Kim HH, Han BK, et al. Changes in cancer detection and false-positive recall in mammography using artificial intelligence: a retrospective, multireader study. The Lancet Digital Health 2020;2(3):e138-e48. doi: <a href="http://dx.doi.org/10.1016/S2589-7500%2820%2930003-0">http://dx.doi.org/10.1016/S2589-7500%2820%2930003-0</a>	Evaluation study: unclear proportion of screening mammograms. Reader study: In parts temporal validation confirmed by corresponding author via email.
415. Polat K. Application of Attribute Weighting Method Based on Clustering Centers to Discrimination of Linearly Non-Separable Medical Datasets. J Med Syst. 2012;36(4):2657-73.	Separation of two different image datasets (liver and breast)
416. Sechopoulos I, Mann RM. Stand-alone artificial intelligence - The future of breast cancer screening? Breast. 2020;49:254-60.	Narrative review

## Publications excluded after review of full-text articles – Update database searches

### Publications

Reference	Main reason for exclusion
<b>Population – Image type (e.g. digitised film images; not FFDM images) (n=18)</b>	
1. Abubacker NF, Hashem IAT, Hui LK. Mammographic Classification Using Stacked Ensemble Learning with Bagging and Boosting Techniques. <i>Journal of Medical and Biological Engineering</i> 2020;40(6):908-16. doi: <a href="http://dx.doi.org/10.1007/s40846-020-00567-y">http://dx.doi.org/10.1007/s40846-020-00567-y</a>	Population – Image type
2. Arora R, Rai PK, Raman B. Deep feature-based automatic classification of mammograms. <i>Medical &amp; biological engineering &amp; computing</i> 2020;58(6):1199-211. doi: <a href="https://dx.doi.org/10.1007/s11517-020-02150-8">https://dx.doi.org/10.1007/s11517-020-02150-8</a>	Population – Image type
3. Bakthavachalam MD, Albert Antony Raj S. A study on breast cancer analysis by using k-nearest neighbor with different distances and classification rules using machine learning. <i>European Journal of Molecular and Clinical Medicine</i> 2020;7(3):4842-51.	Population – Image type
4. Gautam N, Singh A, Kumar K, et al. Investigation on performance analysis of support vector machine for classification of abnormal regions in medical image. <i>Journal of Ambient Intelligence and Humanized Computing</i> doi: 10.1007/s12652-021-02965-9	Population – Image type
5. Graewingholt A, Duffy S. Retrospective comparison between single reading plus an artificial intelligence algorithm and two-view digital tomosynthesis with double reading in breast screening. <i>Journal of medical screening</i> 2021:969141320984198. doi: <a href="https://dx.doi.org/10.1177/0969141320984198">https://dx.doi.org/10.1177/0969141320984198</a>	Population – Image type
6. Jahangeer GSB, Rajkumar TD. Early detection of breast cancer using hybrid of series network and VGG-16. <i>Multimedia Tools and Applications</i> 2021;80(5):7853-86. doi: 10.1007/s11042-020-09914-2	Population – Image type
7. Kakileti ST, Madhu HJ, Krishnan L, et al. Observational Study to Evaluate the Clinical Efficacy of Thermalytix for Detecting Breast Cancer in Symptomatic and Asymptomatic Women. <i>JCO global oncology</i> 2020;6:1472-80. doi: <a href="https://dx.doi.org/10.1200/GO.20.00168">https://dx.doi.org/10.1200/GO.20.00168</a>	Population – Image type
8. Ketabi H, Ekhlasi A, Ahmadi H. A computer-aided approach for automatic detection of breast masses in digital mammogram via spectral clustering and support vector machine. <i>Physical and Engineering Sciences in Medicine</i> 2021;44(1):277-90. doi: <a href="http://dx.doi.org/10.1007/s13246-021-00977-5">http://dx.doi.org/10.1007/s13246-021-00977-5</a>	Population – Image type

Reference	Main reason for exclusion
9. Khamparia A, Bharati S, Podder P, et al. Diagnosis of breast cancer based on modern mammography using hybrid transfer learning. Multidimensional systems and signal processing 2021;1-19. doi: <a href="https://dx.doi.org/10.1007/s11045-020-00756-7">https://dx.doi.org/10.1007/s11045-020-00756-7</a>	Population – Image type
10. Melekoodappattu JG, Kadan AB, Anoop V. Early detection of breast malignancy using wavelet features and optimized classifier. International Journal of Imaging Systems and Technology doi: 10.1002/ima.22537	Population – Image type
11. Melekoodappattu JG, Subbian PS. Automated breast cancer detection using hybrid extreme learning machine classifier. Journal of Ambient Intelligence and Humanized Computing doi: 10.1007/s12652-020-02359-3	Population – Image type
12. Melekoodappattu JG, Subbian PS, Queen MPF. Detection and classification of breast cancer from digital mammograms using hybrid extreme learning machine classifier. International Journal of Imaging Systems and Technology 2021;31(2):909-20. doi: 10.1002/ima.22484	Population – Image type
13. Rao PMM, Singh SK, Khamparia A, et al. Multi-class Breast Cancer Classification using Ensemble of Pretrained models and Transfer Learning. Current medical imaging 2021 doi: <a href="https://dx.doi.org/10.2174/1573405617666210218101418">https://dx.doi.org/10.2174/1573405617666210218101418</a>	Population – Image type
14. Shaikh TA, Ali R. An intelligent healthcare system for optimized breast cancer diagnosis using harmony search and simulated annealing (HS-SA) algorithm. Informatics in Medicine Unlocked 2020;21:100408. doi: <a href="http://dx.doi.org/10.1016/j.imu.2020.100408">http://dx.doi.org/10.1016/j.imu.2020.100408</a>	Population – Image type
15. Solanki YS, Chakrabarti P, Jasinski M, et al. A Hybrid Supervised Machine Learning Classifier System for Breast Cancer Prognosis Using Feature Selection and Data Imbalance Handling Approaches. Electronics 2021;10(6) doi: 10.3390/electronics10060699	Population – Image type
16. Thawkar S. A hybrid model using teaching-learning-based optimization and Salp swarm algorithm for feature selection and classification in digital mammography. Journal of Ambient Intelligence and Humanized Computing doi: 10.1007/s12652-020-02662-z	Population – Image type
17. Thawkar S, Ingolikar R. Classification of masses in digital mammograms using Biogeography-based optimization technique. Journal of King Saud University-Computer and Information Sciences 2020;32(10):1140-48. doi: 10.1016/j.jksuci.2018.01.004	Population – Image type
18. Xiao M, Zhao C, Li J, et al. Diagnostic Value of Breast Lesions Between Deep Learning-Based Computer-Aided Diagnosis System and Experienced Radiologists: Comparison the	Population – Image type

Reference	Main reason for exclusion
Performance Between Symptomatic and Asymptomatic Patients. <i>Frontiers in Oncology</i> 2020;10:1070. doi: <a href="http://dx.doi.org/10.3389/fonc.2020.01070">http://dx.doi.org/10.3389/fonc.2020.01070</a>	
<b>Population – Subpopulation (e.g. only cancer cases) (n=3)</b>	
19. Graewingholt A, Rossi PG. Retrospective analysis of the effect on interval cancer rate of adding an artificial intelligence algorithm to the reading process for two-dimensional full-field digital mammography. <i>Journal of medical screening</i> 2021;969141320988049. doi: <a href="https://dx.doi.org/10.1177/0969141320988049">https://dx.doi.org/10.1177/0969141320988049</a>	Population - Subpopulation
20. Lang K, Hofvind S, Rodriguez-Ruiz A, et al. Can artificial intelligence reduce the interval cancer rate in mammography screening? <i>European radiology</i> 2021 doi: <a href="https://dx.doi.org/10.1007/s00330-021-07686-3">https://dx.doi.org/10.1007/s00330-021-07686-3</a>	Population - Subpopulation
21. Lee SE, Han K, Kim E-K. Application of artificial intelligence-based computer-assisted diagnosis on synthetic mammograms from breast tomosynthesis: comparison with digital mammograms. <i>European radiology</i> 2021 doi: <a href="https://dx.doi.org/10.1007/s00330-021-07796-y">https://dx.doi.org/10.1007/s00330-021-07796-y</a>	Population - Subpopulation
<b>Population – &lt;90% screening mammograms or unclear proportion (n=3)</b>	
22. Ashiba HI. A proposed framework for diagnosis and breast cancer detection. <i>Multimedia Tools and Applications</i> 2021;80(6):9333-69. doi: <a href="https://doi.org/10.1007/s11042-020-10131-0">10.1007/s11042-020-10131-0</a>	Population – <90% screening mammograms or unclear proportion
23. Cui Y, Li Y, Xing D, et al. Improving the Prediction of Benign or Malignant Breast Masses Using a Combination of Image Biomarkers and Clinical Parameters. <i>Frontiers in oncology</i> 2021;11:629321. doi: <a href="https://dx.doi.org/10.3389/fonc.2021.629321">https://dx.doi.org/10.3389/fonc.2021.629321</a>	Population – <90% screening mammograms or unclear proportion
24. Kalyani K. CNN analysis for mammogram disease detection. <i>European Journal of Molecular and Clinical Medicine</i> 2020;7(9):1540-43.	Population – <90% screening mammograms or unclear proportion
<b>Internal validation – Cross validation (n=5)</b>	
25. Africano G, Arponen O, Sassi A, et al. A Comparison of Regions of Interest in Parenchymal Analysis for Breast Cancer Risk Assessment. <i>Annual International Conference of the IEEE Engineering in Medicine and Biology Society IEEE Engineering in Medicine and Biology Society Annual International Conference</i> 2020;2020:1136-39. doi: <a href="https://dx.doi.org/10.1109/EMBC44109.2020.9176200">https://dx.doi.org/10.1109/EMBC44109.2020.9176200</a>	Internal validation – Cross validation
26. Hassan SA, Sayed MS, Abdalla MI, et al. Breast cancer masses classification using deep convolutional neural networks and transfer learning. <i>Multimedia Tools and Applications</i> 2020;79(41-42):30735-68. doi: <a href="https://doi.org/10.1007/s11042-020-09518-w">10.1007/s11042-020-09518-w</a>	Internal validation – Cross validation

Reference	Main reason for exclusion
27. Heidari M, Lakshmivarahan S, Mirniaharikandehei S, et al. Applying a random projection algorithm to optimize machine learning model for breast lesion classification. IEEE Transactions on Biomedical Engineering 2021 doi: <a href="http://dx.doi.org/10.1109/TBME.2021.3054248">http://dx.doi.org/10.1109/TBME.2021.3054248</a>	Internal validation – Cross validation
28. Hsu CH, Chen X, Lin WW, et al. Effective multiple cancer disease diagnosis frameworks for improved healthcare using machine learning. Measurement 2021;175 doi: <a href="https://doi.org/10.1016/j.measurement.2021.109145">10.1016/j.measurement.2021.109145</a>	Internal validation – Cross validation
29. Jiang MK, Han L, Sun H, et al. Cross-modality image feature fusion diagnosis in breast cancer. Physics in Medicine and Biology 2021;66(10) doi: <a href="https://doi.org/10.1088/1361-6560/abf38b">10.1088/1361-6560/abf38b</a>	Internal validation – Cross validation
<b>Internal validation – Split sample (n=4)</b>	
30. Gnanasekaran VS, Joypaul S, Sundaram PM, et al. Deep learning algorithm for breast masses classification in mammograms. Iet Image Processing 2020;14(12):2860-68. doi: <a href="https://doi.org/10.1049/iet-ipr.2020.0070">10.1049/iet-ipr.2020.0070</a>	Internal validation – Split sample
31. Guan Y, Wang X, Li H, et al. Detecting Asymmetric Patterns and Localizing Cancers on Mammograms. Patterns (New York, NY) 2020;1(7) doi: <a href="https://dx.doi.org/10.1016/j.patter.2020.100106">https://dx.doi.org/10.1016/j.patter.2020.100106</a>	Internal validation – Split sample
32. Shen Y, Wu N, Phang J, et al. An interpretable classifier for high-resolution breast cancer screening images utilizing weakly supervised localization. Medical image analysis 2021;68:101908. doi: <a href="https://dx.doi.org/10.1016/j.media.2020.101908">https://dx.doi.org/10.1016/j.media.2020.101908</a>	Internal validation – Split sample
33. Suh YJ, Jung J, Cho B-J. Automated Breast Cancer Detection in Digital Mammograms of Various Densities via Deep Learning. Journal of personalized medicine 2020;10(4) doi: <a href="https://dx.doi.org/10.3390/jpm10040211">https://dx.doi.org/10.3390/jpm10040211</a>	Internal validation – Split sample
<b>Intervention – Detecting subtypes (n=1)</b>	
34. Vedalankar AV, Gupta SS, Manthalkar RR. Addressing architectural distortion in mammogram using AlexNet and support vector machine. Informatics in Medicine Unlocked 2021;23:100551. doi: <a href="http://dx.doi.org/10.1016/j.imu.2021.100551">http://dx.doi.org/10.1016/j.imu.2021.100551</a>	Intervention – Detecting subtypes
<b>Outcomes – No relevant outcomes (n=1)</b>	
35. Nct. Mammography Screening With Artificial Intelligence (MASAI). <a href="https://clinicaltrials.gov/show/NCT04838756">https://clinicaltrials.gov/show/NCT04838756</a> 2021	Registered study protocol, no relevant outcomes
<b>Full text not available via Document Supply (n=2)</b>	



Reference	Main reason for exclusion
36. Sathya Priya T, Ramaprabha T. Deep learning based image segmentation with alexnet feature extraction for classification of mammogram images. International Journal of Pharmaceutical Research 2021;13(1):4995-5009. doi: <a href="http://dx.doi.org/10.31838/ijpr/2021.13.01.690">http://dx.doi.org/10.31838/ijpr/2021.13.01.690</a>	Document Supply cancelled request: no location found.
37. Yi XC, Hou J. Segmentation of Medical Image Based on Superpixel Boundary Perceptual Convolutional Network in Cancer Diagnosis and Treatment. Journal of Medical Imaging and Health Informatics 2021;11(1):254-60. doi: 10.1166/jmihi.2021.3425	Document Supply cancelled request: no location found.
<b>Already picked up by original searches (n=2)</b>	
38. Lindholm P, Eklund M, Dembrower K, et al. Effect of artificial intelligence-based triaging of breast cancer screening mammograms on cancer detection and radiologist workload: a retrospective simulation study. The Lancet Digital Health 2020;2(9):e468-e74. doi: <a href="http://dx.doi.org/10.1016/S2589-7500%2820%2930185-0">http://dx.doi.org/10.1016/S2589-7500%2820%2930185-0</a>	Same article as Dembrower (2020), already picked up by original search
39. Pacile S, Lopez J, Chone P, et al. Improving Breast Cancer Detection Accuracy of Mammography with the Concurrent Use of an Artificial Intelligence Tool. Radiology Artificial intelligence 2020;2(6):e190208. doi: <a href="https://dx.doi.org/10.1148/ryai.2020190208">https://dx.doi.org/10.1148/ryai.2020190208</a>	Already picked up by original search

### Sub-studies or datasets of included studies

Reference	Excluded study / dataset and reason
Balta 2020 <sup>25</sup>	None
Dembrower 2020 <sup>26</sup>	None
Lang 2020 <sup>27</sup>	None
McKinney 2020 <sup>29</sup>	<ol style="list-style-type: none"> <li>1) <b>Retrospective clinical comparison</b> with original decisions of UK and US readers, respectively, excluded due to internal validation test set (split sample).</li> <li>2) <b>Comparison with reader study</b> excluded due to internal validation test set (split sample).</li> <li>3) <b>Simulation study</b> excluded as it is based on test accuracy estimated obtained using internal validation test sets (split sample).</li> </ol>
Pacilè 2020 <sup>30</sup>	None
Rodriguez-Ruiz 2018 <sup>34</sup>	Excluded <b>AI as stand-alone reader</b> due to lack of outcomes such as sensitivity and specificity (only AUC).
Rodriguez-Ruiz 2019 <sup>32</sup>	Excluded <b>AI as stand-alone reader</b> due to lack of outcomes such as sensitivity and specificity (only AUC).
Rodriguez-Ruiz 2019 <sup>33</sup>	Excluded <b>data sets A and D-H</b> as <90% screening mammograms or unclear proportion of screening mammograms. Excluded <b>data set B</b> as no relevant outcomes reported.
Salim 2020 <sup>35</sup>	None
Schaffter 2020 <sup>36</sup>	Excluded the <b>Kaiser Permanente Washington (KPW) dataset</b> as it was used for training and evaluation (split sample).
Watanabe 2019 <sup>37</sup>	None
Lotter 2021 <sup>28</sup>	<p>The paper reports on 5 test sets; only one data set (Site D) is an external test set of screening FFDMs.</p> <p>Two test sets are excluded as they are also used for training, one test set uses DBT (not FFDM) images, and one test set uses diagnostic (not screening) FFDMs.</p> <p>The study of pre-index cancers was excluded as the analysis included a sub-population of cancers with a negative previous screening result, therefore the analysis was based on images of subpopulations by screening outcome.</p>
Raya-Povedano 2021 <sup>31</sup>	Simulated autonomous AI triaging strategy excluded as simulation study.

#### Appendix 4 Additional baseline characteristics of included studies

STUDY	Method of enrichment	Confirmed cancer (prevalence) n (%)	Cancer type n (%)	Cancer size/grade (invasive only)	Breast density n (%)
Lotter 2021 <sup>28</sup>	<p>Matched case-control study:            Cancer cases: all patients from a single health system in Massachusetts with qualifying index (screening mammograms interpreted as suspicious and confirmed to be malignant by pathology within three months) and pre-index exams (from the same set of women as the index exams: screening exams interpreted as BI-RADS 1 or 2 12–24 months prior to the index exams) over the specified time period using a local cancer registry.</p> <p>Non-cancer cases: selected from a single health system in Massachusetts to have a similar distribution in patient age and breast density compared with the cancer cases using bucketing (negative exam followed by an additional BI-RADS 1 or 2 interpretation at the next screening exam 9–39 months later).            BI-RADS &gt;2: 131 (46%)            BI-RADS 1 or 2: 154 (54%)</p>	131 (46.0%)	ILC or IDC: 88 (67.2%) DCIS: 38 (29.0%) Other: 5 (3.8%)  Lesion type Soft tissue 87 Calcifications 53 (adds up to 140 though)	For all 131 cancers: 0-1cm: 45 (34.35%) 1-2cm: 27 (20.6%) 2-5cm: 11 (8.4%) >5cm: 3 (2.3%) Unknown: 45 (34.35%)	Non-cancer (n=154): Non-dense (A&B) 96 (62.3%) Dense (C&D) 58 (37.7%)  Cancer (n=131): Non-dense (A&B) 81 (61.8%) Dense (C&D) 50 (38.2%)

STUDY	Method of enrichment	Confirmed cancer (prevalence) n (%)	Cancer type n (%)	Cancer size/grade (invasive only)	Breast density n (%)
McKinney 2020 <sup>29</sup>	<p>Images from all women at one US academic medical centre who were biopsied during this time period and a random subset of women (~5%) who never underwent biopsy.</p> <p>BI-RADS 0, 4 or 5: 929 (30%)  BI-RADS 1,2 or 3: 1,809 (58%)  No Bi-RADS score: 359 (12%)</p>	686 (22.2%)	Data for 553/686 with BI-RADS score: Invasive 364/553 (65.8%) DCIS 163/553 (29.5%) Other 26/553 (4.7%)	NR	NR
Rodriguez-Ruiz 2019 <sup>33</sup>	<p>Mammograms collected on cancer outcome from Dutch digital screening pilot project: 80 biopsy-proved cancer cases and 120 negative cases.</p> <p>Case selection: 1) cases in which the lesion was rated as obvious, cases with only microcalcifications, and cases in which not all four cranial-caudal and mediolateral oblique views of both breasts were available were excluded. 2) Prior screening mammograms in which a malignant lesion was already visible n=17 mammograms. 3) From the remaining cases, random selection of 63 screen-detected cancer cases from incident screening rounds.</p> <p>Negative case selection: 1) 20 false-positive cases that were verified by normal follow-up (no biopsy), 2) random selection of 100 non-referred mammograms with at least one normal follow-up screen.</p>	79 (39.7%)	NR	NR	NR

STUDY	Method of enrichment	Confirmed cancer (prevalence) n (%)	Cancer type n (%)	Cancer size/grade (invasive only)	Breast density n (%)
Salim 2020 <sup>35</sup>	All women with a diagnosis of breast cancer from the Swedish Cohort of screen-age women were included and a random sample of healthy women.	739 (8.4%)	Invasive 640 (86%) IDC 514/640 (80%) ILC 82/640 (13%) other 43/640 (7%) missing 1/640 (0.15%)  In situ 85 (12%) Missing information 14 (2%)	Median 15mm (IQR 10-21mm)	Mammographic percent density, % Median 21.9 IQR 13.8-32.1
Schaffter 2020 <sup>36</sup>	No enrichment: consecutive sample of screened women from 1 Swedish centre	780 (1.1%)	Invasive 681 (87.3%) DCIS 99 (12.7%)	NR	NR
Balta 2020 <sup>25</sup>	No enrichment: consecutive sample of screened women from 1 German centre	114 (0.64%)	NR	NR	NR
Dembrower 2020 <sup>26</sup>	All women diagnosed with breast cancer who attended two consecutive screening rounds from the Swedish Cohort of screen-age women were include. Healthy women were randomly sampled from the same cohort.	547 (7.4%)	NR	NR	NR
Lang 2020 <sup>27</sup>	No enrichment: Consecutive sub cohort of the prospective population-based Malmö Breast Tomosynthesis Screening Trial in which every third woman who was invited to attend regular screening was invited to participate (random sample)	68 (0.71%)	IDC 33/68 (48.5%) ILC 11/68 (16.2%) ITC 10/68 (14.7%) DCIS 11/68 (16.2%) Other (e.g. papillary carcinoma, apocrine tumour) 3/68 (4.4%)	Grade 1 24/56 (42.9%) Grade 2 25/56 (44.6%) Grade 3 7/56 (12.5%)	NR

<b>STUDY</b>	<b>Method of enrichment</b>	<b>Confirmed cancer (prevalence) n (%)</b>	<b>Cancer type n (%)</b>	<b>Cancer size/grade (invasive only)</b>	<b>Breast density n (%)</b>
Rava-Povedano 2021 <sup>31</sup>	No enrichment: Mammograms from Spanish tomosynthesis screening trial Original outcomes: Normal readings (with two-year follow-up): 14,795 (92.5%) FP recalls: 1,078 (6.7%) Screen detected cancers: 98 (0.6%) Interval cancers: 15 (0.1%)	113 (0.7%)	Cancer type: Mass 67 (59.3%) Architectural distortion 21 (18.6%) Asymmetry 4 (3.5%) Calcification 21 (18.6%)  Histologic type: IDC 80 (70.8%) ILC 5 (4.4%) Other invasive 1 (0.9%) DCIS 27 (23.9%)	For all 113 cancers: Grade 1 49 (43.4%) Grade 2 40 (35.4%) Grade 3 24 (21.2%)	Category A 3,648/15,986 (22.8%) Category B 8,153/15,986 (51.0%) Category C 3,749/15,986 (23.5%) Category D 436/15,986 (2.7%)
Pacilè 2020 <sup>30</sup>	Enrichment method not reported. The final dataset included 80 true-positive, 40 false-negative. Data underwent a quality check performed by an experienced breast radiologist to exclude examinations not meeting acquisition standards or presenting identifiable features (e.g., nipple retraction, invasive cancer larger than approximately 2.5 cm, bilateral cancer, and others to minimize recall bias), and for false-negative examinations, that malignant lesions were visible and identifiable in retrospect.	120 (50%)	Histologic type: IDC 75 (62.5%) DCIS 27 (22.5%) ILC 6 (5.0%) Other 12 (10.0%)  Lesion type: Mass 64 (53.3%) Calcification 30 (25.0%) Asymmetry 13 (10.8%) Architectural distortion 13 (10.8%)	NR	Category A 15.00% (36/240) Category B 43.75% (105/240) Category C 34.58% (83/240) Category D 6.67% (16/240)

STUDY	Method of enrichment	Confirmed cancer (prevalence) n (%)	Cancer type n (%)	Cancer size/grade (invasive only)	Breast density n (%)
Rodriguez-Ruiz 2019 <sup>32</sup>	Examinations from cancer, false-positive and normal cases were consecutively collected from one US and one European centre until predefined distribution of selection was achieved. Mammograms were reviewed by one radiologist to ensure image quality 9 were excluded (3 for poor image quality, 3 without link to case report findings and 3 with obvious signs of cancer)	100 (41.7%)	Lesion type: Mass 49 (49%) Calcifications 30 (30%) Asymmetry 10 (10%) Architectural distortion 6 (6%) Both calcifications and mass lesions 5 (5%)  Histologic type: IDC 64 (64%) DCIS 13 (13%) ILC 18 (18%) Invasive tubular carcinoma 6 (6%) Other 3 (3%) (4 examinations showed 2 histologic cancer types)	Median 13 mm <sup>2</sup> IQR 4-22 mm <sup>2</sup>	BI-RADS breast density A 28 (12%) B 133 (55%) C 64 (27%) D 15 (6%)
Watanabe 2019 <sup>37</sup>	Mammograms were selected from an archive of false negative mammograms (dataset from a community healthcare facility in Southern California). mammograms were originally interpreted by community-based radiologists using the R2 ImageChecker CAD v10.0	90 (73.8%)	Mass 50 (55.6%) Microcalcifications 16 (17.8%) Mass and Microcalcifications 9 (10.0%) Architectural Distortions 5 (5.6%) Mass and Architectural Distortions 4 (4.4%) Asymmetry 3 (3.3%) Architectural Distortion and Microcalcifications 1 (1.1%) Microcalcifications and Asymmetry 1 (1.1%) Focal Asymmetry 1 (1.1%)	NR	Fatty 4 (4%) Scattered 43 (48%) Heterogeneously dense 37 (41%) Extremely dense 6 (7%)

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