



MammoReader Device Labeling

Revision 01



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1 Brief Device Description

The MammoReader is a Computer-Aided Detection (CAD) system intended for use as an aid to radiologists reading mammograms. The MammoReader consists of proprietary software integrated with general purpose computing equipment and a high-resolution x-ray film scanner. The MammoReader allows mammography films to be digitized using the film scanner. The resulting digital images are automatically analyzed in order to detect suspicious regions in each image. The results of automated detection are presented to the radiologist on a computer display in the form of low-resolution images with marks indicating suspicious locations on each image. The radiologist is instructed first to review each case in the conventional manner and then re-examine the original films at any suspicious locations identified by the system before making a final assessment for the case.

2 Indications for Use

The MammoReader is a computer system intended to identify and mark regions of interest on standard mammographic views to bring them to the attention of the radiologist after the initial reading has been completed. Thus, the system assists the radiologist in minimizing observational oversights by identifying areas on the original mammogram that may warrant a second review.

3 Contraindications

There are no contraindications for the use of this device.

4 Warnings

Warnings to the Radiological Interpreter

- **It is critical that the radiologist reviews the films in the conventional manner first, before reviewing the MammoReader system results. To review the MammoReader results before reviewing the films runs the risk of the so-called satisfaction-of-search error, in which the radiologist fails to examine the unmarked areas of the films with adequate vigilance.**

- The MammoReader will not mark all regions that are indicative of cancer.
- The MammoReader system may not detect a lesion in both views. This should not be taken as an indication that the lesion is less likely to be indicative of cancer.
- The system was not designed to detect all areas that may be suspicious for cancers. Detection of skin thickening, nipple retractions or vague opacities are areas not detected by the MammoReader.

- **Therefore the interpreter must not be dissuaded from taking further action regarding a region simply because the system did not mark that region.**

- **The nature of the analysis software is such that many marked regions are not indicative of cancer. Indeed the system places an average of 0.83 marks per image, the vast majority of which do not, in fact, represent cancer. It is up to the interpreter to decide if further action is necessary regarding a marked region without regard to the fact that the region was detected by the system. The MammoReader is an aid in detecting suspicious regions for re-examination, not an aid for interpretation or assessment of observed regions.**

- The low-resolution images generated and displayed by the MammoReader are not intended nor are they suitable for interpretation. Assessment of mammograms should be based solely on the x-ray films. The MammoReader low-resolution images with the generated marks are to be used only for locating regions to be re-examined on the films.
- The effectiveness of the analysis of mammograms from patients with implants by the MammoReader system has not been established.

Warnings to the Radiological Technician

- The quality and cleanliness of the films submitted to the MammoReader for digitization and analysis has a direct effect on the quality of the resulting analysis. Be sure that all films are clean and dry and free from all marks prior to scanning.
- To receive best results and to ensure proper operation of the MammoReader system, the quality of the films must meet MQSA standards.
- It is important to follow instructions regarding barcode labeling and film orientation while loading films into the MammoReader scanner. Failure to follow these instructions may result in inaccurate detection results or may cause the system to not generate detection results.
- Maintain the scanner according to instructions in the MammoReader System Manual. Keep the scanner cover closed at all times when not placing films into the input tray.

Warnings to all Users

- As with all electronic equipment, care must be taken around the MammoReader system to prevent electrical shock. Always remove power from any device in the system before opening covers for maintenance or cleaning. If any system components are damaged or have had liquids spilled on them, do not operate the system. Contact ISSI or authorized service personnel.
- Access to the MammoReader is restricted. No other applications are allowed on that machine beyond what is installed by ISSI at the time the system is configured.
- Certain components of the MammoReader system are standard computing and display equipment that can generate and radiate radio frequency energy. If the components are not used in accordance with the instruction manual, they may cause harmful interference to radio communications. Operation may cause unacceptable interference to radio and TV reception. The system must not be operated in the vicinity of medical devices labeled as having, or known to have, potential interference with standard computers and display monitors.
- To help prevent electric shock, plug all power cables into properly grounded power sources. The cables are equipped with three-prong plugs to help ensure proper grounding. Do not use adapter plugs or remove the

grounding prong from a cable. If you must use an extension cable, use a three-wire cable with properly grounded plugs.

- Be sure that nothing rests on the system's cables and that the cables are not located where they can be stepped on or tripped over.
- Do not cover the openings on the component enclosures. The openings are for air convection to protect the equipment from overheating. Also, do not place the system near a source of heat.
- Do not place objects on the scanner.
- Ensure that neckties, jewelry, or hair do not become entangled in the scanner feeder during operation.
- Except for running the tack sheet through the scanner and the cleaning card through the barcode printer, disconnect the system power cords before any cleaning process.

5 Precautions

- The system allows the same views of the left and right breasts to be displayed in either of two configurations: right image to the left of the reviewer, or right image to the right of the reviewer. It is recommended that the images be displayed in a manner consistent with film presentation on the film viewer.
- Before using the MammoReader system, all users should be properly trained and have reviewed the MammoReader System Manual and/or the MammoReader Physician's Manual, and the MammoReader Device Labeling.
- Film size requirements for the MammoReader is limited to X-ray films where either the height or the width is approximately 10 inches (i.e. 8x10 in., 18x24 cm or 10x12 in., 24x30 cm).
- The MammoReader System is set up to use only ISSI supplies, i.e. barcode labels, tack sheets, etc.

6 Adverse Effects

There are no known direct adverse effects on health or safety related to the use of the MammoReader. Indirect risks are that the device may fail to detect and mark some actionable region and/or may mark regions that are not actionable. Refer to Warnings for the Radiological Interpreter above.

7 Non-Clinical Studies

The following sections summarize testing that was performed, the results of that testing, and a description of how the software detects cancers, so the radiologist may better understand how to properly use the MammoReader system.

7.1 Benchmark Testing

Benchmark testing is aimed at measuring the expected performance of the Image Analysis Module of the MammoReader system. Performance is defined in terms of the percentage of cancers that the system can detect and the average number of marks displayed for each image. A large database of digitized mammograms has been used to benchmark the true positive and false positive detection rates for the MammoReader. Each case in the database contains information about the location and type of each cancer as identified by an experienced radiologist. All cancers were verified by biopsy. All negative exams were verified by normal follow-up.

To estimate the sensitivity of the MammoReader system, the Image Analysis Module was run on 465 cancer cases. There were 440 cases with a single cancer, 23 cases with two cancers, and 2 cases with three cancers. In 169 cases, clustered calcifications were the only sign of cancer. The remaining 296 cases had other types of malignancy present (a mass, architectural distortion, or asymmetry). The MammoReader detected at least one cancer region in 89.3% ($\pm 1.4\%$) of the cancer cases. For cases that had malignant calcification clusters as the only sign of cancer, the MammoReader detected at least one cluster 91.0% ($\pm 2.2\%$) of the time. The detection rate for the remaining cancer cases that contained malignant masses was 87.4% ($\pm 1.9\%$).

To estimate the false positive rate of the MammoReader system, the Image Analysis Module was run on 265 negative cases. There were an average of 0.83 marks per image. There were an average of 0.12 calcification marks per image and 0.71 mass marks per image.

Benchmark testing of the MammoReader shows that on average 1.53 true positive prompts are generated per case among cancer cases and 3.32 false positive prompts are generated for non-cancer cases. Since the system limits the number of detections per case, the MammoReader generates an average of 2.32 false positive prompts in cancer cases. This means that even among cancer cases the fraction of marked regions that are cancerous is estimated to be only 40%.

7.2 Repeatability Testing

Some variability in the outcome of the MammoReader is expected from one run to the next regardless of whether films are digitized multiple times on one system or on different systems. The source of this variability is the scanner. The software produces the same output for the same digital image. To measure this variability and its potential effect on estimates of system sensitivity, a repeatability study was designed and executed. Sixty (60) cases were used each having a single cancer detected by the MammoReader in at least one view during a baseline run. These cases were selected from all consecutive screening cancer cases with negative prior exams collected at one clinical site. Fifty-Seven (57) of the cases had a cancer identified by a radiologist in both views. The remaining three cases had a cancer identified in one view.

Excluding the baseline run, the 60 cases were digitized two times on each of three different scanners. The analysis results of the MammoReader were recorded and reviewed to determine if the lesions were detected for each run. A probability measure of the repeatability of the outcome of the system was calculated based on the number of runs in which the MammoReader results matched the baseline results in terms of either detecting or not detecting a particular cancer region. The estimated probability (\pm standard error) of repeating the same outcome in the same view for a particular lesion (or image level repeatability) is 93.3% ($\pm 2.3\%$). The probability of repeating the outcome of either detecting the lesion in at least one view or not detecting the lesion in either view (or case level repeatability) is 97.5% ($\pm 2.0\%$).

Of the 60 cases used in the repeatability study, 19 have calcifications clusters visible in both views and 41 have other signs of cancer. For the calcifications cases, the probability of repeating the same outcome on the image and case level is 95.5% ($\pm 3.4\%$) and 99.0% ($\pm 2.3\%$) respectively. For cases with other signs of cancer, the image level repeatability is 92.2% ($\pm 3.0\%$), and the case level repeatability is 96.8% ($\pm 2.7\%$).

Compared to the baseline run, an average of 5.6% of the instances of cancer were missed in the 6 test runs that were detected in the baseline run. An almost identical average of 5.7% of the instances of cancer were detected in the 6 test runs that were missed in the baseline run. Statistical analysis shows no significant difference in the overall sensitivity between all possible pairs of runs.

8 Summary of Clinical Testing

8.1 Definitions

Term	Definition
Screening mammogram	A routine mammogram obtained for a woman who did not exhibit physical symptoms of breast cancer, and who was not undergoing further evaluation for a specific finding, at the time of the exam.
Diagnostic mammogram	A mammogram obtained for a patient experiencing physical symptoms consistent with breast cancer, or to evaluate a specific finding.
Current exam	A diagnostic or screening mammogram that led to the diagnosis of breast cancer, or a diagnostic mammogram that was obtained in the process of diagnosing breast cancer in a symptomatic woman.
Prior exam	The most recent screening mammogram with a negative assessment obtained prior to a current exam.
BI-RADS™	Breast Imaging Reporting and Data System.
BI-RADS™ Assessment	A value of 0 to 5 that indicates the overall assessment of a mammogram as follows: <ul style="list-style-type: none"> 0 – other procedures required 1 – negative 2 – negative exam; benign findings 3 – probably benign, short interval follow-up suggested 4 – suspicious abnormality, biopsy should be considered 5 – highly suggestive of malignancy
Actionable lesion	A lesion that a radiologist would consider suspicious enough to warrant further evaluation including additional imaging or biopsy for the patient.
Recall rate	The percentage of cases in which the radiologist finds actionable lesions.
Unaided review	A conventional review of a screening mammogram performed by a trained radiologist for the purpose of identifying signs of breast cancer.
Aided review	A review of a screening mammogram that involves using the results of the MammoReader before making a final assessment for a case.

8.2 Sensitivity Study Results Summary

Three radiologists independently reviewed each of 327 current and prior mammography exams of confirmed cancer cases. The cases were consecutive cancers, for which prior mammograms could be located, diagnosed at one of 6 different clinical sites. The sites included a private radiology practice, a university-affiliated hospital, a large not-for-profit hospital, two breast health centers and a medical center affiliated with a large Health Maintenance Organization. The current and prior mammography exams were performed between 1995 and 2000. The prior exam was obtained up to 31 months prior to the current exam, and the average patient age was 65 with a range of 39 to 87 years. All cancer cases with available prior screening exams assessed as negative at the time of screening were used excluding:

1. Cases with missing films.
2. Cases in which the lesion was noted in the prior report.
3. Cases with implants.

Two sets of three experienced radiologists participated in this study. All six radiologists were MQSA certified, had an average of 17 (range of 12 to 24) years of experience in mammography, and read an average of 6,328 (range of 2,078 to 16,000) mammograms in the year prior to the study.

Each radiologist had access to the films of both current and prior exams as well as their reports. Each of the three radiologists was asked to independently assess whether a lesion described in the current report was visible in the prior exam. If judged visible in the prior, the radiologist was asked to subjectively assess whether the identified lesion would warrant patient recall in a standard screening environment if the attention of the radiologist is drawn to that lesion.

The MammoReader was run on all 327 current and prior exams. A lesion was considered detected by the MammoReader if the system correctly marked the location of the lesion in at least one view as determined by a radiologist.

Table 1 shows the number of cancer cases in which the radiologist located a lesion in the current exam, and the percent of these cases in which the lesion was detected by the MammoReader. The table also shows a breakdown of these percentages for diagnostic and screening current exams, as well as detection rates for cases in which a calcifications cluster was identified versus other types of lesions.

Table 1: Detection results on current exams in the Sensitivity Study (there is overlap between cases with calcifications clusters and cases with other types of lesions).

	Total Cases	Lesion Located in Current Exam	Lesion Detected by Mammo-Reader	% Detected of Total Located	95% C.I. Lower Bound	95% C.I. Upper Bound
All current exams	327	322	268	83.23	78.69	87.14
Diagnostic current exams	96	94	79	84.04	75.05	90.78
Screening current exams	231	228	189	82.89	77.37	87.54
Screening currents with calcification clusters		72	66	91.67	82.74	96.88
Screening currents with other types of lesions		163	129	79.14	72.09	85.10

The MammoReader is intended for use as an aid to help reduce the chances of missing a lesion due to oversight in the course of normal reading. The prior screening exams originally read as negative were targeted in the study as cases that could potentially have benefited from the MammoReader. Because of the way the system is intended to be used in standard practice, the system benefit in detecting a cancer that would otherwise be overlooked will only be realized if the radiologist agrees that a particular region marked by the system is suspicious. Hence, the detection of a lesion in the prior exam originally read as negative is meaningful only for lesions that a radiologist is most likely to deem actionable if his or her attention is somehow focused on the location of that lesion.

Table 2 shows the number of prior cases in which the same lesion in the prior exam was deemed actionable by all three radiologists, by two out of three or by one out of three. Each case is counted only once in one of the three categories (i.e. if a case has one lesion deemed actionable by all three radiologists and a second lesion deemed actionable by two out of three, the case is counted only once in the 3/3 category and so on). The table also shows the number of cases in which the same lesion was detected correctly by the MammoReader system.

The last row of Table 2 shows weighted sums of the cases in each category. The cases in each category are weighted by the fraction of radiologists who deemed the cases to be actionable. Cases in the top category are weighted by 3/3 or 1. Cases in the next category are weighted by 2/3, and cases in the last category are weighted by 1/3.

Table 2: Prior cases with lesions judged actionable by 3, 2, or 1 of 3 radiologists. The weighted sum of the total cases actionable is the result of multiplying the number in each category by the fraction of radiologists who deemed the cases actionable within that category then adding the resulting weighted numbers.

	Number of Cases	% Deemed Actionable of 327 Prior Exams	95% C.I. Lower Bound	95% C.I. Upper Bound	Number Detected by Mammo-Reader	% Deemed Actionable and Detected of 327 Prior Exams	95% C.I. Lower Bound	95% C.I. Upper Bound
Deemed actionable by 3 of 3	53	16.21	12.38	20.66	39	11.93	8.62	15.94
Deemed actionable by 2 of 3	56	17.13	13.20	21.65	41	12.54	9.15	16.62
Deemed actionable by 1 of 3	56	17.13	13.20	21.65	26	7.95	5.26	11.43
Weighted Sum	109	33.33	28.24	38.73	75	22.94	18.49	27.88

A larger percentage of the lesions found actionable by all three radiologists were detected by the MammoReader (39/53 or 74%) than the lesions found actionable by only one of the three radiologists (26/56 or 46%). This indicates that the system is more likely to detect lesions that are detected by and/or appear suspicious to more of the radiologists.

When more radiologists agree that a particular lesion is actionable, it is less likely that the lesion would be missed during routine screening if the attention of the radiologist had somehow been focused on that lesion. The weighted sum of 109 provides an estimate of the total number of cases, out of the 327 prior exams that are most likely to be deemed actionable if the MammoReader points out the location of the lesion to an interpreting radiologist during routine screening. The weighted sum of 75 provides an estimate of the number of cases with actionable lesions actually detected by the MammoReader.

This study shows that about 33% (109/327) of the cancer cases collected in the study show actionable signs of the cancer in the prior exams that were originally read as negative. The MammoReader detected the actionable lesion in 69% (75/109) of these cases, or 23% (75/327) of all prior exams.

The time intervals between the current and prior exams on which lesions were deemed actionable, and were detected by the MammoReader, ranged from 4 to 27 months with an average of 14 months. This study showed that 23%, or approximately one in four to five of those women diagnosed with breast cancer and who had had an earlier screening mammogram within the prior 4 to 27 months, could have had their cancers discovered earlier by an average of 14, and a range of 4 to 27, months.

8.3 Specificity Study Results Summary

Ten radiologists affiliated with three different clinical sites participated in this study. The radiologists were MQSA certified, had an average of 10 (range of 1 to 20) years of mammography experience, and read an average of 2,818 (range of 849 to 7,013) mammograms in the year prior to the study. The sites included a university affiliated research center, a not-for-profit large hospital, and a private radiology group practice.

Three hundred consecutive routine-screening exams obtained between July 19 and July 29, 2000 were collected from one of the sites. The cases were not pre-selected in any way and hence, each case may or may not have been read as negative at the time of screening. Cases were only excluded if any of the films were missing or were not available. The average patient age was 51 (range of 34 to 82).

All 300 cases were run through the MammoReader. The system generated 205 calcification clusters and 894 mass marks. Since these cases are routine screening exams, we assume that virtually all of these marks are false detections. This results in a false detection rate of 0.17 clusters and 0.75 masses per image, or an overall false detection rate of 0.92 marks per image. Note that these results are for a different data set than the normal cases used in the benchmark testing described in Section 7.1.

The cases were randomized such that each radiologist read a different set of 150 cases aided and the remaining 150 cases unaided. Further, each case was read by a different randomly selected group of five radiologists aided and by the other five radiologists unaided. The study resulted in 150 aided and 150 unaided readings per radiologist, or a total of 1,500 aided and 1,500 unaided readings across all radiologists.

Each radiologist had access to the screening exam and its prior exam if available. The cases were read in the same sequence within a session and the radiologists were instructed to review each case in the conventional manner before reviewing the MammoReader results. The radiologists did not know if a case was to be read aided or unaided until they finished their conventional review and requested the MammoReader results. Radiologist assessment was provided in the form of an overall BI-RADS assessment for each case.

The recall rate, defined as the percentage of cases assigned a BI-RADS assessment of 0, 4 or 5 out of the total cases reviewed, was calculated for the 1,500 aided and 1,500 unaided readings across all radiologists. Aided and unaided recall rates were also calculated for each radiologist individually. Table 3 shows the average recall rates for each radiologist and the average recall rates across all aided versus unaided readings. The average recall rates (and exact 95% confidence intervals) are 18.1% (16.1%, 20.1%) for the aided readers, and 15.1% (13.3%, 17.0%) for the unaided readers. The difference between aided and unaided recall rates of 3% (95% confidence interval of 1% to 5%) is statistically significant ($P = 0.03$).

Table 3: Recall rates for aided and unaided readings including BI-RADS 0, 4 or 5 as recall (N/A in this table indicates that the recall rate is not available because radiologist had less than one year experience).

RAD	Years Exp.	Mamm. Read per Year	Aided Recall Count	Unaided Recall Count	Aided Recall Rate (%)	Lower Bound for C.I.	Upper Bound for C.I.	Unaided Recall Rate (%)	Lower Bound for C.I.	Upper Bound for C.I.	Reported Recall Rate (%)
1	12	2,415	24	21	16.00	10.53	22.86	14.00	8.88	20.60	12.17
2	5	849	45	29	30.00	22.80	38.01	19.33	13.35	26.57	17.50
3	4	3,000	32	20	21.33	15.07	28.76	13.33	8.34	19.84	15.00
4	11	7,013	42	37	28.00	20.98	35.91	24.67	18.00	32.36	16.35
5	14	2,078	23	27	15.33	9.98	22.11	18.00	12.21	25.10	8.25
6	1	1,000	45	30	30.00	22.80	38.01	20.00	13.92	27.30	N/A
7	15	3,886	10	12	6.67	3.24	11.92	8.00	4.20	13.56	7.80
8	20	3,076	24	19	16.00	10.53	22.86	12.67	7.80	19.07	14.80
9	4	2,876	13	18	8.67	4.70	14.36	12.00	7.27	18.30	13.70
10	14	1,983	13	13	8.67	4.70	14.36	8.67	4.70	14.36	10.70
Total			271	226	18.07	16.15	20.11	15.07	13.29	16.98	

When reading cases aided, the radiologists were asked to review the cases in the conventional manner before reviewing the outcome of the MammoReader, and subsequently making their final assessments. The radiologists had the option to make free notes on each case. Four of the 10 radiologists made specific notes indicating that the MammoReader caused them to recall a case that they would not have recalled otherwise. The radiologists indicated this in 5, 1, 1, and 2 out of the 150 cases they each read unaided and then aided.

Based on these notes, it is estimated that an average of 2 to 3 (between 1% and 2%) of the 150 cases read aided by each radiologist were given a recall assessment as a result of reviewing the outcome of the MammoReader and re-examining the films. This along with the measured aided and unaided recall rates indicate that use of the MammoReader can result in a small increase in the recall rate. This increase is acceptable considering the improvement in earlier detection.

8.4 Conclusions Drawn from Clinical Studies

The clinical data demonstrated that use of the MammoReader would have helped the mammographer detect a certain percentage of cancers on screening mammography that had been missed, with an acceptable increase in callback rate.

An unblinded retrospective study of 327 cancer cases showed that 23% (95% CI, 18-28%) of women diagnosed with breast cancer, who had had prior screening mammograms, could have had their cancers discovered earlier, by an average of 14 months, with use of the MammoReader. The study was not designed to measure the percentage of additional cancers that would be detected in a screening population, which includes both women who have and who have not had prior screening mammograms. The percentage derived from the study was based on the number of cancers marked by the system and judged to be actionable by mammographers in mammograms obtained up to 31 months prior to diagnosis. This percentage may be overestimated because the study radiologists were asked to render unblinded judgments as to the actionability of a lesion identified in retrospect.

In a second clinical study, done independently of the first, ISSI found that use of the MammoReader increased the callback (false positive) rate from 15.1% to 18.1%, a relative increase of 20% (95% CI, 6.6%-32.9%). The callback rate is necessarily increased, because the MammoReader is intended only to alert a mammographer to additional areas on the mammogram that she or he may have failed to notice. In particular, it is specifically intended not to change a mammographer's decision to work up a lesion (i.e., to call the patient back) based on the initial (unaided) review of the mammogram.

9 Principles of Operation

The MammoReader algorithms look for the following primary signs of breast cancer: spiculated lesions, architectural distortions, ill-defined masses, well-defined masses, asymmetric densities, and clusters of microcalcifications. For the purpose of marking 'Regions of Interest (ROIs), microcalcification clusters are considered one type of ROI and all other abnormalities are grouped together as a general class of mass ROI.

The System ranks findings by suspiciousness based on the criteria of the algorithm. It then marks those regions that are above a fixed threshold but marks no more than two mass ROIs or two microcalcification ROIs per film. The number of mass ROIs is further limited to no more than four per case. It may be possible for more ROIs to be marked if there are ties in the rankings of multiple findings. Since there is a fixed upper limit on the number of ROIs the system will mark, an abnormality clearly visible in both views (CC and MLO) may only be marked in one view.

9.1 Masses

The MammoReader system looks for the following characteristics when searching for masses:

1. Radiating structures that would be characteristic of spiculated lesions and architectural distortions.
2. Dense regions with visible boundaries that could be associated with spiculated lesions, ill-defined masses, and well-defined masses.
3. Asymmetry when compared to approximately the same location in the opposite breast. Asymmetry could be a characteristic of all the mass types.
4. The mass region detected must be roughly circular or oval and within the approximate size range of 0.5cm in diameter to slightly over 4cm in diameter.

All four characteristics do not have to be present in order for the system to generate an ROI marker. However, the more of these characteristics that are present, the more likely the system is to generate a marker. For example, a spiculated lesion does not necessarily require a central mass in order to be detected. A well-defined mass will not respond to the algorithm that detects spicules, but would still be detected if it were distinct enough from surrounding tissue.

Mass ROIs are marked with a crosshair at the centroid of the detected mass. The size of the crosshair marker is scaled with the size of the mass detected.

For masses, false positive detections can occur for benign masses and lymph nodes. Crossing breast tissue and tissue radiating from the nipple region can cause a high response to the spiculation algorithm, thereby causing false positive mass detections. Since the software is capable of detecting subtle masses, dense breast tissue and nodular parenchymal patterns can result in a mass detection. The system is also capable of detecting masses that are only partially visible or against the chest wall. As a result, skin folds near the corners of the breast or in the pectoral muscle are occasionally marked.

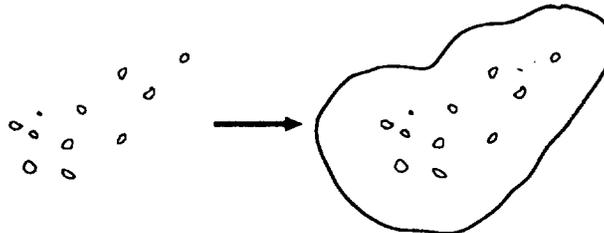
9.2 Microcalcifications

The MammoReader system looks for the following characteristics when searching for microcalcification clusters:

1. Clusters of three or more bright spots within a radius of 2.5mm.
2. Individual calcifications that range in size from approximately 0.1mm to 1.1mm in diameter.

The system examines properties such as size, shape, and contrast when searching for individual bright spots. Clusters are examined for properties associated with spacing between individual calcifications and the distribution of the calcifications within the cluster.

Microcalcification clusters are marked with an outline that is meant to show the extent of the cluster. Given a group of individual calcification detections, the ROI marker is drawn to surround all of them as in the figure below.



A cluster of detected calcifications and the ROI marker generated.

For calcification clusters, benign calcification clusters can cause a false positive detection. Occasionally, larger lucent-centered calcifications are broken into three or more components during individual calcification detection thereby causing a false positive. Even though an effort is made to avoid calcified arteries from being marked by the system, they are often the cause of false positive cluster detections. Artifacts such as deodorant, talcum powder, and other ointments may simulate calcifications in a mammogram image. These can also be marked by the system. Occasionally, linear strands of breast tissue can be flagged by the system as a calcification cluster. Rarely, but still possible, scratches on the film and/or film pick-off can cause a false positive detection.

10 Conformance to Standards

The MammoReader main system components including computing equipment, monitors, film scanner, barcode printer, and laser printer are in compliance with the UL standard for Information Technology Equipment (I.T.E.) per UL1950 or UL60950.

The server computer and monitor, scanner, barcode printer, and laser printer also comply with the EU Low Voltage Directive as demonstrated by testing to the CENELEC standard EN60950.

11 How Supplied

The MammoReader system hardware components consist of commercially available computing equipment combined with off-the-shelf and proprietary software. Hardware components include an X-ray film scanner, a computer processor, disk storage, barcode readers, a system printer, a barcode printer, and electronic displays. The device is delivered as an integrated system with an enclosure and specific installation configurations.

12 Operator's Manuals

The following manuals are provided with the MammoReader System:

1. *MammoReader System Manual*
Describes the entire MammoReader processing system including the maintenance requirements, troubleshooting guide, etc.
2. *MammoReader Physician's and MammoReader Device Labeling Manual*
Provides instruction for the Radiologists' interpretation of the analyzed images and an overview of the system capabilities and limitations.

13 References

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