

LABELING

ESSENTIAL PRESCRIBING INFORMATION

CAUTION: United States Federal Law restricts this device to use by or on the order of a physician.

DEVICE DESCRIPTION

The *Novation*^{DR} consists of an image acquisition system, hardcopy display, and softcopy workstation. It utilizes several components of the Siemens Mammomat 3000 Nova film-screen mammography x-ray system (K932672) for the production of x-rays, for supporting compression of the breast, and for the physical support of the digital image receptor licensed from the Hologic SeleniaTM (SeleniaTM) system (P010025). It also uses the same image capture algorithms, image processing algorithms, and image display algorithms for softcopy display and hardcopy printouts as the SeleniaTM system. The *Novation*^{DR} maintains the same features as the Siemens Mammomat 3000 Nova including the Automatic Exposure Control (AEC) system and anode/filter combinations of Molybdenum/Molybdenum (Mo/Mo), Molybdenum/Rhodium (Mo/Rh), and Tungsten/Rhodium (W/Rh).

The Siemens Mammomat 3000 Nova x-ray stand holds the Hologic amorphous selenium (a-Se) digital image receptor with an active area of 24 x 29 cm, which directly converts incoming x-ray photons to digital image data. At the acquisition workstation, the user enters the patient identification data (or receives it from a work list), acquires, processes, and displays the images for image preview. These images are then forwarded either for hardcopy printing or softcopy display to the MammoReport^{Plus} for review and diagnosis.

INDICATIONS FOR USE

The Siemens Mammomat *Novation*^{DR} Full Field digital Mammography System (*Novation*^{DR}) generates digital mammographic images that can be used for screening and diagnosis of breast cancer and is intended for use in the same clinical applications as traditional film-based mammographic systems. Mammographic images can be interpreted by either hardcopy film or by softcopy at a workstation.

CONTRAINDICATIONS

None known.

WARNINGS AND PRECAUTIONS

The following Cautions and Warnings are found in the Mammomat Novation^{DR} Users Manual:

- **WARNING:** For U.S. only: until such time as an FDA approved accreditation process for full-field digital mammography has been developed, the Novation^{DR} must only be used in current MQSA certified facilities.
- **WARNING:** This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.
- **WARNING:** Avoid using a rewritable CD-ROM as permanent storage media. If the rewritable CD-ROM is full, the data on the disc will be overwritten.
- **WARNING:** Unless they are protected, patient records are stored only temporarily in the local database. Since database space is limited, the oldest patient records and their associated images are periodically deleted to reclaim space for new patients. We strongly recommend that data be sent to an output device.
- **WARNING:** There is a possible squeezing hazard during motorized movements. Be aware of the jam risk that can occur in the working area of the MAMMOMAT.
- **WARNING:** The fact that an exam is incomplete does not prevent the patient record and associated images from being deleted as part of the system's storage space reclamation process. For more information about the reclamation and how to protect a patient record and associated images from being deleted, see DirectRay for Siemens Full Field Digital Mammography (FFDM) Acquisition Workstation Software User's Manual.
- **WARNING:** As is known, some components of disinfectants are detrimental to health. Their concentration in breathable air must not exceed a legally determined limit. We recommend that the appropriate directions on use issued by the manufacturers of these agents be strictly observed.
- **CAUTION:** If the MAMMOMAT is started from being completely shut down the detector should be powered on at least 1 hour before intended use. If it is used sooner than 1 hour after being powered on from complete shutdown, image quality can be affected. The start-up time can be shortened to approximately 5 minutes if the MAMMOMAT is started from standby mode.
- **CAUTION:** Any edits of patient and exam information must be done before clicking the Accept button. Clicking the Accept button ensures that the images go to the correct patient file. Editing this information after image acquisition does not change the information already associated with the image and therefore cannot be resent to archive devices. The images should be accepted or rejected. (see DirectRay for Siemens Full Field Digital Mammography [FFDM] Acquisition Workstation Software User's Manual).
- **CAUTION:** Using the "D" Mode significantly increases the dose delivered. This mode must only be used clinically after consultation with the interpreting physician.
- **CAUTION:** If you click the Exit button, you must restart the acquisition workstation. This takes approximately five minutes.
- **CAUTION:** Do not spray the unit! The cleaning fluid must under no circumstances penetrate into the unit.

- **CAUTION:** Substances, such as anaesthetics and skin disinfectants, used during biopsies can damage or discolor the plastic part of the compression plates. Immediately wipe off with a wet cloth any of these substances spilled on the compression plates.

The following Cautions and Warnings are found in the Mammomat *Novation*^{DR} Installation and Start-up Manual:

- **WARNING:** The existing ground conductor in the mains cable must under no circumstances be disconnected when operating the oscilloscope. Life-threatening electric shock hazard exists. For those measurements, in which any resulting ground loop may falsify the measuring result, use the differential amplifier (difference measurement).
- **WARNING:** If the system is only switched off at the control panel line voltage will still be present at the generator line connection (see wiring diagram). Life-threatening electric shock hazard exists. Disconnect mains cable and comply with the information on this page.
- **WARNING:** After shutdown of the system, there may still be 380 V DC present on the intermediate circuit. Life-threatening electric shock hazard exists.
- **WARNING:** The edges of the metal curtain of the stand are very sharp. They may cause severe injury.
Apply the protective strips as mentioned in Section “Protective strips for the metal curtain” after removing the covers from the stand. Remove the protective strips only when the covers are to be mounted or when vertical adjustment of the swivel-arm system is necessary.
- **WARNING:** The edges of the metal curtain of the stand are very sharp. They may cause severe injury. Remove the protective strips carefully when the covers are to be mounted. Store the strips in the holders provided on both sides of the curtain.
- **CAUTION:** The p.c. boards contain electrostatic highly sensitive components. If not regarded, the components could be damaged. Use ESD-equipment, ground prior to making contact and place the components on a conductive surface.
- **CAUTION:** The unpacking must be carefully performed. There’s a risk for foot injuries when handling heavy parts. Wear safety footwear.
- **CAUTION:** Remove the protective strips before performing vertical adjustment of the swivel arm. If not removed, the protective strips could be damaged. Make sure the protective strips are removed before adjustments.
- **CAUTION:** Risk of damages. If the covers are exposed to internal stress, cracks might arise. The following work must be carried out with caution.
- **CAUTION:** The front cover must not press against the collimator. Risk of damage. Be careful while attaching the front cover.

The following Cautions and Warnings are found in the FFDM AWS Users Manual:

- **WARNING:** The DirectRay FFDM system includes no user serviceable parts. For service assistance, contact the vendor who supplied the system.
- **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

- **CAUTION:** The DirectRay FFDM Detector should be powered on at least 1 hour before intended use. If it is used sooner than 1 hour after being powered on, image quality can be affected.
- **CAUTION:** If you click the Exit button, you must restart the DirectRay FFDM Acquisition Workstation. This takes approximately five minutes.
- **CAUTION:** Accessible from the Admin menu, the DR Device Control function has a selection called DirectRay Power Off. This does not turn off power to any other system components except the DirectRay FFDM Detector, and should be used only when directed by a Siemens service representative.
- **CAUTION:** Edit the patient information before image acquisition to make sure the images go to the correct file. Editing this information after image acquisition does not change the information already associated with the image and therefore cannot be resent to archive devices.
- **CAUTION:** Edit the exam information before image acquisition to ensure the images go to the correct file. Editing this information after image acquisition does not change the information already associated with the image and therefore cannot be resent to archive devices.
- **CAUTION:** Typically, you should not power the DirectRay FFDM Detector off; you would only do this at the direction of a service representative.

The following Cautions and Warnings are found in the FFDM AWS Service Manual:

- **CAUTION:** Backup files prior to this procedure cannot be restored under any circumstances. The results of previously backed up data set will cause a system level file mismatch. Therefore, this procedure should only be performed during system installation.
- **CAUTION:** Make sure that you are choosing the appropriate package. For example, do not install a “Simulation” package on a customer’s system.
- **CAUTION:** MWL must not be running while you are attempting to configure the function. When MWL is running, it writes files. There is a possibility that MWL will overwrite a file that you have changed and your changes will not be preserved.

The following Cautions and Warnings are found in the MammoReport^{Plus} Instruction Manual:

- **WARNING:** In case of problems operating the MammoReport^{Plus} according to the Instructions for use, contact service.
- **WARNING:** If the connection with PACS temporarily is down or if the case/images are not stored on PACS, the message “Receiving images” will not disappear. Under these circumstances the user must make sure that no images are missing before reporting the case.
- **WARNING:** If the images sent from the acquisition station are commented, the comments will not be visible in the MammoReport^{Plus}.
- **WARNING:** If an image for some reason is loaded incompletely or not loaded at all, do not diagnose the patient. Reschedule the case/session.
- **WARNING:** If the images look strange or are flickering, do not diagnose the patient. Contact service.

- **WARNING:** To obtain maximum information from the images, display them in original resolution. The Roaming option is only available from Single tiling modes.
- **WARNING:** DICOM printouts from the MammoReport^{Plus} must not be used for diagnostic purposes.
- **WARNING:** Do not diagnose a patient before all images of the case have been loaded.
- **WARNING:** If the reporting dialog is opened before all current MLO and CC images have been shown in full screen layout, the user will be warned (provided that option “Missed view safety warning” is enabled in the Tools window). This is to make sure the user is aware that the evaluation will be made without having reviewed the images in single tiling (or higher) resolution.
- **WARNING:** Report assessment categories 1-3 will result in a “Control” status. This means that the patient should be invited for the next screening round (e.g. two years later). Report assessment categories 4-5 will result in a “Recall” status. This means that the patient should be examined further.
- **WARNING:** The reports are only stored on the MammoReport^{Plus} workstation, but they can be printed out on paper. Make sure that the reports have been printed before they are deleted from the MammoReport^{Plus} workstation.
- **WARNING:** The defined resolution in magnified area does not apply for CLAHE images.
- **WARNING:** To obtain maximum information from the images, display them in original resolution. The “Missed view safety warning” only notifies the user whether the CC and MLO images have been displayed in full screen view or not. In full screen view images are not displayed in original resolution
- **WARNING:** When reviewing a case for the third time, the case must not be part of a session containing other cases. Create a session containing this case only, or select the case and use the ViewNow function. Otherwise the third reading will not be added to the report.
- **CAUTION:** The markings will be visible in the report, but only for current images. Markings made by one Radiologist will not be visible for other Radiologists.
- **CAUTION:** When deleting a marking, both the marking and its annotations will be deleted.
- **CAUTION:** Do not spray the equipment. The cleaning fluid must not penetrate into the MammoReport^{Plus} workstation and monitors.

The following Cautions and Warnings are found in the MammoReport^{Plus} QC Manual:

- **WARNING:** Image quality must be checked after installation, monitor service and Preventative maintenance.
- **CAUTION:** The created Service user account for quality control purposes must only be used for the tests described in this document.
- **CAUTION:** Do not spray the equipment. The cleaning fluid must not penetrate into the MammoReport^{Plus} workstation and monitors.

The following Caution statement is found in the Quality Control Manual for the Mammomat Novation^{DR} FFDM:

- **CAUTION:** Using the “D” Mode significantly increases the dose delivered. This mode must only be used clinically after consultation with the interpreting physician.

POTENTIAL ADVERSE EFFECTS

The following is a listing of potential adverse effects that apply to mammography and are also applicable to digital mammography using the Mammomat Novation^{DR} digital system.

- Excessive breast compression
- Excessive x-ray exposure
- Electric shock
- Infection and skin irritation
- Abrasion or puncture wound

SUMMARY OF CLINICAL STUDIES

The Mammomat *Novation*^{DR} is based on the Siemens Mammomat 3000 Nova mammography x-ray system cleared in Pre-Market Notification, K932672. It uses the same image acquisition subsystem and image display subsystem as the Hologic SeleniaTM system for mammography screening and diagnosis approved in Pre-Market Application, P010025. FDA and Hologic agreed that Siemens could reference the clinical studies performed by Hologic, Inc. (PMA Number P010025 and PMA supplement P010025/S1). A summary of Hologic’s Clinical studies follows.

A. Study Objectives

A multi-center clinical trial of the SeleniaTM full field digital mammography device was conducted in the United States comparing results obtained with its digital imager to results obtained with screen-film mammography systems. Sensitivity, receiver operating characteristics (ROC), and specificity analyses were performed. A side-by-side feature comparison was also performed..

B. Study Population

Women aged 40 or older undergoing standard screening mammography were included in this study. Women were excluded from the study if they were pregnant; had breast implants; had palpable abnormalities; had existing significant breast trauma; or were unable or unwilling to execute the written consent form.

A readers’ study was performed with an enhanced cancer population. The study cohort consisted of 200 patients, 48 pathology-proven cancers and 152 noncancers either pathology-proven or confirmed by 1-year follow-up, for a total of 400 mammography cases (200 screen-film exams and the 200 corresponding digital exams). Images were acquired from four institutions: University of Virginia, University of California Los Angeles, Good Samaritan Hospital of West Islip, New York, and Thomas Jefferson University Hospital.

C. Demographics

The average age for the women in the study was 56.3 years with a range from 39.8 – 90.6 years. 83.5% of the women were white, 10.5% were African-American, 2.5% Asian, 1.5% other, and 2.0% unknown.

Forty-four (44) patients (91.7%) had a single cancerous lesion, and four patients (8.3%) had two lesions. Cytology results for single cancerous lesions were LCIS (lobular carcinoma in situ—regarded as a pre-malignant condition) in four patients (9.1% of 44) and either DCIS (ductal carcinoma in situ) or invasive carcinoma in the remaining 40 (90.9% of 44). None of the cytology results in the four patients with two cancerous lesions were LCIS. Histology results for cancerous lesions were in perfect agreement with cytology results.

D. Image Acquisition and Interpretation

Twelve MQSA-qualified radiologists interpreted the screen-film and LDBI mammograms. The readers were not aware of the patient's history or any other diagnostic information. To reduce memory as a factor in film interpretation, reading of the screen-film and LDBI mammograms on the same patient were separated by an interval of at least four weeks. Images were read in an environment that simulated routine screening and diagnostic practice. Original screen-film mammograms and hard copy LDBI mammograms were viewed in random order on a multiviewer. Use of a magnifying glass was permitted.

Radiologists worked with a clinical research assistant, responsible for prompting the radiologist and recording the results on the appropriate Case Report Forms. Radiologists were first asked to indicate the density of the breast parenchyma using the BIRADS lexicon. Next, the radiologist was asked if there were any mammographic findings present for the case. The types of abnormalities (i.e. masses, calcifications, architectural distortions, and asymmetric densities) were noted, and the radiologist was instructed to select the "most suspicious" finding. The case report form had breast profiles reproduced with a grid so that the radiologists could indicate the approximate location of the suspicious finding.

In addition, the radiologists were asked to indicate whatever additional workup they would recommend based on the present examination, including comparison to previous films, spot compression, magnification spot compression, ultrasound, biopsy, etc. The readers were then asked to assign an "estimated probability of malignancy for this patient (0-100%)." They were also asked to provide a BIRADS score for the case. If, initially, they assigned a score of 0 (needs further evaluation), they were asked to assign another score other than 0 "if they had to choose from 1 to 5."

After completing the reading of all the cases, a Features Analysis was carried out using the images from the 48 patients positive for cancer. The radiologists were shown side-by-side CC and MLO views of the screen-film and LDBI images from the breast positive for cancer. Each breast was shown for the patient with bilateral cancer. In all, 49 pairs of screen-film and LDBI images were shown to the radiologists for comparison. The radiologists were asked to rate the difference in image quality using a scale from -3 to +3 for six features including pathology.

E. Results

There was a 5.5% decrease in initial BIRADS=0 classifications for the LDBI, compared with screen film mammography. This difference is statistically significant ($p = 0.0197$, 95% CI 1.07% to 10.05%). It is also clinically important, as BIRADS=0 classifications are associated with delays in receiving results of screening mammography (e.g., pending comparison to previous films), and/or recall of the woman into the clinic for further workup.

Summary of Results of Analyses Concerning Accuracy of LDBI

Test	Outcome	LDBI vs. Screen Film	95% CI for Difference	p-value
BIRADS \geq 3	Specificity	+2.7%	(-1.9%, 7.2%)	0.2104
	Sensitivity*	-7.6%	(-12.9%, -2.4%)	0.0086
BIRADS \geq 4	Specificity	+2.0%	(-2.5%, 6.5%)	0.3449
	Sensitivity	-5.2%	(-11.5%, 1.1%)	0.0965
Workup Beyond Comparison to Previous Films	Specificity	+3.7%	(-1.1%, 8.5%)	0.1212
	Sensitivity*	-7.6%	(-14.9%, -0.3%)	0.0419
Recommendation to Biopsy	Specificity	+1.5%	(-0.0%** , 3.1%)	0.0514
	Sensitivity	-2.1%	(-0.7%, 2.9%)	0.3729
ROC: Stated Probability of Malignancy	Average A_z	-0.0343	(-0.0736, 0.0050)	0.0863
ROC: Final BIRADS Classification	Average A_z	-0.0442	(-0.0964, 0.0080)	0.0963

* $p < 0.05$

**Value before rounding is slightly less than zero.

Based on these specificity results, not statistically significant increases in false positive rates for the LDBI were observed compared to screen film mammography. Therefore it is reasonable to conclude that the LDBI is not associated with an increase in overall work-up, or biopsies, of lesions that turn out to be benign, beyond comparison to previous films.

While two of these estimated decreases in sensitivity were statistically significant, analyses of sensitivity reflect, at least in part, a bias against the LDBI. This bias is expected due to design of this particular study, in which subjects were selected on the basis of mammogram results obtained by screen film and not by LDBI.

The bias arises because enrichment of the trial population by cancers necessitates excluding most of the subjects whose screen film mammograms were negative. By including thereby only a small portion of them along, with all the subjects whose screen film mammograms were positive, it diminishes access to most of the subjects whose digital mammograms would have been positive in the face of a negative screen film mammogram. The result is that for those subjects with cancer,

enrichment lowers the digital sensitivity relative to the screen film sensitivity, and, for those subjects without cancer, enrichment lowers the digital false positive rate relative to the screen film false positive rate, or equivalently it raises the digital specificity relative to the screen film specificity.

Multivariate LABMRMC analyses show that the estimated difference in average area under the ROC curves for the LDBI compared with screen film mammography is not statistically significant, using either the stated probability of malignancy or the final BIRADS classification to estimate the ROC curves.

F. Safety

No adverse consequences (serious or otherwise) were reported for patients enrolled during the study.

G. Conclusions

The results of the clinical studies described above provide a reasonable assurance of the safety and effectiveness of the Lorad Digital Breast Imager (P010025) for screening and diagnostic breast imaging.

CONFORMANCE TO STANDARDS

The Siemens MAMMOMAT Novation^{DR} Full Field Digital System meets the following standards:

- IEC 601-1 Medical electrical equipment, general requirements for safety. (1988).
- IEC-601-1-1 Medical electrical equipment, collateral standards: safety requirements for medical electrical systems. (1991)
- IEC-601-1-2 Medical electrical equipment, collateral standard, electromagnetic compatibility for medical electric systems. (1993)
- IEC-601-1-3 Medical electrical equipment, collateral standard, requirements for radiation protection in diagnostic X-ray equipment. (1994)
- IEC-601-1-6 (Committee draft) Usability: Analysis, test and validation of human factors compatibility. (
- IEC-601-2-28 Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis. (1993)
- IEC 601-2-32 Associated equipment of X-ray equipment. (1994).
- IEC 60601-2-45/FDI Script 2000-06-23; Particular requirements for the safety of mammographic stereotactic devices.
- IEC 61000-3-2 (second edition 2000-08) Electromagnetic compatibility (EMC) Part 3-2: Limits – Limits for harmonic current emissions. (Equipment input current 16A/phase).
- SS-EN- 61000-3-3/1995-03-24 Electromagnetic compatibility
- UL 2601 Medical Electrical Equipment, Part 1 – General requirements for safety.
- IEC 604406 & DIN 6832 Cassette standards, which the object tables shall be made.

- IEC 62B/425/NP Evaluation and routine testing in medical imaging departments- Acceptance testing – Image display devices.
- Medical Device Directive 93/42/EEC Annex II.
- American College of Radiology: Recommended specifications for new mammography equipment: Screen film X-ray systems, Image receptors and film processors. June 1995.
- ACR Mammography Quality Control Manual. 1999.
- ACR Stereotactic Breast Biopsy, Quality Control Manual, 1999.
- Blue Book. MDA Evaluation Report MDA/95/40, 1995: Further revisions to guidance notes for health authorities and NHS thrusts on mammographic X-ray equipment for breast screening.

TRAINING PROGRAM

Users must ensure that they have completed the Siemens *Novation*^{DR} training program prior to conducting patient exams. The Siemens training program will address the personnel training requirements under MQSA regulations in product labelling to assure that the prospective users are aware of the required eight hours of training for any medical physicist, technologist, or interpreting physician.

OPERATORS MANUAL/DIRECTIONS FOR USE

The users should refer to the Operators Manuals for directions on how to use the Siemens Mammomat *Novation*^{DR} FFDM system.

PRODUCT COMPLAINTS

Any healthcare professional (e.g., customer or user of this system of products) who has any complaints or has experienced any dissatisfaction in the quality, durability, reliability, safety, effectiveness, and/or performance of this product should notify Siemens. If the device malfunctions and may have caused or contributed to a serious injury of a patient, Siemens Medical Solutions, Inc. should be notified immediately by telephone, fax, or written correspondence.