

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

## **DEVICE DESCRIPTION**

The Lorad M-IV Mammography System is the host mammographic x-ray system for the Lorad Digital Breast Imager (LDBI). In conjunction with the M-IV system, the LDBI includes an image acquisition system, a workstation and hard-copy display. The image acquisition system includes the digital image receptor, which is a large area array mosaic of twelve charge coupled devices (CCDs) optically coupled to a large area thallium activated cesium iodide (CsI:TI) scintillator plate. The image receptor covers an area of 18.6 cm x 24.8 cm. At the Operator Control Panel, the user selects x-ray exposure technique factors and adds patient identification data. The Workstation Computer includes a monitor, keyboard, mouse, interface electronics, and storage devices, an uninterruptible AC power supply and DC power supplies. The Workstation Computer acquires, processes and displays the digital images. The images are then processed for printing and are transmitted to the peripheral hard copy laser film printer. Contrast and brightness are set automatically or they can be user adjusted prior to printing.

## **INDICATIONS FOR USE**

The Lorad Digital Breast Imager generates digital mammographic images that can be used for screening and diagnosis of breast cancer. The Lorad Digital Breast Imager is intended for use in the same clinical applications as traditional screen-film mammographic systems.

## **CONTRAINDICATIONS**

There are no known contraindications.

## **WARNINGS AND PRECAUTIONS**

Lorad Digital Breast Imager (LDBI)

- For U.S. only: until such time as an FDA approved accreditation process for full-field digital mammography has been developed, the LDBI must only be used in MQSA certified screen-film facilities.
- The LDBI Monitor has not been approved for final interpretation of examinations. Final interpretations should be done from films only. Images shown on the monitor are for quality assurance or confirmation purposes only.
- Only images produced by Lorad-recommended laser printers should be used for final interpretation of examinations. For compatible printers, see the latest product data sheets for the system, which can be obtained from Lorad or your sales representative.
- All quality control tests described in the QC manual must be performed at the prescribed frequencies as required under MQSA regulations.

- To assure continued high level operation of the LDBI, the recommended quality control procedures must be followed.
- NEVER switch off the Uninterruptible Power Supply (UPS) except in emergency (due to the risk of data loss).
- To minimize potential damage from thermal shock to the Digital Image Receptor, follow the recommended procedure to shut down the equipment.
- For maximum protection from x-ray exposure, the operator must always remain entirely behind a protective radiation shield for the duration of the exposure.
- If system anomalies or abnormal operation occur, DO NOT use this system. It is the user's responsibility to correct the problems or to have authorized service personnel correct the problems, before the system is used.
- DO NOT open any panels or covers. Lethal voltages are present within the interior of the LDBI Power Supply Unit, Computer Cart and the host mammography machine.
- Any changes to the interconnections must be performed by Lorad authorized personnel.
- Never operate this device in zones where there is a risk of explosion. Electrical equipment used in the presence of flammable anesthetics or oxygen may cause an explosion.
- AVOID direct exposure to the beam. The Optical Disk Drives equipped with this system are a Class I Laser Product. Invisible laser radiation is present if the case to an optical disk drive is open.
- DO NOT store any magnetic media near or on devices, which produce magnetic fields since stored data may be lost.
- Only LDBI recommended accessories should be used with this equipment. Failure to heed this warning may cause unexpected functions and possible data loss.
- Software other than those provided by Lorad specifically for use with this system must NOT be loaded onto the system.
- Adequate cleaning and disinfection is necessary to prevent disease transmission. Be sure to thoroughly clean and disinfect equipment surfaces that contact the patient and all equipment surfaces likely to become soiled during use.
- Never use corrosive solvent or abrasive detergents or polishes. Select cleaning agents that do not damage plastics (polycarbonates), aluminum or carbon fiber.
- Improper cleaning methods or the use of certain cleaning and disinfection agents can damage the equipment, cause poor imaging performance or increase the risk of electric shock. To avoid possible injury or equipment damage:

- Do not use harsh detergents, abrasive cleaners, high alcohol concentration or methanol at any concentration. If skin preparations contain high alcohol concentrations, allow sufficient drying time before applying compression;
- Do not expose equipment parts to steam or high temperature sterilization;
- Never allow liquids to enter the internal parts of the equipment. Do not apply cleaning sprays or liquids directly to the equipment; always use a clean cloth dampened with the spray or liquid. If you become aware of liquid entry, disconnect the electrical supply and have the equipment checked by qualified service personnel before returning it to use.
- Always follow the germicide manufacturer's instructions and precautions for mixing, storage, and method of application, contact time, rinsing requirements, protective clothing, shelf life and disposal to help assure effective and safe use of the product.

### **Potential Adverse Effects**

The following is a list of potential adverse effects that apply to mammography and are also applicable to digital mammography using the Lorad Digital Breast Imager.

- Excessive breast compression
- Excessive X-ray exposure
- Electric shock
- Infection
- Skin irritation, abrasions, or puncture wounds

### **SUMMARY OF CLINICAL STUDIES**

#### **A. Study Objectives**

A multi-center clinical trial of the Lorad Digital Breast Imager full field digital mammography device was conducted in the United States comparing results obtained with the LDBI 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 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, no 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 for screening and diagnostic breast imaging.

**CONFORMANCE TO STANDARDS**

The Lorad Digital Breast Imager (LDBI) meets the following standards:

- IEC 601-1: Medical electrical equipment - General requirements for safety
- IEC 601-1-2: Medical electrical equipment - Collateral standard: Electromagnetic compatibility for medical electric systems
- IEC 601-1-3: Medical electrical equipment - Collateral standard: Requirements for radiation protection in diagnostic X-ray equipment
- IEC 601-1-4: Medical electrical equipment - Collateral standard: programmable electrical medical systems
- IEC 601-2-32 Medical electrical equipment - Particular requirements for the safety of associated equipment of x-ray equipment

**TRAINING PROGRAM**

Users must ensure that they receive training on the LDBI with Lorad training programs prior to use on patients. Lorad training programs will address the new MQSA training regulations in product labeling to ensure that 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 user should refer to the Operator Manuals for directions on how to use the Lorad Digital Breast Imager.

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**PRODUCT COMPLAINTS**

Any health care 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 Hologic. If the device malfunctions and may have caused or contributed to a serious injury of a patient, Hologic should be notified immediately by telephone, fax, or written correspondence.