Seno Iris™ Diagnose Mode

Seno Iris in Diagnose mode features softcopy reading with customizable protocols and CAD display.

Seno Iris, Diagnose mode, is suited for reading direct Digital Mammography (MG), Computed Radiography (CR), and Breast Tomosynthesis (BTO and CTO) images from multiple major manufacturers, as well as for viewing digitized screen film images. The Seno Iris, Diagnose mode, also displays other breast imaging modalities, such as Ultrasound and MRI for a comprehensive diagnostic review.

Image Viewing Features

Image Presentation & Processing

- Auto-scale: Fits the largest breast into display viewport and scales all other images correspondingly
- Auto-align: Paired symmetric image alignment of mispositioned breasts during acquisition
- Auto-update: Newly arriving data (e.g. additional views, CAD) is displayed immediately
- Automatic pre-fetching of prior exams with a visual indication of the pre-fetching status
- Image Folder: A thumbnail gallery gives an overview of all images available for a patient
- Hanging Protocols: fully customizable sequence of layouts
- Fast stepping to next protocol layout
- Linked Pairs: All images can be zoomed simultaneously and panned with auto-alignment
- Zoom options:
 - Auto-scale
 - Free continuous zoom
 - Quadrant zoom
 - Zoom navigator
 - Magnifying glass
- Cross-link: Displays plane of point selected in corresponding image view

- Invert images
- Change orientation (rotate, flip)
- Cineloop control for mouse wheel
- Media viewer to view 2D and 3D images
- Contrast (WW) and brightness (WL)
 - Automatic vendor-specific WW/WL settings
 - Interactive adjustments per image, or per study, or on all images
- Printing improvements
 - Print screen
 - Multiple printers configuration
- Annotations using shapes and text stored as DICOM**
- Presentation State
- Distance, area and angle measurement
- Enhanced search functions
- Customizable display of information from the image's DICOM header
- Ability to organize specific exams in Case Collections.

• These cases are protected from being purged from the local disk.

- Individual per user settings and preferences
 - Patient browser arrangement
 - Hanging protocols
 - Search criteria
 - Printer settings
 - Cineloop speed
 - Tool bar position
 - Font and icon sizes

• eContrast: image processing algorithm that enhances the global contrast of a mammo image. It can be applied only to GE acquired images and requires RAW data. Multiple strengths available to satisfy user preference.





SenoBright* (Contrast Enhanced Spectral Mammography) Review

• Dedicated hanging protocol: step-by-step side-by-side comprehensive display of SenoBright dataset

• Cross-Fading: automatic gradual transition between SenoBright views helping radiologists correlate the contrast uptake of a given area in the recombined view to the corresponding one in the low energy view

• Toggle: button allowing the switch between SenoBright views in a given viewport.

Digital Breast Tomosynthesis Review

• Straight forward visual identification of all series of tomosynthesis planes and slabs

• Dedicated tools to review tomosynthesis data sets: cine-loop, bookmarks, breast localizer, breast height ruler

 V-Preview: Reconstructed image from tomosynthesis projections that appears as a 2D image and is an aid in navigation (only available for SenoClaire images)

• The reconstructed V-Preview image can be stored as a separate BTO (Breast Tomosynthesis Object) DICOM object and auto-sent to another BTO destination.

- Advanced V-Preview navigation tools.
- 3D CAD Enhanced V-Preview (optional license¹).

• The V-Preview image should not be used as a standalone image, and the corresponding slabs or planes must also be reviewed before diagnosis. It is for navigation only and does not replace FFDM.

CAD Display

- Displays CAD markers for micro-calcs and masses
- Supports DICOM CAD Structured Report (SR) objects
- CAD Inspector allows navigation through all CAD

markers and displays corresponding area magnified in an overlay window.

User Management

• Unique user names and passwords.

Keypad Support Options¹

- ShuttlePRO™ for ergonomic tomosynthesis reading
- Fully configurable keypad to user preferences
- Second Edition Keypad: ergonomic and backlit keypad.

¹ This option is not available in all countries. Please ask your GE

representative if this option is available in your country.

Worklist Capabilities

• Manages the comprehensive work and data flow needed for both the diagnostic and screening mammography exams from medical history collection to final reporting.

Assembles DICOM worklists from various sources

- Interfaces with RIS via DICOM Worklist SCU
- If needed, it can automatically create reading tasks for newly arriving images

• Facilitates communication between Radiologist and Technologist via worklist task assignments

• Provides shared reading worklists for multiple readers on multiple Seno Iris, Diagnose mode, workstations, helping to prevent accidental double reading

• In a double reading environment, it creates tasks for first, second and consensus readings.

Quality Assurance

- Provides comprehensive documentation of every reading task
- Status overview of open and finished tasks (per patient and per user)
- Performance statistics (completed tasks, reading status).

Access Control

• User and group administration

• Roaming login: Each user has access to his worklist at any Seno Iris, Diagnose mode.

Administration

• Configuration of workflow through access rights

• Manual override of task distribution e.g. for vacation or replacement.

Interfaces

- DICOM Storage SCP and SCU
- DICOM Query and Retrieve SCU
- DICOM Print SCU
- DICOM Modality Worklist SCU
- Supports DICOM 6000 overlays
- Read and create DICOM CD/DVD including a DICOM viewer
- Store reports as DICOM SR, DICOM Presentation State and encapsulated DICOM PDF
- Send reports via MLLP protocol as HL7 messages
- Image compression and decompression using JPEG 2000
- Supports decompression of JPEG Lossless, Non-Hierarchical, First-Order Prediction (Process 14 [Selection Value 1]) compressed images



• Ability to drag and drop images to other Windows® applications.

IHE Integration Profiles – Actors Implemented

- • Mammography Image
 - Image Display
 - Print Composer
- Scheduled Workflow (SWF)
 - Image Display
 - Evidence Creator
- Consistent Presentation of Images (CPI)
 - Image Display
 - Evidence Creator
 - Print Composer
- Access to Radiology Information (ARI)
 - Image Display
 - Report Reader
- Evidence Documents
 - Image Display
 - Evidence Creator
- Simple Image and Numeric Report (SINR)
 - Report Reader
 - Report Creator (for desktop PC only)
- Portable Data for Imaging
 - Portable Media Creator (with DVD and USB option)
 - Portable Media importer (with DVD and USB option)

Hardware requirements

- Processor: 4 core CPU or better
- Operating System Storage: 1 device with at least 10GB free space
- Data Storage: 1 × 1TB or more
- RAM: 32 GB or more
- Option to connect one monitor
- Hardware slot for graphics card
- Graphic card: 2GB RAM and OpenGL 4.0 or higher
- DVD+/-RW Optical Drive
- Network interface: 1 × Ethernet
- Control monitor: resolution of 1280×1024 pixels
- Diagnostic monitors for primary diagnostic
- interpretation of mammography images
- Seno Iris is compatible with Windows 7 64bit only.

Hardware available from GE

- Intel® Xeon® processor
- 1 × 256 GB, 2 × 1 TB SSD (additional 1TB optional)
- 32 GB RAM
- 8 x DVD+/-RW Optical Drive
- USB Standard Keyboard
- Laser Scroll USB Mouse (6 buttons).
- Windows® 7 Professional (64 bit).

Displays

Eizo** MX191 1MP Display for Patient and Report Management

(Product not intended for Mammo Diagnostic Use)

- 48.1 cm (19") TFT Color Monitor
- Native resolution: 1280 x 1024
- Viewing angle: 178°
- Contrast ratio: 2000:1
- Luminance: 300 Cd/m2 (typical)

• Weight: 6.2 kg (13.66 lb) (with stand); 4.4 kg (9.70 lb) (without stand)

- Power requirements: AC 100 120V, 200 240V: 50-60 Hz
- Power consumption: 41W
- Power Consumption in Save Mode: 0.8W or less.

Barco** Mammo CORONIS 5MP LED Blue Base Grayscale

- Active screen diagonal: 540 mm (21.3")
- Native resolution: 5MP (2560 x 2048) resolution
- Viewing angle: 170°
- Contrast ratio 1200:1
- DICOM calibrated luminance (native white): 600 cd/ m2
- Front sensor adjustments (I-Guard)
- Weight: 13.6 kg (29.7 lbs)
- Display Dimensions Portrait (w x h x d):
 - Portrait : 407 x 523~623 x 235mm
 - Landscape: 493.5x479~579x235mm
- Power requirements: AC 90 264V, 45 65 Hz
- Operational temperature range: 0 to 40°C (32 to 104°F)
- Digital Video Input: DVI Dual Link / DisplayPort
- USB-hub with 1 upstream and 2 downstream ports
- Mercury free



Barco** CORONIS Uniti 12MP (MDCG-12133) Blue Base Grayscale LCD

- Active screen diagonal: 853.44 mm (33.6")
- Native resolution: 12MP (4200 x 2800) resolution
- Viewing angle: 178°
- Contrast ratio 1200:1
- DICOM calibrated luminance (native white): 1000 cd/ m2
- Front sensor adjustments (I-Guard)
- Weight: 33 kg (72.8 lbs)
- Display Dimensions (w x h x d) : 795 x 610 x 300mm
- Power requirements: AC 100 240V
- Operational temperature range: 0 to 35°C (32 to 95°F)
- Digital Video Input: DVI Dual Link / DisplayPort
- USB-hub with 1 upstream and 3 downstream ports

Eizo** GX540 LCD monitors (Clear Base) Mammo Tomosynthesis

- Native resolution: 2560 x 2048
- Viewing angle: 176°
- Contrast ratio: 1200:1
- Luminance: 1200 cd/m2
- Weight: 11.5 kg
- Display dimensions (H x V): 338 x 422 mm (13.3 x 16.6")
- Power requirements: AC 100 120V, 200 240V, 50-60 Hz
- Power consumption (typical): 47W.

Options

• Additional Eizo MX191 1MP monitor 48.1 cm (19") TFT Color Monitor

Standards and Regulations

Seno Iris, Diagnose mode, meets the following requirements:

• CE marked according to Medical Device Directive (MDD) 93/42/EEC

• Conforms to DIN EN 12052 (DICOM 3.0)

• Complies with ISO 13485 Quality Management System – Medical Devices/Design and Development, Production, Installation, Distribution and Servicing of Systems for Mammography.

About GE Healthcare

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our "healthymagination" vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality around the world. Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company (NYSE: GE).Worldwide, GE Healthcare employees are committed to serving healthcare professionals and their patients in more than100 countries. For more information about GE Healthcare, visit our website at <u>www.gehealthcare.com</u>.

GE Healthcare Chalfont St.Giles, Buckinghamshire, UK



You Tube GE Healthcare

GE Healthcare, Europe Headquarters Buc, France +33 800 90 87 19

GE Healthcare, Middle East and Africa Istanbul, Turkey + 90 212 36 62 900

GE Healthcare, North America Milwaukee, USA + 1 866 281 7545



GE Healthcare, Latin America Sao Paulo, Brazil + 55 800 122 345

GE Healthcare, Asia Pacific Tokyo, Japan + 81 42 585 5111

GE Healthcare, ASEAN Singapore +65 6291 8528

GE Healthcare, China Beijing, China + 86 800 810 8188

GE Healthcare, India Bangalore, India +91 800 209 9003

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