Quality Control Testing of Stereotactic Breast Biopsy Units: Siemens and GE


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QC Testing Recommendations for Stereotactic Breast Biopsy Units

- ACR accreditation recommendations
- State requirements
- Manufacturer's recommendations
- Technologist & Physicist QC

Technologist QC Tests

- Reviewed by physicist
- Physicist must know how to perform tests to properly review

Physicist's Annual Survey (ACR)

1) Unit assembly eval.
2) Collimation assess.
3) Focal spot/resolution
4) kVp accuracy/repro.
5) HVL
6) AEC or Manual exposure assessment
7) Digital receptor uniformity
8. Exposure and Dose
9. Image Quality
10. Artifact Evaluation
11. Localization accuracy

Learn Before Starting:

- Connections (upright DSM)
- Power startup
- Getting into the program
- Running the program
- Data analysis menus
- Exiting the program
- Power shutdown

LOOK AT THE MANUALS BEFORE YOU START !

Getting Started

LET A TRAINED TECHNOLOGIST SHOW YOU HOW TO INSERT THE DIGITAL IR

Physicist's Annual Breast Biopsy Equipment Quality Control Tests

As per ACR Accreditation Program …
Per "Manufacturer's Recommendations"

OPDIMA™ : Large-area CCD-based X-ray Image Sensor for Spot Imaging and Biopsy Control in Mammography

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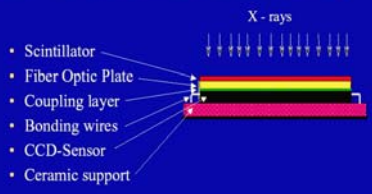
# OES GmbH, D-91349 Egloffstein
Philips Imaging Technologies, NL-5656 AA Eindhoven

Detector Design



- Scintillator
- Fiber Optic Plate
- Coupling layer
- Bonding wires
- CCD-Sensor
- Ceramic support

Detector Design

- Scintillator - CsI(Tl)
  - Thickness = 100µm ± 10%
  - 67% absorption (27kV Mo/Mo + 4cm PMMA)
- Fiber Optic Plate
  - Fiber length = 4mm
  - Fiber diameter = 6µm
  - Extra Mural Absorption (EMA)
  - Lead glass is used to provide additional radiation protection

Detector Design

- Detector area of 49mm x 86mm
- Pixel size = 12µm
- 4096 x 7168 Matrix
- ≈ 30 Million pixels

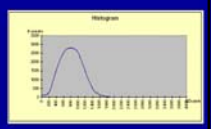
- Two read-out modes:
  - 2x2-binning => 24µm
  - 4x4-binning => 48µm

Electronics

- CCD and electronics integrated into a film-cassette-sized "camera".
- Low dark current design of CCD and readout electronics.
- Specially designed power management of camera electronics.
  - Low heat generation => cooling by convection in ambient air is sufficient.

Automatic Exposure Control (AEC)

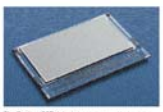
- Part of the CCD is used as an AEC detector
- Average histogram of pixel values of 800 AD-units.
- 23-35 kVp for Mo/Mo, Mo/Rh and W/Rh, for 1-6 cm PMMA.



Spatial & Contrast Resolution

- Spatial Resolution
  - 20 lp/mm for 2x2-binning
  - 11 lp/mm for 4x4-binning
- Contrast Resolution
  - 0.22% in contrast resolution v.s. 0.67% for film at same dose (Kodak® 2000 system)

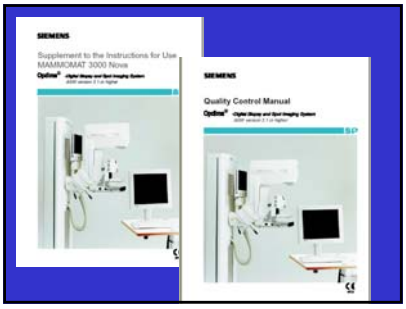
Opdima



Opdima – let the images speak for themselves

Digital detector cassette fits into all 18 x 24 tables	
Field of View	49 x 85 mm
Detector resolution / Matrix:	
Normal	10 lp/mm, 1024 x 1792 pixels
High	20 lp/mm, 2048 x 3548 pixels
Pixel depth	12 bits
Time to image display after aquisition	
Normal resolution	5 s
High resolution	20 s
Workstation	
Type	SUN Ultra 10
CPU	440 MHz
RAM / Hard disk	128 Mbyte / 9 Gbyte
Monitor	
Type	21" color
Resolution	1280 x 1024

Image processing functions	
Windowing	Mouse controlled
Zoom	0.7x, 2x, 4x, 8x times
Magnifying glass	2x, 4x, 8x times
Inversion	Black/ white, White/black
Histogram	Display of gray values
Electronic ruler	Measures distances in mm
Panning	Roam a zoomed image
Filter	Edge enhancement, smooth, noise etc.
Archiving	
Hard disk	9 Gbyte (up to 4000 images)
Magneto Optical Disk	2.3 Gbyte (up to 1000 images)
DICOM (option)	
Secondary Capture	Send and Receive (SCU / SCP)
Digital X-ray	Send and Receive (SCU / SCP)
Mammography	Send and Receive (SCU / SCP)
Documentation	
Printer connection	Network or point-to-point



Test 1: Spatial Resolution

Objective

To ensure that a sufficient spatial resolution is obtained with the Opdima system.

Procedure

3 The grid object table shall be used

4 Select Mo/Mo.

5 To get a proper mAs-value, perform a test exposure in AEC-mode with 4.5 cm PMMA without the bar pattern (it might interfere with the sensitive area of the AEC). Use the same kVp-parameter that was used during the latest Acceptance Test of Opdima.

6 Manually select (on the control panel of M3000) the mAs-value that is closest to the measured AEC mAs value and use it during the following measurements (with AEC mode disabled).

7 Position the "Bar-pattern" on 4.5 cm of PMMA, 1 cm from the chest wall edge. Position the bar pattern diagonally, i.e. with the bars at an angle approximately 45 degrees to the anode-cathode axis. Make an exposure at normal resolution.

8 Use the magnification tool and change grayscale settings to optimize viewing conditions for this evaluation. The grayscale settings are changed using the "brightness" and "contrast" controls in Opdima, either using the scroll bars at the right side of the screen, or by clicking with the middle button of the mouse and dragging. Adjust these settings in order to get the best possible image of the bar pattern. For example, if using 27 kVp and Normal resolution, a gray scale center of 380 and of width 110 might be useful. Note that these values are only guidelines - depending on the specific systems, other values might be more appropriate.

9 Examine the image and determine the highest line-pair resolution where dark/light lines can still be differentiated, and note this value in the test report tables (appendix).

10 Repeat step 3-7 with a W/Rh[1] target/filter combination, if used clinically.

11 Repeat step 2-6, but make the exposure at high resolution this time.

Performance Criteria and Corrective Action

The measured resolution shall be at least 10 lp/mm in normal mode, and at least 13 lp/mm in high-resolution mode[12].

The focal spot condition of the X-ray tube affects the system resolution for M3000 with Opdima. The most likely cause for a decrease in spatial resolution is a degradation of these components. Therefore, if a decrease in spatial resolution can clearly be seen (but the resolution is still above the action levels stated above) it is recommended to perform a normal film exposure of the bar-pattern, so that the cause of the decrease in spatial resolution can be determined. If it can be seen on both Opdima and on film, the x-ray tube needs to be checked. If the decrease is seen only with Opdima, a re-calibration of Opdima is recommended, and shall be performed by a Siemens Field Service Engineer.

If a decrease of resolution below the action levels stated above occurs, the problem must be detected and corrected by a Siemens Field Service Engineer before further examinations are performed with the system.

Test 2: AEC accuracy

Objective

To assess the performance of the AEC (automatic exposure control) function with different exposure conditions.

Required equipment

PMMA phantoms ranging from 2 to 8 cm in thickness.

Introduction

In this test, images shall be obtained using different combinations of kVp, anode/filter material and object thickness. The AEC is designed to control the exposure so that the mean AD-value of the images obtained of homogeneous phantoms shall be close to 600 independently of these parameters.

For some combinations of kVp, object thickness and anode/filter material, the minimum mAs-value (12 mAs), or maximum mAs-value (500 mAs, or lower due to filament-monat 3000 limits) is the limiting factor for proper AEC functionality. These combinations are of no clinical relevance and should not be tested, and have been marked with a gray color in the test report tables (appendix).

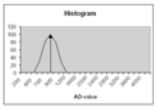


Fig. 6 Histogram

Procedure

1 Start a new examination.

2 Enter Spot mode.

3 In the first part of the test, images shall be taken at normal resolution, and the mammography unit shall be used with a grid object table.

4 Initially, place 2 cm of PMMA on the object table.

5 The first image shall be obtained using 26 kV and Mo/Mo as exposure parameters.

6 Examine the image and measure the mean value. The grayscale parameters (center and width) are shown in the upper bar of the Opdima window. The center value is approximately the mean value and shall be used as such in this test. Note that these values (grayscale center and width) are automatically set to optimal when an image is captured, but will be affected by adjustments made to brightness or contrast in Opdima. Because of this, no adjustments shall be done to these parameters before reading the AD center-value, in order to get a correct reading.

7 Fill in the mean (center) value in the appropriate space in the test report tables (appendix).

8 Repeat step 4-7 with all combinations of object thickness, kV-parameter and anode/filter-combination that are found in the test report tables in the appendix.

9 If used clinically, repeat step 4-8 using a grid table and high resolution mode, as well as stereotactic table in normal resolution mode. When testing the AEC in stereotactic mode, make sure that the tube is in the 0° position. Corresponding appropriate kV and anode/filter combinations that need to be tested are found in the test report tables (appendix).

Performance Criteria and Corrective Action

The measured mean value shall be equal to 600 +/- 15% (above 680 and below 920) for all examined combinations of object table, anode/filter material, kV-value and object thickness.

Test 2: AEC performance capability

Grid table, normal resolution

Table 1: Measured mean value, using 2 cm PMMA				
Anode/filter	26 kV	28 kV	30 kV	32 kV
Mo/Mo				

Table 2: Measured mean value, using 4 cm PMMA				
Anode/filter	26 kV	28 kV	30 kV	32 kV
Mo/Mo				

Table 3: Measured mean value, using 6 cm PMMA				
Anode/filter	26 kV	28 kV	30 kV	32 kV
Mo/Mo				
Mo/Rh				
W/Rh				

Table 4: Measured mean value, using 8 cm PMMA				
Anode/filter	26 kV	28 kV	30 kV	32 kV
Mo/Rh				
W/Rh				

Stereotactic table, normal resolution

Table 8: Measured mean value, using 2 cm PMMA				
Anode/filter	26 kV	28 kV	30 kV	32 kV
Mo/Mo				

Table 9: Measured mean value, using 4 cm PMMA				
Anode/filter	26 kV	28 kV	30 kV	32 kV
Mo/Mo				

Table 10: Measured mean value, using 6 cm PMMA				
Anode/filter	26 kV	28 kV	30 kV	32 kV
Mo/Mo				
Mo/Rh				
W/Rh				

Table 11: Measured mean value, using 8 cm PMMA				
Anode/filter	26 kV	28 kV	30 kV	32 kV
Mo/Rh				
W/Rh				

Test 3: Phantom Image Quality Test

Objective

To ensure that sufficient image quality is achieved.

5 Repeat the procedure using High Resolution mode.

Performance Criteria and Corrective Action

The number of fibers, specks and masses that shall be differentiable are given in the table below:

Table 2: Performance criteria

Phantom used	Fibers	Specks	Masses
RMI 156	>= 4	>= 3	>= 3
RMI 1565	>= 2	>= 2	>= 2

These performance criteria are actually identical for the two different evaluation phantoms, since it is the larger fibers, specks and masses that have been omitted in the RMI 156. The smaller objects are identical in the two phantoms.

Test 4: Monitor Check and Viewing Conditions

NOTE!

See Supplement to the Instructions for Use - Opdima how to display the SMPTE test pattern image and the clinical image.

Objective

To assess the quality of the monitor used with Opdima.

Required equipment

SMPTE test pattern image, clinical image, calibrated luminance meter (with through-the-lens viewing, "point and shoot")

Procedure

1. **The ambient light in the room affecting the monitor shall be measured using the luminance[14] meter. It is necessary that the luminance meter permits measuring the spot luminance from a distance (typically 1 m) from the object being studied, in order to allow the measurement to include reflected light. Therefore, the luminance meter shall be "point and shoot" with "through the lens viewing". Follow the instructions for use for the luminance meter and measure the luminance at the black monitor screen when the screen is turned *off*. Note this value in the test report tables (appendix).**
2. **Display the SMPTE test pattern according to the instruction in the Supplement to the Instructions for Use for Opdima.**
3. **The gray scale is shown as a series of squares in the center of the SMPTE image, ranging from black (0%) to white (100%) in a semi-rectangle. The 0% and 100% squares each contain smaller squares within them that represent signal**

level steps of 5% and 95% respectively. You should be able to differentiate the inner square from the larger square that contains it. The 5% square is normally quite difficult to discern.

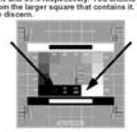


Fig. 7 Location of squares

4. **Visually check the monitor's performance by looking for streaking, fluttering and shadows.**
5. **The spatial resolution (linearity) and aliasing (distortion) of the monitor are within acceptable limits if the high contrast bar patterns in the test image can be seen as patterns of white and black pairs. To use the pattern: In each corner of the image as well as in the very center, inspect the 6 squares filled with varying**

widths of alternating black/white horizontal and vertical lines. You should be able to differentiate all the lines, from fat to narrow (6 pixels, 4 pixels, and 2 pixels) both horizontally and vertically.

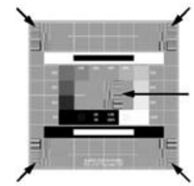


Fig. 8 Location of contrast bar patterns

6. **Use the luminance meter to measure the intensity of black (0%) and white (100%) areas on the SMPTE-image on the screen.**
7. **Calculate the ratio white intensity / black intensity.**

Annually - Medical Physicist

Performance Criteria and Corrective Action

- The ambient light should be kept as low as is possible in the room. We do not state a performance criteria that must be reached, but it is recommended that the ambient light measurement in step 1 under Procedure should give a luminance of less than 1 cd/m². This is important in order to be able to reach the intensity ratio - requirement stated below.
- The ratio white intensity / black intensity shall be equal to or higher than 40 to ensure that sufficient contrast can be obtained. Check if the ambient light measured in step 1 has increased since the last annual test or since the Acceptance Test. If this is the case, try to identify which changes to lightning (new, moved or adjusted light sources) that has occurred. Ambient light shall always be kept at the minimum required to be able to work comfortably with the system. If the intensity criteria is not met and action is taken to reduce ambient light, this test (*Test 4: Monitor Check and Viewing Conditions*) shall be repeated before failure is stated. A procedure for adjusting the contrast and brightness settings of the monitor can also be found in the Acceptance Test. If the ratio white intensity / black intensity is still lower than 40, this test has failed.
- The 5% and 95% squares shall be differentiable.
- All contrast bar patterns shall be differentiable.
- There shall not be any monitor defects detected during step 4) that could influence a diagnose - i.e. the monitor shall not manifest visual defects that could in any way be misinterpreted for a "clinical" finding.
- All objects shall be differentiable in the clinical image.

If any of the tests above fails, even if the guidelines in the technical manual to adjust contrast and brightness have been followed, then this test fails and no further examinations shall be done with the system before the problem has been corrected. The monitor may have to be replaced if the problem can not be corrected in any other way.

Test 6: AEC and Air Kerma reproducibility

Objective

To assess short-term reproducibility of the AEC (automatic exposure control) as well as reproducibility of Air Kerma.

Required equipment

Grid object table, 4 cm PMMA phantom

Procedure

1. **Position 4 cm PMMA on the grid object table.**
2. **Make an AEC exposure with an appropriate anode/filter and kVp combination that is used clinically, for example 27 kVp and Mo/Mo.**
3. **Make an exposure and record the mAs-value**
4. **Examine the image and measure the mean value. The grayscale parameters (center and width) are shown in the upper bar of the Opdima window. The center value is approximately equal to the mean value and shall be used as such in this test. Note that these values (grayscale center and width) are automatically set to optimal when an image is captured, but will be affected by adjustments made to brightness or contrast in Opdima. Because of this, no adjustments shall be done to these parameters before reading the AD center-value, in order to get a correct reading.**
5. **Fill in the mean (center) value in the appropriate space in the test report tables (appendix).**
6. **Calculate the histogram center / mAs ratio.**
7. **repeat step 3 to 6 nine more times in the exact same manner.**
8. **Calculate the COV for the mAs-values as well as for histogram/mAs ratio.**
9. **Repeat step 2 to 8 if Mo/Rh and/or W/Rh are used clinically, select clinically appropriate kVp's.**

Performance Criteria and Corrective Action

The COV (Coefficient Of Variation) for the mAs-value as well as for the histogram center / mAs - ratio shall not exceed 5%.

If the COV for the ratio histogram center / mAs exceeds 5%, the Air Kerma shall be measured in the same manner as it is done for analog (film/screen) systems, since this is probably the source of the problem.

Test 10: Opdima Camera Artifacts

Objective

To assess the degree of artifacts visualized in a phantom image.

Required equipment

Grid object table, 4.5 cm PMMA phantom.

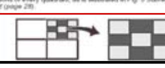
Procedure

This test shall be done for both Normal and High Resolution.

1. **Position 4.5 cm PMMA on a grid object table**
2. **Make an AEC exposure with an appropriate anode/filter and kVp combination that is used clinically, for example 27 kVp and Mo/Mo.**

Performance Criteria and Corrective Action

- Column artifacts might be seen by using magnification. If a column is seen it shall not be larger than 0.1mm. Use the electronic ruler in the Opdima software for this measurement. The electronic ruler can be used with any magnification, this does not change the measured value.
- In-homogenic fields might be seen with a homogenous phantom such as PMMA, this is normally not seen in breast tissue and it's appearance will almost disappear when a clinical center and window is used for grayscale settings. The automatic center and window setting will be very sharp for a homogenous phantom and small contrast differences will be emphasized. However, the intensity difference between two quadrants of the image shall not be greater than 3%. This can be measured by using the pointer tool in the tool box and taking 20 readings in each quadrant, and then calculating the average. The values shall be taken equally from all regions in each quadrant. To ensure this, it is recommended that 4 values are taken from each of the 5 subregions of every quadrant, as is illustrated in Fig. 3 Subregions in each quadrant (page 28).



- Grid-line Artifacts – If grid lines (a pattern of vertical columns) are visible on these flat-field images, the speed of the grid has to be increased. The high speed shall be prolonged to 1500ms with 99% and the low speed shall be set to 40%. A Siemens Field Service Engineer shall do this adjustment.
- Our criteria for accepting artifacts in the digital image is that they shall not have similar characteristics to (I.e. which could be mistaken for) a clinical finding, such that they neither crate nor hide potentially decisive clinical findings. However, several known artifacts for film/screen systems., for example, the "heel" effect and other in-homogeneities in the image can be corrected for by digital systems.

Typical examples of artifacts that can be seen on film vs. similar artifacts on digital images:

Type of Artifact	Film/Screen Imaging	Digital Imaging
Dot	Dust or screen damages	Pixel defect
Lines	Scratches on the screen	Column defect

If any column larger than 0.1mm, inhomogenic fields exceeding 3%, grid-line artifacts that might have clinical importance or an artifact that could be mistaken for a finding is reported in this test, the problem must be detected and corrected by a Siemens Field Service Engineer before further examinations are performed with the system.

SenoVision - Digital Spot and Stereotactic System

- Upgrade onto DMR 800T
  - Space utilization
- Best image quality available
- Higher application utilization
- Easy to use

SenoVision – MFOV Digital Mammography System

- Digital capability required
- Differentiate GE technology and clinical applications
  - A new "concept" in medium FOV mammography
  - Full compatibility with Senographe DMR
  - Senographe 800T upgradeability

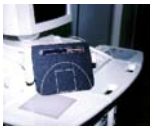
SenoVision

- Diagnostic work-up
  - Digital mags
- Biopsy
- Needle localizations

- 8cm x 8cm FOV CCD
  - Largest coverage area in the industry

- So What?
  - Better spatial orientation within the breast
  - Covers >15% of "normal" breast vs. 6% available by other manufacturers
  - Appropriate coverage for digital spot, digital magnification & digital needle localization

- Unique CCD coupling
  - Parallel fiber optic tapers minimize / eliminate SNR loss or image blurring; 1:1 ratio
  - Image quality at least equal to film in all applications (40 microns)
- Unique Packaging
  - Digital "film / screen" like cassette
  - Same radiological parameters as film-screen
  - No dose increase necessary
  - Standard DMR Bucky or mag holder and stereotactic positioners
  - Easy to use during standard procedures



SenoVision

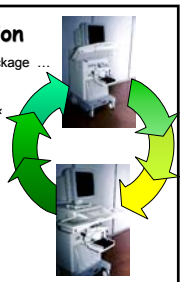
Stereotactic Improvements …

- Automated Needle Positioner
  - Motorized and manual
  - Three pre-selected patterns with up to 4 targets
  - User selectable targets
  - Compatible with Lateral Biopsy Approach
- Compatible with Biopsys Mammotome
  - Lateral Biopsy Approach

- Computer System with User Friendly Interface
  - Auto Window / Level
  - Magnify & contrast glass
  - Simple patient data management
  - DICOM archiving & networking
  - LaserCam interface and/or paper printer
  - Short & long term storage
    - Hard Disk
    - CD-Rom
- Developed on GE Advantage Windows platform
  - Advantage of GE connectivity & networking

SenoVision

The Whole Package …



- Single console / cart device
  - Integrated 18cm x 18cm view box
  - Integrated writing / working space
  - Accessory storage designed into the cart
  - Stores in mammo suite – 2 ft. space needed
- InSite™ compatible remote diagnostics
  - Improve uptime
  - Decrease time to repair

Exposure Modes

Overview

When the Senographe DMR is in "digital" mode (workstation operational and Digital Cassette installed in the cassette receptor), two modes are available:

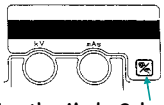
1. **AES (Automatic Exposure Setting)**
2. **Manual**

The AES mode allows three selections, allowing the operator to adjust the exposure for optimum image quality as a function of the composition of the breast:

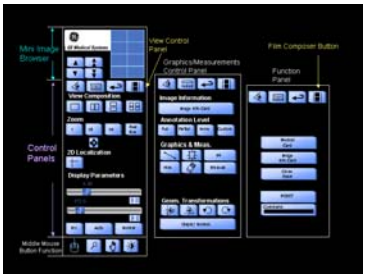
- **MEAN: recommended when the breast composition is about 50% glandular and 50% adipose.**
- **ADIP: recommended for mostly adipose breasts. Exposure is decreased relative to MEAN.**
- **DENS: recommended for mostly glandular breasts. Exposure is increased relative to MEAN.**

Note: The AOP (Automatic Optimization Parameters) and AEC (Automatic Exposure Control) modes of the Senographe DMR cannot be used with the Digital Cassette, but remain fully available for use with conventional film/screen cassettes.

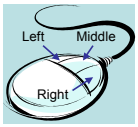
Mode Selection



By pressing the Mode Selection key on the Senographe DMR control keyboard (illustrated above) repeatedly, you can cycle through the available selections.



The left mouse button is used to select functions and items.



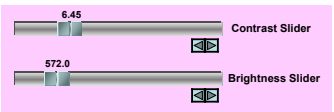
The middle and right mouse buttons are used for specific functions, described in the appropriate sections of the manual.

Zoom Control

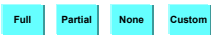
- Zoom=1 corresponds to a full resolution display: each pixel on the screen corresponds to a pixel on the Digital Cassette sensor.
- Zoom=1/2 and Zoom=1/4 correspond to a half and quarter resolution display, respectively: a pixel on the screen corresponds to the average of either 4 or 16 pixels on the Digital Cassette sensor.
- Real Size: the image on the screen is displayed with the same size as that of the Digital Cassette sensor.

Display Parameters (Contrast/Brightness) Controls

Contrast and Brightness Sliders



Annotation Level



Full: All annotations are displayed

Partial: A predefined subset of annotations is displayed. They show the information that most users normally like to see on each image

None: No annotation is displayed on the image

Custom: This button opens the Custom window with the list of available annotation groups

Segment

Press the Segment button to place a line segment on the image that you can use to measure the distance between two points.

The squares at each end of the segment are called the handles.

Ellipse

Press the Ellipse button to place an ellipse on the image, that you can use to highlight an area of interest or to measure the area delimited by the ellipse.

The ellipse is displayed with four handles around it, four tick marks on the ellipse itself, and a cross mark in the center.

Middle Mouse Button Panel

The function of the middle button of the mouse (also referred to as the Multi-Function mouse button)

Magnifying Glass

- To select this function, click with the left button on the (Magnifying glass) button.
- To use the function, move the mouse pointer to the part of the view you are interested in, and press and hold the middle mouse button.

Image Scroll

- To select this function, click with the left button on the (Scroll) button.
- To use the function, move the mouse pointer onto the view and press and hold the middle mouse button to drag the image around as required.

Contrast/ Brightness Control

- To select this function, click with the left button on the (Contrast/Brightness) button.
- To use the function, move the mouse pointer onto the view and press and hold the middle mouse button.