Planmed Nuance Full Field Digital Mammography (FFDM) system

Summary

Planmed Nuance FFDM system is ideal for both high throughput screening and diagnostic mammography facilities. The system offers ultimate digital imaging performance combined with exquisite design and user ergonomics. Open interface through DICOM enables Planmed Nuance FFDM System to be seamlessly integrated to medical imaging and information environment.

Nuance/Nuance Excel FFDM Unit

- Direct digital mammography unit
- Either standard size (Nuance) or large detector (Nuance Excel)
- MaxView Breast Positioning System
- Excellent ergonomics with Side Access Patient Positioning
- Fully automatic Flex-AEC
- Optional Nuance DigiGuide digital stereotactics
- Pages 4-5 and 6-7

Acquisition Workstation (AWS)

- Included in Nuance delivery
- Fast image acquisition and automatic image optimization with Nuance Acquire software
- Optimized for high throughput screening and diagnostic mammography
- Reader-ready images at AWS
- High-resolution 3 megapixel display
- Nuance Manager for system maintenance and quality control (page 10)
- Pages 8-9

Nuance Acquire Station (NAS)

- Optional acquisition station for Planmed Nuance
- Housing for the acquisition workstation, isolation transformer, and optional UPS
- Motorized vertical movement for optimal ergonomics
- Optional swivel display arm for diagnostic purposes
- Page 11

Nuance Softview Review Workstation (RWS)

- Optional review workstation for FFDM
- Two high-resolution 5MP displays
- Customizable workflow with prior mammograms
- Dedicated softcopy reading tools
- Optional DigiPad short-cut key panel
- Optional Softview Plus for multi-modality support
- Optional CAD
- Page 12-13
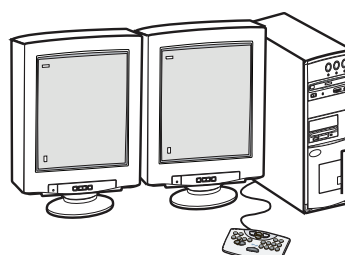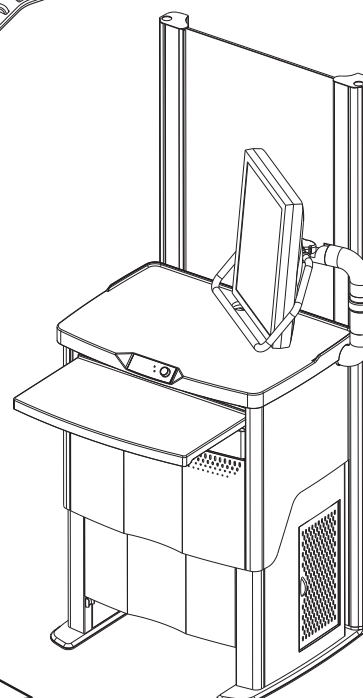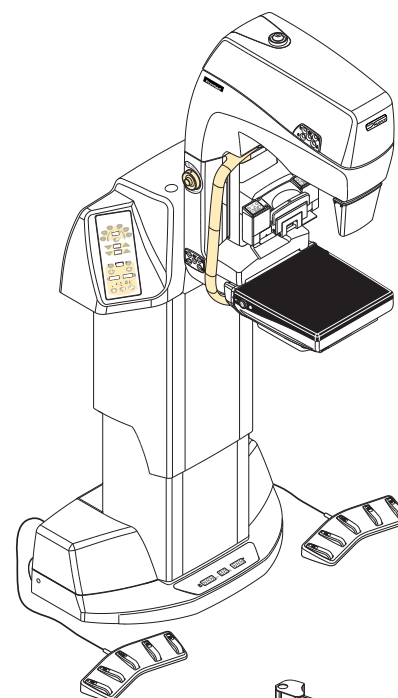
Planmed Nuance Excel

Key Facts
- **Direct digital mammography unit with optional low-dose tube and filtration**
- **Large 24 x 31 cm detector**
- **MaxView Breast Positioning System**
- **Excellent ergonomics with Side Access Patient Positioning**
- **Fully automatic Flex-AEC**
- **Optional Nuance DigiGuide digital stereotactics**

Nuance Excel Full Field Digital Detector
- Direct digital acquisition with Amorphous Selenium (α-Se) detector
- 85 μm pixel size
- 2,816 x 3,584 pixel matrix

Acquisition Workstation (AWS)
- High performance digital image acquisition workstation
- Integrated to optional Nuance Acquire Station (NAS)

X-ray Tube
- High Speed Bi-angular, rotating anode
- Molybdenum target or optional tungsten (W) target
- Anode rotation speed 9700 rpm
- 0.1/0.3 mm focal spot, 300 000 HU
- Adjustable Proximal collimator
- Beryllium window of 1.0 mm
- Dual motorized filters: 30 μm Mo, 25 μm Rh or optional 60 μm Rh, 75 μm Ag with automatic change
- Motorized diaphragms, built-in spot collimator
- Bias circuitry to prevent focal spot blooming effect
- Air and oil cooled
- Tube protected by microprocessor controlled continuous monitoring of the tube load

X-ray Generator
- Low dose high frequency constant potential microprocessor controlled generator
- Anode current:
  Large focus
     - maximum 110 mA (Toshiba E7290)
     - maximum 120 mA (Varian M113 / M113T)
  Small focus
     - maximum 35 mA (Toshiba E7290)
     - maximum 42 mA (Varian M113 / M113T)
- Anode voltage: 20-35 kV with 1 kV step
- 5-660 mAs (Toshiba E7290)
- 5-720 mAs (Varian M113 / M113T)
- 187 - 264 VAC, 50/60 Hz, single phase
- Automatic line voltage compensation
- 15 Amps

Exposure Control Modes
- Anatomically adaptable Flex-AEC
- Automatic sensor selection
- Operation modes: Advanced AEC with Auto-kV, standard AEC and manual mode

C-Arm
- SID 65 cm
- Dual control panels, one on each side of the unit
- Enhanced C-arm driving circuit kit for faster and softer movements
- Motorized, isocentric C-arm rotation with selectable reference projections for quick, easy and light operation
- C-arm angulation from -135° to +180 °
- C-arm vertical travel from 80 to 140 cm
- Digital display of projection angle
- Motorized telescopic column with two adjustable speeds
- Unique Side Access patient positioning provides extra space for patient access and improved patient positioning ergonomics
- Motorized beam collimation: continuously adjustable radiation field with imaging field illumination
- Specially coated ergonomic handles provide excellent touch and feel
- Chin guard with magnetic locking

Compression
- Motorized compression with selectable speed levels
- Patient-friendly degressive compression paddle movement
- Digital display of compression force and breast thickness
- Adjustable compression force limit and digital display
- Fine-tuned compression adjustment either manually or with foot-controls
- Automatic or manual release of the compression after the exposure
- Quick and safety release

Bucky
- Easily attachable ultra light-weight Buckys
- Gently heated Bucky surface provides unique positioning comfort
- Rounded corners for improved patient comfort and hygiene
- Tailor-made special grid to further enhance contrast and resolution
- Microprocessor controlled precise movement
- 36 l/cm; 5:1 grid ratio
- Active detector area 23.9 x 30.5 cm

MaxView Breast Positioning System
- Integrated feature and design
- Integrated MaxView lower module with in/out control buttons for both sheets
- Digital display of traction distance
- Pulling velocity 3-5 mm/s
- Max pulling distance 50 mm

- Dedicated, radiolucent, clear plastic uppper and lower sheets
- MaxView foot controls for driving both sheets
- Safety release

Equipment Base

- Either bolted or optional turnable base
- Integrated third display for projection angle, compression force, breast thickness and traction distance
- Dual trailing MaxView foot controls to operate compression, traction and vertical drive of the C-arm

General

- Compact size and light-weight
- Ergonomic and patient friendly design
- Nuance DigiGuide can be retrofitted
- Standard colour off-white RAL 9016

Optional Features:

Low dose TriFilter technology

- *Tungsten anode with special filtration*

Nuance Acquire Station

- *See NAS specifications for details*

Turnable Base

- *Excellent maintenance access*

Geometric Magnification

- *Light-weight magnification platform with integrated abdomen shield*
- *1.6x or 1.8x magnification factors*
- *Large positioning area with rounded corners for increased patient comfort*
- *Digital display of magnification factor*

Shielding

- *Planmed radiation shield*

Nuance DigiGuide Digital Stereotactics

- *The most light-weight biopsy unit on the market*
- *Compact and easy to attach to the mammography unit*
- *Integrated control electronics and cabling*
- *Ultra-light carbon fibre detector housing without grid and with rounded edges*
- *Multifunctional DigiGuide software for efficient stereotactic imaging*
- *Integrated software module for Nuance Acquire AWS with 3MP high-resolution display*
- *Lateral biopsy assembly for Mammotome®ST*
- *Lateral arm for Bard Vacora*

Planmed Accessory Storage

- *With shelves or drawers, stockable*

CONFIGURATION:

Planmed Nuance Excel includes:

Planmed Nuance Excel digital mammography X-ray unit	FED00590
X-ray tube, Varian / X-ray tube, Toshiba / Tungsten X-ray tube for Excel, Varian	FED00484/ FED00586/ FED00499
Digital detector (Nuance Excel)	FED00288
Nuance Excel Bucky 24x30 cm	FED00121
Mo/Rhodium filter or Rh/Ag filter	FED00117/ FED00500
Adjustable compression paddle assembly 24x30 cm with lock	FED00169
Adjustable compression paddle assembly 18x24 cm with lock	FED00170
MaxView Breast Positioning System	FED00130
Side Access with readiness for stereotactics	FED00134
Turnable base including delivery support / Short fixed base including delivery support / Free standing base	FED00185/ FED00216/ FED00184
Transportation barrow handle with wheels / Transportation barrow handle without wheels	FED00189/ FED00585
Acquisition workstation PC with Nuance Acquire software	FED00631
Acquisition workstation display (3 MP)	FED00137
Exposure switch assembly with cable / Exposure switch assembly without cable	FED00214/ FED00215
Packing for Nuance/Nuance Excel/Nuance Classic	FED00149
Packing for acquisition workstation (AWS)	FED00320
Packing for digital detector	FED00151
User's Manuals	
Installation Manual	
Technical Manual	
Spare Parts Manual	

Planmed Nuance

Key Facts

- **Direct digital mammography unit with optional low-dose tube and filtration**
- **17 x 24 cm detector size**
- **MaxView Breast Positioning System**
- **Excellent ergonomics with Side Access Patient Positioning**
- **Fully automatic Flex-AEC**
- **Optional Nuance DigiGuide digital stereotactics**

Full Field Digital Detector

- Direct digital acquisition with Amorphous Selenium (α-Se) detector
- 85 µm pixel size
- 2,016 x 2,816 pixel matrix

Acquisition Workstation (AWS)

- High performance digital image acquisition workstation
- Integrated to optional Nuance Acquire Station (NAS)

X-ray Tube

- High Speed Bi-angular, rotating anode
- Anode rotation speed 9700 rpm
- Molybdenum target or optional tungsten (W) target
- 0.1/0.3 mm focal spot, 300 000 HU
- Adjustable Proximal collimator
- Beryllium window of 1.0 mm
- Dual motorized filters: 30 µm Mo, 25 µm Rh or optional 60 µm Rh and 75 µm Ag with automatic change
- Motorized diaphragms, built-in spot collimator
- Bias circuitry to prevent focal spot blooming effect
- Air and oil cooled
- Tube protected by microprocessor controlled continuous monitoring of the tube load

X-ray Generator

- Low dose high frequency constant potential microprocessor controlled generator
- Anode current:
  Large focus
    - maximum 110 mA (Toshiba E7290)
    - maximum 120 mA (Varian M113 / M113T)
  Small focus
    - maximum 35 mA (Toshiba E7290)
    - maximum 42 mA (Varian M113 / M113T)
- Anode voltage: 20-35 kV with 1 kV step
- 5-660 mAs (Toshiba E7290)
- 5-720 mAs (Varian M113 / M113T)
- 187 - 264 VAC, 50/60 Hz, single phase
- Automatic line voltage compensation
- 15 Amps

Exposure Control Modes

- Anatomically adaptable Flex-AEC
- Automatic sensor selection
- Operation modes: Advanced AEC with Auto-kV, standard AEC and manual mode

C-Arm

- SID 65 cm
- Dual control panels, one on each side of the unit
- Enhanced C-arm driving circuit kit for faster and softer movements
- Motorized, isocentric C-arm rotation with selectable reference projections for quick, easy and light operation
- C-arm angulation from -135° to +180 °
- C-arm vertical travel from 80 to 140 cm
- Digital display of projection angle
- Motorized telescopic column with two adjustable speeds
- Unique Side Access patient positioning provides extra space for patient access and improved patient positioning ergonomics
- Motorized beam collimation: continuously adjustable radiation field with imaging field illumination
- Specially coated ergonomic handles provide excellent touch and feel
- Chin guard with magnetic locking

Compression

- Motorized compression with selectable speed levels
- Patient-friendly degressive compression paddle movement
- Digital display of compression force and breast thickness
- Adjustable compression force limit and digital display
- Fine-tuned compression adjustment either manually or with foot-controls
- Automatic or manual release of the compression after the exposure
- Quick and safety release

Bucky

- Easily attachable ultra light-weight Buckys
- Gently heated Bucky surface provides unique positioning comfort
- Rounded corners for improved patient comfort and hygiene
- Tailor-made special grid to further enhance contrast and resolution
- Microprocessor controlled precise movement
- 36 l/cm; 5:1 grid ratio
- Active detector area 17.1 x 23.9 cm
- Multifunctional Bucky handle for tightening the lower MaxView sheet, for carrying the Bucky and for easy storage

MaxView Breast Positioning System
- Integrated feature and design
- Integrated MaxView lower module with in/out control buttons for both sheets
- Digital display of traction distance
- Pulling velocity 3-5 mm/s
- Max pulling distance 50 mm
- Dedicated, radiolucent, clear plastic uppper and lower sheets for the small and large Bucky
- MaxView foot controls for driving both sheets
- Safety release

Equipment Base
- Either bolted or optional turnable base
- Integrated third display for projection angle, compression force, breast thickness and traction distance
- Dual trailing MaxView foot controls to operate compression, traction and vertical drive of the C-arm

General
- Compact size and light-weight
- Ergonomic and patient friendly design
- Nuance DigiGuide can be retrofitted
- Standard colour off-white RAL 9016

Optional Features:

Low dose TriFilter technology
- *Tungsten anode with special filtration*

Nuance Acquire Station
- *See separate NAS specifications*

Turnable Base
- *Excellent maintenance access*

Geometric Magnification
- *Telescopic magnification platform with integrated abdomen shield*
- *Easily selectable 1.6x, 1.8x, and 2.0x magnification factors with a single adjustable tower*
- *Large positioning area with rounded corners for increased patient comfort*
- *Digital display of magnification factor*

Shielding
- *Planmed radiation shield*

Nuance DigiGuide Digital Stereotactics
- *The most light-weight biopsy unit on the market*
- *Compact and easy to attach to the mammography unit*
- *Integrated control electronics and cabling*
- *Ultra-light carbon fibre detector housing without grid and with rounded edges*
- *Integrated software module for Nuance Acquire AWS with 3MP high-resolution display*

- *Multifunctional DigiGuide software for efficient stereotactic targeting*
- *Lateral biopsy assembly for Mammotome®ST*
- *Lateral arm for Bard Vacora*

Planmed Accessory Storage
- *With shelves or drawers, stockable*

CONFIGURATION:
Planmed Nuance includes:

Planmed Nuance digital mammography X-ray unit	FED00664
X-ray tube, Varian / X-ray tube, Toshiba / Tungsten X-ray tube, Varian	FED00484/ FED00586/ FED00638
Digital detector (Nuance)	FED00669
Nuance Bucky 18x24 cm	FED00666
Mo/Rhodium filter or Rh/Ag filter	FED00117/ FED00500
Adjustable compression paddle assembly 18x24 cm with lock	FED00170
MaxView Breast Positioning System	FED00130
Side Access with readiness for stereotactics	FED00134
Turnable base including delivery support / Short fixed base including delivery support / Free standing base	FED00185/ FED00216/ FED00184
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User's Manuals	
Installation Manual	
Technical Manual	
Spare Parts Manual	
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Planmed Nuance
Acquisition Workstation (AWS)

Key Facts
- **Acquisition workstation for Planmed Nuance / Nuance Excel**
- **Fast image acquisition and automatic image optimization with Planmed Nuance Acquire software**
- **Optimized for high-throughput screening and diagnostic mammography**
- **Reader-ready images at AWS**
- **High-resolution 3 megapixel display**
- **Nuance Manager for system maintenance and quality control**

AWS Computer
- Multi-core CPU
- Minimum 4.0 GB RAM
- Dual, fast (15 000 rpm) 146 GB SAS hard drives in RAID1, mirrored
- DVD recorder
- Keyboard/mouse
- Microsoft Windows XP Pro, SP2
- 10/100/1000 Base T Ethernet
- Isolation transformer

Monitor
- One high-resolution 21" greyscale flat-panel display
- 3 MP medical imaging board, display resolution 2048 x 1536
- Image conformance and consistency software with optional external calibration sensor
- Optional 2nd LCD monitor (19")

Nuance Acquire Software
- Versatile image acquisition software for Planmed Nuance
- Dedicated software solution for high throughput screening and diagnostic mammography
- Optionally available integrated Nuance AWS DigiGuide software module

Procedure & Patient Information Input
- Patient information input via keyboard or DICOM modality worklist (optional)
- Data fields include:
  - Patient name
  - Patient ID, gender, date of birth, age
  - Study ID
  - Accession number
  - Referring physician, radiologist, operator
  - Study description
  - Procedure, body part
  - Additional info
  - Department, institution
- Application generates date and number of images
- Pick list can be created for ease of input
- Certain fields may be set to default

Reader-Ready Image Display
- Acquired images automatically presented on the display in correct orientation
- Automatic image optimization (see Image Quality Enhancement Package)
- Reader-ready image displayed at AWS
- Reject image function with reject analysis interface for quality control

Image Optimization Package
- Sophisticated analysis performed per image to determine characteristics and unique processing parameters
- Automatic multi-step optimization applied to images
- Combines following parameters in unique combinations for each image
  - Curved LUT settings
  - Noise reduction
  - Dynamic range compression
  - Image enhancement filters
- Protocols are applied automatically to the incoming raw image in the background

General Viewing
- Single series tile viewing
- Layout controls
- Thumbnail navigation bar
- Navigation controls
- Hide toolbars and thumbnails to maximize image on screen and minimize background light

Software Tools:

Image Manipulation and Processing
- Includes zoom, pan, invert, orientation and magnify
- Line measurement tool
- Automatic window level based on DICOM – IOD
- Interactive and pre-set window level
- Pan, Zoom, Scroll, Window all on the mouse buttons
- Edge enhancement (unsharp-mask)

Advanced Image Manipulation Module
- ROI auto window/level
- Pre-set image zoom including full resolution and true size
- Arbitrary rotate image
- Annotation and measurement
- Text / number annotation
- Image markers
- Rectangular / ellipse region of interest (ROI)
- Free hand ROI
- Angle measurement
- Save tagging information in images
- Supports cut & paste to windows clipboard

Consult File Creation
- Images captured for creation of a DICOM file for viewing by other workstations
- Capture tagged images through single mouse click

DICOM JPEG Lossless Compression
- Supports JPEG lossless compression as specified by the DICOM standard

Temporary Data Storage & Management
- Local database storage
- % capacity remaining (high/low water mark)
- Image acquisition date exceeds preset age
- Lock image tool to protect image from deletion
- Search criteria Patient index, search, series/image index
- Single series delete (each image stored as a DICOM series)
- Study list filter and sorting tools

Communications & Data Input
- DICOM storage, query/retrieve, storage commitment
- Configuration of DICOM devices by authorized user via configuration menu, including port and DICOM AET (Applications Entity Title)
- Images can be manually or automatically forwarded to a preset DICOM destination

Nuance Manager
- Status information display
- System performance logging
- Operating and ambient temperature recording
- System maintenance tools
- Quality assurance and calibration tools

Optional Features:

Nuance DigiGuide software
- Integrated Nuance AWS DigiGuide software module

Nuance Acquire Station
- *See NAS specifications on page 11*

Planmed Mammography Information System (MIS)
- *See MIS specification on page 14*

Display Calibration Sensor
- *External sensor for display calibration*

Uninterruptible Power Supply
- *In the event of power failure, UPS ensures that minimal data is lost*

DICOM Print & Capture Module
- *Postscript and DICOM print*
- *Images captured for printing*
- *Layout and capture controls with print queue status & control*

DICOM Single Media Archive with Viewer Module
- *Enables individual or multiple studies to be burned to a CD or MOD as a single media shelf archive or for distribution.*
- *CD/MOD format is DICOM Part 10 file structure*
- *Can be read from any Part 10 reader*
- *User selectable CD Viewer can be burned to the CD*
- *User interface enables sorting of the column headers for quick patient listings*
- *Search capabilities*

DICOM Modality Worklist MWL
- *Query and manage patient demographics via DICOM MWL interface*

DICOM Modality Performed Procedure Step (MPPS)
- *MPPS is used for sending procedure information to HIS/RIS*

Planmed Nuance Manager

Key Facts
- **Central control interface in the Planmed Nuance / Nuance Excel AWS**
- **System performance monitoring**
- **Environmental conditions recording**
- **Quality control tools**
- **Essential for system maintenance**

System maintenance
- Intuitive and user-friendly interface
- Essential tool for technical support
- Included in the Planmed Nuance acquisition workstation (AWS)
- Optionally available for quality control at the Planmed Nuance Softview review workstation

Ease of Use
- All essential software buttons in one window
- No need to look for icons at the Windows desktop
- Central display of system performance and messages

Acquisition Start-up
- Planmed Nuance Acquire acquisition software startup
- Clearly displayed messages indicate when the system is ready for imaging

FFDM Unit Operation and Performance Logging
- Nuance Manager window displays information on system status
- Creates automatically logs on unit performance

Environmental Conditions Recording
- Correct system and ambient temperature is essential for FFDM system operation
- Nuance Manager records environmental conditions at all times

Interactive Quality Control
- Interactive software tools for FFDM quality control
- Independent test image acquisition and archiving
- The system indicates if some of the tests have not been regularly performed or if the results are outside the limits
- Long-term follow-up is included with graphical results display
- The quality assurance protocol can be easily customized according to local requirements

System Maintenance
- Nuance Manager includes tools for the Planmed Nuance FFDM System calibration and general maintenance

Technical Support Solutions
- Flex-AEC calibration tool for signal measurement from the calibration phantom image
- Nuance Manager log collection utility is an invaluable tool for technical support
- With one mouse click, the system creates a compact archive of all relevant system information that can be sent by email to service provider for additional support

Optional Features:

Mammography Workflow Programming Interface
- *In Nuance Manager, the user can design an automatic C-arm driving sequence by simply dragging and dropping.*
- *The sequence can then be activated from the Planmed Nuance unit by pressing a single workflow key*

Key Facts
- **Optional acquisition station for Planmed Nuance and Nuance Excel**
- **Housing for the acquisition workstation, isolation transformer, and optional UPS**
- **Motorized vertical movement for excellent ergonomics**
- **Optional swivel display arm for diagnostic purposes**

Technologist Center for Planmed FFDM
- Designed for digital imaging with the Planmed FFDM Systems
- Optional housing for the AWS components (see pages 8-9)
- Constitutes a high-performance FFDM technologist center together with the Planmed Nuance AWS
- Provides easy access to AWS features
- Extra confidence and better performance

Designed for High Throughput Screening and Precise Diagnostic Procedures
- Swift operation allows the technologist to concentrate on working with the patients and to maintain good working pace
- Optimized for multi-use facility with both screening and diagnostic mammography procedures

Optimal Ergonomics for All Users
- Motorized vertical movement with 33 cm travel
- Extra large tabletop with plenty of working space
- Large enough for two displays
- For even larger space, both displays can be installed on the optional swivel display arms

Comfort and Hygiene
- Silent movement and smoothly closing compartments minimize potential patient distraction and anxiety
- Station covers and special table-top material are easy to clean

Housing for AWS components
- High performance workstation computer
- Keyboard and mouse
- High resolution display
- Optional Uniterruptible Power Supply
- Isolation transformer

Safety
- Strong covers and sturdy structure protects sensitive electronic equipment and digital data
- Extra durable materials ensure prolonged use

Quality Control Center
- QC phantoms, display calibration sensor etc. can be stored in the NAS drawer, from where they are always available
- Smooth movement of the drawer helps to ensure that the sensitive equipment is in perfect condition

Versatile Installation Possibilities with Integrated Cable Management
- All cables are neatly installed and not hanging loose
- If needed, cables can also be drawn up via cable conduits in the optional radiation protection screen

General
- Compact and strong structure
- Ergonomic and user friendly design
- Standard colour off-white RAL 9016

Optional Features:

Swivel Display Arm
- *290 degree turn*
- *Easier diagnostic procedures with reference mammograms*
- *Enables the display to be viewed from the other side of the radiation protection screen*
- *Integrated display cable management*
- *The station can incorporate two swivel display arms*

Shielding
- *Integrated or free standing radiation shield with 0.3 or 0.5 mm Pb eqv.*

Uninterruptible Power Supply
- *In the event of power failure, UPS ensures that minimal data is lost*

Planmed Nuance Softview Review Workstation (RWS)

Key Facts
- **Optional review workstation for Planmed FFDM**
- **Two high-resolution 5MP displays**
- **Customizable workflow for softcopy reading with prior mammograms**
- **Dedicated softcopy reading tools**
- **Optional DigiPad short-cut key panel**
- **Optional Softview Plus for multi-modality support**
- **Optional CAD**

Review Workstation Computer
- Multi-core CPU
- Minimum 4.0 GB RAM
- Dual, fast (15 000 rpm) 146 GB SAS hard drives in RAID1, mirrored
- DVD recorder
- Keyboard/mouse
- Microsoft Windows XP Pro, SP2
- 10/100/1000 Base T Ethernet

Monitors
- Two high-resolution 21" greyscale flat-panel displays
- 5MP medical imaging board, display resolution 2560 x 2048
- Image conformance and consistency software
- Optional 3rd LCD monitor (19")

Nuance Softview Review Software
- Optimized for high through-put softcopy reading
- Supports display resolutions up to 5MP
- Supports portrait format displays in addition to landscape
- Supports display of DICOM GSPS objects and Group 6000 overlays
- Supports 1- 4 display monitors
- Viewing parameters can be preset across all displays
- VGA monitor support for ultrasound images
- 10-bit monitor support

General Viewing Features
- Single series tile viewing
- Layout controls
- Thumbnail navigation bar
- Navigation controls
- Hide toolbars and thumbnails to maximize image on the screen and minimize background light
- Configuration tool for right mouse button short cuts

Automated Workflow
- Smart multi-step protocol creation wizard with point and click multi step guide
- Protocols defined per individual user, per modality, per procedure type

- All key display parameters may be pre-set into a protocol that is triggered automatically based on matching criteria
- Protocol parameters include Window/level, zoom/pan, layout, overview, image order, series arrange, study arrange, historical studies
- Protocols may be configured across multiple monitors
- Define common protocols for users on same network
- Roaming profiles enable user to login at any workstation
- Users can define positioning on current and prior studies for comparison
- Users can define which prior study to be displayed (Most recent prior or Baseline)
- User can select customizable layout for setup of viewing protocols
- Multi-step protocols can be created allowing users to step through different views within a study with a single click of a button
- Extra views are displayed after all steps in the multi-step protocols have been displayed
- Automatic panning of images together (applicable to images that are facing to the same direction)
- Enhanced automatic fit to viewport. For MG images, the application zooms to the image to fit the anatomy to the viewport
- Option to automatically omit non-screening diagnostic images from prior studies

Advanced Workflow
- Dynamic worklist update
- Background loading of next study

Software Tools:

Image Manipulation
- Includes zoom, pan, invert, orientation and magnify
- Interactive and pre-set window level
- Pan, Zoom, Scroll, Window all on the mouse buttons
- Automatic window level based on user defined ROI
- Manual background shutter
- Step-through image display to ensure that the whole breast is viewable

Mammography Specific Tools
- Tools that replicate those used with film mammography including:
  - Bright Light tool to brighten small areas of the image
  - Masking tool to show one-third of the image
  - Binocular tool allows users to block out areas of the image to focus more closely on a small area
- Quick view keys for current and prior MG views
- Cross correlation tool duplicates regions of interest over multiple MG images of the same patient

Paired Viewing Tools
- Image comparison tools for evaluating current and prior or symmetric images simultaneously
- Includes paired zoom, pan and magnification tools

Planmed Nuance Softview Review Workstation (RWS)

Advanced Annotation and Measurement

- Line, angle, ellipse and ROI measurement tools
- Annotation tools
- All annotations and measurements stored per DICOM grayscale softcopy presentation state
- Annotation layers can be turned on and off
- Create contours on MG images using the lesion contouring tool for dynamic , quantitative measurements

Image Post Processing

- Automatic window level based on DICOM – IOD
- Interactive curve LUT (look up table) support for flexible dynamic range compression
- Edge enhancement (unsharp-mask)

Print

- Print to a GDI or Postscript printer

Consult File Creation

- Images captured for viewing by other workstations
- Capture tagged images through single mouse click
- Useful for sending annotations to non-GSPS supporting viewers

Communications and Data Input

- DICOM 3.0 Storage SCP (receives DICOM data)
- Supports DICOM data types: MG (mammography)
- Optional multi-modality support (Softview Plus)
- Easy to use DICOM communication user interface
- DICOM 3.0 SCU – Query retrieve SCP

DICOM JPEG Lossless Compression

- Supports JPEG lossless compression as specified by the DICOM standard

User Administration and Customization

- Customization of user privileges/preferences
- Database capacity gauge, auto deletion criteria
- Creation of user defined worklist
- Study list filter and sorting tools
- Edit/merge patient data (with appropriate access rights)
- Change of status in local database (read, not read, plus configurable states)
- Protect studies from deletion

HIPAA Security and Privacy Features

- Unique user name and password authenticates user access
- Audit trail tracks user actions
  - User name, patient study, date/time, status changes
  - Actions: viewing, annotations, printing, transfer, consult, mark study as read without viewing all images

Integrating Healthcare Enterprise (IHE) compliant

- IHE Integration Statement available for additional information

Optional Features:

Planmed DigiPad

- *Dedicated short-cut panel for the Planmed Nuance Softview*
- *Ergonomically designed short-cut panel for softcopy reading*
- *Large buttons for easy navigation in Nuance Softview software*
- *Adjustable green background light enables efficient working in the softcopy reading room*
- *Easy to configure for optimal review process*

Nuance Softview Plus for Multi-Modality Support

- *Supports DICOM data types: CT, MR, CR, SC, NM, US, XA, DX, RF, PT*
- *Modality based display automatically selects correct tool bar, layouts and window level presets according to modality type*
- *Multi-Modality Presentation Feature Package*
  - *Multiple stack view with linked or unlinked viewports*
  - *Multiple series loaded as a stack into multiple viewports*
  - *Multiple stack control tools*
- *Images from different modalities can be viewed and manipulated at the same time using the optional 3rd LCD monitor*
- *Also available as a multi-modality upgrade package*

DICOM Print

- *True size print capabilities*
- *Print composer enables priority setting, status updates and printer selection/composition*
- *DICOM 3.0 Print*
  - *12-bit printing*
  - *Images captured for printing from 2D*
  - *Capture tagged images or individual frames*
  - *Layout and capture controls with print queue status and control*

DICOM Single Media Archive Module

- *Enables individual or multiple studies to be burned to a CD or MOD as a single media shelf archive or for distribution.*
- *CD/MOD format is DICOM Part 10 file structure*
- *Can be read from any Part 10 reader*
- *User selectable CD Viewer can be burned to the CD*
- *User interface enables sorting of the column headers for quick patient listings*
- *Search capabilities*

- *Integrated CAD Results (page 15)*
- *Integration of CAD package with results presentation*

- *Planmed MIS (page 14)*
- *Versatile mammography information management*

Planmed Mammography Information System (MIS)

Key Facts
- **Optional real-time information management system**
- **Automatic invitation and patient scheduling**
- **Manages e.g. electronic screening forms and radiologist reading and reporting**
- **Records and sends results of the exams and requests for procedures**
- **Modular, web-based system with interfaces to HIS/RIS and PACS**

Planmed MIS Workflow
- Typical MIS controlled workflow in a mammography practice:
  1. Data acquisition from the external registry
  2. Automatic data export to the Planmed MIS
  3. Automated appointment scheduling
  4. Invitation sending to the patient
  5. Patient registering upon arrival
  6. Patient information input in Nuance Acquire software with MIS DICOM Modality Worklist
  7. Readings with Nuance Softview (Radiologist 1, Radiologist 2)
  8. Discussion (Additional mammography, Verifying examinations, Surgery)
  9. Letter to the patient indicating results

Simple to Use
- No unnecessary information on the screen
- Clear patient information and status display
- Easy reschedules and status updates
- Multi-language support

Web-based System
- Information available for all MIS workstations in real-time
- Additional MIS display for Planmed workstations

Configurable User Privileges
- For each step of the workflow, only necessary information is available
- Changes and corrections are easy to make

Bulk Booking and Data Handling
- Hundreds of reservations at once
- Can handle booking at organizational level for multiple departments and rooms

Invitations and Scheduling
- Target group invitations for screening mammography
- Automated scheduling, cancellation, and rescheduling
- Reminders for patients that failed to come
- Scheduling for additional examinations

Registering Data from Screening Forms
- Background patient information in electronic format
- Scars, molds, and other findings can be entered into the system by simply drawing with the mouse

Integrated to Planmed Softview
- RWS integrated MIS is optionally available
- Offers All-At-Once image and information retrieval for optimal review workflow
- Soft interface to PACS

Double Reading and Discussion Management
- Planmed MIS can automatically recognize and present the cases for second reader
- Radiologists can identify cases that require discussion

Surgery Requests and Reports
- Planmed MIS ensures that minimal time is lost if surgery is required, and that the results are easily available when needed

Results Recording and Sending
- Examination results are recorded to the MIS database, from where they can be retrived at any time
- Automatic result information for the patients

Information Provider for the Staff
- Planmed MIS ensures that the staff is prepared for any additional procedures and their results

Connectivity
- The Planmed MIS interface allows easy integration to HIS/RIS and PACS
- Implemented optional connections include also external cancer registries, laboratory and invoicing systems, and eLetter services

Key Facts

- **Optional Computer Aided Detection (CAD) for Planmed FFDM**
- **Separate CAD server with high processing power**
- **Raw images automatically from AWS to the CAD server**
- **CAD markers at RWS as DICOM Structured Report**
- **DigiPad CAD marker on/off button**
- **Intended to be used as an additional help after the initial read**

Smart Mammography CAD Algorithm

- Automatically identifies and marks regions commonly associated with cancer
- Utilizes image processing, feature comparison, and pattern recognition in the detection process
- Analyses typical mammography views plus implant, rolled, tiled or mosaic, magnification, and spot views

Detected Features

- Suspicious clusters of calcifications
- Spiculated and non-spiculated masses
- Architectural distortions
- Asymmetric densities

Typical CAD Scenario

- Typical basic automated CAD data flow is presented below
- 1. Images are acquired at the AWS
- 2. The operator closes the study and the sending of images starts automatically
- 3. Raw images are sent to the CAD server as one DICOM association per image
- 4. Processed images are sent to the RWS as one DICOM association per image. Also raw images may be sent
- 5. After the CAD computation is finished, the results are sent to RWS
- Also available for multi-system environment with several acquisition and review systems

Fast Processing

- 30 cases (4 views/case) per hour

Extra Help for Radiologist

- Typically radiologists find 60-80% of cancers
- CAD finds an additional 15 to 25%
- CAD helps the radiologist to detect cancer earlier

One CAD for All

- One server can process data from maximum of 4 Planmed Nuance or Planmed Nuance Excel FFDM units (optional connections 2 - 4)
- CAD markers can be distributed to unlimited number of review workstations

Markers

- Draws boxes around calcifications and circles masses
- Marker size dependent on the finding
- Indicate the edge of the region
- DICOM Structured Report (SR)

DigiPad CAD Display Feature

- CAD access button in DigiPad short-cut panel
- Allows easy swithing CAD markers on and off

Hardware and Software

- Server PC
- CAD marker display option in Planmed Softview RWS
- 10/100/1000 Base T Ethernet

CAD, PACS, and Third Party RWS

- Tested compatibility with multiple PACS systems
- Suitable also for specified third party RWS's with different CAD marker presentation protocols

Planmed Nuance Workstation Feature Comparison

For details, see workstation specifications.

● standard / ○ optional		Nuance AWS	Nuance AWS with DigiGuide	Nuance Softview RWS	Nuance Softview Plus RWS
Workstation	High performance workstation computer	●	●	●	●
	Medical-grade grey scale monitor(s) (3MP / 5 MP)	●	●	●	●
	Additional LCD monitor	○	○	○	○
	Nuance Acquire Station (NAS)	○	○		
	Monitor quality control software	●	●	●	●
	Display calibration sensor	○	○	○	○
	Nuance Manager software	●	●	○	○
	Modality support: MG	●	●	●	●
	Modality support: MG, CT, MR, CR, SC, NM, US (Softview Plus multi-modality support)			○	●
General features	Customization of user privileges/preferences			●	●
	Image acquisition control with patient information input	●	●		
	Display studies	●	●	●	●
	General viewing controls (e.g. layout and navigation)	●	●	●	●
	Basic image manipulation and analysis (e.g. magnify, zoom, invert, line measurement, window/level)	●	●	●	●
	Mammography specific review tools & protocols			●	●
	Postscript or GDI print	●	●	●	●
	Basic image post processing (e.g. edge enhancement)	●	●	●	●
	Local database storage with study list management	●	●	●	●
Advanced features	Advanced image manipulation tools (e.g. ROI w/l)	●	●	●	●
	High resolution & multi monitor display support	●	●	●	●
	Image optimization package	●	●		
	Automatic image sending to CAD server	○	○		
	Integrated CAD markers display			○	○
	DigiPad short-cut panel for softcopy reading			○	○
	Automated workflow			●	●
	JPEG2000 decompression	○	○	●	●
	Multi-modality presentation feature package			○	●
DigiGuide features	StepWise biopsy procedure assistant	○	●		
	Needle guide unit software for stereotactic targeting	○	●		

Planmed Nuance Workstation Feature Comparison

● standard ○ optional	Nuance Acquire	Nuance Acquire DigiGuide	Nuance Softview	Nuance Softview Plus
Storage	●	●	●	●
Query/Retrieve	●	●	●	●
Storage Commitment	●	●	●	●
JPEG Lossless Compression	●	●	●	●
DICOM print	○	○	○	○
Single Media Archive (Media Storage)	○	○	○	○
Consult File Creation	●	●	●	●
RIS-client Integration			○	○
Modality Worklist	○	○		
Modality Performed Procedure Step (MPPS)	○	○		

See DICOM conformance statements for details

Planmed FFDM Pre-installation Checklist

Pre-installation checklist for Planmed Nuance FFDM installations
NOTE: LOCAL RADIATION SAFETY AND OTHER APPLICABLE REQUIREMENTS HAVE TO BE FOLLOWED

Customer contact information   Sales rep/contact person:

	Requirements	**Check before installation**	**Checked?**
1	**General**		
1.1	Operating conditions	Altitude requirement is met.	☐
1.2		Temperature and humidity requirements are met.	☐
1.3		Does the air-conditioning exist and function as required?	☐
1.4	Radiation protection	Consult the radiation physicist for advice on radiation protection.	☐
1.5	Softcopy review	Suitable environment for softcopy reading.	☐
1.6	Special environmental requirements apply?	Seismicity, mobile installation etc. Yes/No Specify:	☐
1.7	Other site specific general requirements		☐
2	**Electrical**		
2.1	Power supply	Suitable power supply available.	☐
2.2	UPS recommended	Is suitable UPS available? Yes/No	☐
2.3	Other site specific electrical requirements		
3	**Mechanical**		
3.1	The unit has to be bolted to the floor	The floor structure has to support bolting.	☐
		The floor has to fulfil the flatness requirement.	☐
3.2	Room dimensions	Is there need for turnable base (installation close to the wall)? Yes/No	☐
3.3		Is there space for the Nuance unit and the Nuance Acquire Station? Yes/No	☐
3.4	Other site specific issues		
4	**Software**		
4.1	Local IT support	Yes/No Contact:	☐
4.2	Hospital network connection availability	Does suitable network exist? Yes/No	☐
4.3	Virus protection and OS updates	How the site is prepared to keep the computer systems updated? Yes/No	☐
		Is there requirement/need for remote diagnostic system for the equipment? Yes/No	☐
4.4	DICOM printer	Yes/No, Specify: Contact:	☐

Pre-installation checklist for Planmed Nuance FFDM installations
NOTE: LOCAL RADIATION SAFETY AND OTHER APPLICABLE REQUIREMENTS HAVE TO BE FOLLOWED

Customer contact information			Sales rep/contact person:

	Requirements	**Check before installation**	**Checked?**
4.5	PACS	Yes/No, Specify: Contact:	☐
4.6		If the site has no PACS, specify long term storage method:	☐
4.7	HIS/RIS	Yes/No, Specify: Contact:	☐
4.8	Planmed MIS	Is there requirement/need for Planmed MIS? Yes/No	☐
4.9	Softcopy review	Yes/No Specify RWS: Is the RWS located in the same building? Yes/No If No, specify location in additional information field.	☐
4.10	PACS viewers	Are PACS viewers used? Yes/No, Specify: Does the viewer support GSPS? Yes/No	☐
4.11	CAD	Is there need/requirement for CAD? Yes/No	☐
4.12	Other site specific software issues		
5	**Training**		
5.1	What type of on site training is required?	Training required Yes/No Specify:	☐
6	**Delivery and Installation**		
6.1	Access	Check door dimensions.	☐
6.2	Storage room	Enough storage room available for delivery.	☐
6.3	Detector is delivered separately with specific storage conditions	Delivery and storage condition requirements are met.	☐
6.4	Is there existing floor plan?	Plan cable runs and ducting.	☐
7	**Service and lisencing**		
7.1	Service contract	Is there need/requirement for service contract? Yes/No	☐
7.2	Licence program for AWS/RWS	Yearly licence renewal or advance licence for multiple years? Yes/No	☐
8	**Additional information**		
9	**Status**		
	Form completed, date: Expected delivery/installation: Case closed, date:		

Planmed Nuance DigiGuide System

Key Facts
- **Stereotactic system for FFDM**
- **Available for both Nuance and Nuance Excel units**
- **Includes Nuance biopsy unit and integrated Nuance AWS DigiGuide software module**
- **The system can change from screening to diagnostic mode by a simple click of a button**
- **Full DICOM compatibility with optional software modules**

Digital detector
- Direct digital acquisition with Amorphous Selenium (α-Se) detector
- 85 µm pixel size
- Available for both standard (Nuance) or optional large (Nuance Excel) detector
- High quality digital images for stereotactic needle biopsy
- Efficient digital image acquisition
- Optimized image displayed within seconds on the computer screen
- Automatically saved image and patient information in the Nuance Acquire database

Multifunctional Nuance Acquire DigiGuide software
- Integrated optional software package for Planmed Nuance acquisition workstation
- With a single mouse click Nuance AWS transforms to fully equipped workstation for diagnostic mammography procedures
- Designed to assist lesion identification and diagnosis, and to guide perform biopsies
- Patient information input either manually or automatically from optional DICOM modality worklist
- Nuance DigiGuide includes specified tools for lesion marking and stereotactic targeting. In addition, most of the Nuance Acquire image optimization tools are readily available.

Full compatibility with Planmed stereotactic biopsy unit
- Removable biopsy needle unit weighs only 4 kg
- Motorized compression feature with manual fine-tuning possibility
- Accurate positioning of the biopsy needle with digital stereo images
- Reference point, lesion marking, and needle length selection on the computer screen

Digital image storage and retrieval
- Easy access to records in Nuance Acquire DigiGuide database
- Tools to edit, archive, backup, review, and maintain patient records
- Comparison of recent and prior images
- Optional DICOM modules, see Nuance Acquire software specifications

General
- FFDM stereotactic biopsy system
- The most light-weight biopsy unit on the market
- Compact and easy to attach to the mammography unit
- Integrated control electronics and cabling
- Ultra-light carbon fibre detector housing without grid and with rounded edges
- Includes multifunctional Nuance AWS DigiGuide software module for digital stereotactic procedures

Optional Features:

DICOM Modules
- *DICOM Print, Storage and Modality Worklist*

Lateral Biopsy Accessories
- *Lateral biopsy assembly for Mammotome®ST*
- *Lateral arm for Bard Vacora*
- *Lateral arm for core biopsy procedures*
- *Compression paddle for lateral biopsy procedures*

CONFIGURATION
Planmed Nuance DigiGuide System includes:

Needleguide for Nuance DigiGuide	20006203
Adapter for motorized compression	20004649
Stereo collimator	20006064
Hand-held control box	07004080
Holder kit for hand-held control box	20004838
Carbon fibre lower paddle (Planmed Nuance) / Carbon fibre lower paddle (Planmed Nuance Excel)	20002948/ 20006070
Needle guide bushes GA 14, 20 pcs	
Calibration toolkit (including calibration phantom, calibration needle, guide bushes for calibration needle, plastic ruler 20cm, feeler gauge 0.05 mm and Nuance DigiGuide cushion.)	
Control electronics of the needle guidance unit integrated inside the mammography X-ray unit, and controlled with the DigiGuide software	
DigiGuide software	
User's Manual	

● standard ○ optional	Analog stereotactics		Digital stereotactics		
	Sophie Classic-line Cytoguide	Nuance Classic Cytoguide	Sophie Classic-line DigiGuide	Nuance Classic DigiGuide	Nuance DigiGuide
SID	60	65	60	65	65
Biopsy unit weight	6 kg	4 kg	6 kg	4 kg	4 kg
Image size (cm)	9.5 x 5.5	10.3 x 5.5	5 x 5	5 x 5	15 x 6
Biopsy area (cm)	5.2 x 4.2	5.2 x 4.2	5.2 x 4.2	5.2 x 4.2	5.2 x 4.2
Range of projection angle for biopsy (freely selectable)	-120° - +165°	-120° - +165°	-120° - +165°	-120° - +165°	-120° - +165°
Detector type	Film	Film	CCD-based cassette	CCD-based cassette	α-Se-based FFDM detector
AEC	●	●	●	●	●
Motorized cassette movement		●		●	
Automatic collimation	●	●	●	●	○
Lateral holder for Mammotome® ST	○	○	○	○	○
Lateral arm for Bard Vacora	○	○	○	○	○
Lateral arm for core biopsy	○	○	○	○	○
Compression paddle for lateral arm	○	○	○	○	○
Spot imaging capability			●	●	●
Motorized compression		○		●	●
Internal cabling/connectors	●	●		●	●
Interactive user interface			●	●	●
DICOM communication			○	○	○
One-Button Stereo Workflow				●	●