

XR HYBRID, VAMC SALT LAKE CITY, UT
PO# 660-B70040

Description

System description:

The single plane X-ray angiography system for digital acquisitions was designed to meet the requirements of modern angiography and interventional procedures, with a focus on interventional radiology with combined applications.

C-arm ceiling-mounted stand:

System cable outlet at the ceiling carriage, on the patient's left side.

- Up to 5 preprogrammed work positions, additional 50 user-definable work positions and 3 direct positions can be stored and recalled from table side.
- One single joystick for patient angle oriented operation of C-arm and change of source image distance (SID).
- Integrated computerized collision protection
- C-arm positioning 0° to the head end and variable up to 135° to the left and right side along the patient longitudinal axis.
- Double oblique projections of $\pm 100^\circ$ in orbital movements and up to 330° (+180°/-150°) in rotational movements.
- Variable C-arm speeds up to 25°/s.
- Variable focal-spot-to-detector distance between 90 cm and 120 cm.
- Isocenter-floor distance 108 cm.
- Focus-isocenter distance 78.5 cm.

MULTISPACE.T

The stand can be positioned on the left or right of the patient or at the head end, or at any angle in between. It can be moved longitudinally to any position along the length of the patient and also has a park position at a sufficient distance from the patient.

In Focus allows the projection angle to the patient to remain unchanged when rotating the C-arm around the table.

IsoTilt allows the projection angle to the patient to remain unchanged when tilting the patient table (if the tilting function is available).

Both In Focus and IsoTilt improve the efficiency of an examination because there is no need to spend time adjusting the projection angle.

Patient table configuration

Table

- Direct patient access from all sides, both through the swiveling table and large tabletop cantilever.
- Electromechanical release of table swivel at the touch of a button at the table.
- Telescopic foot with motor-driven height adjustment.
- Maximum patient weight: 250 kg. It is possible to install up to 40 kg of additional accessories, plus a further 100 kg for patient resuscitation.

The table can be rotated to ensure quick access to the patient even in emergency situations.

Tabletop

Patient positioning tabletop made of carbon fiber in wide, straight design for universal use. The tabletop is straight all the way to the head area.

Description

Mattress

Matching, special-foam mattress, 4 cm, incl. a latex-free cover.

This visco-elastic comfort mattress reacts to temperature and has the special property of adapting to the individual body shape under the influence of body weight and heat.

Application-specific accessories

- ECG cable clips
- Unilateral armrest: Carbon fiber armrest for cardiology and arm angiography to slide underneath the positioning mattress.
- Infusion bottle holder
- Instrument tray: Plastic instrument tray to be positioned at the patient table above the patient. It is swivable and height-adjustable, so that it can be positioned directly or sideways above the patient.
- Arm holder (1 pair): Two arm holders for comfortable lateral arm positioning along the patient's body.
- Hand switch for radiation release and additional control functions.

If narrow tabletop is selected:

- Head-end holder: Accessory rail plus holder, which is installed at the head end of the narrow tabletop. For attaching hand grips, shoulder supports, head supports, articulated arm supports, and anesthesia curtain.
- Handgrips with support
The patient can hold on to these hand grips with his arms above his head resting comfortably on the supports. This is beneficial for examinations requiring the arms to be held in a specific position. The two stainless steel hand grips with two radiolucent arm rests (12.5 x 24.5 cm/ 4.9" x 9.65") are mounted to the accessory rails of the head-end holder.
It can only be used in combination with the narrow tabletop and with the head-end holder.

Operating modes

Fluoroscopy

- Digital pulsed fluoroscopy with pulse frequencies of 7.5 p/s, 10 p/s, 15 p/s, and 30 p/s in 1k/12 bit matrix. Pulse rates of 0.5 - 4 p/s are also possible with CAREvision.
- Overlay fade: On-line overlay of the reference image onto the active fluoroscopy. This improves efficiency and safety during interventional procedures because additional information which is clinically necessary can be displayed directly in the live fluoroscopy image.

Card acquisition

Digital card acquisition technology with frame rates of 7.5, 10, 15, and 30 f/s acquisition, display, and storage in 1k matrix.

Digital acquisition technology

Digital acquisition technology with frame rates of 0.5 to 7.5 f/s in 1k/12 bit matrix and digital real-time filtration.

Single image and serial acquisitions with time-controlled and manually variable frame rate.

The 1k image matrix with a bit depth of 12 bits allows an excellent image contrast by using 4,096 shades of grey. Thus, the image quality meets highest expectations in angiography and fulfills all prerequisites for precise diagnostics and safe interventions.

Digital Subtraction Angiography:

Digital Subtraction Angiography with frame rates of 0.5 to 7.5 f/s, including pixel shift, remask, roadmap, peak opacification for iodine contrast (MaxOpac), and CO₂ contrast (MinOpac); adding of the anatomical background (landmark) from 0 to 100%.

Includes the "Advanced Roadmap" additional function which offers the following clinical benefits:

Description

- DSA image can be selected as a mask for Roadmap
- Zoom can be changed during Roadmap
- Catheter and vascular contrast can be changed separately

Unexpected patient movements in DSA acquisitions can be corrected easily with Auto Pixelshift. This saves time for the user and improves image quality.

CLEARmap

Special 2D Roadmap operating mode creating a vessel map from a DSA-scene using Maximum Opacification technique. As an additional operating mode, you can also decide to pick one frame out of a DSA run (i.e. for venous access in Roadmap).

This provides improved image quality compared to conventional Roadmap, and reduces x-ray dose and contrast media.

CLEARmatch

Automatic/Online pixel shift processing for most accurate subtracted image display during Roadmap and DSA based on real time movement detection and compensation.

Six degrees of freedom - vertical, horizontal, rotational, zoom and shearing movement (left and right) - allowing highest possible efficacy. In order to show the most recent information in raw format, the pixel shift operation is applied to the mask image. This optimized way of pixel shifting ensures a perfect match of Roadmap image and native fluoro image, being shown at the Assist monitor.

CARE package

ALARA principle

Siemens follows the ALARA principle: "As Low as Reasonably Achievable"; the CARE package (Combined Applications to Reduce Exposure) was developed based on this research and development principle to protect the examiner and the patient.

Dose saving

- CAREfilter: Intelligent control software that minimizes X-ray dose. During fluoroscopy and acquisition, special copper prefilters are automatically inserted into the X-ray beam depending on current X-ray transparency, which is calculated continuously. This is necessary to ensure that the optimal prefilter value is always active. This automation makes work easier for the user because the optimal filter setting need not be adjusted manually for each case.
The adaptive Cu prefiltration has five steps (0.1, 0.2, 0.3, 0.6, 0.9 mm) and is used to lower the reference air kerma and improve radiation quality by reducing the low-energy X-ray radiation.
- CAREvision with as20 detector: Pulsed fluoroscopy with additional, reduced pulse rates of 0.5, 1, 2, 3, 4, 6 p/s. Adaptation of pulse rate to the current application requirements for significant reduction of radiation exposure, especially during interventional procedures.
- CAREvision with as40HDR detector: Pulsed fluoroscopy with additional, reduced pulse rates of 0.5, 1, 2, 3, 4 p/s. Adaptation of pulse rate to the current application requirements for significant reduction of radiation exposure, especially during interventional procedures.
- CAREprofile: Radiation-free positioning of the primary and semi-transparent diaphragms by means of graphic display in the LIH (Last Image Hold). Collimator shutters and semi-transparent filters can be adjusted as a graphical overlay on the last-image-hold without any need for fluoroscopy or radiation.
- CAREposition: Radiation-free object repositioning by means of graphic display of the X-ray center beam and image edges in the LIH image. With CAREposition it is possible to reposition the object under visual control without radiation.
- In case of table movements the current position of the central beam and the image edges are superimposed on the LIH image as orientation points.
- Low dose acquisition: enables dose savings of up to 67 % during the examination. The Low Dose Acquisition protocol can be released with a separate pedal on the footswitch.

Dose monitoring

Description

- CAREwatch: Display of the measured dose-area product and the calculated patient reference air kerma on the flat-screen display. Electronics unit with DIAMENTOR measurement chamber integrated in the collimator housing for dose acquisition.
Configurable screens on the data display and imaging system monitor:
During fluoroscopy: Reference air kerma rate.
During fluoroscopy interval: Accumulated reference air kerma or dose-area product, or percentage of the reference air kerma limit (total from fluoroscopy and acquisition).
- CAREguard: Monitoring the reference air kerma. If the accumulated reference air kerma exceeds one of the three configurable limits, a warning appears on the live display and tableside on the touchscreen control. This allows ideal monitoring of the accumulated reference air kerma during the examination.
- CAREmonitor: Special model-based monitoring of the measured skin entry dose, taking into account the geometric conditions of the system (actual device angulation, table position, patient weight, patient size). It then continually displays whether the skin entry dose applied to a specific region of the patient's body exceeds a specific configurable upper limit. CAREmonitor continually calculates and displays the actual accumulated skin entry dose as a portion of this upper limit. This helps the user to detect a potential patient hazard at an early stage. The patient is therefore better protected against the damaging effects of radiation.

Dose documentation

- CAREreport: Dose information as part of the DICOM Structured Report. After each examination, the information is available in DICOM format and can be sent to a DICOM archive together with the image data, for example. Saving dose information in DICOM format also enables flexible analysis and further processing via a DICOM-capable analysis software/database.
- CARE Analytics: Standalone PC program for analyzing doses in angiography, CT, and radiological examinations. The data can be exported to statistics programs such as Microsoft Office Excel and SPSS for further analysis. CARE Analytics is available for download from the Siemens Intranet.

CLEAR package

The CLEAR package enables optimized image quality through real-time processing of the image data without increasing the radiation dose.

- CLEARpulse optimizes the X-ray pulse in two ways: the high pulse power allows for additional filtration to reduce radiation. In addition CLEARpulse shortens the X-ray pulse through the use of grid-pulsed flat emitter technology in concert with a high anode rotation speed. The required X-ray energy can be provided in a shorter period of time, thereby shortening the X-ray pulse by up to 43% at constant tube voltage. Moving objects like coronary arteries can be visualized sharper and with less blurring artifacts.
- CLEARcontrol: The new histogram analysis provides a more homogeneous image impression by harmonizing over- and underexposed areas of the image. This is done fully automatically, thus eliminating any further manual user corrections through windowing.
- CLEARview: Dose-dependent filtering of the image data efficiently suppresses image noise, enabling clear, sharp images, even for low-dose acquisitions.
- CLEARvessel: Every pixel is analyzed in real time, and vessel edges are shown in high contrast without adding noise to the image.
- CLEARmotion: Fine moving structures, such as small vessels and guidewires, are detected in the image and motion artifacts are suppressed efficiently. The visibility of small moving vessels and guidewires is improved significantly during fluoroscopy.

In addition there is Dynamic Density Optimization (DDO) for on-line harmonization of native series and single images.

Image generation

X-ray generator

Microprocessor-controlled high-frequency X-ray generator with automatic dose rate control.

- Power output: 100 kW at 100 kV (IEC 60601-2-7 and IEC 60601-2-54).
- SID tracking: Automatic tube current adaptation to focal-spot-to-detector distance.
- CAREmatic: Automatic X-ray control system for fully automatic calculation and optimization of exposure data based on fluoroscopic data.
- Patient transparency monitoring.
- Tube load monitoring with indication in the live display.

Description

The optimal X-ray parameters depend on the transparency of the patient at the current angulation, measured during fluoroscopy. These parameters are continuously calculated and updated. Test shots are no longer required. This ensures superior image quality and minimum radiation exposure for user and patient with every exposure release.

GIGALIX 125/30/40/90 - X-ray tube assembly

Triple-focus high-performance X-ray tube assembly with unique flat emitter technology for generating extremely high tube currents of max. 250 mA in fluoroscopy and 1000 mA in acquisition. This provides very good image quality even with heavier patients or steep angulations. The focus is always quadratic and permits outstanding perceptibility of small structures with a nominal quadratic focus of 0.3/0.4/0.7. The anode has a high heat storage capacity of 5.2 MHU and the metal center tube with liquid bearing technology allows a maximum cooling power of 1520 kHU/min. This means that pauses are not required during radiation, even for lengthy procedures. The X-ray tube is almost silent, which is an additional benefit for patient and user.

as40HDR flat detector

The digital high-resolution dynamic flat detector with integrated removable grid is especially designed to fulfill the requirements of interventional imaging. The detector features 16-bit analog-to-digital conversion, resulting in a gray scale resolution of 65,536 gray scales. This in turn improves contrast resolution in 3D imaging with *syngo DynaCT*.

The increased scintillator layer thickness of 750 µm results in a high DQE (Detective Quantum Efficiency) of 77%, thereby improving image quality at low radiation doses.

154 µm pixel arrays provide highest spatial resolution (3.25 LP/mm) and excellent contrast. Acquisition frame rates of up to 60 f/s are possible.

Usable input formats:

- Overview mode 30 cm x 38 cm
- Zoom 1: 30 cm x 30 cm; diagonal 42 cm
- Zoom 2: 22 cm x 22 cm; diagonal 32 cm
- Zoom 3: 16 cm x 16 cm; diagonal 22 cm
- Zoom 4: 11 cm x 11 cm; diagonal 16 cm
- Zoom 5: 8 cm x 8 cm; diagonal 11 cm

The flat detector is mounted on a motorized rotating turntable at the C-arm. It can be rotated by 90°, so that it can be adjusted to landscape format or portrait format. Any angle in between can be adjusted. Motorized adjustment of the detector-patient distance.

The as40HDR flat detector offers additional operating functions directly on the detector housing, such as angulation, FD rotation (cranial/caudal, RAO/LAO), and change of the focus-detector distance.

Removable grid:

The grid can easily be removed, saving the user time in examinations not requiring a grid. For example in pediatrics, where dose reduction is especially important.

Angio collimator

Compact multileaf collimator with rectangular blade, wedge-shaped finger filters for DSA and cardiological applications and graduated filter.

- Independent rotation and shift of filter blades
- Automatic synchronous rotation of detector and collimator unit to compensate image rotation at the different examination positions of the support stand.
- Rotation also possible via table side control enabling upright images of objects or body parts not aligned with the table e.g. arms.

Description

- Manual rotation of the detector and collimator unit using the control right on the detector housing.
- Five-step adaptive Cu pre-filtration (CAREfilter) to reduce the equivalent skin dose and improve radiation quality through dose saving for the soft radiation parts. Filter steps: 0.1; 0.2; 0.3; 0.6; 0.9 mm Cu.
- Electronics unit with DIAMENTOR dose measurement chamber integrated in the collimator housing, for acquisition of the dose-area product and the calculated patient entry air Kerma at the patient entrance reference point (CAREwatch).

StraightView

The flat detector and the multileaf collimator are installed on a motorized rotating turntable on the C-arm. They automatically line up with the table swivel, thus ensuring upright images of objects which are in line with the table. The flat detector and multileaf collimator can also be rotated together at any angle relative to the table, enabling upright presentation and collimation of objects which are not in line with the table.

Image processing

- Image display as positive and negative, windowing, contrast and brightness control, electronic display shutter, image shift (roaming), vertical and horizontal image inversion, magnifying glass, and zoom functions
- Storing of single images as reference images for acquisition and fluoroscopy
- Quantification: angle and length measurements, automatic and manual calibration
- Text functions: user-definable image annotation, free annotation or by means of text components, comments line for the image, R/L display
- Fast and direct access to all series, single images, reference images, and photo file images via MULTIMAP. Access possible both in the examination and in the control room for displaying or post-processing images

Imaging system

Dual architecture

In order to provide highest level system availability, the imaging system consists of two independent computer systems that manage central tasks such as real-time image processing during fluoroscopy or acquisition as well as post-processing and networking functionality separately from one another. This ensures the best possible system performance and availability.

Image storage capacity

25,000 images in 1k/12 bit image matrix. This can be optionally extended to 50,000 / 100,000 images.

Image export and networking

DVD/CD burner

DVD drive for automatic digital image storage in the background on DVD-/CD-ROM for off-line data exchange in DICOM format.

Networking

- Network interface (1000 BaseT) with the following integrated DICOM services:
- DICOM Send: Sending of images into the DICOM network: The DICOM Send function enables fully automatic transfer of generated image data to a DICOM archive and/or a DICOM workstation. The user can perform his examinations without interruption, while the system is fully automatically transferring the images to the archive scene by scene. This is a background process, and thus does not interfere with the ongoing fluoroscopy or acquisition.
- DICOM Storage Commitment (StC): Feedback from the image archive. The DICOM StC function automatically gives feedback on whether the generated image data were successfully transferred. This provides the necessary certainty to the user before deleting the acquired images locally in the imaging system.
- DICOM-Query/Retrieve: Retrieval of archived images from a digital archive or from a workstation: Already archived image data from a previous examination can be fully retrieved and is then available for review and processing. The user can request CT or MR system images from the archive and display the image in the examination room. There is no need for a separate workstation.

Description

- DICOM Structured Report: All the quantification results obtained on the system as well as all dose information on the individual radiation releases can be saved in DICOM SR (enhanced SR) format and transferred to a DICOM network.

Note concerning DICOM interface(s)

The description in the DICOM Conformance Statement downloadable from the Internet is exclusively binding for the functionality of the DICOM interface(s).

Functionalities across interfaces with/between partner systems require explicit validation, since the interpretation of the interface by the partner/target system is not part of the product's responsibility.

A modification of the interface that might be required is not included in the offer; e.g. for the rare case that available configurations are not sufficient. With regard to expenses for interface configurations that might be required, the agreements on maintenance/service of the product apply.

ECG image data

Recording, storage, and display of an ECG lead. The ECG lead is displayed and stored together with the image information.

Display and display suspension

Displays in the exam room

Live and Assist displays are 19" TFT color and gray scale flat-screen displays with high luminance and extended viewing angle.

- Screen size: 19" (48 cm)
- Resolution: 1,280 x 1,024 (pixels)
- Excellent brightness for the entire service life: 400 cd/m² at a contrast ratio of 1000:1
- Flicker-free and distortion-free image display
- Ambient light sensor for optimum adaptation of the image display to the room brightness

Reference images are shown on the Assist display.

Data for device and table position, dose data, and system messages are displayed in the examination and control room on both the live and the Assist display.

Displays in the control room

19" high-contrast display for live image display in the control room is included as a desktop version.

Display suspension

Ceiling-mounted, swiveling, rotating, and height-adjustable display suspension system with longitudinal travel. It features two 19" high-contrast TFT displays for live and reference image display in the examination room (Standard configuration - unless modified).

Operation

syngo

The intuitive syngo operating elements allow for managing the whole process from preparation of the patient to image post processing in a safe, reliable, and time efficient way.

Footswitch

A 4-pedal wired footswitch to release fluoroscopy, exposure, and table brake as well as a configurable additional function is included as standard.

In the examination room

For an ideal workflow, full operation capabilities for the system can be accessed directly at the patient table. These include complete system operation through modular control elements for controlling C-arm movements, the patient table, and the multileaf collimator.

Description

syngo-based touchscreen with multi-functional joystick for operation of the imaging system, including post-processing and quantification as well as selection of the organ programs. The touchscreen is specifically configurable to individual clinical requirements.

This means that the user can operate the system on their own without having to leave the examination room if this is deemed necessary by the situation.

In the control room

Standard Siemens *syngo* control via country-specific keyboard and mouse for all imaging system functions such as image post-processing, storing, and configuring of organ programs.

Siemens Remote Service SRS™

Prepared for Siemens Remote Service SRS™ (during warranty, then with service contract):

- Hardware and software remote diagnosis.
- System remote configuration, e.g. adding of a DICOM node.

Early warning system ensuring system operation.

***syngo* Evolve**

syngo Evolve is a service feature that is offered as a separate sales option. It is a key component of our upgrade strategy and allows you to take advantage of technological advancements.

Customer Care - the customer care solution from Siemens Healthcare

From the moment you purchase your Siemens system you will benefit from many services that are offered by "Customer Care"*. These include:

- Initial application training
- Interactive e-learning for various applications
- Free customer magazines
- Arrangements for clinical training via a global network
- Free trial licenses

You will find information on our e-learning program and further details on general "Customer Care" services on the Internet.

* The availability of "Customer Care" services may be restricted for some systems.

User Training

Siemens recognizes the significant investment you are making in purchasing a new imaging system and are determined that you are able to realize the full capability of this new system. Siemens clinical applications training ensures you have every opportunity to fully utilize your new system.

Content of user training: Handover Training and Follow-up Training

- Introduction to the functions, options, and handling of the Angiography system
- Instruction on the use of the Angiography system together with modern, highly-developed applications

Delivery & duration of the user training varies and may be country specific so for additional information please contact your local Siemens representative.

Automap optimizes the procedure workflow, especially during interventions. A selected reference image displaying the needed medical information (e.g. before dilatation) is used as the basis for moving the system to the correlated position automatically. The intervention can be continued immediately without manually repositioning the patient. On the other hand, the system is able to select a reference image for the current device position. In case of changes in device position, this enables the user to see the corresponding reference images quickly and safely.

- $\pm 15^\circ$ head up/head down positioning.
- Iso-tilt functionality for maintaining the projection during table tilt along the patient axis.
- Motorized, power-dependent table movement in longitudinal direction when the table is tilted (power-assisted control).
- Electromechanical release of table swivel at the touch of a table button.
- Max. patient weight 200 kg. It is possible to install up to 40 kg of additional accessories.

- $\pm 15^\circ$ lateral tilting range.
- $\pm 15^\circ$ head up/head down positioning.
- Iso-tilt functionality for maintaining the projection during table tilt along the patient axis.
- Motorized, power-dependent table movement in longitudinal direction when the table is tilted (power-assisted control).
- Max. patient weight 200 kg. It is possible to install up to 40 kg of additional accessories.
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Excellent image quality from the abdomen to the feet is due to the fact that adjustable parameters such as acquisition frame rate, measuring fields, position of collimator blades and semitransparent filters are stored specifically for each table position. That way the different X-ray transparencies for abdomen, legs and feet can be compensated and a consistent image quality with best possible contrast is achieved. Just one single injection of contrast media protects the health of the patient and gives the physician an instant, subtracted image display of the peripheral blood vessels.

PERISTEPPING:

Peripheral digital stepping angiography with only a single contrast medium injection under visual control of the bolus flow.

Gantry stepping with zeego and ceiling mounted systems, table stepping with floor mounted and biplane systems.

- Position-dependent variable frame rates.
- Fully automatic exposure control.
- Automatic storage of the collimator setting for each step.

PERIVISION:

Peripheral digital stepping angiography with online subtraction display in an examination procedure with only one single contrast medium injection under visual control of the bolus flow.

- Only one single automatically acquired mask image for each individual position.
- Position-dependent variable frame rates.
- Fully automatic exposure control.

Automatic storage of the collimator setting for each step

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Angle-triggered digital rotation angiography enables dynamic image display with 3D effect. Dynamic subtraction with optimum alignment of masking and filling, and automatic pixel shift in the entire scene.

- Rotation speed is 60°/s (Artis zeego and Artis ceiling) and 45°/s (Artis floor and Artis biplane).
- Acquisitions with frame rates in 1k matrix from 0.5 to 7.5, 10, 15, 30 f/s (standard) and 60 f/s with reduced spatial resolution can be selected,
- Angle triggering allows a reduction in dose through a reduced acquisition frame rate while at the same time achieving better image quality.

Includes DYNAVISON DR for native rotation angiography and DYNAVISON DSA for subtracted rotation angiography. Reconstruction at the syngo X Workplace is not possible with this operating mode.

Note: For biplane systems rotation angiography is available in plane A only.

Measuring program integrated in the imaging system for objective, precise and reproducible evaluation of vessels.

- Automated contour detection.
- Determination of degree of stenosis.
- Automatic and manual reference diameter determination.
- Automatic and manual calibration methods.

- Distance and angle measurement.

The Vessel analysis allows precise quantification under sterile conditions, direct at table side with the touchscreen control. This speeds up the intervention and makes the procedure safer for the patient. The reports can be easily stored in the patient folder for documentation and to show the correct analysis of dilatations etc.

Especially to be used for vessel sizes between 0.5 mm and 50 mm.

Scientific measuring program integrated in the imaging system for evaluation of the functionality of the left ventricle.

- Automated and manual contour detection.
- Automatic end-diastole/end-systole detection.
- Calculation of ejection fraction, volumes and indices (area, length and Simpson methods).
- Centerline, radial and regional wall movement analyses
- Automatic and manual calibration methods.
- Distance and angle measurement.

Scientific measuring program integrated in the imaging system for clinically validated, objective, accurate and reproducible evaluation of coronaries.

- Automated contour detection.
- Determination of degree of stenosis.
- Automatic and manual reference diameter determination.
- Stenotic Flow Reserve
- Automatic and manual calibration methods.
- Distance and angle measurement.

QCA allows precise quantification under sterile conditions, direct at table side with the touchscreen control. This speeds up the intervention and makes the procedure safer for the patient. The reports can be easily stored in the patient folder for documentation and to show the correct analysis of dilatations etc.
Especially to be used for vessel sizes between 0.5 mm and 7 mm.

QCA (Quantitative Coronary Analysis) is based on the gold standard in coronary analysis: CAAS II (Cardiovascular Angiography Analysis System Mark II) from Pie Medical, Netherlands.
The algorithms come from the Thorax Center of the Rotterdam Erasmus University. They are clinically validated and internationally recognized for scientific purposes (Multicenter Studies).

Contents:

The syngo X Workplace is a dedicated workstation for image postprocessing. Its functionality can be extended with additional software functions to suit specific user or clinical needs in angiography, surgery, and cardiology. The use of the licensed software is limited exclusively to the specific syngo X Workplace included with this configuration.

syngo X Workplace PC

The high-performance workstation is equipped with an Open GL accelerator board to support 3D applications. To exchange medical images on DICOM-compatible CD-Rs and DVDs, the system is equipped with a CD/DVD burner.

syngo X Workplace can be connected to an existing network via 1000/100/10 Mbit Ethernet.

Examination room: 19" color flat display or Artis Large Display connection kit

With this configuration, if an Artis Large Display is ordered - the configuration includes a connection kit for the Artis Large Display. If an Artis Large Display was not ordered - a display is delivered additionally for the examination room...

Control room: two 19" color flat displays or Artis Cockpit connection kit

In this configuration, there are also two displays for the control room or two connection kits for an Artis Cockpit.

The Siemens 19" LCD color display features very high contrast even under very bright ambient light conditions. The Gamma curve was precisely adapted to the CIE/DICOM recommendation and is thus especially suited for gray scale display.

LCD color display

- 19" (48 cm) screen size
- Resolution: 1280 x 1024 (pixels)
- Excellent brightness for the entire service life: 137 cd/m² at a contrast ratio of 300:1.
- Flicker-free and distortion-free image display
- Anti-glare screen

The controlled background lighting provides stable lighting throughout the entire product life cycle.

syngo X Workplace Basic User Software

The *syngo X Workplace* software features an intuitive and thus easy to learn user interface developed from prototypes tested in close cooperation with users.

Standard functions such as filming or image review, and optional clinical application software, are performed in individual processes on dedicated task cards. A number of functions and input parameters, as well as the language used, can be selected according to individual requirements.

Package includes the following software licenses

Basic software with CD and dongle for the following functions:

- Patient Browser
- Filming
- Viewer
- System services

Patient Browser:

- Patient management.
- DICOM communication with Send, Receive, Query/Retrieve, Print.
- Reading and importing image data from CDs/DVDs.
- Module for writing DICOM CDs/DVDs for data exchange. Writing is in background mode.

Filming:

A virtual filmsheet shows a 1:1 display of the film sheets to be printed. This permits an effective preview of the filming job and the windowing of images, as well as providing a large number of evaluation functions.

Viewer:

The Viewer supports interactive 2D review, evaluation, and documentation functions. Multiple studies from the same patient can be displayed side-by-side for comparison.

- Image display: 1.024² screen matrix, configurable with up to 64 image segments.
- CINE display: Automatic or interactive dynamic presentation technique for the visualization of time and volume series.
- Synchronized viewing of multiple series.
- Measurement and annotation: Text annotation; distance, angle, circle, ROI and pixel lens, depending on information available from the acquisition system.

System services:

Microsoft Office Word, Excel, PowerPoint plus Outlook are supported (not provided!).

- Any user-selectable file, such as cardiac or angiographic acquisitions, DSA or 3D AVI video sequences, can be burned to CD, or exported to USB stick, to prepare quality presentations and demos of pathologies.
- Network module: For connection to a local Ethernet (Gigabit or 100 Mbit) for communication with networked archives, printers, diagnostic and therapy workstations, and teleradiology routers.

Scope of functions

- Network stations can be configured.
- Unlimited selection of stations.

3D image generation

3D rotational angiography

In 3D rotational angiography, a sequence of 2D projection images is acquired by a C-arm performing a fast rotation around the isocenter in which the patient is positioned.

Image data are transferred automatically to a *syngo* X Workplace for time-optimized 3D image data reconstruction.

- All parameters required for the 3D reconstruction are included in the organ program. This enables optimized image quality and easy handling, as well as the fastest possible 3D reconstruction.
- Rotation speed is up to 88°/s (Artis zeego with *syngo* Dyna3D HighSpeed), 60°/s (Artis ceiling), and 45°/s (Artis floor and Artis biplane).
- Angle triggering allows a reduction in dose through a reduced acquisition frame rate while at the same time achieving better image quality. In addition, it allows for accurate subtracted rotational scans.

3D reconstruction and visualization of a volume are performed in real time in volume rendering technique, MPR, and MIP. 3D Rotational angiography is used in particular as support in interventional radiology and neuroradiology in the angiography laboratory. Based on dedicated acceleration hardware the primary reconstruction results are available in full diagnostic quality in the examination room within 19 seconds for high contrast images and less than 42 seconds for soft tissue DynaCT images. Subsequent secondary reconstructions are available even faster.

Note: For biplane systems rotation angiography is available in plane A only.

***syngo* DynaCT**

syngo DynaCT is especially suited to support radiologists and neuro-radiologists during interventional procedures in the angiography suite with both endovascular and non-endovascular procedures. *syngo* DynaCT provides enhanced decision making during oncology procedures such as chemoembolization and RF-ablations. In neuroradiology, *syngo* DynaCT allows the visualization of bleedings, the ventricular system of the brain and microstent placement.

With *syngo* DynaCT it is possible to visualize a soft tissue difference of 10 HU (Hounsfield Units) of an object 5 mm in size, or 5 HU for an object 10 mm in size, in a Thick-MPR display (measured with a CATPHAN 16 CT phantom with the CTP 515 module). Homogeneous image quality is achieved across the entire image. As a result, critical regions such as the base of the skull can be displayed with a lot fewer artifacts.

DynaCT also offers:

- a new reconstruction algorithm optimized for cone beam geometry
- a 20sDR-H 109 kV DynaCT acquisition reducing beam hardening artifacts and therefore improving e.g. detection of bleedings in DynaCTs with intravenous injection of contrast material
- faster 3D acquisition in 4x4 Binning mode

In conjunction with Artis zeego, *syngo* Dyna3D HighSpeed – being the fastest 3D protocol on the market – enables acquisitions to be generated in less than 3 seconds. As a result, moving organs such as the lungs can be displayed with a lot fewer artifacts. In addition, ~30% of contrast material can be saved which is important esp. in procedures requiring injection of a high volume of iodine (e.g. for enhancement of the aorta).

***syngo* DynaPBV Body**

syngo DynaPBV Body provides 3D physiologic information regarding blood volume in lesions and surrounding tissue. The visualization of color-coded blood volume maps is based on a special dual-sweep *syngo* DynaCT acquisition program followed by an elaborated computation of the blood volume steady-state information. The software can demonstrate e.g. successful complete embolization of tumors, but it can also reveal critical physiologic changes in tissue perfusion e.g. after coil-embolization of side branches feeding non-tumor-bearing tissue, or it can also help in discovering suspicious (re-)perfusion around treated tumors indicating potential tumor recurrence.

3D Image Manipulation

The 3D XWP comes with applications that facilitate interactive volume rendering, accelerated by a high-end 3D graphics card. It offers support for large data records of up to 1,600 images (512 x 512 matrix).

In angiography, surgery, and cardiology, the three-dimensional information is used for diagnosis, planning of therapy and documentation.

Diagnosis and treatment can be performed in one session. This offers a significant advantage thanks to the fully-integrated workflow, for example the

- Transfer of the projection angle (that has been adjusted by the user in the XWP 3D volume) to the C-arm

stand.

- Realtime synchronization between reconstructed volume and C arm position (Volume following the C arm position)
- Indication whether the angulation can be achieved at the C-arm without collision with the patient or table.
- Interventional volume measurement.

Features:

- Reconstruction protocols for visualization of vessels, bones, clips and coils.
- The result of the reconstruction can be native or subtracted.
- Modification of reconstruction area to allow zoom via reconstruction.
- Visualization with shading and light source for an improved three-dimensional impression.
- Interventional volume measurement.
- Link between C arm geometry and reconstructed volume: driving the C arm to exact projection position according to the view of the reconstructed volume and/or setting the volume to follow realtime C arm positions.

Image data:

- Viewing of volume data from AX, CT, MR, and PET modalities.
- Loading of two volume data sets simultaneously.
- Multiple Layouts: single (1on1), double (2 on1) and quadruple (4on1) for MPR display.
- Two displays are supported for simultaneous display of two volumes side-by-side.

Image display modes:

- VRT, Color VRT, MIP, MinIP, and MPR rendering.
- Thin slice renderings for VRT, MIP, and MinIP.
- Variable light source.
- Shading effects.

Volume editing:

- Cut planes.
- Editing of clip planes and control volumes.
- ROI punching.

Presets:

- Series-specific bookmarks, to store and retrieve volume visualization parameters.
- Global presets for series-unspecific application of volume visualization parameters.

Output:

- Radial ranges, including macro range definitions.
- 2D and 3D measurements, measurement grid, distance measurement and annotations.
- AVI format export with selectable compression format and compression ratio.
- TIFF, PNG, BMP, JPEG image export.
- Send to film sheet.
- Sending of parallel ranges results to PACS.

3D accessories

Includes the accessories required for 3D setup and calibration:

- Plexiglas calibration phantoms
- Line phantom for image quality control
- Form filter
- 3D data link

Dual volume visualization

Enables the differentiation between two high-contrast 3D objects that have virtually the same contrast density by choosing different visualization presets for the two simultaneously loaded volumes. This enables clear

differentiation between e.g. contrast-filled vessels, bones, stents, clips or coils.

Furthermore, it allows the display of one low-contrast and one high-contrast volume in one view, often realized as embedded MPR where the high-contrast volume is visualized in VRT and the soft-tissue information is shown as MPR slice. This can be used e.g. for visualization of the anatomical structure of tumors in combination with the feeding vessels.

3D roadmap

The operator can overlay any 3D volume or planning data, or excerpts of it, onto the live fluoro image. Via a Fade in – Fade out with the joystick the degree of visibility of the overlaid information can be determined at any time. This tool offers the physician real-time three dimensional guidance for more confidence. It avoids repeated injection of contrast material during fluoroscopy by overlaying a 3D vessel tree instead. The 3D roadmap is automatically updated in real-time according to any table, C-arm, zoom and SID changes. Even changes due to patient movement can be manually updated.

The 3D volume can be overlaid on regular fluoro as well as on subtracted fluoro (Roadmap) or acquisition series. The overlay appears on the display of the syngo X Workplace so the 3D Roadmap information is available in parallel with the regular 2D images of the live display of the acquisition system.

Fusion functionality

A fused CT, MR or PET image can be overlaid with live fluoroscopy in combination with 3D roadmap functionality providing information during interventional procedures that are available neither in 2D X-ray nor in 3D rotational angiography.

The package includes 3D/3D Fusion, which allows to spatially align two 3D volumes from the same or different modality in such way that the anatomical structures overlay each other. Any *syngo* DynaCT or *syngo* Dyna3D image can be fused with datasets from e.g., CT, MR or PET.

For PURE systems only: this package contains also the following functionalities:

The package includes in addition 2D/3D Fusion, which allows to spatially align any pre-acquired 3D volume of the patient with two 2D X-ray projections. This eases the workflow during the procedures and reduces the X-ray dose because no additional 3D acquisition is required.

Workflow support for needle-guidance

Provides a menu guided intuitive 3 step approach for consistent needle positioning results:

Step 1:

Definition and check of the needle path on a DynaCT or an external CT or MR or PET-CT dataset.

Step 2:

Check of automatically proposed progression views that will be used for monitoring the needle procedure.

Step 3:

Alignment and progression of the needle under fluoro control while the planned needle path is overlaid on the live image of the acquisition system. Easy switch between the defined progression views to control the real needle position and direction in all three dimensions.

Subsequently, a control scan can be performed and automatically fused with the planning volume using fusion functionality. *syngo* DynaCT, CT, PET or MR images are accepted for the image fusion.

Registration Algorithms:

- easy-to-use visual alignment with 6 degrees of freedom (3x translation, 3x rotation)
- landmark based registration with convenient landmark editor for point-based registration using anatomical landmarks
- storage of transformation matrix with datasets after registration for later retrieval

Visualization Techniques:

- Side-by-side visualization of both datasets with correlated pointer and correlated scrolling with dog ears
- 2D fade in monochrome or pseudo-color with adjustable balance between the two superimposed data sets.

Workflow support for embolization guidance

Based on a contrast-enhanced DynaCT, CTA or MRA, the actual catheter position as well as the distal ends of the vessels feeding a lesion are marked and the navigation path is automatically calculated. The ability to graphically overlay this path with the current fluoroscopy image even offering a selection of different visualization options such as (centerline, outlines, 3D vessel representation) reduces the use of contrast material and lowers navigation time and hence total fluoroscopy dose during embolization procedures of e.g. tumor-feeding vessels.

As a second feature, segmentation and volume computation of a 3D structure such as a tumor nodule can be done based on CT, MR, PET-CT or late phase DynaCT volume datasets. The segmented object can also be overlaid with live fluoroscopy using the 3D roadmap functionality for improved orientation and target visualization during the

intervention. The automatically computed volume can be used for estimation of the amount of (chemo-/radio-) embolic material needed.

For PURE systems only: toolbox functionality also included:

Toolbox is a generic application to interactively mark structures of interest in a 3D volume, e.g. a *syngo* DynaCT image, using points and lines. Analogously to *syngo* 3D Roadmap, these markings are projected onto the live 2D X-ray illustrating the position of the 3D anatomical structure within the live X-ray.

Included functionalities:

- Automatic extraction and overlay of anatomical outlines of the 3D volume on live 2D image.
- Overlay of any lines and dots drawn on the VRT or MPRs on live 2D image.

This functionality provides an easy link between information that may only be visible in the 3D volume (VRT or MPRs) and the fluoroscopy or roadmap images.

2D Image Manipulation

***syngo* Angio Viewer**

The *syngo* Angio Viewer enables dynamic review of DSA scenes (in subtracted or native display) and their post-processing at the *syngo* Workplace, with functions such as:

- Remasking.
- Pixelshift.
- Anatomic background.
- Opacification etc.
- Review of DYNAVISON and PERIVISION scenes

***syngo* iFlow**

syngo iFlow allows the visualization and analysis of blood flow and 2D perfusion in the examined organs. This information is based on the time-to-peak calculations from a routine DSA acquisition and can be applied as simple click-of-the button postprocessing to arbitrary pre-acquired DSA scenes. The calculations can be shown as a color-map of the whole organ. It is also possible to calculate blood flow and perfusion characteristics for regions defined by the user, and display them as ROI (region of interest) curves. These graphics support the analysis of blood flow dynamics in the defined region.

***syngo* Scene Compare**

Dual monitor support for dynamic side-by-side comparison of two scenes or for the evaluation of bi-planar scans in synchronized mode. It can also be used to compare scans to single images. In Interventional Oncology, this functionality can be used to compare pre- and post-interventional 2D scenes or iFlow images for evaluation of changes in blood flow characteristics as a result of the therapy.

Common functions

Inroom control functionality

Allows for remote control of the *syngo* X-Workplace from the examination room via touchscreen and joystick mounted table-side or on a trolley.

For this, a set of functions is offered inroom for e.g. 3D image assessment and manipulation, 3D navigation, multimodality image integration, or for actively following the steps of a pre-defined workflow.

***syngo* Expert-i**

syngo Expert-i enables the physician to interact with the *syngo* X Workplace from virtually anywhere.

When clinical questions arise at the *syngo* X Workplace, a second user with a Windows PC can quickly and efficiently access the *syngo* X Workplace via the network. He or she can assume full control of every application on the *syngo* X Workplace and can see all screen content that is displayed for the local user on the main monitor. This allows the parties involved to discuss clinical questions via phone and quickly reach solutions on a joint basis.

DICOM

Industrial standard for the transmission of information between DICOM-compatible units from different manufacturers. The scope of functions is described in detail in the DICOM Conformance Statement and in the standard version includes the Transmission/ Reception, Query/ Retrieve and Basic Print functions.

Note concerning DICOM interface(s)

For diagnostic purposes, only hardcopy cameras/laser printers explicitly approved for this system may be used.

The description in the DICOM Conformance Statement downloadable from the Internet is exclusively binding for the functionality of the DICOM interface(s).

Functionalities across interfaces with/between partner systems require explicit validation, since the interpretation of the interface by the partner/target system is not part of the product's responsibility.

A modification of the interface that might be required is not included in the offer; e.g. for the rare case that available configurations are not sufficient. With regard to expenses for interface configurations that might be required, the agreements on maintenance/service of the product apply.

Based on a special *syngo* DynaCT acquisition program with automatic processing, the blood volume is displayed color-coded. This offers special advantages during neuroradiological interventions (e.g., stroke/malformation) because it allows under- and oversupplied parenchymal areas to be displayed.

The image series are created in the Peristepping or Perivision mode and combined to a native full-format image on the *syngo* Workplace.

The full-format images can be printed out on laser or paper printer. For diagnostic purposes only hardcopy cameras/laser printer expressly approved for this system may be used.

Sensis Vibe is the vital core where all events, decisions, measurements, and data from your procedures are captured. It reduces administrative effort and standardizes documentation and reporting* across interventional entities. Sensis Vibe intuitively blends into the rhythm of the interventional floor and tunes up your workflow efficiency.

*for documentation and reporting, see recommended options

System hardware configuration

- HemoBox signal input unit (dimensions 147 x 230 x 80 mm; with cabling and mounting kit for Modura table rail and IV poles; liquid ingress protection class IPX4). For non-invasive blood pressure, four invasive pressure inputs, four invasive pressures dP/dt, SpO2 oxygen saturation, 12-channel ECG, ECG-based respiration**, respiration rate from capnography (option), two temperature channels**. With table-side buttons for balancing, NIBP measurement, cardiac output and muting audible vital signs alarms.
- Examination room display: one 19" display with DCS mounting kit and cabling (resolution 1280 x 1024 pixels)
- Control room: PC, keyboard, mouse, two 19" displays (resolution 1280 x 1024 pixels)

**these products/features are not commercially available in all countries. Due to regulatory reasons their future availability cannot be guaranteed. Please contact your local Siemens Healthcare organization for further details.

Acquisition software

- Sensis Hemo application
Acquisition software to support monitoring and full disclosure recording of vital signs and invasive measurements and calculations of hemodynamic parameters in adult and pediatric cardiovascular interventions, such as left and right heart catheterizations, heart valve examinations and general angiography procedures. The system features a comprehensive, user-adaptable catheter site list. Pullback measurements can be done using one of the following methods: single pullback, sequential pullback, virtual pullback.
As a standard, the system provides the following calculated and derived hemodynamic parameters: pressure calculations, rate of pressure change (dP/dtmax), gradients, shunts, cardiac output, valve area, work and power, cardiac index, flow and stroke volume, resistances, regurgitation.

Measured values, calculated and derived parameters can be compared, analyzed and edited (what-if scenarios) in flow sheet structured by procedure conditions.

Sensis Vibe comes with a redesigned, lean user interface for mouse- and keyboard-based operation with customizable hot keys and adjustable split-screen mode

Waveforms display can be programmed for layout and color. Can be displayed on up to five configurable pages per procedure type.

- Workflow support license
- Vital signs alarms license and audio module

Productivity Tools

- *syngo* multitasking operating system
- *syngo* database system
- Sensis Security Manager
- Sensis Communication Manager
- Sensis Configuration Manager
- Artis interface for bi-directional data exchange (patient data, X-ray snapshots, dose data, ECG signal, table-side Sensis operation), ethernet-based
- Ethernet communication to hospital network
- DICOM worklist
- DICOM MPPS license
- Export waveforms**
- Generic printer interface (see data sheet for minimum requirements)
- Archiving via central DICOM nodes
- Export of discrete values via ASCII flat file or XML

**these products/features are not commercially available in all countries. Due to regulatory reasons their future availability cannot be guaranteed. Please contact your local Siemens Healthcare organization for further details.

Accessories and parts included in delivery

- Starter kit vital signs
- ECG cable kit (IEC1 and IEC2)
- HemoBox analog out cable

Recommended options (not included in delivery)

- FFR license to integrate Volcano and St. Jude Medical FFR devices
- Sensis Vibe FlashDoc (Master or Client)
- Graphical reporting tools (Heart Picture Illustrator, Coronary Tree Illustrator)
- Report workstation licenses to enhance the documentation workflow outside the control room
- Additional interfaces (if applicable)
- Upgrades to Sensis Vibe or compatible versions for your existing Sensis units
- Starter kits to ensure everything is in place for your first Sensis Vibe-guided procedure
- Sensis UPS

Ready for

- Siemens Remote Service (during warranty, option for service contract)

- Interface and database customizing (offered via customer service)

It is mandatory to have a power backup for Sensis. A UPS needs to be provided either by the hospital or purchased from Siemens Healthineers. The minimum requirements for the UPS are defined in the Sensis data sheet.

Sensis FFR is compatible with

- the St. Jude Aeris™ receiver, which is directly connected to a channel of the HemoBox. (The receiver and appropriate interface cable is delivered by St. Jude.)
- the Volcano pressure wires, which are connected to a channel of the Sensis HemoBox via a Volcano Smartmap. (The Smartmap and appropriate interface cable is delivered by Volcano.)
- the ACIST Rxi Rapid Exchange FFR system for Vavvus micro catheters. The Rxi system is connected to the HemoBox. (The Rxi and appropriate interface cable is delivered by ACIST.)
- Available for Sensis Vibe systems and Sensis/AXIOM Sensis XP systems running on software version VC11D and higher.

The systolic area index is calculated based on the simultaneous measurement of the invasive blood pressure in the left and right ventricle. The systolic area index is the ratio of (right ventricle systolic area / left ventricle systolic area) during inhalation to (right ventricle systolic area / left ventricle systolic area) during exhalation. After selection of an inhalation and exhalation beat, the value is calculated and stored in the procedure log. Studies report that a systolic area index value > 1.1 is a safe indicator for constrictive pericarditis.

Software included:

Sensis Information System (SIS)

- Sensis Information System (SIS)
- Microsoft SQL 2014 database
- Sensis Vibe documentation tool (FlashDoc)
- Sensis Report Generator
- Sensis Report Composer
- Microsoft Word 2007 software
- Sensis Communication Manager
- Sensis Security Manager
- Sensis Backup Manager
- Sensis Configuration Manager
- Sensis Statistics Manager
- Sensis Database Manager
- DICOM Report Export license

Hardware included:

Server hardware as specified in the data sheet, Windows Server 2012 R2 server operating system

Software included:

Sensis Information System (SIS)

- Microsoft SQL 2014 database
- Sensis Vibe documentation tool (FlashDoc)
- Sensis Report Generator
- Sensis Report Composer
- Microsoft Word 2007 software
- Sensis Communication Manager
- Sensis Security Manager
- Sensis Backup Manager
- Sensis Configuration Manager
- Sensis Communication Manager
- Sensis Statistics Manager
- Sensis Database Manager
- DICOM Report Export license

It is mandatory to have a power backup. A UPS needs to be provided either by the hospital or purchased from Siemens Healthineers. The minimum requirements for the UPS are defined in the Sensis data sheet.

The Report Workstation software includes the following licenses:

- Sensis Patient Explorer (5)
- Sensis documentation tool (FlashDoc) (5)
- Sensis Report Generator (5)
- SQL database client license (5)
- Barcode reader network license (5)

See data sheet for minimum requirements for the customer-supplied PC.

- Pentium III 700 MHz or higher.
- 512 MB RAM or higher
- 30 GB disk/DVD/CD-ROM
- Network connection (Ethernet or WLAN)
- Windows XP Professional
- Microsoft Office 2003, Office 2007 or Office 2010

Available for Sensis/Sensis Vibe.

Each license can be installed on any number of PCs, but only be used by up to three users simultaneously.

Included message types (Inbound)

ADT A01, A03, A04, A05, A08, A11, A23, A39, A40, A44, A46, A47, A49 + ORMO 01.

Included message types (Outbound)

- ORU R01 (e.g. export clinical data like exam comments, diagnoses, hemodynamic pressure measurement data,

etc.).

- DFT P03 (Export of billing data for an examination to an external HIS or CIS).

For further details, see the Sensis HL7 interface specification.

Configuration and customizing of HL7 interface is available at a surcharge through customer service.

Contains:

- 3.8m ECG trunk cable
- radio translucent limb lead electrode cable kit
- radio translucent chest lead electrode cable kit

Measurements are based on Microstream non-dispersive infrared (NDIR) spectroscopy to continuously measure the amount of CO₂ during every breath, the amount of CO₂ present at the end of exhalation (etCO₂) and during inhalation (FiCO₂), and the respiratory rate for neonates, pediatric and adult patients.

Respiration rate range 0 – 150 breaths/minute

etCO₂ range HemoBox 0 – 150 mmHg

etCO₂ range ComboBox/iSIB 0 – 99 mmHg

Contains:

- cardiac output catheter cable
- cardiac output intermediate cable 1m
- thermistor cable Ohmeda
- thermistor cable Edwards

Thermistors are not included in this kit.

Contains:

- Power supply
- Base station.
- Mobile scanner
- Connection cables
- Software license

The lower body radiation protection can be attached to the accessory rails either on the right or on the left side of the patient positioning table.

It consists of the following shielding units:

- A basic unit shielding the area between accessory rails and the floor. It is flexible and can be adapted to the examiner's preferences.
- One LB radiation protection pivot swivel element that can move out of the way during collisions with the tube and still retain its protective function.
- Two clip-on units pointing upwards from the upper edge of the basic unit with a length of 57 cm and 27 cm.

The scattered radiation shielding units can be attached to the basic unit in an overlapping and fan-shaped way to allow closed, adapted scattered radiation protection even in the lower thorax area.

The maximum load of the accessory rails is 40 kg, the weight of the attached scattered radiation protection is 8 kg.

Radiation protection attached via a ceiling-mounted, mobile stand for protection against scattered radiation; incl. 4 m ceiling rail.

- Swivable and rotatable around the fixed point, range of rotation 360°.
- Counter-balanced, height-adjustable support arm.
- Acrylic glass with Pb equivalent of 0.5 eq (w x h: 61 cm x 76 cm), with recess for interventional examinations.

Mach LED 130F examination light with focusable light system. Can also be installed on the Portegra2 ceiling support of the portable radiation protection panel.
It is therefore fully integrated into the ceiling-installed radiation protection system of the Artis Zee/Q/Zen family.

- Luminance: 60,000 Lux for 100 cm distance
 - Working distance: 70 to 140cm
 - Color rendering index Ra: 95
 - Color temperature: 4,300 Kelvin
 - Focusable spot size: 14 to 25cm
 - Diameter of light head: 33cm
 - Number of LEDs: 19
 - Total input power: 20 VA
 - Max. reach of the spring arm combination: 185 cm
 - Total weight of light head with grip sleeve: 2,4kg
- Lamp power connection 230V or 115V possible

Communication / Intercom system for communication between examination room and control room, with additional footswitch for conversation selection in the examination room.
Microphone and control box on the console in the control room.
With adaptive acoustic filter for background noise suppression in the examination room.
Microphone in the examination room installed on the ceiling.

*Ordering information that can be deleted from the final version of the offer follows:
Intercom - Comfort replaces the old intercom system (without adaptive acoustic filter for background noise suppression).
Delivered as an option only, not included in the basic configuration*

This SW license enables your system to support enhanced user and system management, including:

- User authentication to prohibit unauthorized access
- Privileges to define user/role based functionality
- Permissions to control data access
- Audit trails to log system and data access

The infusion bottle holder serves for attaching a maximum of 4 infusion bottles directly at the accessory rail of the patient positioning table.

- No obstruction due to additional stands in the room.
- Safe administration of infusions even with the table moving or tilting.

*Ordering information that can be deleted from the final version of the offer follows:
Not in conjunction with the Surgery carbon tabletop.
Already included in the basic configuration.
Can also be ordered as an option.*

The ECG cable is locked directly onto the patient positioning tabletop by means of the cable clips made of easy-to-clean plastic material.
That means, the cables follow the tabletop movements and do not interfere with the C-arm angulations during an

examination.

Ordering information that can be deleted from the final version of the offer follows:

Not in conjunction with the Surgery table.

Already included in the following basic configurations:

- Interventional cardiology
- Electrophysiology
- Pediatric cardiology
- Combination Interventional cardiology / radiology
- Combination Interventional radiology / cardiology
- Cardiothoracic surgery

Can also be ordered as an option.

The head holder is used to position the patient's head during the examination. Using the cushions or wedges, the patient's head is secured in the head holder.

Cushions with large, medium, and small dimensions are included to support the head.

The head holder is attached to the narrow tabletop with two knurled screws and a mounting device. Possible only with the 4 cm thick special foam mattress.

Ordering information that can be deleted from the final version of the offer follows:

Possible only in connection with the narrow tabletop and thin mattress, the neuro tabletop used previously is no longer possible.

Not in conjunction with the Surgery table.

Already included in the following basic configurations:

- Neuroradiology
- Neurosurgery

Can also be ordered as an option.

The insert with accessory rails attached to the right, left, and head end slides over the outer edges of the patient positioning tabletop.

It is locked in place through two screws on either side. The part to be inserted underneath the tabletop consists of radiolucent carbon fiber material, which avoids disturbing edges in the image.

Max. load capacity of the accessory rails: 40 kg.

Length of the accessory rails: 45 cm.

Ordering information that can be deleted from the final version of the offer follows:

For wide tabletops.

Delivered as an option only, not included in the basic configuration.

Not in conjunction with the Surgery table.

The insert with accessory rails attached to the right and left slides over the outer edges of the patient positioning tabletop.

It is locked in place through two screws on either side. The part to be inserted underneath the tabletop consists of radiolucent carbon fiber material, which avoids disturbing edges in the image.

Max. load capacity of the accessory rails: 40 kg.

Length of the accessory rails: 45 cm.

Ordering information that can be deleted from the final version of the offer follows:

For wide tabletops.

Delivered as an option only, not included in the basic configuration.

Not in conjunction with the Surgery table.

The flexible, curved anesthesia screen holder serves as a holder for sterile cloths (anesthesia screen) between head and abdominal area of the patient. With its two brackets it is attached to the accessory rails of the accessory rail or head module, which slides over the outer edges of the tabletop.

Weight: 1 kg.

*Ordering information that can be deleted from the final version of the offer follows:
Depending on the tabletop used and the type of examination, the head module or one of the two accessory rail modules must be available.
Delivered as an option only, not included in the basic configuration.*

The stainless steel instrument tray is attached to the accessory rail at the foot end at the same height as the patient positioning tabletop.
Dimensions 53 cm x 65 cm (w x l).
Max. load: 5 kg.

*Ordering information that can be deleted from the final version of the offer follows:
Not in conjunction with the Surgery table.
Delivered as an option only, not included in the basic system unit*

For Artis tabletops, the two arm holders help to laterally position the arms comfortably along the patient's body. They are slid laterally underneath the mattress, level with arms, and fixed by the patient's body weight. The patient's arms can be immobilized with commercially available securing straps (not included). Two pairs of arm holders of different length and height (matching the mattress height) are supplied, that are suitable both for thick and thin mattresses.

An arm holder weighs 8 kg.

*Ordering information that can be deleted from the final version of the offer follows:
Not in conjunction with the Surgery table and multi-section metal / carbon tabletop or the multi-section Surgery metal / carbon tabletop RoW.
Already included in the following basic configurations:*

- Combination Interventional cardiology / radiology
- Interventional radiology
- Neuroradiology
- Combination Interventional radiology / cardiology
- Vascular surgery
- Neurosurgery

Can also be ordered as an option.

This support makes it possible to position the patient's arm comfortably in various positions underneath the tabletop, e.g. in the elbow position at an angle of 90° parallel or transversally to the wide tabletop. The positioning of the arms can be adjusted according to the arm length and thickness with an additional included pad for the armrest.

The armrest is attached to the tabletop under the mattress without the need for an additional attachment.

*Ordering information that can be deleted from the final version of the offer follows:
The armrest for vertebroplasty and kyphoplasty can be used with the wide Artis tabletop.
Delivered as an option only, not included in the basic configuration.
Not in conjunction with the Surgery table.*

During interventions requiring the patient to be positioned on the tabletop in prone position, the head can comfortably be positioned on a head pad filled with soft gel material.
An oxygen tube can be inserted into the patient's mouth from the side.

*Ordering information that can be deleted from the final version of the offer follows:
The head positioning device can be used in combination with the kyphoplasty armrest.
Delivered as an option only, not included in the basic configuration.*

Ordering information that can be deleted from the final version of the offer follows:

Not in conjunction with the multi-section Surgery metal / carbon tabletop or the multi-section Surgery metal / carbon tabletop RoW.

Delivered as an option only, not included in the basic configuration.

Rail profile (short table attachment) for table operation

- Weight: 1.4 kg
- Rail length: 12 cm
- Width: 20 cm
- Height: 14.5 cm

Rail profile (long table attachment) for device operation (with or without table operation)

- Weight: 2.8 kg
- Rail length: 25 cm
- Width: 20 cm
- Height: 14.5 cm

Printing Acquisitions using a Virtual Filmsheet

Selecting "Auto-Print" automatically forwards the images stored in the virtual filmsheet to the printer. This optimizes the workflow, eliminating the need for user interaction. In addition, a specific layout can be configured on the virtual filmsheet, which the user can review and edit on the monitor at any time. As a result, printing is only required after the layout has been optimized on the monitor, saving time and costs.

Note:

For diagnostic purposes, only hardcopy cameras/laser printers explicitly approved for this system may be used.

The description in the DICOM Conformance Statement downloadable from the Internet is exclusively binding for the functionality of the DICOM interface(s).

Functionalities across interfaces with/between partner systems require explicit validation, since the interpretation of the interface by the partner/target system is not part of the product's responsibility.

A modification of the interface that might be required is not included in the offer; e.g. for the rare case that available configurations are not sufficient.

With regard to expenses for interface configurations that might be required, the agreements on maintenance/service of the product apply.

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Sent in MPPS:

- **Total dose-area product**
- **Number of exposures**
- **kV** per image (DICOM Exposure Dose Sequence)
- **ms** per image
- **mA** per image

Note concerning DICOM interface(s)

For diagnostic purposes, only hardcopy cameras/laser printers explicitly approved for this system may be used.

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Display mount

The longitudinally mobile, swiveling, rotating, and height adjustable display holder with extended working range contains a large color flat display.

All cables are integrated.

The double-articulated arm of the "extended working range" display holder provides greater flexibility and a greater positioning range for the Large Display.

Technical data for the display holder:

- Longitudinal travel range 315 cm.
- Height adjustment range 75 cm.
- Swivel range between the articulated joint and the suspension at the ceiling-mounted carriage ± 150 degrees.
- Swivel range between the freely-suspended cantilever arm and the articulated joint ± 120 degrees.
- Display swivel range 330° .

The large display area allows for both large display and the free positioning of examination-relevant video signals. The fully integrated tableside control allows for selection from among twelve layout variants.

For the diagnostic color display in TFT technology, with high luminance and extended viewing angle, the gamma curve has been adapted particularly for gray scale display according to the CIE / DICOM recommendation.

Video signals such as live, assist and reference images, *syngo* X Workplace, Sensis/recording systems, PACS, HIS/RIS, ultrasound, ECG, external video, endoscope, mapping systems, system and table position, system messages and dose information can be individually positioned and displayed on the Large Display, if connected.

If the dual reference function is available, parallel static reference images are displayed on both reference monitors.

Technical specification for the 60" display:

- Display size (W x H) 60", 133 cm x 74.8 cm
- Screen size 60", 153 cm
- Resolution: 3840 x 2160 (pixels); 8 megapixels at 4 x HD.
- Color depth $16.7 \cdot 10^6$ colors.
- excellent brightness over the lifetime: 300 cd/m² at a contrast ratio of 4000:1.
- Flicker-free and distortion-free image display.

Technical specification for the 55" display:

- Display size (W x H) 55", 121 cm x 68 cm .
- Screen size 55" 139 cm
- Resolution: 3840 x 2160 (pixels); 8 megapixels at 4 x HD.
- Color depth $1.07 \cdot 10^9$ colors.
- excellent brightness over the lifetime: 350 cd/m² at a contrast ratio of 1450:1.
- Flicker-free and distortion-free image display.

Technical specification for the 56" display:

- Display size (W x H) at 56", 124.4 cm x 70 cm

- Screen size at 56" (142.2 cm)
- Resolution: 3840 x 2160 (pixels); 8 megapixels at 4 x HD.
- Color depth 16.7 10⁶ colors.
- excellent brightness over the lifetime: 300 cd/m² at a contrast ratio of 800:1.
- Flicker-free and distortion-free image display.

Bypass concept

In case of error, such as controller failure, the Large Display switches automatically to bypass mode and emergency fluoroscopy is displayed on the Large Display.

Backup concept

The Large Display has a backup concept to ensure against power supply failure (2 separate power supplies for the left and right sides of the Large Display).

Note: If a Large Display is selected, the Artis basic configuration includes a connection kit for the large display instead of the displays for the examination room.

The type of large display can be chosen with a separate position.

The Large Display video controller 18 receives various internal and external video signals for presentation to scale on the Large Display.

Up to 18 external and internal video sources can be connected (max. 14 DVI-D and 4 analog (VGA) channels).

Important images for diagnostic purposes can be displayed to scale in their original size on the Large Display. Less important, non-diagnostic information can be displayed at a reduced size by the interpolation algorithm for image information integrated in the video controller.

An enlarged or reduced display can be selected individually via the display configurations at the fully integrated tableside control. The video controller then takes over interpolation and adaptation of image size.

In waveform images with high resolution, such as for electrophysiological recording systems, the curves are displayed free of artifacts because of a special interpolation algorithm.

Large color flat display

The IPS panel technology combined with the large display area represents a new dimension in medical image display.

This technology combines high luminance and high contrast, consistent for all viewing angles. It provides an incomparable image impression especially for gray scale images.

For the diagnostic color display in TFT technology, with high luminance and extended viewing angle, the gamma curve has been adapted particularly for gray scale display according to the CIE / DICOM recommendation.

Technical specification for the 55" display:

Display size (W x H) 55", 121 cm x 68 cm.

Screen size 55", 139 cm

Resolution: 3840 x 2160 (pixels); 8 megapixels at 4 x HD.

Color depth 1.07 10⁹ colors.

excellent brightness over the lifetime: 400 cd/m² at a contrast ratio of 1450:1.

Flicker-free and distortion-free image display.

Backup concept

The Large Display has a backup concept to ensure against power supply failure (2 separate power supplies for the left and right sides of the Large Display).

Preparation for the dedicated ACUSON Freestyle Elite ultrasound system on the Artis to allow for viewing of ultrasound images at the Large Display, transfer of demographic patient information, and mounting of the ultrasound system on the back of the Large Display.

The solution works in combination with "ACUSON Freestyle Elite w. Artis Access" ultrasound system (to be ordered separately - not included in this part number).

The ANGIOMAT Illumena Pedestal contrast medium injector can be positioned anywhere at the patient positioning table on a mobile unit, for direct operation of all functions in the examination room.

The injector system includes:

- A mobile foot stand with a power pack, a contrast medium warmer, a connection cable (12m) for the hand switch and a Siemens universal connection cable (5 m) for triggered operation.
- A support arm with injector head.
For filling rate control the injector head has an ergonomically designed filling lever.
- A control console with touchscreen operation and Siemens style display.

Display and operation

- All injection parameters are displayed on the touchscreen display of the control panel, with the main parameters additionally shown at the injector head.
- After switching on the injector, the language for display and operation can be selected: German, English, French, Italian, Spanish or Japanese.

Functions

Pressure limitation;

Angio mode: 200 mL syringe: 75 to 900 PSI in 1 PSI increments and 517 to 6205 kPa in 1 kPa increments; all other syringes, 75 to 1200 PSI in 1 PSI increments and 517 to 8273 kPa in 1 kPa increments, 75 PSI to 300 PSI and 517 kPa to 2068.

Flow rates

Angio-Cardiac and Angio-Peripheral mode: 0.1 to 40.0 ml/s in 0.1 ml/s increments up to 9.9 ml/s, 1.0 ml/s increments thereafter 0.1 to 999 ml/M in 0.1 ml/M increments up to 9.9 ml/M, 1.0 ml/M increments thereafter

Inject Delay, x-ray delay, scan delay (CT mode), phase delay

0 to 300 seconds: if delay is less than 10 seconds the programmable increment is 0.1 seconds. if delay is greater than or equal to 10 seconds the programmable increment is 1 second.

Pressure rise time (rate rise)

0 to 10 s in 0.1 seconds increments.

Injection time in Angio mode with duration selected:

1 to 999 s in 1 second increments.

Volume:

0.1 to volume in syringe 0.1 ml increments up to 9.9 ml, 1.0 ml increments thereafter

Fill rate:

Forward or Reverse- 0.2-25 ml/sec

Accelerates from zero to maximum in less than 0.5 seconds, by rotating the fill-control bar to the fast position.

Number of storable injection programs:

- 45 in Angio mode.
- 45 in CT mode.
- **Included in the scope of delivery** Installation & clinical applications training
- 12-month warranty

Power supply

- 100-127 V and 220-240 V, 50/60 Hz with automatic selection of the correct supply voltage. 10 A current. Rating max. 1500 W, 100 W during standby.

Eaton 93PM-150/150 4-Wire UPS Electronics Cabinet: 150kW Frame cabinet with three (3) Power Modules (UPM) configured as a 150kW capacity system specifically for a medical imaging application. 480 volts input / 480 volts output, 4-Wire + Gnd. Double Conversion Topology, Unit efficiency up to 97% (up to 99% with ESS), Unit output rating @ Unity Power Factor, Input current distortion < 3% @ 100% load, Patented ABM Technology, Patented HotSync parallel firmware control, Scalable Architecture, Parallel Redundancy and Capacity capable. Onboard monitoring of UPS status via front panel display is standard. Includes single feed input with three (3) circuit breaker (BIB, MBP, MIS) integrated maintenance bypass in a 14.7" wide right-mounted sidecar. Four (4)

internal min-xslot communication card bays. One (1) Power Xpert Gateway UPS Mini-Slot Card (PXGMS) included.

Included Services: Start-up (7x24): PLUS One (1) year on-site labor coverage (7x24).

UPS Cabinet Dimensions: 36.7"W x 42.0"D x 74.0"H

UPS Cabinet Weight: 1,566 Lbs.

Eaton 93PM UPS Electronics Cabinet Seismic/OSHDP Mounting Kit: This kit includes the necessary brackets and instructions for seismic or OSHDP installation of the 93PM 150kW Frame UPS electronics cabinet and sidecar.

For sites requiring OSHDP installation and inspection, these brackets must be used to install the 93PM UPS electronics cabinet and sidecar in order for the installation to meet OSHDP certification requirements.

Eaton 93PM 480Vdc OSHDP Battery System: One (1) IBC-L Integrated Battery Cabinet consisting of one (1) string of 240 cells (@480Vdc), 40 Batteries, and 500A Circuit Breaker in cabinet. Full load back-up time @ 150kW of 7.1 minutes. Includes internal bracing and seismic/OSHDP mounting kit to make this battery solution OSHDP certified.

Battery Cabinet Dimensions: 32.3"W x 42.0"D x 74.0"H

Battery Cabinet Weight: 4,265 Lbs.

Eaton 93PM Remote Monitoring Device: Wall-mounted display panel for monitoring the UPS status in the imaging suite when the UPS is located elsewhere in the facility. Requires Power Xpert Gateway Mini-Slot Card for interface with the 93PM UPS (included with the 93PM UPS quoted above).

RMP Dimensions: 5.9"W x 0.8"D x 3.2"H

RMP Weight: 0.5 Lbs.

Eaton Power Xpert Gateway UPS Mini-Slot Card (PXGMS): This card can provide Web/SNMP and Modbus TCP/IP connectivity and functionality for the 93PM UPS system for the purpose of remotely monitoring the status of the UPS via an Ethernet network connection.

Industrial-grade anti-fatigue floor mat that provides comfort and durability. As a high-quality product designed to fight fatigue, it provides support for tired, aching feet, legs and back. Beveled edges for safety. Size 3'x5'.

The RaySafe i2 package enables continuous improvement of working procedures in X-ray environments by providing staff with personal, real-time information about scattered X-ray dose.

- The Real-Time Display enables immediate changes in working procedures in order to minimize dose
- The Personal Dosimeters supply the Real-Time Display with information about each individual's personal dose
- The Dose View software makes it easy to review radiation data.
- The optional Dose Manager software makes it easy to report, export and archive radiation data.

The RaySafe i2 system includes:

- 1 x RaySafe i2 Real-Time Display
- 4 x RaySafe i2 Dosimeters
- 1 x Dose View software package
- 1 x RaySafe i2 Cradle
- 1 x RaySafe i2 Mounting Rack
- Installation and a one (1) year warranty provided by Unfors

Optional Accessories

Additional RaySafe i2 Dosimeter Order No. **AS10655940**

RaySafe Dose Manager software package Order No. **AS10655941**

Technical specifications :

Dosimeter

Weight 30 g (1.06 ounces)

Operational quantity Hp(10)

Real-Time Display

All X-ray dose rate/s and accumulated dose/h that are received from dosimeters in range. The memory size accommodates f.i.250 dosimeters with 50 h X-ray dose rate history each.

Dose Manager PC requirements

Dose View PC requirements

Upgrade of system with enhancement of the DynaCT functionality to DynaCT Cardiac.

- ECG-triggered 3D acquisitions (multiple C-arm rotations, approx. 30 seconds exposure time) as well as for
- untriggered 3D acquisitions (one C-arm rotation, approx. 5 seconds exposure time).

ECG-triggered acquisitions provide greater temporal resolution, which is helpful for imaging cardiac morphology with a lot of motion.

Clinical applications currently supported by DynaCT Cardiac:

Electrophysiology:

- 3D visualization of the left atrium to support ablation of atrial fibrillation (segmentation of the left atrium using InSpace EP, must be ordered separately)
- 3D visualization of the coronary venous tree to support biventricular pacemaker implantation

Interventional Cardiology/Surgery:

- Planning, support and follow-up before, during and after heart valve replacement through 3D visualization of the aortic valve and coronary ostia

Pediatrics:

- 3D visualization of the congenital heart defects before and after surgical interventions: There are low-dose organ programs especially developed for pediatric acquisitions available.

syngo DynaCT Cardiac is especially suited for the planning, performance and follow-up of interventions through display of current cardiac 3D morphology directly in the cath lab.

syngo iPilot (order as separate option) enables simultaneous overlay of the live fluoro image (display of components used during the intervention) with 3D image data (display of 3D morphology); no separate recording procedure is required.

DynaCT Cardiac Volume can also serve as a basis for magnetic navigation systems (e.g., Niobe Navigant) or (in

connection with *syngo* InSpace EP Segmentation, separate option) can be used by electroanatomical mapping systems (CARTO, Ensite NavX) for increased precision of electrophysiological mapping as well as time savings.

The *syngo* EVAR Guidance workflow includes the following steps:

Create Vessel Tree - Automatic detection of the aorta and the main branching vessels (such as the left and right renal arteries). Additional vessels can be added with just one click. The vessel's centerline is marked to provide an easy indication of segments' length. Bones can be removed automatically from the abdominal CT dataset.

Define landmarks – A vessel mesh model is created to allow for automatic generation of important landmarks:

- Ostia rings - for each branching vessel a ring is generated to clearly mark the vessel ostia.
- Landing zone rings – corresponding to each branching vessel, landing zone rings are calculated, suggesting possible landing zone. These rings can be easily adjusted along the aorta.
- For each vessel an optimal C arm angle is calculated and stored into the system memory. During the procedure, these stored positions can be easily driven to, without the use of radiation. The selection between the stored positions for the vessels is easily done via the table side control.
- To allow for a flexible workflow, the segmentation results, the aortic mesh model and landmarks are saved when the patient study is closed. They are stored with the case and recalled when the patient study is opened again. Preparation of the case be done at any time before the procedure.

Overlay – The outlines of the aortic mesh model and/or the landmarks can be overlaid onto the live fluoroscopy image, following image fusion (registration). Both 2D/3D fusion and 3D/3D fusion are possible. The fusion process can be achieved from table side without having to step back into the control room.
