

1

AlluraClarity FD20 C R8.2

1

The AlluraClarity FD20 (Ceiling) single-plane cardiovascular system comprises a ceiling mounted C-arm stand and digital imaging X-ray system for cardiovascular diagnostic and interventional procedures.

ClarityIQ technology is the foundation of AlluraClarity systems touching every part of the imaging system.

ClarityIQ incorporates powerful state-of-the-art image processing technology, developed by Philips research, all working in real-time enabled by the latest computing technology:

- Noise and artifact reduction, also on moving structures and objects
- Image enhancement and edge sharpening;
Automatic real-time patient and accidental table motion correction on live images.
- Flexible digital imaging pipeline
- ClarityIQ systems have a flexible digital imaging pipeline from tube to display that is tailored for each and every application area such as Cardio or Neuro. This gives the flexibility to select virtually unlimited application-specific configurations.
- With ClarityIQ over 500 system parameters are fine-tuned for each application area; the result of years of Philips clinical leadership. It is now possible to filter out more X-ray radiation, use smaller focal spot sizes, shorter pulses, thereby fully utilizing the unique capabilities of the Philips MRC X-ray tube.

The AlluraClarity FD20 system uses an integrated single-host concept. The system is comprised of five functional building blocks: Geometry, X-ray Generation, Image Detection, Viewing, and User Interface. Each functional building block is explained in further detail including accessories.

GEOMETRY

The AlluraClarity FD20 Stand

The Allura stand consists of a ceiling-mounted C-arm. The stand has the following capability:

- The L-arm can be rotated and can be moved in longitudinal direction allowing a three-sided patient approach and total body coverage.
 - L-arm rotation around the patient table: +90, 0, -90 degrees.
 - L-arm longitudinal movement: 300 cm
 - This movement features auto-stops at the parking position, cardio/neuro position and lower peripheral position.

The Allura stand allows a very wide range of projections, including PA and AP imaging.

- In the head position (0 degrees position, L-arm parallel to patient table):
 - C-arm rotation range (degrees): 120 LAO to 185 RAO

- C-arm angulation range (degrees): 90 CA to 90 CR
- (Full angulation capability determined by patient position)
- In the side position (+90 / -90 degrees position, L-arm perpendicular to patient table):
 - C-arm rotation range (degrees): 90 LAO to 90 RAO
 - C-arm angulation range (degrees): 185 CA to 120 CR or 120 CA to 185 CR
 - (Full angulation capability determined by patient position)
- The stand provides fully motorized fast movements with variable and configurable maximum speed.
 - Variable C-arm rotation speed, up to 25 degrees per second
 - Variable C-arm angulation speed, up to 18 degrees per second
- L-arm rotation and longitudinal movement: motorized and manual
- C-arm depth is 90 cm
- The FD20 Dynamic Flat Detector features Xper Access which allows the flat detector to be positioned in either portrait or landscape imaging modes in 3 seconds.
- The variable source image distance between focus and Dynamic Flat Detector input screen is motorized from 86.5 to 123 cm.
- The stand features BodyGuard a capacitive sensing collision avoidance system for patient protection.

Patient support

The Xper Table

- Patient support with flat carbon fiber tabletop
- Table top length of 319 cm, width 50 cm
- Metal-free overhang 125 cm
- Floating table-top movement of 120 cm longitudinal and 35 cm transversal range.
- Motorized height adjustment from 74.5 to 102.5 cm
- Maximum cantilever of 223 cm, for full patient coverage
- Maximum patient weight 250 kg plus 500 N for CPR (or 225 kg plus 1000 N) in any longitudinal position of the table top
- Xper Geometry and Imaging Modules for exam room controls.
 - The operating modules can be attached to either side of the table.

Patient Support Accessories set

- One cerebral filter
- Three rail accessory clamps
- One IV stand
- One slow recovery foam mattress
- One Set of Arm Supports (FCV0248)
- One Set of Patient Straps (FCV0250)
- One Head Support (FCV0251)
- One Arm Support (FCV0258)
- One Table-mounted Radiation Shield
- One anti-fatigue mat with Philips logo

X-ray Generation

The AlluraClarity FD20 comprises an integrated dedicated X-ray system, micro-processor controlled Certeray generator based on high frequency converter technique. The user interface control of this X-ray Generator is incorporated in the Xper module, Xper Desktop Viewing Console, and the Xper on-screen displays.

- The Certeray generator comprises:
 - X-ray generator: 100 kW
 - Voltage range: 40 - 125 kV
 - Program selection:
 - Pulsed X-ray up to 3.75 , 7.5 , 15 , 30, frames/s for digital dynamic exposures
 - Pulsed X-ray for pulsed fluoroscopy (3.75, 7.5, 15, 25, 30 frames/s).
 - Minimum exposure time of 1ms.
 - ECG triggered acquisition: allows acquiring one exposure for each QRS peak with selectable delay time
 - Automatic kV and mA control for optimal image quality prior to run to save dose
 - Optimal X-ray tube load incorporated in the Certeray generator
- An X-ray collimator with single semi-transparent wedged filter with manual and automatic positioning.
- SpectraBeam filtering of low energy radiation to optimize image quality and dose efficiency with the MRC-GS 0508 X-ray tube.
- Xper Beam Shaping, which means that, both shutters and wedges can be positioned on the Last Image Hold without the need for X-ray radiation.

Fluoroscopy

- Three programmable fluoroscopy modes
 - Each mode can be set to different composition of dose rate, pulse speed, filter setting, and image processing (noise reduction, adaptive contour enhancement, and adaptive harmonization).
- Roadmap Pro
 - Roadmap Pro can be selected from the Xper imaging module and/or Xper module.
 - A vessel map is created and superimposed with (un)subtracted live fluoroscopy. Acquisition runs can be done during Roadmap without losing the vessel map. Roadmap Pro features Smart Settings in special clinical modes that are optimized to visualize special materials such as coils and glue. Live processing of the vessel map, the device map and the landmark map can be done on the Xper Module. Xres for vascular procedures is standard part of Roadmap Pro.
 - **Disclaimer:** AMC only corrects movement artifacts in two dimensions. Three dimensional movements such as swallowing or rotation of the head cannot be corrected.
 - In Roadmap Pro R2 "Automatic Motion Compensation" (AMC) is added to the roadmap functionality. During roadmap, small movements of the patient can lead to subtraction artifacts. These artifacts might conceal important clinical information. "Automatic Motion Compensation" compensates for rigid, uniform (skeletal/table) translations and is therefore very effective in interventional (neurology) applications where subtraction imaging is applied.
 - **Disclaimer:** AMC only corrects movement artifacts in 2 dimensions. 3 dimensional movements like swallowing or rotation of the head cannot be corrected.

- Xper Fluoro Storage, a grab function allows storage and archiving of both a fluoro image and the last 20 seconds of Fluoroscopy, called Xper Fluoro Storage. These fluoro images or fluoro runs can be archived as a regular exposure run.

X-ray tube

The AlluraClarity FD20 has the Maximus ROTALIX Ceramic grid switch tube assembly MRC 200 GS 0407 integrated in the C-arc. This MRC tube has an anode heat storage capacity of 2.4 MHU and 0.4/0.7 mm. nominal focal spot values. The tube has a maximal loading of 30 and 67 kW. Dynamic pulsed fluoroscopy uses grid switching technology to eliminate soft radiation and improve image quality. SpectraBeam allows for filtration of the x-ray beam with (a combination of) 0.2, 0.5 or 1 mm CU-equivalent filters.

Tube housing ROT-GS 1004 is for oil-cooling and has a build-in thermal safety switch. A rotor control unit is build-in for continuous rotation of the anode disk. The heat exchanger CU 3101 is for direct and continuous forced cooling with oil.

IMAGE DETECTION

The AlluraClarity FD20 comprises the following image detection chain:

- A 30 cm by 40 cm FD20 Dynamic Flat Detector with eight imaging modes.
 - 30 x 38, 30 x 30, 26 x 26, 22 x 22, 19 x 19, 16 x 16, 13.5 x 13.5, and 11 x 11 cm
- The digital output of the FD20 flat detector is 2k*2.5k image matrix at 16 bits depth for the largest mode
- The flat detector subsystem features Xper Access, the detector can be rotated over 90 degrees, it moves from portrait to landscape back & forth
- DQE (Detective Quantum Efficiency) >77 %
- The pixel pitch: 154 x 154 microns

Viewing

The AlluraClarity FD20 comprises the following components in order to display the clinical images in the control and examination room:

Displays

Examination Room

Two 19-inch monochrome LCD monitors designed for medical applications. The first display is used for viewing live images. The second display is the reference monitor.

- 19-inch monochrome TFT-LCD display with a 160 degree viewing angle.
- Native format 1280x1024 SXGA
- 10-bit gray-scale resolution with gray-scale correction

These monitors are not delivered when FlexVision XL, EP Cockpit or EP Cockpit XL is selected.

The monitor ceiling suspension in the exam room can be configured to accommodate 3, 4, 6 or 8 LCD monitors and includes motorized height adjustment. The height-adjust feature is dependent on the room ceiling height. When FlexVision XL, EP Cockpit or EP Cockpit XL is selected the monitor ceiling suspension is configured for one of those options.

- Of the two medical monochrome LCD monitors included in the MCS, one is used for viewing of live images and the other serves as the first reference display. Reference images or runs are controlled by infra-red remote-control Xper ViewPad.
- The On-Screen Display provides status information on stand rotation, angulation, display of system messages, X-ray tube load status, selected fluoroscopy mode, selected detector Field of View, and both the rate and accumulation of the dose area product and skin dose. For cardiac applications, the system also monitors and displays body zone specific Air Kerma data (10 zones).

Control Room

One 19-inch color LCD monitor used as a data monitor.

- 19-inch color TFT-LCD display
- Native format 1280x1024 SXGA

One 19-inch monochrome LCD monitor (Xper review monitor) designed for medical applications.

- 19-inch monochrome TFT-LCD display
- Native format 1280x1024 SXGA
- 10-bit gray-scale resolution with gray-scale correction

These control room monitors are not delivered when EP Cockpit or EP Cockpit XL is selected. The Graphical User Interface on the monochrome monitor has the following features and functions:

- Step through file, run, or images
- File, and run overview
- Contrast, brightness, and edge enhancement settings
- Flagging of runs or images for transfer
- Applying text annotation in images
- Optional DICOM printing
- Executing Quantitative Analysis Packages if available
- Subtraction functionality
- Zoom/pan functionality
- Electronic shutters
- Video invert
- View trace, stacking of images
- Landmarking

Acquisition

The acquisition segment coordinates the parameters for automatic exposure control. The program is selected via the Xper module or Xper Desktop Console.

Exposure techniques:

- Serial imaging for DA and DSA with automatic exposure setting
- Single shot mode

- Acquisition frame rates:
 - 0.5 to 6 fps at 2048 x 2048
 - 15 and 30 fps at 1024 x 1024

The AlluraClarity FD20 offers a storage capacity of:

- 50,000 images at matrix size of 1024 x 1024
- 12,500 images at matrix size of 2048 x 2048
- Maximum number of examinations is 999, with no limit to the maximum number of images per examination

USER INTERFACE

Xper is comprised of three elements: 1) Xper Settings, which customizes the system to each user preferred settings. 2) Xper User Interface 3) Xper Integration, which makes advanced integration functionally available such as DICOM Query / Retrieve, background archiving, and Xper Fluoro Storage.

The Xper User Interface uses User Interface modules in the Examination Room with On-Screen Display.

The On-Screen Display is positioned on the left side of the reference monitor. The following system information is displayed

- X-ray indicator and X-ray tube temperature condition
- Gantry position in rotation, angulation, and Source Image Distance
- Detector field size display
- General System messages
- Selected Frame speed
- Fluoroscopy mode
- Integrated fluoroscopy time
- Skin Dose and Dose Area Product
- Stopwatch

The Xper ViewPad contains the preprogrammed function settings. The system provides with two Xper Viewpads. The following functions are provided:

- Run and image selection
- File and run cycle
- File overview
- Store to Reference image file
- Copy image to photo file
- Digital (fixed) zoom and panning
- Recall reference images
- Laser pointer, intended to point at regions of interest on the imaging monitors
 - LED indication of laser pointer on/off and battery low
- Subtraction on/off
- Remasking
- Landmarking

Remote Intercom

The separate intercom which is connected independently from the system that allows separate placement of the intercom at the preferred working position in the control room and examination room.

Table Side Modules

Two Xper Modules are provided for use. The first Xper Module is mounted tableside. The Second Xper Module (NCVA778) is located in the control room. These modules use a touch screen, which can be operated when draped with sterile covers. The Xper Module contains the following functionality:

- Acquisition settings
- Selection of Xper Setting allows the user to set frame rates and X-ray generation settings applicable for the type of the preferred intervention
- Image Processing

The Xper Geometry module can be positioned on all sides of the patient table, while keeping the button operation intuitive. The Xper Geometry module provides the following functionality:

- Tabletop float and table height position
- Source Image Distance selection
- Longitudinal movement of the Gantry along the ceiling
- Gantry rotation in an axis perpendicular to the ceiling
- Store and recall of two scratch gantry positions including SID
- Emergency stop button

The Xper Imaging module can also be positioned on three sides of the patient table, while keeping the button operation intuitive. The Xper Imaging module provides the following functionality:

- Fluoroscopy Flavor selection defined per Xper Setting
- Shutters and Wedge positioning
- Xper Fluoro Storage and Grab
- Selection of the Detector field size
- Shutter positioning
- Reset of the fluoroscopy buzzer

Pan Handle

- The Pan Handle is an extension of the control facility for floating movements of the tabletop.

Control Room

The control room comprises a Xper Review Module, Xper Desktop Module, a keyboard, and a mouse. The Xper Review Module offers the basic functions for review. The Xper Review Module contains the following functionality:

- Power on/off
- Tagarno wheel to control the review of a patient file
- File and run cycle
- Contrast, Brightness, and Edge enhancement settings

- File, Run, Image stepping and run and file overview
- Delete run
- Image invert and digital zoom
- Reset fluoroscopy timer and enable/disable X-ray

System information is displayed on the bottom of the data monitor:

- Stopwatch and Time
- System guidance information
- Dose Area Product (DAP) and Skin Dose, and accumulative dose
- Frame speed settings, fluoroscopy mode, and accumulated fluoroscopy time
- Exposure and fluoroscopy settings as Voltage (kV), Current (mA) and pulse time (ms)
- Geometry Information as rotation, angulation, and SID

Scheduling

The patients can be listed and selected per date, physician, and intervention type. Previous DICOM patient studies can be uploaded with the DICOM Query Retrieve function in the Allura system.

Patient management protocols are flexible and allow for multiple studies to be selected under one patient identification number. This means that new studies can be appended to an earlier patient file. Furthermore, each study can contain multiple examinations to allow for split administrative purposes. Each examination contains multiple files, like acquisition file, reference file, and QA results file.

Preparation

The preparation page provides the information of the room and patient preparation of each individual physician. The preparation page is customizable per Xper Setting and allows each physician to provide his own room protocols. This preparation page makes hard copies of the protocol instructions redundant.

Acquisition

The acquisition page contains information on the current selected patient.

Review

The review page allows for reviewing of patients:

- Previous examination cases
- Review of other DICOM XA or DICOM SC studies

Radiation Dose Structured Report

Collection of dose relevant parameters and settings and export to a DICOM database (e.g. PACS, RIS), according IEC60601-2-43, 2nd Edition.

The reported data can be used for, for example:

- Quality improvement: evaluating trends in X-ray dose performance per facility, system and operator.

- RDSR enables analysis of average dose levels & variance for routinely performed exams and procedures.
- Typical system usage can be extracted from the data.

Secondary Capture Dose Report

- The Secondary Capture Dose Report function allows the user to save & transfer, manually or automatically, a patient Dose Report to PACS in DICOM secondary capture format.
- The dose report will be stored in the related patient image folder.

Archive

Continuous Autopush (NCVA090)

Continuous Autopush is an archive accelerator, which ensures that background archiving continues with minimal disruptions.

Clinical studies can be archived to a CD or a PACS. The archive process can be completely automated and customized with Xper Settings. Parameters like multiple destinations, archive formats can be selected to the individual needs and wishes for programming under the Xper Settings.

The Xper DICOM Image Interface enables the export of clinical images to PACS. The export formats are based on DICOM 3.0 protocols. The system exports clinical studies in Cardiac DICOM XA Multi-Frame or DICOM Secondary Capture formats.

- The export format is configurable in 512x512, 1024x1024 2048 x 2048 (unprocessed) matrix.
- The examination can be sent to multiple destinations for archiving and reviewing purposes.
- The Xper DICOM Image Interface provides DICOM Storage and DICOM Storage Commitment Services.
- The DICOM Query/Retrieve function allows older DICOM XA MF and DICOM SC studies to be uploaded in the system. Furthermore, additional information can be appended to a study, while keeping the patient identification the same.

Remote Service

Access to the system from a Remote location is possible via network or modem connection. Remote access to a system can shorten the time needed for e.g. changing system settings or problem diagnosis.

Clinical Education Program for the Allura Xper System

Essentials OffSite Education:

Philips will provide up to two (2) Cardiovascular Technologists, Registered Technologists, Registered Nurses, or other system operator as selected by customer, with in-depth didactic, tutorial, and hands-on training covering basic functionality and work-flow of the cardiovascular imaging system. In order to provide trainees with the ability to apply all fundamental functioning on their system, and to achieve maximum effectiveness, this class should be attended no earlier than two weeks prior to system installation.

In the event that an EP Navigator workstation has also been ordered, the offsite training course will be tailored to focus on the electrophysiology functionality of the FD system and the EPN workstation.

In the event that your main FD system will be dedicated to Cardiac applications your offsite training course will be tailored to focus on the Cardiac functionality.

This twenty-eight (28) hour class is located in Cleveland, Ohio, and is scheduled based on your equipment configuration and availability. Due to program updates, the number of class hours is subject to change without notice. Customer will be notified of current, total class hours at the time of registration. This class is a prerequisite to your equipment handover OnSite Education. CEU credits may be available for each participant that meets the guidelines provided by Phillips. Please refer to guidelines for more information. Travel and lodging are not included, but may be purchased through Phillips. It is highly recommended that 989801292102 (CV Full Travel Pkg OffSite) is purchased with all OffSite courses.

Handover OnSite Education:

Phillips Education Specialists will provide twenty-eight (28) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. Students should attend all 28 hours, and must include the two OffSite education attendees. CEU credits may be available for each participant that meets the guidelines provided by Phillips. Please refer to guidelines for more information. Note: Site must be patient-ready. Phillips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. It is highly recommended for systems that are fully loaded or for customers with a large number of staff members to also purchase 989801292099 (CV Add OnSite Clin Educ 24h).

Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref #106107-110915

2

FlexVision XL 8 Input Package

1

The FlexVision XL8 input package provides eight isolated wall connection boxes and eight legacy converters.

Isolated Wall Connection Box

This Isolated Wall connection Box facilitates connection of the video source via standard DVI cable/connector and lossless transfer of the video signal over the approximate 30 m cable distance. It can be mounted in the exam room or in the control room, depending on the location of the video source.

The quantity of the VWCB's has to be calculated as follows:

For each video signal to FlexVision XL on Vascular System: 8 VWCB

Note:

No VWCB is required in case a video signal is connected directly to a dedicated LCD from the following sources:

- 1) Xper Live/ref Slaving
- 2) Interventional HW (XtraVision), ViewForum, Xcelera (only if workstations are powered by Allura Xper)
- 3) Xper IM

Legacy Video Converter

The Legacy Video Converter enables conversion from VGA towards DVI for supported input resolutions as listed in the table below.

Signal type Native resolution Image Aspect Ratio

VGA 640x480 4:3

SVGA 800x600 4:3

XGA 1024x768 4:3

SXGA 1280x1024 5:4

SXGA+ 1400x1050 4:3

UXGA 1600x1200 4:3

WXGA 1280x800 16:10 (8:5)

WSXGA 1440x900 16:10 (8:5)
 WSXGA+ 1680x1050 16:10 (8:5)
 WUXGA 1920x1200 16:10 (8:5)
 2K 2048x1080 19:10
 TV1080I/P 1920x1080 16:9
 TV 480I 720x480 4:3
 TV 480P 704x480 4:3

3

FlexVision XL, XperHD, Snapshot

1

FlexVision XL is an integrated viewing solution designed to give you full control over your viewing environment.

The FlexVision XL provides the ability to:

- Display information from up to 8 sources simultaneously (incl. third party systems) on the Philips 58-inch color LCD with LED backlight in the Exam Room.
- Resize and/or enlarge information at any stage during the case.
- Select and customize viewing lay-outs of the Philips 58-inch color LCD via the Xper table-side module
- Overview connected equipment (incl. third party systems) from a single location.

XperHD on FlexVision XL brings High Definition viewing for clinical images. Native resolution of FD20 can be displayed. Excellent sharp and crisp clinical images can be displayed at full size without digital zoom.

Xper HD brings:

- High Definition imaging
 - Sharp images at full size without zoom
 - High Definition display at native resolution
 - Up to 2k*2k image display fully integrated
 - High Definition for the ultimate detail
 - Enhanced small vessel visualization

The FlexVision XL consists of:

- DVI video composition unit.
 - o The DVI video composition unit allows the user to direct and switch the video output of all connected medical equipment to specific sub windows of the Philips 58-inch color LCD with LED backlight in the Exam Room.
 - o The DVI video composition unit is operated from the Xper tableside module.
 - o The DVI video composition unit supports a wide variety of display formats (up to 1920x1200)
 - o Up to 9 external inputs are connected to the DVI video composition unit via Wall Connection Box(es).
- Medical grade, high resolution color LCD in the Exam Room
 - o This display supports the image quality requirements for monochrome X-ray images as well as color images and replaces all displays normally delivered with an Allura Xper FD or AlluraClarity system for the Exam Room.
 - o Main characteristics are:
 - 58-inch, 8 Megapixel color LCD
 - Native resolution: 3840x2160
 - Brightness: Max: 700 Cd/m2 (typical) stabilized: 400 Cd/m2
 - Contrast ratio: 4000:1 (typical)
 - Wide viewing angle (approx. 176 degrees)
 - Constant brightness stabilization control
 - Lookup tables for gray-scale, color and DICOM transfer function
 - Full protective screen Ingress Protection: IP-21

- Large color LCD control (Xper Module)
 - o Resize and/or enlarge information at any stage during the case via the Xper tableside module in the Exam or Control Room
 - o Select viewing lay-outs via the Xper table-side module in the Exam Room
 - o Create new layouts by matching inputs to desired locations on preset templates.

- Monitor Ceiling Suspension
 - o Monitor ceiling suspension for use in the Exam Room carries the 58-inch color LCD screen, providing highly flexible viewing capabilities. The monitor ceiling suspension is height-adjustable and moveable along ceiling rails. It can be positioned on either side of the table.

- Snapshot
 - o The snapshot function allows the user to store/save a screen-capture of any image on the 58-inch display as a DICOM Secondary Capture image to a connected PACS. The snapshot-all function allows the user to store/save a screen-capture for each displayed image in the Exam Room / Control Room as separate DICOM Secondary Capture images.

4

3D-RA Complete

1

The combination of Allura 3D-RA with 3D dynamic roadmap offers a real time registration of "live" 2D fluoro and a 3D-RA angiography volume (3D roadmap) or a previous acquired CT or MR data set (CT/MR roadmap). With the roadmap a better understanding of the anatomy can be obtained for procedure planning or risk assessment

Allura 3D-RA assists physicians in decision making for treatment strategy in endovascular procedures, neuro or vascular surgery or even radiotherapy. Allura 3D-RA reduces the number of DSA acquisitions and fluoroscopy time needed to perform an examination. This means less X-Ray dose for the patient and the medical staff and a reduced quantity of dye, leading to reduced procedure costs. Allura 3D-RA provides a unique assessment after treatment due to the use of non-subtracted images that allows to show devices stents, coils, clips and provide the optimal stand projection for endovascular treatment. Allura 3D-RA provides a wide range of communication facilities to export 3D images.

1 Image Acquisition

Image acquisition is performed with the Rotational Angiography feature of the Allura Xper FD series with the flexibility to position the C-arm in either head or side position. C-arm in Head position: the Rotational Angiography run is performed over a scan range of 240 degrees with a rotation speed up to 55 degrees/sec. C-arm in Side position: the Rotational Angiography run is performed over a scan range of 180 degrees with a rotation speed up to 30 degrees/sec.

2 3D Vessel Reconstruction

The rotational run is automatically transferred and displayed as a 3D vessel model: with the Real-Time digital link (option) 120 images are reconstructed into a 3 dimensional model within seconds. Additional reconstructions, using the Reconstructive Zooming Technique, can be performed as well.

3 Workflow:

Allura 3D-RA in combination with the Allura Xper FD series will provide an optimal workflow via the following workflow enhancers:

Complete automated 3D-RA process from 3D acquisition to 3D Viewing: no user interaction needed.

3D Automatic Position Control (3D-APC): When the optimal working position has been chosen via the Allura 3D-RA interventional tool, the C-arc will automatically steer to this position.

3D Follow C-arc: When the position of the C-arc (not using any X-ray) is changed, the 3D volume will automatically follow the position of the C-arc. This means the position of the C-arc (and therefore the 2D projection) and the 3D volume are always aligned. As last seen; when the user leaves the patient in the model and later selects that patient again, the Allura 3D-RA interventional tool will return to the image last used by the user.

Mouse over: When moving the mouse cursor over a button the mouse over text will show up to explain the function of that specific button.

4 Calibration

Allura 3D-RA calibrations are performed by Philips Healthcare Customer Support. Allura 3D-RA calibration data are stable over at least 6 months time.

5 Viewing

A Real Time user interface is available with 3D-RA, providing 3D object viewing in any space direction. A graphical display of (C-arm) stand position including angulation/rotation for any projection.

Philips' CRM (Contrast Resolution Management) Technology for a considerable increase in contrast resolution in all volumes.

Various Image Rendering possibilities: Volume/Surface Rendering, MIP, Endoscopy, SUM (pseudo x-ray image) Gradient rendering; the possibility to display the vessel structure transparently.

Cut-plane function to get a precise insight of the shape of the pathology

Orthoviewer providing a multi-planar visualization of objects using the different Image Rendering possibilities.

MPR (Multi-Planar Reformatting): enables visualization of the volume in all three standard projections (coronal, sagittal and axial) Especially useful for optimal viewing of spine procedures (e.g. Vertebroplasty)

SpineView: special acquisition protocol for optimal viewing of the spine, especially osteoporotic vertebrae

CalcView: allows visualization of Hyper dense plaque in 3D, separately or in relation to the lumen. 5 different distance measurements calculated in the same volume, including "Quick measurement" feature

Volume calculation

Automated Vessel Analysis (AVA), provides information on vessel segment diameter, area and length with only three mouse-clicks. Endoscopic and cross sectional views are available.

Computer Assisted Aneurysm Analysis (CAAA), providing information on Aneurysms, like volume, neck size etc..

Catheter tip shape simulation, providing information on how to shape the catheter tip.

Virtual stenting; Ability to simulate a stent placement in a selected vessel segment for proper stent sizing. All relevant data of the simulated stent are displayed

Annotation: text can be added to a volume to capture comments.

Interpolative Zoom

Reconstructive Zooming Technique, 2 additional user defined reconstructions focused on the Volume Of Interest (VOI) using different cube size and voxel resolution.

Subtraction of reconstructed volumes, allowing to visualize vessels without embolization devices (stents, coils, clips,...) to assess the outcomes of treatment

Automatic Voxelshift: compensates for movement when rendering subtracted or superimposed volumes

Set the grey values WW/WL

Store/Recall of user defined projections.

6 3D-RA on Xper Module

The 3D-RA on XPER MODULE integrates the off-line 3D-RA application in the Allura Xper system. It allows operation of 3D-RA with the Xper module in the examination room during an examination. Display of 3D-RA imaging in the examination room has to be arranged for the monitor ceiling suspension with an additional monitor or with MultiVision (sharing an existing monitor). Following 3D-RA functions are available on the Xper module:

- Image rotation
- Image translation
- Start mouse mode
- Snapshot
- Segmentation (window-width/window-level control)
- 3D zoom control
- Store/recall views
- Recall Anterior-Posterior view
- Select 3D APC / Follow stand mode

7 3D and MR/CT Roadmap

3D Roadmap extends the capabilities of the integrated 3D product by providing a sustainable 3D roadmap to support interventional procedures. The 3D Roadmap option matches the real-time 2D fluoro images with the 3D-RA reconstruction or a previous acquired CT or MR data of the vessel tree. It provides a 3D real time insight of the advancement of the guide wire, catheter and coils through complex vessel structures.

Image Acquisition

The 3D Roadmap is based on the visualization of the vessel tree out of 3D-RA. THE MR/CT roadmap is based on visualization of the anatomy on previous acquired CT or MR data sets which are match with the X-ray unit by registration of the CT or MR data sets with a low dose 3D-RA scan. The roadmap is activated with one button touch at tableside (Xper Module). Select the roadmap function on the touch screen module, activate fluoroscopy and the roadmap is activated. The "live" 2D fluoroscopy image is overlaid with the 3D volume of the vessel tree and is automatically displayed on the roadmap monitor in both the examination and control room.

Table side control

The bidirectional link between the X-ray system and the roadmap allows the user to select the optimal stand position for the procedure in two ways. 3D Automatic Position Control allows the gantry to automatically move to the best interventional projection as shown on the roadmap monitor. 3D Follow C-arc allows the roadmap to remain in sync with the 2D projection, automatically adjusting viewpoint as the gantry is repositioned.

The roadmap is dynamic, providing the freedom to change:

- The angulation of the C-arc;
- The rotation of the C-arc;
- The Field of View;
- The Source to Image Distance.

i.e. if the geometry system is changed, the image angle changes accordingly, real-time.

Intuitive, fully controlled from tableside:

- Landmarking to adjust the intensity of the anatomical reference surrounding the vessels;
- 3D blending to fade in/out the 3D view;
- WWWL settings to control the contrast/brightness;

- Store and review runs for reporting and archive purposes;
- Store snapshots and movies

8 Archiving

Transfer to:

Optional Hard Copy unit (DICOM Print)

Any optional DICOM compatible device (e.g. PACS/ViewForum/Xcelera), supported are DICOM XA, DICOM SC, DICOM CT and DICOM 3D

Any PC in a standard PC compatible format (JPEG,AVI)

One or multiple DVD's, CD-ROM(s) for easy archiving

Store a subset of exportable objects (snapshots and AVI Movies) to a USB removable memory device.

CV 3DRA Handover OnSite Education:

Philips Education Specialists will provide sixteen (16) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref# 222-100615

5

Xper Live/Ref Slaving

2

Xper Live/Ref Slaving

The Xper Live/Ref Slaving will enable the option to slave the Live or Ref video source from the Allura Xper. The total amount of

Xper Live/Ref Slaving that can be selected is max 4.

Xper Live/Ref Slaving is possible:

- In Control Room (w/ FCV0011(B/W monitor in Control Room)
- In Philips MCS (additional monitor excluded from this option)
- (w/ FCV0519 1 or 2 MCS from Skytron/Steris

6

RIS / CIS DICOM Interface

1

This package allows communication of the Allura Xper system with a local information system (CIS or RIS). The interface uses the DICOM Worklist Management (DICOM WLM) and Modality Performed Procedure Step (DICOM MPPS) standards.

If a hospital has an Allura Xper system and an information system it can receive patient and examination request information from the information system and report examination results in order to:

- Eliminate the need for retyping patient information on the Allura Xper
- Prevent errors in typing patient names and registration numbers (ensuring consistency with IS information to prevent problems in archive clusters or to search for a name in case of later retrieval)
- Inform the IS about the acquired images and radiation dose

Upon request from the Allura Xper system the complete worklist with all relevant patient and examination data is returned from the IS to the Allura Xper system. For each patient the following information will be shown on the Allura Xper after it has been retrieved from the IS:

Patient Identification:

- Patient name
- Patient ID
- Birth date

- Sex

Examination/Request Information:

- Accession number
- Scheduled procedure step start time
- Scheduled performing physician's name

It is possible at all times to enter patient demographics information manually within the Allura Xper system in case of an emergency or in case the local Information System connection is down.

On request of the clinical user the Allura Xper will report the following information about the selected patient to the IS:

Patient Identification:

- Patient name
- Patient ID
- Birth date
- Sex

Examination/Request Information:

- Accession number
- Performed procedure step status start/end date and time
- Performing physician's name
- Referenced image sequence

Radiation dose:

- Total time of fluoroscopy
- Accumulated fluoroscopy dose
- Accumulated exposure dose
- Total dose
- Total number of exposures
- Total number of frames

Further detailed information can be found in the Allura Xper DICOM Conformance Statement.

The interface requires an EasyLink (hardware and software) if the IS is not compliant with DICOM Work List Management and Modality Performed Procedure Step.

7

**Standard Line Rate Video
Output**

1

This interface provides image output to standard line rate video peripherals, such as VCRs or paper printers. This option also comprises automatic start and stop of a VCR, synchronous to the generation of X-ray (fluoroscopy and exposures).

8

Lab Reporting

1

Lab Reporting allows the user to generate and print simple reports in modality stand-alone situations. The user is able to incorporate free text and clinical images. The reporting functionality is suited for local printing and email. Part of the report is generated automatically from administrative data (e.g. patient/exam data hospital name) and required data (e.g. run-log dose information and event-log).

Dicom Print provides the possibility to interface to any DICOM Printer. This is an automated printing protocol. The option provides Print Manual Overrides, Print Job submission, and Print Job management.

Rotational angiography provides real-time 3D impressions of complex vasculature and coronary artery tree. It acquires multiple projections with just one contrast injection via a fast rotational scan of the region of interest.

Rotational Angiography can be used during screening procedures to quickly determine the optimal projection for the study as the angle (rotation/angulation) of the projection is indicated on each image.

Compared with traditional angiography, Rotational Angiography can save considerable time, dose and contrast, while providing image detail required for diagnostic and therapeutic decisions.

A rotational scan is possible both with the Allura Xper systems in the side position (ceiling mounted systems) and in the head position, providing the flexibility to perform procedures virtually from head to toe.

C-arm in side position:

- Max. rotation Speed: 30 degrees/s
- Max. rotation Angle: 180 degrees

C-arm in head position:

- Max. rotation Speed: 55 degrees/s
- Max. rotation Angle: 305 degrees

Max. Frame speeds are given by the framespeed specifications of the system configuration.

The speed and range of rotation are the highest available (see table). The very high speed allows using less contrast, whereas the very wide rotation range provides a complete evaluation of the anatomy.

A contrast run can be followed up with a mask run, to allow image/run subtraction.

The stand is designed for a very high mechanical stability. It offers precise positioning and high reproducibility, assuring you of high quality images and excellent subtraction studies.

Operation of Rotational Angiography is extremely easy. The procedure is selected, set up and executed virtually in a matter of seconds, supporting the highest patient throughput.

A set of dedicated acquisition programs is available on the Xper Module and can be selected at the touch of a button. The rotation end- and start-positions are easily selected. The procedure is controlled from the exposure hand- or footswitch.

Bolus Chase solves the problem of cumbersome step movements, the mismatch between blood flow and selected program, and lack of real-time image information.

The bolus run is followed with a mask run while using the same speedcurve and framespeed as generated during the bolus run. Viewing is possible in the subtracted and non-subtracted mode. If subtracted viewing is not required, the mask run can be skipped.

Comprising:

- automatic exposure control
- tabletop motordrive and hand-held speed controller (tableside)
- technique selection using Xper module, available both tableside and in control room (Xper FD20, FD20/10)

CO₂ View Trace Software
Software package which enables tracing (stacking) of images acquired with CO₂ injections. This function can be used during postprocessing next to view trace of images acquired with iodine injection.

Storage extension provides an increased storage capacity for

Allura Centron system the storage is increased from:
- 50.000 to 100.000 images at 1024x1024 matrix

14 FD Dual Fluoro 1

Dual Fluoro for Flat detector systems

The Dual Fluoroscopy mode allows digitally processed fluoroscopy in parallel with trace subtract fluoroscopy, providing a non subtracted reference fluoro image for complex interventions.

This option provides an additional fluoro channel in parallel to the default fluoro channel. The Dual fluoroscopy mode is selected via the Xper module.

The trace subtracted fluoro image will be displayed on the exam monitor, the non-subtracted fluoro image is displayed on the reference monitor.

In Dual Fluoro mode, The fluoroscopy image on the exam monitor can be zoomed digitally with a factor 2, providing a larger view of the region of interest for complex interventions. The fluoro zoom function is controlled via the Xper module.

15 FD SmartMask 1

SmartMask simplifies roadmapping procedures by overlaying a selected reference image with fluoroscopy on the live monitor in the exam room.

The reference image can be faded in/out with variable intensity, controlled from tableside.

SmartMask uses the reference image displayed on the reference monitor.

Any previously acquired image can be used as reference.

SmartMask facilitates pre- and post- intervention comparisons to assess treatment results

16 FULL AUTOCAL 1

The AutoCal option is a software package to be used in conjunction with quantitative analysis software packages. It provides an auto calibration procedure for an object to be analyzed that is placed in the iso-center. When the object to be analyzed (e.g. Left Ventricle Vessel Segment) is placed in the iso-center AutoCal avoids the need to:

- acquire an additional image series containing a sphere or grid for calibration purposes
- calibrate manually on a calibration object (e.g. catheter) displayed in the image or image series to be analyzed

17 Vascular Quant.Sw pkg(Xper) 1

Functions:

- vessel diameter / stenotic index
- automated vessel analysis
- calibration routines

In addition the package allows manual measurements of line lengths (absolute and ratio's) and angulations. Multiple measurements in one image are possible.

Compatible with:

- Allura Xper FD10 Rel 3 and FD10/10 Rel 2 onwards
- Allura Xper FD20 Rel 2 and FD20/10 Rel 2 onwards
- Allura CV20 R1 onwards

18 Cath Arm Support 1

For brachial catheterisation and digital imaging technique
The support is made of X-ray transparent material with exception of the fixing clamp and pivots.

19

Peripheral X-ray Filter

1

Peripheral X-ray Filter
Set of flexible x-ray filters to provide an uniform density in angiographic examinations of the lower peripheral area.

Comprising:

- Comprising:
- one central filter, at the top edge provided with sizing markers at every 5 cm, length : 1 m
 - two side filters, length: 1 m

20

Pivot for table base.

↑

For angiographic- and interventional procedures of the upper peripherals.

Allows pivoting of the table base around its vertical axes.

Allows pivoting of the table base around its vertical axes.
Pivot range from -90 degrees to + 180 degrees (or -180 to +90 degrees) with locked positions on 0, -13/+13 (facilitating arm-angiography) and -90/+90 and 180 degrees.

Comprising:

- pivot device with graduated scale to be mounted on the universal floor plate of the table.

Compatible with Xper Table

21

Interventional Tools Hardware

1

Interventional Tools Hardware

The Interventional hardware is the hardware for the 3D interventional tools and enables import and viewing of DICOM compatible data from other Imaging modalities.

The Interventional Hardware comprises at least:

- Computer Workstation
- CR 19" display
- 16 GB memory
- 2 TB disk for the operating system, application software and application data
- Internal CD-Rom / DVD writer
- Mouse tablet to interact with all the interventional tools at the table side.

Conditionally:

Conditionally.
FD Calibration Tool Kit for 3D-RA

22

. Real time image link

1

Real Time digital image link to an off-line Allura Interventional Hardware station. This applies on the applications 3D-RA, StentBoost and 3D-CA on the Interventional Hardware. This dedicated digital link sends raw or processed image data (depending on the application) real time during monoplane exposures to the connected Interventional Hardware station, to allow instant results of the applicable reconstruction after the exposure run.

In biplane systems, this digital link is available for the frontal channel only.

23

Xper CT R3 plus

↑

Xper CT R3 plus

XperCT extends the capabilities of the interventional suite offering CT like imaging to visualize bone, soft tissue and vessels in case of contrast enhanced acquisition. A wide range of XperCT protocols are available for different procedures varying from neuro to abdominal, up to high resolution stent imaging. All protocols can be selected at the tableside via the XperModule. The XperCT acquisition scan acquires up to 60 frames/sec (frame rate extension is included). The high frame rates are beneficial for the dedicated abdomen protocols, requiring only a short breath hold for the patient and providing optimal image quality. Fast acquisitions protocols require a 5 to 10 seconds scan.

The XperCT imaging process is fully automated in the Allura Xper system. The XperCT 3D volume is displayed automatically in less than a 1 minute (from acquisition to display), with the fastest protocols taking only 25 seconds. No user interaction is required. Especially in critical cases it is important to obtain a fast overview.

XperCT R3 also includes major image quality improvements:

- Metal Artifact Reduction: reduce the artifacts caused by metal presence in the region of interest
- BMI Noise Reduction: reduce the noise caused by large size patients

Metal artifact reduction is an improved algorithm on XperCT that allows minimizing the artifacts caused by the metal presence in the region of interest. The most typical example of metal presence are: metal implants, coils or stents with stainless steel structure. In case the original XperCT shows metal artifacts, the interventional radiologist can perform a second reconstruction and select for Metal Artifact Reduction, which will remove the artifacts caused by the metal present.

BMI noise reduction is a new algorithm that allows for an improved IQ of XperCT, reducing the artifacts caused by excessive body mass index patients.

In case the original XperCT shows artifacts caused by the results of excessive BMI, the interventional radiologist can perform a second reconstruction and select for BMI Noise Reduction, which will smoothen the image, providing a better image quality. Note: BMI Noise Reduction is only available when Abdominal XperCT runs is selected

The XperCT 3D volume can be viewed in the control room and in the examination room. The viewing package comprises:

- 3D volume viewing in any desired orientation
- Slice viewing in any desired orientation
- Slice viewing at any slice thickness with a minimum of 0.5 mm
- Five distance measurements calculated in the same volume, including "Quick measurement" feature
- Cut-plane functionality to provide precise insight into anatomical structure
- Unique high-resolution reconstructive zoom technique
- Graphical display of stand position including rotation and angulation parameters
- Contrast and brightness control
- Contrast resolution 5-10 Hu
- Spatial resolution of the initial reconstruction: 10 lp/mm
- Contrast range -1000 to 2000 Hu
- High resolution imaging mode produces
- 512x512x512 volume rendered reconstructions
- XperCT can be controlled via the Xper 3D module and the mouse at tableside.

The XperCT volume can be matched with (when additional options are available) Allura 3D-RA

and pre acquired CT or MR volumes. This view allows to combine multiple images from different modalities in order to provide additional anatomical insight.

This new multimodality volume can be viewed with the following functionality:

- Automatic or manual registration of the two volumes from the same patient
 - The resulting volume can be viewed with complete 3D-RA viewing functionality
 - The XperCT slice can be overlaid onto the 3D vessel for better assessment of the region of interest
 - Three different contrast rendering options to allow optimal viewing of the 3D vessel in the soft tissue structure (128x128x128, 256x256x256 and 512x512x512 volumes)
 - Movie clip recording functionality (AVI) to capture dynamic views
 - 3D automatic position control at tableside: When an optimal working position is selected from the 3D-RA volume the C-arc steers itself to the selected position
 - 3D Follow C-arc at tableside: When selected, the 3D-RA volume automatically follows the position of the C-arc.
 - XperCT data and 3D-RA with XperCT overlay is stored in the same patient file as all other patient related data. All this data can be reviewed at any time
- And sent to:

- Any optional DICOM compatible device (e.g. PACS/ViewForum/Xcelera), supported are DICOM XA, DICOM SC, DICOM CT and DICOM 3D
- Any PC in a standard PC compatible format (JPEG,AVI)
 - And stored/archived on
 - A PACS systems as DICOM Secondary Capture images or movies
 - USB removable memory device
 - One or multiple DVD's, CD-ROM(s) for easy archiving
 - Hard copy via the (DICOM Print) protocol

Clinical Education Program for XperCT

CV XperCT Handover OnSite Education:

Philips Education Specialists will provide eight (08) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref# 335-100615

24

18 INCH LCD MONITOR IN THE EXAM ROOM 2

18" Monochrome LCD monitor. The LCD monitor is intended for viewing in the examination room and is designed for medical applications.

The main characteristics are:

- 18 inch monochrome TFT-LCD display
- Native format 1280x1024 SXGA
- 10 bit gray-scale resolution with gray-scale correction
- Wide viewing angle (approx 160 degr)

- High brightness (max 600 Cd/m2 default 500 Cd/m2) with ambient light dependent brightness control
- Push buttons for control functions on front
- User programmable and standard reference setting
- On Screen Display
- Internal selectable lookup table for gray-scale transfer function
- Internal power supply (110-240 VAC)
- Including LCD protection screen

25 **Black Anti-Fatigue Floor Mat w/ Blue Logo** 1

Blue Anti-Fatigue Floor Mat w/ Logo

26 **Rad Shield w/ Arm (Contoured) 61X76** 1

Contoured Rad Shield with Arm rest. 61X76

27 **Double LCD Monitor Cart** 1

Stand alone monitor cart for two LCD Monitors

28 **Cable Spooler** 1

29 **10 Meter DVI Cable Set** 2

10 meter DVI cable set with zipper hose cover.

30 **Mach 3 Dual Focus Lamp 220v** 1

The Mach 3 DuoFocus exam lamp brings daylight quality lighting to the interventional suite. The lamp provides a color rendering index Ra of 96.5. The focusable light field size is 8 – 35 cm with a working distance of 60 – 150 cm.

31 **Mark 7 Arterion, Table Mount** 1

The Mark 7 Arterion Injection System is the latest in MEDRAD's "Mark" series of angiographic injectors. Compared to earlier systems, the Mark 7 Arterion injector head is lighter and easier to use so you can focus more on the patient.

The clear and intuitive user interface guides you through proper set-up, and highlights the information you need to perform safe procedures.

Unique to the market, the front load system simplifies set-up and makes for a cleaner tear down. The clear syringe provides a higher level of confidence that you are ready to inject.

Made from a clear material, the Mark 7 Arterion syringe (Catalog ART 700 SYR) allows you to easily view the inside of the syringe for smoother purging of air. And MEDRAD's famous fluid dots are still there to help-round for fluid, oval for air.

The table mount injector solution ensures the contrast injector is conveniently placed and always available when it is needed. It provides a clean workspace without occupying valuable floor space. System includes:

- Table Mount
- display control panel
- 6 ft. coiled hand switch
- operation manual (CD)
- 10 ft. head cable

- syringe heat maintainer
- imaging system interface cable for the Allura / Allura Xper
- consumables starters kit

For the MEDRAD Mark7 Injector system Philips is only the distributor. MEDRAD provides the service as well as the application support of both versions unless stated differently in the Philips Service Agreement

System Specifications:

- Flow Rate 0.1-45.0 ml/s in 0.1 ml increments
- 0.1-59.9 ml/m in 0.1 ml increments
- Volume 1-150 ml in 1 ml increments
- Pressure Limit 100-1200 psi in 1 psi increments
- (150ml syringe) 689-8273 kPa in 1 kPa increments
- Rise Time 0.0-9.9 seconds in 0.1 increments
- Delay Time 0.0-99.9 seconds in 0.1 increments
- Fill Speed 1-20 ml/s
- Fill Volume 1-150 ml
- Syringe Size 150 ml
- Syringe Heat Maintainer 35 °C (95 °F) ± 5 °C (9 °F)
- Protocol Memory 40 Protocols
- Injection Memory History

32	Ceiling Track w/Column & Handle Ext	1
	Mavig 2.5m Ceiling Track with Ceiling trolley, 360 degree column, and brake handle extension.	
33	DVI Supply Box	2
	Enclosure box for 5v monitor power supply	
34	CV Full Travel Pkg OffSite	2
	Includes one (1) participant's airfare from North American customer location to Cleveland, Ohio, with lodging, ground transportation, and meal expenses. Breakfast/dinner provided by the hotel, and lunch/breaks are catered by Philips. All other expenses will be the responsibility of the attendee. Details are provided during the scheduling process. Note: Cancellation/rescheduling policy strictly enforced.	
	Education expires one (1) year from equipment installation date (or purchase date if sold separately).	
35	Universal Power Supply	1
	25 KVA Universal Power Supply for R8.2, fluoro only.	