

V.A. Medical Center

7400 MERTON MINTER BLVD

SAN ANTONIO, TX :78229

PO#: 671-B30018

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**Allura Xper FD20 C Rel. 8.1**

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Allura Xper FD20 monoplane system is a state of art X-ray imaging system that can be customized to support a wide range of applications including peripheral, abdominal, cerebral, thoracic, cardiac and non-vascular interventional and diagnostic procedures.

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

**GEOMETRY****The Allura Xper 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 79 to 107 cm
- Maximum cantilever of 223 cm , for full patient coverage
- Maximum patient weight 250 kg with 25 kg of accessories plus 500 N for CPR 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 Allura Xper FD20 comprises an integrated dedicated X-ray system, micro-processor controlled Velara CFD 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 Velara CFD generator comprises:

- X-ray generator 100 kW
- Voltage range is 40 - 125 kV
- Maximum current 1250 mA at 80 kV
- Program selection
  - Pulsed X-ray for pulsed fluoroscopy; 3.75, 7.5, 15 and 30 frames/s
  - Pulsed X-ray for (subtracted) acquisition up to 6 frames/s for vascular applications
  - Minimum exposure time of 1 ms
  - Automatic kV and mA control for optimal image quality prior to run to save dose
  - An X-ray depth collimator with two semi-transparent wedged filters with manual and automatic positioning

- SpectraBeam filtering of low energy radiation to optimize image quality and dose efficiency with MRC-GS 0407 X-ray tube.
- Grid switching at dynamic pulsed fluoroscopy
- Xper Beam Shaping, positioning of both shutters and wedges 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 Allura Xper 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 Allura Xper 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 14 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) >73 %
- The pixel pitch: 154 x 154 microns

## Viewing

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

## Displays

### Examination Room

Two 18-inch monochrome LCD monitors designed for medical applications. The first display is used for viewing live images. The second display is the reference monitor.

- 18-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 18-inch monochrome LCD monitor (Xper review monitor) designed for medical applications.

- 18-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 images/s at 2048 x 2048, 12-bit matrix

The Allura Xper 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 functionality 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 is provided 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 (NCVA081)

- 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.

## **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. 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 Philips. Please refer to guidelines for more information. **Travel and lodging are not included, but may be purchased through Philips. It is highly recommended that 989801292102 (CV Full Travel Pkg OffSite) is purchased with all OffSite courses**

**Handover OnSite Education:** Philips 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 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. **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).** The above education entitlements expire one (1) year from equipment delivery date. Ref# 106107318-091207

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.

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| <b>3</b> | <b>Standard Line Rate Video Output</b>   | <b>1</b> |
|          | 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).  |          |
| <b>4</b> | <b>Lab Reporting</b>   | <b>1</b> |
|          | 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). |          |
| <b>5</b> | <b>Physio Viewing</b>  | <b>1</b> |
|          | Physio Viewing allows for the acquisition, storage and display of up to four channels of physiological data, in parallel with X-ray acquisition. The user can select one of the recorded physio signals for display, together with the acquired image.   |          |
| <b>6</b> | <b>Subtracted Bolus Chase</b>  | <b>1</b> |
|          | For visualization of vessel structures when the blood flow is difficult to estimate, in particular in the lower peripherals.   |          |

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

During digital acquisition in non-subtracted mode with uninterrupted real-time image display, the contrast bolus is followed (chased) interactively by a motorized table scan movement using a hand-held speedcontroller to adapt the speed of the table scan to the contrast flow. The framespeed can be adapted as well.

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.

Subtracted Bolus Chase gives fast, accurate results for increased patient throughput and improved patient management. Automated exposure control and precise speed control assure a high quality images and excellent subtraction studies.

Comprising:

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

7	<b>FD SmartMask</b>	1	<p>SmartMask simplifies roadmapping procedures by overlaying a selected reference image with fluoroscopy on the live monitor in the exam room.</p> <p>The reference image can be faded in/out with variable intensity, controlled from tableside. SmartMask uses the reference image displayed on the reference monitor.</p> <p>Any previously acquired image can be used as reference.</p> <p>SmartMask facilitates pre- and post- intervention comparisons to assess treatment results</p>
8	<b>extension to 30Fr/sec (mono)</b>	1	<p>Frame Rate Extension increases the system acquisition speed for cardiac applications that require high speed imaging. The frame rate extension increases the acquisition speed to 15fps and 30fps with a 1024x1024 matrix.</p>
9	<b>FULL AUTOCAL</b>	1	<p>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:</p> <ul style="list-style-type: none"> <li>• acquire an additional image series containing a sphere or grid for calibration purposes</li> <li>• calibrate manually on a calibration object (e.g. catheter) displayed in the image or image series to be analyzed</li> </ul>
10	<b>Ventricular Quant.Sw pkg(Xper)</b>	1	<p>Left Ventricular Quantification Software Package. Software package for the analysis of single plane Left ventricular angiograms. Calculates the Ejection fraction and local wall motion parameters in different formats.</p> <p>Functions:</p> <ul style="list-style-type: none"> <li>• Various LV-volumes</li> <li>• Ejection Fraction</li> <li>• Cardiac Output</li> <li>• Centerline Wall Motion</li> <li>• Slager Wall Motion</li> <li>• Regional Wall Motion</li> <li>• Calibration routines</li> </ul> <p>In addition the package allows manual measurements of line lengths (absolute and ratio's) and angulations. Multiple measurements in one image are possible.</p> <p>Comprising:</p> <ul style="list-style-type: none"> <li>• software license</li> </ul> <p>Compatible with:</p> <ul style="list-style-type: none"> <li>. Allura Xper FD 10 Rel 3 and FD10/10 Rel 2 onwards</li> <li>. Allura Xper FD20 Rel 2, FD20/10 Rel 2 onwards</li> </ul>
11	<b>Coronary Quant.Sw pkg(Xper)</b>	1	

Functions:

- diameter measurement along the selected segment
- cross sectional area
- %-stenosis
- pressure gradient values
- stenotic flow reserve
- 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.

Comprising:

- software license

Compatible with:

- . Allura Xper FD 10 Rel 3 and FD10/10 Rel 2 onwards
- . Allura Xper FD20 Rel 2, FD20/10 Rel 2 onwards

<b>12</b>	<b>Vascular Quant.Sw pkg(Xper)</b>	<b>1</b>
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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

<b>13</b>	<b>Cath Arm Support</b>	<b>1</b>
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For brachial catheterisation and digital imaging technique  
The support is made of X-ray transparent material with exception of the fixingclamp and pivots.

<b>14</b>	<b>Peripheral X-ray Filter</b>	<b>1</b>
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Set of flexible x-ray filters to provide an uniform density in angiographic examinations of the lower peripheral area.

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

<b>15</b>	<b>Pivot for table base.</b>	<b>1</b>
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For angiographic- and interventional procedures of the upper peripherals.

Provides improved table access for patient transfer.

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

16 **CABLE CARRIER CS** 1

Additional carrier for suspension of cable hose from X-ray tube assembly or TV monitor.

17 **19" Color LCD monitor in Exam Room** 4

19" Color LCD monitor in Exam Room

19" flat panel color monitor. This LCD monitor is intended for viewing in the examination room and is designed for medical applications.

The main characteristics are:

- 19 inch Color TFT-LCD display
- Native format 1280x1024 SXGA
- Wide viewing angle (approx 170 degr)
- operated Brightness level 200 Cd/m2
- On Screen Display of control functions operated via touch buttons on front
- Internal power supply (90-264 VAC)

Compatible with:

Standard PC format (RGBHV)

DVI interface standard

UL60601-1

Allura Cardio/Vascular systems

Mains connection: 110 - 240 V

Dimensions : 425(W)x375(H)x97(D) mm

Weight: 7 kg.

Colour: mushroom, front ultra dark grey

18 **Two rows of 3 (6M)** 1

19 **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).

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**Airfare to Cleveland for  
Biomed Training**

2

Includes one (1) participant's airfare from North American customer location to the Cleveland Training Center (CTC) in Cleveland, Ohio. All other expenses will be the responsibility of the attendee. Details are provided during the scheduling process. Note: Cancellation/rescheduling policy strictly enforced. Expires one (1) year from the earlier of equipment delivery date or purchase date.

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**Food Transpt Lodging for  
Cleveland Biomed Training**

22

Includes one (1) day of modest lodging, ground transportation, and meal expenses in Cleveland, Ohio for one (1) attendee. All other expenses will be the responsibility of the attendee. Details are provided during the scheduling process. Note: Cancellation/rescheduling policy strictly enforced. Although this part is only for one day, it is sold in multiple quantities to account for entire length of course. Expires one (1) year from the earlier of equipment delivery date or purchase date.

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**XD3970ALLURAFD7.6PART1C  
TC9**

2

Course Number: XD3970

System Codes: 722010, 722011, 722012, 722013

Course Title: Allura Xper Rel 7.6 Part 1

Course Length: 9 days (exclude Saturday, Sunday, and Philips holiday)

Delivery Method(s): Instructor-Led

Modality: iXR

Location: PHC, SLC, CTC

Target Audience: Service Engineers.

**DESCRIPTION:**

Part 1 trains the Customer Support engineer to a technical level which will enable him/her to perform Planned Maintenance (PM) and basic Corrective Maintenance (CM) on Allura Xper systems, according to the Customer Support philosophy. He / She will also be able to assist during a system installation.

Part 1 can be followed up by part 2, intended for dedicated Cardio Vascular modality Engineers.

Part 2 focuses on setting to work (configuration) and extended Corrective Maintenance.

The following Allura Xper systems are covered:

FD10 release 7.6

FD10/10 release 7.6

FD20 release 7.6

FD20/10 release 7.6

FD20/20 release 7.6

**PREREQUISITES:**

CS9020 BASIC NETWORKING

XC3002 X-RAY SYSTEMS BASIC PART 2

**COURSE OBJECTIVES:**

The engineer will learn how to:

- Operate the system, as far as required to perform service tasks.
- Make use of the service documentation.
- Make use of basic functionality of the service tools.
- Perform Planned Maintenance:
  - Safety checks
  - Performance checks
  - Adjustments
 (Not included: Mechanical checks)
- Create a backup of the system.
- Perform a restore of the system.

- Perform basic CMI with help of the service documentation and service tools.
- Faultfinding using the System Manual Corrective Maintenance.
- Focus on replacement of parts with a high exchange rate.
- Retrieve the log file from the system to escalate a problem.
- Customize positions for Automatic Position Control in the EPX-database.

#### MAJOR TOPICS:

Introduction Allura Xper systems

Operating

Service documentation

Service tools

Planned Maintenance

Corrective Maintenance

System Architecture

X-ray generation

Geometry

Operator controls

Power supply

Imaging

System control

Radiation safety

Image quality

Customization

Software

\* PHILIPS PROPRIETARY MATERIALS SUCH AS DIAGNOSTIC SOFTWARE AND SERVICE DOCUMENTATION ARE NOT INCLUDED IN THE TRAINING AND WILL NOT BE AVAILABLE FOR USE OUTSIDE OF THE TRAINING ENVIRONMENT. THE TRAINEE MUST RETURN ALL PROPRIETARY MATERIALS RECEIVED DURING THE TRAINING AT THE END OF THE TRAINING. CUSTOMER ACKNOWLEDGES AND AGREES THAT NEITHER CUSTOMER NOR TRAINEE WILL RECEIVE A LICENSE TO SUCH PROPRIETARY MATERIALS AND THAT THE TRAINEE MAY NOT BE ABLE TO FULLY UTILIZE THE TRAINING WITHOUT THE USE OF SUCH PROPRIETARY MATERIALS. (CERTAIN LICENSES MAY BE OBTAINED THROUGH PURCHASE OF AN ALLIANCE CO; OP AGREEMENT.) Course dates and location to be finalized by Philips. Philips shall attempt to accommodate Customer requested dates and training location. The price quoted includes course tuition. Travel and living expenses are not included, but may be purchased separately through Philips.

#### IMPORTANT Notes Regarding Admission to Philips Customer Engineer Training Courses:

1. Trainee must meet all prerequisites
2. Course expires one (1) year from equipment installation date (or purchase date if sold separately)
3. Customer must sign Philips Nondisclosure statement
4. Trainee must sign Philips Nondisclosure statement
5. Customer must sign Philips terms and conditions of training

23	Blue Anti-Fatigue Floor Mat w/ Logo Blue Anti-Fatigue Floor Mat w/ Logo	1
24	Rad Shield w/ Arm (Contoured) 61X76 Contoured Rad Shield with Arm rest. 61X76	2
25	Cable Spooler	2



- 26                                      **Exam Lamp 220v**                                      2  
Spring arm mounted examination light for cardiovascular applications
- 27                                      **Portegra 2 360 Ceiling Column**                                      2  
Portegra 2 360 Column w/ trolley and ceiling track
- 28                                      **Volcano Control Console**                                      1  
A full-size control console that can be used in the patient room. While one control console is found in the s5i core bundle, some accounts wish to add a second control console to their system. This can be mounted on the bedrails. Connects directly to the CPU via USB or in the patient room via the USB extender. Note: if mounting on bedrails, requires the ordering of "Control Console Rail Bracket Kit"
- 29                                      **Volc Cont Console Rail Brkt Kit**                                      1  
Used in conjunction with the full-size control console to allow the console to be mounted to the patient bedrails.
- 30                                      **Volcano Joystick Option Kit**                                      1  
A compact joystick that comes with a clamp to be mounted on the patient bedrails. Some physicians prefer to control the IVUS system via a joystick, and this option provides this functionality. Can be operated under the sterile drape.
- 31                                      **Volcano Print Kit**                                      1  
A compact color thermal printer that is used to print IVUS images for physician reference, the patient file, or to provide to the patient. Connects directly to the CPU in the control room via USB.
- 32                                      **Volcano Video Switch Opt kit**                                      1  
In cases of established labs that have limited monitors on the boom, an optional 4-port video switch permits for toggling of multiple video inputs to one monitor. If the lab already has a video switch with an open port, this option would not be required.
- 33                                      **Volcano GE ECG Cable Kit**                                      1  
The VH IVUS functionality from Volcano requires an input signal from the labs ECG signal. This custom connector ensures connectivity for the ECG signal from a specific ECG system. NOTE: Every s5i installation will require an ECG connection. Note the labs ECG system when ordering.
- 34                                      **Volcano IVUS s5i**                                      1  
The base components required to operate a Volcano IVUS s5i system, including: the system CPU; a control console for the control room; a bedside touchpad controller; a patient interface module (PIM); an isolation transformer through which power is supplied to the CPU; a USB extension kit which transmits data and power between the CPU and patient bedside-mounted peripherals; a 19" LCD monitor for the control room. The core bundle also includes installation of components, excluding pulling cables, which will be done by Philips.

Cables required to operate the Volcano IVUS s5i system. The kit includes a patient interface module (PIM) cable, a shielded CAT5 Ethernet cable, an ECG cable, and a grounding cable. These cables need to be laid in the dedicated pipe connecting the patient table area to the control room. All cables in this kit are 30 meters in length.

Patient interface module (Pimmett) for FFR wires and all hardware required for the Fractional Flow Reserve

35	System Admin	1
	Removal of existing Philips cath lab	

36	Turnkey Operation	1
	TurnKey price for room prep.	

1

### Isolated Wall Connection Box

4

#### 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 via MultiVision: 1 VWCB (max = 4)

For each video signal to FlexVision XL on Cardio System: 1 VWCB (max = 9)

For each video signal to FlexVision XL on Vascular System: 1 VWCB (max = 8)

For each 3rd party video signal directly connected to an LCD in the MCS: 1x 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

2

### MultiVision 4x 1

1

MultiVision is the integrated video switch for high quality Progressive Display video sources. It can switch either B&W (RGB based) or color signals, with up to 4 inputs to one output.

MultiVision allows to share a Reference Display- or extra color monitor in the ceiling suspension in the exam room between the Xray system and other sources, such as a Xcelera viewstation, an Ultrasound system, a Interventional Tools station (like StentBoost, 3D CA) etc. These sources can be

allocated in the exam room or in the control room of the cath lab.

The switch is controlled by a button on the Xper Module. MultiVision provides a black image when a not operational input is selected.

Each external video source requires a Wall Connection box (not included in the MultiVision package) for the connection to a MultiVision input: only the Xper 2nd Ref Display as possible source does not require such box. The wall connection box also provides 230 V Power Supply for the connected video sources; however, in total maximum 1400 W can be supplied to the sources all together.

#### Comprising:

- video switch unit with cabling for max 4 B&W- or Color sources
- soft key button implemented on the Xper Module

#### Compatible with:

- Allura Xper series Rel 3 (monoplane versions) resp Rel2 (biplane versions) onwards.
- external video sources that comply with following requirements:

- qualified medical electrical equipment [IEC 60601-1], or IEC 950 equipment combined with a multiple socket outlet [IEC 60601-1]
- can be connected to the same earth as the Philips Protective Conductor Bar (PPCB).
- provide video-output that matches the display range of the XB monitor or Colour

Monitor that is used for display

- provide a slave monitor output

Power requirements: refer to system configuration

### 3 Legacy Video Convertor 4

Legacy Video Convertor

The Legacy Video Convertor enables conversion from VGA towards DVI.

The Legacy Video Convertor 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

TV 576I 720x576 4:3

TV 576P 704x576 4:3

TV 720P 1280x720 16:9

### 4 Medrad Xper Cable Rack Mnt 1

### 5 Medrad Provis Rack Mount 1

The MARK V ProVis rack mount version is a contrast medium power injector which is dedicated for system integration.

The injector is accomplished with microprocessor control of the flow rate the volume and the pressure. A dual turret syringe system is applied suitable for 2x150 ml disposable syringes.

- flow rate can be set in ml/sec. ml/min. and ml/hour.
- display of achieved rate volume pressure and time.
- constant update and display of total injected contrast per patient

- injection programs can be stored and retrieved.

**Comprising:**

- electronic unit for rack mounting with power cable (3 m)
- injector head with controls heater system and cable (4.6 m)
- two disposable 150 ml syringes with pressure jackets and dual turret.
- control panel with cable (15 m)
- hand switch with coiled cable
- system interface cable 24 m with D connector
- rack mount installation kit
- table mount for injector power head of the injector MARK V ProVis
- Connector kit for injector head which is a kit for mounting the connector of the injector head extension cable at the connection box of the Angio DIAGNOST 5 table with cover for connection box of the AD5 for insulated mounting of the injector head connector
- mounting material
- injector head extension cable 18 m with mounting instructions for connector assembly

**6**

**Universal Power Supply**

**1**

**25KVA UPS system, fluoro only.**

## **STATEMENT OF WORK (SOW) FOR PROPOSAL**

Request for Construction:

**Audie L. Murphy Memorial Veterans Hospital**

**Renovate Cath Lab 2**

Project No. **671-13-723**

Provide all labor, materials, tools and equipment, and construction services necessary for the renovation in Cath Lab 2 on the 6<sup>th</sup> floor area C at the Audie L. Murphy Memorial Hospital.

### **Renovate Cath Lab 2 for installation of new equipment**

Renovations shall comply with VA specifications and all applicable city, county, state, and federal regulations and codes and OSHA standards.

#### **Scope of Work:**

General Contractor is to provide all labor, materials, tools, and equipment to perform work for electrical power requirements, millwork, and cosmetic appearance as required per construction documents and specifications titled Renovate Cath Lab 2 for installation of new equipment.

A site visit is required prior to bidding.

The contractor shall provide all labor, materials, tools, and equipment needed to prepare site of Cath Lab 2 located on 6<sup>th</sup> floor area C at Audie L. Murphy Memorial Veterans Hospital, San Antonio, Texas. This work includes, but is not limited to, the installation of:

- Provide and install Data and 110 duplex plugs every 4' with red plugs to indicate emergency circuits, plugs shall be 80" AFF.
- Remove and replace upper and lower cabinets; new cabinets shall be stainless steel
- Remove sink; (DO NOT REPLACE)
- Provide and install new counter top.
- Replace all recessed light canisters with LED lights MR 16 or 20.
- Remove window on east wall and install dedicated canister LED light with dedicated dimmer switch.
- Remove all ceramic tiles from the walls and replace ceramic tile in the entire room except ceiling. Tile and pattern shall match Cath Lab 1.
- Remove and replace 2 ea. Isolation panels with square D panels located in Cath Lab and Corridor
- Remove and replace floor with seamless floor
- Remove Stenophone
- The contractor shall install a surfaced mount stainless steel box containing 3ea duplex 110 emergency electric plugs and 1ea. 220 electrical emergency plugs.

- Ceiling, walls without tile, and areas needing repair or patch work due to renovation shall be 1 ea coat primer and 2 ea. coats painted.

Contractor shall conduct a site visit to verify dimensions and locations. The contractor shall maintain the integrity of all electrical installations to support the Cath Lab 2 equipment being installed by Phillips. The contractor and Phillips shall work hand and hand to complete this project as contracted by Bio-Med. All work is to be accomplished at Audie L. Murphy Memorial Veterans Hospital San Antonio, Texas. General Contractor shall provide qualified supervision necessary to completely prepare site for building operations, to include demolition and removal of existing portions of structures. Contractor shall adhere to all specifications, and shall be responsible for all construction period services to include but not limit itself to all phasing of construction, demolition of existing areas to be renovated, as pertain to electrical specification.

### **Electrical:**

- All electrical receptacles shall be installed according to the 2011 NFPA 70 National Electrical Codes, and the NFPA 101 Life Safety Code. From interior electrical panels located in Cath Lab 2 and Corridor as indicated on drawing. The contractor shall provide and install 110 duplex plugs, 220 plug, dimmer switch, and recess LED canisters.
- Wiring shall be installed in conduit in the interstitial space above ceiling, ran in interior walls, and terminated flush with interior walls (110 plugs and data drops on walls shall be 18" AFF). All plugs which are emergency plugs shall be red. Data drops shall be installed in the interior walls parallel to each 110 plug, each data drop shall consist of conduit in interior wall, electrical box, and blank plate noting data drop. Please note: only existing data plugs shall be rewired and terminated, any additional data drops do not require wire or termination.
- East wall window shall require removal with wall reconstruction. In the same location on the ceiling add a LED recess light canister and dimmer switch.

### **Construction:**

- Existing upper and lower cabinets shall be removed to include sink. Replace upper and lower cabinets with stainless steel cabinets and new counter top. The cabinets shall match the draws and shelves of the old cabinets. The sink will not be replaced.
- The existing tile shall be removed, replacement of tile shall be the entire room, the ceiling shall be patched to match existing ceiling and painted with 1 ea. coat primer and 2ea. coats of paint. All other spaces that are affected by construction shall be primed and painted.
- General Contractor shall administer the construction project to include but not limited to Interim Life Safety Measures, Infectious Control Risk Assessments and all work is to be in accordance with the Life Safety Codes having jurisdiction. Contractor shall also comply with VA specifications and all applicable ADA, OSHA, city, county, state, and federal code regulations...

- Also provide a certification of no active Tuberculosis. All personnel involved in the construction or renovation activity shall be educated and trained in infection prevention measures established by the medical center.
- Ensuring certification that the contractor has a medical program that addresses tuberculosis. The medical program shall include written assurance that each employee has no active tuberculosis. All contract employees assigned to the work site shall have a pre-placement tuberculin screening within 90 days prior to assignment to the worksite as recommended by the Center for Disease Control (CDC). This can be the CDC two-step skin testing or a Food and Drug Administration (FDA) approved blood test. Employees manifesting positive screening reactions to the tuberculin shall be examined per current CDC guidelines prior to working on VHA property. If the employee is found without evidence of active (infectious) pulmonary tuberculosis (TB), a statement documenting examination by a physician must be on file with the employer (construction contractor), noting that the employee with a positive tuberculin screening test is without evidence of active (infectious) pulmonary TB. If the employee is found with evidence of active (infectious) pulmonary TB, the employee would require treatment with a subsequent statement as outlined above before being allowed to return to work on VHA property.
- General Contractor shall coordinate all work via the VA-COR at the hospital to construct, complete, and provide turn-key construction per the following set of plans and specifications.
- No on-site parking will be provided.
- No on-site staging of materials will be provided.

Information Systems Officer, Information Protection: The contractor will not have access to VA Desktop computers nor will they have access to online resources belonging to the government while conducting services.

Privacy Officer: The contractor will not have access to Patient Health Information (PHI) nor will they have the capability of accessing patient information during the services provided to the VA.

Project #: 671-13-723

Completion Date: Within 60 days of NTP

Source: TBD

Mary K. Gonzales, PM

Project Engineer, Engineering