

XR CATH LAB AND US , VAMC PORTLAND, OR  
PO# 648-B41005

**1 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

**2 AlluraClarity FD20 R8.2 FlexMove 1**

AlluraClarity FD20 FlexMove 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.

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 FlexMove 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.

The AlluraClarity FD20 with FlexMove option allows placement in a normal operating theater.

- The new ceiling construction enables the use of Laminar Airflow.
- In case no imaging is needed, the system can be parked in the corner, which allows a normal operating area when doing open surgery and enables the user to make full use of the lab.
- The head-end side of the patient is still available for anesthesia and therefore not blocked by the Allura system.

## **GEOMETRY**

### **The AlluraClarity FD20 FlexMove Stand**

The Allura FlexMove stand is a stable assembly of a C-arm and a ceiling suspended L-arm. The ceiling suspended L-arm provides the following advantages:

- The new ceiling construction allows the system to be steered over the patient by using a joy-stick which prevents table panning which is not wanted in a lot of cases.
  - The system can be positioned behind a physician or someone of the staff which gives them all the space they need around the patient and can be moved in a simple manor whenever needed.
  - The new ceiling construction allows the system to be moved around the patient and be brought in from any position.
  - When a minimally invasive procedure has to convert to open surgery, the system can easily be moved out of the way.
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- The Allura Xper system with FlexMove takes only limited amount of space around the table and for that reason has limited impact on the workflow of the physicians and staff in the room.
- The FlexMove option is available for two different ceiling heights being 2900mm and 3100mm.
- 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.
  - FlexMove coverage: Y stroke 4400mm, X-stroke 2600mm
- 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

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- 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
    - o 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
    - o Roadmap Pro can be selected from the Xper imaging module and/or Xper module.
    - o 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
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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 146 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**

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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.

Unless otherwise stated, with FlexMove an integration kit is supplied for a third party Monitor Ceiling Suspension (MCS) containing crucial parts for operating the equipment.

Two medical monochrome LCD monitors are included for the exam room. One monitor is used for viewing of live images. The second monitor serves as the first reference display. Reference images or runs are controlled by infra-red remote-control Xper Viewpad.

- 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
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- 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 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
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- 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
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## 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 protocols. This preparation page makes hard copies of the protocol instructions redundant.

## Acquisition

The acquisition page contains information on the current selected patient.

## Review

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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

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**

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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 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).**

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

### **Clinical Education Program for FlexMove C-Arm**

#### **FlexMove C-Arm OnSite Education:**

Philips Education Specialists will provide twenty-four (24) hours of pre-training applications for up to (8) students selected by customer, including technologists from night/weekend shifts if necessary. This training will be coordinated to provide instruction on the operation of the FlexMove C-Arm prior to the Go Live handover date of the entire Allura Imaging System. **In the event that a Maquet OR table** with 24 hours of pre training has also been purchased this FlexMove 24 hour training will be used as a post handover follow up session. No CEU credits will be available for this session. Please refer to guidelines for more information. Note: The equipment must be entirely operational. Philips personnel are not responsible for actual patient contact or operation of the equipment during the education sessions except to demonstrate proper equipment operation.

Education expires one (1) year from equipment installation date (or purchase date if sold separately) . Ref #699-20110915

Performing a structural heart procedure can be a breath-taking and tense intervention. HeartNavigator Release 1 provides support in planning of the procedure and additional live image guidance during the procedure. Previously acquired DICOM cardiac CT-datasets can be used as input. The CT-dataset can be presented in 3D and overlaid with the live-fluoroscopy to provide 3D real time insight during the procedure.

Planning:

DICOM Cardiac CT dataset can be used for the determination of the optimal intervention strategy. Optimal view planes for the X-ray device can be programmed with CT data. Furthermore, HeartNavigator Rel.1 is able to automatically segment anatomical structures, landmarks and planes out of DICOM cardiac CT-datasets. Different tools are available to help the user with the planning:

- Different anatomical visualization tools can be selected to visualize the desired anatomical structures
- Different anatomical landmark points are available to help the user to better understand the orientation and positioning of devices
- Different sizes of virtual devices which can be selected and projected on the CT data to give a reference on how the device would fit the patient

Image Acquisition en Procedure Execution:

During live image guidance HeartNavigator can be fully operated from table side using the XperModule. The user can overlay the acquired images on the 3D reconstruction of HeartNavigator.

The bidirectional link between the X-ray system and HeartNavigator 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 projection shown on the HeartNavigator monitor. 3D Follow C-arc allows the overlay to remain in sync with the 2D projection, automatically adjusting the viewpoint as the gantry is repositioned. Different visualization options are available like 3D volume and vessel outline to select as overlay.

### Clinical Education for Heart Navigator:

**iXR Heart Navigator OnSite Education:** Philips Education specialist will provide sixteen (16) hours of education for up to (4) students selected by the customer . The Physicians performing the procedures are required to be part of the training session. CEU credits may be available for each participant that meet 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 the equipment during the educations sessions except to demonstrate proper equipment operation.

**iXR Heart Navigator OnSite Live Case Follow Up Education:** Philips Education Specialist will provide twenty -four (24) hours of education for Physicians and staff for live case use of the Heart Navigator software. This will be a follow up visit to the initial training of the Heart Navigator software. It is required that Live Valve implantation studies be performed during this education session. No CEU credits will be available for this session. 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 the equipment during the education sessions except to demonstrate proper equipment operation.

Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref # 694698-20110915

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### **EchoNavigator R1**

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Structural heart procedures often rely on X-ray imaging to visualize the devices, while simultaneously relying on TEE Echo imaging of soft tissue and anatomical structures. EchoNavigator is a real time imaging product that supports the procedure by combining both X-ray and xPlane and 3D Echo in an interactive, intuitive and procedurally relevant way. The EchoNavigator is based on a real time platform that combines the 3D TEE Echo and X-ray. It provides two visual outputs, one for the control room and one for the examination room. A mouse and mouse tablet (with attachment to table) is included to operate the EchoNavigator functionality from the table side. A dedicated color 24" wide screen LCD display for the control room is included. A FlexVision XL display solution is required for the examination room. EchoNavigator includes an Interventional Echo Link. The Interventional Echo Link provides a high speed 2D and Live 3D digital connection based on high bandwidth Ethernet network adapter with PCI express bus interface.

Features EchoNavigator:

To facilitate the interpretation of Echo images, EchoNavigator allows for multiple user-defined live views (renderings) of Echo data, showing relevant anatomical structures from different angles simultaneously in real time.

The image orientation of a selected Echo view can be automatically synchronized with the X-ray image, which defines in absolute terms the spatial relation between X-ray and Echo images. This spatial relation remains intact with 3D Follow C-arc. Follow C-arc synchronizes the Echo image orientation with the X-ray projection, automatically adjusting the viewpoint as the gantry is repositioned. 3D follow C-arc for EchoNavigator is included.

To further help the understanding of the two different images, EchoNavigator projects the ultrasound field of view (Ultrasound cone) as an outline into the X-ray view.

Multiple markings can be placed soft tissue anatomical structures in the Echo image and these marking points automatically appear in the X-ray to provide context and help guidance.

To support the workflow and the communication between the X-ray and Echo-operator, the user can interrogate the relevant anatomical structures in the Echo data from table side.

Requires:

- EchoNavigator compatible Echo system, probes, and licenses/software
- EchoNavigator compatible Allura system, hardware, and licenses/software
- FlexVision XL display solution

### **IXR EchoNavigator Imaging Systems OnSite Education:**

Philips Imaging Systems Clinical Education Specialist will provide eight (8) hours of education for up to four (4) students, selected by customer, including technologists from weekend/night shifts as necessary. CEU credits are not available for this portion of training. 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 #819-20121213

## **2 DAY USCE ENT L3D TEE w/trav**

2 Day Purchased TEE University with Travel - A variety of Live 3D TEE University course offerings are available to meet your educational needs. Live 3D TEE provides cardiologists, anesthesiologists, and cardiac surgeons novel and exiting realistic views to aid in patient care. The 2 Day PUR TEE University Tuition includes both the tuition and the corresponding travel package.

Due to travel and scheduling requirements, a twenty-one (21) day notification of cancellation is required or training / education entitlements will be forfeited. Curriculum is subject to change without notice.

Travel & Accommodations for one (1) registered attendee. Includes one (1) participant's airfare from a North American customer location to a Philips North America Ultrasound Clinical Education training location with modest lodging, ground transportation and meal expenses for up to 3 days. Breakfast/dinner are provided by the hotel and lunch/breaks are catered by Philips Healthcare. All other expenses will be the responsibility of the attendee (ie. Baggage fees, meals while traveling, transportation to and from customer's home airport). Details are provided during the scheduling process.

## **1 DAY USCE ENT CES ONSITE**

1 Day On-Site CES – Ultrasound training designed specifically to meet the customers' needs; one business day (up to 8 consecutive hours) with one of our Philips Clinical Education Specialists. Education is provided Monday-Friday during normal business hours.

\*Note: Philips Healthcare personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. The training sessions should be attended by Ultrasound Sonographers as identified by the department director. Site must be patient-ready.

## **2 DAY USCE ENT 400lvl w/trav**

2 Day 400 Level Tuition Only - Use only for a two-day level 400 Ultrasound Clinical Education course. Travel and lodging included. NOTE: A twenty-one (21) day notification of cancellation is required or education will be forfeited. Curriculum is subject to change without notice.

<b>5</b>	<b>System is AlluraClarity</b>	<b>1</b>
<b>6</b>	<b>3D-RA R.6</b>	<b>1</b>

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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 at Xper Module (option); With the Xper module the physician has all required 3D functionality at tableside. At the touch screen module functionality like rotating, panning, zooming, AVA, virtual stenting, 3D-APC and 3D Follow C-arc can be performed. With the mouse tablet all other functions can be performed so that there is no need for the Physician to leave the examination room.

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  
CalciView: 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 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.

Clinical Education Specialists will provide sixteen (16) hours of tailored CV 3DRA OnSite Education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. CEUs are not available in all cases. Please read Guidelines for more information, which will be provided to you during the scheduling process. Education Hours: Mon – Fri 8:00am to 5:00pm, except Monday and Friday are half-days to allow for trainer's travel. Note: 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 delivery date (or purchase date if not sold with equipment).

## FlexVision XL with XperHD

FlexVision XL for Allura Xper FD & AlluraClarity systems with large 56-inch high resolution color LCD in the Exam Room. 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 2 to 8 screens simultaneously from up to 16 sources (incl. third party systems) on the Philips 56-inch color LCD in the Exam Room.
- Resize and/or enlarge information at any stage during the case.
- Select and customize viewing lay-outs of the Philips 56-inch color LCD via the Xper table-side module

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
- Overview connected equipment (incl. third party systems) from a single location.

The FlexVision XL consists of:

- OmniSwitch
  - OmniSwitch allows the user to direct and switch the video output of all connected medical equipment to specific sub windows of the Philips 56-inch color LCD in the Exam Room.
  - OmniSwitch is a 16 channel video-switch operated from the Xper tableside module. 16 channels are available for a mix of up to 7 internal and up to 9 external inputs.
  - OmniSwitch supports a wide variety of display formats (up to 1600x1200).
  - External inputs are connected to OmniSwitch via Wall Connection box(es).
- Medical grade, high resolution color LCD in the Exam Room
  - 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 system for the Exam Room.
  - Main characteristics are:
    - 56 inch, 8 Megapixel color LCD
    - Native resolution: 3840x2160
    - Brightness: Max: 450 Cd/m<sup>2</sup> (typical) stabilized: 350 Cd/m<sup>2</sup>
    - Contrast ratio: 1200:1 (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)

- Resize and/or enlarge information at any stage during the case via the Xper tableside module in the Exam or Control Room
- Select viewing lay-outs via the Xper table-side module in the Exam Room
- Create new layouts by matching inputs to desired locations on preset templates.
- Isolated Wall Connection Boxes
  - Up to 8 Isolated Wall Connection Boxes can be connected to FlexVision XL.
  - Through Isolated Wall Connection Boxes, 3rd party equipment can be connected to the FlexVision Omniswitch.
- Snapshot
  - o The snapshot function allows the user to store/save a screen-capture of any image on the 56" 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 Room as separate DICOM Secondary Capture images. The FlexVision XL can be mounted on a 3 party MCS. This gives the possibility to be more flexible in the positioning of the FlexVision XL in the exam room. This is often requested in Hybrid OR's

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## StentBoost sw Rel. 2.0

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StentBoost is a unique interventional tool to improve visualization of stents in the coronary arteries during interventions. This, Philips exclusive, innovative interventional tool produces a highly augmented image of a deployed stent in coronary arteries - while the catheter is still in place. The StentBoost image helps clinicians to make a thorough check of stent expansion, and see the position of stents in relation to other objects, like other stents, without the use of extra contrast or other 'expensive' consumables. This allows interventional cardiologists to immediately take any corrective action required while your patient is still in the examination room.

The way it works

StentBoost automatically detects the stent delivery markers image after image. In each image StentBoost aligns the markers with the markers of the previous image. By doing this all radiopaque material in the close proximity of the markers will be enhanced and items further away from the markers will be greyed out.

The result provides enhanced contrast of the environment surrounding the markers, including the stent, while background noise is faded out.

StentBoost Workflow

### 1. Image acquisition

StentBoost is based on a maximum of 40 frames out of a cine run. Depending on the frames speed this takes the user 2-3 seconds.

### 2. Image transfer

The run will automatically be transferred to the interventional workstation and show up in the StentBoost software.

The Real time link (NCVA590) is a unique option within the Allura Xper FD10 R.2 and Allura Xper FD10/10 and allows instant access to the StentBoost image.

### 3. Region of Interest definition

The StentBoost software shows the acquired run with a predefined Region of interest. With the region of interest user has to indicate where the markers of the stent delivery markers are located in the image run.

### 4. StentBoost

After definition of the region of interest, the user presses next and within seconds, the boosted image shows up on the screen.

A real time operation user interface is available with StentBoost, providing:

- Review of StentBoost runs, before and after processing
- Viewing tools like Brightness/Contrast, Pan and Zoom to optimize the image displayed
- Automatic stent delivery system marker identification
- Reliability feedback regarding the enhanced run
- Manual quality improvement; Manual correction possibility for marker identification
- View patient info like, Birth date, Gender, Patient ID, Exam ID, Exam date, Run date, Run time, Hospital name, Physician name, RAO/LAO
- Creation of exportable items:
  - movies (AVI format)
  - snapshots (jpeg format)
  - The step 5, 6 and 7 are not mandatory.

#### 5. Calibration

To create a StentBoost image no calibration is needed. For the measurement support tool four calibration methods are included:

- No calibration
- Auto calibration based on calibration data generated by the Allura Xper system when the autocall function is installed (MCV5681),
- Marker distance of the stent delivery markers,
- Catheter calibration

#### 6. "Measurement"

"Measurement" an option within the StentBoost package supports the clinician in his/her decision-making in determining the percentage of remaining stenosis in the stent.

#### 7. Archiving

Transfer to:

- Optional Hard Copy unit (DICOM Print)
- Optional third party station (snapshots images in DICOM Secondary Capture format)
- Any computer via a web server functionality with images in a standard file format (JPEG, AVI movies)
- 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.

#### 8. StentBoost release 2.0 comprises:

- StentBoost release 2.0 Software Package
- User manual on compact disc
- Software release bulletin
- DICOM Conformance Statement
- StentBoost IQ verification Phantom

#### 9. Compatible with:

- Allura Xper FD10 R 1.x
  - Allura Xper FD20
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- 
- Allura Xper FD10 R. 2
  - Allura Xper FD10/10

10. Pre-requisite for StentBoost R 2.0:

- Interventional Hardware (NCVA106)

**9**

### **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 ortosearch fora 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



- 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.

<b>12</b>	<b>**</b>	<b>Xper Swing</b>	<b>1</b>
		<p>XperSwing allows dual-axis rotational coronary angiography to gather more information in less time and with less X-ray and contrast dose. XperSwing acquires simultaneous RAO/LAO cranial-caudal views in just one acquisition run by moving the C-arm in a curved trajectory instead of multiple acquisitions. XperSwing 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, providing image detail required for diagnostic and therapeutic decisions and to obtain a real-time 3D impression of the coronary artery tree.</p> <p>In total seven pre-programmed trajectories are available:</p> <ul style="list-style-type: none"> <li>• Three for Left coronary imaging</li> <li>• Two for Right Coronary imaging,</li> <li>• Two generic trajectories.</li> </ul> <p>The choice depends on size and weight of the patient. These trajectories are designed to fully cover all conventional projections for a diagnostic coronary angiography. Rotation and angulation movements are combined in one complete scan trajectory, using the maximum rotation and angulation speed of the Allura Xper system. (55 resp 30 degr/sec). XperSwing is possible in the side position (ceiling mounted systems) and in the head position</p> <p>XperSwing functionality includes, but is not limited to</p> <ul style="list-style-type: none"> <li>• 15 frames per seconds acquisition to allows using of less contrast.</li> <li>• Wide rotation range provides a complete evaluation of the anatomy.</li> <li>• Precise positioning and high reproducibility, assuring you of high quality images and excellent subtraction studies.</li> <li>• Set up and executed in a matter of seconds.</li> <li>• Set of dedicated acquisition programs with the trajectories available on the Xper Module</li> <li>• The rotation end- and start-positions can be selected.</li> <li>• Acquisition procedure is controlled from the exposure hand or footswitch.</li> </ul>	

<b>13</b>	<b>**</b>	<b>Subtracted Bolus Chase</b>	<b>1</b>
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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.

Functions:

- Various LV-volumes
- Ejection Fraction
- Cardiac Output
- Centerline Wall Motion
- Slager Wall Motion
- Regional Wall Motion
- 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

**17      \*\*                      Coronary Quant.Sw pkg(Xper)                      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

**18      \*\*                      Vascular Quant.Sw pkg(Xper)                      1**





The interventional tools hardware is the computer that enables the 3D interventional tools, it allows to import and view DICOM compatible data from other imaging modalities. The interventional Hardware comprises at least a Harddisk containing operating system and application software.

- 25**    \*\*                      **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.
- 26**    \*\*                      **3D RA Control for Xper Module**                      **1**
- Table Side Module functionality for Allura Xper FD20 used with Integris 3D-RA Release 4.2.
- For further improvement of interventional procedures efficiency the following workflow enhancers are made available in the examination room: With the Xper touchscreen module the physician has all 3D functionality needed at tableside. Functionality like rotating panning zooming AVA Virtual stenting 3 and 3D Follow C-arc can be performed. No need for the Physician to leave the examination room. 3D Automatic Position Control (3D-APC); when the optimal working position has been chosen via the Integris 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.
- 27**    \*\*                      **3D Roadmap**                      **1**
- 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 fluoroscopy images with the 3D-RA reconstruction 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. 3D roadmap has automatic motion compensation for the neuro runs. When the automatic motion compensation function is active, this functionality will constantly correct the motion artifacts which can be present in the 3D Roadmap image.
- Image Acquisition
- The 3D Roadmap is based on the visualization of the vessel tree out of 3D-RA. The 3D Roadmap is activated with one button touch at tableside (Xper Module). Select the 3D Roadmap function on the touch screen module, activate fluoroscopy and the 3D Roadmap is activated. The "live" 2D fluoroscopy image is overlaid with the 3D volume of the vessel tree and is automatically displayed on the 3D roadmap monitor in both the examination and control room.
- Intuitive, fully controlled from tableside:
- The bidirectional link between the X-ray system and the 3D 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 3D Roadmap monitor. 3D Follow C-arc allows the 3D Roadmap to remain in sync with the 2D projection, automatically adjusting viewpoint as the gantry is repositioned
- Landmarking to adjust the intensity of the anatomical reference surrounding the vessels;
  - 3D blending to fade in/out the 3D view;
  - WW/WL settings to control the contrast/brightness;
  - Store and review runs for reporting and archive purposes;
  - Store snapshots and movies.
-

3D Roadmaps can be 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/archieved 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

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### MR/CT Roadmap

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MR/CT Roadmap extends the capabilities of the integrated 3D product by providing a sustainable 3D roadmap based on previous acquired CT or MR scans to support interventional procedures. The MR/CT Roadmap option matches the real-time 2D fluoroscopy images with the 3D volume of CT or MR.

The CT or MR data can visualize in either 3D (e.g vascular structure) or with 2D slice in the same orientation as the 2D fluoro image. It provides a 3D real time insight of the advancement of the guide wire, catheter and coils through complex vessel and anatomical structures

#### Image Acquisition

A previously acquired CT or MR scan can be imported into the system and matched with a low dose 3D-RA or XperCT scan The MR/CT Roadmap is activated with one button touch at tableside (Xper Module). Select the MR/CT Roadmap function on the touch screen module, activate fluoroscopy and the MR/CT Roadmap is activated. The "live" 2D fluoroscopy image is overlaid with the MR/CT volume presented in 2D or 3D and is automatically displayed on the roadmap monitor in both the examination and control room.

Intuitive, fully controlled from tableside:

The bidirectional link between the X-ray system and the MR/CT 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 MR/CT Roadmap monitor. 3D Follow C-arc allows the MR/CT Roadmap to remain in sync with the 2D projection, automatically adjusting viewpoint as the gantry is repositioned.

- Easy 2 step registration of the MR/ CT volumes
- Landmarking to adjust the intensity of the anatomical reference surrounding the vessels and tissue
- 2D and 3D blending to fade in/out the 2D or 3D view;
- WW/WL settings to control the contrast/brightness;
- Store and review runs for reporting and archive purposes;
- Store snapshots and movies.

MR/CT Roadmaps can be 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/archieved 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.

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### Xper CT R3 plus

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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. 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 Plus 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/archieved 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

**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

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**XperGuide Rel 2 SW**

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XperGuide enables real-time needle guidance in the angio suite. Virtual needle paths are created on an XperCT dataset or on the previous acquired CT or MR dataset. XperGuide option matches the real-time 2D fluoroscopy images with the 3D volume of XperCT, CT or MR; to visualize the actual needle path versus the virtual path previously planned.

This volumetric dataset can be viewed in any slice direction. A wide range of gantry projections can be used to define the needle path.

Path planning can be done:

- By drawing a virtual needle path on an XperCT, MR or CT slice
- By defining entry and target points on different XperCT,MR or CT slices
- By defining a help line on a 3D volume XperGuide automatically calculates the optimal gantry projections for the path and transfers them to the planning to draw the needle path.

The calculated virtual needle paths can be viewed on the XperCT, MR or CT slices, to verify if this path is feasible. XperGuide supports planning of multiple needle trajectories. During the needle procedure, XperGuide is fully controlled at tableside. When XperGuide is active, guidance is automatically active when the fluoro pedal is pressed. The live 2D image is projected over the XperCT, MR or CT volume The gantry can be positioned in the calculated gantry positions or controlled manually. The XperGuide images (live 2D fluoro projected over the XperCT, MR or CT volume) will follow the gantry projections.

At table side, XperGuide adapts in real-time to the following parameters:

- Changes in the angulation of the C-arm
- Changes in the rotation of the C-arm
- Changes in the field of view
- Changes in the source image distance

XperGuide run are in the same patient file as all other patient related data. All this data can be reviewed at any time.

XperGuide runs are stored together with the XperGuide movies and snapshots can be 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/archieved 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 XperGuide**

**CV XperGuide 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 # 336-100316

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### **Personal Dose Meter (1 piece)**

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Personal Dose Meter.

The Personal Dose Meter (PDM) is a small and easy to wear active Xray dose meter intended to measure

and store received Xray dose of staff, present in an Xray room during radiation. The PDM has build-in

wireless communication to connect to the DoseAware Base Station for real time dose-rate indication and

has a long battery life for maintenance-free usage. In addition it can be personalized to increase interest

and awareness. The PDM not only records warning level profiles every second for a total of 3600 sec

(cyclic overwritten), but also stores accumulated dose data every hour for maximum 5 years.

A clip and a lanyard holder are included to facilitate easy wearing.

The PDM can be configured via the cradle and DoseView (and the optional Dose Manager) software for

the following attributes:

- Full name (max 40 bytes)

- Display user name (max 16 bytes)
- User group from list
- PDM ID (max 16 characters)
- Position on body
- Date & time = Real Time Clock, synchronized with local time, and being the clock master for the DoseAware system. With each
- connection PDM => Base Station => Dose Manager the timing is synchronized automatically.
- Date of PDM assignment to a person
- Dose history reset
- Sleep mode On/Off
- Annual dose limit

The PDM has following specifications:

- Operational unit: HP10
- Dose range: 1 $\mu$ Sv – 10 Sv
- Dose resolution: 1  $\mu$ Sv
- Dose uncertainty: 5% or 1  $\mu$ Sv
- Dose rate range: 10  $\mu$ Sv/hr - 50 mSv/hr
- (3 nSv/s - 15  $\mu$ Sv/s)
- Response time: < 4 s, 40  $\mu$ Sv/hr – 100  $\mu$ Sv/hr; < 1 s above 100  $\mu$ Sv/hr
- Energy dependency X-, Gamma-rays: N40-N160 (33keV – 118 keV)
- Average battery life: 3 – 5 years, depending on daily use
- Weight: 30 gr
- Dimensions: 45 x 45 x 10 mm (w x h x d)
- Personalization: 8 inlays with colour
- Communication radio: Center frequency 868.3 Mhz for Europe version  
915 Mhz for USA version

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### Mark 7 Arterion, Table Mount

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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

DoseAware is a unique solution providing staff working in an X-Ray environment with direct, real time dose feedback, enabling them to optimize their behaviour and reduce exposure to scattered dose. The DoseAware bundle comprises:

- 1 BaseStation Package
- 10 PDMs
- DoseManager
- 2 PDM racks.

### **Base Station Package**

The Base Station is the heart of the DoseAware system. It offers Online View, which displays real time dose rate and immediate dose data for any Personal Dose Meter (PDM) in range. The Walk-Up View enables easy access to personal dose history and PDM settings.

The Base Station has a touch screen interface and wireless communication with the PDM. The PDM dose information is stored within the Base Station and can be retrieved by the DoseAware Dose Manager software via a standard network interface to complete the DoseAware system with archiving and reporting functions.

The Base Station package includes also:

- a cradle and the DoseView software package that can be installed on a local PC (not included), which has Windows XP or Vista as operating system.
- Mounting material for the Base Station, facilitating mounting on a wall or on a Philips Monitor Ceiling Suspension or a Philips mobile C-arm system.

### **10 Personal Dose Meters**

The Personal Dose Meter (PDM) is a small and easy to wear active X-ray dose meter intended to measure and store received X-ray dose of staff, present in an X-ray room during radiation. The PDM has build-in radio-frequency wireless communication (868.3 Mhz for Europe version, 915 Mhz for USA version) to connect to the DoseAware Base Station for real time dose-rate indication and has a long battery life for maintenance-free usage. In addition it can be personalized to increase interest and awareness. The PDM not only records warning level profiles every second for a total of 3600 sec (cyclic overwritten), but also stores accumulated dose data every hour for maximum 5 years. A clip and a lanyard holder are included to facilitate easy wearing.

The PDM can be configured via the cradle, DoseView, and Dose Manager Software.

### **Dose Manager Package**

The Dose Manager is a software program that serves as archive and reporting facility for all dose data of the DoseAware system. It allows tracking of multiple PDM's at a location.

Core functionality is:

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- Store and manage dose history for multiple PDM's
- Collect all dose history from connected Base Stations via the network
- Browse dose history of PDM's as graph or table
- Export dose data for personal analysis with other software tools, like Windows Excel
- Create and print reports of dose history

**Interface:**

- 15.0 inch high resolution display with wide viewing angle
- Quick Keys and Active Mode
- Laptop style Alphanumeric QWERTY keyboard
- 8 TGCs and 2 LGCs
- Ergonomic carrying handle
- Includes AC adapter , power cord and system battery pack
- 2 USB flash drives on system
- 80 GB hard drive
- Internal DVD RW drive

**Architecture:**

All-digital compact broadband beamformer, Microfine 2D focusing with Dynamic Focal Tuning that includes Advanced X-Res signal processing, 170 dB full time input dynamic range 18,432 digitally-processed channels, Continuously variable steering in 2D, color and Doppler modes 2D Opt signal processing with 4X multi-line parallel processing and frequency compounding.

**Intelligent Controls:**

The CX50 has been designed to make portable exams easy and efficient. With a single button, iSCAN technology automatically samples data for a new level of 2D and Doppler optimization iSCAN one-touch Intelligent Optimization, iSCAN one-touch Intelligent Color Optimization, iSCAN Doppler one-touch optimization.

**Transducers:**

Supports Compact family of transducers featuring PureWave imaging technology in the S5-1, CX7-2t, C5-1, D5CWC. Also supports the high resolution S12-4, S8-3, C8-5 and L12-3 transducers. All transducers provide breakthrough frequency bandwidths and array configurations. These transducers also have ergonomically designed lightweight flexible cables and compact connectors.

**Modes:**

- 2D
  - M-mode
  - Anatomical M-mode
  - Color M-mode
  - Pulsed Wave Doppler
  - Color Power Angio (CPA)
  - Continuous Wave Doppler
  - Invert and Color Invert
  - Color compare mode
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## 100662 CX50 CompactXtreme

Line #	Part #	Description	Qty
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- Dual mode
- Duplex for simultaneous 2D and Doppler
- 2D Optimization Signal Processing
- Live Compare
- Tissue Harmonic Imaging (THI)
- Reconstructed zoom with pan (read zoom)
- Write zoom
- Pulse Inversion Harmonic imaging
- Adaptive Doppler
- Adaptive Color Doppler
- Color Tissue Doppler imaging
- Pulsed Wave Tissue Doppler imaging
- Active Native Data - manipulation of image data
- DICOM Networking
  - Ethernet @100Mb/second Includes DICOM wired and wireless "G" and "N".
  - Provides DICOM 3.0 network print and store and storage commitment
  - Performed Procedure Step (pps)
  - Modality Worklist
- DICOM Structured Reporting

### Cineloop review

- On-board workstation-class data management with thumbnail previews and storage of images, loops, and reports. Retrospective and prospective clip capture to internal drive or removable media  
Integrated DVD/CD burning capability for storage of images or export in DICOM, JPEG and .avi for PC compatibility. Philips DICOM viewer option to imbed in media transfer for easy viewing of study on most PCs.
- Maintenance and Serviceability
- Remote Access for Expedient Clinical and Technical Support
- Flexible Service Agreements
- Clinical Application and Educational Support

### Cinical Education

**1 Day PAS Onsite** - Ultrasound system or upgrade onsite training provided by a PAS (Product Applications Specialist) for specific system applications or upgrades; not per modality. *Education is provided Monday - Friday during normal business hours.* Note: Philips Healthcare personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. The training sessions should be attended by the appropriate healthcare professional as identified by the department director. *Repeat training for staff non-attendance will not be accepted.* Site must be patient-ready to meet training expectations. All onsite training day expires within 90 days from system or upgrade installation date. Exceptions are for 3D Stress onsite training (which expires 9 months from system or upgrade installation date) and Fusion & Needle Navigation onsite training (which expires 180 days from system or upgrade installation date).

## 100662 CX50 CompactXtreme

Line #	Part #	Description	Qty
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\*\*\*THE NUMBER OF ONSITE TUITIONS YOU RECIEVE MAY VARY BASED ON PURCHASED OPTIONS. PLEASE CONSULT YOUR SALES REPRESENTIVE FOR FURTHER DETAILS\*\*\*

*All Tuitions must be registered prior to the expiration date. The course chosen must be taken within 90 days of expiration.*

<b>2</b>	**	<b>Vascular Clinical Option</b>	<b>1</b>
<p>This clinical option includes Tissue Specific Imaging software and SonoCT for Cerebrovascular, Peripheral vascular, abdominal vascular and Transcrainial applications. This clinical option also includes in depth analysis and reporting packages for vascular applications. Freehand 3D is also provide within this clinical option. Allows operation for vascular applications of the C5-1, S5-1, L12-3, L15,7io, L12-5 50 and D5cwc transducers.</p>			
<b>3</b>	**	<b>S5-1 Transducer</b>	<b>1</b>
<p>Features compact connector designed for reliability and improved ergonomics. Compatible with both EPIQ and CX50 systems. Manufactured in accordance with the European Union's Restriction of Hazardous Substances (RoHS) directive.</p> <p>PureWave crystal Sector array transducer with 5 to 1 MHz extended operating frequency range for adult cardiology, abdominal, vascular, TCD and Acute Care.</p>			
<b>4</b>	**	<b>C5-1 Transducer</b>	<b>1</b>
<p>Features compact connector designed for reliability and improved ergonomics. Compatible with both EPIQ and CX50 systems. Manufactured in accordance with the European Union's Restriction of Hazardous Substances (RoHS) directive.</p> <p>C5-1 broadband, Curved Array PureWave crystal transducer with 5 to 1 MHz extended operating frequency range for abdominal, obstetrical, gynecological, interventional, vascular, contrast acute care and regional anesthesia applications.</p>			
<b>5</b>	**	<b>English Manual</b>	<b>1</b>
<p>Operation Manual</p>			
<b>6</b>	**	<b>1st SVC Manual for Gov</b>	<b>1</b>