Allura Xper FD20 Series

INSTRUCTIONS FOR USE

Version 0.1 of Document version 3.0

English

Philips Medical Systems 9896 002 05471

PHILIPS

Published by Philips Medical Systems
Nederland B.V.

Philips Medical Systems Nederland B.V. reserves the right to make changes to both this Instructions for Use and to the product it describes. Product specifications are subject to change without notice. Nothing contained within this Instructions for Use is intended as an offer, warranty, promise or contractual condition, and must not be taken as such.

Document number:
9896 002 05471 2007

Unauthorized copying of this publication may not only infringe copyright but also reduce the ability of Philips Medical Systems to provide accurate and up-to-date information to users.

Published in the Netherlands.

CE 0344

Philips Medical Systems 9896 002 05471

Contents

Philips Medical Systems 9896 002 05471

9896 002 05471
Philips Medical Systems

1 Introduction

Philips Medical Systems 9896 002 05471

Philips Medical Systems 9896 002 05471

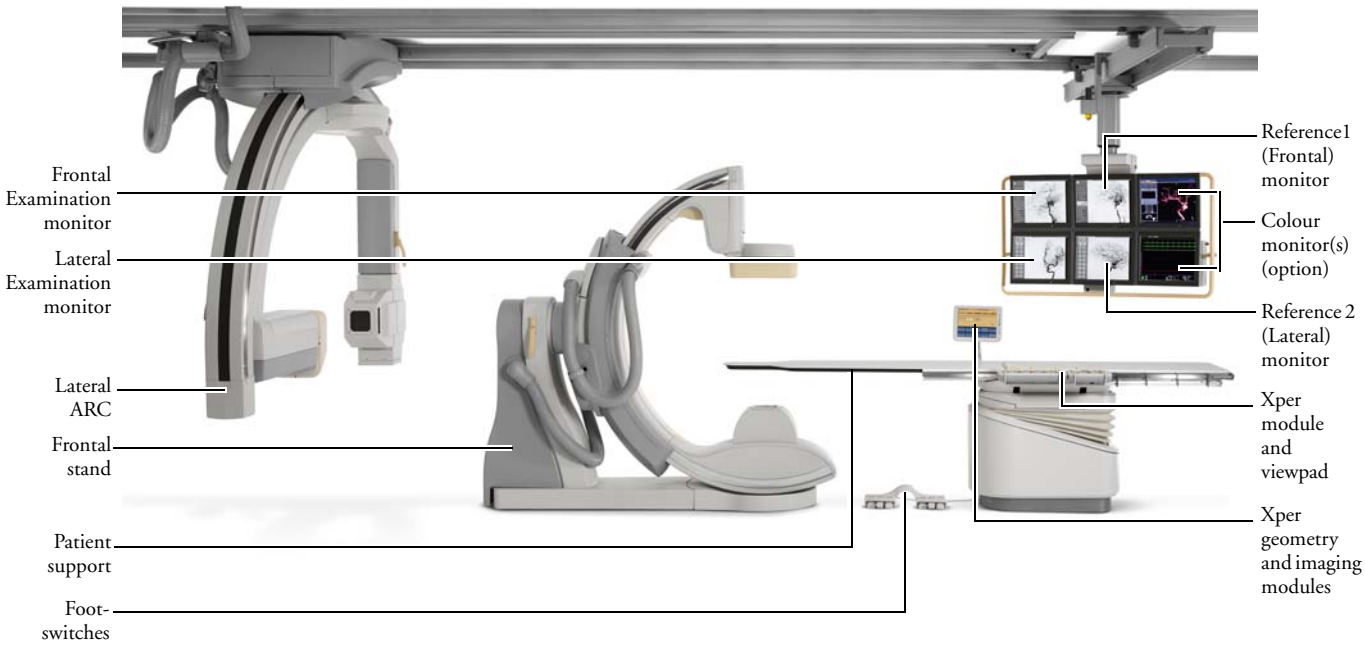
1 Introduction

1.1 About the Allura Xper FD20 series

The Allura Xper FD20 series, used for diagnostic and interventional vascular procedures, consists of;

- Allura Xper FD20, monoplane with ceiling suspended frontal stand.
- Allura Xper FD20, monoplane with a floor mounted frontal stand.
- Allura Xper FD20/10, biplane with ceiling suspended Lateral ARC and a floor mounted frontal stand.
- Allura Xper FD20/20, biplane with ceiling suspended Lateral ARC-N and a floor mounted frontal stand.

Philips Medical Systems 9896 002 05471



New picture here with FD20 on the Lateral ARC-N.

Figure 1.1 General system components in the examination room

NOTE ***Monitor positioning in the monitor ceiling suspension can be freely configured, i.e. not necessarily the order shown above.***

For monoplane systems, there will not be a Lateral ARC or lateral channel monitors and the frontal stand may be floor mounted or ceiling suspended. Also there will be a three-pedal Footswitch

1.2 About these Instructions for Use

These Instructions for Use give a general system description for the Allura Xper FD20 systems.

Philips Medical Systems 9896 002 05471

Instructions for Use identification

In order to identify the Instructions for Use and the system for which they are intended to be used, a label has been placed on the Frontal stand. The label indicates the following:

- Type: a unique code which identifies the kind of system, as follows:
  - 722 003: Allura Xper FD10
  - 722 005: Allura Xper FD10/10
  - 722 006: Allura Xper FD20
  - 722 008: Allura Xper FD20/10 and Allura Xper FD20/20.
- ON: Order Number.
- SN: Serial Number.

The following illustration is an example of such a label, note that each system delivered will have its own unique numbers:

Figure 1.2 Label (example)

All Instructions for Use supplied with your system will be identified using the same labelling information (Type, ON and SN). For CD(s) the label is attached to the front of the CD(s) case, and for printed matter the label is attached to either the Front cover or rear of the title page.

Before using these Instructions for Use with your system, ensure that the label, situated on the Frontal stand, and all the related materials, supplied with the system, are identified with the same labelling information.

This English language version of the Instructions for Use was originally drafted, approved and supplied by Philips Medical Systems under the product part code (Document number) indicated on the rear of the Title Page.

The following table details the Instructions for Use that have been supplied with the Allura Xper FD20 series system:

Instructions for Use (IFU)
Product IFU (this document)
User Interface
Basic Operation

Philips Medical Systems 9896 002 05471

Instructions for Use (IFU)
Extended Operation
Quantitative Analysis
Accessories

The combination of Instructions for Use, detailed in the table above, describes the most extensive configuration of the Allura Xper FD20 series, with the maximum number of options and accessories. Not every function described may be available on your product.

These Instructions for Use are intended to assist users in the safe and effective operation of the product described. The 'user' is considered to be the body with authority over the equipment; 'operators' are those persons who actually handle the equipment.

Before attempting to operate the Allura Xper FD20 series, you must read these Instructions for Use, noting and strictly observing all **WARNINGS and CAUTION** notices.

This symbol, used throughout the Instructions for Use, indicates a WARNING.

WARNINGS ***A WARNING alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the operator or patient.***

CAUTIONS ***A CAUTION alerts you to where special care is necessary for the safe and effective use of the Allura Xper FD20 series. Failure to observe a caution may result in minor or moderate personal injury or damage to the Allura Xper FD20 series or other property, and possibly in a remote risk of more serious injury, and/or cause environmental pollution.***

NOTES ***NOTES highlight unusual points as an aid to the operator.***

This 'Introduction' section gives information about compliance and regulatory requirements.

Section 2 'Safety' details the safety directions that must be observed to ensure the safe and effective use of the Allura Xper FD20 series system.

Section 3 'Installation' provides information about the equipment connections.

Section 4 'System and error messages' gives a complete list of all messages that can displayed on the user interfaces.

Philips Medical Systems 9896 002 05471

Section 5 'Maintenance' specifies the planned maintenance activities for the system, and also includes those activities that must be performed by the user prior to using the system.

Section 6 'Product disposal' gives information about the disposal of part of, or all of, the equipment in an environmentally friendly way.

Specifications for the equipment used in the system can be found in section 7 'Technical data'.

Section 8 'Appendices' provides additional and supporting information, including information about the safety devices for the stand and table movements.

The 'Index' allows quick and easy reference to the information contained in these Instructions for Use.

1.3 Compliance

Terms as used in the Instructions for Use

As defined by Philips, the Allura Xper FD20 series system includes those items supplied to form a functioning unit. Under the terms of the IEC regulations the Allura Xper FD20 series system should be referred to as the Allura Xper FD20 series equipment.

NOTE ***Refer to section 8.3.4 'IEC Definitions' for a definition of the terms 'System' and 'Equipment'.***

The Philips Allura Xper FD20 series complies with relevant international and national standards and laws. Information on compliance will be supplied on request by your local Philips Medical Systems representative, or by the manufacturer, from:

Philips Medical Systems
Dept. Corporate Industrial Policy and Technology
P.O. box 10.000
5680 DA Best, The Netherlands
Fax: +31 40 27 63017

The Philips Allura Xper FD20 series complies with relevant international and national law and standards on EMC (electromagnetic compatibility) for this type of equipment when used as intended. Such laws and standards

Philips Medical Systems 9896 002 05471

define both the permissible electromagnetic emission levels from equipment and its required immunity to electromagnetic interference from external sources.

WARNINGS

- ***The use of accessories, transducers and cables other than those specified for this equipment, may result in increased emissions or decreased immunity.***
- ***The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the user must verify that the system operates normally in the configuration in which it will be used.***

1.4 Intended use

This Philips Allura Xper FD20 series is intended to be installed, used and operated only in accordance with the safety procedures and operating instructions given in this Instructions for Use for the purposes for which it was designed. The purposes for which the Allura Xper FD20 series is intended are given below. However, nothing stated in this Instructions for Use reduces user's responsibilities for sound clinical judgment and best clinical procedure.

The Allura Xper FD20 series is intended for:

- Dedicated vascular and neurovascular imaging applications, including diagnostic and interventional procedures. This includes, e.g. peripheral, cerebral, thoracic and abdominal angiography, as well as PTCAs, stent placements, embolisations and thrombolysis.
- Cardiac imaging applications including diagnostics, interventional procedures (such as PTCA, stent placement and atherectomies), pacemaker implantations and electrophysiology (EP).
- Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.

NOTE ***Use of the Allura Xper FD20 series system in the OR environment is restricted, the system should not be used for surgery applications, only for endo-vascular procedures.***

Philips Medical Systems 9896 002 05471

Installation, use and operation of this Allura Xper FD20 series is subject to the law in the jurisdiction(s) in which the Allura Xper FD20 series is being used. Users must **only** install, use and operate the Allura Xper FD20 series in such ways as do not conflict with applicable laws, or regulations, which have the force of law.

Uses of the Allura Xper FD20 series for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use or operation, may relieve the manufacturer (or his agent) from all or some responsibility for resultant non-compliance, damage or injury.

CAUTION ***Federal law restricts this device to sale by or on the order of a physician.***

1.5 Compatibility

The Allura Xper FD20 series described in this Instructions for Use should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible by Philips Medical Systems. A list of such products and components is available on request from the contact address given in the paragraph on 'Compliance'.

Changes and/or additions to the Allura Xper FD20 series should only be carried out by Philips Medical Systems or by third parties expressly authorized by Philips Medical Systems to do so. Such changes and/or additions must comply with all applicable laws and regulations that have the force of law within the jurisdiction(s) concerned, and with best engineering practice.

WARNING ***Changes and/or additions to the Allura Xper FD20 series that are carried out by persons without the appropriate training and/or using unapproved spare parts may lead to the Philips Medical Systems warranty being voided. As with all complex technical products, maintenance by persons not appropriately qualified and/or using unapproved spare parts carry serious risks of damage to the Allura Xper FD20 series and of personal injury.***

Philips Medical Systems 9896 002 05471

1.6 Contra-indications

This Philips Allura Xper FD20 series should not be used if any of the following contra-indications exist or are thought to exist.

Special precautions must be taken and/or caution must be exercised in the following cases:

- Special consideration must be given to the protection of the embryo or fetus during radiological examination or treatment of women known to be pregnant.
- Sensitive body organs (e.g., lens of eye, gonads) must be shielded whenever they are likely to be exposed to the working beam.
- Acute skin burns (patients).
- Acute hair loss (patients).
- Chronic radiation injury (staff).

1.7 Training

Users of this Allura Xper FD20 series must have received adequate training in its safe and effective use before attempting to operate the Allura Xper FD20 series described in this Instructions for Use. Training requirements for this type of device will vary from country to country. Users must make sure they receive adequate training in accordance with local laws or regulations.

If you require further information about training in the use of this Allura Xper FD20 series, please contact your local Philips Medical Systems representative.

Alternatively, contact the manufacturer, at:

Philips Medical Systems
Dept. Corporate Industrial Policy and Technology
P.O. box 10.000
5680 DA Best, The Netherlands
Fax: +31 40 27 63017

Philips Medical Systems 9896 002 05471

1.8 Other manuals

This Instructions for Use describes the Allura Xper FD10 series. If additional equipment is used with the system, each will have its own manual.

Philips Medical Systems 9896 002 05471

1.8 Other manuals

2 Safety

Philips Medical Systems 9896 002 05471

Philips Medical Systems 9896 002 05471

2 Safety

2.1 Important safety directions

Philips Medical Systems products are all designed to meet stringent safety standards. However, all medical electrical equipment requires proper installation, operation and maintenance, particularly with regard to human safety.

It is vital that you read, note, and where applicable, strictly observe all **DANGER** notices and safety markings on the Allura Xper FD20 series equipment.

It is vital that you follow strictly all safety directions under the heading SAFETY and all **WARNINGS** and **CAUTIONS** throughout this manual, to help ensure the safety of both patients and operators.

In particular, you must read, understand and know the 'Emergency procedures' described in this 'Safety' section before attempting to use the equipment for any patient examination.

You should also note the following information given in the 'Introduction' section of this manual:

- 1.4 'Intended use'
- 1.6 'Contra-indications'
- 1.7 'Training'

Only qualified and authorized personnel may operate this equipment. In this context, qualified means those legally permitted to operate this type of medical electrical equipment in the jurisdiction(s) in which the equipment is being used, and authorized means those authorized by the user of the equipment.

Personnel operating the equipment and personnel in the examination room must observe all laws and regulations which have the force of law within the jurisdiction(s) concerned. If you are in any doubt about the laws and regulations which apply to the operation of this equipment, do not use it.

Philips Medical Systems 9896 002 05471

WARNINGS

Maintenance & faults:

- ***Do not use the Allura Xper FD20 series equipment for any application until you are sure that the User Routine Checks have been satisfactorily completed, and that the periodic maintenance of the Allura Xper FD20 series is up to date.***
- ***If any part of the Allura Xper FD20 series is known (or suspected) to be defective or wrongly adjusted, DO NOT USE the Allura Xper FD20 series until a repair has been made. Operation of the Allura Xper FD20 series with defective or wrongly adjusted components could expose the operator or the patient to radiation or other safety hazards. This could lead to fatal or other serious personal injury, or to clinical misdiagnosis/clinical mistreatment.***

You can find information about the 'User Routine Checks Programme' and the periodic 'Planned Maintenance Programme' in the 'Maintenance' section of this Instructions for Use.

WARNINGS

Safety awareness:

- ***Do not use the Allura Xper FD20 series system for any application until you have read, understood and know all the safety information, safety procedures and emergency procedures contained in this SAFETY section. Operation of the Allura Xper FD20 series without a proper awareness of how to use it safely could lead to fatal or other serious personal injury. It could also lead to clinical misdiagnosis/ clinical mistreatment.***

Adequate training:

- ***Do not use the Allura Xper FD20 series for any application until you have received adequate and proper training in its safe and effective operation. If you are unsure of your ability to operate this Allura Xper FD20 series safely and effectively DO NOT USE IT. Operation of this Allura Xper FD20 series without proper and adequate training could lead to fatal or other serious personal injury. It could also lead to clinical misdiagnosis/clinical mistreatment.***
- ***Do not operate the Allura Xper FD20 series with patients unless you have an adequate understanding of its capabilities and functions. Using this Allura Xper FD20 series without such an understanding may compromise its effectiveness and/or reduce the safety of the patient, you and others.***

For information about training, please refer to 'Training' in the 'Introduction' section of this manual.

Philips Medical Systems 9896 002 05471

WARNINGS

Safety devices:

- ***Never attempt to remove, modify, override or frustrate any safety device on the Allura Xper FD20 series. Interfering with safety devices could lead to fatal or other serious personal injury.***

Intended use & compatibility:

- ***Do not use the Allura Xper FD20 series for any purpose other than those for which it is intended.***
- ***Do not use the Allura Xper FD20 series with any products other than those which Philips Medical Systems recognizes as compatible. Operation of the Allura Xper FD20 series for unintended purposes, or with incompatible products, could lead to fatal or other serious injury. It could also lead to clinical misdiagnosis/clinical mistreatment.***

Intended use of the Allura Xper FD20 series system is described under the heading 'Intended use' in the 'Introduction' section of this Instructions for Use. Compatibility is discussed under the heading 'Compatibility' in the 'Introduction' section of this Instructions for Use.

2.2 Emergency procedures

WARNINGS

- ***In the event of a system movement emergency, press emergency STOP to block all movements except manual stand rotation and tabletop float (for table without tilt only).***
- ***To ensure free all-round access to the patient, do not switch off the X-ray system using a local mains power switch.***

In the event of a clinical emergency involving a patient, e.g. a patient requiring Cardio Pulmonary Resuscitation (CPR):

- DO NOT press emergency power off
- move the Flat Detector away from the patient
- pivot the table to provide clear all-round access to the patient
- move the tabletop into the fully retracted position
- adjust the tabletop height, as required
- perform CPR.

Philips Medical Systems 9896 002 05471

2.3 Electrical safety

WARNINGS

Multiple portable socket outlets with insulation transformers:

- ***Multiple portable socket outlets with insulation transformers are not to be placed on the floor. If liquids are spilled on the multiple portable socket outlets there is a risk of electric shock hazard which can lead to serious or fatal injury to the patient and/or damage to equipment.***
- ***Multiple portable socket outlets with insulation transformers that are part of the system including the Allura Xper FD20 series equipment are only to be used for equipments that are part of that system. Connection to non-approved equipment can lead to serious or fatal injury to the patient and/or damage to equipment.***
- ***Multiple portable socket outlets with insulation transformer supplied with the system including the Allura Xper FD20 series equipment have been designed for a specified maximum load.***
  It is not permitted to connect other electrical equipment that is not part of the system including the Allura Xper FD20 series equipment to these multiple portable socket outlets.
  The electrical safety of the Allura Xper FD20 series equipment cannot then be guaranteed and could lead to serious or fatal injury to the patient and/or damage to equipment.

Non-medical electrical equipment:

- ***Non-medical electrical equipment that is a part of the system including the Allura Xper FD20 series equipment and is required to be supplied from a multiple portable socket outlet with insulation transformer is not to be connected to a normal mains electrical supply.***
  The electrical safety of the Allura Xper FD20 series equipment may then be compromised and could lead to serious or fatal injury to the patient and/or damage to equipment.

Covers and cables:

- ***Do not remove covers or cables from this Allura Xper FD20 series unless expressly instructed to do so in this Instructions for Use. Dangerous electrical voltages are present within the Allura Xper FD20 series. Removing covers or cables could lead to serious or fatal personal injury.***

Philips Medical Systems 9896 002 05471

Covers or cables should only be removed by qualified and authorized service personnel. In this context, qualified means those legally permitted to work on this type of medical electrical equipment in the jurisdiction(s) in which the product is being used, and authorized means those authorized by the user of the product.

Only use the Allura Xper FD20 series in rooms or areas that comply with all applicable laws (or regulations having the force of law) concerning electrical safety for this type of equipment. Always electrically isolate this Allura Xper FD20 series from the mains electrical supply before cleaning, disinfecting or sterilizing it.

Equipotential ground connection

An equipotential ground (earth) connection point is provided. This Allura Xper FD20 series may only be used in areas meeting local standards for electrical safety in rooms used for medical purposes, such as the US National Electrical Code. International Electro-technical Commission (IEC) also gives guidance on equipotential ground (earth) connection points.

2.4 Mechanical safety

WARNING ***Do not remove covers from the Allura Xper FD20 series unless expressly instructed to do so in this Instructions for Use. Moving parts are present within the Allura Xper FD20 series. Removing covers could lead to serious or fatal personal injury.***

Covers should only be removed by qualified and authorized service personnel. In this context, qualified means those legally permitted to work on this type of medical electrical product in the jurisdiction(s) in which the product is being used, and authorized means those authorized by the user of the product.

Philips Medical Systems 9896 002 05471

2.5 Explosion safety

WARNINGS

- ***Do not use the Allura Xper FD20 series in the presence of explosive gases or vapours, such as certain anaesthetic gases.***
- ***Do not use flammable or potentially explosive disinfecting sprays. The resultant vapour could ignite, causing fatal or serious injury and/or damage to equipment.***
- ***Use of the Allura Xper FD20 series in an environment for which it was not designed can lead to fire or explosion.***

2.6 Fire safety

Use of an electrical product in an environment for which it was not designed can lead to fire or explosion. Fire regulations for the type of medical area being used should be fully applied, observed and enforced. Fire extinguishers should be provided for both electrical and non-electrical fires. All operators of the Allura Xper FD20 series should be fully aware of and trained in the use of fire extinguishers and other fire-fighting equipment, and in local fire procedures.

WARNING ***Only use extinguishers on electrical or chemical fires which are specifically labelled for those purposes. Using water or other liquids on an electrical fire can lead to fatal or other serious personal injury.***

If it is safe to do so, attempt to isolate the Allura Xper FD20 series from electrical and other supplies before attempting to fight a fire. This will reduce the risk of electric shocks.

Philips Medical Systems 9896 002 05471

2.7 Electromagnetic compatibility (EMC)

The Allura Xper FD20 series complies with relevant international and national law and standards on Electromagnetic compatibility (EMC) for this type of product when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from the Allura Xper FD20 series and its required immunity to electromagnetic interference from external sources.

Other electronic products exceeding the limits defined in such EMC standards could, under unusual circumstances, affect the operation of the Allura Xper FD20 series.

Medical electrical products need special precautions regarding EMC, and need to be installed and put into service according to EMC information provided in the accompanying documents.

The use of accessories and cables other than those specified, may result in increased emission or decreased immunity.

The Allura Xper FD20 series should not be used adjacent to or stacked with other products. If adjacent or stacked use is necessary, it should be observed to verify normal operation.

See also 8.4 ‘EMC compliance’.

Portable and mobile phones

Other electronic equipment that exceeds EMC radiation standards, such as certain portable and mobile RF communications equipment, can affect medical electrical equipment, when used within a specified range.

CAUTION ***Portable and mobile RF communications can affect medical electrical equipment. Use caution when using such communication devices within the specified range of medical electrical devices.***

Philips Medical Systems 9896 002 05471

2.8 Radiation safety

Operators are strongly urged to acquaint themselves with the current recommendations of the International Commission on Radiological Protection, and in the United States, with those of the US National Council for Radiological Protection.

- ICRP, Pergamon Press, Oxford, New York, Beijing, Frankfurt, São Paulo, Sydney, Tokyo, Toronto
- NCRP, Suite 800, 7910 Woodmont Avenue, Bethesda, Maryland 20814, USA

The X-ray equipment is intended for procedures in which the Air Kerma (AK) levels can be high enough during normal use to constitute a risk of deterministic effects.

Full use must be made of all the equipment's radiation protection features and of all radiation protection devices, accessories, systems and procedures available to you as the operator.

Information about radiation protection devices, and their uses, can be found in the Allura Xper FD system 'Accessories' Instructions for Use.

WARNING ***Do not attempt to remove, modify, override or frustrate any safety device on the equipment. If you do interfere with safety devices, this could lead to serious or fatal injury.***

Use only the prescribed Air Kerma (Rate) (AK(R)) necessary to perform a particular examination or treatment.

Radiation guidelines

Always apply the following rules when using radiation equipment:

- never radiate unless absolutely necessary
- radiate for as short a time as possible
- when possible, use automatic AKR control
- stay as far away from the radiated object as possible
- always wear an apron
- use badges to monitor the radiation received
- collimate as much as possible
- keep the focal spot to skin (object) distance as large as possible

Philips Medical Systems 9896 002 05471

- remove all unnecessary obscuring objects from the primary beam (including the operator's hands)
- for extra operator safety, keep the X-ray source under the table.
- use the radiation disable switch at all times, except when the radiation procedure is in progress to prevent the possibility of radiation being emitted by an inadvertent activation of an irradiation switch.
- release all hand/foot switches in case the display of live images stops.
- release and depress the foot/hand switches again when the requested X-ray does not start or stop automatically.

Filtration

The maximum attenuation equivalent of the tabletop is 1.43 mm Al. The minimum inherent filtration (at 75 kV) of the X-ray tube/collimator is 2.5 mm Al.

Besides a wedge filter of 1 mm brass (CuZn37 R-019; 22 mm Al equivalent at 75 kV), an additional filter can be set, depending on the Beam Limiting Device (BLD) that has the following values:

BLD Type number (12NC)	Additional Filter		Filtration in mm Al-eq. (at 75 kV)
	No.	Filter	
9896 010 22×××[1]	1	0.1 mm Cu + 1.0 mm Al	4.0
	2	0.4 mm Cu + 1.0 mm Al	11.0
	3	0.9 mm Cu + 1.0 mm Al	21.5

[1] × = any digit 0 to 9

NOTE ***For information on stray radiation, refer to 7 'Technical data'.***

Dosimeter calibration

Refer to the instructions specified in the Service Manual.

Philips Medical Systems 9896 002 05471

2.9 Network safety, security and privacy

Customer Role in the Product Security Partnership

We recognize that the security of Philips Medical Systems products is an important part of your facility's security-indepth strategy. However, these benefits can only be realized if you implement a comprehensive, multi-layered strategy (including policies, processes, and technologies) to protect information and systems from external and internal threats.

Following industry-standard practice, your strategy should address physical security, operational security, procedural security, risk management, security policies, and contingency planning. The practical implementation of technical security elements varies by site and may employ a number of technologies, including firewalls, virus-scanning software, authentication technologies, etc.

As with any computer-based system, protection must be provided such that firewalls and/or other security devices are in place between the medical system and any externally accessible systems.

The USA Veterans Administration has developed a widely used Medical Device Isolation Architecture for this purpose. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy.

Philips Medical Systems 9896 002 05471

2.10 Toxic or hazardous substances and elements

The following table details the Toxic or hazardous substances and elements which are present in the Allura Xper FD system:

Allura Xper FD System	Toxic or Hazardous Substances and Elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr^{6+})	Polybrominated Biphenyls (PBB)	Polybrominated Diphenyl Ethers (PBDE)
Electronic modules	X	O	O	O	O	O
Flat screens	X	X	O	O	O	O
Detector	X	O	O	O	O	O
Radiation sheilding	X	O	O	O	O	O
Collimator	X	O	O	O	O	O
Grid	X	O	O	O	O	O
X-ray tube	X	O	O	O	O	O
Electromechanical parts	O	O	O	X	O	O

O: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006.

X: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in SJ/T11363-2006.

In this product, perchlorate material is present in Lithium coin cells and/or batteries. Perchlorate Material - special handling may apply, for more information, go to:

www.dtsc.ca.gov/hazardouswaste/perchlorate

Philips Medical Systems 9896 002 05471

2.10 Toxic or hazardous substances and elements

3 Installation

Philips Medical Systems 9896 002 05471

Philips Medical Systems 9896 002 05471

3 Installation

3.1 Introduction

The Allura Xper FD20 series equipment must be installed and configured completely by a trained service engineer as part of delivery and hand-over. During its use or due to changes in the place of installation, modifications to the equipment or configuration may be necessary. This must be carried out by a trained service engineer.

The information contained in this chapter is mandatory under the terms of IEC 60601-1-1. A guide for the correct connection of the equipment is described in this document.

General

The Allura Xper FD20 series equipment satisfies the terms of IEC 60601-1 and provides inside and outside the patient environment, the level of safety stipulated in IEC 60601-1-1 provided that the equipment listed in the table below has been provided with the electrical safety measures described.

Philips Medical Systems 9896 002 05471

3.2 Equipment connections

Item Nr.	Equipment forming part of the system	IEC or ISO standard	Location of equipment	Electrical safety measures
1	Allura Xper FD20 series X-ray equipment An Allura Xper FD20 series X-ray equipment consists of the following main parts, which have been located inside the patient environment : • Table with control modules. • Frontal and Lateral stand. • Frontal and Lateral X-ray tube housing assembly with beam limiting devices. • Frontal and Lateral Flat detector (FD) assembly. • Ceiling suspended monitors, and target light. • Optional radiation shields • Optional examination light • Optional injector An Allura Xper FD20 series X-ray equipment consists of the following main parts, which have been located outside the patient environment : • Monitors. • Keyboard and mouse. • Control modules. • Workstation(s). • Frontal and Lateral X-ray generator and cooling units. • Peripheral cabinets • Main cabinet for system control/mains power distribution with user interfaces and viewing monitors.	IEC 60601-1/ UL 2601-1	Partly in and outside the patient environment	The electrical connections (ATY-X2; MDAI-X2; MDP-X1; MDY-X24; MDY-X34; NP-X105; NP-X106; NP-X111) to other Medical Electrical equipment are according to IEC 60601-1.
2	Network /Xcelera/Viewforum workstation and network printer.	IEC standard	Outside the patient environment	The network workstation or printer shall be connected via Ethernet isolator TN-X2.

Philips Medical Systems 9896 002 05471

Item Nr.	Equipment forming part of the system	IEC or ISO standard	Location of equipment	Electrical safety measures
3	Physio / ECG	IEC 60601-1 / UL2601-1	In patient environment	• The equipment shall be connected to MDY-X24 of the Allura Xper FD20 series X-ray equipment. • PE of Physio/ECG shall be connected to the PE of a wall outlet. The PE of this wall outlet shall have a direct connection with the busbar, on which the X-ray equipment has been connected. • The mains cable shall be connected to a multiple portable socket outlet with insulating mains transformer (according to IEC60601-1-1).
4	Report printer	IEC standard	Outside the patient environment	• The equipment shall be connected to CY-X35. • PE of printer shall be connected to the PE CY-X500. • The mains cable of the printer shall be connected to CY-X200.

Philips Medical Systems 9896 002 05471

Item Nr.	Equipment forming part of the system	IEC or ISO standard	Location of equipment	Electrical safety measures
5	Room interface (examination light, roomlighting, door contacts, hospital emergency switch contact)	IEC 60601-1/ UL 2601-1	Outside the patient environment	• The equipment shall be connected to NP-X105, NP-X106, ATY-X2 and NP-X111 of the Allura Xper FD20 series X-ray equipment. • The hospital devices shall meet IEC60601-1 / UL 2601-1. • No screened connection cables shall be used. • The circuits of the hospital devices shall be insulated from the protective earth.
6	Video equipment: • First Medical DVD Recorder	IEC standard	Outside the patient environment	• The equipment shall be connected to CY-X30 of the Allura Xper FD20 series X-ray equipment. • PE of the video equipment shall be connected to PE CY-X500. • The mains cable of the video equipment shall be connected to CY-X5.
	• Second Medical DVD Recorder	IEC standard	Outside the patient environment	• The equipment shall be connected to CY-X31 of the Allura Xper FD20 series X-ray equipment. • PE of the video equipment shall be connected to PE CY-X500. • The mains cable of the video equipment shall be connected to CY-X6.

Philips Medical Systems 9896 002 05471

Item Nr.	Equipment forming part of the system	IEC or ISO standard	Location of equipment	Electrical safety measures
7	EPMed (integrated)	IEC 60601-1	Inside and outside the patient environment	• The equipment shall be connected to TE-X4 (ethernet) and the Monitor Ceiling Suspension (video signals) of the Allura Xper FD20 series X-ray equipment. • The PE of EPMed equipment HAY-X100 shall be connected to PE NP-X100, and the PE of the Bedside Cart HAB-X (earth) shall be connected to SAF-X100. • The mains cable of the EPMed, HAY-X6 and HAB-X (Mains) shall be connected to the local mains.

Philips Medical Systems 9896 002 05471

4 System and error messages

Philips Medical Systems 9896 002 05471

Philips Medical Systems 9896 002 05471

4 System and error messages

4.1 Message and error handling

If a warning or error is detected, a message is displayed in the operator guidance message area [12] on the Reference monitor and in the Guidance message area [2] of the AGD on the Data monitor. Messages are displayed at the moment the error occurs and for as long as the error conditions remain. If more than one error is detected, the message relating to the error with the highest priority is displayed. If an action type message is displayed, the system cannot be used. If a warning type message is displayed, the system can be used with reduced performance.

An updated list of messages is still required.

Some messages relate to a specific channel (frontal/lateral) and are only displayed on the associated monitor.

For certain errors the system will reset automatically. Contact Service if automatic resets occur frequently.

4.1.1 Error messages

The following table shows all error and warning messages valid for the Allura Xper FD20 series system:

Displayed Message	Action/Meaning
An error occurred. No further details available.	Unknown error
An invalid heart rate has been entered	The heartrate entered was negative, or not within the acceptable range
An invalid height has been entered	The height entered was negative, or not within the acceptable range
An invalid weight has been entered	The weight entered was negative, or not within the acceptable range
Button active. Release button to complete startup	Call service
Centerline wall motion can not be computed	The centerline wall motion analysis cannot be computed

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Centerline wall motion graph cannot be displayed	The centerline wall motion graphic cannot be displayed
Communication error with worklist manager	Ris communication error.
Correction not applied, please retry	The ventricle correction is not applied, please retry
Current image is not yet calibrated	The dicom file did not contain a calibration factor
Detection failed, please retry	The ventricle detection failed, please retry
DETECTOR Bodyguard Override	The user is pointed out that the BodyGuard at the detection that limits the speed of the CArm or Propeller to very low speed is overridden
DETECTOR+TUBE Bodyguard Override	The user is pointed out that the BodyGuard at the detection and tube that limits the speed of the CArm or Propeller to very low speed if overridden
Error in normals-file title	This error occurs if normals files are used and there is an error in the title of the file
Error reading file	The application could not read from a file
Error reading font section, defaults used	The FONT section of the shared settings file is not correctly formatted
Error reading normals-file	This message is presented to the user if the application has problem reading the normals files. Normals files determine the normal values for a population in Regional Wall motion analysis
Error reading report section, defaults used	The REPORT section of the shared settings file is not correctly formatted
Error reading setup section, defaults used	The SETUP section of the shared settings file is not correctly formatted
Error reading spreadsheet section, defaults used	The SPREADSHEET section of the shared settings file is not correctly formatted
Error reading UI section, defaults used	The UI section of the shared settings file is not correctly formatted
Error reading version of normals-file	The version info in the header of the normals file is not correct

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Error writing file	The application could not write to a file
ERROR: Geometry configuration mismatch	Configuration info on NT does not match with embedded
Exposure not possible	No communication with the Interventional Hardware
Exposure not possible, reselect application	Exposure disabled. Reselect clinical application
Exposure not possible. Reselect procedure	• Fullfill precondition for exposure run • Finalize error during Definition run • Geometry initially in replay state which is not allowed
Exposure not possible: emergency power active	No exposure possible due to hospital emergency power
Exposure not possible: image disk full	• No exposure possible due to full image disk • Exposure disabled due to full image storage disk
Exposure not possible: Not enough storage space	Exposure disabled due to insufficient available storage space for this run
Exposure not possible: system problem	Exposure disabled. Reselect clinical application
Exposure not possible: tube anode not at operating speed	Exposure disabled due to X-ray tube anode not at operating speed
Exposure not possible: Tube overload	Exposure disabled due to tube housing contact open
Exposure not possible: tube rotor problem	Exposure disabled due to X-ray tube anode not at operating speed
Exposure preparation canceled, please retry	Exposure canceled. Retry
Exposure preparation failed, please retry	Exposure canceled. Retry
File already exists	A file already existed
File not found	A file could not be found
Fluoroscopy cancelled, please retry	Fluoroscopy canceled. Retry
Fluoroscopy failed, please retry	Fluoroscopy canceled. Retry
Fluoroscopy not possible, reselect application	Fluoroscopy disabled. Reselect clinical application
Fluoroscopy not possible: system problem	Fluoroscopy disabled. Reselect clinical application

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Frontal stand not in working position, frontal X-ray disabled	The frontal geo stand is not in working position
Geometry module control room not operable	Call service
Geometry module examination room not operable	Call service
Geometry problem. Reselect procedure	A Geometry problem that can only be solved by starting the procedure from scratch
Illegal centerline normals file, using defaults	The file, containing the values of healthy people, is corrupt
Illegal format in normals file	The format of the normals file is incorrect
Illegal radial normals file, using defaults	The file, containing the values of healthy people, is corrupt
Illegal regional normals file, using defaults	The file, containing the values of healthy people, is corrupt
Illegal slager normals file, using defaults	The file, containing the values of healthy people, is corrupt
Image disk error, deselect fluo subtract mode	Fluoroscopy disable due to image disk error. Deselect subtract mode
Image disk full, deselect fluo subtract mode	Fluoroscopy disabled due to full image disk. Deselect subtract mode
Image in other plane is not yet calibrated	Image in other plane is not yet calibrated
Imaging module control room not operable	Call service
Imaging module examination room not operable	Call service
Incorrect library detected	The Algorithm Library version is wrong
Initialization error	Initialisation failed
Injector not ready, arm injector	Exposure disabled. Coupled injector not ready
Injector unavailable, reselect procedure	Exposure disabled. Reselect clinical application
Internal error	An internal error occurred in the application. There are a number of reasons why this message can be displayed. Restart the application and try again. If internal errors keep occurring, call Service.
Invalid application, please select another application	Invalid clinical application has been selected

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Invalid normals detected	This message is presented to the user when the normals-files contain invalid values. The Normals file are standard text files
Invalid procedure, please select another procedure	Invalid clinical procedure has been selected
Job failure, please retry	• Unknown error
	• Failure accessing objects in the source repository
	• Job failure, invalid or not existing ROID input parameter
	• The job contains invalid or incomplete parameters
	• Connecting failed: Network or DICOM association problems
	• The printer can not execute the required command
	• The pixel depth is not valid
	• Unknown error value is returned from the ACP component.
Lateral stand not in working position, lateral X-ray disabled	The lateral geo stand is not in working position
Longitudinal table movement not available. Reselect procedure	The Longitudinal movement is not available FDPA is not possible
Missing or corrupt DICOM file	A DICOM file cannot be read because it is missing or it contains corrupt data
No cardiac wall results can be computed	The wall thickness related results cannot be computed
No centerline normals file, using defaults	The file, containing the values of healthy people, cannot be found
No chemicals available.	No chemicals for development available
No connection with printer.	No connection with printer. Printer Not Found
No crossing lines allowed	When lines are crossing each other when drawing a density measurement, it is not always clear what the user meant to include in the density calculation, therefore crossing lines are not allowed in a XYZ measurement

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
No edges found. Use other image or centerline	The part of the image on which the contour-detection is performed does not have enough contrast or is saturated. Therefore the edges could not be detected. Adjusting user adjustable contrast and/or brightness does not influence this problem
No exposure possible, reselect procedure	Exposure disabled. Manual settings refused. Reselect clinical procedure
No film available	• No media on stock • The supply magazine is not available
No fluo possible: Selected app. does not support fluo	Selected clinical application does not support fluoroscopy
No fluo possible: Selected aux. doesn't support fluo	Fluoroscopy not supported
No fluoroscopy possible, reselect application	Fluoroscopy disabled. Manual settings refused. Reselect clinical application
No radial normals file, using defaults	The file, containing the values of healthy people, cannot be found
No regional normals file, using defaults	The file, containing the values of healthy people, cannot be found
No slager normals file, using defaults	The file, containing the values of healthy people, cannot be found
No X-ray possible: Tube not inline with detector	Radiation disabled due to X-ray tube not in line with X-ray detector
Out of angulation range	The angulation of this image is out of the acceptable range
Out of rotation range	The rotation of this image is out of the acceptable range
Panhandle not operable	Call service
Path not found	The directory path does not exist
Print report failed, check printer	Examination reports could not be printed
Printer communication error, please retry	• Something wrong on DICOM protocol level • Waiting for reply took to long
Printer configuration is not correct	Configuration items are missing or incorrect

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Printer problem, inspect printer	• Something wrong with the receiver magazine, e.g. full
	• User should inspect the printer
	• Hardware error
	• Not enough memory available in printer
	• The processor of the printer detects an error
Query failed, check search parameters and try again	The query failed
Query for worklist from worklist manager failed	RIS query failed
Radial wall motion can not be computed	The radial wall motion analysis cannot be computed
Receiver film magazine full	The receiver magazine is full
Regional wall motion can not be computed	The regional wall motion analysis cannot be computed
Release foot\handswitch and restart system	Exposure\Fluoroscopy hand\foot switch pressed while starting system
Reporting: cannot copy image, try again	• Unable to create the PNG file in the pre-defined time.
	• Unable to link the PNG file to data base. As Examination folder deleted.
Review module control room not operable	Call service
Rotation scan time too low. Reselect procedure	Rotational scan time too short
RPML-file could not be parsed	An error occurred during parsing of the report definition file
Run aborted:tube overload limit	• Run aborted:tube overload limit
	• Exposure disabled due to overloaded X-ray tube
Select procedure to continue	Select procedure to continue
Select Smart Mask not possible	Select Smart Mask not possible
Slager wall motion cannot be computed	The Slager wall motion analysis cannot be computed
Speed controller not operable	Call service

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
System failure	Error in database
Target position NOT reached	For whatever reason the APC stand movement has not reached its targetposition.
The correction drawn is too short	Not enough points to complete a correction
The correction is too short	Internally, a line is presented as an array of points between start and end of the drawn correction. When there are not enough points (line is too short) the algorithm is not able to calculate the result
The printer door is not closed	Close the printer door
The requested film type is not available	The requested medium is not on stock
The requested number of copies is not supported	n.a.
Transfer: close exam failed, try again.	Automation Job failed, (AutoArchive or AutoExport).
Transfer: communication error	• The connection failed due to network or DICOM problems
	• Something wrong on protocol level
Transfer: configuration error	The system is configured wrong.
Transfer: invalid data, try to restart job	Invalid or corrupt data objects
Transfer: system failure, try to restart job	• The data repository is not accessible
	• Data objects not found or locked.
	• A data object is not supported by the repository, and therefore skipped.
	• A data object is rejected by the repository.
	• The job contains invalid parameters.
TUBE Bodyguard Override	The user is pointed out that the BodyGuard at the tube that limits the speed of the CArm or Propeller to very low speed if overridden
Tube overload	X-ray tube overload
Tube overloading, please finish run	Tube is in overload during exposure
Unknown projection, please select another image	The projection of the selected image is unknown
WARNING: Adjustment of frontal stand required	Reported when the Frontal Stand has lost the stored adjustment data

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
WARNING: Area AK(R) measurement not recorded	Call service
WARNING: Bodyguard defect, move at own risk	Sensor defect detected at POST, call service
WARNING: Bodyguard dirty, move at own risk	Sensor a little bit wet or dirty. no safety issue
WARNING: Bodyguard very dirty, clean sensor	Sensor very dirty or defect detected after POST
Warning: Chemicals low	Availability of chemicals reached threshold value
WARNING: collimator communication defect	Communication with collimator defect, cannot be used, call service
WARNING: collimator general defect	Collimator defect, cannot be used, call service
WARNING: DETECTOR Bodyguard active	The BodyGuard at the detector limits the speed of the C-arm or Propeller to very low speed
WARNING: DETECTOR+TUBE Bodyguard active	The BodyGuard at the detector and tube limits the speed of the C-arm or Propeller to very low speed
WARNING: Door contact failure, please close door	Door contact failure. Ensure the examination room door has been closed
WARNING: Emergency stop activated, reset to continue	The user has pressed the emergency stop button. A warm restart is required to enable the motorized movements again
WARNING: exposure buzzer defect	End-of-exposure buzzer unavailable, call service
Warning: Exposure not possible	Call service
Warning: Film jam	Something wrong with transportation of medium
Warning: Film supply low	The number of media on stock reached a threshold value
WARNING: Fluo buzzer defect	Fluoroscopy buzzer defect, call service
Warning: Frontal geometry standposition unknown	The position of the frontal stand is unknown
WARNING: Grabbing disabled; image disk error	Grabbing disabled; image disk error

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
WARNING: Image disk error; no storage possible	Image disk error: no storage possible
WARNING: Larc Collision Switch activated	The user is pointed out that there is a collision with the LArc
Warning: Lateral geometry standposition unknown	The position of the lateral stand is unknown
WARNING: Limited image size due to rotated detector position	Flat detector is being rotated.
WARNING: low storage space %1!s! exposures left	Low disk space allows storage of max. x exposure images
WARNING: Motorized movement not available	The motorized movement is not ready for use because it is malfunctioning or not present
WARNING: No DAP measurement possible	Area X-ray dose not recorded, call service
Warning: position not reachable, press footswitch or cancel	n.a.
WARNING: Projection not reachable	Target projection not reachable during recall due to mechanical constraints
WARNING: Radiation indication lamp defect	X-ray indicator defect, call service
WARNING: Rotate Detector error, move to landscape manually	The detector spinangle is unknown. User should move it manually to default position.
WARNING: Shutters unavailable	Shutter defect, cannot be moved, call service
WARNING: Wedges unavailable	Wedge defect, cannot be moved, call service
X-ray not possible: flat detector overheated	Radiation disabled due to overheated detector
X-ray not possible: system shutdown	Exposure disabled because system is shutting down
X-ray not possible: system shutdown	Fluoroscopy disabled because system is shutting down
X-ray not possible: tube defect	Radiation disabled due to X-ray tube defect (focus), call service
XRes unavailable.	XRes unavailable

4.1.2 System messages

System messages are messages with a lower status of importance and are displayed to inform the user about active system processes. The following table shows the System messages valid for all Allura Xper FD20 series system:

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
%1Examination protected. Confirm deletion?	%1Examination protected, Proceed?
%1Examination protected.Nothing archived or printed. Confirm deletion?	%1Examination protected, nothing archived or printed, Proceed?
%1Toggle protection. Confirm toggle?	%1Toggle protection. Proceed?
%1Toggle protection. Nothing archived or printed. Confirm toggle?	%1Toggle protection. Nothing archived or printed. Proceed?
3DRA/CA	Displayed on OMD/AGD when APC 3D-RA is performed using the geometric position of selected 3DRA image
Acquisition is currently active	• Other action performed while Acquisition Active
	• Unknown error
Add run and mark image	Select an image run to combine with the current analysis
Apex is not in a LAO projection	The wrong image was used for Lateral Apex positioning
Apex is too close to valve	The apex is the point that is the furthest away from the valve
Apex not on contour	A check on the calculation results failed
Arterial curvature too large	The vessel that is indicated for detection has too many curves
Automatic detection of the sphere failed	The calibration module was not able to autodetect a sphere
Bad exposure conditions found	The exposure of the image is incorrect, or the image depth (number of bits/pixel) is set incorrect in the Dicom file.
Biplane APC is only selectable in examination room.	Biplane APC is not allowed from the control room because of limited system visibility
Biplane fluoroscopy not possible	Biplane fluoroscopy not possible
Busy with system startup or recovery. Please wait...	Wait until system has been started up
Calibration in progress	n.a.
Cannot merge existing examinations	Can not change examination ID into an existing examination ID.

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Cannot start prefetching of images from a different patient	Can not start prefetch on different patient
Cannot start prefetching of images from the same examination	Can not start prefetch on same examination
Changed settings take effect in next analysis	Occurs in current analysis when user changes something in Setup
Check table longitudinal moves free. Bodyguard will be switched off.	Notify user about table movement
Combination of AccNr and RequestID already exists	Combination of AccNr and RequestID already exists
Combining Analysis	Combining the new selected image run with the current analysis
Confirm Rotation scan end-position	-
Confirm Rotation scan start-position	-
Connection with worklist manager lost	Ris connection is temporary off line.
Connection with worklist manager restored	Ris connection is back on line.
Contour too small for Centerline Wall Motion	The detected contour is not big enough in order to perform a Centerline Wall Motion Analysis
Contour too small for Radial Wall Motion	There are not enough points in the contour in order to calculate a radial wall motion
Contour touches boundary	Warning indicating that the contour touches the image boundary
Correct the contour or create a report	n.a.
Correction crosses opposite edge	A correction is drawn by the user which would (if calculated) have a negative stenosis
Correction too small	A correction to the contour has been requested that is too small to process
Could not draw the sphere, please retry	Displayed when the manual marking of the sphere fails
Delete or modify a density measurement	n.a.
Delete or modify a length measurement	n.a.
Delete or modify an angle measurement	n.a.
Density square too small	XYZ rectangle was drawn too small

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Difference(s) in DICOM file detected	Differences were detected in administrative items, such as patient name, run, series, date, between the first loaded, the ED or the ES image
Do you really want a new acquisition selection?	Do you really want a new acquisition selection?
Draw a density measurement	n.a.
Draw a length measurement	n.a.
Draw an angle measurement	n.a.
Draw the contour	n.a.
Draw, modify or delete a density measurement	n.a.
Draw, modify or delete a length measurement	n.a.
Draw, modify or delete an angle measurement	n.a.
Edit contour, select analysis, or create report	n.a.
Emergency power active: low load fluo flavor selected	Degraded image quality due to hospital emergency power
Enter a calibration factor	Enter a calibration factor
Enter corrections and select processing method	Enter corrections and select processing method
Enter restrictions, finish with double click	Enter restrictions, finish with double click
Error parsing INI-file. Defaults used	The data in the .INI file was not correct and the Analysis module used it's default values for the values it could not read
Error parsing SET-file. Defaults used	The data in the .SET file was not correct and the Analysis module used it's default values for the values it could not read
Exam can not be discontinued.	n.a.
Examination cannot be added to the local database	Entry from other modality in worklist (e.g. MR)
Examination cannot be closed	n.a.
Examination cannot be deleted	n.a.
Examination cannot be selected for reviewing	• Selected examination can not be selected for reviewing • Incorrect reviewing examination selected
Examination ID already exists, use other	Examination already exists
Examination is already selected for acquisition	Examination is already selected for acquisition

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Exposure not possible	The interventional Hardware is busy or not ready
FieldService, user may not save QA report image	n.a.
Fluo grab not possible: image disk full	Fluoroscopy images cannot be stored
Fluo grab not possible: system problem	Fluoroscopy images cannot be stored
Fluoroscopy	Name to identify a fluo grab run
Fluoroscopy disabled due to max fluoroscopy time elapsed	Fluoroscopy disabled due to max fluoroscopy time elapsed
Fluoroscopy trace not possible	Fluoroscopy trace not possible
FluoStore not available: Image disk full	FluoStore not available due to full image disk
For subtracted images use autocal or pixelsize cal	The image in use is a subtracted image. Only manual pixelsize or autocalibration is available for subtracted images
Free image disk space becomes low, please delete exams.	Low on storage space for examination. Delete examinations.
Function can not be applied on imported examination.	n.a.
Function can not be applied, AccNr and RequestID in use.	n.a.
Function can not be applied, pending jobs in the queue.	n.a.
Geometry module pedestal not operable	Call service
Geometry not in Rotation scan start-position	Move frontal stand into working position for Rotation scan
Geometry unavailable. Reselect procedure after Geometry restart	n.a.
Illegal input text format	Illegal text format.
Imaging module pedestal not operable	Call service
In order to move the LArc, move Frontal Stand to headside	When the Frontal Stand is parked (PolyG2 Floor) or at nurse or doctorside (Clea Floor) the LArc cannot be parked.
Incorrect contour for centerline WM calculation	The contour drawn by the user could not be used to calculate the Centerline Analysis
Incorrect query criteria	Incorrect query criteria

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Indicate catheter segment to calibrate on	n.a.
Indicate center-point of sphere	The selected calibration method is a semi automatic sphere calibration
Indicate the known distance with two points	n.a.
Indicate three points at the rim of the sphere	n.a.
Invalid characters in Examination ID	Invalid examination id.
Invalid characters in name	Invalid person name
Invalid characters in Patient ID	Invalid patient id.
Invalid characters in Request ID or Accession Number	Invalid accession number and/or request id.
Invalid combination of PatientID, AccNr and RequestID	Invalid combination of PatientID, AccNr and RequestID.
Invalid examination id	n.a.
Job failed.The examination folder was deleted	Job failed.The examination folder was deleted.
LArc must be parked for APC frontal. Move to parkposition	Lateral stand longitudinal position is not parked. Lateral stand must be moved to the parkposition first.
LArc not ready for APC. Move to workarea or parkposition	Lateral stand longitudinal position is inbetween. Lateral stand must be moved to workarea or to the parkposition first.
License key error	No license key found
Longitudinal table movement not available. Reselect procedure	The Longitudinal movement is not available FDPA is not possible
Mark the image	n.a.
Maximum number of images in report reached	Maximum number of images in report reached
Monoplane fluo mask, biplane fluoroscopy not possible	Monoplane fluoroscopy mask, Biplane fluoroscopy not possible
Move frontal stand into working position for Rotation scan	n.a.
Move stand into doctor side position	n.a.
Move stand into head side position	n.a.
Move stand into nurse side position	n.a.
Move stand into proper position	n.a.
No autocal information found	Displayed when no SID/SOD can be found

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
No more save positions, overwriting last save	The maximum number of save positions was reached. The last results saved will be overwritten
No Name	Prefix emergency patient name
No name supplied for new patient.	Patient name is not supplied for new patient
No standard image used for input	An internal error with a mini-image occurred
Number of average calibrations exceeds maximum	The maximum number of calibrations to be averaged was exceeded
Parallel angle lines not allowed	It is not possible to calculate an angle of horizontally placed lines
Park LArc, prior to start Bolus Chase	Request to park the lateral stand
Park LArc, prior to start Rotation scan	-
Park LArc, prior to start Rotation scan	-
Patient name part too long	Patient name part too long
Performed step %1!s! of the calibration	n.a.
Pixel size is out of limits	The pixelsize should be within specified boundaries
Please move table out of the XrayBeam and press footswitch	n.a.
Please press exposure footswitch	n.a.
Please release footswitch	n.a.
Please wait ...	Please wait while the system completes the action; if it takes more than 20 seconds, warm reboot the system
Position table at start position	n.a.
Preferences file is corrupt	The preferences file was corrupted. Preferences files are used to store the last used values
Press speed controller to move table back	n.a.
Procedure selection in progress. Please retry	Procedure selection in progress when attempt to start X-ray
Ready for first Rotation scan	Ready for rotational angio definition run
Ready for second Rotation scan	Ready for rotational angio replay run
Ready to acquire mask run	Ready to acquire mask run

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Reduced speed due to Detector orientation	When Detector is not positioned at Portrait or Landscape the BodyGuard cannot be relied on. Therefor the angulation and rotation speed is reduced like when the BodyGuard is OutOfRange
Reference 1	Displayed on OMD/AGD when APC Reference is performed using the geometric position of the image on Reference monitor 1
Reference 2	Displayed on OMD/AGD when APC Reference is performed using the geometric position of the image on Reference monitor 2
Reference Biplane	Displayed on OMD/AGD when APC Reference is performed using the geometric position of the image on Reference monitor 1 and 2
Release footswitch and park lateral stand	n.a
Release footswitch and rotate detector to landscape	n.a.
Release footswitch, move frontal stand to head position	n.a.
Reporting: failed to insert image, fluoroscopy run	n.a.
Reporting: failed to insert image, no selection	n.a.
Restriction is not correct	The restriction performed by the user does not conform to the description in the manual (intended use)
Restrictions discarded, too complex	Too many or too complex restrictions were made. The detection will proceed after discarding all restrictions
Resubmitted	Job Resubmitted
Reverse position selected	User message displayed when Geo subsystem is restarting
Rotation scan not available. Reselect procedure	-
Rotation scan time: %1!s! seconds	Time needed to make rotational scan

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Rotation speed reduced to 30 degr/s	If for DRA the CArm the position is greater ½30°½ the Propeller may only move with 30°/sec.
Segment too broad	The width of the vessel exceeds the maximum detectable width. Detected contour may be incorrect.
Select a measurement type	n.a.
Select another channel	Select another channel
Select another image or correct the contour	n.a.
Select arterial segment. Double click when ready	n.a.
Select calibration or analysis method	n.a.
Select distance	n.a.
Select French size	n.a.
Select one of the calibration methods	n.a.
Select procedure to continue	A condition requires that the procedure has to be reselected
Select sphere diameter	n.a.
Selected examination cannot be reopened for acquisition	n.a.
Send report failed	Error in email application
Sequence	Displayed on OMD/AGD when APC Sequence is selected
Shutters unavailable May expose outside detection area	Radiation possibly outside detector area due to unavailable collimator
Smart Mask selected	n.a.
Stand not ready for APC. Move to workarea.	Frontal stand must be moved to workarea first.
Stenosis too short	The obstruction (Stenosis) indicated is too short to perform an analysis
System Service Mode	Fieldservice mode
Table limit Override	The Restriction that limits the TiltPatientSupport and ChangeHeight is overridden.
Table limit reached. Use Override to continue	The PatientSupport Movement has stopped due to the SafeArea Restriction

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Table/Stand collision-prevention active	Motorized movement is stopped or not started by software to prevent a collision between the table and the frontal stand
Testshot Failure, overexposed, please retry	Overexposed Testshot
Testshot Failure, please retry	Testshot failed, retry
Testshot Failure, Underexposed, please retry	Underexposed Testshot
The centerline drawn has too many points	he user created too many centerline segments (clicked too many times)
The centerline drawn is too short	A centerline is drawn with not enough segments, i.e. less than two points
The report can now be saved	n.a.
The restriction crosses the arterial centerline	The user has drawn a restriction that crosses the centerline of the artery
The restriction drawn is too short	A minimum length is needed by the algorithm library in order to restrict
This examination is already closed	n.a.
This patient already exists, merge with existing patient?	The patient id already exists. Do you want to merge the patient information?
This request already exist, do you want to merge with the existing?	The AccessionNumber and/or RequestID already exists. Do you want to merge the study information?
Too few centerline points defined	The user has not drawn enough segments in order to detect a contour (minimum 2)
Too many centerline points defined	The user has created too many segments when drawing the centerline
Too many entries found, restrict WLM query	n.a.
Too many measurements	The maximum number of measurements allowed has been reached
Total free space %1!s! images	x images can be stored
Transfer: imported images cannot be exported	n.a.
Transfer: no job submitted, check selection criteria	Transfer: No ROIDs were selected for this job.
Tube anode not at operating speed: low load fluo flavor selected	Degraded image quality due to X-ray tube anode not at operating speed

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
Tube overloaded: low load fluo flavor selected	Degraded image quality due to overloaded X-ray tube
Tube rotor problem: low load fluo flavor selected	Degraded image quality due to X-ray tube anode not at operating speed
Unable to determine the side to correct	It is not known which side to correct
Unexpected CFR or Hemo values	The range for CFR (SFR) needs to be between 0 and 5
Update is not allowed	n.a.
Valve is not correctly indicated	The user has positioned the valve marker on the wrong place
WARNING- Run subtract might fail: write problem	During the acquisition of the first run in a Run-subtract Bolus-chase or Run-subtract Rotational scan procedure a write error occurred, resulting in not having stored one or more images on disk. This may lead to bad run-subtraction results afterwards. The operator can continue and take this risk, or reselect the procedure and start all over again.
WARNING: %1!s! seconds exposure left on image disk.	x sec of exposure can be stored on an almost full image storage disk
WARNING: Acceptance Required	New settings loaded by FS
WARNING: Adjustment of lateral stand required	Reported when the Lateral Stand has lost the stored adjustment data
WARNING: Automatic archiving failure	No automatic archiving for closed examination folder
WARNING: Automatic printing failure	No automatic printing for closed examination folder
WARNING: Automatic write to CD failure	No automatic archiving for closed examination folder
WARNING: AutoWedgeFollow function not available	Autowedge follow function is not available
Warning: Biosense image correction filter active.	Indicates that the BioSense image correction filter is active
Warning: BodyGuard is switched off	The user is warned that during the free interactive FDPA movement the bodyguard is switched off

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
WARNING: DAP measurement not recorded	Area X-ray dose not recorded, call service
WARNING: Exposure stopped, maximum run length reached	Exposure stopped, maximum run length reached
WARNING: flat det. coolant low finish case, call service	Finish case, call service
WARNING: flat det. cooler problem finish case, call service	Finish case, call service
WARNING: flat det. too hot, finish case, call service	Degraded image quality due to 'hot' detector, call service
WARNING: flat detector warming up, lower image quality	Degraded image quality due to 'warming up' of the detector
WARNING: Grabbing stopped, maximum run length reached	Fluoroscopy image grabbing stopped, maximum run length reached
WARNING: Large focus defect, small focus used	X-ray tube large focus defect. Radiation with small focus
WARNING: less than 1000 images can be stored	Less than 1000 exposure images can be stored due to almost full image disk
Warning: Mask-run acquisition not possible	Geometry has no capabilities for making a replay run
WARNING: Move shutters into beam, reduce SID	Move shutters inside X-ray beam to obtain optimal image quality
WARNING: Moving stand or table with Coll. Switch Override	The collision switch of the LArc is overridden
WARNING: Physio data unavailable	No physio data available
Warning: Reduced IQ, Perform pre-scan calibration	Warning for STA prescan calibration
WARNING: Room temp. too high, lower image quality	Lower image quality due to too high room temperature
Warning: Rotate detector before start Rotation scan	n.a.
WARNING: Small focus defect, large focus used	X-ray tube small focus defect. Radiation with large focus
WARNING: spectral filter unavail., may exceed dose lim.	Degraded image quality due to unavailable spectral filter
WARNING: System self test failed, X-ray affected	Self test failed which may affect X-ray

Philips Medical Systems 9896 002 05471

Displayed Message	Action/Meaning
WARNING: TUBE Bodyguard active	The BodyGuard at the tube limits the speed of the C-arm or Propeller to very low speed
WARNING: tube grid defect, radiation w/o grid	X-ray tube grid defect. Radiation without grid, call service
Warning: Write error, run-subtraction might fail	Write error, subtraction might fail
Worklist manager not configured	BWLM not configured
X-ray disabled	Radiation disabled
X-ray not possible, please close door	Radiation disabled due to open examination room door, close door

4.2 System restart

For information about restarting the system, refer to the Allura Xper FD system 'Basic operation' Instructions for Use, section 'Switching the system ON/OFF'.

Philips Medical Systems 9896 002 05471

5 Maintenance

Philips Medical Systems 9896 002 05471

Philips Medical Systems 9896 002 05471

5 Maintenance

5.0 Introduction

To ensure satisfactory operation the Philips Allura Xper FD20 series requires periodic planned maintenance and routine user checks. These are essential to keep the equipment operating safely, effectively and reliably. Planned maintenance may only be carried out by qualified and authorized service technicians. In this context, qualified means those qualified to work on this type of medical electrical equipment in the jurisdiction in which the equipment is being used, and authorized means those authorized by the user of the equipment. Philips is able to provide a full planned maintenance and repair service on either a call basis or a contract basis. Contact your Philips Service Organization.

NOTE ***To ensure that planned maintenance is performed at the prescribed intervals, the user should issue a request, to the maintenance organization, for planned maintenance to be carried out in accordance with the 'Planned maintenance programme' detailed below.***

5.1 Planned maintenance programme

Planned maintenance tasks may only be carried out by qualified and authorized service technicians, and are comprehensively described in the service documentation. A summary of the planned maintenance programme is given in the table below.

WARNING ***Make sure that the system is in the 'disable radiation' mode before you start any maintenance procedure (Review module, |Disable radiation| button [6]). If during maintenance the radiation is not disabled, inadvertent exposure of personnel to radiation can occur. This can cause serious injury.***

Philips Medical Systems 9896 002 05471

Check	Reason	Frequency
Controls and indicators	Check accuracy and functioning of:	
	• All controls	6 monthly
	• All visible/audible indicators	6 monthly
	• Table controls/movements	6 monthly
	• SID	6 monthly
	• Shutter speed	6 monthly
Collision sensors	Check that applied movement is inhibited and that an audible alarm is generated	6 monthly
Oil level	Check oil level and clean oil filter	6 monthly
Earth (ground)	Check maximum earth (ground) of whole system	Yearly
Air filters	Clean	Yearly
Image quality	FD AK check, monitors and stability	Yearly
Allura Xper FD20 series system	Calibrate (Velara generator)	Yearly
End-stops	Check condition (Look for damage)	Yearly
Stand motion	Calibrate	Yearly
PCBs and racks	Ensure secure fitting and check for dust and corrosion	Yearly
Bearings	Check freedom from dust, grease and oil	Yearly
Mechanical	• Counterweight fasteners and cables	Yearly
	• All mechanical stops (limits)	Yearly
	• Brakes and locks	Yearly
	• Grease/lubricate	Yearly
FD cooling	Air filter/liquid filter, check pump	Yearly
FD cooling	Replace coolant	Yearly
FD	Calibrate	2 Yearly
Warning (DHHS) label on Xper module	Check for presence and readability of warning label	2 yearly
Mains transformer secondary windings of mains power distribution unit	Check insulation resistance	2 yearly
Physio/ECG, report printer	Ensure mains electrical supply is provided from a 'Multiple portable socket outlet with insulating transformer'	2 yearly

Philips Medical Systems 9896 002 05471

Check	Reason	Frequency
Alignment	• Collimator alignment and field limitation • Beam alignment and centering	2 yearly 2 yearly
Patient straps	Replace straps	2 yearly
Oil hoses	Replace oil hoses	5 yearly

5.2 Routine user checks programme

The user of the equipment must establish a programme of routine user checks as detailed in the table below. Normally, the user will instruct the operator to perform these checks. However, it is for the operator of the equipment to ensure that all checks have been satisfactorily completed before using the equipment for its intended purpose. Routine user checks may be carried out by the user.

Check	Reason	Frequency
Allura Xper FD20 series equipments	Check for evidence of collision damage	Before the equipment is used
Allura Xper FD20 series equipments	Check the condition of the spacer (if fitted) and the cable protective hoses (ornamental hoses) and ducting	Before the equipment is used
All accessible parts of the stand and table	Check for collision damage	Daily (see note)
All accessories	Availability and integrity	Daily (see note)
All controls	Ensure correct functioning	Daily (see note)
Brakes and wheels	Ensure correct functioning	Daily (see note)
All indicators	Ensure correct functioning	Daily (see note)
Cabling	Inspect for kinks and/or cracks	Daily (see note)
Table cleanliness	Hygiene and to ensure safe and optimum life of equipment	Daily, or as needed
Accessories	To ensure that applicable accessories are fastened securely to the table, especially the footrest	Daily
Radiation shield(s)	Check for cracks or tears (fluoroscopy)	Weekly

Philips Medical Systems 9896 002 05471

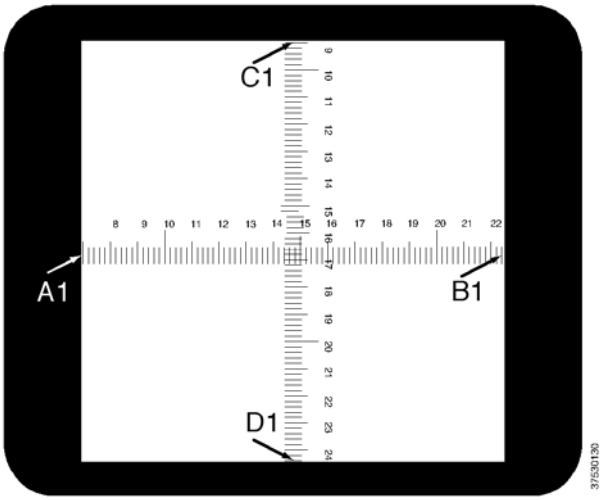
Check	Reason	Frequency
Inscriptions and labels	Check for legibility	Weekly
Frontal C-arm and Lateral ARC-N	To ensure optimum life of equipment check that the tracks are free from dust, grease or other particles	Weekly
XperCT user calibration	To ensure optimum image quality	Daily

NOTE ***Visual and/or audible checks during routine use. Refer to Service documentation.***

5.2.1 Beam limitation

How to check the beam limiting device (shutters)

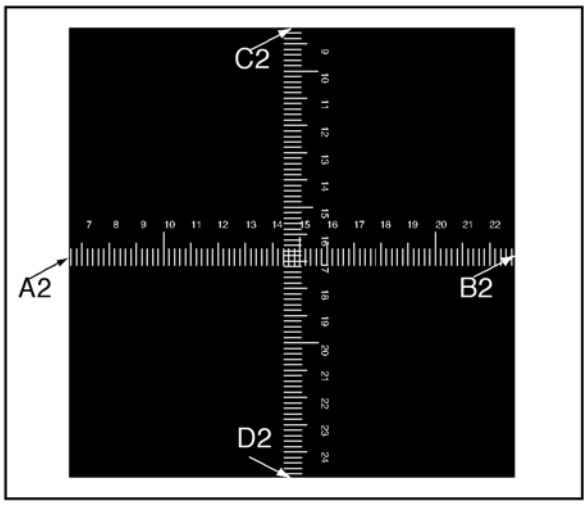
1. Press the |Frontal shutter| joystick [11] on the Xper imaging module to reset the shutters.
2. Position the tabletop horizontally and adjust it to maximum height.
3. Position the C-arm stand (in the frontal position) with the X-ray beam perpendicular to the tabletop.
4. Position two lead rulers crosswise on the tabletop and use tape to attach the rulers.
5. Use the |Frontal SID| joystick [13] on the Xper geometry module to move the Flat Detector as close as possible to the rulers.
6. With the |Detector fieldsize| toggleswitch [1] on the Xper imaging module, select an appropriate Flat Detector field size.
7. Initiate fluoroscopy by pressing footswitch [4], release the footswitch.
8. Use the |Float tabletop| control [1] on the Xper geometry module to position the center of the intersection of the two lead rulers to the center of the image.
9. Initiate fluoroscopy by pressing footswitch [4] and write down the ruler values (A1 to D1), corresponding to the edges of the image (see illustration below).



10 Position an adequate size film cassette on top of the rulers.

11 Expose the film by performing fluoroscopy [4].
The maximum density of the developed film should be 0.9 ± 0.1.

12 Write down the ruler values (A2 to D2) (see illustration below).



13 Determine the distance [X] in cm between the focal spot and the tabletop.

14 For each edge (A to D) calculate the following:
- |Value 2 - Value 1| ≤ X/50.

Philips Medical Systems 9896 002 05471

EXAMPLE A1 = 7; A2 = 6.8 and X = 85, the formula gives:

$|6.8 - 7| \leq 85/50$ (= $0.2 \leq 1.7$), which is OK.

If any calculated value is larger than X/50, the beam limiting device is malfunctioning and Service should be called.

5.3 Remote service

Remote service session

The authorization for performing remote service is part of the service contract. Without this authorization remote service will be disabled.

Remote system modifications and service actions that interfere with normal system use, must be authorized by putting the system in service mode.

Interfering remote service activities can be interrupted at any time by the clinical user in order to resume normal use of the system, e.g. in case of an emergency examination.

Remote service activities are indicated to the user.

WARNING ***In order to allow remote access, the user must switch to the 'Field service' mode. The system remains in this mode, indicated by a visible bar/flag, until the user switches back to the normal operating mode. Runs made when the system is in the 'Field service' mode will be stored under the 'Field service' mode and will not be visible to the user. Always ensure that the system is switched back to the normal operating mode following any remote service activities.***

Remote service functionality is limited in order to guarantee safe operation of the system, independent of the remote service activities. It is not possible to remotely activate any safety related function, such as X-radiation or potentially harmful mechanical movements.

Also, it is not possible to remotely modify Patient or examination information in the systems database.

When extracting data from the system, all private patient information (i.e. name, date of birth, etc.) is omitted.

The remote access protocol is a standard protocol and not dependent on the system's version. The remote service center does not need knowledge about the system version or configuration in order to contact the system.

System availability should be maximum for remote service. The remote service policy includes automatic remote system access during times that the system is not normally used:

- 24 hr data inspection access should be possible. No other functionality is required at that time (Part of system may be down).
- Availability should however not lead to unacceptable system wear, cost or power consumption. A compromise may be needed, e.g. a guaranteed timeslot in which the system is accessible.

It should be possible to load new software parts and parameter sets on the system via the remote service connection:

- Downloaded software and parameter sets will only become available for the clinical user after system verification by the user (for limited modifications) or by an on-site service engineer. When the downloaded software fails, the original situation can be restored.
- The tools used for loading new software must be verified according to the applicable standards.

It will be possible to transfer images from the system to a service PC and vice versa via the central service connection.

Verification test after remote service

After certain remote service actions, a verification test can become necessary. When indicated by Service that a verification test is required, the clinical user shall perform the test procedure as follows:

1. Under fluoroscopy conditions, test the collimator (wedges/shutters) for proper function.
2. Without X-ray radiation, test the movements of the table and the stand for proper function.
3. Test the system for proper behaviour as follows:
   - Set the stand to a vertical position.
   - On the table, position a phantom (lead rulers) in the X-ray beam area.

Philips Medical Systems 9896 002 05471

- Adjust the SID to 1 m (39.4 inches) and select the smallest detector format.
- Perform a fluoroscopy and check if the system behaviour is normal and the kV and mA values indicated on the AGD and the reference monitor are within the specified range.
- Perform a digital cardiac or vascular exposure run and check if the system behaviour is normal and the kV and mA values indicated on the AGD and the reference monitor are within the specified range.

5.4 Anti-virus updates

The Allura Xper FD20 series system is equipped with anti-virus software which is designed to detect viruses on your system and to deny access to infected files, before they can do any damage.

Anti-virus definitions should be updated on a regular basis, usually every day. The Anti-virus definitions update mechanism automatically looks for updated virus definition files at system startup and implements them, if available.

NOTE ***For optimal protection, it is advisable to restart the system as soon as new virus definitions are loaded onto the system.***

5.5 Cleaning and disinfection

Cleaning and disinfection of the Philips' Allura Xper FD20 series will normally be required in connection with most of the intended applications. Guidelines for each are given below.

WARNING ***To avoid electric shock, always isolate the equipment from the mains electrical supply prior to cleaning, disinfecting or sterilizing it.***

CAUTION ***Never allow water or other liquids to leak into the equipment as this may cause short-circuits or corrosion.***

Philips Medical Systems 9896 002 05471

5.5.1 Cleaning

Enamelled parts and aluminium surfaces

Enamelled parts and aluminium surfaces should only be wiped clean with a damp cloth and mild detergent, and then rubbed down with a dry woollen cloth. Never use corrosive cleaning agents, solvent or abrasive detergents or polishes. If you are uncertain of the nature of a cleaning agent, do not use it.

Chrome parts

Chrome parts should only be cleaned by rubbing down with a dry woollen cloth. Do not use abrasive polishes. To preserve the finish, use non-abrasive wax.

Patient straps

The Patient straps can be washed and sterilized. Patient straps should be washed/cleaned, as required, in accordance with the manufacturer's instructions.

5.5.2 Disinfection

All parts of the equipment, including accessories and connecting cables, can be disinfected by wiping them with a cloth dampened with disinfectant. Never use corrosive or solvent disinfectants. If you are in any doubt about the nature of a disinfecting agent, do not use it.

WARNING ***Flammable or potentially-explosive disinfecting sprays must not be used since the resultant vapour could ignite causing injury and/or damage to equipment.***

CAUTION ***Disinfecting a medical equipment room by means of sprays is not recommended since the vapour can penetrate the equipment causing electrical short-circuits or corrosion.***

If non-flammable, non-explosive spray disinfectants are to be used, the equipment must first be switched off and allowed to cool. This prevents convection currents drawing disinfectant mist into the equipment.

Plastic sheeting must be used to cover the equipment thoroughly, following which disinfectant spraying can take place. Once all traces of the disinfectant vapour have dispersed, the plastic sheeting can be removed and the equipment itself can be disinfected in the recommended way.

Philips Medical Systems 9896 002 05471

If a spray has been used, the operator must be satisfied that all traces of the vapour have dispersed before switching the equipment on again. Disinfection techniques for both the equipment and the room must comply with all applicable laws and regulations which have the force of law within the jurisdiction in which the equipment is located.

Philips Medical Systems 9896 002 05471

6 Product disposal

Philips Medical Systems 9896 002 05471

Philips Medical Systems 9896 002 05471

6 Product disposal

6.1 Introduction

Philips Medical Systems is concerned to help protect the natural environment and to help ensure continued safe and effective use of the Allura Xper FD20 series system through proper support, maintenance and training. Philips equipment is therefore designed and manufactured to comply with relevant guidelines for environmental protection. As long as the equipment is properly operated and maintained it presents no risk to the environment. However, the equipment may contain materials which could be harmful to the environment if disposed of incorrectly. Use of such materials is essential for the implementation of certain functions and for meeting certain statutory and other requirements.

This section of the Manual is directed mainly at the user of the equipment or system, the body with legal authority over the equipment. Operators are not usually involved in disposal, except in the case of certain batteries (section 6.4 'Fitting, removing and disposing of batteries').

6.2 Passing the Allura Xper FD20 series system on to another user

If the Allura Xper FD20 series system is to be passed on to another user who is to use it for its intended purpose, then it should be passed on in its complete state. In particular, the existing user should make sure that all the product support documentation - including this Manual - is passed on to the new user. A new user should be made aware of the support services that Philips Medical Systems provides for installing, commissioning and maintaining the equipment or system, and for the comprehensive training of operators. Existing users must bear in mind that passing on medical electrical equipment to new users may present serious technical, medical and legal risks. The original user may remain liable even if the equipment is given away.

Philips Medical Systems 9896 002 05471

Existing users are strongly advised to seek advice from their local Philips Medical Systems representative before agreeing to pass on any equipment. Alternatively, contact Philips Medical Systems at the address given below.

Philips Medical Systems
Dept. Corporate Industrial Policy and Technology
P.O. box 10.000
5680 DA Best, The Netherlands
Fax: +31 40 27 63017

Once the equipment has been passed on to a new user, the previous user may still receive important safety-related information, such as bulletins and field change orders. In many jurisdictions there is a clear duty on the previous user to communicate such safety-related information to new users.

Previous users who are not able or prepared to do this should inform Philips Medical Systems about the new user, so that Philips Medical Systems can provide the new user with safety-related information.

6.3 Final disposal of the Allura Xper FD20 series system

Final disposal is when the user disposes of the equipment or system in such a way that it can no longer be used for its intended purposes.

Philips Medical Systems 9896 002 05471

WARNING ***Do not dispose of the Allura Xper FD20 series system (or any parts of it) with industrial or domestic waste. The system may contain materials such as lead, tungsten or oil, or other hazardous substances that can cause serious environmental pollution. It is advisable to contact your Philips Service Organization before disposing of the Allura Xper FD20 series system.***

Philips gives support for:
- recovery of reusable parts
- the recycling of useful materials by competent disposal companies
- safe and effective disposal of equipment.

For advice and information, contact your Philips Service Organization first, or otherwise Philips Medical Systems at the address below.

Philips Medical Systems
Dept. Corporate Industrial Policy and Technology
P.O. box 10.000
5680 DA Best, The Netherlands
Fax: +31 40 27 63017

6.4 Fitting, removing and disposing of batteries

6.4.1 Battery replacement for remote control

For safe operation, the batteries must be replaced at regular intervals. To replace the batteries, open the cover on the rear of the remote control, remove the old batteries and place new batteries in the position indicated in the battery compartment.
Battery type: Philips 'PENLITE' LR03.

NOTE ***Batteries harm the environment; dispose of the old batteries in an environmentally sound way.***

CAUTION ***Always remove the batteries if the remote control will not be used for some time.***

Philips Medical Systems 9896 002 05471

6.4 Fitting, removing and disposing of batteries

7 Technical data

Philips Medical Systems 9896 002 05471

Philips Medical Systems 9896 002 05471

7 Technical data

7.1 Specifications

7.1.1 Environmental requirements

- Ambient temperature: 15 - 30° C.
- Humidity: 20 - 80%.

NOTE ***In order to allow unrestricted air flow around the cabinets of the Allura Xper FD system, do not place any item(s) on top of the cabinets.***

7.1.2 Mains

	Velara Generator	Main Cabinet
Recording mode of operation	Continuous + short time loading	Continuous
Supply configurations	3 phase Y, 4 wires (L1, L2, L3, PE)	3 phase Y, 4 wires (L1, L2, L3, PE)
Mains Voltage	380 - 460V ± 10%	190 - 600V ± 10%
Max. Mains resistance	≤100mΩ for 380V ≤150mΩ for 400V ≤200mΩ for 440V - 480V	N/A
Hospital Mains fuse	63 Amp slow/blow	43 to 63 Amp slow/blow. Input wiring must be accordingly.
Frequency	50/60Hz	50/60Hz
Measured current: - Standby, - Maximum	 < 2 Amp per phase 290 Amp during 4 mSec pulses	N/A
Power consumption: Operation Fluoro (typical) Operation Exposure (typical)	 3.95 kVA (90kV, 5mA, cont.) 49.9 kVA (90kV, 320mA, 1sec)	Max. 11 kVA
Power Dissipation	870 W (1 Watt = 1 Joule/sec)	650 W (1 Watt = 1 Joule/sec)

Philips Medical Systems 9896 002 05471

The maximum power available for external equipment (3 additional PC modalities including accessories):
- 1400 Watts, at 230 V ± 10%, 50 and 60 Hz.

7.1.3 X-ray generators

- Velara CVFD microprocessor-controlled 100 kW high-frequency converter generator (two generators for biplane systems).
- Minimum exposure time of 1 ms.
- Program selection.
- Voltage range: 40 kV to 125 kV.
- Max current:
  - MRC-GS 04-07: 802 mA at 80 kV.
  - MRC-GS 05-08: 1062.5 mA at 80 kV.
- Automatic kV and mA control for optimal image quality prior to run to safe dose.
- Max continuous power for fluoroscopy: 2.4 kW for 0.5 hour and 2 kW for 8 hours.
- Nominal power (highest electrical power): 100 kW (1000 mA at 100 kV) (IEC 601-2-7/1987)
- Reference loading conditions: 110 kV, 18 mA continuous.
- Pulsed X-ray of 3.75, 7.5, 15 and 30 frames/sec. in monoplane and biplane mode for pulsed fluoroscopy.
- Pulsed X-ray of 0.5 to 6 frames/sec. for digital subtracted acquisition in monoplane and biplane mode.
- Pulsed X-ray up to 6 frames/sec. for digital acquisition in monoplane and biplane mode. 15 and 30 frames/sec. optional.
- Noise < 55 dB(A).

7.1.4 X-ray tubes

MRC-GS 04-07 and cooling unit CU 3101 (frontal)

- Maximus ROTALIX Ceramic tube MRC-GS 04-07 with anode heat storage capacity of 2.4 MHU and 0.4/0.7 mm nominal focal spot values, maximal 30 and 67 kW short time load.
- Grid switching at pulsed fluoroscopy
- Continuous loadability: 3400 W (at 21 degrees Celsius room temperature)
- Dose management with SpectraBeam filtration, with 0.2, 0.5, 1 mm CU eq.

Philips Medical Systems 9896 002 05471

- Tube housing ROT-GS 1004 for oil-cooled X-ray tube with thermal safety switch
- Cooling unit heat exchanger for direct and continuous forced cooling with oil
- High Voltage cables.

MRC-GS 05-08 and cooling unit CU 3101 (lateral)

- Maximus ROTALIX Ceramic tube MRC-GS 05-08 with anode heat storage capacity of 2.4 MHU and 0.5/0.8 mm nominal focal spot values, maximal 45 and 85 kW short time load
- Grid switching at pulsed fluoroscopy
- Continuous loadability: 3400 W (at 21 degrees Celsius room temperature)
- Dose management with SpectraBeam filtration, with 0.2, 0.5, 1 mm CU eq.
- Tube housing ROT-GS 1003 for oil-cooled X-ray tube with thermal safety switch
- Cooling unit heat exchanger for direct and continuous forced cooling with oil
- High Voltage cables.

7.1.5 LCD monochrome and colour monitors (18 inch)

- Weight: 7.7 kg
- Size (width x height x depth): 41.0 x 36.2 x 10.5 cm (16.1 x 14.3 x 4.1 in)
- Mains voltage: 90 - 264 V
- Mains frequency: 50 - 60 Hz
- Maximum power consumption: 70 W.

7.1.6 LCD monitor ceiling suspension and actuator

Weight, load and dimensions:

Type	Max. total weight (kg)	Width x Height x Depth (mm)
2-fold	115	850 x 590 x 400 (mono-plane only)
3-fold	145	1424 x 790 x 524 (mono-plane only)
4-fold	155	1250 x 1150 x 524
6-fold	180	1424 x 1150 x 524

Philips Medical Systems 9896 002 05471

Movement range:

Type	Longitudinal (mm)	Lateral (mm)	Vertical (mm) Ceiling height 2900 mm
2-fold	ca. 3600	ca. 3000	520 (mono-plane only)
3-fold	ca. 3600	ca. 3000	520 (mono-plane only)
4-fold	ca. 3600	ca. 3000	320
6-fold	ca. 3600	ca. 3000	320

Actuator

- Mains voltage: 230 V
- Mains frequency: 50 - 60 Hz
- Maximum power consumption: 500 W
- Maximum speed: 12 mm/s (0.5 in/s).

7.1.7 Examination light

- Light intensity: 30,000 Lux.
- Colour temperature: 4300° K.
- Colour rendering index Ra: 96.
- Focusable light field size: 14 - 25 cm (5.5 - 9.8 inch).
- Working distance: 70 -140 cm (27.6 - 55.1 inch).
- Light intensity at 30,000 Lux: 114 W/m^2.
- Lamp type: halogen 22.8 / 24 V 50 W.
- Mains power: 220/240 V.

7.1.8 Automatic wedge filter

One or two semi-transparent wedge-shaped filters, automatically or manually adjusted to the projector.

7.1.9 Imaging chain (per channel)

Frontal channel

30 x 40 cm (12 x 16 inch) six mode Flat Detector subsystem:

- 7 input fields with the following image format (field of view) sizes are available at all SID positions:
  - 48 cm (19 inch)
  - 42 cm (17 inch)
  - 31 cm (12 inch)

Philips Medical Systems 9896 002 05471

  - 26 cm (10 inch)
  - 22 cm (9 inch)
  - 19 cm (7.5 inch)
  - 15 cm (6 inch).
- FD rotation: 90°
  - Time to rotate from portrait to landscape (and vice versa): 3 sec.
  - Maximum rotation speed: 45°/sec.
- Pixel size: 154 x 154 µm
- Detective Quantum Efficiency (DQE): >73% at low spatial frequencies.
- Spatial resolution properties:

MTF	
1.0 lp/mm	>60%
2.0 lp/mm	>30%
nyquist	>15%

- Dynamic range linear within 2% up to 4300nGy.
- Output digital video: 1960 x 2480 image matrix, at 14 bits depth for the largest mode.
- Acquisition speed:
  - 0.5, 1, 2, 3, 4 and 6 fps standard and 15, 30, 50 and 60 fps optional.
  - image resolution up to 1960 x 2048 pixels for vascular monoplane imaging.
- Fluoroscopy speed: 3.75, 7.5, 15 and 30 frames per second at 1024 x 1024.

Lateral channel

30 x 30 cm (12 x 12 inch), triple mode Flat Detector subsystem:

- 6 input fields with the following image format (field of view) sizes are available at all SID positions:
  - 42 cm (17 inch)
  - 31 cm (12 inch)
  - 26 cm (10 inch)
  - 22 cm (9 inch)
  - 19 cm (7.5 inch)
  - 15 cm (6 inch).
- Pixel size: 154 x 154 µm
- Detective Quantum Efficiency (DQE): >73% at low spatial frequencies.
- Spatial resolution properties:

Philips Medical Systems 9896 002 05471

MTF	
1.0 lp/mm	>60%
2.0 lp/mm	>30%
nyquist	>15%

- Dynamic range linear within 2% up to 4300nGy.
- Output digital video: 1960 x 2480 image matrix, at 14 bits depth for the largest mode.
- Acquisition speed:
  - 0.5, 1, 2, 3, 4 and 6 fps standard and 15 and 30 fps optional.
  - image resolution up to 1960 x 2048 pixels for vascular biplane imaging.
- Fluoroscopy speed: 3.125, 6.25, 12.5 frames per second at 1024 x 1024.

Geometrical fill factor (per channel)

The geometrical fill factor is the fraction of the pixel area sensitive to the incoming signal, which can be divided into two parts:

- The geometrical fill factor of the photodiode, also called optical fill factor, is 69%.
- The geometrical fill factor of the scintillator, also called X-ray fill factor, is 100%, due to a continuous scintillator.

Quantum limited performance

The operation range of the sensor is specified to be operated with system doses between 10nGy and 4300nGy, at a maximum speed of 30 frames per second. Within this range the device is operated quantum limited.

7.1.10 Beam carriers

Frontal channel, floor mounted C-arm stand

- Rotation speed: 0 - 25°/s (variable) (these speeds are only valid when the stand is in its working position, otherwise the maximum speed is 8°/s).
- Angulation speed: 0 - 25°/s (variable) (these speeds are only valid when the stand is in its working position, otherwise the maximum speed is 8°/s).
- Projection angles: see table below.

C-arm position	Angulation (degrees)	Rotation (degrees)
Head-end of table	90 caudal to 90 cranial	120 LAO to 185 RAO

9896 002 05471 Philips Medical Systems

- The X-ray beam field is always aligned with the image receptor area and the reference axis is always perpendicular to the image receptor plane.
- Isocenter to floor: 113.5 cm (44.7 inch).
- Focal spot to isocenter: 81 cm (31.9 inch).
- Focal spot to FD (SID): 89.5 to 119.5 cm (35.2 to 47 inch).
- FD movement speed: 10 cm/s (towards patient); 15 cm/s (away from patient).
- Throat depth: 90 cm (35.4 inch).
- Motorized stand rotation: 90° left to 90° right.
  - Stand rotation speed: 12°/s.

Rotational scan

- From 185° RAO (-rotation) to 120° LAO (+rotation) (stand in its head position parallel to the table (propeller movement)) at a speed of up to 55°/sec.

Lateral channel, ceiling suspended Lateral ARC-N (double C-arc)

- Rotation and angulation speed: 8 °/s.
- Projection angles: see table below.

L-arc position	Angulation (degrees)	Rotation (degrees)
Head-end of table	45 Caudal to 45 cranial	27 RAO to 115 RAO

- The X-ray beam field is always aligned with the image receptor area and the reference axis is always perpendicular to the image receptor plane.
- Iso-center to floor: 113.5 cm (44.7 inch).
- Focal spot to iso-center: 76.5 cm (30.1 inch).
- Focal spot to image intensifier (SID): 87.5 to 130.3 cm (34.4 to 51.3 inch).
- FD movement speed: 6 cm/s (towards patient); 9 cm/s (away from patient).
- Longitudinal movement: 300 cm (118 inch) (manual or motorized).
- Motorized longitudinal movement speed (optional): 12 cm/s (outside working area), 6 cm/s (inside working area).
- Minimum ceiling height: 297 cm (117 inch).

Philips Medical Systems 9896 002 05471

7.1.11 Xper Table

Patient support

- Dimensions:

Neuro tabletop dimensions

Cardio tabletop dimensions

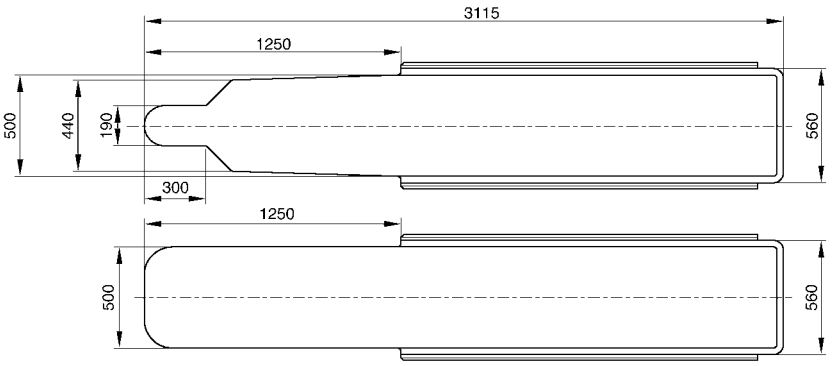


Figure 7.1 Xper tabletop dimensions

- Maximum patient weight: 250 kg.
- Additional weight reanimation equipment: 50 kg.
- Maximum weight of all accessories (total): 25 kg.
- Movements:
  - Lateral movement stroke: 180 mm.
  - Lateral motorized movement (maximum) speed:150 mm/sec. ±20 mm/sec.
  - Longitudinal movement stroke: 1200 mm.
  - Longitudinal motorized movement speed: 150 mm/sec. ±20 mm/sec.
  - Height movement is always motorized.
  - Height movement stroke: 785-1065 mm (distance between upper side of tabletop and floor.
  - Height movement stroke with swivel applicable: 865-1145 mm.
  - Height movement (fixed) speed: 30 mm/sec. ±2 mm/sec.
  - Tilt movement is always motorized.
  - Tilt movement angle range: -20° to 20°.
  - Tilt movement (fixed) speed: 2°/sec ±0.2°/sec.

Philips Medical Systems 9896 002 05471

- Pivot movement is always manual.
- Pivot movement angle: 180°/-90° or 90°/-180°.
- Mechanical arret positions: 0°, ±13° and ±90°.

- Swivel movement is always motorized.
- Swivel movement stroke: 782 mm.
- Swivel movement (maximum) speed: 20°/sec.

- Cradle movement is always motorized.
- Cradle movement angle: ±20°.
- Cradle movement (fixed) speed: 4°/sec ±0.4°/sec.

7.1.12 Ceiling suspended radiation shield

The ceiling suspended radiation shield comprises:
- 75/90 cm counter balanced two section suspension arm
- 40 x 50 cm tiltable lead acrylic shield, lead equivalence 0.5 mm Pb
- 35 x 50 cm lead apron, lead equivalence 0.5 mm Pb.

The total weight of the radiation shield and arm is 19 kg.

7.1.13 Accessory bracket for ceiling suspended radiation shield

Accessory bracket for mounting the ceiling suspended radiation shield, comprising:
- mounting spigot with a 32 mm diameter groove for securing the ceiling suspended radiation shield.

Mechanical rating: 200 Nm maximum.

7.1.14 Contrast medium power injectors

- ANGIOMAT Illumina
  - Synchronized with the system.
- MEDRAD Mark V ProVis
  - Synchronized with the system.
- MEDRAD Atlanta
  - Synchronized with the system.
- ACIST Voyager E2000
  - Synchronized with the system.
- ACIST CVI
  - Synchronized with the system.

Philips Medical Systems 9896 002 05471

7.1.15 Storage media

Xcelera DICOM Recorder

- Refer to the Xcelera DICOM Recorder 'Instructions for Use'.

7.1.16 Network data

Xper DICOM image interface

- Maximum Ethernet transfer speed (see note): 100 Mbit/s.
- Transfer speed for images (see note): 2 Mbyte/s.

RIS/CIS DICOM interface

- Maximum Ethernet transfer speed (see note): 10 Mbit/s.

NOTE ***Transfer speeds mentioned above depend on the local situation (network load and external station).***

Philips Medical Systems 9896 002 05471

7.2 Stray radiation

7.2.1 Protection against stray radiation

Technique factors: 110kV, 3600 mAs, no additional filter

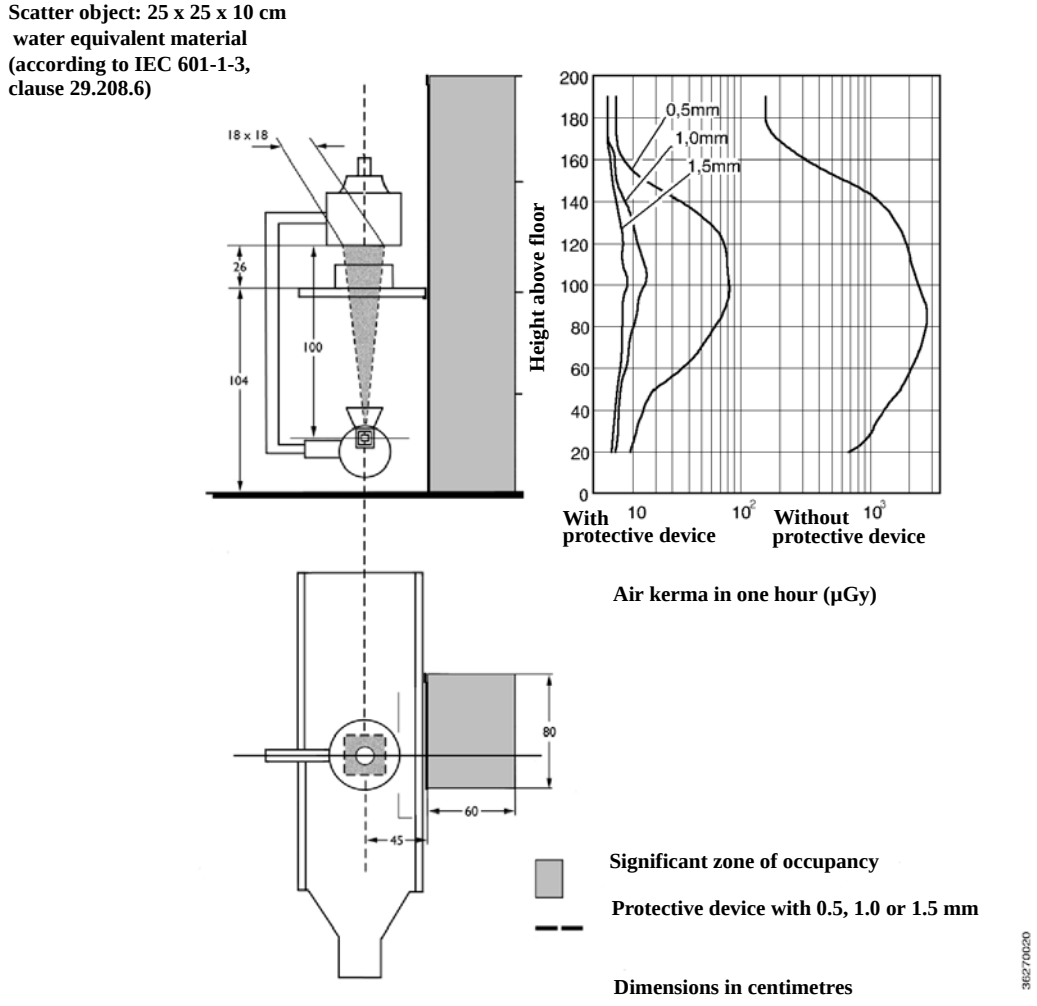


Figure 7.2 Technique factors graph

NOTE ***As you can see in the illustration, the protective device lowers the AK by at least one order of magnitude.***

The indicated 'significant zone of occupancy' is designated to be used for radiologic examinations according to section 1.4 'Intended use'.

Influence of additional filtering on protection against stray radiation

Figure 7.2 presents the protection against stray radiation, if no additional filter is applied.

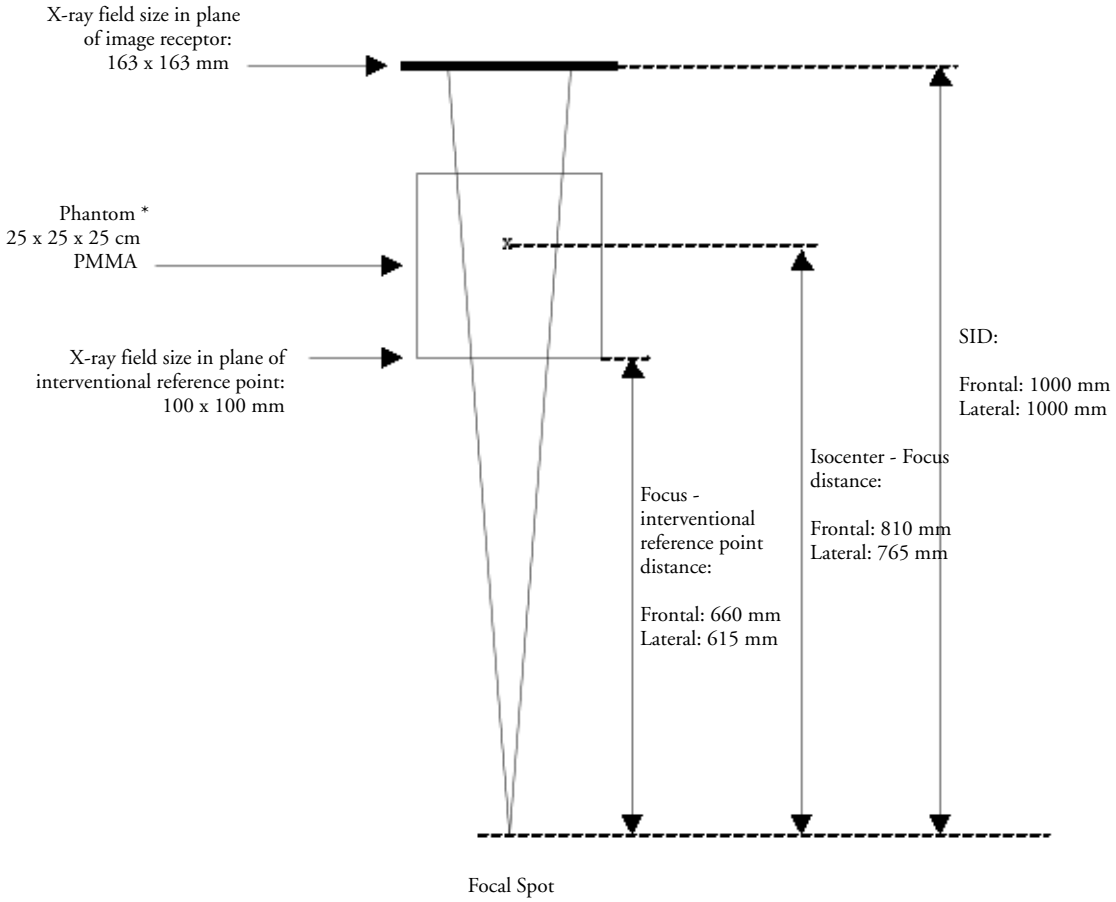
The following table presents the AK values as percentages of the curves as function of the additional filter selection (for filter selection see section 2.8 'Radiation safety').

kV	Filter	Reduction (%)			
		No protection	0.5 mm lead equivalence	1.0 mm lead equivalence	1.5 mm lead equivalence
110	0	100	100	100	100
	1	66	87	85	76
	2	38	69	64	53
	3	19	49	47	32
90	0	64	33	34	46
	1	39	27	24	31
	2	19	20	15	17
	3	8.5	12	9.0	9.2
70	0	35	6.0	13	22
	1	18	4.1	7.2	12
	2	7.1	2.4	3.1	4.6
	3	2.3	1.3	1.0	1.9

Philips Medical Systems 9896 002 05471

7.2.2 Stray radiation, isokerma data

Measurement configuration for Allura Xper FD20/20



*) Scatter object 25 x 25 x 25 cm Polymethyl-methacrylate (PMMA) according to IEC 60601-2-43, clause 29.208.101

Figure 7.3 Measurement configuration graph

Normalized isokerma map at 1 m (39.37 in.) above floor, for Allura Xper FD20/20 stand, frontal position

Technique factors: Fluoroscopy 120kV, no additional filter

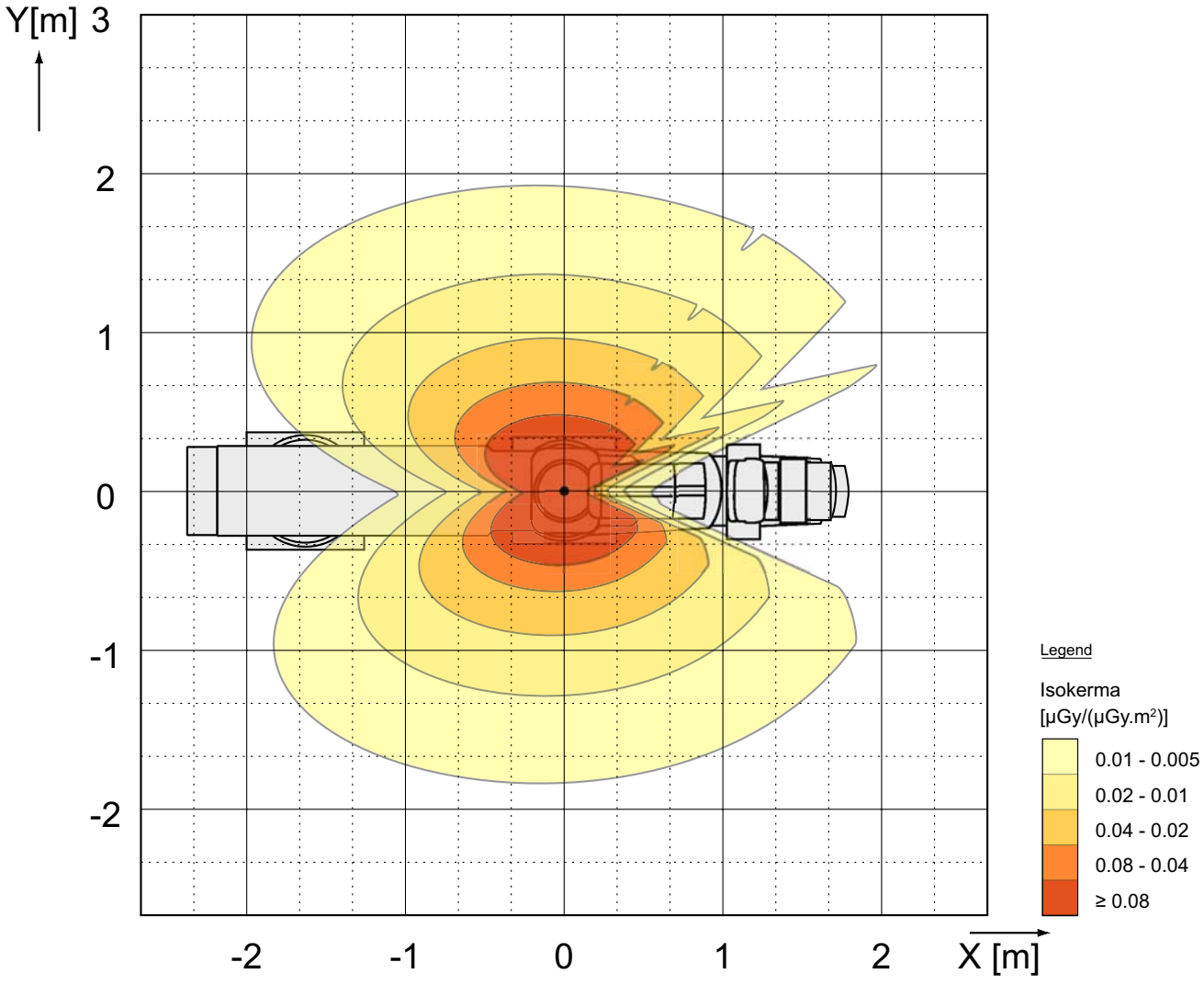


Figure 7.4 Isokerma map at 100 cm (39.37 inch) height

Normalized isokerma map at 1.5 m (59.10 in.) above floor, for Allura Xper FD20/20 stand, frontal position

Technique factors: Fluoroscopy 120kV, no additional filter

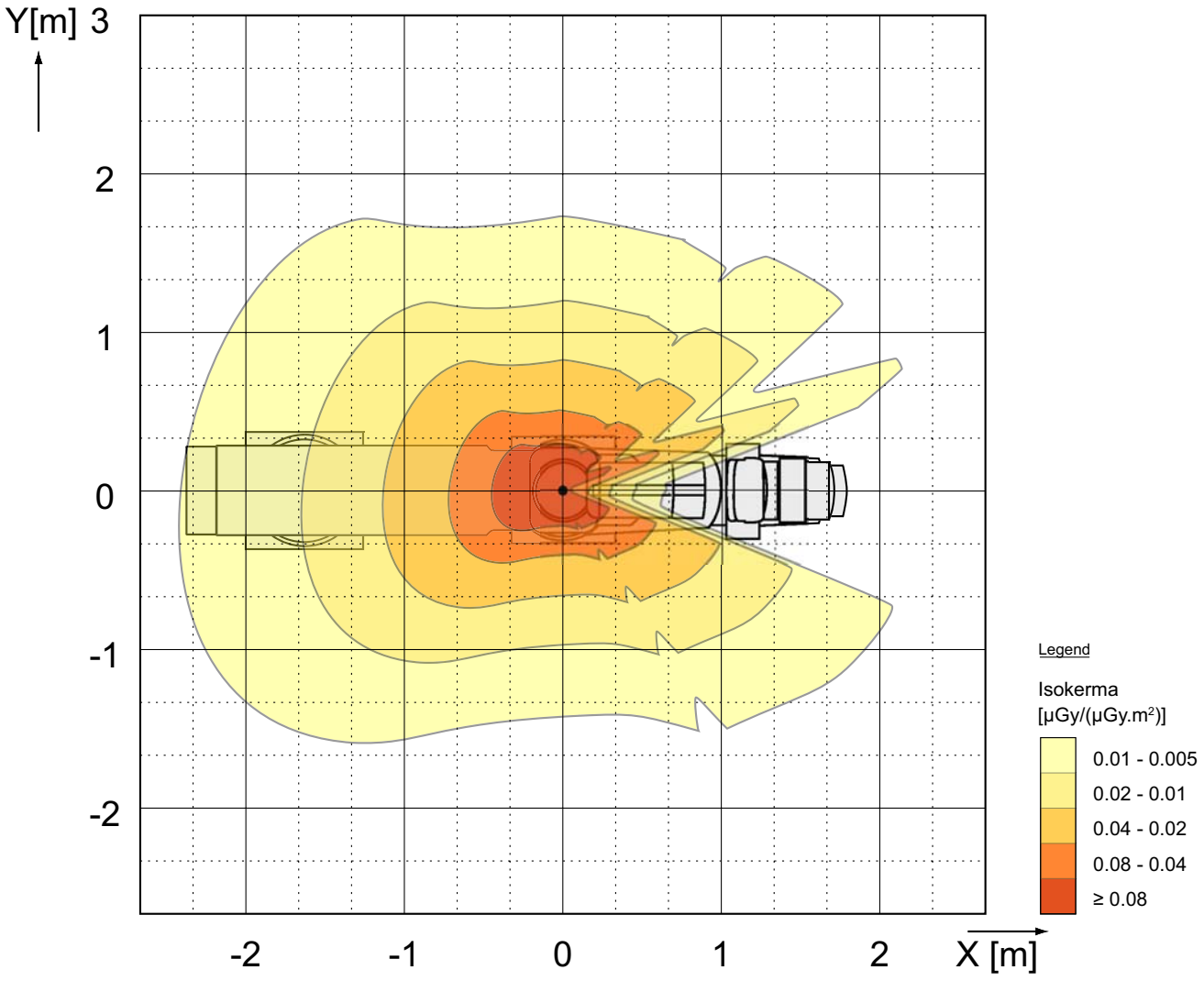


Figure 7.5 Isokerma map at 150 cm (59.10 inch) height

Normalized isokerma map at 1 m (39.37 in.) above floor, for Allura Xper FD20/20 stand, lateral position

Technique factors: Fluoroscopy 120kV, no additional filter

New picture here, showing isokerma mappimg for FD20/20 system.

Figure 7.6 Isokerma map at 100 cm (39.37 inch) height

Normalized isokerma map at 1.5 m (59.10 in.) above floor, for Allura Xper FD20/20 stand, lateral position

Technique factors: Fluoroscopy 120kV, no additional filter

New picture here, showing isokerma mappimg for FD20/20 system.

Figure 7.7 Isokerma map at 150 cm (59.10 inch) height

Influence of additional filtering on isokerma maps

The isokerma maps in Figure 7.4 through Figure 7.7 present the normalized stray radiation data, if no additional filter is applied

The following table presents the normalized AK values as percentage of the curves as function of the additional filter selection (for filter selection see section 2.8 'Radiation safety').

Additional filter used	Percentage of normalized AK values
0	100
1	160
2	290
3	530

Philips Medical Systems 9896 002 05471

8 Appendices

Philips Medical Systems 9896 002 05471

Philips Medical Systems 9896 002 05471

8 Appendices

8.0 Introduction

This section provides the user with additional background and supporting information.

Section	Description
8.1	Standards and regulations
8.2	Safety devices for stand and table movements
8.3	Glossary
8.4	EMC compliance
8.5	Abbreviations

8.1 Standards and regulations

The Philips equipment complies with all relevant national and international standards and laws. Information on compliance with these standards will be issued, on request, by your Philips Medical Systems representative or by contacting:

Philips Medical Systems
Dept. Corporate Industrial Policy and Technology
P.O. box 10.000
5680 DA Best, The Netherlands
Fax: +31 40 27 63017

8.1.1 Measurement of technical parameters

The following measurements are required in order to check compliance of the technical parameters of the system:

Philips Medical Systems 9896 002 05471

Peak tube voltage during continuous fluoroscopy

Direct kVp measurements should never be made with the HV dividers normally supplied to field service. The kVp is factory calibrated for FDA compliance. The kVp must be measured with a digital voltmeter connected to measuring points EH:X3 (AV-HV) and EH:X30 (GND) at pcb 'DIG kV/mA', where 1 V equals 20 kVp.

Peak tube voltage during radiography, cine fluorography and pulsed fluoroscopy

Direct kVp measurements should never be made with the HV dividers normally supplied to field service. The kVp is factory calibrated for FDA compliance. The kVp must be measured with an oscilloscope connected to measuring points EH:X3 (AV-HV) and EH:X30 (GND) at pcb 'DIG kV/mA', where 1 V equals 20 kVp.

Tube current during continuous fluoroscopy

Measured with a digital mA meter connected, instead of the 'mAs' plug, onto EG:100. The measured mA value must be corrected by subtracting the current flowing via the measuring divider resistor, by the following expression:

$$I_{\text{divider resistor}} = kV_{\text{set}} / 2 \times R_{\text{divider resistor}}$$

where: the value R of the divider resistor is equal to 100Mohms for non GS-tubes and 70Mohms for GS-tubes.

Tube current during radiography and cine fluoroscopy

The peak value of the tube current is measured with an oscilloscope connected via a RC-filter onto EG:100 (mAs plug) and GND, (Figure 11-1), where 1 V equals 200 mA. The measured value has to be corrected by subtracting the current flowing via the measuring divider resistor, by the following expression:

$$I_{\text{divider resistor}} = kV_{\text{set}} / 2 \times R_{\text{divider resistor}}$$

where: the value R of the divider resistor is equal to 100Mohms for non GS-tubes and 70Mohms for GS-tubes.

Tube current during pulsed fluoroscopy

The peak value of the tube current is measured with an oscilloscope connected via a RC-filter onto EG:100 (mAs plug) and GND, (Figure 11-1), where 1 V equals 200 mA. The measured value has to be corrected by subtracting the current flowing via the measuring divider resistor, by the following expression:

$I_{\text{divider resistor}} = kV_{\text{set}} / 2 \times R_{\text{divider resistor}}$

where: the value R of the divider resistor is equal to 100Mohms for non GS-tubes and 70Mohms for GS-tubes.

The average tube current, Ipulsed fluoro, is calculated by means of the expression:

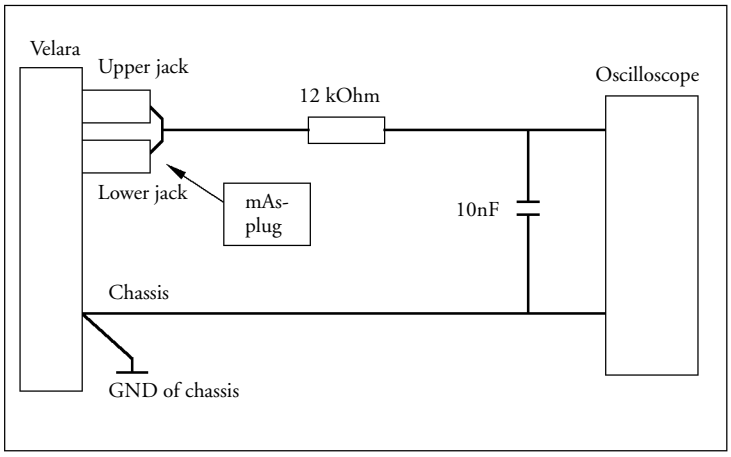
$I_{\text{pulsed fluoro}} = I_{\text{peak}} \times t \times f$

where: I = electrical current [A], t = exposure time [s] and f = frequency [Hz]

Exposure time

The exposure time is measured with an oscilloscope connected to measuring points EH:X3 (AV-HV) and EH:X30 (GND) at pcb 'DIG kV/mA', where 1 V equals 20 kVp. The exposure time is the time during which the measured kV remains equal to or greater than 75% of the maximum value.

Philips Medical Systems 9896 002 05471



mAs

Measured with a digital mAs meter connected, instead of the 'mAs' plug, onto EG:100. The measured mAs value must be corrected with the mAs product of the current flowing via the measuring divider resistor, by the following expression:

$mAs_{divider} = I_{divider} \times$ Exposure time

Indicated values and readings are accurate within the following limits:

Parameter	Range	Accuracy
kV (continuous fluoroscopy)	40 - 110 kV	</= 3%
kV (cine fluorography, radiography)	40 - 125 kV	</= 3%
kV (pulsed fluoroscopy)	40 - 110 kV	</= 3%

Philips Medical Systems 9896 002 05471

Parameter	Range	Accuracy
mA (continuous fluoroscopy)	0.2 - 30 mA	</= 2% ± 0.1 mA
mA (fluorography, radiography)	1 - max. mA max. mA according to tube type	</= 8% ± 0.1 mA, t_{exp} < 35 ms </= 3% ± 0.1 mA, t_{exp} >/- 35ms
mA (pulsed fluorography)	1 -30 mA (average value)	</= 8% ± 0.1 mA, t_{exp} < 35ms
Exposure time (cine fluorography, radiography, pulsed fluoroscopy).	1 ms - 16 s	</- 2% ± 0.1 ms
Post exposure time display	1 ms - 16 s	</- 2% ± 0.1 ms
mAs	0.5 - 850mA	</- 2% ± 0.1 mAs

NOTES

- ***Tolerances do not allow for inaccuracies of measurement.***
- ***t_{exp} in seconds, f in Hz.***

8.1.2 Security and Privacy Requirements

It is the policy of Philips Medical Systems to adhere to all the required standards and regulations. To assist the hospital in fullfilling the Health Insurance Portability and Accountability Act (HIPAA) requirements, introduced by the United States Department of Health and Human Services, the following functionality has been added to the Allura Xper FD20 series system:

Access control

Intended to restrict access to the system to authorized users only:

- customisable on/off, a user log-on/log-off procedure is required to gain access to the system
- access to the system is granted according to a customisable list of authorised users
- a separate list of user-accounts is included, but which is not integrated with the Xper settings physician list.

Philips Medical Systems 9896 002 05471

Audit trail

Required to log user activities which are information-security critical:
- applies to logging-on, reading and/or modifying clinical information
- requires that means be provided for auto-backup on a hospital server, e.g. the use of an external standard 'Syslog' server.

Network time synchronization

Intended to synchronize system time to an external time-standard:
- uses a standard Network Time Protocol (NTP)
- the coupling is configured by Field Service during system installation.

Security and node authentication

Intended to secure the exchange of clinical data and restrict this exchange to pre-determined nodes:
- Applies to RIS/CIS and PACS nodes, e.g. archives and viewers
- does not apply to e-mail data, e.g. clinical reports sent via e-mail
- does not apply to Field Service access
- uses standard Transport Layer Security Protocol
- the user can decide at installation to use encryption (this may result in reduced performance).

Computer systems cannot be guaranteed to be safe in an insecure network. The user should provide some level of network protection e.g. installing firewalls.

Implementation

In order to meet the requirements described above the Allura Xper FD20 series implements the solution defined by the Integrating the Healthcare Enterprise (IHE) year 4 Basic Security profile.

The Basic Security Integration Profile establishes security measures which, together with the Security Policy and Procedures of the Enterprise, provide patient information confidentiality, data integrity and user accountability.

The following IHE roles can be identified within the Allura Xper FD20 series system:
- modality
- image creation
- image display
- secure node.

Philips Medical Systems 9896 002 05471

In order to fulfil these roles, and to implement the Basic Security Profile, the Allura Xper FD20 series system must be able to generate messages relating to:
- security and networking related changes made via Field Service
- system starting and shutdown (the system plays a part in a number of IHE roles, as detailed above. It will not, however, generate a message for the start-up of each activity. This is because these roles are initiated in parallel and too many messages would need to be generated)
- export of images, e.g. examination printed on film or paper, or examinations saved to a file for Field Service
- examinations transfer to a remote network node
- examination deletion, i.e. examinations not 'Scheduled', 'Prepared' or 'Completed', or with origin 'Other'
- examinations which are 'In progress'
- user authentication
- security alerts, i.e. secure node authentication failure or invalid certificate.

Field Service

Field Service is used to enable the following configuration items based on information supplied by the hospital:
- authentication and encryption
- time synchronization
- configuration of the 'Syslog' server
- configuration of any other programs, e.g. tools used to install certificates.

Certificates

Certificate requests should be handled by the hospital. The hospital should decide on a procedure to create the Certificate request and import the certificates.

The hospital should also define the types of certificates required, for example:
- the certificate of the machine itself
- the certificates of the machines it chooses to trust
- the certificate of the Certificate Authority (CA).

Certificates should always be signed by someone else, i.e. no self-signed are allowed. However, the signer of the certificate need not be present on the system. Self-signed certificates are the certificates required by the Integrating the Healthcare Enterprise (IHE).

The following should also be specified:
- the location of the certificates (local machine)
- the location of the tools for certificate installation.

Philips Medical Systems 9896 002 05471

Certificates should be used between nodes to enable them to validate the identity of each other.

It is the responsibility of the Integrating the Healthcare Enterprise (IHE) to define the maximum validity period of certificates in its security policy.

8.1.3 Type B symbol

The type B "applied part" symbol can be found on the patient table:

Figure 8.1 Type B 'applied part' symbol

Definition 'applied part'

A part of the equipment which in normal use:

- must come into physical contact with the patient for the equipment to perform its function, or
- can be brought into contact with the patient, or
- needs to be touched by the patient.

Where normal use is defined as follows:
Operation (including routine inspection and adjustments by the operator and stand-by) as described in the instructions for use.

8.1.4 Image Tests

Results from a clinical evaluation of the Philips dynamic Flat Detector show that images produced in both fluoroscopy and acquisition are similar or better than the current level of Philips Image Intensifier/TV images.

The general impression is that the noise is less obtrusive on the detector imaging in comparison with the Image Intensifier/TV imaging.

Some stents and angioplasty wires are more visible with the dynamic Flat Detector than with the conventional Image Intensifier/TV.

Fluoroscopy imaging in steep angles and rotations, i.e. 'Spider' view, is improved with the dynamic Flat Detector.

Philips Medical Systems 9896 002 05471

8.1.5 Typical Air Kerma

For typical data see Addendum 'Reference Air Kerma (rate) for Allura Xper FD20 series'.

8.2 Safety devices for the stand and table movements

WARNING ***During execution of both manual and motorized movements of the C-arm, Lateral ARC or the table, the operator is responsible for the safety of patient, staff and equipment. The operator must avoid collisions in order to prevent serious injury to patient and staff or damage to the equipment.***

The system is provided with several safety devices to help the operator avoid collisions and carry out the appropriate movements.

See also, the Allura Xper FD system 'Basic Operation' Instructions for Use, section 'BodyGuard and collision switch protection'.

NOTE ***The safety features apply to motorized movements only.***

The system is provided with the following safety features:

- 'dead mans' principle
- bodyguards
- collision switches
- balanced movements
- slip clutches
- soft collision technology
- reduced performance.

Dead mans' principle

All movement controls must be kept activated by the operator to start and continue a motorized movement. Releasing the control stops the movement. A degree of run-out must be taken into account depending on the speed of the movement.

Philips Medical Systems 9896 002 05471

BodyGuards

A BodyGuard is not a switch device but a device that senses distance and controls the maximum permitted speed of the movement. All motorized movements of the C-arm and table are controlled by the BodyGuard system.

The system will protect the patient by slowing down movement speeds when an object is detected within a certain safety distance. The detection system does not prevent all collisions, but due to the reduced movement speeds these collisions will not be harmful if they occur.

WARNINGS

- ***During execution of a rotational scan, all BodyGuard sensors are switched off.***
- ***BodyGuard sensors are switched off when the 'Smart BodyGuard override' function is active.***

Biosense® compatibility

When the Biosense® Electro Physiology system is applied in combination with the Allura Xper FD20 series system, the Biosense® coil, mounted under the tabletop, interferes with the Allura system in the following ways:

- When the Biosense® coil is activated, it will impair the normal operation of the X-ray tube cover BodyGuard sensor on the frontal stand such that it is not reliable.
- The frontal stand can collide with the Biosense® equipment mounted under the tabletop because the X-ray tube cover BodyGuard sensor is not sensitive to the Biosense® equipment.

Collision switches

The collision switches on the Lateral ARC will detect a collision and stop motorized movements to prevent injury to the patient and personnel, or damage to equipment. Collision switches are not active when the Lateral ARC is in the parked position.

WARNING

Collision switches are switched OFF when the 'Collision Override Mode' function is active. It is the responsibility of the operator to ensure that the stand will be moved away from the collision situation.

Balanced movements

If movement of a device is balanced, e.g. the stand rotation movement, it can be carried out manually.

Philips Medical Systems 9896 002 05471

Slip clutches

Slip clutches are provided between motor and drive. They only operate in balanced movements. If a collision occurs and the motor keeps running, the clutch starts slipping thus limiting the collision impact.

Soft collision technology

The maximum motor current is calibrated to be just greater than that required for normal movement. During operation all motor currents are continuously monitored. If a collision occurs the current will increase until it attains the calibrated threshold value. The stand will then automatically back-off from the object by a short reverse movement to clear the collision.

Reduced performance

If the BodyGuard becomes defective, stand movements are only possible at reduced speed. Meanwhile a message is displayed on the Xper On Monitor Display of the Reference monitor and the Acquisition and Geometry Display of the Data monitor to alert the operator to this situation.

Xper patient table

All the motorized table movements are monitored and controlled by the BodyGuard system on the C-arm stand.

WARNINGS

- ***The BodyGuard sensors must be kept dry, otherwise the BodyGuard system will operate with reduced efficiency and the maximum speeds are limited to 8°/s. An audible warning is sounded during movement and a warning message is displayed on the Xper On Monitor Display on the Reference monitor [xx] and the Acquisition and Geometry Display on the Data monitor [xx]. Collisions must be avoided as this can cause injury to the patient and/or damage to the equipment.***
- ***The safety devices only operate if the stand and table are in a normal working position and normal projections are applied. If other stand positions and projections are applied during operations a collision can occur while the moving part is out of range of a BodyGuard sensor or a collision sensor. Such collisions must be avoided as they can cause injury to the patient. If the table is pivoted by more than 13° the BodyGuard cannot fully safeguard the patient during rotation and angulation movements.***
- ***Do not place a solid non conducting object on the patient as such objects cannot be detected by the BodyGuard sensor. A collision can then occur with the object causing injury to the patient.***

Philips Medical Systems 9896 002 05471

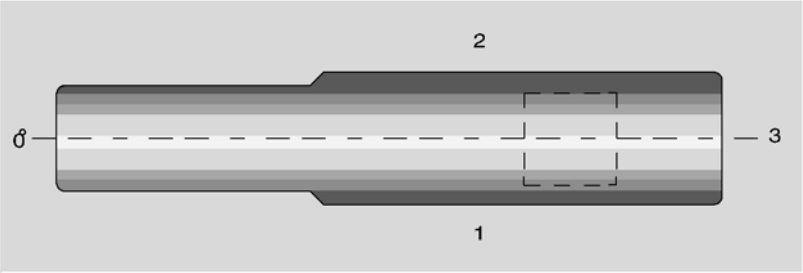
- ***When the tabletop is fully extended towards the C-arm, do not lower it and do not angulate the C-arm caudally as the tabletop can collide with the inside of the C-arm trapping the patient's fingers.***

CAUTION ***If extreme projections are required, there is risk of collision between the C-arm stand and an operating module and/or table mounted radiation protection device. This must be avoided as it can cause damage to the equipment.***

8.3 Glossary

8.3.1 System definitions

Doctor and nurse side of table



Top view of patient table

1 Doctor side
2 Nurse side
3 Foot end

The 'doctor side' is the right side of the table, which is defined as the right side of the patient. The patient lies on his/her back on the table with feet pointing towards the tablebase. With this patient orientation, the left side of the table is the 'nurse side' and the 'foot-end' is the side towards which the patient's feet are pointing.

Acquisition examination

An acquisition examination is automatically created if a scheduled patient record is selected for Acquisition at the Data monitor.

The examination attributes for that examination are derived from the selected scheduled patient record and the physician record belonging to that scheduled patient record.

All acquired runs (both exposure and grabbed fluoro) are stored in the acquisition file of the selected acquisition examination.

If an acquisition examination has no patient name present, the system will create one automatically with the patient name: '# NO NAME'.

Examination

An examination consists of a number of examination attributes such as patient name, examination ID and examination date (all entered by the operator in an examination schedule) and a number of exposure runs. When an examination has been scheduled for acquisition, images can be acquired and will be collected in a file for that examination.

Examination report

The 'Report examination' function allows the operator to print AK/DAP and examination information concerning the acquisition examination on a locally connected printer. Printing is a background process and the next acquisition examination can be selected as soon as the print process has been started.

Exposure run

An exposure run consists of a number of images, up to four physiological data streams and some run attributes which describe the properties of the exposure run. Typical run attributes are: 'spatial resolution of the images', 'number of images in the run', 'acquisition parameters' (e.g. Xper setting name, kVp value), 'image processing parameters', etc.

For image processing parameters different sets are maintained, one for image processing during acquisition, one for image processing during review (this set can be modified by the operator), both for subtracted and non-subtracted display.

Philips Medical Systems 9896 002 05471

Indication of free space for exposures

There is no continuous display of the amount of free space on the image disks. When a new acquisition examination is selected, the system displays a guidance message indicating the total amount of free disk space available. During the examination, guidance messages are generated in case the free space should become a problem:

- When the total amount of free disk space drops below the limit defined in the Xper settings, a warning guidance message will be generated each time an exposure run is made. The operator can then manually delete old examinations in order to get more free disk space.
- When less than 1000 images are available for exposure, a warning guidance message is generated.
- When less images are available for exposure than needed to complete a normal run, the exposure run cannot be started. A guidance message is generated to indicate this fact.

If any of the following warning messages is displayed during an examination, carry out the required action:

Displayed message	Action
WARNING: less than 1000 images can be stored	Remove patients and/or examination folders
WARNING: low storage space%1!s! exposures left	Remove patient and/or examination folders
WARNING: Possibly not enough free disk space	Delete not used examinations to make some disk space

NOTES

- ***If the last of these three messages is displayed for the first time, the examination can be finished.***
- ***Before starting a new examination, delete or unprotect examinations in order to make more space.***

Free disk space can be obtained in the following ways:

- Automatically:
  - When a new acquisition examination is selected, the system will try to obtain enough disk space for this examination. This is done by deleting old examinations that have been archived and have not been manually protected.

Philips Medical Systems 9896 002 05471

- Manually:
  - The operator may delete old examinations at any time. This will make free disk space available that was used by those examinations.

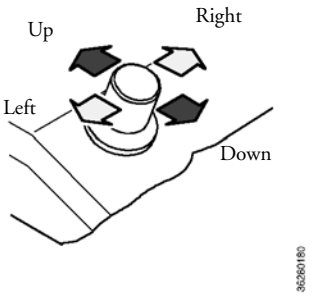
Viewing examination

To review an examination (other than the acquisition examination), an examination should be selected for viewing from the review folder. The 'done list' is a list of all finished examinations including the current acquisition examination. The selected examination becomes the viewing examination.

There can be only one viewing examination at any time. All review functions performed using the Review monitor operate on the viewing examination.

Unless a viewing examination other than the acquisition examination is explicitly selected, all reviewing functions performed will be related to the acquisition examination.

Joystick directions



8.3.2 Dose related definitions

Air Kerma (AK)

Kinetic energy released in air by ionizing radiation. The unit of kerma is the Gray [Gy] (where: 1Gy = 1J/kg (Joules per kilogram)). Where Air Kerma is used in this manual, the IEC defined Reference Air Kerma is meant.

Reference air kerma

Air kerma expressed as an equivalent value at the interventional reference point. Also known as skin dose.

Philips Medical Systems 9896 002 05471

Air Kerma Rate (AKR)
Air kerma per unit of time.

Dose Area Product (DAP)
Product of the area of the cross-section of an X-ray beam and the averaged air kerma over that cross-section. The unit is the Gray square meter [Gy.m2].

Dose Area Product rate
DAP per unit of time

Skin dose
See Reference Air Kerma.

Interventional Reference Point (IRP)
For interventional X-ray equipment, specified point on the reference axis used as a reference location for the indication of patient-incident air KERMA and air kerma rate.

8.3.3 Geometric terms

Geometric term	Explanation
Angulation (ANG)	Movement in the longitudinal plane of the patient from head to feet or vice versa. Angulation clockwise is denoted as positive or plus.
Anterior/Posterior (AP), Posterior/ Anterior (PA)	With the patient is in a supine position: • AP is when the X-ray tube is above the patient • PA is when the X-ray tube is under the patient.
Caudal (CAUD)	The imaging device is angulated in the direction of the patient's feet with patient in head-to-stand position (i.e. positive angulation).
Cranial (CRAN)	The imaging device is angulated in the direction of the patient's head (i.e. negative angulation).
Frontal	Direction of the X-ray beam perpendicular to the patient in the vertical plane.
Height	Direction perpendicular to the patient in the vertical plane.
Isocenter	Point in space around which both the rotation and angulation movements occur.
Lateral	Direction of the X-ray beam perpendicular to the patient in the horizontal plane.

Philips Medical Systems 9896 002 05471

Geometric term	Explanation
Left Anterior Oblique (LAO)	X-ray beam perpendicular to the longitudinal axis of the patient with the imaging device on the left side of the patient (i.e. positive rotation).
Longitudinal	Direction of a movement in the horizontal plane parallel to the longitudinal axis of the patient.
Rotation (ROT)	Movement around the longitudinal axis of the patient. Clockwise rotation is denoted as positive or plus.
Right Anterior Oblique (RAO)	X-ray beam perpendicular to the longitudinal axis of the patient with the imaging device on the right side of the patient (i.e. negative rotation).
Source-Image Distance (SID)	Distance between the X-ray tube focus and the input screen of the imaging device.
Transversal	Direction of a movement in the horizontal plane perpendicular to the longitudinal axis of the patient.

Patient orientation

Patient orientation refers to the position of the patient on the table and the direction of the X-ray beam.

The displayed angle information is patient oriented. This means that the patient orientation, stand rotation, angulation and L-arm position are all taken into account when displaying the angle information.

Angle information

Angle information is displayed on the On Monitor Display (OMD) of the Reference monitor and at the Acquisition and Geometry Display (AGD) of the Data monitor.

The displayed angle titles depend on the system configuration, cardiac or vascular, which is EPX (customization) defined.

	Cardiac	Vascular
Rotation	LAO	Rot +
	RAO	Rot -
Angulation	CAUD	Ang +
	CRAN	Ang -

Philips Medical Systems 9896 002 05471

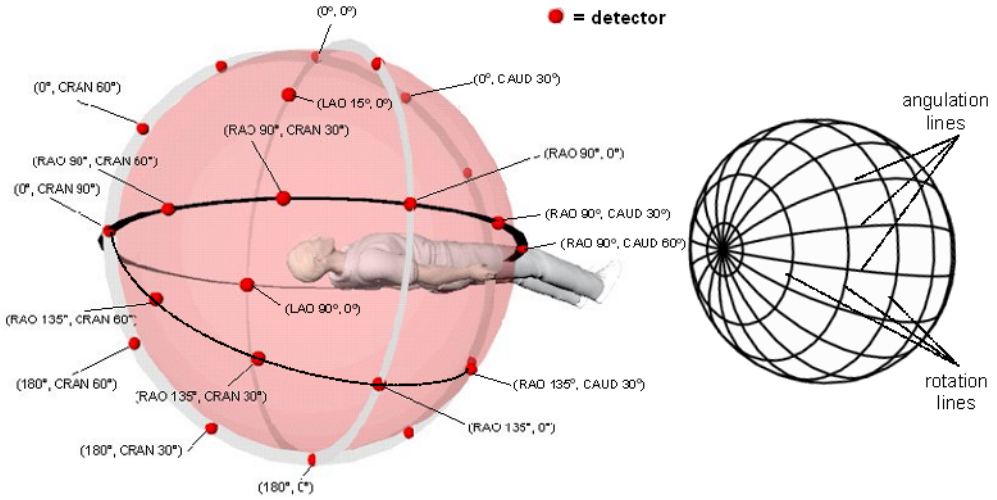


Figure 8.2 Angle information

When the L-arm is in the head position, rotation and angulation of the X-ray beam always results in a detector movement across either a rotation or angulation line. Therefore, only one angle is changing.

When the L-arm is not in the head position and the angulation is not 0°, then a rotation of the X-ray beam always results in the detector crossing both rotation and angulation lines. Also, if rotation is not 0° (180°), then an angulation of the X-ray beam always results in the detector crossing both angulation and rotation lines. Therefore, both angles are changing.

Patient and beam positioning

Source Image Distance (SID)

The SID is the distance from the Focal Spot of the X-ray source to the X-ray sensitive layer in the image detector, in the center of the detector. The accuracy of the SID is 1 mm, see Figure 8.3.

Source Object Distance (SOD)

The SOD, which is the distance of the Focal Spot of the X-ray source to the Beam IsoCenter, see Figure 8.3.

The SOD is a fixed value which is 76.5 cm for the PolyG2, Larc-C and Larc-N and 81 cm for the Clea.

Philips Medical Systems 9896 002 05471

Interventional Reference Point

The Interventional Reference Point is a point in the center of the X-ray beam at 15 cm from the Beam IsoCenter in the direction of the Focal Spot of the X-ray source, see Figure 8.3.

Minimum Source Skin Distance

The Source Skin Distance is the actual distance between the Focal Spot and the skin of the patient, where the X-ray radiation enters the patient, see Figure 8.3.

The minimum Source Skin Distance is 38 cm, in accordance with HHS, for which purpose a spacer is supplied.

NOTE ***It is the operator's responsibility to use the spacer which is according HHS.***

Source Skin Distance HHS

The Source Skin Distance HHS is used for Entrance Doserate Limitation according to HHS (FDA) legal standards. The Source Skin Distance HHS is the distance from the Focal Spot of the X-ray source to a point 30 cm (300 mm) in front of the mechanical surface of the Image Detector when no anti-scatter grid attached.

The Source Skin Distance HHS is calculated based on the SID and the Receptor Correction: SSD(HHS) = SID - 30(cm) - Receptor Correction

Source Skin Distance IEC

The Source Skin Distance IEC is used to calculate and display the skin-dose applied to the patient according to the IEC legal standards. The Source Skin Distance IEC is the distance from the Focal Spot of the X-ray source to the Interventional Reference Point.

The Source Skin Distance IEC is a fixed value which is 61.5 cm for the PolyG2 and 66 cm for the Clea.

Philips Medical Systems 9896 002 05471

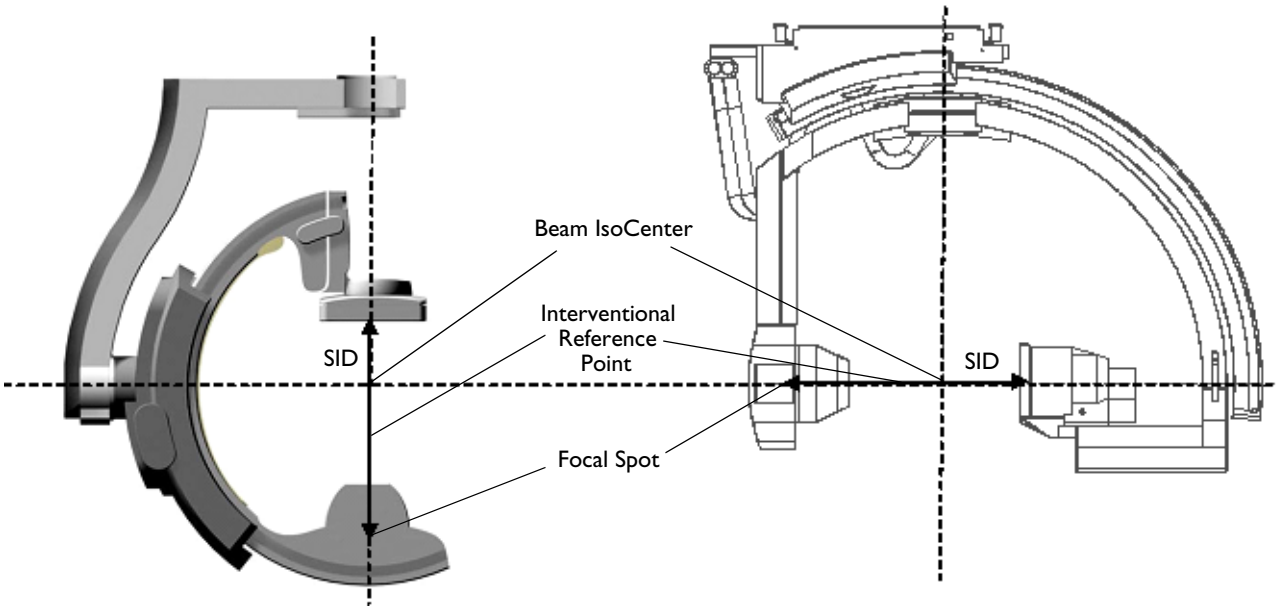


Figure 8.3 Some reference points of the X-ray beam in frontal and lateral stand

Patient Space

The Patient Space is the distance from the Beam IsoCenter to the surface of the Image Detector, as determined by the edges of the detector, see Figure 8.4. The maximum Patient Space is an indication of the maximum patient-thickness that allows (3)DRA.

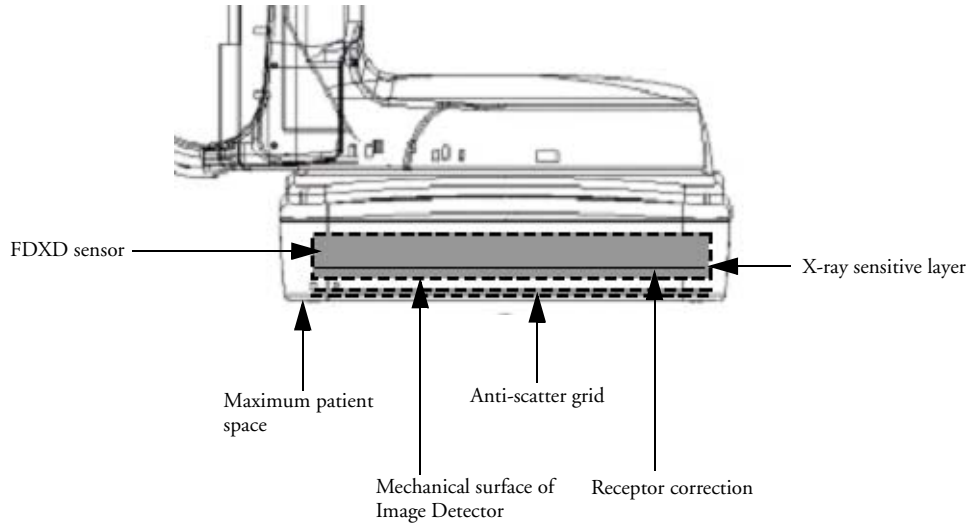


Figure 8.4 Layout of Image Detector and anti-scatter grid

Receptor Correction

The Receptor Correction is the distance between the mechanical surface of the Image Detector without anti-scatter grid and the X-ray sensitive layer inside the Image Detector.

For the FD20 the Receptor Correction is 10 mm.

Point Of Interest (POI) and IsoCenter

The POI Height is the height of the Point Of Interest in the patient relative to the surface of the tabletop.

The POI Height Offset is the deviation in height of the Point Of Interest in the patient relative to the Beam IsoCenter but possibly shifted longitudinal (along the tabletop surface) and/or lateral (horizontal). The POI Height Offset changes when the tabletop is moved up or down. When the Point Of Interest in the patient is higher than the Beam IsoCenter, in case there is no longitudinal or lateral offset, the POI Height Offset > 0.

Philips Medical Systems 9896 002 05471

Likewise, the POI Longitudinal Offset is the deviation in longitudinal direction of the patient. The POI Longitudinal Offset changes when the tabletop is moved longitudinal and when the X-ray beam is moved longitudinal. When the X-ray beam is moved towards the patient's feet the POI Longitudinal Offset > 0.

The POI Lateral Offset is the horizontal deviation lateral to the patient. The POI Lateral Offset changes when the tabletop is moved lateral. When the patient is moved to his/her right direction the POI Lateral Offset > 0.

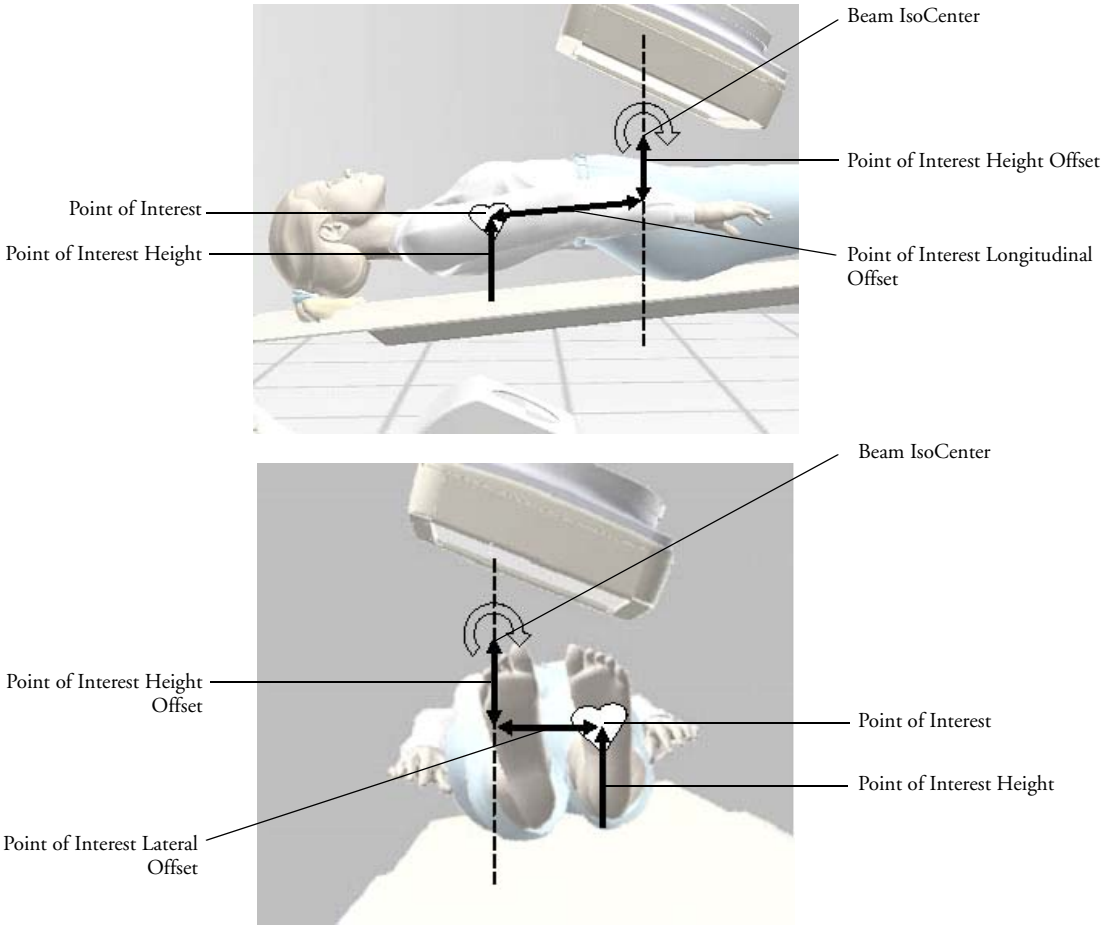


Figure 8.5 Point Of Interest and Beam IsoCenter and tiltangle

Table Height

The Table Height is the height relative to the floor of the longitudinal centerline of the tabletop below the Beam IsoCenter. When the tabletop is floated lateral or longitudinal the Table Height does not change. But when the tabletop is tilted non-IsoCentric or cradled the Table Height changes.

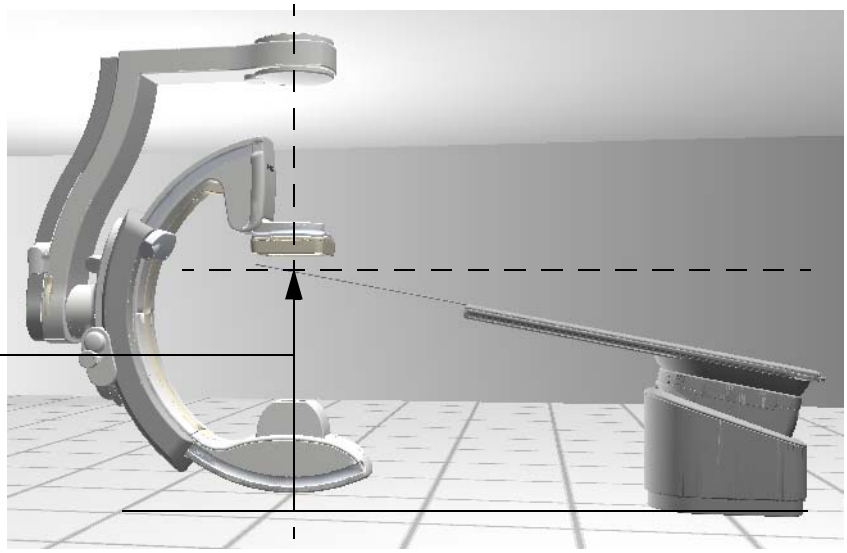


Figure 8.6 Definition of Table Height in relation to tilted table

Philips Medical Systems 9896 002 05471

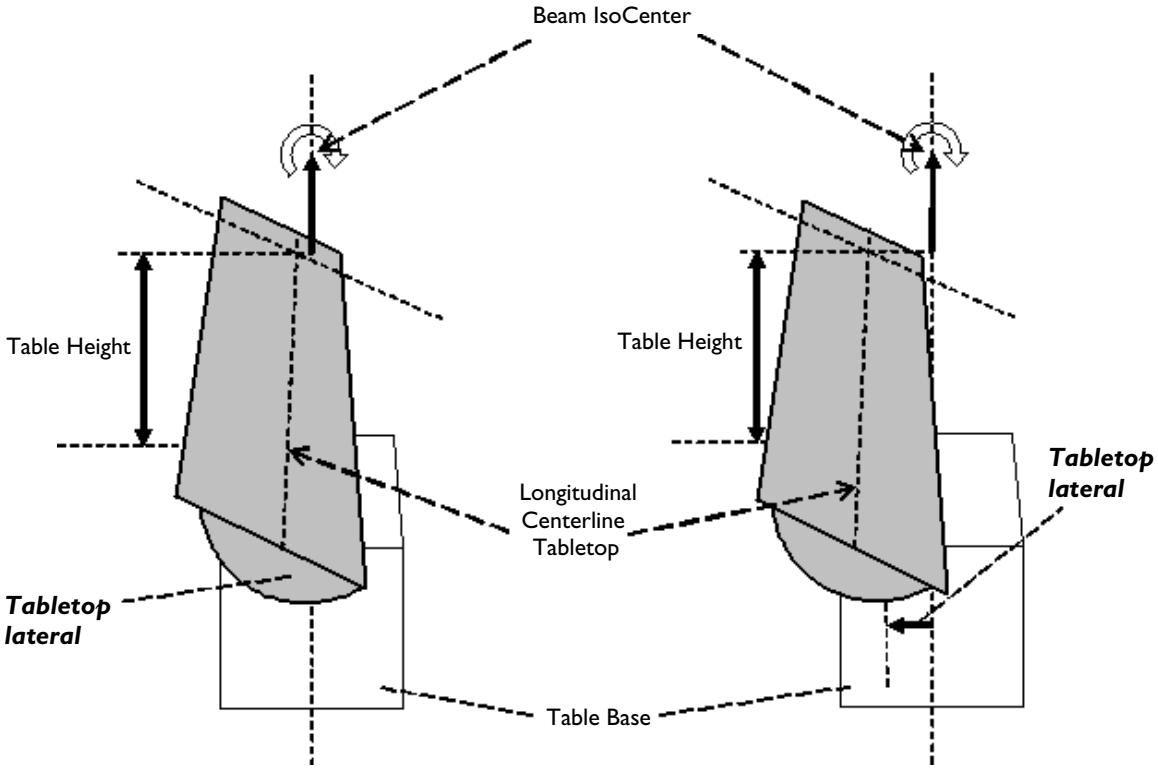


Figure 8.7 Definition of Table Height in relation to cradled table

Default Point Of Interest (POI)

When e.g. a new patient is selected the system will use a default Point Of Interest (POI) as long as the operator has not defined a new Point Of Interest (when Store Iso Center is pressed). The default Point Of Interest is defined in EPX with the parameters DefaultPOIHeight, DefaultPOILongitudinal and DefaultPOILateral.

These parameters are defined relative to a coordinate-system which is defined between the heels of the patient on the surface of the tabletop (see Figure 8.8). With the default position of the patient on the tabletop, nose-up and legs-down and with the top of the head aligned with the top of the tabletop, the position of the coordinate-system is defined assuming a DefaultPatientLength. The DefaultPatientLength (mm) is also defined in EPX.

Philips Medical Systems 9896 002 05471

Default POI Longitudinal

Default POI Longitudinal is the distance (mm) of the default Point Of Interest from the bottom of the patients feet.

Default POI Lateral

Default POI Lateral is the position (mm) of the default Point Of Interest in the patient sideways. When positioned to the right of the patient (doctor side of the table), the value is negative. When positioned to the left of the patient (nurse side of the table) the value is positive.

Default POI Height

Default POI Height is the distance (mm) of the default Point Of Interest in the patient from the surface of the tabletop.

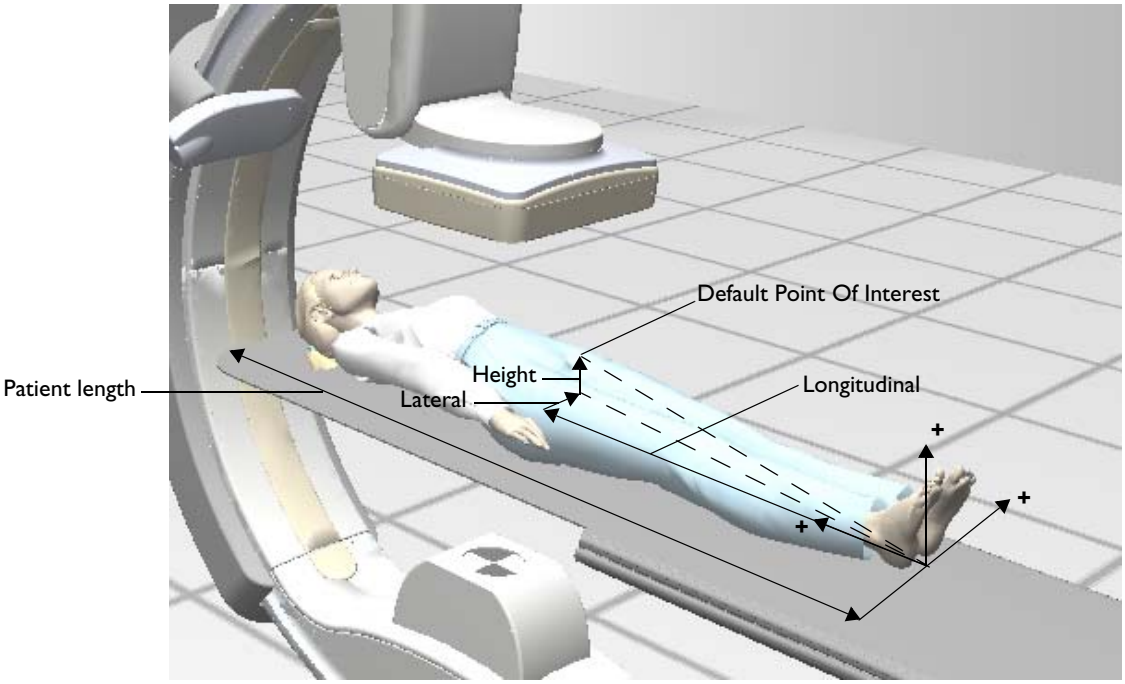


Figure 8.8 Default Point Of Interest

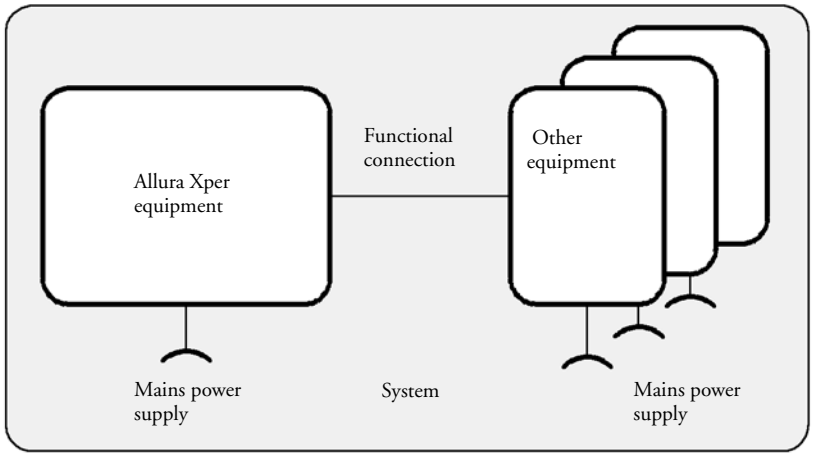
Philips Medical Systems 9896 002 05471

8.3.4 IEC Definitions

NOTES

The definitions listed below have been extracted from the following:

- ***IEC standards 60601-1: Medical electrical equipment - Part 1: general requirements for safety.***
- ***IEC 60601-1-1: Medical electrical equipment - Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems.***



Medical electrical equipment (Equipment)

Electrical equipment provided with not more than one connection to a particular mains supply and intended to diagnose, treat, or monitor the patient under medical supervision and which makes physical or electrical contact with the patient and/or transfers energy to or from the patient and/or detects energy transfers to or from the patient

'Equipment' includes those accessories as defined by the manufacturer which are necessary to enable the normal use of the equipment.

Functional connection

Any connection, electrical or otherwise, including those intended to transfer signals and/or power and/or substances.

Medical Electrical System (System)

A combination of items of equipment at least one of which must be medical electrical equipment and interconnected by functional connection or by use of a multiple portable socket outlet.

Philips Medical Systems 9896 002 05471

Patient Environment
Any volume (space) in which intentional or unintentional contact between patient and parts of the System or some other persons touching parts of the System can occur.

Multiple portable socket outlet
A combination of two or more socket outlets intended to be connected to, or integral with, flexible cables or cords, and which can easily be moved from one place to the other while connected to the supply.

NOTE ***A multiple portable socket outlet may be a separate item or an integral part of medical or non-medical equipment.***

8.4 EMC compliance

The Allura Xper systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Allura Xper systems should ensure that they are used in such an environment.

Electromagnetic emissions

Guidance and manufacturers's declaration - electromagnetic emissions		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Allura Xper systems use RF energy only for their internal functions. Therefore, their RF emissions are low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Allura Xper systems are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Philips Medical Systems 9896 002 05471

Electromagnetic immunity

Guidance and manufacturers's declaration - electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance (advise especially if compliance is not met)**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines n.a	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the ac mains voltage prior to application of the test level.			

Philips Medical Systems 9896 002 05471

Electromagnetic immunity - Portable and mobile RF communications equipment

Guidance and manufacturers's declaration - electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Allura Xper system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = [3{,}5/3]\sqrt{P}$ at 150 KHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = [7/3]\sqrt{P}$ at 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of the equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorbtion and reflection from structures, objects and people.			

Philips Medical Systems 9896 002 05471

Guidance and manufacturers's declaration - electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Allura Xper system is used exceeds the applicable RF compliance level above, the Allura Xper system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Allura Xper system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances

The Allura Xper systems are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the Allura Xper system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Allura Xper system as recommended below, according to the maximum output power of the communications equipment.

Philips Medical Systems 9896 002 05471

Recommended separation distances between portable and mobile RF communications equipment and the Allura Xper system			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = [3{,}5/3]\sqrt{P}$	**80 MHz to 800 MHz** $d = [3{,}5/3]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [7/3]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorbtion and reflection from structures, objects and people.

Philips Medical Systems 9896 002 05471

8.5 Abbreviations

Abbreviation	Explanation
%A-sten	percentage Area stenosis
%D-sten	percentage Diameter stenosis
AEP	Area Exposure Product
AK(R)	Air Kerma (Rate)
ANG	Angulation
AP	Anterior/Posterior
APC	Automatic Position Control
AVA	Automated Vessel Analysis
BC	Bolus Chase
BSA	Body Surface Area
CAUD	Caudal
CF	Calibration Factor
CI	Cardiac Index
CIS	Cardiology Information System
CO	Cardiac Output
CRAN	Cranial
CREF	Regional Contribution to global EF
CRT	Cathode Ray Tube
CWM	Centerline Wall Motion
DA	Digital Angiography
DAP	Dose Area Product
DICOM	Digital Imaging and Communications in Medicine
DSA	Digital Subtraction Angiography
ECG	Electro Cardio Gram
ED	End Diastolic
EDV	End Diastolic Volume
EF	Ejection Fraction
EMC	Electro-Magnetic Compatibility
EPX	Examination, Patient type and X-ray operator
ES	End Systolic
ESV	End Systolic Volume

Philips Medical Systems 9896 002 05471

Abbreviation	Explanation
FD	Flat Detector
FF	Free Format
HCU	Hard Copy Unit
HDT	Head Down Tilt
HIPAA	Health Insurance Portability and Accountability Act
HIS	Hospital Information System
HR	Heart Rate
HUT	Head Up Tilt
ID	Identification
IEC	International Electro-technical Commission
IR	Infrared Radiation (viewpad)
IS	Information System
KVM	Keyboard/Video/Mouse (KVM switch)
LAO	Left Anterior Oblique
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LIH	Last Image Hold
LVA	Left Ventricular Analysis
MDVDR	Medical Digital Video Disc Recorder
MPPS	Modality Performed Procedure Step
Obs.D	Obstruction Diameter
Obs.len	Obstruction length
OMV	On Monitor Viewpad
OSD	On Screen Display
PA	Posterior/Anterior
PACS	Picture Archiving and Communication System
PC	Personal Computer
PE	Protective Earth
QCA	Quantitative Coronary Analysis
QVA	Quantitative Vessel Analysis
RAO	Right Anterior Oblique
Ref.D	Reference Diameter
RIS	Radiology Information System

Philips Medical Systems 9896 002 05471

8.5 Abbreviations

Abbreviation	Explanation
ROI	Region Of Interest
ROT	Rotation
RWM	Regional Wall Motion
SID	Source to Image Distance
SV	Stroke Volume
SWM	Slager Wall Motion
TFT	Thin Film Transistor
TSD	Tabletop Shifting Device
TSF	Trace Subtract Fluoroscopy
TSM	Touch Screen Module
TTD	Tabletop Travel Distance
VCR	Video Cassette Recorder
VFR	Variable Frame Rate
WLM	Worklist Management
WM	Wall Mass
WS	Wall Stress
WT	Wall Thickness
WV	Wall Volume
XDR	Xcelera DICOM Recorder

Philips Medical Systems 9896 002 05471

Index

Philips Medical Systems 9896 002 05471

R

S

T

Philips Medical Systems 9896 002 05471