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|  | R&D: System Designer |
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| Department: | Research & Development |

# Approval

| **Role** | (approval via electronic signature in document management tool) |
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| R&D: Department Manager SD |
| R&D: System Test Designer |
| Q&R: Dev QA Officer |

# Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Date** | **Author** | **Source** | **Changes/Comments** |
| 2019-Mar-12 | A. Gevers | D-353452 | Created, based on ‘VoIP input for SRS R3.0’ (DHF297241) Rev. 01.  Added Clea3 floor & L-arc3 for neuro biplane FD20/15N with AD7X, IBR and butterfly.    Added Tags:   * SRS.Allura.Intgr.Interfaces.RemoteConnectionSettings     Removed Tags:      Changed Chapters/Tags:   * Par 2.3 Comparison to previous product release * SRS.Allura.Conf.XperFDSeriesConfigurations * SRS.Allura.Conf.Stand-RelatedItems * SRS.Allura.Conf.UI-RelatedItems * SRS.Allura.Conf.Licenses * SRS.Allura.Func.SystemCustomization * SRS.Allura.Func.MovementDisable/Enable * SRS.Allura.Func.PatientOrientedMovement * SRS.Allura.Func.ImageBeamRotation * SRS.Allura.Func.RotateFDXDDetector * SRS.Allura.Func.Dual-AxisAcquisition |
| 2020 Apr 03 | W. Engelaar | D-418023 | New Tag:   * SRS.Allura.Intgr.3rdAnd4thMultiView; introduction 3rd and 4th MultiView     Removed Tag:   * SRS.Allura.Conf.Licenses: license information divided over affected tags;   + SRS.Allura.Intgr.FHDVideoSources   + SRS.Allura.Intgr.MultiView   + SRS.Allura.Intgr.AdditionalMultiView   + SRS.Allura.Intgr.Multivision   + SRS.Allura.Intgr.SwitchableMonitors   + SRS.Allura.Intgr.Flexvision   + SRS.Allura.Intgr.Flexvision.KeyboardMouse   + SRS.Allura.Intgr.Flexspot   + SRS.Allura.Intgr.Flexspot.AdditionalWorkspot   + SRS.Allura.Intgr.Flexspot.SecondFlexspot   + SRS.Allura.Intgr.OpenVideoInterface.LargeScreen   + SRS.Allura.Intgr.OpenVideoInterface.LargeScreenDownscaled   + SRS.Allura.Intgr.VideoSlave   + SRS.Allura.Intgr.4KVideoInputOutput   + SRS.Allura.Intgr.Interfaces.RealTimeImageLink   + SRS.Allura.Intgr.Interfaces.ControlAuxiliarySystems   + SRS.Allura.Intgr.WLMSystems   + SRS.Allura.Func.PositioningIndicationWithoutRadiation   + SRS.Allura.Func.TableTilting   + SRS.Allura.Func.APCPredefined   + SRS.Allura.Func.APCReference   + SRS.Allura.Func.APC3DReference   + SRS.Allura.Func.APCTable   + SRS.Allura.Func.X-rayImageProcessing   + SRS.Allura.Func.EPTriggering   + SRS.Allura.Func.DVDRecordControl   + SRS.Allura.Func.Roadmap   + SRS.Allura.Func.Roadmap.SmartMask   + SRS.Allura.Func.DualFluoro   + SRS.Allura.Func.ExposureSubtract   + SRS.Allura.Func.SetInjectorCoupling   + SRS.Allura.Func.PhysioAcquisition   + SRS.Allura.Func.ClassicDRA   + SRS.Allura.Func.XperCT   + SRS.Allura.Func.DualPhaseXperCT   + SRS.Allura.Func.FreeInteractiveFDPA   + SRS.Allura.Func.Dual-AxisAcquisition   + SRS.Allura.Func.StoreReferenceRun/Image   + SRS.Allura.Func.Measurement   + SRS.Allura.Func.NormalSubtraction   + SRS.Allura.Func.RunSubtract   + SRS.Allura.Func.Tracing   + SRS.Allura.Func.CO2Tracing   + SRS.Allura.Func.BolusChaseReconstruction   + SRS.Allura.Func.Marker   + SRS.Allura.Func.VesselAnalysis   + SRS.Allura.Func.VentricularAnalysis   + SRS.Allura.Func.PrintSheetCreation   + SRS.Allura.Func.PrintJobControl   + SRS.Allura.UI.Help.Customize   + SRS.Allura.UI.TSM.Image   + SRS.Allura.UI.Image.Pointer   + SRS.Allura.UI.ComfortThemes   + SRS.Allura.UI.Clinical-UILanguage   + SRS.Allura.Conf.UI-RelatedItems     Changed Tags/Chapters:   * SRS.Allura.Intgr.Interfaces.RealTimeImageLink; not limited to unprocessed x-ray images * SRS.Allura.Qual.ClinicalResponseTimes.Movement; Update for APC recall * SRS.Allura.Func.FluoroFlavours, SRS.Allura.Func.ExposureFramespeed; CVPRJ00397225: Update available fluoro/exposure speeds * SRS.Allura.Conf.Control-RoomDisplays; introduction 3rd and 4th MultiView workspot * Comparison to previous product release: introduction 3rd and 4th MultiView Workspot * SRS.Allura.Intgr.FHDVideoSources, SRS.Allura.Intgr.OpenVideoInterface.LargeScreenDownscaled; introduction 3rd and 4th MultiView * SRS.Allura.SLS.ECO.ProductLabeling; Reference update, removed obsolete standard * SRS.Allura.Intgr.VideoSlave for VoiP * SRS.Allura.Conf.SupportedConfigurations; CVPRJ00390692 * SRS.Allura.Conf.XperFDSeriesConfigurations; CVPRJ00390692 * SRS.Allura.Func.XperCT; relating DRA and DAR to applications * SRS.Allura.Func.DualPhaseXperCT; Addition of fluoroscopy flavour * SRS.Allura.Serv.SingleLabConnection * SRS.Allura.Serv.Upgrading * SRS.Allura.Serv.Backup/Restore * SRS.Allura.Qual.ClinicalResponseTimes.Acquisition: split switch use cases * SRS.Allura.Qual.ClinicalResponseTimes.System; start up after total power down * SRS.Allura.Qual.ClinicalResponseTimes.Admin; moved items from SRS.Allura.Qual.ClinicalResponseTimes.Acquisition * SRS.Allura.Func.PhysicianSpecificSettings, SRS.Allura.Func.APCPredefined; added physician specific APC positions     Merged with updates for DHF270546 SRS Azurion R2.1 Rev11:    New Tag:   * SRS.Allura.SLS.fse-safety     Removed Tag:   * SRS.Allura.Qual.IQContrastResolution3D     Changed Tags/Sections:   * SRS.Allura.Qual.ClinicalResponseTimes.Acquisition * SRS.Allura.Conf.MCS-RelatedItems * SRS.Allura.Conf.Stand-RelatedItems * SRS.Allura.Qual.ClinicalResponseTimes.Admin * SRS.Allura.Intgr.AuxiliarySystems   International markets, Normative Reference; added DIN6862-2:2019-02 |
| 2021 Jul 29 | W. Engelaar | Revision A | Closed Open Issues:   * Electronic IFU, CVPRJ00397770, not in scope for R3.0 * MM TSM, CVPRJ00397771, not in scope for R3.0 * Automatic View trace, CVPRJ00329974, not in scope for R3.0. * Merge with updates Azurion R2.2, done for DHF376258 Rev C.     Merge General:   * Name change: Trumpf changed to TruSystem * Added separate document "Appendix Applicable Standards of People's Republic of China".     Merge Added Tag:   * SRS.Allura.Func.APCPathway     Merge Renamed Tag:   * SRS.Allura.Intgr.Trumpf changed to SRS.Allura.Intgr.TruSystem     Merge Changed Tags/Sections, other than name change   * SRS.Allura.Conf.XperFDSeriesConfigurations * SRS.Allura.Conf.Table-RelatedItems * SRS.Allura.Func.PriorityConstraints * SRS.Allura.Func.SystemCustomization * SRS.Allura.Func.DisplayActualPosition * SRS.Allura.Func.TableLock * SRS.Allura.Func.APCStore/Recal * SRS.Allura.Func.APCReference * SRS.Allura.Func.APCTable * SRS.Allura.Func.FreeInteractiveFDPA * SRS.Allura.Func.BolusChaseReconstruction * SRS.Allura.Serv.SystemInformation * SRS.Allura.Qual.ClinicalResponseTimes.Movement * List of applicable standards     Changed tags/Sections, not related to the merge with R2.2:    New Tag:   * SRS.Allura.SLS.ECO.EnergyConsumption     Updated Tags/Sections:   * SRS.Allura.Qual.ClinicalResponseTimes.System; differentation between China and rest of the world, rephrased conditions for measurement. * SRS.Allura.Qual.ClinicalResponseTimes.Admin; update for select for review, CVPRJ00406570. * SRS.Allura.Qual.IQFactory/ServiceMeasurements, addition general standard for China. * SRS.Allura.Conf.Control-RoomDisplays; monitor type for 3rd and 4th MultiView. * SRS.Allura.Func.SwitchSystemPowerOn.VideoOnly; include 3rd and 4th MultiView. * SRS.Allura.Conf.Stand-RelatedItems, SRS.Allura.Phys.laminarAirflowCompatibility; Added optional Ceiling rail covers for FlexArm. * SRS.Allura.Phys.ClimaticEnvironmentalConditions, SRS.Allura.Phys.MechanicalEnvironmentalConditions, replacing reference by overview of actual specifications. * List of applicable standards; Added reference to NIST for USA. * SRS.Allura.Intgr.AuxiliarySystems, Clarfied support of (integrated) workstations and RTO clients. * SRS.Allura.Intgr.DoseAwareXtend, Holder for reference dosimeter can be mounted on MCS. * SRS.Allura.Intgr.FHDVideoSources, update for supported number of sources. * "Comparison to previous product release", minor change: 135 degrees Z-rotation. |
| 2022 Jan 18 | W. Engelaar | Revision B | Resolved open issues:   * Updated applicable standards list * Replaced security tags     Merge with updates Azurion R2.2, done for DHF376258 Rev F   * SRS.Allura.Qual.ClinicalResponseTimes.System     Added Tag:   * SRS.Allura.SLS.DoD, replaces reference to NIST in applicable standards list.     Updated Tags/Sections:   * "References", Update to include reference for SUS-008 and SUS-016 * SRS.Allura.SLS.ECO.ProductLabeling; added reference to SUS-016. * SRS.Allura.Conf.UI-RelatedItems, SRS.Allura.Conf.Control-RoomDisplays; no 32" monitor for NPI. * SRS.Allura.Qual.ClinicalResponseTimes.Arch, decreased values for export. * "Appendix\_Applicable\_Chinese\_Standards"; updated * SRS.Allura.Intgr.AuxiliarySystems, maximum number of integrated workstations for DVI, and available RTO connections. * "Comparison to previous product release", comparison to R2.2 instead of R2.1. * SRS.Allura.SLS.ECO.EnergyConsumption, identified predicate for Azurion R3.0 as Azurion R2.1.   SRS.Allura.Conf.Table-RelatedItems, straps mandatory for AD7XT and AD7NXT. |
| 2022 Jun 12 | Willem Engelaar | Revision C | Merge with Azurion R2.2 Revision H, updated Tag   * SRS.Allura.Conf.Table-RelatedItems, added optional leg support board.     Updated Tags/Sections:   * "Privacy and Security", removed obsolete security tags. * SRS.Allura.Qual.ClinicalResponseTimes.Movement, increased accepted response time for ORT, CVPRJ00417016. * SRS.Allura.Func.TableTilting, license only required for magnus table, CVPRJ00418025. * SRS.Allura.Intgr.DoseAwareXtend, SRS.Allura.Conf.RemainingComponents, DoseAware (Xtend) is an option not a compatibility. * SRS.Allura.Conf.XperFDSeriesConfigurations, SRS.Allura.Conf.SupportedConfigurations, added which configurations are supported as remanufactured systems, indicated table constraints for neuro biplane.   SRS.Allura.Phys.ClimaticEnvironmentalConditions, removed non-system level  and non-applicable requirements. |
| 2022 Sep 29 | Willem Engelaar | Revision D | Added Tag: SRS.Allura.Serv.FSInstructions, to comply with UNS update.    Updated tags   * throughout document: replaced butterfly by helical. * SRS.Allura.Qual.IQFactory/ServiceMeasurements, moved IQ standard YY/T 0740 to appendix with applicable standards for China. * SRS.Allura.Phys.MechanicalEnvironmentalConditions, allocated detailed requirements to units in the SDS, CVPRJ420578. |
| 2022 Nov 10 | Willem Engelaar | Revision E | Updated Tags:   * SRS.Allura.Conf.UI-RelatedItems, wired footswitch is always part of system, wireless footswitch is an option, For NPI, new Geo modules are supplied for all configurations with and without IBR. * SRS.Allura.Serv.FSInstruction, Instructions are available covering overall installation and de-installation. |
| 2023 Jul 18 | Lukasz Berek | Revision F | Updates due to submitted Product Defect.   * Updated applicable standards list: Note 2 added for National Deviation DE: Sachverständigen-Prüfrichtlinie (SV-RL), CVPRJ00436204. |

# Open Issues

None

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# DOCUMENT INTRODUCTION

## Purpose

This document contains the overall requirements for the product family and release as mentioned in the document title on the front page, and serves as the overall contract between internal customers and the development project.

Intended readers are: stakeholder representatives, writers of detailed requirements-specs, design team, test team, and other development crew.

## Scope

Throughout this document the term *'the system'* is used to refer to a product family member.

Scope of this document are all configurations of the system, including configurations with IP based video infrastructure (newly installed products) as well as configurations with DVI based video infrastructure (upgraded products as specified in the par. Upgradability existing X-Ray systems).

## References

|  |  |  |
| --- | --- | --- |
| **Reference** | **Identification** | **Title / additional remarks** |
| [REF-1] | DEP107491 | VA requirements QA/QC Rev: 7/2001, contains the Quality Assurance/Quality Control protocol procedures requested by the Department of Veterans Affairs |
| [REF-2] | Doc number: 00000304 | Philips Standards: SUS-008 Product environmental labeling requirements |
| [REF-3] | Doc number: 00000235 | Philips Standards: SUS-016 Environmental requirements for IFU and DHF |

## Definitions & Abbreviations

|  |  |
| --- | --- |
| **Term** | **Description** |
| 3D | 3 Dimensional |
| 4K | = 4096\*2160 resolution |
| AEP | Area Exposure Product |
| AD7XT | Angio Diagnost 7X Tilt |
| AD7XNT | Angio Diagnost 7X Non-Tilt |
| AiT | Automations in system Test |
| APC | Automatic Position Control |
| ATC | Automatic Thickness Control |
| BIST | Build- In SelfTest |
| CR | Control Room |
| CIS | Cardiology Information System |
| CSA | Canadian Standards Association |
| DAR | Dual-Axis Rotation |
| DICOM | Digital Image COmmunication in Medicine, a standard for medical data exchange |
| DL DVI | Dual Link DVI |
| DP | DisplayPort |
| DRA | Dynamic Rotational Angiography |
| DVD | Digital Versatile Disk |
| DVI(-D) | Digital Visual Interface(, digital signals only) |
| ECG | ElectroCardioGram |
| EMC | Electro Magnetic Compatibility |
| EP | Electro Physiology |
| EPX | Examination, Patient-type and X-Ray operator driven presetting mechanism |
| ER | Exam Room |
| FlexMove | Frontal stand ceiling suspension with both longitudinal and transversal movement |
| FD | Flat Detector |
| FDA | Food and Drugs Administration, legal body in United States of America |
| FDPA | Flexible Dynamic Peripheral Angiography (Bolus Chase) |
| FDXD | Flat Dynamic X-Ray Detector |
| FHD | Full HD = 2Mpix = 1920\*1080 |
| FRU | Field Replaceable Unit |
| FS | Field-Service |
| FSE | Field-Service Engineer |
| IBR | Image Beam Rotation (the detector and collimation are synchronized). |
| IHE | Integrating the Healthcare Enterprise (institution in US) |
| I/O | Input / Output |
| IQ | Image Quality |
| I&V | Integration and Verification |
| IVUS | Intra-Vascular Ultrasound |
| JPEG | Joint Photographic Experts Group |
| LIH | Last Image Hold |
| Maquet | Operating Room Table (ORT) from Getinge |
| MCS | Monitor Ceiling Support |
| MPix | Mega Pixels |
| MPPS | Modality Performed Procedure Step, part of DICOM RIS protocol |
| MRC | Maximus Rotalix Ceramic X-Ray tube |
| MTBF | Mean Time Between Failure |
| MTTR | Mean Time To Repair |
| NPI | New Product Introduction |
| OR | Operating Room |
| ORT | OR-table, operating table |
| PACS | Picture Archiving and Communication System |
| POST | Power-On SelfTest |
| Procedure Step | An examination. Normally a study contains one procedure step. In case a WLM system is connected, a study can consist of multiple scheduled procedure steps. |
| QHD | Quad HD = 4Mpix =  2560\*1440 |
| RADAR | Remote Application for Diagnostics Analysis and Reporting |
| RIS | Radiology Information System |
| RSN | Remote Service Network |
| RTO | Real Time Output |
| SAN | Synchronization Area Network |
| SCP | Service Class Provider (DICOM term) |
| SCU | Service Class User (DICOM term) |
| SID | Source Image Distance |
| SLR | Standard Line-Rate |
| SMPTE | Society of Motion Picture and Television Engineers |
| SRS | System Requirements Specification |
| STI | Soft-Tissue Imaging |
| Study | One or more procedure steps on the same patient (most likely from the same day) which relate to one single diagnostic question or referral. |
| TO | Take-Over |
| TruSystem | Operating Room table (ORT) from Hillrom |
| TSL | Test-Shot Lock-in |
| TSM | Touch Screen Module |
| UHD | Ultra HD = 8MPix = 3840\*2160 resolution |
| UPS | Uninterruptible Power Supply |
| USB | Universal Serial Bus |
| VA | Veterans Administration |
| VGA | Video Graphics Array |
| Viewport | A viewport is part of the screen where the video source/image/images (plural in case of mosaic overview mode) can be displayed. |
| VideoOverIP | VoIP = Video over Internet Protocol;  Method for transmitting video over IP (Internet Protocol) network |
| WCB | Wall Connection Box |
| WLM | WorkList Management |
| XY | Refers to FlexMove or FlexArm with longitudinal (Y) and transversal (X) stand movement |

# PRODUCT OVERVIEW

## Device Classification

The device classification of the product family is class II for the US according to USA Federal Regulations, class IIb for Europe according European Medical Device Regulation and class III according to the MDR Health Canada Medical Device Regulations.

## IEC 60601-1 Classification

**High altitude operation mode**

Operation altitude is rated at max. 3000 meters (see clause 8.9.1.5 of IEC60601-1 3rd Ed. and XN-039059).

**Expected service life**

Expected service life is 10 years (see clause 3.28 of IEC60601-1 3rd Ed.).

## Comparison to previous product release

There are no major changes compared to Azurion 2.2 product release.

A minor change compared to Azurion 2.2 product release is the introduction of a new video distribution infrastructure (IP based) with full support of the legacy (DVI based) video distribution infrastructure.

Other minor changes are:

1. Available in combination with IP based video distribution infrastructure:
   1. support for 4K video inputs (in this release display in native 4K resolution only on 3rd party 4K displays)
   2. Increased flexibility in terms of workspot configurations: (Additional, 3rd, and 4th) MultiView workspot, Second FlexSpot and number of video inputs
   3. Reduction of the required floorspace in the Technical Room, by eliminating one cabinet (in labs with FlexVision and/or FlexSpot)
   4. Improved (service) diagnostics of all devices of the video distribution system
2. New Clea3 floor with new motors, new tube cover, IBR and 135 degrees Z-rotation
3. New L-arc3 with new motors, new tube cover and speeds comparable to frontal stand
4. Introducing helical as new dual-axis movement
5. Some minor functionality enhancements and bugfixing

# CONFIGURATION AND PACKAGES REQUIREMENTS

This chapter focuses on configuration components and licenses.

## Introduction

The overview discriminates according to different market segments.

SRS.Allura.Conf.SupportedConfigurations

The following FD configurations shall be supported:

|  |  |
| --- | --- |
| Configuration | Characteristic discriminators |
| Azurion FD12 | Poly-G Ceiling/Floor stand with FD12 detector |
| Azurion FD15 | Clea-Floor stand with FD15 detector |
| Azurion FD20 | Clea-Ceiling/Floor stand with FD20 detector |
| Azurion FD12/12 | Poly-G Floor with FD12 & Larc-C with FD12 |
| Azurion FD20/12 | Clea-Floor with FD20 & Larc-N1) or Larc-C with FD12 |
| Azurion FD20/15 | Clea-Floor with FD20 & Larc-N or Larc-C with FD15 |
| Azurion FD20 OR-table | Clea-Ceiling stand with FD20 detector |
| Azurion FD12/12 OR-table | Poly-G Floor with FD12 & Larc-C with FD12 |
| Azurion FD20/12 OR-table | Clea-Floor with FD20 & Larc-C with FD12 |
| Azurion FD20/15 OR-table | Clea-Floor with FD20 & Larc-N or Larc-C with FD15 |

Note 1): Azurion FD20/12 Clea-Floor with FD20 & Larc-N with FD12 is not supported for NPI. This configuration is only supported for the installed base.

The following configurations are also supported as remanufactured systems:

|  |  |
| --- | --- |
| Configuration | Characteristic discriminators |
| Azurion FD12 | Poly-G Ceiling stand with FD12 detector and AD7 table |
| Azurion FD20 | Clea Floor stand with FD20 detector and AD7 table (no FlexMove) |

## Detailed Configuration requirements

**Applied symbols:**

1) In subsequent tables, additional detailing of configurations uses following abbreviations and indications:

Mpl       = Monoplane system

Ce        = Monoplane Ceiling system, suspended by longitudinal rail

XY-fa    = Monoplane Ceiling system, suspended by double-pivot arm (FlexArm)

XY-fm   = Monoplane Ceiling system, suspended by X-Y rails (FlexMove)

Fl          = Floor mounted Monoplane system

Bpl        = Biplane system (FD12/12 and FD20/12)

NB        = Neuro Biplane (FD20/15)

Mag      = Magnus Maquet

Tru        = Hillrom TruSystem 7500

2) Symbols are used in the tables have following meaning

+   = included in a system, not an option

++ = twice included in a system, not an option (in case of a Biplane system)

#   = each system comprises exactly one of the items marked with # in one cell

%  = each system comprises at least one of the items marked with % in one cell.

o   = option; is an extension based on extra hardware and/or based on a (software) license key

c   = compatibility based upon interfacing with the system

3) Use of sub-tags

To deal with limited table space, sub-tags are used; to be appended to the specified table tag.

Example:

Table tag = SRS.Allura.Conf.XperFDSeriesConfigurations; sub-tag = .std-1

Resulting complete tag = SRS.Allura.Conf.XperFDSeriesConfigurations.std-1

SRS.Allura.Conf.XperFDSeriesConfigurations

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| sub tag | Systems: | FD12  FD12/12 | | | FD20 | | | | FD  15 | FD20/12  FD20/15 | |  |
|  | item | Ce | Fl | Bpl | Ce | XY  fa | XY  fm | Fl | Fl | Bpl | NB | notes |
| .std | Geo Stand |  |  |  |  |  |  |  |  |  |  |  |
| -1 | Poly-G2-C | # |  |  |  |  |  |  |  |  |  | Poly-G2-C is supported for remanufacturing |
| -2 | Poly-G3-C | # |  |  |  |  |  |  |  |  |  |  |
| -3 | Poly-G2-F |  | + | + |  |  |  |  |  |  |  |  |
| -4 | Clea-2-C |  |  |  | + |  | + |  |  |  |  | Clea-2-C is supported for remanufacturing (not XY fm) |
| -5 | Clea-3-C |  |  |  |  | + |  |  |  |  |  |  |
| -6 | Clea-F |  |  |  |  |  |  | # | # | # | # |  |
| -7 | Clea-3-F |  |  |  |  |  |  |  |  |  | # | Only in combination with AD7 table |
| -8 | Larc-N |  |  |  |  |  |  |  |  | 5) | # |  |
| -9 | Larc-C |  |  | # |  |  |  |  |  | # | # |  |
| -10 | Larc-3-N |  |  |  |  |  |  |  |  |  | # | Only in combination with AD7 table |
| .pt | Patient Table |  |  |  |  |  |  |  |  |  |  |  |
| -1 | AD7XT | # | # | o | o | o | o | # | # | o | o |  |
| -2 | AD7XNT | # | # | o | o | o |  | # | # | o | o |  |
| -3 | Maquet Magnus |  |  | c | c | c | c |  |  | c | c |  |
| -4 | Hillrom TruSystem |  |  |  |  | c | c |  |  |  |  | See SRS.Allura.Intgr.TruSystem |
| .ms | Monitor Ceiling Support |  |  |  |  |  |  |  |  |  |  |  |
| -1 | Rail suspended MCS | % | % | % | % | % |  | % | % | % | % |  |
| -2 | Spring-arm boom | % | % | % | % | % | % | % | % | % | % |  |
| -3 | Spring-arm boom XL | % | % | % | % | % | % | % | % | % | % |  |
| -4 | 3rd party boom | % | % | % | % | % | % | % | % | % | % | MCS Monitor integration kit |
| -5 | 3rd party boom XL | % | % | % | % | % | % | % | % | % | % | MCS Monitor integration kit XL |
| .xrc | X-ray chain |  |  |  |  |  |  |  |  |  |  | ++= frontal & lateral |
| -1 | Tube MRC 200+ 0508 | + | + | ++ |  |  |  |  |  | +1) | +1) |  |
| -2 | Tube MRC 200+ 04072) |  |  |  | + | + | + | + | + | +1) | +1) |  |
| -3 | Collimator Nicol3) | + | + | ++ | + | + | + | + | + | ++ | ++ |  |
| -5 | AEP dose-meter | o | o | o | o | o | o | o | o | o | o | AEP calculated by default, optionally hardware based |
| -7 | Detector FD124) | + | + | ++ |  |  |  |  |  | # | # |  |
| -8 | Detector FD15 |  |  |  |  |  |  |  | + | # | # |  |
| -9 | Detector FD20 |  |  |  | + | + | + | + |  | # | # |  |

Notes:

1)          Frontal channel MRC0407; lateral channel MRC0508

2)          MRC 200+ 0407 ROT-GS1008 for FD20 XY-fa; ROT-GS1004 for all other configurations

3)          Nicol v4 on Clea-3, L-arc 3-N and Poly-G3 Ceiling. All other stands Nicol v3

4)          Monoplane configurations PX2121S or PX2121C/V; biplane configurations PX2121C/V only

5)          Azurion FD20/12 Clea-Floor with FD20 & Larc-N with FD12 is not supported for NPI. This configuration is only supported for the installed base

SRS.Allura.Conf.MinimalRoomSize

The systems as mentioned in SRS.Allura.Conf.XperFDSeriesConfigurations in their minimum configuration shall fit in a room with the following minimum sizes:

|  |  |  |
| --- | --- | --- |
| System configuration  (for all FD configurations) | Minimum room size | notes |
| Fl | 5.8 m length x 4.1 m width | = 24 m2 |
| Ce / NB | 6.1 m length x 4.1 m width | = 25 m2 |
| Bpl | 6.5 m length x 4.1 m width | = 27 m2 |
| XY-fa | 7.1 m length x 4.9 m width | = 35 m2 |
| XY-fm | 7.8 m length x 6.2 m width | = 48 m2 |

SRS.Allura.Conf.Table-RelatedItems

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| sub |  | AD7XT | AD7XNT | Maquet |  |
| tag | item |  |  | TruSystem | notes |
| . ptf | Features |  |  |  |  |
| -1 | neuro tabletop | # | # |  |  |
| -2 | cardio tabletop | # | # |  |  |
| -3 | universal tabletop |  |  | % |  |
| -4 | carbonfiber & neuro tabletops |  |  | % | variants A0…A7 for Maquet  variants Carbon Floatline, Carbon Spine, SQ14-Xtra and universal for TruSystem |
| -5 | tabletop brake option | o | o |  | VA kit: when power off, friction brake is applied to prevent movement of tabletop |
| -6 | table pivot option | o | o | + | see SRS.Allura.Func.PivotRotationTableBase |
| -7 | table swivel option | o | o |  | only for Clea-F, see SRS.Allura.Func.SwivelMovementTableBase |
| -8 | motorized -float | o | o | + | motorized longitudinal and lateral tabletop movements |
| -9 | table tilt option | o |  | + | see SRS.Allura.Func.TableTilting |
| -10 | table cradle option | o |  | + | see SRS.Allura.Func.TableCradle |
| -13 | floor spacer | o | o |  | ‘retention plate’, as mitigation against spillage in OR |
| .pta | AD7XT / 7XNT accessories |  |  |  |  |
| -1 | table-mounted radiation shield | o | o |  |  |
| -2 | peripheral filters | o | o |  |  |
| -3 | arm supports | o | o |  |  |
| -4 | head support | o | o |  |  |
| -5 | patient straps | + | + |  | Mandatory in combination with AD7XT and AD7NXT |
| -6 | rail accessory clamp | o | o |  |  |
| -7 | tabletop accessory clamp | o | o |  |  |
| -8 | mattress | o | o |  |  |
| -9 | table covers (non-sterile) | o | o |  | in hybrid OR, table-base, for cleaning purposes |
| -10 | additional OP-rail | o | o |  | extended positioning for UI modules |
| -11 | auxiliary OP-rail kit | o | o |  | positioning for third party equipment |
| -13 | neuro wedge | o | o |  | for patient posturing |
| -14 | table rail cable guide | + | + |  |  |
| -15 | ratchet compressor | o | o |  | compression belts with Ratchet-winding mechanism for symmetrical compression |
| -16 | handgrip and clamp set | o | o |  | table clamps and handgrips |
| -17 | neuro head holder | c | c |  |  |
| -18 | Leg support board | o | o |  | For use in AngioCT |

SRS.Allura.Conf.Stand-RelatedItems

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| sub |  | Poly-G | | | Clea | | | | L-arc |  |
| tag | Item | Ce | XY  fm | Fl | Ce | XY  fm | XY  fa | Fl | Bpl | **notes** |
| .std |  |  |  |  |  |  |  |  |  |  |
| -1 | Extended rail | o | o |  | o | o | o |  | o | FlexArm: 4.3m; standard: 6.0m or 7.8m. |
| -2 | L-arm long | # | # |  | # | # |  |  |  |  |
| -3 | L-arm short | # | # |  | # | # |  |  |  |  |
| -4 | Flexarm long |  |  |  |  |  | # |  |  |  |
| -5 | Flexarm short |  |  |  |  |  | # |  |  |  |
| -6 | Ceiling rail covers |  |  |  |  |  | o |  |  | See SRS.Allura.Phys.LaminarAirflowCompatibility |
| -7 | Optical imaging system |  |  |  | o | o | o |  |  | see SRS.Allura.Intgr.OpticalImagingSystem |
| -8 | Coverbags | c | c | c | c | c | c | c | c | Arc / Tube / Detector / TSM |

SRS.Allura.Conf.MCS-RelatedItems

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| sub | item |  |  |  |  |  | notes |
| tag |  | Rail susp | 3rd party boom | 3rd party boom XL | Springarm | Springarm XL | Up to two rail suspended MCS and in total up to four MCS of different type and configuration can be combined in one system |
| .frm | MCS frame |  |  |  |  |  |  |
| -1 | Frame | + |  | + | + | + |  |
| -2 | VxH= 1x2 | % | % |  | % |  | 2 x 27” |
| -3 | VxH= 1x2 + 1 |  |  |  | % |  | 2 x 19" + 1 x 27" |
| -4 | VxH= 2x2 | % | % |  |  | % | 4 x 27” |
| -5 | VxH= 2x2 + 2 | % |  |  |  | % | 6 x 27” |
| -7 | Large Screen | % |  | % |  | % | 58” XL |
| -8 | Large Screen + 2 | % |  | % |  | % | 58” XL + 2 x 27” |
| .dsp | MCS displays |  |  |  |  |  | max. number is configuration dependent;  In combination with IP based video infrastructure the total number of all monitors installed on MCSs/booms in ER and FHD monitors installed outside MCSs/booms in CR and ER never exceeds 20. The maximum doesn’t include FlexVision, Slave FlexVision, (Second) FlexSpot, Basic CR, MultiView and Additional MultiView monitors |
| -1 | 27” diagnostic color | % | % | o | % | o | 27" color monitor, min. 400 cd/m2, resolution 1920x1080, aspect ratio 16:9 |
| -2 | 32” diagnostic color1) |  | o |  |  |  | 32" color monitor, min. 400 cd/m2, resolution 1920x1080, aspect ratio 16:9 |
| -4 | 19” multi-purpose |  |  |  | o |  | 19" color monitor (only for VxH= 2x1 + 1) min. 250 cd/m2, resolution 1280x1024, aspect ratio 5:4 |
| -5 | 58” XL | % |  | % |  | % | 58” color monitor, min. 400 cd/m2, resolution 3840x2160, aspect ratio 16:9 |
| -9 | Dummy fill | o |  |  | o | o |  |
| .swm | Switchable Monitors |  |  |  |  |  |  |
| -1 | 27” or 32” diagnostic color1) | o | o |  |  | o | Up to 16 switchable monitors, can also be offered without MCS |

 Note:

1)  32" monitors are not part of NPI.

SRS.Allura.Conf.Control-RoomDisplays

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| sub |  |  |  |  |
| tag | item | DVI based infra | VoIP  based infra | notes |
| . crd | control room displays |  |  |  |
| -1 | acquisition and review monitor | # | # | Both 24" color monitors with native image resolution of 1920x1080 and aspect ratio 16:9. |
| -2 | FlexSpot primary monitor | # | # | Instead of acquisition and review monitor, a 27" color monitor with native image resolution of 2560x1440 and aspect ratio 16:9. |
| -3 | FlexSpot secondary monitor | o | o | Requires FlexSpot primary monitor, 27" color monitor with native image resolution of 2560x1440 and aspect ratio 16:9. |
| -4 | additional FlexSpot | o |  | Requires FlexSpot primary monitor, 27" color monitor with native image resolution of 2560x1440 and aspect ratio 16:9; shall be placed either in the control or exam room. |
| -5 | slave monitor1) | o | o | 24” (desk version) or 27” (boom version) or 32" (boom version) color monitor with native image resolution of 1920x1080 and aspect ratio 16:9, e.g. extra live monitor. |
| -6 | MultiView |  | o | Requires acquisition and review 24" color FHD monitors, |
| -7 | Additional MultiView |  | o | Requires acquisition and review monitor, extra 24" color FHD monitor, mouse and keyboard; |
| -8 | Second FlexSpot primary monitor |  | o | Requires FlexSpot primary monitor, 27" QHD color monitor, mouse and keyboard; shall be placed either in the control or exam room. |
| -9 | Second FlexSpot secondary monitor |  | o | Requires Second FlexSpot primary monitor, 27" color QHD monitor; shall be placed at the same location as Second FlexSpot primary monitor |
| -10 | 3rd MultiView |  | o | Requires extra 27" color QHD monitor, mouse and keyboard.  Only in combination with FlexSpot, second FlexSpot, and 4th MultiView |
| -11 | 4th MultiView |  | o | Requires extra 27" color QHD monitor, mouse and keyboard.  Only in combination with 3rd MulitView |

Note:

1)  32" monitors are not part of NPI.

SRS.Allura.Conf.UI-RelatedItems

|  |  |  |  |
| --- | --- | --- | --- |
| sub  tag | item | monoplane | biplane |
| .xs | X-ray switches |  |  |
| -1 | footswitch 3f | + |  |
| -2 | footswitch 6f |  | + |
| -3 | wireless footswitch 3f | o |  |
| -4 | wireless footswitch 6f |  | o |
| -5 | additional footswitch CR 3f | o |  |
| -6 | additional footswitch CR 6f |  | o |
| -7 | additional footswitch ER 3f | o |  |
| -8 | additional footswitch ER 6f |  | o |
| -9 | X-ray handswitch | + | + |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| sub tag | item | Monoplane | | | XY (fm/fa) | | | biplane | | |
| AD7 XT | AD7 XNT | Maq | AD7 XT | AD7 XNT | Maq Tru | AD7 XT | AD7 XNT | Maq |
| ui | UI-modules |  |  |  |  |  |  |  |  |  |
| -1 | ControlModule NT |  | +1) |  |  |  |  |  |  |  |
| -2 | ControlModule Tilt | +1) |  |  |  |  |  |  |  |  |
| -3 | ControlModule Flex |  |  |  | +1) | +1) |  |  |  |  |
| -4 | ControlModule ORT | o2) | o2) | +1,3) |  |  |  |  |  |  |
| -5 | ControlModule ORT Flex |  |  |  | o2) | o2) | +1,3) |  |  |  |
| -6 | ControlModule Geo NT7) |  |  |  |  |  |  |  | +1) |  |
| -7 | ControlModule Geo Tilt7) |  |  |  |  |  |  | +1) |  |  |
| -8 | ControlModule Geo ORT7) |  |  |  |  |  |  | o2) | o2) | + |
| -9 | ControlModule Geo NT IBR |  |  |  |  |  |  |  | +1) |  |
| -10 | ControlModule Geo Tilt IBR |  |  |  |  |  |  | +1) |  |  |
| -11 | ControlModule Imaging | o4) | o4) | o4) | o4) | o4) | o4) | + | + | + |
| -12 | speed controller | o5) | o5) | o5) | o5) | o5) | o5) |  |  |  |
| -13 | pan handle | o | o |  | o | o |  | o | o |  |
| -14 | TouchScreenModule | +6) | +6) | +6) | +6) | +6) | +6) | +6) | +6) | +6) |
| -15 | review module | + | + | + | + | + | + | + | + | + |
| -16 | viewpad (cardio) | # | # | # | # | # | # | # | # | # |
| -17 | viewpad (mixed) | # | # | # | # | # | # | # | # | # |
| -18 | ControlModule Geo ORT IBR |  |  |  |  |  |  | o2) | o2) | + |

Notes:

1)          Additional ControlModule optional for CR

2)          Optional as additional ControlModule on pedestal for ER

3)          On pedestal

4)          ControlModule imaging optionally available for ER (not in combination with 2))

5)          Required for FDPA, not an option for TruSystem

6)          Additional TSM optional for CR and (on pedestal) for ER

7)          Not for NPI, applicable for modules already present in the installed base

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| sub | item | Table type | | | notes |
| tag |  | AD 7XT | AD 7XNT | Maquet TruSystem |  |
| .mi | miscellaneous |  |  |  |  |
| -1 | TSM swingarm | + | + | + |  |
| -2 | Pedestal | o | o | + | trolley to attach UI modules; for AD7X(N)T including Pedestal Wall Conn. Box; for ORT including Surgery Wall Conn. Box |
| -3 | Two-way Intercom | o | o | o |  |
| -4 | Keyboard + Mouse in CR | + | + | + | in CR; additional second keyboard + mouse in case of additional FlexSpot |
| -5 | Mouse in ER | o | o | o | Requires a license |
| -7 | MultiVision Switch | o | o | o | see SRS.Allura.Intgr.Multivision |
| -8 | KVM-Switch | o | o | o | see SRS.Allura.Intgr.KVM-Switching, requires DVI based video infrastructure |
| -10 | MCS Auxiliary box | + | + | + | for viewpad-receiver and X-on light on 3rd party booms |

SRS.Allura.Conf.RemainingComponents

|  |  |  |  |
| --- | --- | --- | --- |
| sub tag | item | availability | notes |
| .ps | Partner Systems |  | See for details corresponding requirement in Room-Specific Auxiliary Systems section |
| -1 | DoseAware Xtend | o |  |
| .mi | Miscellaneous |  |  |
| -1 | Ceiling Suspended radiation shield | o |  |
| -2 | Examination light | o |  |
| -3 | X-ray spacer | o | limits minimum Source Skin Distance (Health and Human Services (HHS) requirement). Mandatory for 21 CFR 1020.30. |
| -4 | Drip stand | o |  |
| -5 | Medical DVD recorder | o | Requires DVI based video infrastructure |
| -6 | 1 phase UPS | o | see SRS.Allura.Func.PowerFailureBehaviour |
| -9 | UPS control | c | see SRS.Allura.Intgr.ExternalThreePhaseUPS |
| -10 | VideoSlave | o | see SRS.Allura.Intgr.VideoSlave |
| -11 | Open video interface | o | see SRS.Allura.Intgr.OpenVideoInterface.LargeScreen, |
| -12 | DVD burner | o | see SRS.Allura.Func.StoreToMedia |
| -13 | HD output | o | see SRS.Allura.Intgr.OpenVideoInterface.LargeScreenDownscaled; in DVI based video infrastructure it requires FlexVision open video interface |
| -14 | Video scan converter | o | for 50/60 Hz SLR TV output, requires DVI based video infrastructure |
| -15 | Wall-connection boxes | o | see SRS.Allura.Intgr.FHDVideoSources, requires DVI based video infrastructure |
| -16 | Auxiliary System Input Connection Box | o | see SRS.Allura.Intgr.FHDVideoSources, requires IP based video infrastructure |
| -17 | 4K Auxiliary System Input Connection Box | o | see SRS.Allura.Intgr.4KVideoInputOutput,  not available in combination with DVI based video infrastructure |

## Core Functionality

Core functionality is defined as functionality which is not dependent on the presence of any license key.

The following functions are in the core:

* Clinical core functionality is a subset of all functionality as defined in chapter FUNCTIONAL REQUIREMENTS. The subset is determined by subtracting all functionality that is dependent on any license key.
* All functionality needed to install a system and to perform basic checks to initially verify correct system working condition.
* User messages (see SRS.Allura.Func.DisplayUserMessages).
* Tooltip (balloon) help.

## Software-Keyed Clinical Options

A Clinical Option gives additional clinical functions/features/characteristics and is enabled through a software license key. Two types of licenses exist:

* counted license: used to implement licenses that restrict the number of items that can be used, e.g. number of video outputs.
* uncounted license: used to implement licenses that restrict the usage of a certain feature (on/off)

SRS.Allura.Conf.ImageStorageOptions

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| sub |  |  |  |  |  |
| tag |  |  | 5122 | 1K2 | (2K)2 |
| .xs | **Capacity Keys** 5 |  |  |  |  |
| -1 | Single | + | 100.000 | 25.000 | 6250 |
| -2 | Double6 | o | 200.000 | 50.000 | 12500 |
| -3 | Quadruple6 | o | 400.000 | 100.000 | 25000 |
| .gc | **Frame-rate Keys** 1 |  |  |  |  |
| -1 | Basic | + | 12 img/s | 12 img/s | 6 img/s |
| -2 | Cardiac6 | o | 30 img/s 3 | 30 img/s 3,4 | 6 img/s |
| -8 | Pediatric6 | o | 60 img/s 2 | 30 img/s 3,4 | 6 img/s |

Notes:

1. These figures do not apply to fluoro or to scenarios and represent maximum frame-rates expressed in images/second (img/s) within limits set by detector and configuration.
2. In biplane this is frame rate per channel, and in addition to 60 img/s also 50 img/s is supported.
3. Cardiac and pediatric also supports 25 img/s instead of 30 img/s.
4. With processing algorithm ClarityIQ (see SRS.Allura.Func.X-rayImageProcessing) only <= 25 img/s @ 1K2 is supported.
5. The image sizes give an indication how many of these sized images can be stored, the system is not limited nor bound to these sizes as they vary depending on detector size and configuration.
6. This option requires a license

# INTEGRATION & INTEROPERABILITY REQUIREMENTS

This chapter focuses on integration with other systems/equipment, in and outside the exam room.

## UPS Integration

SRS.Allura.Intgr.ExternalThreePhaseUPS

The system shall support powering from a dedicated external 3-phase UPS in case of a power outage of the hospital mains.

SRS.Allura.Intgr.BackupPowerActive

The system shall provide an interface to switch to reduced power in case of a power outage of the hospital mains.

Configurable at installation, high-power consumption functions (like exposure) are switched off in case the hospital runs on backup power or the system is powered from an external three phase UPS. Low-load fluoro and functions to free a patient remain available.

## Mechanical Integration

SRS.Allura.Intgr.EquipmentRack

An equipment rack shall be provided for placing external equipment near the table.

* Provided connections are: optional and country-specific hospital mains power outlets, WCB (only in combination with DVI based video infrastructure), Auxiliary System Input Connection Box mounting and cabling, infusion extension rods, extension arm with Video Electronics Standards Association (VESA) interface, optional and country-specific gas outlets for O2, NO2 and vacuum, and optional hospital Ethernet connections.
* It shall be possible to position the equipment rack on both sides of the table-end perpendicular to the table.

SRS.Allura.Intgr.Interfaces.AuxiliarySystemMounting

The system shall provide mechanical interfaces and cabling to mount external equipment to:

* Patient Table
* Monitor Ceiling Suspension
* Monitor Ceiling Carriage

## Video Integration

SRS.Allura.Intgr.FHDVideoSources

In combination with IP based video integration infrastructure, FlexVision exam room display configuration and FlexSpot + 2nd FlexSpot, or MultiView + Additional MultiView (i.e. no other CR/ER displays), the system shall support connecting up to 20 FHD auxiliary systems and up to 4 integrated workstations.

In combination with DVI based video infrastructure the system shall support up to 16 FHD video sources, of which up to 11 video sources (total number from the integrated workstations and auxiliary systems).

The system shall offer the flexibility to connect auxiliary systems in the control room, the examination room (on MSCs, walls or equipment racks) and the technical room.

For VoIP configurations, the support of FHD video sources is licensed. This is a counted license for the number of video sources. The license does not actually limit the number of FHD video sources that can be connected.

SRS.Allura.Intgr.VideoSourcesMaintainIQ

The system shall provide set of approved measures to display video and/or optimize image quality of compatible auxiliary system video source, when displaying it on the system’s monitors or providing for use outside the system.

SRS.Allura.Intgr.VideoInputInterface

The following types of video interfaces shall be supported for connecting auxiliary systems:

* DP (only in combination with IP based video infrastructure)
* DVI-I including non-interlaced VGA

SRS.Allura.Intgr.KVM-Switching

Switching display, keyboard, and mouse enables the control room user to access any functionality in auxiliary applications (running on dedicated Philips PC’s). There is no implicit integration of information.

SRS.Allura.Intgr.MultiView

MultiView user can select what video source (1 of max 8, it is configurable what video sources shall be selectable) shall be displayed and controlled (keyboard/mouse support over USB) on the review monitor. Other type of data exchange between auxiliary equipment and X-Ray System is not supported.

MultiView requires a license. This is a counted license for the number of configurable sources.

SRS.Allura.Intgr.AdditionalMultiView

A second workspot (keyboard, mouse, single monitor) next to acquisition and review monitor shall be offered, which can be a workspot in the control room or exam room. One video source (out of max. 8, it is configurable what video sources shall be selectable) can be selected to be displayed and controlled (keyboard/mouse support over USB). Video can originate from the system itself or from auxiliary systems.

Additional MultiView requires a license. This is a counted license for the number of configurable sources.

SRS.Allura.Intgr.3rdAnd4thMultiView

In combination with FlexSpot and second FlexSpot, a 3rd and 4th workspot (keyboard, mouse, single monitor) shall be offered, which can be a workspot in the control room or exam room. One video source (out of max. 8, it is configurable what video sources shall be selectable) can be selected to be displayed and controlled. Video can originate from the system itself or from auxiliary systems. The 3rd and 4th MultiView require a separate license per workspot. This is a counted license for the number of configurable sources.

SRS.Allura.Intgr.Multivision

MultiVision enables to display video on the exam room display originating from multiple video sources.

* The user can select the current video source for display.
* Video can originate from the system itself and/or from auxiliary systems (e.g. Interventional Workspot, IVUS).
* Not available in combination with Switchable Monitors or FlexVision.
* In a DVI configuration, the control room review monitor is selectable as video source and max. 4 other video sources are configurable.

MultiVision requires a license

SRS.Allura.Intgr.SwitchableMonitors

The system shall provide an option to flexibly switch during the procedure all available video sources to monitors in the examination room (within or outside MCSs/booms) and control room.

Video sources can be displayed on at most 16 monitors.

Switchable Monitors requires a license.

In combination with DVI based video infrastructure, if FlexVision is present at most 8 switchable monitors are supported.

In VoIP based infrastructure the license is a counted license for the number of Switchable Monitors.

SRS.Allura.Intgr.Flexvision

FlexVision enables flexible viewing for displaying multiple video sources (live images but also video from other systems) on one large screen display in the exam room with which the user can determine the layout, the position and size of multiple video sources on one large screen display in the exam room.

* Layouts are predefined. A layout divides the large screen in viewports.
* The user shall be able to select a preset (a preset contains the layout and for each viewport the specific video source shown in the viewport) to be applied on the large screen.
* The user shall be able to create, delete, change, save and rename a preset.
* The user shall be able to select which source is displayed in which viewport.
* The user shall be able to hide/unhide the video source display in a viewport.
* The user shall be able to swap the video sources of two viewports in a preset.
* The user shall be able to enlarge a specific viewport and restore it to its original size.
* The user shall be able to display video sources in native resolution.
* Display of 2k2 images shall be supported.
* Video can originate from the system itself and from auxiliary systems (configurable set, e.g. Interventional Workspot, IVUS).

In combination with VoIP based infra, FlexVision requires a license.

The display of 2K2 images requires an additional license.

SRS.Allura.Intgr.Flexvision.Snapshot

With FlexVision, a single viewport or all viewports at once can be grabbed and stored as image under the current acquisition study.

SRS.Allura.Intgr.Flexvision.KeyboardMouse

With FlexVision, the system shall allow for remote control of auxiliary systems via on-screen keyboard and touchpad (on TSM) and / or wireless mouse. This requires a license.

SRS.Allura.Intgr.Flexspot

Provides the user with the same features as for FlexVision in the control room. Exception is that FlexSpot doesn't support display of 2k2 images. In combination with VoIP based infrastructure, FlexSpot requires a license.

A second monitor for the FlexSpot workspot shall be offered. This second monitor requires a license.

SRS.Allura.Intgr.Flexspot.KeyboardMouse

With FlexSpot, the system shall allow for remote control of auxiliary systems via keyboard and mouse.

SRS.Allura.Intgr.Flexspot.AdditionalWorkspot

A second workspot (keyboard, mouse, single monitor) next to FlexSpot shall be offered, which can be a workspot in the control room or exam room. One video source can be selected to be shown. Video can originate from the system itself and from auxiliary systems (configurable set, e.g. Interventional Workspot, IVUS).

The additional FlexSpot requires a license.

SRS.Allura.Intgr.Flexspot.SecondFlexspot

A second workspot (keyboard, mouse, one or two monitors) next to FlexSpot shall be offered, which can be a workspot in the control room or exam room. It shall provide the user with the same features as FlexSpot. Second FlexSpot requires a license.

A second monitor for the second workspot shall be offered. This second monitor requires a license.

SRS.Allura.Intgr.VideoDisplayInterface

The system shall support the display of its own video sources and/or sources provided by auxiliary systems on its examination/control room monitors and large screen.

SRS.Allura.Intgr.OpenVideoInterface.LargeScreen

The system shall provide a large screen video output (DP1.2 or, in combination with DVI based video infrastructure, 2\*DL-DVI) that contains a copy of the large screen of FlexVision. In VoIP infrastructure, this requires a license.

SRS.Allura.Intgr.OpenVideoInterface.LargeScreenDownscaled

The system shall provide a downscaled copy of the large screen of FlexVision video output in FHD resolution (DP is the interface in combination with IP based video infrastructure and SL-DVI in combination with DVI based video infrastructure).

In combination with IP based video infrastructure that video output shall be also available (configurable) for switching on Flexspot, (Additional,3rd, and 4th) Multiview and Switchable Monitors.

In VoIP infrastructure, the availability of the downscaled copy requires a license.

SRS.Allura.Intgr.VideoSlave

VideoSlave enables showing a copy of an X-ray video source (e.g. Live/Ref1, Ref2/Ref3, Review for monoplane system) or auxiliary system video source on a static video output. The static video output can be connected to a slave monitor (powered by the system) or to an external monitor/video system.  
  
In combination with IP based video infrastructure:

* maximum of 2 slave monitors in CR (close to the main workspot) and additionally maximum of 10 slave monitors at flexible location (in CR/ER outside of MCSs/Booms, part of total pool of 20 FHD monitors)
* maximum of 40 outputs for use outside the system. Every video output requires a counted license. The license does not actually limit the number of video outputs.
* DP is the video output standard
* Duplicating a X-ray video source that is already displayed on another monitor requires a license. The licenses are counted licenses for the number of duplicated video outputs.

In combination with DVI based video infrastructure:

* maximum of 5 slave monitors (from that max 3 in CR)
* maximum of 8 outputs for use outside the system
* DVI-D is the video output standard

SRS.Allura.Intgr.4KVideoInputOutput

It shall be possible to connect to the system (connection available on MCS or wall) QHD, UHD or 4K video sources (max 2) and output it:

* as downscaled FHD video source to the system monitor or external video system
* optionally directly (no switching possibility for a clinical user) to a 4K 3rd party monitor(s) (mounted on a 3rd party monitor boom or installed in the control room)

Connecting one 4K video source and displaying its output on the 4K 3rd party monitor shall not impact the total number of FHD video sources of the auxiliary systems that can be connected to the system by more than 10.

Connecting and outputting 4K external inputs are both licensed. These are counted licenses for the number of 4K auxiliary system input connection boxes and 4K outputs installed. The licenses are not enforced.

SRS.Allura.Intgr.NativeIQ

When the video signal is not displayed on the system monitor the system shall be able to offer a transparent image path such that it can be used by a 3rd party system. Transparent image path between the system input and output is a point to point 3rd party video signal distribution that doesn’t make any change to the signal being distributed.

## Auxiliary Systems Data Exchange & Control

SRS.Allura.Intgr.Interfaces.DataExchange

The system shall provide communication interfaces to exchange data with compatible auxiliary systems

* Patient and examination related data
* Acquisition related data
* Dose data
* ECG data
* Geometry related data

SRS.Allura.Intgr.Interfaces.ServiceDataRetrieval

The system shall provide communication interfaces to retrieve service data from compatible auxiliary systems and provide it to the (remote or local) service user

* Regularly saved log-files
* Diagnostic data saved for technical support

SRS.Allura.Intgr.Interfaces.RealTimeImageLink

The system shall provide communication interfaces to provide x-ray images of the frontal channel in real time to compatible auxiliary equipment during x-ray acquisition. This requires a license.

SRS.Allura.Intgr.Interfaces.ControlAuxiliarySystems

The system shall provide communication interfaces to control compatible auxiliary systems from the systems user interface

* with wireless mouse on the auxiliary system’s graphical UI displayed on FlexVision
* with mouse and keyboard on the auxiliary system’s graphical UI displayed on Flexspot
* from TSM by a generic button based UI tailored by the auxiliary system or by a graphical UI streamed from the auxiliary system including (multi-)touch control. This requires a license
* control shall be established automatically when (mobile) compatible auxiliary system is connected

SRS.Allura.Intgr.Interfaces.ControlFromAuxiliarySystems

The system shall provide communication interfaces to allow compatible auxiliary systems to

* select EPX procedures which may or may not be specific for the auxiliary system (i.e. they are selectable only by the auxiliary system)
* set APC target positions
* lock/unlock the table
* set specific acquisition parameters (e.g. injector coupling, patient orientation, biopsy mode, etc.)
* push a secondary capture image to a reference viewport

SRS.Allura.Intgr.Interfaces.RemoteConnectionSettings

The system shall provide communication interfaces to store and retrieve RSN remote connection settings.

## Room-Specific Auxiliary Systems

SRS.Allura.Intgr.AuxiliarySystems

With FlexSpot it shall be possible to install dedicated Philips auxiliary systems in the cabinet in the technical room. FlexSpot shall provide infrastructure to gain access from control room to the media devices available on these PCs;

on DVI based video configurations the maximum number of PCs from dedicated Philips auxiliary systems installed in the cabinet in the technical room is three.

on VoIP based video configuration the maximum number of PCs from dedicated Philips auxiliary systems installed in the cabinet in the technical room is four.

The maximum number of RTO clients in the system (TR/CR/ER) is five for VoIP based configurations, and six for DVI based configurations.

Without FlexSpot it shall be possible to install a single PC from dedicated Philips auxiliary systems in the cabinet in the technical room. However no further infrastructure except power and network access is provided.

SRS.Allura.Intgr.AblationEquipment

The system shall be tolerant against the electromagnetic fields of ablation equipment and catheter tracking systems.

SRS.Allura.Intgr.DoseAwareXtend

The system shall optionally provide integration with the DoseAware Family product, which means:

* In combination with DoseAware Xtend, video can be shown on the Azurion display.
* Azurion provides X-ray procedure related information to DoseAware Xtend.
* A reference dosimeter can be attached to the frontal stand.

In combination with DoseAware the system shall provide electrical and mechanical integration of the DoseAware basestation on the MCS frame.

SRS.Allura.Intgr.Magnus

Compatibility with Magnus OR table of Maquet.

* Move table via system’s UI modules and Magnus UI modules to position table top, tilt, cradle and set height.
* Move table for reset geometry, APC iso-center and FDPA.
* Stop table movements in case of emergency stop.
* Detect collisions and allow override table movements.
* Synchronize table lock setting, patient orientation setting, table positions, status and capabilities.

SRS.Allura.Intgr.TruSystem

Compatibility with TruSystem 7500 OR table of Hillrom

In combination with the FlexArm:

* Move table via system's UI modules and TruSystem UI modules to position table top, tilt, cradle and set height.
* Move table for reset geometry, APC iso-center.
* Stop table movements in case of emergency stop.
* Detect collisions and allow override table movements.
* Synchronize table lock settings, patient orientation setting, table positions, status and capabilities.
* Excluded are: FDPA, iso-centric tilt, and Syncra tilt.

In combination with the FlexMove there is limited integration:

* Table can be locked by the system
* The system's emergency stop also stops all active table movements

SRS.Allura.Intgr.OpticalImagingSystem

The system shall optionally provide an optical imaging system to support auxiliary systems (e.g. compatible surgical navigation systems). The optical imaging system consists of video cameras positioned around the detector. The video stream of each camera is available for auxiliary systems. Parameters of the cameras are accessible and controllable by auxiliary systems.

## Peripheral Devices

SRS.Allura.Intgr.PhysioEquipment(ECG)

Compatibility with ECG signals from haemo equipment (acquisition of physiological signals, see SRS.Allura.Func.PhysioAcquisition).

SRS.Allura.Intgr.DVDRecorders

Compatibility with a medical DVD recorder for real-time storage of acquisition images.

* DP is the video output standard (in combination with IP based video infrastructure)
* SLR Video (PAL, NTSC) is the video output standard (in combination with DVI based video infrastructure)

SRS.Allura.Intgr.LocalPaperPrinters

Compatibility with general off-the-shelf local and network 2D printers.

## Injector Integration

SRS.Allura.Intgr.Injectors

The system shall provide interfaces to mount, power and control an injector.

## Departmental Image Storage Providers and Image Storage Users

SRS.Allura.Intgr.ImageExportImport

The system can be connected to departmental image storage providers (e.g. Xcelera PACS) and/or storage users.

* Compatibility according to DICOM conformance statement.
* Support for Query (DICOM SCU), Export (DICOM SCU) and Import (DICOM SCP).
* Supported formats: XA-multi-frame, Secondary Capture, JPEG-lossless.
* Supported features: Grayscale and non Grayscale Standard Display Compatible, DICOM Presentation state, Storage Commit.

## Departmental Worklist Management (WLM) Systems

SRS.Allura.Intgr.WLMSystems

The system can be connected to the hospitals Worklist management system (e.g. RIS/CIS). This requires a license.

* Compatibility according DICOM conformance statement.
* Support for DICOM-SCU Worklist and MPPS (Modality Performed Procedure Step) protocol.

SRS.Allura.Intgr.NonDICOMWLMSystems

RIS systems which are not using DICOM Worklist management can be connected via an external Philips product, which translates most RIS protocols to the DICOM protocol.

## Network Film Printers

SRS.Allura.Intgr.NetworkFilmPrinters

The system can be connected to Network Film Printers.

* Compatibility according DICOM (Basic Grayscale Print Meta class).
* Supported DICOM features: Gray Scale Display Standard, Presentation LUT (Look Up Table).
* Support for most commonly used printers to guarantee printing image quality.

## Compatibility With Media

SRS.Allura.Intgr.Media

In control room, support for storage on CD/DVD and USB according general PC format and DICOM. Also importing from CD/DVD and USB according DICOM is supported.

# UPGRADABILITY REQUIREMENTS

## Upgradability existing X-Ray systems

This release will be available for initial deliveries (always in combination with IP based video distribution infrastructure) and as software only field upgrade for Azurion system releases < R3.0. Upgrade will not impact external interfaces of the upgraded system.

# FUNCTIONAL REQUIREMENTS

In this chapter the functions are grouped according to their role in the normal workflow.

## Global Functional Behavior

### Workflow Flexibility

SRS.Allura.Func.Workflow.Flexibility

The user shall be able to have a workflow according local preferences.

* Different studies/procedure steps can overlap in time, i.e.
  + The user shall be able to suspend the current acquisition study/procedure step, select another study/procedure step for acquisition and later select the suspended study/procedure step for acquisition again.
  + The user shall be able to select a study for viewing besides an already selected study for acquisition.
* Sequence of workflow steps is not fixed, i.e. the user shall be able to switch between administration, image generation, viewing, post-processing, printing, reporting, archiving and distribution for the same study.
* Customizable automated workflow, i.e.
  + Automatic DICOM export.
  + Automatic dose report creation.
  + Automatic DICOM dose structured report.
  + Automatic finishing of the current acquisition study when another study is selected for acquisition.
  + Automatic setting a study to protected against deletion upon finishing of the study.
  + Automatic selecting of procedure card based on RIS code.

### Concurrency

SRS.Allura.Func.Concurrency

This addresses the possibility to use the same or different functions by multiple users at the same time.

* Administrative functions can be performed in the control room concurrent with activities in the exam room with exception of Bolus Chase Reconstruction and 2D-Quantitative Analysis.
* Local or remote service monitoring can be performed while the system is in use.
* Distribution/networking, printing and archiving can be performed with progress in the background.
* Based on switch-to licenses, auxiliary systems can be operated concurrently.
* The control room user can work on the same or a different patient and/or study from the exam room.
* (With FlexSpot) Two control room users can perform different functions on the same patient/study.

### Priority Handling

SRS.Allura.Func.PriorityConstraints

In case of conflicting or ambiguous user requests the following constraints shall apply:

* Overruling priority (high to low): 1) exposure, 2) fluoro, 3) other functions (except movement requests and concurrent working in control room) that are applied to the current acquisition study.
* A function shall be executed as long as requested from at least one UI, with exception of motorized movement requests: parallel movement requests shall be served as long as they are not conflicting.
* External (surgery) tables are equipped with their own user interface modules. For Maquet Magnus, parallel table movement requests shall result in stopping of the motorized table movements. A movement request via a TruSystem UI will stop a table movement requested via the system UI, without starting the newly requested movement. A table request via the system UI is ignored as long as a table movement request via the TruSystem is active.

### Exception Handling

SRS.Allura.Func.ExceptionHandling

A number of exceptional situations can be distinguished:

* A collision shall be indicated, also if other user messages are active.
* After a software error recovery, the system shall guarantee that previously stored clinical information is still available.
* If the user requests a function that cannot be executed in the current system state, for a reason which is not obvious to the user, the system shall display an appropriate user message.
* If the user requests a function and the system cannot execute the function because the system has run out of resources (e.g. storage full), the system shall display an appropriate user message.

### Graceful Degradation

SRS.Allura.Func.GracefulDegradation

In case of a system failure the available graceful degradation mode is entered, in which the system operates with reduced functionality and/or performance; the following rules apply:

* Via user/service guidance the graceful degradation situation is reported to the user.
* In a biplane system a defect in one channel must not prevent use of the other channel.
* The system will not try to automatically find alternate ways to realize the requested functionality.
* It is of the utmost importance that service functionality remains available for diagnosis.

### Demo System Behaviour

SRS.Allura.Func.Import/ExportOfClinicalImages

For marketing and educational purposes (medical fairs, Customer Visit Centre, development, brochures etc) marketing and application department must collect clinical data / images within constraints provided by Philips and customer privacy policies and controls. The collected data must be imported in our Image lab system, processed and exported again. The processed and exported data must then be imported again on the demo system. All privacy information (name, date of birth, physician, etc.) must be left out in demo image results. This feature supports storage of DICOM images (raw and processed images) to an USB-stick or external hard drive to improve the workflow and ease-of-use for application specialists (not intended for clinical users).

## General System Functions

### Power On / Off Functions

SRS.Allura.Func.SwitchSystemPowerOn

The user shall be able to switch the system on which includes system self-tests and service diagnostics.

SRS.Allura.Func.SwitchSystemPowerOn.VideoOnly

On Systems with FlexSpot(s) and/or FlexVision the user shall be able to switch on only the video part of the system, meaning the monitors and the control for FlexSpot(s), FlexVision, Switchable monitors (including Multivision) and (Additional, 3rd or 4th) Multiview including TSM.

SRS.Allura.Func.SwitchSystemPowerOff

The user shall be able to switch the system off; data is preserved to ensure acquired data does not get lost. Power outlets for external systems/equipment shall stay powered, but the user shall be able to switch off the power to these power outlets.

SRS.Allura.Func.SystemRestart

The user shall be able to restart the system to recover faster from a system failure compared to subsequently switching off and on.

SRS.Allura.Func.PowerFailureBehaviour

When the mains power fails:

* Safe operation shall remain guaranteed (e.g. block non-balanced movements, unblock manual movements to enable to free patient).
* Stored patient and system data shall be preserved (except for the last run if no Uninterruptible Power Supply (1 phase UPS) is installed).
* If the 1 phase UPS is installed, the system shall be shut down gracefully instead of an abrupt power off.
* After power is restored, normal operation shall be resumed after pressing the Power on button.

### Room Services

SRS.Allura.Func.RoomLightAndOperationLamp

Configurable at installation, the room-light and/or operation lamp can be switched or dimmed by a dedicated foot pedal, or synchronized to acquisition.

SRS.Allura.Func.DoorContact

The system shall be configurable to have a door contact connected to inhibit start of X-ray while the door is open between exam room and other adjacent rooms/corridor.

SRS.Allura.Func.Intercom

A two way intercom enables to communicate between control and exam room.

SRS.Allura.Func.EmergencyPowerDown

An Emergency Power Down interface shall be offered to switch off all power to the system when the optional 1 phase UPS is installed. A recovery mechanism shall be available to resume normal operation.

### Display General Data

SRS.Allura.Func.DisplayUserMessages

Comprises user guidance or error messages, which is to be displayed at the relevant workspot(s).

* Static messages are displayed as long as a cause exists (e.g. a system error).
* Triggered messages disappear automatically after a predefined time period.
* Confirmation by the user is not required.

SRS.Allura.Func.Display/SetTimeAndDate

The local time is indicated to the user.

* Display format can be changed (e.g. d/m/yr, yr/m/d); standard PC practices.
* Time is set either via Network Time Synchronization or by the user.

### Miscellaneous General Functions

SRS.Allura.Func.DisplayServiceGuidance

Error events initiate a service guidance. The service guidance is logged via the logging capabilities provided by the system. Additionally the error related service guidance is reported to the user.

SRS.Allura.Func.EnableRemoteServiceAccess

With this function the user explicitly enables and grants access for remote service activities.

* Dependent on the type of remote service activity the user will be restricted in using the system.

SRS.Allura.Func.RemoteServiceActiveIndication

When a remote service session is active, this is indicated to the user.

SRS.Allura.Func.ServiceStudies

These are special studies, needed to support the field-service functionality.

* During clinical usage the service studies are not visible.
* During field-service, both clinical and service studies must be visible.

SRS.Allura.Func.Diagnostics

The user shall be able to assess the status and settings of the hospital network interface and all incoming and outgoing network connections.

SRS.Allura.Func.SystemCustomization

Allows the user to customize system settings, that are available for the system's configuration, such as:

* Date, Time and Regional Settings
* User Administration and Administration settings
* List of annotation and performing physician
* Procedure cards and RIS code mapping
* Settings for viewing and quantitative analysis
* Media and DICOM export settings
* APC positions
* Linking DICOM export settings, APC positions and procedure help text to EPX procedures
* Remote support settings
* Defining APC pathways

Saved settings are persistent over system restarts.

System customization settings can be imported and exported.

## Administration Functions

This section focuses on administrative functions to deal with patient data and related information.

### General Administration Concepts

A local database includes all information that is entered manually and generated in acquisition.

* It can contain multiple patients/studies/procedure steps comprising patient data, images, etc.

### Local Administration Functions

SRS.Allura.Func.DisplayStudyList

This function lists the clinical (not field-service) studies present in the system's database.

* The presentation is filtered (e.g. schedule list only).
* The list can be sorted and searched for easy navigation to the targeted patient/study.
* Navigation within patient/study is enabled through the display of representative images ("pictorial index").

SRS.Allura.Func.ShowStudyInfo

The user shall be able to view the information of a selected study, comprising at least:

* Study info: overview of runs, applied EPXs, cumulative dose, fluoro time.
* Run/image info: exposure parameters, projections.

The user shall be able to filter the runs within the selected study.

SRS.Allura.Func.AddStudy

This function enables to add a new entry and related information to the study list.  
If operational, the WLM system provides the data for scheduling (e.g. patient name/ID, scheduled procedure start date/time). Alternatively, it remains possible to add a study entry locally.

SRS.Allura.Func.ModifyStudy

This function enables to modify existing study data. The following data cannot be modified locally:

* Data originating from a WLM system (modify on WLM).
* Auto-stored data (e.g. run info); exception: the run description.

SRS.Allura.Func.DeleteStudy

This function enables to delete a study and all related data from the database.

* Deletion can be done manually, or by the system to free storage space.
* The study is removed from the database and free storage space will increase.
* In case the respective study is protected or tasks (e.g. archiving) are pending, the user is prompted (e.g. to confirm deletion, or to remove the protection).
* The study selected for acquisition cannot be deleted.

SRS.Allura.Func.Protect/UnprotectStudy

Protection safeguards a study from automatic deletion.

* The user shall be able to set the protection on/off.
* Unprotected studies can be deleted by the system (to free-up storage space), unless related pending tasks (e.g. archiving) are not completed yet.
* If sufficient storage space can no longer be created by the system the user shall be warned.

SRS.Allura.Func.Merge

The user shall be able to move a run(s) from one procedure step to a procedure step of another patient.

Also, the user shall be able to import a study from media to another patient in the local database.

### Selecting Study For Acquisition

Before the start of acquisition the related study for acquisition is defined.

In case a WLM system is connected, a study can consist of multiple scheduled procedure steps. In that case, the user selects a procedure step for acquisition.

SRS.Allura.Func.SelectStudyFromScheduledList

This enables the user to select a study/procedure step for acquisition from the scheduled study list.

* The patient name is displayed clearly in the exam room.
* The system is prepared for acquisition; information about any blockage is shown.
* The system acquisition parameters are set according to the current EPX application/procedure.
* For WLM based procedure steps, progress is reported according DICOM MPPS.

SRS.Allura.Func.SelectStudyFromSuspendedList

This function lets the user select a study/procedure step for acquisition from the suspended study list.

Actions are similar compared to selection from the scheduled list, except:

* The last used settings are used to continue acquisition (e.g. dose data, clinical files).
* Newly acquired images are appended to the study/procedure step data.

SRS.Allura.Func.ImplicitSelectionDefaultStudy

If a user didn't select a study/procedure step for acquisition and performs acquisition, the system creates a study/procedure step under which the acquired images are stored.

SRS.Allura.Func.ReopenFinishedStudy

The user is able to re-open a finished study/procedure step and select it for acquisition.

The study/procedure step is re-initialized in such way that a complete workflow scenario may again be applied on the study/procedure step. Actions are similar compared to selection from the scheduled list, except:

* When a finished study/procedure step is selected, new images acquired are appended to the study/procedure step data.
* The procedure card, clinical-file structure, dose report data and other relevant data already attached to this study/procedure step are used as a starting point for any additional X-ray acquisitions.

### Finishing A Study

SRS.Allura.Func.FinishStudy

With this function the user indicates that this study is finished on the system.

* Per procedure step within the study, EPX defined automation tasks are started (e.g. export). After pending jobs (e.g. archiving) are successfully finished, the procedure step is finished and (if MPPS is configured) reported according DICOM MPPS.
* Unless set to protected, the occupied storage space is released for automatic deletion.

## Examination Related Presetting

### EPX Concept

SRS.Allura.Func.EPX

The system provides pre-optimized and/or preferred conditions in subsequent workflow phases via EPX selections, which adapt the system settings according following inputs:

* The kind of Examination (indicated by the application, procedure group).
* The selected Patient type.
* The selected X-ray operator (performing physician).
* The selected procedure.

Patient type and X-ray operator can be based on information from the WLM system, and/or can be selected by the user.

In a biplane system, settings can differ per channel.

EPX selection examples: acquisition-settings, positioning-defaults, image processing, archiving preferences.

### Presetting Functions

SRS.Allura.Func.PresettingFunctions

Presetting is determined by the information in the study/procedure step that is current for acquisition. The user can modify the information.

* The procedure card to be used can be modified.
* The performing physician can be selected from a pre-defined physician list.
* The patient type can be entered/modified manually.
* The EPX application/procedure group/procedure can be selected from a list (which contains only items that can be performed within the system's current configuration).
* EPX application, procedure group and procedure can be selected in control room, as well as in exam room.
* EPX application, procedure group and procedure can be selected during x-ray. The selected settings will then be applied for the next exposure or fluoroscopy run.

SRS.Allura.Func.ManualOverrideEPXParameterValues

According to personal preferences the user shall be able to perform overrides on a subset of EPX values.

* The subset shall be restricted in order to avoid risks of a degraded performance or image quality.
* Unless explicitly specified otherwise changes shall not be possible during acquisition.
* Overriding settings at application level shall be persistent until the same EPX application, another EPX application, patient type, performing physician or procedure step for acquisition is selected.
* Overriding settings at procedure level shall be persistent until the same EPX application, another patient type, performing physician or procedure step for acquisition is selected.

### Customizing Functions

This applies to customization of presettings according local or personal preferences.

SRS.Allura.Func.ProcedureCard

The user shall be offered a procedure based workflow by having procedure specific settings for a procedure step.

A procedure card determines the procedure specific settings, being:

* The EPX selections the user can choose from during the procedure and a default EPX.
* The default preset for FlexVision.
* The default preset for FlexSpot.
* The default preset for Second FlexSpot.
* The patient orientation and surgical view
* Procedure guidance.
* Specific settings for compatible room specific auxiliary systems

Predefined procedure cards shall be delivered with the system. The user can customize procedure cards and organize/group them. The user can set which procedure card shall be used when a procedure step is selected for acquisition. This can also be set automatically based on information from the WLM system (RIS code).

SRS.Allura.Func.PhysicianSpecificSettings

Preferred settings can be obtained for a specific physician;

* EPX parameters
* predefined APC positions

SRS.Allura.Func.ModifyPhysicianList

The user shall be able to create and change the physician list.

* Physician names can be added, deleted, and/or modified.
* If the system is connected to a hospital Worklist Management System, the name of the performing physician of a scheduled procedure step shall be automatically added to the physician list.

SRS.Allura.Func.ModifySelectionTree

Allows to modify the “Tree” of available EPX applications, procedure groups and procedures.

* Elements of the tree can be copied, renamed and/or deleted.
* It is not possible to create elements 'from scratch' (so only via copy of proven sets).
* The scope of this functionality is system-wide, not physician-specific.

SRS.Allura.Func.ModifyEPXParameters

Focuses on changing the value of EPX parameters.

* Complex settings are protected against modification by insufficiently skilled engineers.  
  (setting-specific authorization level versus service-key defined skill level).
* The scope of this functionality can be system-wide, and/or physician-specific.

## Patient And Beam Positioning

This section deals with positioning of patient and/or beam in order to select the anatomical area of interest.

### Orientation Aspects

SRS.Allura.Func.DisplayOrientation

The patient shall be displayed ‘head-up’, facing towards the user, regardless of patient orientation on the table (nose/legs up/down), and stand/detector orientation. This ‘diagnostic view’ adheres to standard clinical practice and prevents diagnostic risks in mistaking left/right patient anatomy.

For the lateral channel in a biplane system the same rule applies if the detector is rotated above the table, the image shall not be flipped if the lateral stand is rotated towards a lateral position.

There are 2 exceptions:

* if ‘surgical view’ is chosen, the image will be left/right reversed in case a patient is positioned nose down  
  (rationale: in order to have intuitive eye-hand coordination).
* in neuro applications (EPX controlled) the lateral-channel display will be left/right reversed  
  (rationale: based on neuro preference; the lateral view has no risk of misinterpreting left/right anatomy).

SRS.Allura.Func.PatientOrientation

The patient can be positioned on the table in one of 4 ways (nose up/down, legs down/up).

The actual patient orientation (nose up/down, legs down/up) can be entered into the system.

* Default orientation is procedure card dependent.
* The orientation can be changed by the user; the override remains valid until a new procedure card is selected.
* This setting is also used for intuitive control of shutters and wedges.

SRS.Allura.Func.SelectSurgicalView

Enables the user to select between surgical view and diagnostic view.

* The surgical view is only available on a configuration with an FD20 and FD15.
* The reversed acquired images must be clearly marked (e.g. inserted icon) to prevent diagnostic mistakes later on.

SRS.Allura.Func.SelectTableSide

The user shall be able in table-oriented mode to maintain intuitive movement control from four table sides. The user shall be able to select the table side on every movement-control UI module individually.

### Combined Patient- And Beam Positioning

This section focuses on movements under direct user control, which are not stand or table specific.

SRS.Allura.Func.ResetGeometry

The user shall be able to put the stand and table in a predefined position, in order to free the patient, or to provide a maximum of accessibility to the patient.

Note: In case of TruSystem table or Maquet Magnus table with universal table top, only the stand is put in a predefined position.

SRS.Allura.Func.EmergencyStop

The user shall be able to stop all motorized movements.

* Within operators reach, red-colored emergency stop buttons are provided.
* Movements to free the patient from the system remain possible.
* Normal operation is resumed after a system restart.

SRS.Allura.Func.MovementDisable/Enable

A disable movement function is provided to avoid accidental activation of movement related functions of table and available stands by laymen (e.g. cleaners). Programmed movements will not be available when movement is disabled.

* The disable function cannot be activated during programmed movements.
* Default state after power-up is enabled.

SRS.Allura.Func.OverrideMovementsBlockage

This function enables the user to override a stop for collision avoidance reasons, in order to reach positions that were otherwise not possible. During override specific measures apply.

SRS.Allura.Func.DisplayActualPosition

The actual position of table and stand is displayed to the user.

Note: Not supported for the TruSystem table, when in combination with the FlexMove.

SRS.Allura.Func.PositioningIndicationWithoutRadiation

This enables positioning before a run is started, in order to save patient radiation dose.

* During (manual or automatic) re-positioning of stand and table the anticipated radiation area shall be displayed (EPX controlled) as an overlay on an image for an EPX defined time.

Note: Not supported for Hillrom TruSystem table or Maquet Magnus table with universal table top

Position indication without radiation requires a license.

### Patient Positioning

This section focuses on moving and positioning the table under direct user control.

SRS.Allura.Func.PositioningTableTop

This applies to motorized or manual positioning of the tabletop in longitudinal and/or lateral direction.

* Table-type dependent manual positioning (so called 'float') is balanced (passive or motor-assist) to prevent the patient from sliding down (e.g. in case of tilt).

SRS.Allura.Func.TableTilting

This enables the user to tilt the tabletop to lift or lower the patient's head relative to his feet (motorized).

* The tilt rotation center is isocentric (except for TruSystem table) within the limits set by the particular table type.
* Customizable, the stand can follow the tilt movement in a synchronous way (except for TruSystem table).
* The tilting movement automatically stops in horizontal position.

Isocentric tilt on the Magnus table requires a license.

SRS.Allura.Func.TableCradle

The table rotates on the longitudinal axis (motorized).

* The cradle rotation center is ISO-centric within the limits set by the particular table type (Maquet/TruSystem OR Tables are excluded)
* The cradle movement automatically stops in horizontal position.

SRS.Allura.Func.ChangingTableHeight

Moves the table up/down (motorized).

* The movement range depends on the table type and on the table tilt/cradle angle.

SRS.Allura.Func.SwivelMovementTableBase

Provides additional longitudinal span to bring the table closer to the stand (AD7-X(N)T only).

* The table base can be positioned in one of two places (movement is motorized).

SRS.Allura.Func.PivotRotationTableBase

This enables the user to rotate the table base either to free a patient or to expose off-center body parts (not motorized).

SRS.Allura.Func.TableLock

The user shall be able to lock/unlock:

* The table pivot movements.
* The table lateral movements.
* All table movements.

For the TruSystem table in combination with FlexMove, the lateral table lock/unlock is not supported via the system UI.

### Beam Positioning

This section focuses on moving and positioning the stand under direct user control.

SRS.Allura.Func.AngulateBeam

Changes the angle between beam and longitudinal-table-axis (motorized).

* Angulation can be performed simultaneously with beam rotation.

During motorized movement the angle position is displayed.

SRS.Allura.Func.RotateBeam

The user shall be able to rotate the beam around the longitudinal-table-axis (motorized).

Intuitive control and display orientation rules (see SRS.Allura.Func.DisplayOrientation) also apply if rotation causes a reversed beam direction.

In biplane systems, the frontal and lateral beam can be rotated simultaneously.

During motorized movement the rotation position shall be displayed.

SRS.Allura.Func.PatientOrientedMovement

In FlexArm (XY-fa) and biplane (Clea3 & L-arc3 only) configurations, if the user angulates or rotates the frontal beam, the detector and collimator angles shall be adapted so to keep the same orientation towards the patient.

SRS.Allura.Func.MoveBeam

The user shall be able to move the frontal and/or lateral beam longitudinal to select a clinical area for acquisition (manual and motorized).

* This function only applies to ceiling suspended configurations.

SRS.Allura.Func.MoveBeamXY

The user shall be able to move the beam longitudinal and/or transversal (manual and motorized).

* To select a clinical area for acquisition as an alternative to positioning the tabletop.
* For standby parking (typically transversal only) during a surgical procedure.
* For normal parking when the stand is not used.

SRS.Allura.Func.ParkorStandbyBeam

Enables the user to move the frontal and/or lateral stand out of the way to a standby or park position to improve access to the patient if the beam is temporarily not used.

* The different ways to move the stand to a park / standby position depend on the particular configuration  
  (examples: lateral movement for Flexarm standby, longitudinal movement in ceiling stands, swing stand base in a Poly-G floor stand).

SRS.Allura.Func.ChangeSIDByDetector

Changes the Source Image Distance (SID) by moving the detector along the beam (manual and motorized).

* The beam width is adapted automatically to maintain the selected detector field-size.

SRS.Allura.Func.ImageBeamRotation

In FlexArm (XY-fa) and biplane (Clea3 & L-arc3 only) configurations, the frontal beam shall be rotatable i.e. collimator and detector rotate simultaneously and stay continuously aligned (IBR).

SRS.Allura.Func.RotateFDXDDetector

Enables the user to rotate the frontal FD20 detector for optimized imaging (manual and motorized).

* User shall be able to rotate the detector by 90° in order to switch between landscape and portrait usage of the detector. Beam width is adapted to maintain the selected detector field size.
* User shall be able to rotate the detector by any angle between 0° and 90° in order to align with specific anatomy.
  + In FlexArm (XY-fa) and biplane (Clea3 & L-arc3 only) configurations, the collimator rotates synchronously to maintain the selected detector field-size.
  + In all other configurations, the collimator is fixed and the beam-width is limited such that the irradiated area is completely visible.

SRS.Allura.Func.Z-RotateStandBase(L-ArmRotation)

Enables the user to rotate the frontal stand for position at the side or head of the table for optimized patient imaging.

Iso-center stand rotation around a vertical axis to accomplish improved access to the patient.

* Function does not apply to the Poly-G floor stand.

SRS.Allura.Func.SwingStandBase

Enables the user to rotate the Poly-G floor stand around a vertical axis far outside the iso-center.

* Enables the user to image objects (e.g. patient's arm) that are not centered on the table.
* Enables the user to rotate the stand away from the table for parking purposes.

### Automatic Position Control (APC)

Focus is on applying pre-defined or user-defined positions in controlling table and/or stand movements.

SRS.Allura.Func.APCCommon

During APC movements the SID shall be maximized in order to reduce the chance of a collision. In case of a collision APC movement is stopped.

SRS.Allura.Func.APCStore/Recall

The system shall allow the user to store and recall multiple geometry positions (i.e. position of stand, table, shutters and wedges) including the receptor field size.

* When a new acquisition study is selected, all stored positions shall be removed.
* The system shall indicate to the user if the system has not reached a selected position.

Note: Table position recall is not supported for TruSystem tables in combination with FlexMove. On AD7X tables recall of longitudinal and lateral table position requires appropriate motors which are optional

SRS.Allura.Func.APCPredefined

The system shall provide pre-defined sets each comprising a sequence of projections (defined by rotation/angulation, SID and Field of View). The sets shall be EPX defined and a set can have max. 20 projections. The user shall be able to customize the sets. Specific sets can be customized for different users.

The user shall be able to recall the projections of a set in sequential order, but alternatively the user shall be able to recall a projection directly.

APC predefined requires a license.

SRS.Allura.Func.APCReference

The user shall be able to recall the geometry positions (i.e. position of frontal and lateral stand, table, shutters and wedges) plus the receptor field size which corresponds to an image that is displayed in a live or reference viewport.

In a biplane system, the user shall be able to recall a position for both frontal and lateral channels independently or simultaneously.

Note: Table position recall is not supported for TruSystem tables in combination with FlexMove. On AD7X tables recall of longitudinal and lateral table position requires appropriate motors which are optional

APC reference requires a license.

SRS.Allura.Func.APC3DReference

The user shall be able to recall the frontal projection (rotation/angulation) that corresponds to a view on the Interventional Workspot (3DRA, XperCT, etc).

Indicated by the Interventional Workspot, the SID shall go to minimum or to maximum (maximum to e.g. prevent hitting the needle) during the recall movement.

APC 3D reference requires a license.

SRS.Allura.Func.APCTable

After the user has brought a point-of-interest into the system’s iso-center, the user shall be able to store the corresponding table position (i.e. table longitudinal, lateral, height, tilt and cradle). The system shall provide a default point-of-interest (EPX defined). When a new acquisition study is selected the 'stored table position' is reset such that the default point-of-interest is in the iso-center.

The user shall be able to recall the stored table position or only the table height.

The system shall indicate to the user if the table is in the stored position.

Note: Not applicable for  Hillstrom TruSystem table with universal table top and Maquet Magnus table with universal table top. On TruSystem tables with the SQ14-Xtra table top only height can be recalled. On AD7X tables recall of longitudinal and lateral table position requires appropriate motors, which are optional.

APC table requires a license.

SRS.Allura.Func.APCPathway

Only available on the FlexArm configuration. A user shall be able to define a pathway of longitudinal, transversal and z-rotation stand positions for the system. For tables with recall capabilities, also a table position can be given for the first and last positions. A user shall be able to recall the pathway, causing the stand and table to be moved to the positions of the pathway in the sequence defined for the pathway.

## Beam Limitation & Conditioning

This section focuses on shaping and filtering the X-ray beam.

### Beam Shape Settings

To restrict X-ray radiation to the clinical region of interest the user can apply shutters. Additionally, the user can apply wedges that reduce X-ray intensity to prevent over-exposure in parts of the image.

SRS.Allura.Func.BeamShapingControls

Controls are made intuitive in the sense that orientation with respect to displayed image is maintained.

SRS.Allura.Func.ShutterAndWedgeIndicationWithoutRadiation

This enables positioning before a run is started, in order to save patient radiation dose.

* Re-positioning causes the anticipated area to be displayed as an overlay for an EPX defined time.

SRS.Allura.Func.Move/ResetShutters

Enables shutters to move in/out.

* Opposite shutters move in pairs; horizontal and vertical pairs can be moved simultaneously.
* Opening stops at the edge of the current detector field (so becomes again visible at a larger field).
* Closing must be immediately visible (i.e. fast moving to edge of detector field, if initially larger).
* In case a user-defined position is overruled (by switching towards a smaller field-size), enlarging the field-size will automatically widen the shutters until the original user-defined position is reached.
* Reset puts the shutters at the edge of the detector field-size.
* The default position of shutters is EPX application/procedure determined.

SRS.Allura.Func.Move/ResetWedges

Enables wedges to move in/out, or rotate. Reset puts the wedges outside the imaging area.

The default position of wedges is EPX application/procedure determined.

SRS.Allura.Func.AutomaticWedgeFollowing

Wedges can be positioned automatically, coupled to the position of the stand.

* The auto-follow position is restored (e.g. after manual overriding) each time the stand is moved.
* This auto-follow behaviour can be switched on or off by the user; default defined in EPX.

### Beam Conditioning

SRS.Allura.Func.X-rayFiltering

The system is equipped with a set of 4 X-ray spectral filters that are used to reduce the patient skin dose and to improve image quality.

* Selection of a filter for exposure is EPX procedure determined; no manual override.
* The filter for fluoro is coupled to the fluoro-flavour (defined in EPX application); no manual override.

## Image Generation

This section describes the functions related to acquisition of X-ray images.

### General Concepts

SRS.Allura.Func.AcquisitionMethods

Image generation (also called acquisition) can be done in a number of ways:

* Fluoro: intended to provide a real-time X-ray image.
* Exposure: intended for real-time diagnostic imaging and documentation purposes. Compared to fluoro a higher signal to noise ratio (S/N) is necessary for diagnostic imaging and the images are always stored, enabling reviewing.

SRS.Allura.Func.BiplaneAcquisition

In a biplane system, the user can acquire a frontal and lateral projection simultaneously, saving procedure time and contrast medium.

* This is manually pre-selected before the start of a run (for exposure), or based on the activated pedal(s) (for fluoro).

SRS.Allura.Func.DoseControlTechniques

X-ray dose-control techniques determine the applied X-ray dose, and have a major impact on resulting image quality.

* 'Cine control' uses previously acquired images and measurements to optimize X-ray settings.
* 'Test-Shot Lock-in' determines fixed settings for a whole run, based on testshot(s).
* 'Automatic Thickness Control (ATC)' uses a previous run to optimize start conditions for a next run.

Control strategy as well as default settings are determined by EPX (optimized for e.g. application).

SRS.Allura.Func.X-rayImageProcessing

Image processing is applied to enhance the diagnostic value and the user's appreciation of the images.

* Processing is EPX controlled to allow optimized images for each type of procedure and each user.
* Fluoro processing depends on the selected fluoro-flavour.

The processing algorithm ClarityIQ is optionally available. The option OncoBlue enables ClarityIQ image processing restricted to abdominal examinations only. ClarityIQ and OncoBlue both require a separate license.

### Common Functionality For Fluoro And Exposure

SRS.Allura.Func.SelectDetectorFieldsize

The detector field-size is the detector area that is being acquired and displayed.

* The user shall be able to select a field-size; for fluoro also during acquisition.
* The available field-sizes and related image quality characteristics depend on the type of detector.
* The default shall be restored when a new procedure step is selected for acquisition, and EPX-dependent at EPX procedure selection.

SRS.Allura.Func.EPTriggering

Acquisition timing can be synchronized to the patients ECG signal.

* The user can select triggering on/off and control trigger-delay.
* Not applicable to low frame-speed vascular exposure.

Synchronization requires a license.

SRS.Allura.Func.LastImageHoldOrAutoCycle

Customizable, after acquisition the last exposed image is displayed or the run is cycled.

* Auto-cycle stops automatically after a customizable time-out (static image remains on display).

SRS.Allura.Func.DoseControlMeasuringFields

The field determines which part of the radiated detector-area is taken into account for dose-control.

* The field is determined in EPX; customizable from a set of available shapes.
* The user cannot override the measuring field.

SRS.Allura.Func.DisplayInfo

Displays detailed information about the current acquisition parameters. The display of information can be customized for live- and review viewport.

SRS.Allura.Func.Select/DeselectStopwatch

General purpose on-screen stopwatch; not coupled to X-ray generation events

SRS.Allura.Func.AntiScatterGrid

Is placed in front of the detector to reduce the influence of scatter radiation on image quality.

* The grid can be mounted and removed by hand (without the need for tools).

SRS.Allura.Func.StripeFilter

A function shall be provided to filter the images with a so called “stripe filter” in order to get rid of image disturbances caused by external equipment via magnetic interference (e.g. Biosense-EP). The filter can be enabled / disabled via EPX.

SRS.Allura.Func.TubeLoadProtectionAndIndication

The system shall safeguard X-ray-generation components and indirectly protect the user and the patient against potential harmful consequences from overloading the tube. Low-load fluoro shall remain available.

SRS.Allura.Func.IndicateRadiationOn

During X-ray generation this is continuously indicated to the user.

* X-ray-on light in and outside the exam room; indications on the UI in exam room and control room.
* Continuous audible signal (fluoro/exposure buzzer); can be configured off.

SRS.Allura.Func.X-RayDisable/Enable

A disable/enable X-ray function is provided to avoid accidental activation of X-ray related functions such as radiation, coupled contrast injection and programmed movements by laymen (e.g. cleaners).

* The disable function cannot be activated during fluoro and exposure active.
* Default state after power-up is configurable.

SRS.Allura.Func.DVDRecordControl

Enables automatic start/stop of a medical DVD recorder, synchronous to generation of X-ray (fluoro and/or exposure).

* EPX controlled, the medical DVD recorder records a copy of the displayed images.

This requires a license.

SRS.Allura.Func.AutomaticElectronicShutters

The area outside the detected image is automatically blanked to hide detected scatter and noise.

SRS.Allura.Func.AcquisitionZoom

Enables the user to zoom the live image during acquisition (center-zoom).

* Zoom value and zoom-center position can be set by the user during Last Image Hold (LIH).
* Acquisition zoom is only allowed if the unzoomed image is displayed also (e.g. in dual-fluoro)

SRS.Allura.Func.DisplayAndReportPatientDose

This applies to Dose Area Product (DAP) and skin-entrance-dose (air-kerma).

* Dose info is displayed during and after acquisition.
* Generated and displayed values comply with legal demands for required accuracy.
* The user is warned if accumulated air-kerma within the current body zone is above a customizable threshold value (default value 2 Gray).
* The cumulative (zone-)dose figures are comprised in the study.

SRS.Allura.Func.RunLogging

Information of stored fluoro and exposure runs is collected in the run log, as part of the study.  
This comprises:

* Figures on accumulated skin-dose and area-dose.
* Applied generator settings (e.g. KV/mA/mS) and X-ray spectral filter; per run.
* Applied geometry (e.g. rotation, angulation) settings; per run.
* Name of EPX procedure, time of acquisition, and number of images; per run.

### Fluoro Specific Functions

SRS.Allura.Func.FluoroFlavours

The user can select between 3 EPX defined flavours, determining e.g. fluoro-frame-rate and X-ray dose.

* The flavour-determined frame-rate can be 30, 25, 20, 15, 12.5, 10, 7.5, 6.25, 5, 3.75, 3.125, 2.5, 1.875, 1.25, 1.0, 0.625, 0.5 img/sec.
* In biplane, frontal frame-rate equals lateral frame-rate (available range same as for monoplane).
* A fourth flavour can be selected by the system in situations where low-load is necessary (e.g. for graceful degradation).
* For legal reasons, a low-dose fluoro flavour is available with a ratio normal/low of at least a factor 2.
* Configurable, a high-dose flavour with a maximum of 20 R/min is offered.
* A flavour can also be selected during fluoro.

SRS.Allura.Func.ActivateFluoro

As long as the user activates fluoro, X-ray is generated and images are acquired and displayed.

* Exposure will temporarily interrupt fluoro; after the exposure switch is released, fluoro is automatically resumed (if still activated).
* After 10 minutes of uninterrupted fluoro, fluoro is automatically stopped.

SRS.Allura.Func.StoreFluoro

Fluoro images are cached with cyclic overwrite for an EPX defined time-span.

* During fluoroscopy, the user can grab (i.e. store) single fluoro images or an image sequence.
* Multiple grabs during a single fluoro run are stored for each grab in its own run.
* After fluoroscopy, auto-cycle displays the cached sequence.
* After fluoroscopy, the user can store this complete cached run as a normal run.
* The cache is cleared at the start of a next fluoro run.

SRS.Allura.Func.FluoroTimeBuzzer

Warns the user after an elapsed accumulated fluoro time of 5 minutes:

* This safety mechanism can be customized on/off, dependent on the local needs and safety regulations.
* The user can deactivate the buzzer.

SRS.Allura.Func.DisplayFluoroTime

The total fluoro time for the current study is displayed.

SRS.Allura.Func.High-DoseFluoroProtection

Customizable, depending on local legislation and/or preferences, the following measures are available:

* Limitation on entrance doserate.
* An audible warning signal, produced during the high-dose fluoro.
* Automatic switch-back towards normal dose settings after a certain time of continuously high-dose fluoro, and/or at the end of high-dose fluoro.

SRS.Allura.Func.ContrastInjection

For fluoro, contrast medium is to be administered manually, and no synchronization or coupling to a motorized injector is provided.

SRS.Allura.Func.Roadmap

The user shall be able to activate or deactivate roadmap.

* If roadmap gets activated, the last used roadmap mode since EPX application selection is used, otherwise the default roadmap mode for this EPX application is used.
* Dependent on the roadmap mode, the system starts roadmap in either the Vessel phase or the Device phase. The active roadmap phase is indicated to the user.
* Selection of a SmartMask is an implicit activation of roadmap. The Device phase is automatically entered.

Subtracted imaging requires a  license.

SRS.Allura.Func.Roadmap.Mode

The user shall be able to select a roadmap mode. Up to 4 roadmap modes shall be present (EPX) to set the exposure-control and image processing-control parameters for the Vessel phase and image processing-control parameters for the Device phase. The current selected fluoro flavour settings are used as the acquisition-control parameters for the Device phase.

SRS.Allura.Func.Roadmap.VesselPhase

In this roadmap phase, a VesselMask from the acquired exposure images shall be created, which will serve as a background image during the roadmap Device phase.

* Contrast is manually injected during the run and subsequent images are ‘traced’: this is for each particular image spot (a pixel) the minimum occurring value is retained (TraceMin).
* Alternatively (for CO2 contrast: white vessels), the maximum occurring value is traced (TraceMax); (selection TraceMin/TraceMax is determined by EPX).
* The images are shown background-subtracted (after X-ray stabilization).
* On Last-Image-Hold, the resulting image is the VesselMask.
* After the run is made, the roadmap Device phase is automatically entered.

SRS.Allura.Func.Roadmap.SmartMask

Alternative to the roadmap Vessel phase, the user can directly select an image from any stored run and use it as the VesselMask (‘SmartMask’) for the Device phase.

* Before selecting, the smart mask can be enhanced using pixel-shift.

Selecting a ‘SmartMask’ requires a license.

SRS.Allura.Func.Roadmap.DevicePhase

In this roadmap phase, the fluoro images shall be displayed according the current roadmap mode settings (EPX), meaning in one of the following Device phase modes:

* LiveSubtract;
* VesselSubtract; or
* VesselUnSubtract.

Exposure runs can be made in-between Device phase runs without losing the related masks.

SRS.Allura.Func.Roadmap.DevicePhase.LiveSubtract

In this mode, the images shall be displayed subtracted with the DeviceMask resulting into the so-called Device image.  
Optionally (EPX determined) the Device image shall be displayed superimposed by the LandmarkMask (containing the bones structure, derived from the DeviceMask).

SRS.Allura.Func.Roadmap.DevicePhase.VesselSubtract

In this mode, the images shall be displayed subtracted with the DeviceMask resulting into the so-called Device image, and the Device image shall be displayed superimposed by the (faded) VesselMask.  
Optionally (EPX determined) the Device image shall be displayed superimposed by the LandmarkMask (containing the bones structure, derived from the VesselMask).

SRS.Allura.Func.Roadmap.DevicePhase.VesselUnSubtract

In this mode, the images shall be displayed unsubtracted (no DeviceMask), but the images shall be displayed superimposed by the (faded) VesselMask.

SRS.Allura.Func.Roadmap.DevicePhase.DeviceMask

During acquisition (in the LiveSubtract and VesselSubtract modes), the so-called DeviceMask shall be calculated from a number of received images (EPX determined).

The DeviceMask shall be retained for subsequent acquisitions, unless one of the following cases occurs:

* The user requests a remask of the DeviceMask.
* Roadmap is deactivated.
* The user selects another SmartMask.
* The user selects a fluoro flavour.

SRS.Allura.Func.Roadmap.DevicePhase.Misregistration

To prevent mis-interpretation, subtracted display is switched-off automatically and a user message is displayed if the VesselMask or DeviceMask does not match live fluoro (regarding SID and geo projection).

SRS.Allura.Func.Roadmap.DevicePhase.Subtraction

During fluoro in the Device phase (after X-ray stabilization), subtraction can be toggled on/off without losing the related masks.

SRS.Allura.Func.Roadmap.DevicePhase.Processing

On Last-Image-Hold the user can change settings interactively, also for the next fluoro run:

* Regular processing functions, e.g. pixel-shift, can be applied to obtain a better match.
* The intensity of the VesselMask and Device image can be altered independently (called ‘Fading’).

SRS.Allura.Func.Roadmap.AutomaticPixelShift

During the roadmap Vessel and Device phases, optionally automatic pixel-shift is applied to the live image (EPX controlled) to compensate for undesired movements.

SRS.Allura.Func.DualFluoro

Enables the user to display the fluoro image simultaneously in subtracted and unsubtracted mode. This requires a license

* The display showing the subtracted image can be zoomed interactively also during live acquisition.

SRS.Allura.Func.ChangeFluoroProcessing

Enables the user to change processing during LIH or Auto-cycle (e.g. contrast/brightness/edge-enhancement).

* The changes remain active until the same EPX application, another EPX application, patient type, performing physician or procedure step for acquisition is selected, or roadmap is activated.

### Exposure Related Functions

SRS.Allura.Func.SelectActiveChannel

In a biplane system this enables the user to select the acquisition channel(s): frontal, lateral or biplane.

SRS.Allura.Func.ExposureFramespeed

Determines the rate at which images are acquired.

* In cardio/cine mode: 60, 50, 30, 25, 20, 15, 10, 7.5, 5, and 3.75 im/sec; EPX defined   
  (within limits set by detector and configuration).
* In vascular Test-Shot Lock-in (TSL) mode: 12, 8, 6, 4, 3, 2, 1 and 0.5 im/sec; EPX-default, user-overridable   
  (within limits set by detector and configuration).
* In biplane, frontal frame-rate equals lateral frame-rate (available range same as for monoplane).

SRS.Allura.Func.SingleShotFootpedal

This enables the user to acquire a single image in vascular/lock-in mode directly via a separate footpedal.

SRS.Allura.Func.TimedVariableFramerates

This enables the user to acquire a vascular/lock-in run in 3 phases with different frame-rates and durations.

* Pre-programmed sequences are available (customizable in EPX).
* The user can modify phase-duration and frame-rate per phase; phase-switch possible during the run

SRS.Allura.Func.ExposureTechniques

Selection and settings of exposure dose-control techniques are determined in EPX and cannot be overridden by the user.

SRS.Allura.Func.ActivateExposure

This causes X-ray radiation, images are acquired, displayed and stored.

* The user is warned when the free space is insufficient to make the next exposure run.
* The run is stopped (in case of max. 1k2) after 1000 images, or when no more image storage free space is available.

SRS.Allura.Func.IntegratedExposure

This feature provides improved image quality with reduced detector noise in vascular/lock-in runs.

* Settings are EPX determined and cannot be changed by the user.

SRS.Allura.Func.ExposureSubtract

Displays the run subtracted after the mask is acquired.

* The mask is automatically selected (EPX procedure defined).
* The user can override subtraction on/off for the complete exposure run (before acquisition has started).
* Optionally automatic pixel-shift is applied to the live image (EPX controlled) to compensate for undesired movements.

Subtracted imaging requires a license.

SRS.Allura.Func.AcquisitionMaskAveraging

Exposure subtraction can be enhanced by averaging several images to obtain an improved mask.

* This feature provides improved image quality with reduced noise.
* Settings are EPX determined and cannot be changed by the user.

SRS.Allura.Func.SetInjectorCoupling

Enables to couple motorized injection to acquisition. This requires a license.

* The user can select between coupled and uncoupled.
* At a new procedure step selection for acquisition, and customizable after every run, the injector is set to uncoupled.
* Timing of injection is based on a fixed "injector response time" and EPX defined image after which injection should start and “Contrast Arrival Time” (user overridable).
* In case the start of acquisition is delayed, a “Count-down bar” is shown representing remaining time.
* Type of injector coupling is customizable:
  + One-knob: X-ray hand- or footswitch control both injection and X-ray.
  + Two-knob: X-ray hand- or footswitch controls X-ray, but injection is enabled by injector handswitch.

### Acquisition Of Physiology Signals

SRS.Allura.Func.PhysioAcquisition

The system can acquire physiological signals together with the X-ray images. This requires a license.

* Number of channels (up to 4) is configurable.
* Only compatible with electrical signals (e.g. ECG; no compatibility with pressure, etc.).
* EPX determined storage (on/off) of all inputs; recording only in parallel with exposure.

## Image Generation Scenarios

This section focuses on acquisition of images during a controlled geometry movement.

### Dynamic Rotational Angiography

In a DRA scan the X-ray beam rotates around the patient's area of interest placed within the iso center.

SRS.Allura.Func.ClassicDRA

The user shall define the end- and start-position of the DRA scan, implicitly executing a test-scan to detect obstructions.

The system shall be able to perform the DRA scan at the side or head of the table (C-arm roll and propellor respectively).

DRA acquisition is only possible for the frontal channel.

The user shall be able to acquire a second run to enable subtracted reviewing.

Settings, including start- and end-positions, shall be defined in EPX, but if allowed in EPX, the user shall be able to choose another end- and/or start-position.

DRA requires a license.

SRS.Allura.Func.DRAFor3D

DRA for 3D is a special case of DRA performed at predefined positions, to enable 3D reconstruction.

Settings, including start- and end-positions, shall be defined in EPX.

The system shall support DRA for 3D at least at the following positions:

* for FlexArm (XY-fa) configuration at head, doctor and nurse side
* for other FD20 and FD15 configurations at head and one side position (doctor or nurse)
* for FD12 only at head position

SID is maximized to allow for 3D scans of obese patients.

SRS.Allura.Func.XperCT

This is a special case of DRA or DAR for 3D enabling reconstruction of soft-tissue. This function is only supported with an FD20 detector.

* The system shall offer dedicated EPX procedures and related settings for Neuro (DRA and DAR) and Abdomen (DRA only) applications.
* The system shall perform acquisition with up to 60 images/second to obtain acceptable scan time.
* The system shall be able to apply slit collimation to reduce patient dose.

SRS.Allura.Func.DualPhaseXperCT

This is a special case of XperCT where two consecutive DRA scans are being made by executing the scans in different phases of contrast propagation, which is known as Dual phase XperCT.

* The two scans are performed in opposite direction to reduce the overall procedure time to minimize the amount of contrast medium.
* For neuro applications, to allow the use of intravenous contrast injections in Dual phase XPerCT scans, the system shall provide a subtracted fluoroscopy flavor with enhanced contrast. It shall enable to detect the arrival of contrast agent in order to start the scan. This application shall be executable from the Control Room.

### Flexible Dynamic Peripheral Angiography (FDPA)

SRS.Allura.Func.FreeInteractiveFDPA

A run is acquired while the user directly controls the longitudinal movement of the table. FDPA requires a license.

* Optionally a mask run with identical auto-movement profile can be made for subtracted review.

Not supported for a TruSystem table with Azurion FlexArm option.

### Dual-Axis Rotation (DAR)

SRS.Allura.Func.Dual-AxisAcquisition

A run is acquired while the X-ray beam is rotated and angulated according a curved movement profile. This function is only available for the frontal channel.

* Scans are performed automatically according pre-defined acquisition/geometry settings; cardiac swing or helical. Cardiac Swing

requires a license.

## Digital File & Data Management

Focus is on the handling of files with images and/or related data, as perceived by the user.

### File & Data Operations

SRS.Allura.Func.CopyImages

The user shall be able to copy a single image, or a selection of images.

SRS.Allura.Func.StoreReferenceRun/Image

The user shall be able to add the active image or run to a reference viewport. This option requires a license.

SRS.Allura.Func.DeleteRun

A complete run (containing one or more images) can be deleted manually.

* Measures have to be taken to prevent accidental deletion (e.g. request the user to confirm).

SRS.Allura.Func.Flagging

The user can flag/un-flag selected images or entire image-runs. This comprises adding a flag marker to the selected images, without implying any further action. Flagging groups the selected images in a set which can be treated as a single entity by other clinical functions. Example: archive the flagged images.

* Flagging does not imply any subsequent action.
* Only one type of flags exists.
* The flagged data is indicated to the user by a flag marker.
* In case of a biplane image/run the user can flag the images from one or both planes.

Note: In combination with e.g. archiving, the flagging mechanism may result in the transference of an incomplete run. As a result, during cine display its dynamic appearance may look peculiar.

## Digital Viewing

Emphasis is in this section on the selection of runs and images and the way this info is displayed.

### Viewing Navigation

SRS.Allura.Func.SelectViewingStudy

Enables the selection of a current viewing study (besides an already selected study for acquisition). The system shall indicate if the current viewing study differs from the study selected for acquisition.

SRS.Allura.Func.NavigateToImageData

Enables the user to zoom-in progressively on a particular file and/or a run, down to a specific image.

* After selection of a study for viewing or for acquisition, the first exposure or fluoro run is active for viewing.
* Exposure overrules the selection and makes the latest acquired run active for viewing.

SRS.Allura.Func.SwitchDisplayFocus

This function switches focus from Exam Display towards Reference Display and vice-versa.

* Acquisition implicitly sets the display focus to the Exam Display.

SRS.Allura.Func.MosaicOverview

Images are minified and displayed as an N\*N mosaic in one or more pages.

* In Run-Overview the mosaic displays each image in the run.
* In File-Overview the mosaic displays a single image from each run in the file.
* In mosaic display mode navigation functions remain available.

SRS.Allura.Func.SelectPhysioDisplay

This function enables to switch on/off physio data as graphics overlay.

* The correct time relation between images and physio on display must be preserved.
* In case of multiple physio sequences, the user can select one recorded channel for display.

### Dynamic Viewing

SRS.Allura.Func.DynamicViewing

This enables the user to view a run in cine mode, e.g. to show the dynamic behaviour of a beating heart.

* In cine mode, interactive image processing (e.g. zoom, subtraction) remains available.
* If the user selects two planes in biplane, the runs are displayed synchronously.

SRS.Allura.Func.Cycle

This function enables to display a sequence of images in cine mode.

* In file-cycle all exposure and fluoro runs in the active file of the current study are cycled sequentially.
* In run-cycle the complete active run is cycled.
* User can set speed.

## Intra-Image Post-Processing

Focuses on intra-image processing functions for customized enhanced display.

### General Concepts

SRS.Allura.Func.OverrideManualAdjustments

This function resets settings (if altered during postprocessing) to “as during acquisition”.

* The user can select the scope of this function to all postprocessing settings, or a defined subset.

SRS.Allura.Func.SelectProcessingFocus

This function allows the user to select whether the processing applies to the images of both channels (in case of biplane runs) or only one.

SRS.Allura.Func.SelectProcessingScope

The user shall be able to set the scope of the interactive post-processing operations within a run:

* the scope may be set to either the whole run or to the active image for annotation;
* the scope may be set to either the whole run, to a selection of images within the run, or to the active image for image enhancement, video invert, pan, zoom, and landmarking;
* the scope may be set to either the whole run, to a selection of images within the run, the active image, active image and all preceding images in the run, active image and all following images in the run for pixel-shift;
* for all other operations the scope is always the whole run.

### Image Enhancement

SRS.Allura.Func.SetImageEnhancement

The user can interactively change image contrast, brightness and/or amount of edge-enhancement to adapt the subjective image quality to personal preference.

SRS.Allura.Func.VideoInvert

Changes the polarity of the image on display, e.g. black bones/vessels to white, and vice-versa.

### Image Presentation

SRS.Allura.Func.SetElectronicShutters

Enables the user to interactively position 4 rectangular shutters to blank part of the displayed image.

SRS.Allura.Func.PanZoom

Enables the user to zoom the image on display and pan the zoom-center.

* The user can determine the zoom factor.
* The user can reset panning towards the image center.

### Annotation & Overlay Text

SRS.Allura.Func.OverlayText

Overlay text comprises image/run-related information and is shown by default (e.g. number, geo-angles).

* Non-essential overlay text can be switched-off by the user to unclutter the display.

SRS.Allura.Func.ManualAnnotation

This enables the user to add text and/or shapes on a certain position into the image on display.

* Annotations can be repositioned, modified, hidden, copied and deleted.
* Annotations can be added to x-ray images and as well on secondary capture images.

SRS.Allura.Func.PredefinedAnnotation

During manual annotation, a list can be displayed containing predefined and user defined text strings, which can be inserted within the current annotation block.

The user shall be able to customize this list:

* The predefined annotations can be deleted and modified.
* The user defined annotations can be added, deleted and modified.

SRS.Allura.Func.Measurement

The user shall be able to add measurements on a certain position into the image on display or on the TSM. This requires a license.

* The following functions are supported: length of a line, angle between 2 lines, and ratio between the length of 2 lines.
* Measurements can be repositioned, modified, hidden, copied and deleted.
* Measurement functionality shall support auto calibration and manual calibration methods to relate distances on display, expressed in pixels, to real-object distances (see SRS.Allura.Func.QACalibration)
* Accuracy of a length measurement shall be within ± 5% in automatic calibration when the measured object is in the iso-center and if the length of the object to be measured covers at least 50 pixels on the monitor
* Accuracy of an angle measurement shall be within ± 2.0 degrees.

## Multi-Image Post-Processing

This section focuses on obtaining additional diagnostic value out of combining multiple images.

### Image Subtraction

SRS.Allura.Func.NormalSubtraction

Minimal movement in acquisition is assumed, to obtain enhanced view with single mask subtraction.

* Enables that the user can step through the run to see the progressive filling of arteries or veins.
* The user can switch subtraction on/off, and/or select another mask from the run.
* Manually, registration errors due to patient movements can be corrected ("Pixel-shift" function).
* A background portion can be added manually for orientation purposes ("Landmarking" function).

Subtracted imaging requires a license.

SRS.Allura.Func.RunSubtract

Subtracted view is obtained for an acquisition run exhibiting intended movement (e.g. DRA). This requires a license.

* Subtraction is based on an acquired mask run; the matching run is automatically selected.

### View-Trace

An image sequence is composed into a single image, giving an overview of the filled vessel-tree structure. The composite image can be viewed in subtracted mode.

SRS.Allura.Func.Tracing

Interactively, images can be added to provide a progressive build-up of the overview.

* In order to exclude some images from the trace operation, skip and undo functions are provided.
* The resulting trace image can be stored for later use (e.g. as SmartMask).

Subtracted imaging requires a license.

SRS.Allura.Func.CO2Tracing

If CO2 contrast medium is used, vessels appear to be white, so in this case it is required to trace maximum instead of minimum pixel values.

* This function is compatible with all other trace options.
* Default selection is EPX defined, but can be overruled by the user.

CO2 tracing requires a license.

### Bolus Chase Reconstruction

SRS.Allura.Func.BolusChaseReconstruction

Bolus Chase Reconstruction (BCR) enables to build a single Bolus Chase reconstructed image of the complete leg(s), by automatically ”stitching” successive images that have been acquired with a Bolus Chase protocol. This requires a license.

* A BCR run shall be made with a specific EPX procedure (Flexible Dynamic Peripheral Angiography (FDPA)).
* Only one channel is supported in biplane configurations (frontal or lateral channel (lateral channel only in case of a PolyG-Floor frontal stand)).
* A reconstructed image can be made from a single contrast run or with both a contrast and mask run (subtracted view is then available).
* BCR shall be started automatically when a new BCR run is acquired. It shall be possible to start reconstruction manually by selecting a previously acquired BCR run.
* The user shall be able to make more than one reconstruction within one study.
* It shall be possible to use the reconstructed image as a reference when navigating through the original images.
* It shall be possible to save the Bolus Chase reconstructed image as a secondary capture image.
* Basic image processing (brightness, contrast, invert, subtraction on/off and landmarking), annotation and measurement functions shall be supported on the original images.
* Basic image processing (brightness, contrast, invert, subtraction on/off and landmarking) shall be supported on the reconstructed image.
* Fixed anatomy navigation mode shall be supported where original images are displayed on the selected patient's fixed anatomy.

Not supported for a TruSystem table with Azurion FlexArm option.

## Marker Functionality

SRS.Allura.Func.Marker

The user shall be able to draw on TSM or live viewport graphical overlay lines in order to mark certain anatomy on the clinical image. This requires a license.

* The marker overlay shall become and stay visible on TSM and live viewport during x-ray acquisition until deleted by the user or until another patient is selected.

## Quantitative Analysis Functions

### General Concepts

SRS.Allura.Func.VesselAnalysis.Accuracy

The system shall provide Coronary Analysis, Vascular Analysis, Left Ventricular Analysis and Right Ventricular Analysis.

* Coronary Analysis (QCA) and Vascular Analysis (QVA) are monoplane applications i.e. analysis is performed on a single image of one channel only. Left and Right Ventricular Analysis (LVA, RVA) are available as mono- and biplane application i.e. in biplane configurations ventricular analysis can be performed on images of one or two channels.
* The user selects an image or run for analysis, using available image navigation functions.
* The user selects the desired analysis function, and performs the related applicable workflow.
* QA-calibration can be applied to express quantitative outcomes on an absolute scale (e.g. in mm).
* Results are shown on the review monitor but can also be copied to one of the reference viewports
* A QA report is generated and stored as a Secondary Capture image in the system database. This report can be displayed, exported or printed.

### Calibration

SRS.Allura.Func.QACalibration

All 2DQA applications and basic measurements (see SRS.Allura.Func.Measurement) shall support auto calibration and manual calibration methods to relate distances on display, expressed in pixels, to real-object distances. Biplane ventricular analysis shall support calibrations for both the frontal and for the lateral channel.

* Automatic calibration is based on geometry settings assuming that the object of interest is placed in the sytem’s iso-center. When Auto Calibration is active, the user shall be warned that the auto calibration is valid only if the ROI is imaged in the iso-center.
* Manual calibration is based on an object of known size which may be a non-tapered catheter (with or without contrast agent), a user indicated straight interval or a radio-opaque sphere
* Manual calibration methods shall allow the user to select and use a different series for calibration than for analysis.
* When 2DQVA is used in subtracted mode, the application shall automatically switch to and only display un-subtracted images in the calibration work-step

### Vessel Analysis (QCA & QVA)

SRS.Allura.Func.VesselAnalysis

The system shall provide vessel analysis for coronary (QCA) and vascular arteries (QVA).

* The Quantitative Analysis shall allow the user to indicate a vessel segment in an un-subtracted or (for QVA only) in a subtracted X-ray image.
* The application shall then automatically detect the contrast-medium filled lumen in that segment and outline its borders as graphical overlays. The user shall be able to manually correct the contour.
* The application shall also display the profile of the vessel-diameter for the vessel segment and compute characteristics of the stenosis.

QCA and QVA both require a separate license.

SRS.Allura.Func.VesselAnalysis.Accuracy

|  |  |  |
| --- | --- | --- |
| Type of measurement | Accuracy (systematic error) | Precision (random error) |
| QCA Vessel diameter | < 0.2mm (for Ø <= 1mm) < 0.1mm (for Ø > 1mm) | < 0.2mm |
| QVA Vessel diameter | < 0.2mm (for Ø <= 20mm) < 1% (for Ø > 20mm) | < 0.2mm |
| Vessel segment length | < 1.0mm | < 2.0mm |

Note: Vessel diameter accuracy is specified for measurements performed on a vessel placed in the iso-center, using automatic calibration. Vessel segment-length accuracy is specified for distances up to 50mm between user-defined markers on an un-foreshortened view of a vessel placed in the iso-center, using automatic calibration.

Note: Accuracy and precision in table above are specified for a single measurement, which are to be distinguished from accuracy specifications for pooled measurements.

Accuracy is decreased when using catheter calibration:

|  |  |
| --- | --- |
| Catheter calibration | Filled catheter >= 6 French |
| Additional error | 7% |

Note: Errors from using unfilled catheters or catheters below 6 French can be 20% or more.

### Ventricular Analysis (LVA & RVA)

SRS.Allura.Func.VentricularAnalysis

The system shall provide ventricular analysis for the left (LVA) and right ventricle (RVA)

* After identification by the user of the aortic valve plane and the apex, the LVA application shall automatically trace and display the outline of a contrast-medium filled left ventricle. Biplane LVA shall similarly establish automatic contours for both the frontal and the lateral plane.
* RVA and LVA application shall allow the user to manually draw contours around the ventricular lumina in end-diastole and in end-systole, and in biplane series for the frontal and the lateral plane, respectively.
* RVA and LVA then computes ventricular characteristics like volumes, ejection fraction and performs wall motion analysis.

LVA and RVA both require a separate license.

SRS.Allura.Func.VentricularAnalysisAccuracy

Using Auto Calibration, the volume methods (excluding the regression formulae) shall be accurate within 5% when applied to X-ray images of ellipsoid phantoms that represent average diastolic and systolic volumes in adults and children, respectively. Errors in Calibration Factors propagate into volume measurements multiplied by approximately a factor of 2 (biplane) to 3 (monoplane) and the IfU shall advise the users not to use catheter calibration for LVA and RVA. Ejection Fraction on the other hand is not sensitive for those inaccuracies

## Printing & Reporting

This section focuses on case documenting and related hard-copy printing of images and reports.

### Print Compose

SRS.Allura.Func.PrintSheetCreation

This function enables manual selection and composition of multiple images on a film sheet. This requires a license.

* The system presents an already filled sheet.
* Default print settings can be customized.
* The user can change the layout and/or add/delete/re-position images.
* A preview function is available to observe the result before actual printing.

SRS.Allura.Func.PrintJobControl

This function enables the user to start and control the actual printing process. This requires a license.

* The user can modify customization-based defaults regarding printer settings and destination.
* The content can be deidentified and the user can define a fictive patient name for the deidentified content.
* The user can submit the job, view job status, abort, delete and retry the job.

### Dose Reporting

SRS.Allura.Func.Reporting.Dose

The system shall be able to create a dose report which contains information for each run and accumulated dose for a study.

* The system shall be able to create the report upon finishing of the study (customizable).
* A preview function is available to observe the resulting report.
* The report can be printed or (DICOM) exported.

## Archiving & Distribution

This section focuses on the archiving and distribution of image data.

### DICOM Networking Functions

SRS.Allura.Func.DICOM.Consistency

It is always required to restore data consistency between the system and a connected node after the cause of an error has been removed (e.g. complete or restart an image transfer after power-down).

SRS.Allura.Func.DICOM.Export

Enables to export (part-of) a study to a remote DICOM workstation or to a DICOM archive.

* Auto-export at the end of run and/or finish study, according EPX defined destination (multiple) and contents (e.g. images, downscaling).
* The user shall be able to get an overview of which runs will be auto-exported upon finishing the study and to which destination.
* For manual export, the user can select the content and the destination.
* For manual export, the content can be de-identified and the user can define a fictive patient name for the de-identified content.
* The selected destination determines the image processing format (raw or processed) which will be used.
* A biplane run is exported as two separate DICOM objects that refer to each other.

SRS.Allura.Func.DICOM.Query

Enables the user to obtain an administrative overview of the information present on a remote workstation or archive.

* The user can enter search criteria and start a query; the query can be aborted.
* The user can sort to optimize the presented query results.

SRS.Allura.Func.DICOM.Import

Enables the user to manually import images from a remote destination (workstation or archive).

* The user selects a remote destination, determines the image data and imports it; or on a remote destination, the user determines the image data and pushes it to the system.
* An original biplane run is reconstructed from separate (frontal and lateral) DICOM objects.

SRS.Allura.Func.DICOM.Export/ImportJobManagement

This function enables to observe a submitted import or export job.

* The user can abort, delete and retry the job.

SRS.Allura.Func.DICOM.DoseStructuredReport

The system shall be able to generate and export a DICOM X-Ray Radiation Dose Structured Report object (RDSR) upon finishing a study.

### Local Media Storage

SRS.Allura.Func.StoreToMedia

This function enables to store image data on media (CD/DVD/USB).

* The user selects DICOM format or PC format.
* With DICOM format, the user can select to store the DICOM viewer with the exported DICOM files.
* With PC format, the user determines the file name for creating a PNG (Portable Network Graphic) file or an MPEG4 (Moving Picture Experts Group) file.
* The content can be deidentified and the user can define a fictive patient name for the deidentified content.

SRS.Allura.Func.RetrieveFromMedia

This function enables to retrieve image data according DICOM from media and store it in the local database.

# SERVICE REQUIREMENTS

This chapter focuses on requirements related to service activities (termed "Field-Service").

## General Requirements

### Field-Service System Access

SRS.Allura.Serv.UserInterface

* The service UI shall provide access to the whole system.
* The service UI shall be based on a standardized service framework and the EPX management tool.
* The system shall provide on-line help information.

SRS.Allura.Serv.Field-ServiceAccessPoints

The system shall provide the following access points to the Field-Service Engineer (FSE):

* ‘Local’ access: the FSE shall be able to log-on to the system in the control room.
* ‘Far’ access: offering non-safety critical functionality via a remote connection, i.e. it will not be possible to remotely activate X-rays or mechanical movements.

SRS.Allura.Serv.AccessRightsAndAuthorization

The user's authorization level shall determine the available service functionality, e.g. without a key only changes with no associated risks are allowed.

SRS.Allura.Serv.SingleLabConnection

The system shall provide one entry point to the lab to service compatible room specific auxiliary systems, i.e. logging retrieval from and remote desktop of other configured systems shall be supported.

The connected auxiliary systems shall be accessible even if the X-ray system is switched off. The remote & local FSE shall be able to troubleshoot connectivity

* between the entry point and other connected systems; and
* between the entry point and RSN.

### Miscellaneous

SRS.Allura.Serv.FSTools

Tools not in the standard service toolkit are included in the system delivery or made available separately.

SRS.Allura.Serv.FSInstructions

Instructions are available on how to unpack, install, de-install, decommission, and packing and disposal of the system and components.

SRS.Allura.Serv.SystemID

The system shall be uniquely identified. A service report shall contain the system ID and hospital name.

## Non-Functional Requirements

### Upgrading Related

SRS.Allura.Serv.Upgrading

The following data shall be retained during an upgrade or can be restored from a previously stored back-up:

* Configuration and calibration data
* EPX (except manually added image processing tastes) and customization data

### Maintenance Related

SRS.Allura.Serv.Maintenance.Planned

The system shall enable the performance of planned maintenance activities to ensure its functionality during its lifetime.

SRS.Allura.Serv.Maintenance.Predictive

The system shall provide remotely accessible indicators of the X-ray tube filament and video distribution components for wear-out analyzing purposes.

## Local Service Functionality

This focuses on local (non-remote) service functionality, after the system has been assembled.

### Installation/Configuration/Adjustment/Customization

SRS.Allura.Serv.InstallSoftware

The initial installation of software and a system upgrade shall adhere to the following.

* The user shall be able to perform the installation/upgrade from a single entry point.
* Software options shall be pre-installed and activated through a standard licensing mechanism (sw-license file).
* User interaction shall only be required in the first 10 minutes of starting the installation/upgrade (this excludes configuration of the system).

SRS.Allura.Serv.Configure

Configuration functions enable the manual selection of basic settings related to:

* The system itself (e.g. licensing file, connected peripherals, display topology, remote service).
* The departmental/hospital environment (e.g. printers, archive, worklist management systems).

SRS.Allura.Serv.Adjust

Build-in correction measures shall provide adjustment functionality to bring the system within specified limits. The service framework shall provide adjustment criteria and procedures to the FSE and hospital technician.

SRS.Allura.Serv.Customize

Customization of EPX apply to the optimization of settings to local hospital and/or user preferences:

* Customization of EPX settings shall be available through the EPX tool, integrated in the service UI.
* Permission to modify certain parameters shall depend on the authorization level of a particular FSE.
* It shall be possible to check all applicable EPX applications and procedures, or immediately after a modification is made to an EPX application and procedure.
* The FSE shall be able to store the modified values or revert to latest verified and applied settings.

### Verification & Report

The scope is to verify and report that the system is within its intended specification (pass/fail).

SRS.Allura.Serv.VerificationTests

Tests are provided to verify proper functioning after installation, upgrading or repair.

* Tests shall apply to safety, function and quality related checks (e.g. X-ray dose, image quality, responsiveness).
* Checks shall provide objective verification results and do not require expert knowledge from the user.
* Built-in test patterns (e.g. SMPTE test image and images to support DIN 6868-157) shall provide a standard visual reference.

SRS.Allura.Serv.AcceptanceTestReport

The system shall be able to generate an acceptance test report that covers all necessary tests for a formal handover to the customer.

### Diagnostics, Faultfinding

Faultfinding is used in corrective maintenance to localize a problem and to determine follow-up actions.

SRS.Allura.Serv.HardwareTests

Applied to diagnose the correct functioning of the Field Replaceable Units (FRU’s) and related interfaces.

* Power-On SelfTests (‘POST’) are performed automatically at system power-up.
* Build-In SelfTests (‘BIST’) enable the FSE to examine a particular FRU into greater detail.

SRS.Allura.Serv.FunctionalTests

The system shall provide tests to check the functional integrity of the system or part of the system.

* The tests shall provide information to enable the FSE to find a fault by reasoning, based on supplied documentation.
* Appropriate (Edoc) documentation shall be provided to guide the FSE in performing successive tests.

SRS.Allura.Serv.NetworkDiagnosis

The system shall provide means to detect and diagnose network connectivity issues

* for the (system internal) control network
* for the real time image link
* for the connection to external DICOM nodes on the hospital network
* for remote service connection

SRS.Allura.Serv.Logging

System information and events are stored and accessible e.g. for diagnostic/faultfinding purposes.

* Logged info comprises of system-info (e.g. configuration), system usage (e.g. user-actions, system-errors, wear-out indicators), and test results.
* FSE functions: read (select/filter/search), clear logfile, export logfile.

### Auxiliary Functions

SRS.Allura.Serv.SiteLog

The FSE shall be able to use an on-system logbook to register the systems history and comments by the FSE.

SRS.Allura.Serv.Backup/Restore

It shall be possible to backup system data and if needed restore, e.g. in case of a disk failure.

* Includes all customization and EPX settings (except manually added image processing tastes) and all system-specific adjustment- and configuration data.
* Backup data can only be restored on the same system on which it was created
* Backup data can be restored only if it was created with the same software version or with a software version for which an upgrade path is defined (see Upgradeability Requirements)

SRS.Allura.Serv.SystemInformation

The FSE shall be able to view system information.  
Note that no table information is available for the TruSystem table in a FlexMove configuration.

SRS.Allura.Serv.SystemInformation.Export

The FSE shall be able to export the system information, targeting:

* Formatted report, containing information to uniquely identify the system.
* Local copy according standard Common Data File format.

## Remote Service Functionality

### Remote Service General Requirements

SRS.Allura.Serv.RemoteAccessAndConnection

The system shall be accessible from a workspot on the Remote Service Network (RSN).

* The system shall be able to connect to the RSN via an Integrated Secure Socket Layer (ISSL)-link or via a Virtual Private Network (VPN) established by a specific RSN Router. ISSL allows establishing a secure tunnel directly from the system over a single outgoing port.
* This 'far-access' mode shall be possible concurrent to local access.
* The key (local or remote) with the highest authorization level shall determine the access rights.

SRS.Allura.Serv.RemoteConnectivityStatus

* The system shall inform the clinical user about the remote connection status
* The system shall provide a remote connection test for clinical user and hospital IT.
* For VPN connected systems it shall be possible to up- and download remote configuration settings from/to the system.

SRS.Allura.Serv.RemoteInterference

Remote access shall be explicitly accepted by the local user unless no interference to the local user occurs.

The local user shall be able to terminate remote access (e.g. to start an emergency procedure).

### Remote Monitoring & Alerting

SRS.Allura.Serv.SystemMonitoring&Alerting

The system shall monitor the system status and pro-actively alert a service center accordingly. The alert shall be sent when ‘pro-active limits’ are exceeded (e.g. indicated by a wear-out sensor).

SRS.Allura.Serv.RetrieveInformation

The remote FSE shall be able to initiate collecting of recent log information from the system (without local user interaction).

With local user interaction, the remote FSE shall be able to retrieve log and trace information (e.g. for offline analysis).

### Remote Software Installation

SRS.Allura.Serv.RemoteSWInstall

It shall be possible to distribute software packages over the RSN and remotely install these on the system.

* The local user is requested to start installation, perform necessary tests, and validate/accept.
* Without associated risks, user interaction is not needed.

### Remote Desktop

Remote desktop enables a remote service center to assist a local user.

SRS.Allura.Serv.RemoteDesktop.ClinicalMode

It shall be possible to provide application support during a clinical procedure with remote desktop.

* A remote (clinical) expert shall be able to observe the case, give advice, and/or assist in controlling the system.
* It shall be possible to disable remote activity in the system configuration.

SRS.Allura.Serv.RemoteDesktop.ServiceMode

It shall be possible to provide support to an on-site service engineer with remote desktop.

* In field-service mode, a remote expert shall be able to observe and assist, e.g. in fault finding/repair.

### Remote Miscellaneous

SRS.Allura.Serv.SystemInformation.Remote

The remote FSE shall be able to view system information.  
The system shall support the transfer of the system information to RSN.

SRS.Allura.Serv.RemoteImageTransfer

The local user shall be able to select an image(s) and transfer the image(s) and related acquisition information (e.g. KV) towards a remote center.

SRS.Allura.Serv.RemoteSFTP

The system shall support data exchange with the RSN using the Secure File Transfer Protocol (sFTP) for both ISSL-link and VPN connected systems

# MANUFACTURING REQUIREMENTS

This chapter focuses on additional requirements related to manufacturing and assembly activities. Requirements on installation, configuration, adjustments, customization, verification & report, diagnostics and faultfinding can be found in chapter SERVICE REQUIREMENTS; automated system test requirements can be found in chapter SYSTEM INTEGRATION AND VERIFICATION REQUIREMENTS.

SRS.Allura.Manf.VerifySystem

The Manufacturer Engineer shall be able to verify that the system is manufactured according to the specification independent of Commercial licenses.  
Tolerances shall be specified for critical measurements which can be influenced by the manufacturing process.

SRS.Allura.Manf.LoadConfiguration

Based on external information, the system shall offer automatic system configuration with only initial user interaction.

# USER INTERFACE REQUIREMENTS

## General Requirements

SRS.Allura.UI.KeyboardMouse

The keyboard and mouse button behavior shall be harmonized throughout the different system applications in the control room.

SRS.Allura.UI.Design.Application

Each system application shall have the same user interface design for use in the control room; likewise each system application shall have the same user interface design for use in the exam room to make it easy for the user to transition from one application to the next.

The control room acquisition and review monitors shall have the same user interface design to host the system applications.

SRS.Allura.UI.Design.FlexibleViewing

FlexVision and FlexSpot shall have the same user interface design for flexible viewing.

SRS.Allura.UI.Help

The user shall be able to access integrated help and electronic Instructions for Use. This includes tooltips, task and procedure guidance and instruction material. The user shall be able to search for a specific topic within the Instructions for Use.

SRS.Allura.UI.Help.Customize

The user shall be able to delete and modify a help header and link a new help header to an imported hospital protocol/checklist. This requires a license.

SRS.Allura.UI.TSM.Image

The TSM shall display live X-ray images for image post-processing, image navigation and moving shutters and wedges on the image.

Beside this live X-ray image, live images can be shown from applications running on other systems that are compatible with the multi-modality TSM. This requires a license

SRS.Allura.UI.TSM.Workspot

The TSM shall offer a workspot in examination and/or control room to control system internal applications but also applications running on other systems.

* The touch screen shall be operable under table side conditions i.e. wearing gloves, covered with a sterile drape and spilled with fluids.
* The user shall be able to use an application on a certain TSM, while another user shall be able to use any other connected application on another TSM.
* The internal state of an application that is shown on multiple TSMs shall be synchronized.

SRS.Allura.UI.Image.Pointer

The user shall be able to show and move a pointer over an area of interest in an image to support collaboration between exam room and/or control room. This requires a license.

SRS.Allura.UI.UIModule

The review and control modules shall support backlighting to allow easy visibility of buttons in e.g. dark examination rooms and give user guidance.

The UI modules at or near the table shall allow control under sterile conditions (e.g. under a sterile cover).

The user shall be able to detach the UI modules from the pedestal resp. table and attach them to the table resp. pedestal.

SRS.Allura.UI.Workspot

Movement and X-ray generating functions shall be controllable at or near the table (e.g on a pedestal).

SRS.Allura.UI.PositionMCSFrame

The user shall be able to position the MCS frame(s) to have a clear view on the monitors from the workspot.

SRS.Allura.UI.ComfortThemes

With FlexVision, the user shall be able to play movies or image slideshows to relax the patient. This requires a license.

SRS.Allura.UI.Clinical-UILanguage

The system can be configured according the following local languages:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| English | French | German | Spanish | Italian |
| Dutch | Danish | Norwegian | Swedish |  |
| Simplified Chinese\* | Traditional Chinese\* | Japanese\* |  |  |

\*Note: No manual (i.e. keyboard) input for Chinese and Japanese language

Support for Japanese and Chinese requires a license.

SRS.Allura.UI.ServiceUILanguage

The service UI for service engineers is in English.

# QUALITY AND PERFORMANCE REQUIREMENTS

In this chapter the requirements are given for the quality and performance requirements.

## X-ray Performance Figures

SRS.Allura.Qual.X-rayPerformance

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Categories/ items** | **must** |  |  | **notes** |
| **Exposure** |  |  |  | with TC 100KW generator and MRC |
| Continuous power | 2.5 |  | KW | exposure and/or fluoro |
| Peak power | 100 |  | KW | exposure |
| Tube current range | 50-1000 |  | mA | exposure |
| KV range | 40-125 |  | KV | exposure |
| Tube current range | 10-200 |  | mA | pulsed Fluoro |
| KV range | 40-125 |  | KV | pulsed fluoro |

## Clinical Response Times

The performance figures are applicable under the following conditions:

* Normal clinical user mode.
* DICOM X-Ray Radiation Dose Structured Report active.
* Without (remote) field service activities.
* No degradation and exception situation like tube overheating or insufficient storage space.
* “historical system usage”:
  + number of patients = 80 (-0+10%)
  + number of runs per patient = 17 (-0+10%)
  + number of images per run per channel = 100  (-0+10%)  
    Lower amounts are allowed due to system configuration limitations (image disk space).

Note on the must values that are mentioned in this and the following section:

* All the measured values shall be below 1.25 x must value.
* The average of the measured values shall be below the must value. The average is calculated over at least 3 values.
* In case of a user action, the response value is defined as the elapsed time between the user action and the related noticeable response.

SRS.Allura.Qual.ClinicalResponseTimes.System

|  |  |  |
| --- | --- | --- |
| **Categories/ items** | **Max.** | **notes:                      (all values in seconds)** |
| Regular System startup (power-up) | 300 | Time until functionality required for the  intended use is available. |
| System startup after total power down | 300  (China only)    360 (Rest of the world) | Measured after external power supply restored to the system. |
| Warm restart | 90 |  |
| Cold restart | 360 | Full cycle from “off” button press to full functionality. |
| Recovery geometry after emergency stop | 105 | Time until all geometry movements available. |

SRS.Allura.Qual.ClinicalResponseTimes.Admin

|  |  |  |
| --- | --- | --- |
| **Categories/** items | **Max.** | **notes:          (all values in seconds)** |
| General response on UI requests e.g.   * switch exposure channel mono/biplane * switch roadmap-on * multiphase frame-rate * subtraction on/off | 1.0 | one action; e.g. display a list, menu. |
| Delete study | 1.0 |  |
| Select study for acquisition | 5.0 |  |
| Select study for viewing | 2.8 |  |
| Select EPX application for current study | 4.0 |  |
| Select EPX procedure for current study | 1.2 | in idle state, not valid when EPX is selected during an active fluoroscopy run |

SRS.Allura.Qual.ClinicalResponseTimes.Movement

|  |  |  |
| --- | --- | --- |
| **Categories/** items | **Max.** | **notes: (all values in seconds)** |
| Move shutters & wedges | 0.5 | from UI up to & including image display. |
| APC recall (start geometry movement) | 1.0 | 1.5 for Maquet & TruSystem: 2.5 if the table is in hibernation mode |
| Start all other movements | 1.0 | 1.5 for Maquet & TruSystem: 2.5 if the table is in hibernation mode |

SRS.Allura.Qual.ClinicalResponseTimes.Acquisition

|  |  |  |
| --- | --- | --- |
| **Categories**/ items | **Max.** | **notes: (all values in seconds)** |
| Switch viewing to fluoroscopy | 1.8 | from pedal press till the first image shown |
| Switch viewing to exposure | 1.8 | from pedal press till the first image shown,  For non-DSA cine |
| 2.5 | from pedal press till the first image shown,  For acquisition types with test-shot lock-in and frame-speeds greater or equal to 4 fr/s |
| Switch fluoro to viewing | 1.8 | from pedal release till display of viewing image on screen |
| Switch exposure to viewing | 1.8 | from pedal release till display of viewing image on screen |
| Switch between exposure/fluoro | 1.8 | For acquisition types without test-shot lock-in and frame-speeds greater or equal to 4 fr/s |
| 2.5 | For acquisition types with test-shot lock-in and frame-speeds greater or equal to 4 fr/s |
| Digital Subtraction Angiography (DSA): delay after test-image | 1.5 |  |
| Change live fluoro settings | 1.5 | Fluo flavour, field-size (incl FD-mode). |
| Change live exposure settings | 0.5 | Frame-rates for multiphase acquisitions |
| Delay between Xray-OFF and Indicators-OFF | 1.0 |  |
| Fluoro pipeline perception latency | 0.200 | Essential for eye-hand coordination. |

SRS.Allura.Qual.ClinicalResponseTimes.3D-Acquisition

|  |  |  |
| --- | --- | --- |
| **Categories**/ items | **Max.** | **notes:            (all values in seconds)** |
| Fastest 3D acquisition head side | 5 | -120° … +120° |
| Fastest 3D acquisition in nurse/doctor side | 6 | -90° … + 90° |

SRS.Allura.Qual.ClinicalResponseTimes.Review

|  |  |  |
| --- | --- | --- |
| **Categories/** items | **Max.** | **notes:          (all values in seconds )** |
| Image stepping | 0.2 | Allowed 0.4 sec for run-subtract. |
| Run stepping, non-subtract | 0.3 |  |
| Run stepping, subtract | 0.6 |  |
| Run overview 4\*4, subtract & non-subtract | 2 |  |
| Run overview 4\*4, run-subtract | 4 |  |
| File overview 4\*4, non-subtract | 2 |  |
| File overview 4\*4, subtract | 4 |  |

Reviewing requirements are not applicable to mosaic overview modes, unless explicitly indicated otherwise.

SRS.Allura.Qual.ClinicalResponseTimes.Arch

performance values apply to transfer over a network with a speed of at least 1Gbps.

|  |  |  |
| --- | --- | --- |
| **Categories/** items | **Max.** | **notes:         (all values in seconds)** |
| Export 10 runs \* 100 images max. 1K2 | 200 | multiframe, 8 bit, with Jpeg |
| Import 40 images max. 1K2 | 900 | singleframe 12bit, with & without Jpeg |
| Export 40 images max. 1K2 | 100 | singleframe 12bit, with & without Jpeg |
| Printing 1 sheet with 12 images | 60 | Printer resolution satisfying source resol. |

## Field-Service Response Times

SRS.Allura.Qual.FSResponseTimes

|  |  |  |
| --- | --- | --- |
| **Categories**/ items | **Max.** | notes |
| **Field-Service Tool** | sec |  |
| Local start-up service framework: |  |  |
| - from start-up to log-on screen | 15 |  |
| - from log-on screen to display framework | 10 | after entering service key password |
| - start-up with already logged on service user | 20 |  |
| Remote start-up service framework | 100 |  |
| Local shut-down service framework: |  |  |
| - from close to service conclusion screen | 6 | after removing service key or after closing the close confirmation screen |
| - from service conclusion screen to shut-down | 3 |  |
| **EPX Management** | sec |  |
| Start-up EPX Management Tool | 30 | includes loading of database settings in editor |
| Store modified settings for verification | 30 | up to modified settings active for try-out |
| Batch verification (one modified EPX-Application/Procedure) | 30 | +10 sec per additional modified EPX-Application/Procedure |
| Store modified changes to system | 120 | up to usable clinical system |
| **Calibration** | min |  |
| Calibrate FD20 | 90 |  |
| Calibrate FD15 | 90 |  |
| Calibrate FD12 | 90 |  |
| Frontal Stand calibration | 340 | calibrate geometry without X-ray |
| Lateral Stand calibration | 225 | calibrate geometry without X-ray |
| Table calibration | 75 | calibrate geometry without X-ray |
| Generator calibration | 90 |  |
| **Image transfer** | sec |  |
| Image max. 5122 - 12 bit | 150 | over 40 Kbps link |

## Image Quality

This section describes the basic Image Quality requirements. The purpose is to describe the system in terms of Image Quality requirements such, that if a system meets the requirements in this specification, the image quality of that system is guaranteed (and acceptable for the end user).

SRS.Allura.Qual.IQKVStabilized

Dose-control requirements for fluoro and cine-exposure, related to energy balance and X-ray penetration.

|  |  |  |  |
| --- | --- | --- | --- |
| Conditions kV stabilized | Field-size | kV stabilized [kV] | Accuracy [%] |
| 2 mm Cu + 20 mm Al and EPX with pre-defined stabilization | All | Pre-defined | ± 4 |

SRS.Allura.Qual.IQmAsStabilized

Dose-control requirements for test-shot lock-in, related to energy balance and X-ray penetration.

|  |  |  |  |
| --- | --- | --- | --- |
| Conditions mAs stabilized | Field-size | kV stabilized [kV] | Accuracy [%] |
| 2 mm Cu + 20 mm Al and EPX with pre-defined stabilization | All | Pre-defined | ± 30 |

SRS.Allura.Qual.IQX-rayOutput

X-ray output requirements of the efficiency conversion for the X-ray generation.

|  |  |  |
| --- | --- | --- |
| Xray tube | Min at delivery [µGy/mAs] | Min during lifetime [µGy/mAs] |
| MRC 200 | 1.75 | 1.57 |

SRS.Allura.Qual.IQHalfValueLayer

Half Value Layer (HVL) requirements to guarantee the patient protection against excessive skin dose.

|  |  |  |
| --- | --- | --- |
| Conditions: 100kV ± 1 kV | Min [mm Al equivalent] | Max [mm Al equivalent] |
| HVL thickness | 3.8 | 4.8 |
| Legal requirement | 3.6 | n.a. |

SRS.Allura.Qual.IQWorkingPoint

Requirements for working point, related to Automatic Gain Control (AGC), to ensure a reliable overall contrast transfer.

|  |  |  |
| --- | --- | --- |
| Acquisition mode | AGC mode | Accuracy must do [%] |
| Fluoro/Cine/TSL/STI/DRA | Active | ± 2 |
| Fluoro/Cine | Fixed/Locked | IQ-DoseAccuracy ± 2 |
| TSL | Locked | ± 2 |
| Single shot with ATC | Active | ± 5 |
| STI/DRA | Fixed | IQ-DoseAccuracy ± 5 |

SRS.Allura.Qual.IQScatterReduction

Requirements for the anti-scatter grid to reduce X-ray scatter (applies to all acquisition techniques).

|  |  |  |  |
| --- | --- | --- | --- |
| Grid lines | Primary Transmission | Contrast Improvement | SID application range |
| Not visible in the final image | ≥ 70 % | 3.7 | 85-120 cm |

SRS.Allura.Qual.IQContrastResolution2D

Requirements related to contrast resolution in 2D applications (based on Leeds TO10 and 1.0 mm Cu).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Cardio | Cardio | Vascular | Vascular |
|  | Fluoroscopy | Exposure | Fluoroscopy | Exposure |
| Nr. visible details | ≥ 70 | ≥ 83 | ≥ 74 | ≥ 100 |
| Dose | 50 ± 10 nGy | 150 ± 25 nGy | 80 ± 15 nGy | 4800 ± 800 nGy |
| Potential | 60 ± 2 kV | 62 ± 2 kV | 65 ± 2 kV | 70 ± 2 kV |

SRS.Allura.Qual.IQDisplaySignalTransfer

Requirements for contrast transfer and stability as perceived on display (applies to all applications).

|  |  |  |
| --- | --- | --- |
| Pre condition:  Calibrated monitor  Monitor type and predefined contrast transfer and predefined working point  Luminance L [Cd/m²] | Luminance tolerance must  [%] | Luminance difference between displays in the ceiling suspension    Luminance difference between viewing ports on large screen displays [%] |
| L | ± 10 | D = 25 |

SRS.Allura.Qual.IQLimitingResolutionSystemLevel

Requirements for sharpness in terms of Limiting Resolution System Level.

|  |  |
| --- | --- |
| Min. [Cycles/mm]; (large focal spot) | Min. [Cycles/mm]; (small focal spot) |
| ≥ 1.7 | ≥ 2.8 |

SRS.Allura.Qual.IQBeamAlignment

Requirements for alignment of tube and collimator at the detector.

|  |  |
| --- | --- |
| Application conditions | Must |
| Standard position (rotation 0, angulation 0) | + 5 mm |
| Extreme position (rotation 90, angulation -45, min. SID) | + 10 mm |

SRS.Allura.Qual.IQGeoStability

Requirements for geometry stability in certain procedures.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Neuro subtract | Trace subtract | FDPA | 3DRA |
| Maximum image shift | +/- 100 µm | +/- 250 µm | +/- 750 µm | +/- 0.2° |

SRS.Allura.Qual.IQBrightnessUniformity

Requirements for brightness non-uniformity (relative to the center).

|  |  |  |
| --- | --- | --- |
|  | Minimum | Maximum |
| Uniformity of brightness | 60 % | 120 % |

SRS.Allura.Qual.IQArtifactsSubjective

Requirements for artifacts as a collection of irregularities in the final image:

* The visibility of artifacts shall be within specified limits as recorded by reference images; this applies to: crosstalk, amplifier crosstalk, bright burn, first image gain, detector defects, anti-scatter grid imperfections (e.g. spots, lines), viewing jitter, focus stability, color impression, non-uniformity, viewing angle dependency.
* Unknown artifacts are judged by image quality and application specialists.

SRS.Allura.Qual.IQFactory/ServiceMeasurements

Requirements for installation and manufacturing quality, related to guarantee reproduction of IQ.

All system-wide level 1 measurements shall be executed and passed as part of manufacturing and/or installation and/or preventive and/or corrective maintenance.Additionally, lower-level measurement tests shall be available to be executed for diagnostic and regulatory purposes.

|  |  |  |
| --- | --- | --- |
| **What is measured** | **Level 1** | **Comments** |
| Dose per image detector | Dose Test and Dose Calibration |  |
| Noise estimate in ROI on FD | Dose Test and Dose Calibration |  |
| Stability noise value in ROI on FD | Fast Dose Verification |  |
| kV-Stabilized | Energy and Signal flow 1 | see SRS.Allura.Qual.IQKVStabilized |
| Video stabilization level | Energy and Signal flow 1 | see SRS.Allura.Qual.IQWorkingPoint |
| mAs-Stabilized Test Shot | Energy and Signal flow 2 | see SRS.Allura.Qual.IQmAsStabilized |
| mAs-Stabilized exposure | Energy and Signal flow 2 | see SRS.Allura.Qual.IQmAsStabilized |
| Calculated power to validate EDL function | EDL verification | Regulatory requirement described by FDA: 21CFR1020.32 (clause(d)). |
| Contrast | Monitor Performance | see SRS.Allura.Qual.IQDisplaySignalTransfer |
| Vignetting | Monitor Performance | see SRS.Allura.Qual.IQBrightnessUniformity |
| Sharpness | Monitor Performance | see SRS.Allura.Qual.IQDisplaySignalTransfer |
| Low contrast check | Monitor Performance | see SRS.Allura.Qual.IQDisplaySignalTransfer |
| **What is measured** | **Lower Level** |  |
| DAP difference AEP meter and dose probe  Skin dose difference AK displayed and dose probe | DAP Measurement and AirKerma Verification | Regulatory requirements described by IEC60601-2-43 (clauses:203.6.4.5 Dosimetric indications) and 21CFR1020.32 (clause (k)(6)) |
| Test to check alignment of x-ray beam with detector field of view | Field limitation | Regulatory requirements described by IEC 60601-1-3 (clause 8.5.3), FDA 21CFR 1020.32 (clause (b)(2) etc), IEC 60601-2-43 (clause 203.8.5.3). |
| Test for verifying x-ray beam vs detector entrance plane | Xray Beam alignment | see SRS.Allura.Qual.IQBeamAlignment & isolated part of Field Limitation test (without sagging and stand maximal application conditions). |
| Horizontal focal spot  Vertical focal spot | Focal Spot size | Focal spot size is conform IEC60336. Focal spot sizes are included in Performance Test Limits for fault finding. |
| Small focus of x-ray tube  Large focus of x-ray tube | Limiting Resolution System Level | SRS.Allura.Qual.IQLimitingResolutionSystemLevel |
| Beam quality x-ray beam in mm Al | Half Value Layer | Regulatory requirements described by IEC 60601-1-3 (clause 7.1, half value layers in x-ray equipment). |
| X-ray output x-ray tube | X-ray Output | SRS.Allura.Qual.IQX-rayOutput |
| Check difference real kV and kV indication ∆kV for 6 measurements (5 manual exposure, 1 fluo technique) | kV-Beam is kV-Desk | Regulatory requirement described by IEC 61223-3-1 (clause 5.2.1, X-ray tube voltage). |
| Qualitative image impression for Germany | Monitor SMPTE | Regulatory requirement described by German DIN6868-157:2014-11 |
| **What is measured** | **Other** |  |
| Air Kerma verification | Dose measurement for verification of the Entrance Doserate Limitation (EDL) mechanism | Regulatory requirement described by FDA: 21CFR1020.32 (clause(d)). |

# PHYSICAL REQUIREMENTS

## Mechanical

No specific requirements apart from targets as derived from requirements stated in section 12.3 Standards, Legal Requirements.

SRS.Allura.Phys.TechnicalRoomCabinetsSpace

In combination with IP based video infrastructure, system components in the technical room shall be placed in max 3 (monoplane systems) and max 4 (biplane systems) 19’’ cabinets.

## Electrical

Most electrical requirements stem from targets as derived from requirements stated in section 12.3 Standards, Legal Requirements.

SRS.Allura.Phys.MainsPower

The system shall be compatible with TN (including multi-source), TN-C, TN-S, TN-C-S symmetric 3-phase mains power configurations in the voltage range 380-480V nominal with a fundamental frequency of 50 or 60Hz. Compatibility with other standard power configurations shall be achieved via external voltage conversion transformers or compatible power inverters.

Note that the system is not compatible with TT-, IT- and asymmetric grounded power systems. These mains power configurations shall be converted to one of the above mains power configurations with an isolation transformer.

## Environmental Conditions

SRS.Allura.Phys.ClimaticEnvironmentalConditions

Following are the expected climatic conditions to which systems classified for operation in "Indoor, non-regulated room" will be exposed. The system shall not be damaged and remain safe after exposure to these conditions, while in operation, transport or storage.

|  |  |  |
| --- | --- | --- |
| Conditions representative for: | Description of requirement | Environmental Conditions |
| Operation | Temperature  (Performance) | +10°C/+30°C |
| Temperature  (Safety) | +10°C/+35°C |
| Maximum Temperature for unit in rack | Ambient T + 5-15 °C  (performance; maximum 45 °C) |
| Temperature change rate | ≤ 0.5 °C/min |
| Relative Humidity  (Performance) | 20% - 80% |
| Relative Humidity  (Safety) | 20% - 93% |
| Condensation | No |
| Transport & Storage | Temperature | Constant:  -25°C (3 days)  +70°C (4 days)    Cycles  25°C/ 97% RH - 40°C/ 93% RH (6 cycles)  -10°C - 45°C (1 cycle) |
| Relative Humidity | 5% - 95% |
| Condensation | Possible1) |
| Operation, Transport & Storage | Air Pressure | 700 - 1100 hPa |

Note: 1) The packaging during transport and storage protects PC cabinets against moisture from condensation.

Directly after exposure to transport and storage conditions, the exposed part or system does not need to be in normal operational mode, but must remain safe. It must return to normal operational mode after acclimatization, once the climatic conditions to which it is exposed are within the operational limits.

SRS.Allura.Phys.MechanicalEnvironmentalConditions

There shall be no impact on system operation and safety after exposure to repetitive bumps and vibration, that are comparable to the expected mechanical conditions during transport.

SRS.Allura.Phys.ElectromagneticCompatibility(EMC)

According to Standard IEC 60601-1-2.

SRS.Allura.Phys.Noise

Acoustical noise level for different areas are listed below:

* Max. 60 dB(A) in exam room, with the following exceptions:
  + Max. 75 db(A) in exam room during ≥ 30 °/sec DRA scan;
  + Max. 71 dB(A) in exam room during all other geometry movements.
* Max. 60 dB(A) in control room.
* Max. 65 dB(A) in technical room.

SRS.Allura.Phys.Cleanability

System parts that can come in contact with the patients' secretions, excretions, other body fluids, or other fluids shall be designed to be cleaned and disinfected by disinfection agents/compounds. All other system parts shall be designed to be cleaned by water with detergents.

SRS.Allura.Phys.LaminarAirflowCompatibility

FlexArm and FlexMove configurations (FD20 XY-fa and XY-fm) shall not impact compliance with hygiene standard (DIN-1946-4, norm Raum Klasse 1A) in operating rooms having a Laminar Airflow. For FlexArm configurations flow-optimized rail covers shall be optionally available.

SRS.Allura.SLS.ECO.EnergyConsumption

The energy consumption of the system shall be equal or less than for the predicate device (Azurion R2.1), when measured on a comparable configuration and under comparable usage.

# SAFETY, LEGAL & SECURITY STANDARDS

## Safety

SRS.Allura.SLS.radiation-patient-dose

The system shall inform the user during and after the examination with patient dose information, to decide on continuation of the treatment. The system shall give a user warning above a (configurable) threshold.

SRS.Allura.SLS.radiation-user-dose

Measures shall be taken to minimize the exposure of the user to X-ray during operation of the system.

SRS.Allura.SLS.intended-image-quality

Measures shall be taken to avoid insufficient image quality during clinical procedures.

SRS.Allura.SLS.movements-failure-detection-and-fault-tolerant

Measures shall be taken to detect errors in the control of motorized movements. When errors are detected, that not directly result in a hazardous situation:

* The system shall allow movements (possibly with reduced performance).
* The user is informed.

SRS.Allura.SLS.xray-imaging-failure-detection-and-fault-tolerant

Measures shall be taken to detect errors in X-ray imaging functionality. When errors are detected that not directly result in loss of imaging functionality:

* The system shall allow imaging (possibly with reduced performance).
* The user is informed.

SRS.Allura.SLS.maintain-minimal-functionality

When the system becomes unavailable for the intended treatment or diagnosis, minimal functionality is maintained as long as possible to terminate the procedure and release the patient from the system.

SRS.Allura.SLS.image-latency

To enable procedures which require hand-eye coordination, the perceived image latency shall not exceed 230 ms.

SRS.Allura.SLS.prevent-lih-live-mixup

The system shall prevent the user from mistaking a still or Last Image Hold image for a live image.

SRS.Allura.SLS.correct-overlay

Measures shall be taken to avoid mismatches between overlay images and the actual image.

SRS.Allura.SLS.consistent-image-orientation

The patient orientation in the X-ray image shall be consistent with the patient to table position and other information as provided by the user.

SRS.Allura.SLS.consistent-patient-and-image-data

* All patient and image data shall be displayed and maintained in a consistent manner throughout the system.
* Manual changes in patient related data shall only be done after explicit confirmation of the operator.

SRS.Allura.SLS.collision-unintend-ui

Measures shall be taken to prevent unintended motorized movements related to user interface design and user interaction with the system.

SRS.Allura.SLS.movement-integrity

Out of control movements (e.g. spontaneous movements, movements with high speed than requested) shall be prevented in all conditions of the system (during start-up, normal use, power failure, power off).

SRS.Allura.SLS.replay-path-free

When the system is executing a programmed movement (pre-programmed or defined by the user) measures shall be taken so that no collision occur.

SRS.Allura.SLS.collision-avoidance

During motorized movements, the system shall help the operator to avoid collisions with a person.

SRS.Allura.SLS.collision-harm-reduction

In cases where motorized movements (despite preventive measures) do lead to collisions of mechanical parts with a person, the collision forces shall be limited to prevent harm.

SRS.Allura.SLS.patient-move-collision

Measures shall be taken to prevent that a movement of the patient results in a motorized or manual movement or results in a collision (i.e. entrapment) of the patient.

SRS.Allura.SLS.careless-manual-operation

During manual movements the system shall help the operator to prevent collisions with a person.

SRS.Allura.SLS.unexpected-manual-behavior

Measures shall be taken to prevent unintended and/or uncontrolled manual movement behavior.

SRS.Allura.SLS.tipping-equipment

Measures shall be taken to prevent movable and static parts of the system from tipping over.

SRS.Allura.SLS.peripheral-equipment

Measures shall be taken to guarantee safe mechanical, electrical and functional compatibility of peripheral equipment and the system.

SRS.Allura.SLS.structural-integrity

Structural integrity of parts and suspensions that constitute a hazard when they fall shall be safeguarded.

SRS.Allura.SLS.table-movement-integrity

The table shall maintain its structural integrity during patient transfer and examination in order to avoid the patient falling from the table.

SRS.Allura.SLS.patient-move-fall

Measures shall be provided to prevent that a patient repositioning on the table results in the patient falling from the table.

SRS.Allura.SLS.unintend-ui-patient-falling

Measures shall be taken to prevent unintended table movements related to user interface design and user interaction with the system.

SRS.Allura.SLS.careless-operator-patient-fall

The system shall provide means to prevent that a user initiated table movement, may lead to the patient falling from the table, and it shall be made clear how to set-up the system for patient transfer.

SRS.Allura.SLS.patient-contamination

The system shall be designed for:

* Cleaning and disinfection of system parts in the patient environment.
* Creating an aseptic environment.

SRS.Allura.SLS.patient-contamin-airborne

The system shall be designed to minimize its contribution to airborne contaminants reaching the patient.

SRS.Allura.SLS.fse-contamin

Measures shall be taken to guide a field service engineer in working with a contaminated system.

SRS.Allura.SLS.electr-shock-prev-staff-patient

Measures shall be taken to prevent electric shock of persons via accessible live parts or tube flash over.

SRS.Allura.SLS.electr-shock-prevention-fse

Measures shall be taken to train the field service engineer not to work with live parts, but switch the system off.

SRS.Allura.SLS.safe-surfaces

The system parts that are designed to come into direct contact with the patient shall be made of material that are known to be bio-compatible.

SRS.Allura.SLS.injector-safety

* Only injectors that are compatible with the system and its environment are to be used.
* Contrast injection shall be single fault safe and 'dead-man' controlled by the user.
* Contrast injection without X-ray imaging shall be avoided.

SRS.Allura.SLS.acoustic-noise

The system shall not produce noise that can lead to hearing impairment (i.e. more than 80 dB(A)).

SRS.Allura.SLS.thermal-safety

The system shall not have hot accessible surfaces which can lead to thermal injuries (burns).

SRS.Allura.SLS.prevent-using-incorrect-in-patient-measurements

Measures shall be taken to prevent incorrect results of image based measurements and to warn the user when the measurement results are possibly incorrect.

SRS.Allura.SLS.fse-safety

Measures shall be taken to guide a field service engineer in (de)installing and maintaining the system in a safe way.

## Privacy And Security

SRS.Security.MD.RemoteAccessPoint

The Azurion shall be protected against attacks via a remote access point.

SRS.Security.MD.HospitalNetwork

The Azurion shall be protected against attacks via the hospital network.

SRS.Security.MD.MalwareOnRemovable media

The Azurion shall be protected against attacks via malware on removable media.

SRS.Security.MD.PhysicalAccess

The Azurion shall be protected against attacks via physical access.

SRS.Security.MD.AttackViaPhysical DeviceModification

The Azurion shall be protected against attacks via physical device modification.

SRS.Security.MD.UnavailabilityOfMedicalDevice

The Azurion shall reduce the impact of Unavailability of Azurion in case Azurion is breached.

SRS.Security.MD.ReputationDamage

The Azurion shall reduce the impact of Reputation damage (manufacturer/hospital) in case Azurion is breached.

SRS.Security.MD.DataBreach

The Azurion shall reduce the impact of Data Breach in case Azurion is breached.

SRS.Security.PHD.RemoteAccessPoint

The Patient Health Data shall be protected against attacks via remote access point.

SRS.Security.PHD.HospitalNetwork

The Patient Health Data shall be protected against attacks via hospital network.

SRS.Security.PHD.MedicalDevice

The Patient Health Data shall be protected against attacks via the Azurion.

SRS.Security.PHD.PhysicalAccess

The Patient Health Data shall be protected against attacks via physical access.

SRS.Security.PHD.PhysicalDismounting

The Patient Health Data shall be protected against attacks via physical dismounting.

SRS.Security.PHD.PatientDataCorrupted

The Azurion shall reduce the impact of  Patient data corrupted in case of Patient Health Data is attacked.

SRS.Security.PHD.DataBreach

The Azurion shall reduce the impact of Reputation damage (manufacturer/hospital) in case Azurion is breached.

SRS.Security.PHD.PatientDataLoss

The Azurion shall reduce the impact of Reputation damage (manufacturer/hospital) in case Azurion is breached.

SRS.Security.HN.AttackViaMedicalDevice

The Hospital Network shall be protected against attacks via Azurion.

SRS.Security.HN.HospitalNetworkBreached

The Azurion shall reduce the impact of:

* Unavailability of Hospital Network,
* Breached hospital infrastructure,
* Disclosed customer data,

in case Hospital Network is attacked through the Azurion.

SRS.Security.RM.AttackViaMedicalDevice

The Removable Media shall be protected against attacks via Azurion.

SRS.Security.HN.RemovableMediaBreached

The Azurion shall reduce the impact of:

* Breached Devices,
* Disclosed Patient Health data,
* Unavailability of data,

in case Removable Media is breached through the Azurion.

## Standards, Legal Requirements

### International Standards

SRS.Allura.SLS.ListOfApplicableStandards

The standards as mentioned in chapter APPLICABLE STANDARDS are applicable.

### Environmental Care

SRS.Allura.SLS.ECO.ProductLabeling

The product shall provide information on labels and in the IfU according the Philips QMS standard 'Product environmental labeling requirements' [REF-2] and "Environmental requirements for IFU and DFU" [REF-3].

### IHE, VA and DoD Requirements

SRS.Allura.SLS.IHE

The system implements all of the transactions specified in the Integrating the Healthcare Enterprise (IHE) Technical Framework to support the IHE Integration Profiles, Actors and Options listed below:

|  |  |  |
| --- | --- | --- |
| *Integration Profiles Implemented* | *Actors Implemented* | *Options Implemented* |
| Cardiac Catheterization Workflow (CATH) | Acquisition Modality | Broad Worklist Query |
| Scheduled Workflow (SWF) | Acquisition Modality | Patient Based Worklist Query, Broad Worklist Query |
| Patient Information Reconciliation (PIR) | Acquisition Modality | none |
| Consistent Presentation of Images (CPI) | Acquisition Modality | none |
| Radiation Exposure Monitoring (REM) | Acquisition Modality | none |
| Consistent Time (CT) | Time Client | none |
| Audit Trail and Node Authentication (ATNA) | Secure Node | none |

SRS.Allura.SLS.VA

Compatibility with mandatory requirements from Veterans Administration (VA) is required (see [REF-1]).

This applies to positioning-related requirements for table and/or stand, requirements for radiation and image generation and DICOM interoperability aspects.

SRS.Allura.SLS.DoD

The system fulfils the requirements for certification according to the Department of Defense (DoD) Risk Management Framework.

# SYSTEM INTEGRATION AND VERIFICATION REQUIREMENTS

This chapter describes requirements to perform the system integration and system verification activities (I&V).

The system shall be designed for testability for the manual and automated system test activities. With automated is meant that no human interaction is required and/or no attendance is required. This approach is called in this document “AiT” meaning Automations in System Test.

SRS.Allura.I&V.Environment

The system shall work in its AiT environment:

* No manual system modifications and content changes are needed for AiT

SRS.Allura.I&V.TestInterface

The system offers a method (to enable test automation) to:

* condition/configure/customize the system for specific tests. This includes software installation (“full install”).
* simulate human interaction and system environmental interaction to enable test automation.
* access/collect system logging and tracing.

SRS.Allura.I&V.ManualTest

For manual testing the system shall have:

* A viewer for logging and tracing;
* Capabilities for content and detail level scaling of system logging and tracing;
* File handling possibilities for logging and tracing and system data;
* Customizable EPX data extraction.
* Support for the use of product test tools;
* Support for fault injection for safety requirements verification.

# Applicable Standards

## International markets

The list below applies to **x-ray imaging equipment including embedded software** that cannot be used separately from equipment. The list is applicable to show compliance with the 3rd edition of IEC60601-1 and its collateral and particular standards.

|  |  |  |
| --- | --- | --- |
| **International standard** | **Edition** | **Title** |
| IEC 60601-1:2005  + Corrigendum C1:2006  + Corrigendum C2:2007  + Interpretation ISH1:2008  + Interpretation ISH2:2009  + Amendment A1:2012 | 3.1 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2:2007 | 3.0 | Collateral standard: Electromagnetic compatibility – Requirements and tests |
| IEC 60601-1-2:2014 + Amendment A1:2020 | 4.1 | Collateral standard: Electromagnetic disturbances – Requirements and tests |
| IEC 60601-1-3:2008  + Amendment A1:2013 | 2.1 | Collateral standard: General requirements for radiation protection in diagnostic X-Ray equipment |
| IEC 60601-1-6:2010  + Amendment A1:2013 | 3.1 | Collateral standard: Usability |
| IEC 60601-1-9:2007  + Amendment A1:2013 | 1.1 | Collateral Standard: Requirements for environmentally conscious design |
| IEC 60601-2-43:2010  + Amendment A1:2017  + Amendment A2:2019 | 2.2 | Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures |
| IEC 60601-2-54:2009  + Amendment A1:2015  + Amendment A2:2018 | 1.2 | Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy |
| IEC 60825-1:2014 | 3.0 | Safety of laser products – Part 1: Equipment classification and requirements |
| IEC 60825-2:2004  + Amendment A1:2006  + Amendment A2:2010  + Interpretation ISH1:2008 | 3.2 | Safety of laser products – Part 2: Safety of optical fiber communication systems |
| IEC 62304:2006  + Amendment A1:2015 | 1.1 | Medical device software – Software life cycle processes |
| IEC 62366:2007  + Amendment A1:2014 | 1.1 | Medical devices – Application of usability engineering to medical devices |
| IEC 62366-1:2015 + Amendment A1:2020 | 1.1 | Medical devices – Part 1: Application of usability engineering to medical devices |
| ISO 14971:2019 | 3.0 | Medical devices – Application of risk management to medical devices |

 The following standards are normatively referenced and are needed to demonstrate compliance with the “top-level” standards listed above.

|  |  |  |
| --- | --- | --- |
| **Normative reference** | **Edition** | **Title** |
| IEC 60336:2005  + C1:2006 | 4.0 | X-ray tube assemblies for medical diagnosis – Characteristics of focal spots |
| IEC 60522:1999 | 2.0 | Determination of the permanent filtration of X-ray tube assemblies |
| IEC 60526:1978 + C1:2010 | 2.0 | High-voltage cable plug and socket connections for medical X-ray equipment |
| IEC 60529:1989 + A1:1999  + A2:2013 + C1:2013 + C2:2015 + A2/C1:2019 | 2.2 | Degrees of protection provided by enclosures (IP Code) |
| IEC 60580:2019 | 3.0 | Medical electrical equipment – Dose area product meters |
| IEC 60601-1-8:2006  + A1:2012 | 2.1  **Note 1** | Part 1-8: Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| IEC 60601-2-28:2017 | 3.0 | Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis |
| IEC 60613:2010 | 3.0 | Electrical, thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis |
| IEC 60627:2013 | 3.0 | Diagnostic X-ray imaging equipment – Characteristics of general purpose and mammographic anti-scatter grids |
| IEC 60806:1984 | 1.0 | Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis |
| IEC 60950-1:2005  + C1:2006 + A1:2009  + Corrigendum of A1 (2012)  +A2:2013 | 2.2  **Note 2** | Information technology equipment – Safety. Part 1: General requirements |
| IEC 62368-1:2018 | 3.0  **Note 2** | Audio/video, information and communication technology equipment – Part 1: Safety requirements |
| IEC 61331-n:2014 (series) | 2.0 | Protective devices against diagnostic medical X-radiation (Parts 1 to 3) |
| IEC 61910-1:2014 | 1.0 | Medical electrical equipment – Radiation dose documentation – Part 1: Equipment for radiography and radioscopy |
| DICOM | (2016c) | Digital Imaging and Communications in Medicine ([http://medical.nema.org](http://medical.nema.org/)) |
| IEC 62220-1-3:2008 | 1.0 | Characteristics of digital X-ray imaging devices. Part 1-3: Determination of the detective quantum efficiency – detectors used in dynamic imaging |
| ISO 10993-1:2018 | 5.0 | Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process |
| ISO 15223-1:2021 | 4.0 | Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied |
| ISO 20417:2021 | 1.0 | Medical devices – Information to be supplied by the manufacturer |
| IEC 80001-1:2010 | 1.0 | Application of risk management for IT-networks incorporating medical devices –  Part 1: Roles, responsibilities and activities |
| DIN6868-157:2014 | - | Image Quality assurance in diagnostic X-ray departments - Part 157: X-ray ordinance acceptance and constancy tests of image display systems in their environment. |
| DIN6862-2:2019 | - | Identification and characterization of radiological images in medical diagnosis - Part 2: Passing on of radiographs and related records in digital radiography, digital fluoroscopy and computed tomography |
| ISO 17664-2:2021 | 1.0 | Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices |

**Note 1:** IEC 60601-1-8 does not apply, as stated in IEC 60601-2-54:2009 and IEC 60601-2-43:2010. However, it must be checked that audible signals generated by x-ray imaging equipment do not interfere with alarm signals generated by other medical devices conforming with IEC 60601-1-8.

**Note 2:** This standard is only applicable to IT equipment

## European Economic Area

The list below contains all **European Directives and Regulations** applicable to medical devices and to medical electrical equipment emitting ionizing radiation. Compliance with harmonized EN standards gives presumption of conformity with the General Safety and Performance Requirements (MDR, Annex I).

|  |  |  |
| --- | --- | --- |
| **Directives** | **Published** | **Title** |
| EU 2017/745 | 2017-04-05  Amended: 2020-04-23 | Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC |
| 2014/53/EU | 2014-04-16  Amended:  2018-07-04 | Directive of the European Parliament and of the Council on the making available on the market of radio equipment and repealing Directive 1999/5/EC |
| 94/62/EC | 1994-12-20  Amended:  2018-05-30 | European Parliament and Council directive on packaging and packaging waste |
| 2006/66/EC | 2006-09-06  Amended:  2013-11-20 | Directive of the European Parliament and of the Council on batteries and accumulators and waste batteries and accumulators |
| EC 1907/2006 | 2006-12-18  Amended:  2019-10-10 | Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) |
| 2013/59/EURATOM  **Note 1** | 2013-12-05 Amended: 2014-01-17 | Council directive laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation |
| 2011/65/EU (RoHS) | 2011-06-08-  Amended:  2021-11-23 | Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (commonly referred to as RoHS); SL with Annex IV |
| 2012/19/EU | 2012-07-24 Amended 2018-06-14 | Directive of the European Parliament and of the Council on waste of electrical and electronic equipment (WEEE, recast) |
| EU 2021/2226 | 2021-12-14 | Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices. |
| DE: Sachverständigen-Prüfrichtlinie (SV-RL)  **Note 2** | 2020-07-01 | Richtlinie für die technische Prüfung von Röntgeneinrichtungen und genehmigungsbedürftigen Störstrahlern durch Sachverständige nach dem Strahlenschutzgesetz und der Strahlenschutzverordnung English: Guideline for the technical inspection of X-ray equipment and interference radiation requiring approval by experts in accordance with the Radiation Protection Act and the Radiation Protection Ordinance. |

**Note 1**     The EURATOM directive does not directly apply to medical electrical equipment but more to the use of (equipment emitting) ionizing radiation. On request from customers, a statement must be provided how Philips Healthcare can assist in meeting the requirements of this directive.

**Note 2**     The compliance to this requirement is managed by the local organization (supplier). A local independent inspection body will verify this compliance.

## Switzerland

|  |  |  |
| --- | --- | --- |
| **Regulation** | **Published** | **Title** |
| CH: 814.542.1 | 2017-04-26 | Verordnung des EDI über den Strahlenschutz bei medizinischen Röntgensystemen (Röntgenverordnung, RöV)  English: Ordinance of the Swiss Federal Department of Radiation Protection in Medical X-Ray Systems (X-ray Ordinance) |

## United Kingdom

|  |  |  |
| --- | --- | --- |
| **Statutory Instrument** | **Published** | **Title** |
| SI 2002 No. 618 | 2002-05-21  Amended: 2020-12-08 | Statutory Instruments 2002 No. 618, Consumer Protection, The Medical Devices Regulations 2002 (as last amended by SI 2020 No.1478) |

## EN standards used for compliance with other directives

|  |  |  |  |
| --- | --- | --- | --- |
| **EN standard** | **Edition** | **Notes** | **Title** |
| EN 62321-n (2013-2014) | 1.0 | **1** | Determination of certain substances in electrotechnical products – Parts 1, 2, 3-1, 3-2, 4, 5 |
| IEC 63000:2016 | 1.0 | - | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |
| EN 50419:2006 | 2.0 | - | Comply with Article 11(2) of WEEE Directive 2002/96/EC and is also applicable to comply with Article 15(2) of the recast Directive 2012/19/EU |
| EN 301 489-1:2017 | 2.1.1 | - | ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements |
| EN 301 489-3:2017 | 2.1.1 | - | Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz |
| EN 301 489-17:2017 | 3.2.0 | - | ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU |
| EN 300 220-1:2017 | 3.1.1 | - | Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz;Part 1: Technical characteristics and methods of measurement |
| EN 300 220-2:2017 | 3.1.1 | - | Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz; Part 2: Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU for non-specific radio equipment |
| EN 300 440:2017 | 2.1.1 | - | Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU |
| EN 62479:2010 | 1.0 | - | Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz) |
| EN 303 204:2016 | 2.1.2 | - | Network Based Short Range Devices (SRD); Radio equipment to be used in the 870 MHz to 876 MHz frequency range with power levels ranging up to 500 mW; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU |
| EN 301 893:2017 | 2.1.1 | - | 5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU |
| EN 300 328:2019 | 2.2.2 | - | Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum |

**Note 1**    These standards are only applicable in case that analytical tests of certain substances need to be made.

## Canada

The table below contains the **Regulations from Health Canada** and Department of Justice that apply to medical electrical equipment and products emitting ionizing radiation. Interventional x-ray imaging systems must comply with these regulations in Canada.

|  |  |  |
| --- | --- | --- |
| **Canada Regulations** | **Date** | **Title** |
| Statutory Orders and Regulations SOR/98-282 | Last amended: 2022-03-02 | Medical Devices Regulations |
| Consolidated Regulations of Canada C.R.C. Chapter 1370 | Last amended: 2021-03-31 | Radiation Emitting Devices Regulations  (Schedule II, Part XII, Diagnostic X-ray equipment) |

**Canadian Deviations to International standards**

|  |  |  |
| --- | --- | --- |
| **Canadian deviation** | **Edition** | **Title** |
| CAN/CSA-C22.2 No. 60601-1:14 | 3.1 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, modified) |
| CAN/CSA-C22.1:2021 | 25 | Canadian Electrical Code, Part I, Safety Standard for Electrical Installations. |
| CAN/CSA C22.2 0.4-17 | 4.0 | Bonding of Electrical Equipment |

## USA

The first table below contains the **USA Federal Regulations** that apply to medical electrical equipment and products emitting ionizing radiation and/or laser light. Interventional x-ray imaging systems must comply with these regulations in USA. The second table contains national deviations from international standards.

|  |  |  |
| --- | --- | --- |
| **USA Federal Regulations** | **Date** | **Title** |
| Code of Federal Regulations, Title 21, Subchapter J, Part 1010 | April 01, 2019 | Performance standards for electronic products: general |
| Code of Federal Regulations, Title 21, Subchapter J, Part 1020.30 | April 01, 2019 | Performance standards for ionizing radiation emitting products – Diagnostic X-ray systems and their major components |
| Code of Federal Regulations, Title 21, Subchapter J, Part 1020.31 | April 01, 2019 | Performance standards for ionizing radiation emitting products – Radiographic equipment |
| Code of Federal Regulations, Title 21, Subchapter J, Part 1020.32 | April 01, 2019 | Performance standards for ionizing radiation emitting products – Fluoroscopic equipment |
| Code of Federal Regulations, Title 21, Subchapter J, Part 1040.10 | April 01, 2019 | Performance standards for light-emitting products – Laser products |
| Code of Federal Regulations, Title 47 | May 2017 | Telecommunication (relevant for FCC certification of monitors) |

|  |  |  |
| --- | --- | --- |
| **USA deviations to international standards** | **Edition** | **Subject** |
| National Electrical Code (NFPA 70) | 2020  **Note 1** | Protection against electrical fire and shock hazards |
| ANSI/AAMI ES60601-1:2005/(R) 2012 and  A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 | 3.1 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (modified) |
| NEMA XR-27:2012  + Amendment A1:2013 | 1.1 | X-ray equipment for interventional procedures User quality control mode |
| NEMA XR-31:2016 | 1.0 | Standard attributes on x-ray equipment for interventional procedures |
| UL 2900-1:2017 | 1.0 | Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements |

**Note 1**     NEC applies to the installation of x-ray imaging systems in hospitals/clinics/etc and may contain additional requirements for the equipment. Some states may use previous versions of NEC (2005 or 2008). Latest version is considered to be state-of-the-art.

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