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# Approval

| **Role** | (approval via electronic signature in document management tool) |
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| MKT: Segment Lead |
| R&D: Department Manager SD |
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| Q&R: DEV QA Manager |

# Revision History

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| --- | --- | --- | --- |
| **Revision Date** | **Author** | **Source** | **Changes/Comments** |
| 2018 Dec 21 | Niels Kramer | D-343701 | Initial version of UNS Azurion R3.0    Based on DHF273533 UNS Azurion R2.1 and DHF279626 UNS Workspots and Videodistribution    Note: as part of the Kaizen BRUNS many user tags have been revised in order to capture the user need better (instead of describing the solution) |
| 2019 Jul 30 | Niels Kramer | D-373113 | Addressed the open issues and updated accordingly |
| 2020 Sept 4 | Marcos Faria Fazenda | D-411395 | Include IQ user need |
| 2021 Nov 15 | Marcos Faria Fazenda | A | Review and update the user needs and claims |
| 2023 Jan 4 | Marcos Faria Fazenda | B | SVER update   * UNS.SmartSuite.BiplaneHeadSpace – removed the better ergonomics claim * UNS.SmartSuite.CollisionDetection – readjusted the wording to reflect what can be validated (current and new) * Removed the manufactured engineer from the user group * UNS.SmartSuite.FullBodyCoverage – add a disclaimer that is not applicable with a leg support board * UNS.SmartSuite.Sterility – removed the word dedicated since we don’t use anymore the Ecolab cover * UNS.SmartSuite.PowerFailure – add a disclaimer that the first bullet point is only applicable for Veteran Healthcare Administration facilities |
| 2023 Feb 9 | Marcos Faria Fazenda | C | Update of the UNS.SmartSuite.StartExamination by removing from the new section: Start the examination from the Exam Room from the MultiSwitch. |
| 2023 Jul 18 | Marcos Faria Fazenda | D | Update the document to reflect the template differences identified between the RV&S and Windchill documents. This assessment had no impact on the evidence already generated. |

# Open Issues

None

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# Document Introduction

## Purpose

This document contains the overall user needs for the Puma project, bringing Azurion 3.0 series (as identified in the Intended Use) to the market. This document describes the user needs with respect to the use of floor and ceiling-mounted X-ray systems. The user needs are (1) either linked to a clinical workflow step, (2) defined as generic user needs, (3) defined as service user needs or (4) defined as regulatory, safety, security, manufacturing and legal needs. The Azurion 3.0 will be validated against these user needs. The intended readers are: marketing and application representatives, regulatory, service and manufacturing representatives, the product program manager, the project’s design team, development and validation crew.

## Scope

The scope of the document is the specific release of the Azurion 3.0 series; containing the monoplane and biplane releases, the 7 series, the 5 and the 3 series, the 12”, 15” and 20” detectors, it covers the needs of the defined user groups.

## References

|  |  |  |
| --- | --- | --- |
| **Reference** | **Identification** | **Title / additional remarks** |
| [REF-1] | DHF372906 | UNS Azurion R2.2 |
| [REF-2] | DHF321455 | Marketing Claims Substantiation Study |
| [REF-3] | DHF350790 | Usability Evaluation Report FE2 Azurion R2.1 |
| [REF-4] | DHF335614 | CSER Mozart Clinical Study End Report |
| [REF-5] | D000696453 | Clinical Evaluation Report Azurion family |

## Definitions & Abbreviations

|  |  |
| --- | --- |
| **Term** | **Description** |
| ALARA | As Low As Reasonably Achievable |
| AK | AirKerma |
| APC | Automatic Position Control |
| BMI | Body Mass Index |
| CAS | Clinical Application Specialist |
| Cath Lab | Catheterization Laboratory |
| CES | Clinical Education Specialist |
| CR | Control Room |
| CIS | Cardiology Information System |
| CT | Computer Tomography |
| CV | CardioVascular |
| CVC | Customer Visit Centre |
| DAP | Dose Area Product |
| DICOM | Digital Image Communication in Medicine, a standard for medical data exchange |
| DSA | Digital Subtracted Angiography |
| DVD | Digital Versatile Disc |
| DVI | Digital Visual Interface |
| ECG | ElectroCardioGram |
| EP | ElectroPhysiology |
| EPX | Examination, Patient-type and X-ray operator driven pre-setting mechanism |
| ER | Examination Room |
| ETTR | Estimated Time To Repair |
| EVAR | EndoVascular Aortic Repair |
| FD | Flat Detector |
| FDA | Food and Drugs Administration, legal body in United States of America |
| FDPA | Flexible Dynamic Peripheral Angiography |
| FOV | Field of View |
| FFR | Fractional Flow Reserve |
| FRU | Field Replaceable Unit |
| FSE | Field Service Engineer |
| HD | High Definition |
| HIS | Hospital Information System |
| HIT | Hospital IT |
| IFR | Instant Wave-free Ratio |
| IFU | Instructions For Use |
| IHE | Integrating the Healthcare Enterprise (institution in US) |
| IQ | Image Quality |
| ISP | IntelliSpace Portal |
| IVUS | Intra-Vascular Ultrasound |
| KVM | Keyboard, Video, Mouse |
| LAF | Laminar Air Flow |
| LAO | Left Anterior Oblique |
| LIH | Last Image Hold |
| LOTS | Look-Over-The-Shoulder |
| LV | Left Ventricle |
| LVA | Left Ventricle Analysis |
| ME | Manufacturer Engineer |
| Mechanically install | Aligned with the Philips terminology and linked to hardware installation/deinstallation |
| MM TSM | Multi Modality Touch Screen Module |
| MPPS | Modality Performed Procedure Step, part of DICOM RIS protocol |
| MR | Magnetic Resonance |
| MTBF | Mean Time Between Failures. |
| MTTR | Mean Time To Repair. |
| NEMA | National Electrical Manufacturers Association |
| OR | Operating Room |
| PACS | Picture Archiving and Communication System |
| PCI | Percutaneous Coronary Interventions |
| PPS | Performed Procedure Step |
| PRS | Philips Remote Service |
| PTA | Percutaneous Transluminal Angioplasty |
| PTCA | Percutaneous Transluminal Coronary Angioplasty (procedure for elimination of areas of narrowing in blood vessels) |
| QA; QCA; QVA | Quantitative Analysis; Quantitative Coronary Analysis; Quantitative Vascular Analysis |
| RAO | Right Anterior Oblique |
| RCIS | Registered Cardiovascular Invasive Specialist |
| RIS | Radiology Information System |
| ROAR | Reach Over Available Room |
| RSE | Remote Service Engineer |
| RVA | Right Ventricular Analysis |
| SHD | Structural Heart Disease |
| SID | Source Image Distance |
| SUS | System Usability Score |
| TACE | Transarterial chemoembolization |
| TAVI | Transcatheter Aortic Valve Implantation |
| TSM | Touch Screen Module |
| UHD | Ultra High Definition |
| UI | User Interface |
| UNS | User need specification |
| USB | Universal Serial Bus |
| VoIP | Video over internet protocol |
| WLM | Work-List Management |
| 3rd party | Non X-ray system |
| Near-zero latency | The ability to share a high amount of data (video/image) almost in real-time (without delay) |

## Use of tags

Each user need and claim has a unique identifier (‘tag’) to ensure identification and traceability along the project. The tags have the following format:

* For user needs: UNS.<name of product>.<name of user need>
  + <Collective name of product\*> = SmartSuite;
  + <Name of user need> = e.g. CreateWorklist, PatientData, Calibration, etc.
* For claims: CLAIM.<name of product>.<type><id>.<name of claim>
  + <Collective name of product\*> = SmartSuite;
  + <type> = C (Clinical), T (Technical), Ease (Ease of Use),
  + <id> = 1,2,3,…>
  + <Name of Claim> = e.g. FlexSpot, FlexVision

*\* Product name is Azurion, but for legacy and traceability purposes we use SmartSuite (project name of Azurion).*

# Intended Use

## Product Description

The Azurion series consists of a number of monoplane and biplane systems with different detector sizes (12”, 15” and 20”).

## Indications for Use / Medical Purpose

The Azurion series (within the limits of the used operating room table) is intended for use to perform:

* Image guidance in diagnostic, interventional, and minimally invasive surgery procedures for the following clinical application areas: vascular, non-vascular, cardiovascular, and neuro procedures.
* Cardiac imaging applications including diagnostics, interventional and minimally invasive surgery procedures.

Additionally:

* The Azurion series can be used in a hybrid operating room.
* The Azurion series contains a number of features to support a flexible and patient-centric procedural workflow.

The Azurion series is intended for all human patients of all ages. Patient weight is limited to the specification of the patient table.

## Intended Operator Profile

The Azurion series is intended to be used and operated by adequately trained, qualified, and authorized healthcare professionals who have an understanding of the safety information and emergency procedures as defined by local laws and regulations for radiation workers and staff.

## Clinical environment

The Azurion series is a fixed and stationary system that can be used in a clinical environment fulfilling the local laws and regulations for radiological X-ray systems in sterile and non-sterile environments.

## General safety and effectiveness

To facilitate safe and efficacious operation of the system by a trained healthcare professional, instructions for use are provided as part of the device labeling and training is provided during system handover.

## Contraindications

Avoid using the system with patients who are pregnant or who may possibly be pregnant. However, the risk may be outweighed by the benefit of diagnosing or treating a serious condition. It is the responsibility of the personnel operating the system to make the decision. Avoid using the system in case of existing radiation injury (operator or patient).

## Operating principle

The system uses X-ray generation, detection and image processing for medical imaging, and additionally displays images from other sources (for example ultrasound). The control mechanisms are input devices and controls for, for example, geometry movements. The system provides feedback by audible and visual means.

# Proposed claims

## Claims (legacy)

No new clinical claims are proposed for Azurion 3.0. Proposed updates of legacy claims [REF-1] relating to Philips ClarityIQ technology will be sustained and are listed in the table below. Depending on the regulatory strategy, not all clinical claims are applicable for all countries.

### Clinical claims

CLAIM.SmartSuite.C1.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| ClarityIQ technology reduces radiation exposure to patients and staff in interventional lab, by providing industry leading image quality at a fraction of the dose.  Our unique ClarityIQ technology makes this quantum leap in dose reduction possible. It reduces X-ray dose while delivering equivalent image quality.1,2,3 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C2.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| Clinically proven  Significantly lower dose - across clinical areas, patients and operators.1 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C3.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| Clinically proven significantly lower dose - based on x peer-reviewed clinical studies with y patients across the globe.1 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C4.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| ClarityIQ technology dramatically reduces X-ray dose, resulting in reduced risk of complications from radiation exposure for patients.1,4 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C5.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| ClarityIQ technology decreases scatter radiation, thereby reducing longterm health risk for physician and staff.1,4 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C6.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| ClarityIQ technology dramatically reduces X-ray dose, thereby enabling longer procedures to treat  obese and high risk patients.1,4 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C7.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| ClarityIQ technology dramatically reduces X-ray dose, thereby enabling longer more complex procedures.1,4 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C8.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| In diagnostic Neuro procedures, Clarity IQ technology reduces patient dose by 62%, compared to a system without ClarityIQ.5,6 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C9.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| In interventional Neuro procedures, Clarity IQ technology reduces patient dose by 65%, compared to a system without ClarityIQ.5,6 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C10.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| In Neuro DSA, ClarityIQ technology reduces patient dose by 75% while maintaining equivalent image quality, compared to a system without ClarityIQ.5,7 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C11.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| In diagnostic coronary angiography, ClarityIQ technology reduces patient dose by 75% while maintaining diagnostic image quality, compared to a system without ClarityIQ.5,8 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C12.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| In cardiac cine, ClarityIQ technology reduces patient dose by 53% while maintaining equivalent image quality, compared to a system without ClarityIQ.5,9 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C13.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| In EP procedures, ClarityIQ technology reduced patient dose by 43%, compared to a system without ClarityIQ5,10 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C14.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| In aortoiliac endovascular procedures, ClarityIQ technology reduces patient dose by 72%, compared to a system without ClarityIQ5,11 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C15.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| In iliac DSA, ClarityIQ technology reduces patient dose by 83% while maintaining image quality, compared to a system without ClarityIQ.5,12 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C16.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| In EVAR procedures, ClarityIQ technology reduces patient dose by 57%, compared to a system without ClarityIQ.5,13 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

CLAIM.SmartSuite.C17.ClarityIQ

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| In repetitive TACE procedures, ClarityIQ technology reduces patient dose by 50% while maintaining image quality, compared to a system without ClarityIQ.5,14 | UNS.SmartSuite. AcquisitionImageQualityAndDose |

#### Footnotes

#### The footnotes are related to the references to scientific papers, section 3.1.1.2.

*1 In multiple individual comparative studies, Philips ClarityIQ was associated with reductions in patient radiation exposure. Here x refers to the number of peer-reviewed clinical studies and y refers to the number of patients. The numbers for x and y are specified in Chapter 2.6 of the Clinical Evaluation Report [REF-5].*

*2 In 3 individual comparative studies, Philips ClarityIQ was associated with reductions in staff [1, 16] or scatter  [17] radiation exposure.*

*3 8 comparative studies explicitly demonstrated equivalent image quality. [6, 8, 9, 11, 12, 15, 17, 18]*

*4 Relationship between radiation exposure and risk of complications, long-term health risk, procedure time and patient characteristics, procedure complexity, as reported in medical guidelines, e.g. [19]*

*5 The results of the application of dose reduction techniques will vary depending on the clinical task, patient size, anatomical location and clinical practice. The interventional radiologist assisted by a physicist as necessary has to determine the appropriate settings for each specific clinical task.*

*6 Results based on total dose area product from a single center retrospective historically controlled cohort study on 614 patients (302 for Allura Xper without ClarityIQ and 312 for Allura Xper with ClarityIQ). Procedural performance (fluoroscopy time and number of DSA images) of the physicians did not significantly differ between the two cohorts. [13]*

*7 Results based on DSA dose area product per frame from a single center prospective study on 20 patients. DSA runs for Allura Xper with ClarityIQ and Allura Xper without ClarityIQ were acquired on the frontal and lateral channel on the same patient under same condition of geometry, field of view and injection protocol. Image quality was based on subjective assessment (score 1-5, 1=very poor, 5=excellent, blinded review by 3 radiologists involved in the study). [12]*

*8 Results based on total dose area product from a single center prospectively randomized cohort study on 70 consecutive patients (35 for Allura Xper without ClarityIQ and 35 for Allura Xper with ClarityIQ). Number of cine images and contrast medium did not significantly differ between the two cohorts, while fluoroscopy time was significantly higher for the ClarityIQ group. Image quality was based on subjective assessment of two cine runs selected from each patient in two specific projections. Ratings for image contrast, resolution and general appearance were not statistically different. Image noise was more apparent for ClarityIQ images. [6]*

*9 Results based on cine dose area product per frame from a single center prospective study on 39 patients. Cine runs for Allura Xper with ClarityIQ and Allura Xper without ClarityIQ were acquired on the same patient under same condition of geometry, field of view and injection protocol. Image quality comparison is based on subjective assessment (side-by-side, score: equal or better than the other, blinded review by 6 independent cardiologists). [15]*

*10 Results based on total dose area product from a single center prospectively randomized cohort study on 136 patients (68 for Allura Xper without ClarityIQ and 68 for Allura Xper with ClarityIQ). Procedural performances (fluoroscopy time and number of cine images) of the physicians did not significantly differ between the two cohorts. [1]*

*11 Results based on total dose area product from a single center prospective historically controlled cohort study on 101 patients (34 for Allura Xper without ClarityIQ and 67 for Allura Xper with ClarityIQ). Procedural performances (fluoroscopy time and contrast medium) of the physicians did not significantly differ between the two cohorts. [16]*

*12 Results based on DSA dose area product per frame from a single center prospective randomized study on 48 patients. DSA runs for Allura Xper with ClarityIQ and Allura Xper without ClarityIQ were randomly acquired on the same patient under same condition of geometry, field of view and injection protocol. Image quality was based on subjective assessment (side-by-side, equal or superior than the other, blinded review by 5 independent radiologists). [17]*

*13 Results based on total dose area product from a single center prospective historically controlled cohort study on 37 patients (18 for Allura Xper without ClarityIQ and 19 for Allura Xper with ClarityIQ). Procedural performances (fluoroscopy time and contrast medium) of the physician did not significantly differ between the two cohorts. [16]*

14 *Results based on total dose area product from a single center prospectively randomized cohort study on 50 consecutive patients randomly assigned to the Allura Xper system with ClarityIQ or Allura Xper system without ClarityIQ. Fluoroscopy time and number of DSA images did not significantly differ between the two cohorts. Fluoroscopy and DSA images of each case were subjectively assessed in blinded, offline reading (score 0-5) by three experienced interventional radiologists. DSA image quality was equally rated between cohorts, while fluoroscopy images of Allura Xper with ClarityIQ were slightly (significantly) degraded. [18]*

#### References to scientific papers

1.   Dekker, L.R., et al., *New image processing and noise reduction technology allows reduction of radiation exposure in complex electrophysiologic interventions while maintaining optimal image quality: a randomized clinical trial.* Heart Rhythm, 2013. **10**(11): p. 1678-82.

2.   Bracken, J.A., et al., *A Radiation Dose Reduction Technology to Improve Patient Safety During Cardiac Catheterization Interventions.* J Interv Cardiol, 2015. **28**(5): p. 493-7.

3.   Durrani, R.J., et al., *Radiation dose reduction utilizing noise reduction technology during uterine artery embolization: a pilot study.* Clinical Imaging, 2016. **40**(3): p. 378-381.

4.   de Ruiter, Q.M., et al., *AlluraClarity Radiation Dose-Reduction Technology in the Hybrid Operating Room During Endovascular Aneurysm Repair.* J Endovasc Ther, 2016. **23**(1): p. 130-8.

5.   Dave, J.K., et al., *A Phantom Study and a Retrospective Clinical Analysis to Investigate the Impact of a New Image Processing Technology on Radiation Dose and Image Quality during Hepatic Embolization.* Journal of Vascular and Interventional Radiology, 2016. **27**(4): p. 593-600.

6.   Eloot, L., et al., *Novel X-ray imaging technology enables significant patient dose reduction in interventional cardiology while maintaining diagnostic image quality.* Catheter Cardiovasc Interv, 2015. **86**(5): p. E205-12.

7.   Haas, N.A., et al., *Substantial radiation reduction in pediatric and adult congenital heart disease interventions with a novel X-ray imaging technology.* IJC Heart & Vasculature, 2015. **6**: p. 101-109.

8.   Kohlbrenner, R., et al., *Patient Radiation Dose Reduction during Transarterial Chemoembolization Using a Novel X-ray Imaging Platform.* Journal of Vascular and Interventional Radiology, 2015. **26**(9): p. 1331-1338.

9.   Lauterbach, M. and K.E. Hauptmann, *Reducing Patient Radiation Dose With Image Noise Reduction Technology in Transcatheter Aortic Valve Procedures.* The American Journal of Cardiology, 2016. **117**(5): p. 834-838.

10.   Nakamura, S., et al., *Patient radiation dose reduction using an X-ray imaging noise reduction technology for cardiac angiography and intervention.* Heart Vessels, 2015.

11.   Schernthaner, R.E., et al., *A new angiographic imaging platform reduces radiation exposure for patients with liver cancer treated with transarterial chemoembolization.* European radiology, 2015. **25**(11): p. 3255-3262.

12.   Soderman, M., et al., *Image noise reduction algorithm for digital subtraction angiography: clinical results.* Radiology, 2013. **269**(2): p. 553-60.

13.   Söderman, M., et al., *Radiation dose in neuroangiography using image noise reduction technology: a population study based on 614 patients.* Neuroradiology, 2013. **55**(11): p. 1365-1372.

14.   Strauss, K.J., et al., *Estimates of diagnostic reference levels for pediatric peripheral and abdominal fluoroscopically guided procedures.* AJR Am J Roentgenol, 2015. **204**(6): p. W713-9.

15.   ten Cate, T., et al., *Novel X-ray image noise reduction technology reduces patient radiation dose while maintaining image quality in coronary angiography.* Netherlands Heart Journal, 2015. **23**(11): p. 525-530.

16.   van den Haak, R.F., et al., *Significant Radiation Dose Reduction in the Hybrid Operating Room Using a Novel X-ray Imaging Technology.* Eur J Vasc Endovasc Surg, 2015. **50**(4): p. 480-6.

17.   van Strijen, M.J., et al., *Evaluation of a Noise Reduction Imaging Technology in Iliac Digital Subtraction Angiography: Noninferior Clinical Image Quality with Lower Patient and Scatter Dose.* Journal of Vascular and Interventional Radiology, 2015. **26**(5): p. 642-650.e1.

18.   Wen, X., et al., *Novel X-ray Imaging Technology Allows Substantial Patient Radiation Reduction without Image Quality Impairment in Repetitive Transarterial Chemoembolization for Hepatocellular Carcinoma.* Academic Radiology, 2015. **22**(11): p. 1361-1367.

19.   Stecker, M.S., et al., *Guidelines for Patient Radiation Dose Management.* Journal of Vascular and Interventional Radiology, 2009. **20**(7): p. S263-S273.

### Technical claims

The Azurion series contain a number of features that will enable the user to experience a flexible and patient-centric procedural workflow. Legacy claims of Azurion 2.2 [REF-1] will be supported.

* The implementation of FlexVision, FlexSpot and ProcedureCards enables the users to customize screen layouts and procedure settings, providing the flexibility to adjust to their departmental or personal preferences. In addition, Instant Parallel Working provides the flexibility to multi-task across several work spots. Please refer to the following user need tags:

<UNS.SmartSuite.FlexVisionPro>

<UNS.SmartSuite.FlexSpot>

<UNS.SmartSuite.ProcedureCards>

<UNS.SmartSuite.ParallelWorking>

* Integrated operation in the exam room provided by the implementation of the Touch Screen Module and FlexVision, facilitates full table side operation (viewing and manipulation). In this way, the user can stay at table side, making it possible to fully focus on the patient. In addition, ProcedureCards capture pre-defined clinical and departmental pre-sets in a logical way, optimized to the clinical procedure. The set up provided by these ProcedureCards will enable the user to simplify routine tasks and stay more focused on the patient, further supporting a patient-centric workflow. Please refer to the following user need tags:

<UNS.SmartSuite.TSMTouchpad>

<UNS.SmartSuite.FlexVisionPro>

<UNS.SmartSuite.ProcedureCards>

* Integrated operation in the exam room provided by the Touch Screen Module Pro (MM TSM) using Streaming UI and FlexVision Pro, facilitates full sterile and non-sterile field table side operation (viewing, measurements and manipulation). In this way, the user can stay at table side, making it possible to fully focus on the patient. Please refer to the following user need tags:

<UNS.SmartSuite.TSMTouchpad>

<UNS.SmartSuite.FlexVisionPro>

CLAIM.SmartSuite.T1.TouchScreenModule

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| **Claim** | **Related user needs** |
| The TSM Pro with streaming technology allows you to perform 5 features at tableside: 1. see other modality user interface using the streaming UI protocol, optimized for 2D touch screen format defined by the modality; | UNS.SmartSuite.TouchScreenModule |
| 2. Using touch screen operation to view and interact with the modality, visible in all screens configured, to support communication between ER/CR; | UNS.SmartSuite.TouchScreenModule |
| 3. Switch between connected 3rd party modalities with a maximum of 2 user interactions; | UNS.SmartSuite.TSMnavigation |
| 4. Automatically display compatible mobile or integrated 3rd party modalities on TSM when connected to the network; | UNS.SmartSuite.TSMPlugandPlay |
| 5. Ability to configure the start-up appearance on TSM based on user preference. | UNS.SmartSuite.TouchScreenModule |

CLAIM.SmartSuite.T2.TouchScreenModule

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| **Claim** | **Related user needs** |
| The TSM Pro allows for integrating and connecting the touch screen operation of compatible applications, this results in less clutter at table side. | UNS.SmartSuite.  TouchScreenModule |

CLAIM.SmartSuite.T3.ProcedureCards

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| **Claim** | **Related user needs** |
| Azurion offers ProcedureCards\* to support simplification, standardization and automation of routine tasks:   * Azurion offers a one-click selection of the system setup from the ProcedureCards, including a user-defined selection of the most used X-ray protocol(s) which will be shown at the first level in the UI; * Azurion offers at least 20 default ProcedureCards; * In addition to the predefined ProcedureCards customized ProcedureCards can be generated by the user and saved under different groups (e.g. per clinical discipline, hospital department, or per user); * 6 parameters can be captured in a single ProcedureCards accordingly to the user requirements:   1. X-ray protocol settings;   2. Patient orientation;   3. FlexVision default screen layout(s);   4. FlexSpot default screen layout(s);   5. On-screen Checklists and Protocols   6. Injection protocol (SmartCT); * ProcedureCards can be transferred/shared with other Azurion systems via USB export, provided compatible system configuration(s) (incl. EPX); * Based on the RIS/HIS/CIS code of the scheduled procedure, the system will automatically (no clicks) select the configured ProcedureCards; * Without RIS code coupling, once the user selects the patient, it takes 3 clicks to select a ProcedureCards.   \* ProcedureCards capture pre-defined clinical and departmental pre-sets in a logical way, optimized to the clinical procedure and specific (departmental or personal) preferences. | UNS.SmartSuite.ProcedureCards |

CLAIM.SmartSuite.T4. FlexVision(Pro)

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| **Claim** | **Related user needs** |
| Azurion with FlexVision Pro offers integrated operation in the exam room: all\* applications in the interventional lab can be viewed and manipulated at table side with a single wireless mouse:   * Flexible layouts: the content, number, and size of viewports can be configured and saved by the user; * FlexVision Pro can connect up to 11 external video signals (not generated directly by the X-ray system) in the Exam Room; * The layout of FlexVision Pro can be edited using the tableside mouse, Touch Screen Module or from the FlexSpot; * Layouts can be changed during the procedure. Changes made ‘on-the-go’ can be saved as a new preset; * There are configurable presets; * Presets can be organized in groups for easy storage and retrieval; * On a monoplane configuration, FlexVision Pro allows to show the X-ray images in native resolution without downscaling; * FlexVision Pro offers the display of external sources in their native resolution to prevent signal distortion due to scaling (up/down); * FlexVision Pro offers snapshot functionality: with one click, screenshots of all displayed video sources are captured and stored in the patient file; * The FlexVision Pro allows for visualizing two full HD video sources in original pixel format at the same time;   *\** For all applications and auxiliary systems which have compatibility with the required digital standard for video distribution, see compatibility list. | UNS.SmartSuite.FlexVision(Pro) |

CLAIM.SmartSuite.T5.TSMTouchpad

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| **Claim** | **Related user needs** |
| Azurion offers integrated operation in the exam room where all\* applications can be viewed in the FlexVision (Pro) and manipulated at table side (also under a sterile bag) with the Touch Screen Module:  The Touch Screen Module Pro allows the user to perform at least 4 new interactions at tableside when compared to previous generation of Allura systems, i.e.   1. See live\*\* clinical images in 2D; 2. Navigate images in 2D; 3. Use mouse pointer which is visible in all screens showing X-ray images, to improve communication in ER/CR; 4. Control the shutters and wedges from TSM.   \* For all applications and auxiliary systems which have compatibility with table side control, see compatibility list.  \*\* The lag is higher compared to display on the regular monitors, but good enough to follow the procedure; not for clinical diagnostic use. | UNS.SmartSuite.TSMTouchpad |

CLAIM.SmartSuite.T6.FlexSpot

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| **Claim** | **Related user needs** |
| FlexSpot is a centralized working spot in the control room that allows to view, control, and manipulate all\* applications within a single view and with one mouse and keyboard, so as to allow more efficient control and monitoring of desired applications:   * Enables quick access to applications with no need to switch between applications and no different mouse control; * The content, number, and size of viewports can be configured and saved by the user; * The user can create configurable presets; * Layouts can be changed during the procedure without having to go into the system settings. Changes made ‘on the go’ can be saved as a new preset; * Presets can be organized in groups for easy storage and retrieval; * Capture and storage of video sources screenshots into the patient file. * FlexSpot connects up to 11 external video signals (not generated directly by the X-ray system) in the Control Room;   FlexSpot can be installed in 4 flexible configurations (one or two FlexSpot with the possibility of adding a second monitor to each FlexSpot) to free up space in the CR and minimize the monitor footprint;  FlexSpot can be used to change the layout of the FlexVision (Pro) in the exam room.  *\** For all applications and auxiliary systems which have compatibility with table side control, see compatibility list. | UNS.SmartSuite.FlexSpot |

CLAIM.SmartSuite.T7.ParallelWorking

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| **Claim** | **Related user needs** |
| Azurion allows to simultaneously run image acquisitions and work on other tasks in the Control Room as described below:  **A.** Parallel working on the **same patient** during X-ray generation:   * Review and process previously and intra-procedurally acquired images; * Perform Quantitative Analysis; * Film (i.e. select/flag images) and export images * Patient administration;   **B.** Parallel working on **a different patient**during X-ray generation:   * Review and process previously and intra-procedurally acquired images; * Perform Quantitative Analysis; * Film (i.e. select/flag images) and export images; * Patient scheduling and administration;   **C.** In addition to the workspot at tableside and the workspot in the control room, an additional spot can be configured (i.e. Additional FlexSpot\* or a Second FlexSpot) on which the user can execute activities in parallel;  **D.** Multitasking option where you can work simultaneously on different applications in the ER and CR.  \* Only applicable for a DVI video infrastructure. | UNS.SmartSuite.ParallelWorking |

CLAIM.SmartSuite.T8.AuxiliarySystems

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| **Claim** | **Related user needs** |
| Azurion allows you to integrate and connect several\* major brands of peripheral equipment and information systems for more seamless and efficient operation.   * CWIS and IControl interface allows for auxiliary systems’ UI integration on Azurion Touch Screen Module; * Connect the viewing system to a wide variety of third party systems (e.g. surgical knife, injector, video screens); * View and interact with intra-vascular ultrasound (IVUS) images from table side; * View and analyse images and volumes, originating from auxiliary systems, together with the images generated by the system; * Position catheters, as well as display and analyse catheter measurements; * Acquire and display physiological signals; * Align (timing) the contrast injection with the runs; * Control the injection of contrast fluid; * The system allows the transfer of images to auxiliary systems for additional processing (e.g. PACS) via a network link.   \* For all applications and auxiliary systems which have compatibility with the required digital standard for video distribution, see compatibility list. | UNS.SmartSuite.AuxiliarySystems |

CLAIM.SmartSuite.T9.DicomNetworkExporting

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| **Claim** | **Related user needs** |
| Azurion allows improved reproducibility and interoperability of exported images compared to previous generation Allura systems on a wide variety of image archives, such as external viewers as PACS. This involves:   * Improved contrast in low and high-level grey areas; * Optimized interpolation through no unnecessary upscaling/downscaling; * IQ subtraction for paediatric (when runs are created unsubtracted initially); * Azurion automatically transfers cardiac data to cardio-PACS (with different settings, e.g. downscale and processed) and radiology data to radiology-PACS (with a different setting, e.g. no downscale and unprocessed) to optimally support mixed procedures (i.e. cardio & vascular in a single procedure); * Azurion reduces the DICOM export time from the system. The export time of both cardiac (multi-frame) and radiology data (single-frame) is at least 2x faster compared to Allura Xper FD R8.2\*.     \* Multi-frame: export of 10 runs\*100 images of 1K. Single-frame: export of 40 images of 1K. | UNS.SmartSuite.DicomNetworkExporting |

CLAIM.SmartSuite.T10.ISPWorkflowIntegration

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| **Claim** | **Related user needs** |
| Azurion allows you to view patient data from IntelliSpace Portal in Exam Room and Control room (i.e. on the FlexSpot).  Azurion with IntelliSpace Portal allows auto patient launch (seamless integration of patient data and clinical information)\*:   * IntelliSpace Portal automatically fetches the pre-interventional data upon selection of the patient acquisition on Azurion; * Auto patient launch removes the need to manually search for the right patient and relevant series of images/runs.     \* If IntelliSpace Portal (R8 or higher) is available in the Azurion room and an iXR plugin is available. | UNS.SmartSuite.ISPWorkflowIntegration |

CLAIM.SmartSuite.T11.FD12DetectorSize

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| **Claim** | **Related user needs** |
| 1. Azurion with FD12”detector can achieve larger field of view (up to 39% larger field of view, based on the surface area) at a selected SID while maintaining projection flexibility compared to 10” detectors.  * support viewing of the aortic valve and a good part of the aortic arch, preferably in one view with minimal table panning, so that one can follow the device when navigating the aortic arch and see the valve at the same time; * support viewing of the whole coronary tree in one view with minimal need for table panning. This can be especially useful during procedures of patient with a dilated heart (cardiac myopathy); * support viewing both the needle insertion point (subclavian or axillary vein) and the whole wire/lead towards the right atrium in one view with minimal table panning and C-arm repositioning. This can be challenging especially for patient with a dilated heart and left ventricle.      1. Azurion with FD12”detector offers:  * a 15% smaller pixel size than 10’’ detector\* resulting in higher limiting resolution, to see the smaller details; * the smallest pixel size in the iXR market\* resulting in higher limiting resolution, to see the smaller details; * almost 2 times more pixels than the 10’’ detectors, to see the smaller details.   \* Pixel size smaller than FD15 of Siemens (Philips/Siemens FD12=154micro, Philips/Siemens FD20=154micrometer, Philips Centron and Siemens Artis one FD15=184 micrometer,Philips/Siemens  FD10=184micrormer, Siemens Q.Zen 15”=160 micrometer, GE=200micrometer, Toshiba=194micrometer, Shimadzu 12’’= 194 micrometer). | UNS.SmartSuite.FD12DetectorSize |

CLAIM.SmartSuite.T12.FD15DetectorSize

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| **Claim** | **Related user needs** |
| Azurion with 15” detector offers a 154% larger field of view than with 10” detectors, to support viewing of larger vascular structures in routine procedures such as renal artery procedures, carotid artery procedures or iliac procedures. | UNS.SmartSuite.FD15DetectorSize |

CLAIM.SmartSuite.T13.ControlRoomDesign

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| **Claim** | **Related user needs** |
| Azurion offers the same monitor configuration in the control room for the biplane as for the monoplane configuration, allowing a minimal footprint in the control room in a biplane lab. | UNS.SmartSuite.ControlRoomDesign |

CLAIM.SmartSuite.T14.LIHTablePanning

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| **Claim** | **Related user needs** |
| Azurion with Zero Dose Positioning allows you to navigate to the region of interest without using X-ray with an indication of the new patient position on both the lateral as the frontal display. | UNS.SmartSuite.LIHTablePanning |

CLAIM.SmartSuite.T15.ViewSimultaneously

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| **Claim** | **Related user needs** |
| Azurion allows you to view the live image, reference image and dual fluoroscopy image simultaneously. For the biplane configuration; one reference image per channel can be viewed at the same time with the live Frontal & Lateral image next to dual fluoroscopy. | UNS.SmartSuite.DualFluoroscopy  UNS.SmartSuite.LiveImageView |

CLAIM.SmartSuite.T16.AmbientVideos

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| **Claim** | **Related user needs** |
| Azurion allows you to show ComfortThemes movies on the FlexVision controlled from the TSM, with the intention to distract patient before the start of the procedure. | UNS.SmartSuite.AmbientVideos |

The Azurion FlexArm is designed to cater to the essential needs of multiple specialties in one room such as a combination of hybrid and endovascular procedures or cardiac and peripheral procedures.

The following claims contain several features that will enable the user to experience a flexible and patient-centric procedural workflow. Such features are:

* Image Beam Rotation and 2700 Rz-rotation;
* An additional pivot point in the C-arm allows the system to move in a lateral direction to the table;
* Central rails that allow full-body coverage without the need to move the patient table combination;
* Number of park and standby positions;
* 3D rotational scans on the head, nurse, and doctor position.

CLAIM.SmartSuite.T17.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm offers full body coverage without the need to move the patient and table configuration. | UNS.SmartSuite.FullBodyCoverage |

CLAIM.SmartSuite.T18.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm offers movements to perform 2D imaging anywhere around the patient without the need to move the patient. | UNS.SmartSuite.FullBodyCoverage |

CLAIM.SmartSuite.T19.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm enables radial access procedures on both sides of the table by only positioning the C-arm to the object (avoiding table or patient movement). | UNS.SmartSuite.ImageOffCenter |

CLAIM.SmartSuite.T20.FlexArm

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| **Claim** | **Related user needs** |
| With FlexArm current Philips rooms can be transformed into an advanced endovascular suite and/or multipurpose suite (target specific). | UNS.SmartSuite.SmallRoom |

CLAIM.SmartSuite.T21.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm is designed to cater to essential needs of multiple specialties in one room such as a combination of hybrid and endovascular procedures or cardiac and peripheral procedures. | UNS.SmartSuite.SmallRoom |

CLAIM.SmartSuite.T22.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm fits in interventional rooms as of 35 m2. | UNS.SmartSuite.SmallRoom |

CLAIM.SmartSuite.T23.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm offers the Highest Reach Over Available Room (ROAR) in Industry for small rooms (area where you can do imaging/available room). | UNS.SmartSuite.SmallRoom |

CLAIM.SmartSuite.T24.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm allows you to build a compact hybrid OR (35m2, LAF compatible). | UNS.SmartSuite.SmallRoom UNS.SmartSuite.CompatibilityLAF |

CLAIM.SmartSuite.T25.FlexArm

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| **Claim** | **Related user needs** |
| Raumklasse 1A (DIN 1946) can be established in an examination room with a Laminar Air Flow system and the FlexArm in parking position. | UNS.SmartSuite.CompatibilityLAF |

CLAIM.SmartSuite.T26.FlexArm

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| **Claim** | **Related user needs** |
| Raumklasse 1A (DIN 1946) equivalence can be established in an examination room with a Laminar Air Flow system and the FlexArm in a working position. | UNS.SmartSuite.CompatibilityLAF |

CLAIM.SmartSuite.T27.FlexArm

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| **Claim** | **Related user needs** |
| Raumklasse 1B (DIN 1946) can be established in an examination room with a Laminar Air Flow system and the FlexArm standard configuration. | UNS.SmartSuite.CompatibilityLAF |

CLAIM.SmartSuite.T28.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm fits in current hybrid ORs/Interventional Rooms with limited additional building reconstruction. | UNS.SmartSuite.CeilingCompatibility |

CLAIM.SmartSuite.T29.FlexArm

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| **Claim** | **Related user needs** |
| By parking the FlexArm at foot or head you create space around the table to perform all applicable hybrid OR procedures that do not require X-ray imaging. | UNS.SmartSuite.MoveToPark UNS.SmartSuite.Raillength |

CLAIM.SmartSuite.T30.FlexArm

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| **Claim** | **Related user needs** |
| With FlexArm you have full body coverage from both sides in any position of the patient while staying aligned with region of interest. | UNS.SmartSuite.FullBodyCoverage |

CLAIM.SmartSuite.T31.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm offers off-center imaging up-to 52 cm from the table center in Side Position (without z rotation) and 118 cm (with z rotation). | UNS.SmartSuite.ImageOffCenter |

CLAIM.SmartSuite.T32.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm C-arc can be positioned in any angle for 2D imaging between -135 and +135 degrees of the C-arc with respect to the standard table position to facilitate the access to the patient, to enable additional work positions, and wider monitor viewing angles. | UNS.SmartSuite.FlexibleAngles UNS.SmartSuite.OptimalWorkingPosition |

CLAIM.SmartSuite.T33.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm increases flexibility during procedure with 3D rotational acquisition (in total 3 positions) and with multiple navigation working positions (in total 7 positions). | UNS.SmartSuite.3Dacquisition |

CLAIM.SmartSuite.T34.FlexArm

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| **Claim** | **Related user needs** |
| Largest lateral standby distance on the market while maintaining 3D registration. | UNS.SmartSuite.FromStandbyToWorkingPosition |

CLAIM.SmartSuite.T35.FlexArm

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| **Claim** | **Related user needs** |
| During 3D navigation the system can be placed in Standby position and resume later while maintaining 3D fusions. | UNS.SmartSuite.MoveToStandby UNS.SmartSuite.FromStandbyToWorkingPosition |

CLAIM.SmartSuite.T36.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm C-arm can be moved around staff and equipment allowing you to maintain the same room setup during the full procedure. | UNS.SmartSuite.FreeEndPositions |

CLAIM.SmartSuite.T37.FlexArm

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| **Claim** | **Related user needs** |
| FlexArm offers unobstructed access at the head-end of the patient for anaesthesia and other clinicians with system movement controlled from a single control panel. | UNS.SmartSuite.FlexMoveControl |

### New technical claims

The following claims are new for Azurion R3.0 compared to R2.2.The SmartSuite Azurion R3.0 series contain a new video distribution system, i.e. the connection between PC and monitor. This flexible video over internet protocol (VoIP) system will enhance viewing flexibility and user experience. A new geometry is also enabled for the Azurion 7 B20/15 LN delivering the positioning of the frontal arc at 135 degrees and image beam rotation for patient-oriented images in every angulation.

Please refer to the following (updated) user need tags:

<UNS.SmartSuite.DisplayConfiguration>

<UNS.SmartSuite.FlexVisionPro>

<UNS.SmartSuite.FlexSpot>

<UNS.SmartSuite.AuxiliarySystems>

CLAIM.SmartSuite.T38.DisplayConfiguration

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| **Claim** | **Related user needs** |
| SmartSuite R3.0 offers increased flexibility in terms of workspot configurations. It allows you to extend the (basic) Workspot with/without MultiSwitch in the control room with an Additional MultiSwitch Workspot:   * The Additional MultiSwitch Workspot supports the parallel working process. In addition to the workspot at table side in the exam room, the primary Workspot in the control room, a 3rd workspot can be configured on which the user can execute activities in parallel; * SmartSuite R3.0 allows you to display and control\*) up to 8 sources (one at a time) on the Additional MultiSwitch without the dependency on the physical connection to the KVM switch.   \* excluding USB data. | UNS.SmartSuite.DisplayConfiguration  UNS.SmartSuite.ParallelWorking  UNS.SmartSuite.AdditionalFlexSpot |

CLAIM.SmartSuite.T39.SecondFlexSpot

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| **Claim** | **Related user needs** |
| SmartSuite R3.0 offers increased flexibility in terms of workspot configurations. It allows you to extend the primary FlexSpot with a second FlexSpot in the control room or exam room:   * The second FlexSpot in R3.0 enriches the working process compared to the current second FlexSpot (i.e. nursespot), as it has all the functionalities of the first FlexSpot (which is currently not the case) In addition to the primary FlexSpot in the control room, a 2nd workspot can be configured (i.e. second FlexSpot) on which the user can execute activities in parallel; * The user is able to view and manipulate different sources on the primary FlexSpot and second FlexSpot; * The second FlexSpot in the exam room allows you to perform tasks (e.g. patient scheduling), without having to leave the exam room; * Multiple FlexSpot configurations can be delivered to suit the hospital workflow:   + One primary FlexSpot with one or two 27’’ monitor(s);   + Primary and secondary FlexSpot with one or two 27’’ monitor(s) per workspot. | UNS.SmartSuite.AdditionalFlexSpot |

CLAIM.SmartSuite.T40.FlexibleSwitching

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| **Claim** | **Related user needs** |
| SmartSuite R3.0 with VoIP technology offers increased switching flexibility, compared to the current DVI infrastructure, in the exam room and control room by enabling a flexible division between inputs, outputs, and displays with the routing flexibility of the network switch:   * Enables multiple signal layouts accordingly to the user preferences, on systems with FlexVision (Pro) and FlexSpot, due to the ability to connect up to 20 external video signals (not generated directly by the X-Ray system); * Systems with 16 Switchable Monitors can connect up to 20 external video signals (not generated directly by the X-Ray system); * Systems with FlexSpot can have up to 3 integrated workstations. | UNS.SmartSuite.DisplayConfiguration |

CLAIM.SmartSuite.T41.Resolution

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| **Claim** | **Related user needs** |
| SmartSuite R3.0 delivers high image quality from multiple sources:   * SmartSuite R3.0 allows the user to view 3rd Party signals/video in native resolution on the respective 3rd Party monitor; * SmartSuite R3.0 with VoIP delivers artefact-free images distributed with near-zero latency via optical fiber. | UNS.SmartSuite.LiveImageView |

CLAIM.SmartSuite.T42.4K

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| **Claim** | **Related user needs** |
| SmartSuite R3.0 connect and routes 4K images for 3rd party monitors without the burden of point-to-point cabling.  SmartSuite R3.0 offers 4K/UHD input connectivity, i.e. 4K/UHD pass through, as well as 4K/UHD scaling. | UNS.SmartSuite.LiveImageView |

CLAIM.SmartSuite.T43.SecurityProtection

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| **Claim** | **Related user needs** |
| SmartSuite R3.0 provides security provisions aligned with the industry standards, including network access restrictions, and user authentication. | UNS.SmartSuite.SecurityProtection |

CLAIM.SmartSuite.T44.PowerViaSystem

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| **Claim** | **Related user needs** |
| All Philips workspots are powered via the system, which implies all workspots can be covered by Universal Power Supply (in case of power outage), allowing you to see the x-ray video signals on all workspots and slave monitors. | UNS.SmartSuite.PowerFailure |

CLAIM.SmartSuite.T45.BiplaneHeadAccess

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| **Claim** | **Related user needs** |
| The positioning of the frontal arc at - 135 degrees free up the head end, enabling:    **Optimal access to the patient**  Positioning of the frontal arc to accommodate the ideal working position. Such as freeing up the head-end for the anesthesiologist and optimal position of medical equipment (e.g. ultrasound). | UNS.SmartSuite.BiplaneHeadSpace |

CLAIM.SmartSuite.T46.ImageBeamRotation

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| **Claim** | **Related user needs** |
| Image Beam Rotation guarantees patient-oriented images in every angulation. The functionality enables easy radial access due to the fact that the image is always aligned with the anatomical structure even when positioned diagonally. No need to pivot the table or re-position the patient. | UNS.SmartSuite.PatientAndBeam |

CLAIM.SmartSuite.T47.AutomaticPositionControl

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| **Claim** | **Related user needs** |
| The full system APC allows the user to recall and store an image or table position. Automatically set back the position of the system (beam carrier(s) and table) to the same position that was used during live, acquisition, reference images and/or manual storage, including the detector orientation, FOV, shutters and wedge positions. | UNS.SmartSuite.Automatic  PositionControl |

CLAIM.SmartSuite.T48.Marker

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| **Claim** | **Related user needs** |
| The digital marker tool allows you to highlight a portion of the region of interest that stays visible during fluoroscopy and exposure, thus providing you visual guidance during the procedure. The tool adapts to changes of magnification, zoom, SID, or detector format. | UNS.SmartSuite.Marker |

#### Ease of Use claims

In May 2017 a simulation study has been carried out by UseLab. Claims below are derived from this study and evidence can be found in the final study report. For these claims no related user needs exist. [REF-2]

CLAIM.SmartSuite.Ease1.FlexArm

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| **Claim** | **Related user needs** |
| Simulation tests with FlexArm systems showed that in procedures that include table pivots, such as radial access procedures, system positioning times were reduced by an average of 27% compared to the Philips Azurion 7C20 system\*.  \* Evaluated with clinical users in a simulated lab environment after approximately 20 minutes of practicing C-arm and table positioning (series 7, ceiling FD20 monoplane configuration). | N/A |

CLAIM.SmartSuite.Ease2.FlexArm

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| **Claim** | **Related user needs** |
| Simulation tests with FlexArm systems showed that in procedures that include table pivots, such as radial access procedures, table positioning movements were reduced by 91% from 19.4 to 1.8 on average per procedure compared to the standard Philips Azurion 7C20 system. Eight participants eliminated all movement\*.  \* Evaluated with clinical users in a simulated lab environment after approximately 20 minutes of practicing C-arm and table positioning. | N/A |

CLAIM.SmartSuite.Ease3.FlexArm

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| --- | --- |
| **Claim** | **Related user needs** |
| 100% of physicians who participated in a simulated use study agreed that with FlexArm the need to pivot the table would be eliminated\*.    \*Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease4.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 100% of physicians who participated in a simulated use study agreed that the FlexArm system would reduce the need to move the table\*.  \*Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease5.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 88% of physicians who participated in a simulated use study agreed that FlexArm would help them save time; in addition, 76% agreed that the stand-by option in particular could help them save time\*.  \*Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease6.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| Physicians who participated in a simulated use study indicated that they believed they would spend an average of 50% less time pivoting the table during radial access procedures with FlexArm than with their regular systems\*.  \* Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease7.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 82% of physicians who participated in a simulated use study agreed that FlexArm would allow them to work more independently compared to their regular systems\*.  \* Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease8.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 94% of physicians who participated in a simulated use study agreed that with FlexArm more tasks could be done without assistance from others\*.  \* Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease9.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 100% of physicians who participated in a simulated use study agreed that FlexArm would allow them to work with great flexibility\*.  \* Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease10.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 88% of physicians who participated in a simulated use study agreed that FlexArm helped to reduce staff and equipment movement in the lab\*.  \* Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease11.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 100% of physicians who participated in a simulated use study agreed that FlexArm offered uncompromised access to the patient's head end\*.  \* Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease12.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 94% of physicians who participated in a simulated use study agreed that FlexArm offers full body coverage without the need to move the patient\*.  \* Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease13.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 76% of physicians who participated in a simulated use study agreed that by using FlexArm they could make more efficient use of their time spent in the lab\*.  \* Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease14.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 100% of physicians who participated in a simulated use study agreed that the FlexArm system was easy to control\*.  \* Evaluated with clinical users in a simulated lab environment. | N/A |

CLAIM.SmartSuite.Ease15.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 94% of physicians who participated in a simulated use study agreed that FlexArm flexibility is capable of supporting new procedures\*.  \* Evaluated with clinical users in a simulated lab environment \*\* Philips does not promote the use of its products in a manner not covered by the intended use. | N/A |

CLAIM.SmartSuite.Ease16.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| The System Usability Score (SUS score) of physicians who participated in a simulated use study for the FlexArm system is 92\*.  \* Evaluated with clinical users in a simulated lab environment. | N/A |

In May and June 2019 a simulation study has been carried out by Philips. Claims below are derived from this study and evidence can be found in the final study report. [REF-3]

CLAIM.SmartSuite.Ease17.TSMEase

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 91% of users in a simulated study found that MM TSM technology increases the ease of use switching between compatible applications (e.g. X-ray, IFR/FFR, Heamo, etc.) during interventions, over their current system(s). | UNS.SmartSuite.UserInterfaceAccess |

CLAIM.SmartSuite.Ease18.TSMThumbnail

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 78% of users in a simulated study found that the ease of use of the MM TSM technology, with its capability of showing application thumbnails, will make it easier to navigate to the right application. | UNS.SmartSuite.UserInterfaceAccess |

CLAIM.SmartSuite.Ease19.TSMApplications

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 78% of users in a simulated study found that the ease of use of the MM TSM technology will increase their utilization of different clinical applications in interventional procedures. | UNS.SmartSuite.UserInterfaceAccess |

CLAIM.SmartSuite.Ease20.TSMFaster

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 83% of users in a simulated study found that MM TSM technology will enable faster procedures i.e. less staff movements to use different clinical applications, fewer clicks to control different applications. | UNS.SmartSuite.UserInterfaceAccess |

CLAIM.SmartSuite.Ease21.iFR

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| 67% of users in a simulated environment believe that the integration between iFR/FFR and Azurion will increase adoption of iFR/FFR. | UNS.SmartSuite.UserInterfaceAccess |

CLAIM.SmartSuite.Ease22.UI

|  |  |
| --- | --- |
| **Claim** | **Related user needs** |
| Users in a simulated environment experience improved ease of use over their current (non Azurion) system.  An extensive user centric design process resulted in intuitive controls that are easy to learn, allowing you to shorten training time/reduce the burden of training. | UNS.SmartSuite.UserInterfaceAccess  UNS.SmartSuite.TaskGuidance  UNS.SmartSuite.IntegratedHelp  UNS.SmartSuite.IntegratedIFU |

Between April 2017 and July 2018 the Miami Cardio Vascular Institute (MCVI)\* runned a clinical study\*\* with a FlexArm in one room and a regular state of the art Philips system in a comparable room to underpin the clinical value in clinical practice. [REF-4]

\* Miami Cardiac and Vascular Institute, 8900 N Kendall Dr, Miami, FL 33176, USA

\*\* Peña C., Tuncay V. *Improving IR Ergonomics Using a Flexible C-Arm System*, Journal of Vascular and Interventional Radiology, Vol. 32, N. 2,  2021

CLAIM.SmartSuite.MCVI.1.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Disclaimer** |
| Physicians reported a significant reduction in the need to move the table for the FlexArm system compared to a regular state of the art Philips system. (P<0.0001) As an example 29.7% of respondents indicated they had to move the table ‘very often’ in room 9 versus 11.7% in room 8, and 9.0% of respondents indicated they felt that they ‘never’ had to move the table in room 8 versus 0.0% in room 9. | Demonstrated in a comparative survey based study in MCVI\* based on 200 cardiology, radiology and vascular surgery procedures. |

CLAIM.SmartSuite.MCVI.2.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Disclaimer** |
| Physicians reported a significant reduction in the need to move user interface devices and reposition X-ray shielding for a FlexArm system compared to a regular state of the art Philips system. (p<0.0001). | Demonstrated in a comparative survey based study in MCVI\* based on 200 cardiology, radiology and vascular surgery procedures. |

CLAIM.SmartSuite.MCVI.3.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Disclaimer** |
| Physicians reported a significant reduction in the risk of losing needle access, catheter- or wire location and the risk of pulling wires/tubes/lines connected to the patient for a FlexArm system compared to a regular state of the art Philips system which could increase patient safety. (p<0.0001). | Demonstrated in a comparative survey based study in MCVI\* based on 200 cardiology, radiology and vascular surgery procedures. |

CLAIM.SmartSuite.MCVI.4.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Disclaimer** |
| Logging data of the FlexArm system showed a median table movement reduction from 27 to 19 movements per procedure compared a regular state of the art Philips system (p<0.001) . Median travel distance of the table reduced from 1647 mm to 969 mm per procedure (p<0.01). Median number of beam movements increased from 1 to 8 movements per procedure (p<0.001). | Demonstrated in a comparative study in MCVI\* based on 160 cardiology, radiology and vascular surgery procedures. |

CLAIM.SmartSuite.MCVI.5.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Disclaimer** |
| 90.6 % of physicians performing radial or other upper extremity access cases found the FlexArm system required a (very) low effort to transition from arm to body imaging. | Demonstrated in a comparative survey based study in MCVI\* based on 38 completed surveys. |

CLAIM.SmartSuite.MCVI.6.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Disclaimer** |
| 97.8 % of physicians performing radial or other upper extremity access cases were satisfied with the ease of imaging off center anatomy of FlexArm system. | Demonstrated in a comparative survey based study in MCVI\* based on 45 completed surveys. |

CLAIM.SmartSuite.MCVI.7.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Disclaimer** |
| Logging date of the FlexArm system showed a substantial number of irradiation events on (fully) extended arms primarily for dialysis shunt interventions and fistulograms. | Demonstrated in a comparative study in MCVI\* based on 160 cardiology radiology and vascular surgery procedures. |

CLAIM.SmartSuite.MCVI.8.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Disclaimer** |
| Physicians reported to be working significantly less often in ergonomically suboptimal positions with FlexArm system than a regular state of the art Philips system.  (p<.0001). | Demonstrated in a comparative survey based study in MCVI\* based on 200 cardiology, radiology and vascular surgery procedures. |

CLAIM.SmartSuite.MCVI.9.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Disclaimer** |
| Physicians reported a significantly higher frequency of never having to work in ergonomically suboptimal positions for a FlexArm system compared to a regular state of the art Philips system (24.2% versus 6.1%, p<0.0001). | Demonstrated in a comparative survey based study in MCVI\* based on 200 cardiology, radiology and vascular surgery procedures. |

CLAIM.SmartSuite.MCVI.10.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Disclaimer** |
| Physicians reported a significant lower frequency of regularly having to work in ergonomically suboptimal positions for a FlexArm system compared to a regular state of the art Philips system (4.0% versus 25.4%, p<0.0001). | Demonstrated in a comparative survey based study in MCVI\* based on 200 cardiology, radiology and vascular surgery procedures. |

CLAIM.SmartSuite.MCVI.11.FlexArm

|  |  |
| --- | --- |
| **Claim** | **Disclaimer** |
| Physicians reported a significantly less pain and/or fatigue for all body areas while working with the FlexArm system compared to a regular state of the art Philips system (p<0.001 for all body areas). | Demonstrated in a comparative survey based study in MCVI\* based on 200 cardiology, radiology and vascular surgery procedures. |

# User needs

## User groups

The following user groups are defined:

* Clinical users:
  + Physicians (Radiologists, Physicians, Surgeons, and Cardiologists): Qualified staff member with specialized training in their field, along with knowledge of X-ray parameters, responsible for the outcome of the procedure;
  + Radiologic technologist: Qualified staff member with specialized training and education for X-ray production;
  + Non-radiologic user (Nurse, CV, RCIS): Qualified staff member with specialized clinical training not in radiology.
* Physicists:
  + Physicist: measurements on X-ray dose, reporting, exporting clinical images, radiation dose reporting, etc.
* Service users:
  + Field Service Engineer (FSE): a qualified user that does installation and maintenance activities on the system;
  + Remote Service User (RSE): a qualified user that does maintenance activities from a remote location;
  + Clinical Application Specialist (CAS): a clinical specialist that provides application support
  + BioMed (BM): technical service user on hospital side (i.e. often these are multi-modality engineers).
* Hospital IT:
  + Hospital IT (HIT): responsible user on hospital side for all that is related to hospital network (e.g. DICOM/PACS/RIS/HIS), hospital network security, and hospital cyberthreats;

## Clinical areas

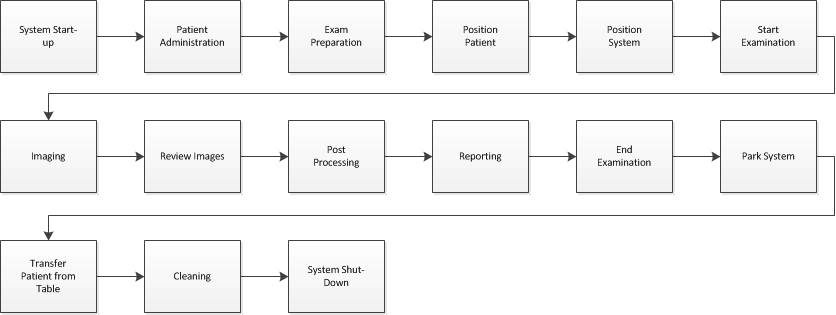
Users of the following clinical areas are involved:

* Percutaneous Coronary Interventions (PCI);
* Structural Heart Disease (SHD);
* Interventional Electro Physiology (EP);
* Interventional Radiology (IR);
* Interventional Oncology (IO);
* Neuroradiology (NEURO);
* Vascular Surgery (VASU);

## User rooms

* Examination room (ER)
* Control room (CR)

## Clinical workflow



### System start-up

UNS.SmartSuite.StartUp

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR>*   * Start-up the whole system; * Enable/disable X-ray to prevent accidental exposures (e.g. during cleaning, patient transfer etc.). * Turn on the displays only in FlexSpot configuration, FlexVision (Pro) and Switchable Monitors (i.e. to access the non-X-ray sources). |
| New | N.A. |

UNS.SmartSuite.TSMPlugandPlay

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Automatically display 3rd party modality information on the TSM when the 3rd party is connected to the network. |
| New | N.A. |

UNS.SmartSuite.AuthorizedUser

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR>*   * Use the system with or without authorization log on; * Limit/restrict the use of the system by users; * In case of an emergency, unblock the use of primary system functionality by any user. |
| New | N.A. |

### Patient administration

UNS.SmartSuite.AddPatientData

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users,  all clinical areas, ER/CR>*   * Import demographic patient/procedural information from the hospital information system (e.g. RIS/CIS); * Manually enter patient data; * Manually add missing information; * Modify added information; * Automatically push/pull information to/from other systems. * Automatically trigger the corresponding procedural information (Procedure Card)  when the system is connected to the hospital information system(e.g. RIS/CIS); * Enter patient data in the Exam Room. |
| New | N.A. |

UNS.SmartSuite.ISPWorkflowIntegration

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, CR/ER>*   * Exchange data between Azurion and IntelliSpace Portal. |
| New | * Automatically launch relevant images on IntelliSpacePortal\* ; * Prefetch of data upon selection of the patient acquisition on Azurion.   \*Available from ISP R8 onwards. |

UNS.SmartSuite.CreateWorklist

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users,  all clinical areas, CR>*   * Create a work list of scheduled patients and associated procedures; * Manually create a work list and add patients; * Automatically create a work list when the system is connected to the hospital information system (e.g. RIS/CIS). |
| New | N.A. |

UNS.SmartSuite.Pre-procedurePlanning

|  |  |
| --- | --- |
| Legacy | The user should be able to:  *<All users, all clinical areas, CR/ER>*   * Use/reuse pre-procedure planning from other systems (e.g. recall projection angles planned on HeartNavigator) for more complex cases. |
| New | N.A. |

UNS.SmartSuite.PatientData

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, CR>*   * Prevent mix-up of patient data/information (e.g. identify viewports with name of current patient, or a warning; resolve patient mix); * Starting imaging without having entered any patient data (e.g. set-up one of the X-ray protocols as default for emergency cases). |
| New | N.A. |

### Exam preparation

UNS.SmartSuite.ExaminationSelectionAndPresetting

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Select the settings for an examination depending on procedure type, patient type and X-ray operator. * Change the procedure type during the examination at tableside without leaving the ER. |
| New | N.A. |

UNS.SmartSuite.ProcedureCards

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * + Select the system set-up, edit, customize, and create their own specific ProcedureCards including quick-save during procedure and the ability to save under different groups (e.g. per clinical discipline, hospital department or per user);   + Select the system set-up (based on the above parameters) from the ProcedureCard with a single click;   + Select a ProcedureCard from at least 20 default ProcedureCards; at least 3 per clinical area;   + Automatically select the configured ProcedureCards, based on the RIS/HIS/CIS code of the scheduled procedure;   + Select a ProcedureCard within a maximum of 3 clicks once the user selects the patient and there is no RIS/HIS/CIS code coupling;   + Import, modify/adapt, configure and export (default) procedural information (ProcedureCards) including at least 6 parameters:     - Short description of procedure;     - Set of X-ray protocols which should be directly available related to the clinical procedure (incl. geometry position, APC position and injector coupling);     - Patient orientation;     - A pre-set screen layout which will be used as default for viewing in ER (FlexVision);     - A pre-set screen layout which will be used as default for viewing in CR (FlexSpot);     - On-screen display of hospital specific checklists & protocols s in exam room and control room;     - Injection Protocol (only in case off SmartCT). |
| New | N.A. |

UNS.SmartSuite.FlexibleViewing

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Select from the available image sources which ones will be displayed on which part of the screen (viewports); and save this display; * Change the display layout and rearrange the position and size of multiple viewports; and save this display; * Swap/move keyboard and mouse focus over selected viewports; * Enable/disable whether the display will be visible in the ER or not; * Connect a dedicated keyboard to an external workstation modality (e.g. Heamo and/or EP). |
| New | * Have flexibility in scaling the size of multiple sources; * Have flexibility in displaying different sources on different monitors; * Show multiple sources with different resolutions on Philips flexible monitors (e.g. Flexvision, Flexspot). |

UNS.SmartSuite.TSMNavigation

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Switch between modalities displayed on the TSM Pro within a maximum of 2 user interactions. |
| New | N.A. |

UNS.SmartSuite.FreeEndPositions

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Move the FlexArm system from/to working position without interference with equipment/persons located at all sides of the table (e.g. anaesthesiologists). |
| New | N.A. |

### Position patient

UNS.SmartSuite.PatientPositioning

|  |  |
| --- | --- |
| Legacy | The user needs to be able to  *< Clinical users/Physicists/ Service users, all clinical areas ER>*   * Position the patient on the table; * Lock the table to prevent unintended table movement; * Adjust the height of the table for ergonomic purposes; * Perform interventions via radial, subclavian and groin access; from head, arm and groin position; user standing at left or right side; * Indicate the proper patient positioning with respect to the system to ensure proper image display; |
| New | * Adjust the table position to optimize the clinical setup. |

UNS.SmartSuite.PatientComfort

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Provide patients with a comfortable position on the table (e.g. ergonomic mattress). |
| New | N.A. |

UNS.SmartSuite.FullBodyCoverage

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Image (2D) the entire body with FlexArm from foot to head from both nurse and doctor sides of the table, without the need to move the patient table combination\*.   \*not applicable when using a leg support board |
| New | N.A. |

### Position system

UNS.SmartSuite.TableSetup

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Position the table top in any orientation and height; * Move the table top to position the region of interest in the center of the X-ray beam; * Move the table top height (up/down) to optimize the working height for the physician; * Move the table top to predefined positions. |
| New | N.A. |

UNS.SmartSuite.RoomSetup

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Position system easy and efficiently (manually/from TSO); * Maintain the sterile field when moving the FD system, while using the system over time; * Position system so as to minimally disrupt laminar airflow in OR settings; * Position system so that the physician can see other staff during the procedure; * In case of biplane, work with both channels or work with either the frontal or lateral channel * Work with the frontal channel if the lateral channel is in parked position. * Position image monitors at a comfortable viewing angle for physician when standing in head/side/arm/left/right position; * Have a clear view on the monitor from work position. |
| New | * Choose a wide range of screen configurations to match the intended procedure mix of the lab. Screen configurations range from separate loose screens to screens combined on single booms to large screens or combinations of those. |

UNS.SmartSuite.Sterility

|  |  |
| --- | --- |
| Legacy | The user needs to be able to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Cover system parts with sterile covers in the immediate vicinity of patients. * Have a draping solution for TSM with regard to:   + Sterility: positioning and control over sterile sections   + Visibility: transparent without reflections   + Responsiveness: response rate using (dirty) gloves comparable to TSM without draping. |
| New | N.A. |

UNS.SmartSuite.OperateSystem

Background information: ‘In control’ means you feel the system doesn’t move too fast and you lose control. ‘Effective’ meaning the system doesn’t move to slow so you have to wait too long and it takes the ‘smartest’ route to the desired position.

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Operate the system such that the movements of the system are effective and in control, both manually and via the operator controls. |

UNS.SmartSuite.PatientOrientation

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * To display the patient’s anatomy (or clinical image) default in such a way that it adheres to the clinical practice (head on top side; left/right as if facing the patient) as commonly used for the various examinations; * Prevent diagnostic risks in mistaking left/right patient anatomy; * To deviate from image display default e.g. adjusting the display orientation at table side, during the case. |
| New | * Indicate the correct patient positioning with respect to the system to ensure proper image display of the region of interest. |

UNS.SmartSuite.LIHTablePanning

|  |  |
| --- | --- |
| Legacy | The user wants to:  <*Clinical users/Physicists/ Service users,* all clinical areas, ER>   * Reposition the patient without using fluoroscopy (Zero Dose Positioning) including an indication of the new position on both the lateral as the frontal display, e.g. by using a graphical image area overlay of the resulting image area when the user moves the table, shutter or wedge or changes the detector field size. |
| New | N.A. |

UNS.SmartSuite.ViewingROI

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * View from various points the region of interest to ensure a correct 3D impression of the anatomy with optimal imaging conditions. |

UNS.SmartSuite.PatientAndBeam

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Operate the system from multiple user positions (e.g. Table Side controlled, pedestal side controlled and remotely controlled from the Control Room); * Rotate the frontal and lateral beam simultaneously in biplane mode; * Get user guidance/feedback about geometry positions, e.g. height, SID, cradle/tilt, shutter and wedge position. |
| New | * The frontal Arc to rotate independently of the detector and collimator, guaranteeing patient-oriented images in every angulation (Azurion 7 B20/15 LN). |

UNS.SmartSuite.3DAnatomyScan

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *< Clinical users/Physicists/ Service users,* all clinical areas, ER/CR>   * Capture the 3D anatomy with a single scan. |

UNS.SmartSuite.Safe3DScan

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *< Clinical users/Physicists/ Service users,* all clinical areas, ER >   * Be sure that 3D scan can be done without any collisions. |

UNS.SmartSuite.MoveToStandby

Background information: Free up space around the table in case if temporarily X-ray is not needed during the procedure.

|  |  |
| --- | --- |
| Legacy | The user wants to:  <Clinical users/Physicists/ Service users, all clinical areas, ER>   * Move the FlexArm system to and from a Standby Position by table side controls. * A standby position is an optimal\* position of the system in the room, when imaging is temporary not needed during a procedure.   \* Optimal is defined as where the gantry is out of the way during the procedure |
| New | N.A. |

UNS.SmartSuite.FlexibleAngles

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * To position FlexArm C-arc in any angle for 2D imaging between -135 and +135 degrees with respect to the standard table position to facilitate access to the patient |
| New | N.A. |

UNS.SmartSuite.FromStandbyToWorkingPosition

Background information: e.g. after a 3D acquisition, going to standby position and going back to working position.

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * For FlexArm configuration return to the last X-ray Position from a Standby Position for any procedure while maintaining previous registration on Philips clinical applications (e.g. Interventional Workspot, EchoNav and Coronary tools. Example 3D roadmap, VesselNavigator overlay. Assuming patient and table remain in same position). |
| New | * Have the largest lateral standby distance on the market while maintaining 3D registration. |

UNS.SmartSuite.PatientOrientedMovements

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * To control the FlexArm projections and movements of the gantry (rotate, angulate, translate)  by moving the X-ray beam (detector + tube) relative to the longitudinal axis of the table / patient; * Navigate to the region of interest through automated FlexArm movements: Image beam rotation, roll, prop, dual Rz rotation, and rail movement in such a way that the user has the perception to steer the X-ray beam. |
| New | N.A. |

UNS.SmartSuite.ChangeDetectorOrientation

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Image in portrait and landscape detector position independent of the gantry position; * Align the detector to the anatomy of the patient independent of the gantry position\*.   \*this option is specific to the FlexArm and Azurion 7 B20/15LN. |
| New | N.A. |

UNS.SmartSuite.OptimalWorkingPosition

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users,* all clinical areas, ER>   * Move the FlexArm system to an optimal working position continuous in a Rz rotation range of +135 to -135 degrees while maintaining the selected projection position to create space for e.g. physician, anaesthesia, equipment or visibility on the display.   \*optimal = a position in the range of 270 degrees minimizing interference with patient accessibility, equipment and viewing angles of the monitors. |
| New | N.A. |

UNS.SmartSuite.BiplaneHeadSpace

Background: the -1350 Rz movement of the frontal Arc allows the user to free up the head space with a biplane system. freeing up the headspace is for example relevant for the anesthesiologist in  order to monitor and respond to the patient’ situation adequately.

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to be able to:  *< Clinical users/Physicists/ Service users, Neuro, ER>*   * Free up the head space in a biplane system. |

### Start examination

UNS.SmartSuite.StartExamination

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/ CR>*   * Start the examination from the Control Room; * Start the examination from the Exam Room from the Additional FlexSpot. |
| New | N.A. |

UNS.SmartSuite.Workspot

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Perform all activities, corresponding to his/her role in the hospital, from a single control point at the location of his/her preference; Control auxiliary systems on those work spots. |
| New | N.A. |

### Imaging

UNS.SmartSuite.ActivateFluoroExposure

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Activate fluoroscopy and exposure; * Use a hand-switch for exposure; * Use a wired footswitch for fluoroscopy/exposure; * Use a wireless footswitch for fluoroscopy/exposure; * Operate with a single action the acquisition system together with the injector; * Save a fluoroscopy run retrospectively (store); * Save a fluoroscopy run prospectively (grab). * In case of biplane:   + Activate fluoroscopy from frontal and lateral channel separately as well as simultaneously   + Activate exposure from frontal and lateral channel separately as well as simultaneously   + Continue the examination with one channel if the other channel has an error. |
| New | N.A. |

UNS.SmartSuite.ChangeFluoroExposure

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Change the X-ray protocol during exposure and fluoroscopy. |
| New | N.A. |

UNS.SmartSuite.AcquisitionImageQualityAndDose

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Select, adjust and save image acquisition settings, for both fluoroscopy and exposures (incl. single shot):   + On the fly   + From various work spots (at table side, in the control room, etc.)   + For various items, such as: Patient Dose, Frame Rate * Display real-time X-ray images; * Display relevant (and regulatory required) acquisition parameters (e.g. kV, mA, DAP) in viewed images; * Save relevant acquisition parameters in stored images/ image data. |
| New | N.A. |

UNS.SmartSuite.DoseControl

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Choose fluoroscopy flavours (e.g. Low, Medium, Normal) and different acquisition settings for same procedure (low vs high dose, low vs high quality) to adjust image quality; * Perform acquisition with As-Low-As-Reasonably-Achievable (ALARA) X-ray dose to patient and staff, i.e. optimize balance between radiation dose and IQ by adjusting relevant settings (e.g. ProcedureCard, DAP, frame rate, FoV). * Activate acquisition from all sides of table (head, side (left/right), arm, feet side, remotely (trolley, control room); * Operate system at a safe distance/shielded (with regard to user exposure dose) during fluoroscopy and acquisition; * See the pre-acquisition time; * Connect multiple footswitches and hand switches in ER/CR to the system; receive dose information; both fluoroscopy and exposure. |

UNS.SmartSuite.LiveImageView

|  |  |
| --- | --- |
| Legacy | The user needs to be able to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Display real-time images from fluoroscopy as well as exposure; * View live and previously acquired images simultaneously; * Record the image stream on a DVD during fluoroscopy/exposure; * For monoplane: Save images for reference up to three different reference screens; * For biplane: Save images for reference up to two different reference screens per channel. In monoplane mode save images up to 3 reference screens for the active channel. |
| New | * Have the ability to view multiple previously acquired images (i.e. reference screens) simultaneously with live; * Show an external source in its native resolution on a 3rd party monitor; * Show multiple sources in their native resolution; * Use 4K/UHD input connectivity to display 3rd party sources; * Deliver artefact-free images distributed with near-zero latency via optical fiber. |

UNS.SmartSuite.EyeHandCoordination

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Perceive that the fluoroscopy images and exposure are displayed in real time and without noticeable delay. |
| New | N.A. |

UNS.SmartSuite.DualFluoroscopy

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * View the fluoroscopy images subtracted and un-subtracted simultaneously (‘Dual Fluoroscopy’); * For biplane; View one reference image per channel at the same time with the live Frontal & Lateral image next to dual fluoroscopy; * Display subtracted and un-subtracted exposures simultaneously; * Digitally zoom in/out the subtracted and un-subtracted live image during Dual Fluoroscopy; * View live image, reference image and Dual Fluoroscopy simultaneously. |
| New | N.A. |

UNS.SmartSuite.BiplaneRealTime

Background**:**in order to navigate interventional tools to, and at the region of interest, the clinical user wants to image from multiple angles to get an impression of the 3D anatomy in real-time. This is for example relevant in cases with torturous vessel structure (e.g. neurology case).

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Perform imaging from two angles simultaneously to obtain multi-dimensional impression of the anatomy in real-time. |

UNS.SmartSuite.BiplaneContrast

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Perform imaging from two angles simultaneously to obtain an impression of the anatomy with a single contrast injection. |

UNS.SmartSuite.EMFieldImageFiltering

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, EP, ER>*   * Apply fluoroscopy and acquisition without artefacts that are introduced by electromagnetic tracking devices. |
| New | N.A. |

UNS.SmartSuite.ImageSubtraction

|  |  |
| --- | --- |
| Legacy | The user wants to  <Clinical users/Physicists/ Service users, all clinical areas, ER/CR >   * Make vessels visible without disturbing background; at image level, at run level and during fluoroscopy; * Toggle between subtracted and un-subtracted display. |
| New | N.A. |

UNS.SmartSuite.Roadmap

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Superimpose vessel image during live fluoroscopy (on both the frontal as the lateral channel) to guide a device (catheter, guide wire or other interventional device) through the vascular structure during fluoroscopy in all patient positions; * Superimpose vessel image in (un-)subtracted mode. |
| New | N.A. |

UNS.SmartSuite.LinkWorkstation

|  |  |
| --- | --- |
| Legacy | The user needs to be able to:  *<all users, all clinical areas, ER/CR>*   * Have a direct (real time link) connection with the Interventional WorkSpot and  Coronary Tools and EchoNavigator and access to relevant Interventional Tools (e.g. StentBoost); * Have adequate image quality for (3D) reconstructions/information at their Philips workstation(s). |
| New | N.A. |

UNS.SmartSuite.DynamicRotationalAngiography

|  |  |
| --- | --- |
| Legacy | The user needs to be able to:  *< Clinical users, all clinical areas , ER/CR>*   * Gain 3-D insight of the patient’s anatomy (by making a dynamic rotational angiography scan where the X-ray beam rotates around the patient's area of interest placed within the iso-center); * Control a rotational scan from all table sides/pedestal (head, foot, nurse, physician, specific); * Make a rotational scan with a wide range of motion to cover the complete patient’s anatomy (from head to toe); * Make a rotational scan with a wide range of motion to cover the complete anatomy of obese (BMI>30) patients. |
| New | N.A. |

UNS.SmartSuite.CardiacSwing

|  |  |
| --- | --- |
| Legacy | The user wants to  *<Clinical users, interventional cardiology, ER>:*   * Acquire images of the patient’s anatomy from multiple views in a single run by rotating the system along curved trajectories around the patient; * Rotate the system along optimized predefined trajectories for adequate image quality; * Rotate the system along dedicated trajectories for the left and the right coronary arteries; * Rotate the system while staying automatically within safe boundaries in order to avoid any collisions between the patient/bystander and System (‘BodyGuard’). |
| New | N.A. |

UNS.SmartSuite.FDPA

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, IR, ER/CR>*   * Acquire (subtracted and non-subtracted) images from the lower abdomen to the feet for showing a survey of the contrast bolus as it progresses over time (‘bolus tracking’); * Perform a single injection run off in Flexible Dynamic Peripheral Angiography (FDPA):   + Perform multiple runs for subtraction;   + Review the whole peripheral vasculature in one image (e.g. image stitching);   + Acquire the FDPA images with the frontal stand or lateral stand in case of PolyG floor frontal stand; |
| New | N.A. |

UNS.SmartSuite.AutomaticPositionControl

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR* >   * Store and recall one table position; * Automatically re-acquire the exact same projection as the reference image currently displayed; * Switch between defined projections, mostly of different views of the same body part; * Customize and store pre-defined projections and sequences as part of the EPX, but without going to the EPX level; * Store temporally and recall up to 20 projections of the system during a procedure (APC Store/Recall); * Move the geometry to predefined projections (patient oriented) and along a sequence of projections defined at EPX level (APC Sequence); * Automatically set back the position of the system (beam carrier(s) and table) to the same position that was used during live, acquisition, reference images and/or manual storage, including the detector orientation, FOV, shutters and wedge positions; * Move the position of the system (rotation and angulation) to the patient oriented projection defined in the interventional tools; * Addition to APC with an APC along a path of positions of the longitudinal, transversal and z-rotation axes and of the table for the FlexArm configuration. |
| New | N.A. |

UNS.SmartSuite.FlexMove

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, VASU/SHD, ER>*   * Move the stand (instead of the table) in XY direction (lateral & longitudinal movements) to position for imaging; * Store and recall multiple XY projections. |
| New | N.A. |

UNS.SmartSuite.X-rayDetectorFieldSize

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Zoom in on displayed image; * View the region of interest by select/adjust/switch Fields of View (FoV); * Identify the current level of magnification during FOV adjustment; * Have the possibility to select a predefined Field Of View upon selection of a specific procedure.   With the FD12:   * See the aortic arch and the valve in one view; * See the whole coronary tree in one view (cardiac myopathy); * See both the needle insertion point (subclavian or axillary vein) and the whole wire/lead towards the right atrium in one view. |
| New | N.A. |

UNS.SmartSuite.PointerOnViewingContainer

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Control a visible pointer on a viewport to indicate to others an area of interest of an image (e.g. finger on TSM in ER, or mouse in CR); * See the pointer on all instances of that viewport. |
| New | N.A. |

UNS.SmartSuite.Marker

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users,* all clinical areas, ER/CR>   * Put multiple marks on the live viewport, from TSM, ER and CR; * Markers can be adjusted or erased; * Markers stay visible during fluoroscopy and exposure; * Markers adapt to changes of magnification (zoom, SID or detector format); * Markers will stay when copy to ref; * Markers will not be stored on image. |
| New | N.A. |

UNS.SmartSuite.X-rayBeamShaping

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Control the radiated area; * Restrict X-ray radiation to the clinical region of interest e.g.:   + Manually positioning shutters;   + Manually closing/opening shutters (in horizontal and vertical direction);   + Automatically position wedges (depending on stand rotation and angulation angles) while moving the beam around the patient (should be configurable depending on the procedure);   + Manually adjust wedges (also if ‘Automatic Wedge Follow’ is active); * Prevent over-exposure at clinical region of interest (e.g. manually adjusting wedges that reduce X-ray intensity); * Blank part of the displayed image by means of image cropping; * Set shutters (positioning, opening/closing) and wedges (moving), with or without radiation; * View actual and new positions on display (with and without radiation); * See the anticipated radiated area without radiation (e.g. displayed as overlay). * Allow (graphical) control of shutters/wedges on the TSM; * View actual and new positions on display and TSM Pro (with and without radiation) in relation to X-ray image. |
| New | N.A. |

UNS.SmartSuite.BiplaneFocusSelection

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Manually change the focus ( frontal, lateral or biplane) for imaging and acquisition, if the automatic focus selection does not apply. |
| New | N.A. |

UNS.SmartSuite.PhysioAcquisition

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, PCI/SHD/EP, ER/CR>*   * Obtain X-ray image information in relation to the heart cycle e.g. by acquisition, display and storage of physiological signals (limited to electrical signals, i.e. ECG) together with the X-ray images; * Manually switch on/off the overlay of the physiological signals on the X-ray images. |
| New | N.A. |

UNS.SmartSuite.ECGTrigger

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, PCI/EP, ER/CR>*   * Synchronize fluoroscopy and acquisition timing with patient’s ECG signal (e.g. ‘ECG triggering’ to acquire images in the same phase of the heart cycle). |
| New | N.A. |

UNS.SmartSuite.InjectorCoupling

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Couple certain automated injector systems; * Perform timed administration (injection) of contrast medium (precise timing depends on patient’s circulation, injection protocol, and imaging protocol); * Set X-ray delay; * Perform manual injection; * Perform automatic injection; * Couple/decouple automatic injection to/from acquisition at EPX level; * Maintain coupling after acquisition; * Perform acquisition with manual injection while coupling is on; * Adjust contrast injector parameters at table side. |
| New | N.A. |

UNS.SmartSuite.FluoroIndicators

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Switch on/off the volume of sounds for acquisition and fluoroscopy; * Stop the 5 minute fluoro time buzzer; * Indicate visually if actual X-ray is given or initiated e.g. “X-ray on” indicator light). |

UNS.SmartSuite.LightsAndOperationLamp

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Switch on/off or dim the room-light and/or operation lamp, optionally synchronized to acquisition. |

UNS.SmartSuite.SoundsRoom

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Have a low level of noise in the room (no disturbing noise in the room, except when immediately attention required, like heart stops). |

UNS.SmartSuite.LastImageHoldOrAutoCycle

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * View/review after fluoroscopy and acquisition the last acquired images; * Select that the last acquisition run is displayed in a cycle. |
| New | N.A. |

UNS.SmartSuite.CompensatePatientMovements

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Perform diagnosis on patients even when small patient and/or table unintended movements occur during acquisition of images (automatic image correction in case of small patient/table movements). * Export motion correction parameters to peripheral systems (such as PACS, workstations); * Do/undo automatic motion correction (toggle) to check and set quality of result. |
| New | N.A. |

UNS.SmartSuite.CollisionDetection

|  |  |
| --- | --- |
| Legacy | The user needs to be able to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER >*   * Rely on a collision avoidance system that:   + Maintains rotation and angulation speeds until it comes close to the patient;   + Is compatible with released Philips native tables and released integrated ORT solutions. |
| New | * Rely on a collision avoidance system that:   + Prevents collision with the patient;   + Allows the user to override the stop and continue at a slow speed in close proximity to the patient and/or system parts. |

UNS.SmartSuite.IntuitiveCollisionDetectionFeedback

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Take appropriate measures in order to avoid and/or resolve collision based on the information and guidance received; * Receive visual feedback (e.g. icons) showing what is causing a collision and where. |
| New | N.A. |

UNS.SmartSuite.ClinicalImagesOnTSM

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR >*   * Process and view images on the TSM\*); * Navigate images on TSM without using remote control; * Zoom/pan images on the TSM without using remote control; * Reset the zoom/panning level on TSM; * Display semi-live the acquired X-ray, IVUS and 3D (SmartCT) images on the TSM.   \*) Image display on TSM is not for diagnostic purposes. |
| New | N.A. |

UNS.SmartSuite.QuickSaveDuringProcedure

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Save image(s); * Save a changed screen layout and save under a different name; * Store temporarily the table position with a single click ; * Store temporarily the position of the system (beam carrier(s) and table), including the detector orientation, FOV, shutters and wedge positions with a single click. |
| New | N.A. |

UNS.SmartSuite.PatientDoseFeedback

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Monitor Dose Area Product (DAP) and Air-Kerma (AK; skin-entrance-dose); * Receive a warning if the accumulated AK is above a configurable limit. |
| New | N.A. |

UNS.SmartSuite.ParallelWorking

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, ER/CR>*   * Simultaneously run image acquisitions and work on other tasks in the Control Room on the same patient during X-ray generation;   + Review and process previously and intra-procedurally acquired images   + Perform QA (without interrupting an examination)   + Film (i.e. select/flag images) and export images;   + Patient administration. * Simultaneously run image acquisitions and work on other tasks in the Control Room on different patients during X-ray generation;   + Schedule an examination on another patient in advance to the current examination;   + Schedule an examination on another patient during (and without interrupting) the current examination;   + Review, post process, measure, print and transfer images of one patient in parallel to performing an examination on another patient;   + Perform QA during (without interrupting an examination);   + Film (i.e. select/flag images) and export images; * Display data of the current patient in the ER, coming from an auxiliary system (e.g. PACS) to enable reviewing previous studies of this patient;   + Use the display(s) in the ER to look at prior images of the current patient or to perform a QA or Bolus Chase Reconstruction (BCR) for the current patient; * Always see the Live X-ray while simultaneously performing patient administration/scheduling/QA task; * Work simultaneously on different touch screen modules in different applications in Exam Room and Control Room. |
| New | * Tailored configuration of the workspot with the possibility of adding additional monitors (up to 6) with a multiswitch capability. |

UNS.SmartSuite.UseInterventionalTools

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * To overlay fluoroscopy images on reconstructed data on any 45 degrees position in a range of Z-rotation range of +135 to -135 degrees, taking into account movement compensation and interactions (excluding table tilt, table cradle and table pivot) |
| New | N.A. |

UNS.SmartSuite.3Dacquisition

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all disciplines, ER/CR>*   * Perform rotational acquisitions from Head and Nurse or Doctor side of the table in the same procedure; * Perform 3D rotational acquisitions from Head, Nurse and Doctor side of the table in the same procedure with the FlexArm system and re-use these images for navigation purposes in 7 working positions (with respect to the standard table position): 1) Head side, 2) Nurse side, 3) Doctor side, 4) +45 degrees, 5) -45 degrees, 6) +135 degrees, and 7) -135 degrees. |
| New | * Perform 3D rotational acquisitions from Head, and Nurse and Doctor side of the table in the same procedure with the Biplane floor system (20”) and re-use these images for navigation purposes in 6 working positions (with respect to the standard table position): 1) Head side, 2) Nurse side, 3) Doctor side, 4) +45 degrees, 5) -45 degrees and 6) +135 degrees (nurse side); * Perform 3D rotational acquisitions of the head from the head side of the table along the predefined trajectory. |

UNS.SmartSuite.ImageOffCenter

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all disciplines, ER>*   * Position the FlexArm gantry centre laterally over at least 52 cm with respect to the table longitudinal centre line without moving staff or equipment which is positioned next to the table or the patient table combination; * Create workspace, at least 118 cm, between the FlexArm stand centre and table longitudinal centre line for example to stay between stand and table, maintaining sterility of the user. |
| New | * Perform radial access procedures on both sides of the table. |

UNS.SmartSuite.IQ

Background: the system should provide image quality that allows the user to perform procedures. This includes, but is not limited to, being able to see anatomy, vasculature, devices and catheters.

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Get images that can be used by the physician to perform procedures. |

### Review images

UNS.SmartSuite.ViewingNavigation

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Review the acquired images of the current examination or images from earlier examinations (from same and different patients); * Run/replay image by image; * Scan through available image data for overview and selection of relevant images; * Clearly see when the displayed patient is not the acquisition patient. |
| New | N.A. |

UNS.SmartSuite.DataHandler

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, CR/ER>*   * Save reference images in specific destinations (e.g. reference file, Photo file, PACS, Information Systems) and in various standard formats. * View/display small pictorials of image series (e.g. by using a data handler) coming from previous examinations (e.g. stored on the system database or retrieved from PACS) or the current examination; * View/display small pictorials of image series arranged by filter settings (e.g. middle image; * View/display relevant details of image series (e.g. pictorial pop-up); * Easily access applications (e.g. Measurements, QA, BCR) from the DataHandler; * Create/edit names for a single or for multiple fluoroscopy/exposure run(s). * Have the last used series filter settings persistently available. |
| New | N.A. |

UNS.SmartSuite.ImageEnhancement

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Adjust image to enhance image review, e.g.:   + Zoom/pan the displayed image;   + Change image contrast, brightness and/or amount of edge enhancement;   + Invert image polarity on display (e.g. invert black vessels to white). |
| New | N.A. |

UNS.SmartSuite.Annotations

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Define/set annotations per image and run; * Select predefined standard annotations; * Reposition and modify annotations; * Control the list of annotations; * Add free text to images/image selection during or shortly after the examination. * Edit run name. * Define/set annotations on X-ray images, screenshots and reconstruction images. |
| New | N.A. |

UNS.SmartSuite.Flagging

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Flag images/runs and sort on flagged images; |
| New | N.A. |

UNS.SmartSuite.Measurements

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Perform a measurement on an image (angle, ratio, length); * Perform manual and automatic calibration; * Perform a distance measurement on TSM Pro. |
| New | N.A. |

UNS.SmartSuite.ReviewModule

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR>*   * Perform controlled image review: * Work with one hand on the review module and one hand on the mouse in order to create an efficient workflow for reviewing and image processing (e.g. ergonomic module design). * Have improved visibility of icons in the dark (e.g. backlighting); |
| New | N.A. |

### Post-processing

UNS.SmartSuite.ImageOverlay

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR>*   * Adjust post-processing parameters of the image; at image level, at run level and for fluoroscopy; * Add portion of background information to processed image (e.g. Contrast Brightness and Edge enhancement (CBE), Landmark, ViewTraced, video invert etc.) * Add/remove/adjust/configure/view/save/export the following data/ information to images:   + Relevant physiology data (e.g. ECG signals);   + Image acquisition related information (e.g. detector size, run time stamp);   + Annotations (predefined as well as added manually). * Customize the default information shown on the live and review image. |
| New | N.A. |

UNS.SmartSuite.processingfocus

|  |  |
| --- | --- |
| Legacy | The user wants to  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Select if the processing applies to the images of both channels or to only one channel. |
| New | N.A. |

UNS.SmartSuite.QA

Background: “2D Quantitative Analysis" (2D-QA) is a post processing software intended to assist physicians through providing quantitative information as additional input for their comprehensive diagnosis decision making process and planning during cardiovascular procedures and for post procedural evaluation. 2D-QA consists of six applications:

The "**2D Quantitative Coronary Analysis**" application is intended to be used for quantification of coronary artery dimensions (approximately 1 to 6 mm) from 2D angiographic images. It allows the user to quantify the dimensions of a coronary vessel and/or stenosis from a non-subtracted angiogram.

The "**2D Quantitative Vascular Analysis**" application is intended to be used for quantification of aortic and peripheral artery dimensions (approximately 5 to 50 mm) from 2D angiographic images. It allows the user to quantify the dimensions of an aorta, a peripheral artery, for example but not limited to the carotid, renal, iliac and femoral arteries, or a stenosis in these from a subtracted or a non-subtracted angiogram.

The "**2D Left Ventricle Analysis**" and the "**Biplane 2D Left Ventricle Analysis**" applications are intended to be used for quantification of left ventricular volumes and local wall motion from monoplane and from biplane angiographic series, respectively. It allows the user to compute the left-ventricular Ejection Fraction, Cardiac Output and Wall Motion from user-reviewed 2D contours in selected ventriculograms.

The "**2D Right Ventricle Analysis**" and the "**Biplane 2D Right Ventricle Analysis**" applications are intended to be used for quantification of right ventricular volumes and local wall motion from monoplane and from biplane angiographic series, respectively. It allows the user to compute the right-ventricular Ejection Fraction, Cardiac Output and Wall Motion from user-reviewed 2D contours in selected ventriculograms.

|  |  |
| --- | --- |
| Legacy | The user needs to be able to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Start Quantitative Analysis; * Outline and quantify of contrast-medium filled vessels (2DQCA and 2DQVA) and ventricles (2DLVA and 2DRVA for monoplane and biplane), respectively, in angiographic X-ray images. |
| New | N.A. |

UNS.SmartSuite.2DQAAccuracyAndPrecision

Background: Established 2DQCA guidelines for systematic and random error values of a state-of-the-art QCA-system can be found in [Reiber-2009]. For 2DQCA applied to clinical images we require for pooled means and standard deviations [Reiber-1993]:

|  |  |  |
| --- | --- | --- |
| **Clinical images** | **Systematic error**  **[mm]** | **Random error**  **[mm]** |
| **Inter-observer variabilities obstructions** | n.a. | < 0.15 |
| **Diameter deviation from an equivalent marketed device** | < 0.13 | n.a. |

The above numbers are specified for measurements with an accurate Calibration Factor (CF from iso-center calibration or distance calibration).

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, IR, ER/CR>*   * Quantify vessels and obstructions with 2DQCA with accuracy and precision in line with established 2DQCA guidelines. |
| New | N.A. |

UNS.SmartSuite.2DQACalibration

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, IR, ER/CR>*   * Automatic and manual calibrate to convert distances measured in the X-ray image to real-world distances. |
| New | N.A. |

UNS.SmartSuite.2DQAAutomatedMeasurement

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, IR, ER/CR>*   * Have automatic contour detection in 2DQCA and 2DQVA of a user-selected vessel and/or stenosis in an angiogram. The user needs to be able to manually edit the provided vessel contours and obstruction borders and trigger a recalculation of the results; * Automatically outline and estimate dimensions of user-indicated coronary segments (sizes 1-6 mm) and obstructions from non-subtracted angiograms (2DQCA); * Automatically outline and estimate dimensions of user-indicated aortic and peripheral artery  (sizes 5-50 mm) segments and obstructions from subtracted and non-subtracted angiograms (2DQVA). |
| New | N.A. |

UNS.SmartSuite.2DQAEfficientToUse

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, IR, ER/CR>*   * Receive automated assistance when execute time-consuming tasks like drawing a contour around a lumen or object; * Obtain automatically generated reports from user-reviewed results. |
| New | N.A. |

UNS.SmartSuite.BolusChaseReconstruction

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, IR, ER/CR>*   * Automatically reconstruct Bolus Chase runs immediately after acquisition in order to create an overview of the peripheral arteries in one image; * Export images to the hospital information system. |
| New | N.A. |

### Reporting

UNS.SmartSuite.DoseReporting

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, ER/CR>*   * Create/obtain a report with dose data:   + Cumulative AK in skin area (in case of Cardiac/Thorax zones)   + Cumulative Air Kerma (AK)   + Cumulative DAP   + Total Fluoro Time * Save/ export dose data (e.g. by using DICOM Radiation Dose Structured Report); * Save/export the report on/to the information system or an external destination in a commonly used file formats. |
| New | N.A. |

UNS.SmartSuite.TableSideTextEntry

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Allow table side text entry without compromising sterility/ hygiene. |
| New | N.A. |

### End examination

UNS.SmartSuite.EndExamination

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Suspend an examination (or intervention) on one patient, continuing with an examination on another patient, and resume the examination on the previous patient a later moment in time; * Close the Exam in the ER from the Additional FlexSpot. |
| New | N.A. |

UNS.SmartSuite.ProvideInformation

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, CR>*   * Provide the hospital administration with patient/ procedure information during/at the end of the examination (e.g. export onto the hospital information system (e.g. RIS/CIS); * Access patient data after closing the examination * Export information to the hospital system about what (events and setting) actually has been performed by the system during/at the end of the procedure (e.g. MPPS manager). |
| New | N.A. |

UNS.SmartSuite.ImageTranfer

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR>*   * Transfer image data to multiple destinations in multiple formats; * Review the status (e.g. scheduled, in-progress, completed), of image data transfer; * Receive confirmation (e.g. successful, non-successful) of image data transfer; * Close examination and receive notification of closure; * Re-open and re-close a closed examination. |
| New | N.A. |

UNS.SmartSuite.DicomNetworkExporting

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, CR>*   * Manually and automatically export images from the X-ray system to PACS and/or an external workstation in the hospital; * Automatically transfer patient data (e.g. images, annotations) to the ISP; * Schedule automatic transfer of images. * Reproduce (grey levels, up/downscaling and (un)subtraction) exported images on a wide variety of image archives, such as external viewers as PACS. * Automatically transfer cardiac data to cardio-PACS (with different settings, e.g. downscale, processed) and radiology data to radiology PACS (with different settings, e.g. no downscale, unprocessed) to optimally support mixed procedures. * Configure transfer actions based on procedures used with different settings to destinations (workstations, PACS), customizable by the user. * Limit/ restrict export settings configuration for unauthorized users; * Show network and status of connected systems with modality related information (e.g. IP address, AE title). |
| New | * Group single images from a study and export as one series to a DICOM destination. * Azurion reduces the DICOM export time from the system. The export time of both cardiac (multi-frame) and radiology data (single-frame) is at least 2x faster compared to Allura Xper FD R8.2\* * Optimized interpolation; * IQ subtraction for paedriatic patients.   \*Multi-frame: export of 10 runs \* 100 images of 1K. Single-frame: export of 40 images of 1K. |

UNS.SmartSuite.EasyUSBExport

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR>*   * Export image data through a USB connected destination; * To select the format (DICOM or standard multi-media formats) and anonymize the data before exporting; * To include a DICOM viewer to the exported data; * Give the exported data a new name. |
| New | N.A. |

UNS.SmartSuite.ExportApp

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, CR>*   * Manage images/runs selected for export (including selection at table side) at table side; * Export selected images/runs to DICOM destinations; * Export in original raw format, in DICOM processed/unprocessed format; * Export imported data. |
| New | N.A. |

UNS.SmartSuite.LocalStorage

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Store/ retrieve fluoroscopy and exposure images with DICOM format on/from external destinations (e.g. PACS, USB, CD, DVD); * Store fluoroscopy and exposure images with DICOM and non-DICOM format on local storage media/devices (e.g. USB, CD, DVD). |
| New | N.A. |

UNS.SmartSuite.Printing

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, ER/CR>*   * Select images and create a film sheet from these images; * Print the film sheet; * Preview the film sheet prior to printing; * Select printer and modify printer settings; * Submit print job and manage print queues; * Create and print film sheet at table side prior/during/after an examination; * Print via DICOM and non DICOM printer. |
| New | N.A. |

UNS.SmartSuite.DeleteRun

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Manually delete a complete run; * Prevent accidental deletion of a complete run. |
| New | N.A. |

### Park system

UNS.SmartSuite.ParkBeam

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Manually and motorized (user controlled) park/position the system (if temporarily not used) out of the way to improve access to the patient. |
| New | N.A. |

UNS.SmartSuite.ManoeuvreBeam

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Manoeuvre the system out of current working area; * Manoeuvre the system around other equipment; * Manoeuvre the system to current working area, either manually, via controls or automated. |
| New | N.A. |

UNS.SmartSuite.FlexMovePark

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, VASU/SHD, ER>*   * Park the stand everywhere where the user wants to, within the system’s limitations. |
| New | N.A. |

UNS.SmartSuite.MoveToPark

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * In case the FlexArm stand is not needed inter procedural, have no hinder of the system and have it parked/placed outside the working area, for example for cleaning, during the night, or for during a procedures that do not require imaging * Park the FlexArm in central rail configuration away against the wall at foot side or head side of the room |
| New | N.A. |

### Transfer patient from table

UNS.SmartSuite.TransferPatientFromTable

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Lower the table top allowing the patient to get off the table in a comfortable way; * Lower the table top allowing the staff to transfer the patient from the table in a comfortable way; * Lock the table top preventing unintended table movement during patient transfer; * To use the system in combination with an OR table; * Easily put aside or remove and mount (without sliding) the flush mounted TSM (e.g. for allowing the transfer of the patient, working on other side). |
| New | N.A. |

### Cleaning

UNS.SmartSuite.Cleaning

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Clean/disinfect system parts in the immediate vicinity of patients; * Easily clean the cable covers. * Receive or have direct access to instructions for appropriate cleaning/disinfection regimes of system parts (e.g. procedure, frequency, materials, and fluids). |
| New | N.A. |

### System shut-down

UNS.SmartSuite.ShutDown

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR>*   * Shut-down the system. |
| New | N.A. |

## Generic

### Hardware

UNS.SmartSuite.FD12DetectorSize

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, PCI/SHD/EP, ER>*   * Achieve a larger field of view when compared to with 10”detectors:   + at a selected SID while maintaining projection flexibility;   + to support viewing of the aortic valve and a good part of the aortic arch, preferably in one view with minimal table panning, so that one can follow the device when navigating the aortic arch and see the valve at the same time;   + to support viewing of the whole coronary tree in one view with minimal need for table panning. This can be challenging especially during procedures of patient with a dilated heart (cardiac myopathy);   + to view both the needle insertion point (subclavian or axillary vein) and the whole wire/lead towards the right atrium in one view with minimal table panning and C-arm repositioning. This can be challenging especially for patient with a dilated heart and left ventricle; * See small details by having a small pixel size, resulting in high limiting resolution. |
| New | N.A. |

UNS.SmartSuite.FD15DetectorSize

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Achieve a 154% larger field of view than the 10” detector, to support viewing of larger vascular structures in routine procedures such as renal artery procedures, carotid artery procedures or iliac procedures. |
| New | N.A. |

UNS.SmartSuite.FD20DetectorSize

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Make images up to 48cm diagonal. |
| New | N.A. |

UNS.SmartSuite.ControlModule

|  |  |
| --- | --- |
| Legacy | The user wants to (at table side):  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Protect the system from ingress of fluids (e.g. IPX4); * Control the system at table side using a compact, simple and waterproof TSO, which allows for sufficient patient access and workspace. * Have visibility and guidance in the dark (e.g. backlighting); * Move the Control Module from the pedestal to the table and vice versa. |
| New | N.A. |

UNS.SmartSuite.TouchScreenModule

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Place Touch Screen Module close to user without impact on sterility; * Position the Touch Screen Module at head/side/foot side of table; * Position the Touch Screen Module at a mounting device on a cart; * Control the Touch Screen Module sterile/unsterile; * Use up to 3 TSM's allowing both synchronized and parallel operation. * Change contrast and brightness settings, zoom pan, subtraction on-off, select examination types (EPX) and recall previously stored geometry positions, APC control; * Control (view and manipulate) 3rd party systems (incl. UltraSound) at table side with/without the use of a single mouse (in case of FlexVision (Pro), the mouse should control FlexVision (Pro) and (CWIS) third party; * Have full control of large display FlexVision Pro (layout, applications, pre-sets and viewport sizes); * On the TSM pro:   + View and navigate live clinical images on TSM in 2D;   + Play runs on TSM;   + Manually drag shutters/wedges on TSM. * Control a mousepointer on the screen (s) to improve communication in ER and CR; * View the user interface on the TSM Pro of the connected modality as presented by the 3rd party; * Configure the order of Icon appearance on TSM Pro based on user preference * Control (view and interact) 3rd party systems at table side using touch screen operation; * Change contrast and brightness settings, zoom pan, subtraction on-off, vascular trace, select examination types (EPX) and recall previously stored geometry positions, APC control. |
| New | N.A. |

UNS.SmartSuite.TouchScreenModuleFluidresistance

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Operate the TouchScreen Module normally when exposed to typical amount of fluids used during the procedure. |
| New | N.A. |

UNS.SmartSuite.ImagingControl

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Control the imaging settings at table side; * Select/adjust/control the detector field size, FOV, position of shutters/wedges, Source Image Distance (SID), X-ray channel, fluoro-buzzer, fluoro-grab, fluoro-flavour, Roadmap Pro on/off. |
| New | N.A. |

UNS.SmartSuite.TSMtouchpad

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Use the TSM as touchpad/ keyboard for manipulating/ navigating the FlexVision (Pro) at table side, also under a sterile bag. |
| New | * Perform new interactions at tableside when compared to previous generations of Allura systems such as:   + See live clinical images in 2D;   + Navigate images in 2D;   + Use mouse pointer which is visible in all screens showing X-ray images, to improve communication in ER/CR;   + Control the shutters and wedges from TSM. |

UNS.SmartSuite.DisplayConfiguration

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * To see all relevant images for his tasks from his/her working position; * In case of FlexVision (Pro), choose screen size (heamo live screen needs to remain in original resolution); * View at selected screen location without having to lean towards the screen (images and UI should be clearly visible and readable); * Slave screens for monitoring purposes; * See a source on multiple monitors; * Connect 3rd party screens; * Connect the system to 3rd party video switching and streaming solutions; * Activate or de-activate a general purpose on-screen stopwatch. |
| New | * Display and control up to 8 sources (one at a time) on the additional MultiSwitch without the dependency on the physical connection to the KVM switch; * Increase switching flexibility when compared to the current DVI infrastructure, in the exam room and control room by enabling a flexible division between inputs, outputs and displays, with the routing flexibility of the network switch; * Enable multiple signal layouts from external sources. * Make sure some sources are always displayed (e.g. always see the live screen(s) and live heamo screen); * Choose which image (live, ref) is shown on which screen in the exam room. * Enables multiple signal layouts accordingly to the user preferences, on systems with FlexVision (Pro) and FlexSpot, due to the ability to connect up to 20 external video signals (not generated directly by the X-Ray system); * Systems with 16 Switchable Monitors can connect up to 20 external video signals (not generated directly by the X-Ray system); * Systems with FlexSpot can have up to 3 integrated workstations. |

UNS.SmartSuite.FlexVision(Pro)

|  |  |
| --- | --- |
| Legacy | The user needs to be able to:  *< Clinical users/Physicists/ Service users, all clinical areas , ER>*   * Define and customize the ER monitor configuration and layout of images on screen; * Add and connect a second/backup screen for live/heamo when a single large monitor is used; * Simultaneously see:   + Live X-ray and Ref X-ray in same size;   + Heamo in proper size, resolution, non-scaled, pixel for pixel;   + Scaled 3rd party/Interventional Tools/QA input (optional and switchable, based on operator request); * Start the system with Heamo in proper size/resolution/non scaled/pixel for pixel and have the option to scale the Heamo back and up again; * Simultaneously see (optional) 3rd party monitors in addition; * Rescale/rezoom display container to its demand; * Seamlessly control (view and manipulate) all viewports at table side with a single means / mouse; * Fully customize the layout (e.g. which applications on screen, size of viewports, number of viewports, position of the status bar) using the table side mouse, TSM or from the FlexSpot; * Create presets, adjust these on-the-go and quickly save changes; * Organize presets in groups for easy storage and retrieval; * Display any (3rd party) system; * Connect at least 11 external video signals (that are not generated directly by the X-ray system; * View X-ray images in native resolution without downscaling; * View external sources in their native resolution to prevent signal distortion due to scaling (up/down); * Create a snapshot of a viewport/all displayed video source with one click, export it as secondary capture and store the snapshot in the patient file; * Fully customize the layout (e.g. which applications on screen, size of viewports, number of viewports, position of status bar) using the table side mouse, TSM or from the FlexSpot; * Visualize two full HD video sources in original pixel format, at the same time, mainly for EP procedures. |
| New | * Improved image quality when downscaling EP sources. |

UNS.SmartSuite.AmbientVideos

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Display ComfortThemes videos on FlexVision controlled from TSM. |
| New | N.A. |

UNS.SmartSuite.ControlRoomDesign

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR>*   * Look over the top of screens in control room to see the exam-room; * Minimize the amount of monitors; * Operate different system applications with harmonized keyboard and mouse interfaces. |
| New | * Have the same monitor configuration in the control room for the biplane and monoplane systems. |

UNS.SmartSuite.FlexSpot

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Seamlessly control (view and manipulate) all viewports within a single view and with a single mouse and keyboard; * Quickly access applications without the need to switch between applications and without different mouse control; * Fully customize the layout (e.g. which applications on screen, size of viewports, number of viewports); * Create presets, adjust these on-the-go and quickly save changes; * Organize presets in groups for easy storage and retrieval; * Display any (3rd party) system; * Connect at least 11 external video signals (that are not generated directly by the X-ray system); * Choose from at least 4 different FlexSpot configurations to accommodate the hospital workflow (single work spot with single monitor, single work spot with two monitors, two work spots with one monitor each, two work spots (one with two monitors and the other with one monitor); * Reduce the footprint of display monitors in the Control Room; * Change the layout of the FlexVision (Pro) from the Control Room; * Create a snapshot of a viewport/all displayed video source with one click, export it as secondary capture and store the snapshot in the patient file; * Visualize the references monitors in separate window (parallel to live). |
| New | * Have flexibility in positioning workspots (e.g. between CR/ER and multiple workspots in the CR); * Layouts can be changed during the procedure without having to go into the system settings; |

UNS.SmartSuite.AdditionalFlexSpot

|  |  |
| --- | --- |
| Legacy | The user needs to be able to:  *<Clinical users, all clinical areas , CR/ER>*   * Occupy a second workspot (next to FlexSpot) in the CR or ER; * Circulating nurse should be able to perform all tasks during a case (e.g. patient scheduling) without having to leave the ER. |
| New | * First and second FlexSpot with one or two 27’monitors(s) per workspot; * Work in the same way has in the first FlexSpot; * View and manipulate different sources on the primary and second workspot. |

UNS.SmartSuite.Intercom

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Communicate verbally between ER and CR (e.g. by using an Intercom). |
| New | N.A. |

UNS.SmartSuite.Pedestal

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, VASU/SHD, ER>*   * Stand in between the pedestal and the table during the procedure; * Move the pedestal (in relation to footswitch); * Operate the system with minimum footprint of the pedestal; * Operate the system with minimum loose cables in the working area; * Operate the system with minimal cables on the floor (e.g. between wall and pedestal) during imaging procedures and open surgery (to prevent tripping hazard, and blocking transport of equipment); * Operate the system with minimum interference of wires of the control units; * Easily and effectively clean the pedestal and related wires; * Move the Control Module, Imaging Module and TSM from the pedestal to the table and vice versa. |
| New | N.A. |

UNS.SmartSuite.Table

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Position the table top in any orientation; * Move the table top to position the region of interest in the centre of the X-ray beam; * Move the table top height (up/down) to optimize the working height for the physician; * Move the table (with pivot or swivel) to be able to reach the entire leg area of a patient during an examination; * Image the patient from head to feet without moving the patient (full body coverage); * Perform an iso-centric tilt bringing the patient's head or feet down e.g. to use earth gravity for contrast fluid positioning (not applicable to FlexArm with Hillrom table); * Perform a cradle tilt to allow the surgeon easy access during surgery or for patient positioning purposes e.g. bring the patient into a special position required for CO2 usage, biopsies of kidney or to slide the patient off the table; * Pivot the table to move the arm of the patient into the X-ray beam for examination of the patient's arm or to bring the patient on/off the table; * Pivot the table 180 degrees; * Avoid accidental activation of movement related functions of table and available stands. |
| New | N.A. |

UNS.SmartSuite.ORTable

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to be able to  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Control all geometry movements from a single control panel; * Attach and detach the TSO and TSM from the table rail during the clinical procedure; * Choose different table tops; * Store and recall table position and set the table to stored positions; * To use the system with reverse table top and 180 deg. pivot. |

UNS.SmartSuite.FlexMoveDesign

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, VASU/SHD, ER>*   * Prevent interference with monitors/lamps as much as possible (integrated cabling); * Obtain a high level of sterility/hygiene in a Hybrid OR (e.g. minimum open cabling at monitor connection); * Minimize the interruption of laminar airflow caused by the system. |
| New | N.A. |

UNS.SmartSuite.SmallRoom

Background: Context: The user wants to optimize room efficiency and therefore needs to know how much the Reach Over Available Room (ROAR) is. The formula for ROAR is:



|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Fit FlexArm in smaller rooms (35m² and more); * Calculate the ROAR by having Imaging Reach of the System data available. |
| New | N.A. |

UNS.SmartSuite.CompatibilityLAF

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Fit FlexArm in ORs offering a free floor and such that Raumklasse 1A (DIN 1946) can be established in an examination room with a Laminar Air Flow system with the FlexArm in parking position and in working position (the latter preferred, but not required); * The user should not experience any jet stream when carriage moves under LAF area. |
| New | N.A. |

UNS.SmartSuite.Raillength

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Adapt the system to the size of the room by the option of different rail lengths; * Be able to move the FlexArm system to the far end of the room to free up space around the table. |
| New | N.A. |

UNS.SmartSuite.CeilingCompatibility

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Install the system in existing rooms; * Reuse the existing Allura/Azurion family ceiling construction as much as possible to avoid reconstruction and save cost. |
| New | N.A. |

UNS.SmartSuite.Carriage

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * To select best treatment position and pass the table at head end from nurse to doctor side and vice versa with the FlexArm system. |
| New | N.A. |

UNS.SmartSuite.TableConfiguration

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Make use of the Allura/Azurion system in endovascular and hybrid procedures   Context: For patient support at installation the user can choose between Angio Table and OR Table Magnus or Hillrom;   * Make use of the system in endovascular and hybrid procedures in one room and optimize for these kind of procedures; * Use special patient accessories support that is required in open procedures with C-arc in imaging or in parking position. |
| New | N.A. |

UNS.SmartSuite.VerticalArmConfiguration

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Place the ceiling mounted system in high and low ceiling rooms with a resp. heights of 310 cm (FlexMove), 290 cm (Long L-arm) and 270 cm (Short L-arm). |
| New | N.A. |

UNS.SmartSuite.MonitorConfiguration

Background: Adjust the system to the optimal viewing position during procedure. To optimize the viewing solution to his needs the user can choose between a set of smaller displays or large screen and adjust the position of the displays on viewing distance and height.

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Adjust the system to his particular viewing needs; * Use the system in hybrid labs with minimal interference with Laminar Airflow; * Be able in interventional labs to position the viewing support at 3 sides of the table, doctor, nurse and foot end; * Adjust the screens on viewing distance and viewing height; * Choose a wide range of screen configurations to match the intended procedure mix of the lab. Screen configurations range from separate loose screens to screens combined on single booms to large screens or combinations of those. |
| New | N.A. |

UNS.SmartSuite.SmoothInteraction

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Move the system in such a way that the acceleration and de-acceleration, the speed and the logic of automated movements is perceived by the user as being effective and in a controlled manner (not too fast, not too slow); * Move the system with minimal\* user interaction.   \*) minimal is with the least possible amount of user interaction. |
| New | N.A. |

UNS.SmartSuite.SystemNoise

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Have a low level of noise in the room of the system when in use (no disturbing system noise when moving the system, except when immediately attention required). |
| New | N.A. |

UNS.SmartSuite.RollSpeed

Background: To reduce image breathing artifacts in e.g. the abdominal region.

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER/CR>*   * Perform a 3D roll scan fast enough for the patient to hold his/her breath. |
| New | N.A. |

### Ease of use

UNS.SmartSuite.UserInterfaceOrientationConcepts

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Operate User Interface (UI) control devices (e.g. joystick) intuitively, meaning that the movement direction of table/stand and shutters/wedges should be:   + As much the same as the relative direction of the UI control device;   + As expected by taking into account:     - The location of the physician;     - The type of procedure (e.g. ‘diagnostic view’ for regular procedures ‘surgical view’ for biopsy procedures);     - The orientation of the displayed image. |
| New | N.A. |

UNS.SmartSuite.Languages

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Read from a user interface in his/her native or at least in familiar language; * Select one user interface language from a range of user interface languages. |
| New | N.A. |

UNS.SmartSuite.NewIdentityUserInterface

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Adjust visual display settings depending on the type of procedure (only relevant features should be displayed); * Have focus on the clinical task and especially on the images (e.g. the legibility of visual display through better icon size, color, contrast, backlight, etc.). |
| New | N.A. |

UNS.SmartSuite.UserInterfaceAccess

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, ER>*   * Control the system at all tableside positions (head-end, foot-end, physician side, nurse side); * Remotely control the system (e.g. via pedestal or from CR); * View and interact with clinical images and runs on the TSM; * Switch between modalities using touch and swipe functionality. |
| New | N.A. |

UNS.SmartSuite.TaskGuidance

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Receive displayed step-by-step guidance/ feedback for purpose of:   + Preparing/ performing clinical tasks efficiently (e.g. rotational scan);   + Minimizing the need for re-training;   + Allowing existing staff to train new staff;   + Show this taskguidance on large screen (yes/no) or only at TSM;   + Open this taskguidance yes or no. |
| New | N.A. |

UNS.SmartSuite.IntegratedHelp

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Electronically search through the user manual for help on specific topics/tasks/problems (e.g. digital help function) integrated into the system. |
| New | N.A. |

UNS.SmartSuite.IntegratedIFU

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Have access to the latest/up-to-date Instructions for Use electronically on the system. |
| New | N.A. |

UNS.SmartSuite.IntegratedTraining

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Access training materials on/onto the system (e.g. help materials, integrated applications/ simulations). |
| New | N.A. |

UNS.SmartSuite.IntegratedChecklistandProtocols

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Make a scan of their checklist(s) (time-out document, compromising text and images) and display it on the screen; * Add Checklists and Protocols (comprising text and images of e.g. injector protocols, kind of disposables etc.) to a Procedure Card; * Recall Checklists and Protocols from a Procedure Card before or during the procedure. |
| New | N.A. |

UNS.SmartSuite.EPXtree

|  |  |
| --- | --- |
| Legacy | The user wants to:  *< Clinical users/Physicists/ Service users, all clinical areas, CR/ER*>   * Perform a simple procedure selection, coupled to the selection of the ProcedureCard. |
| New | * Perform a simple procedure selection, outside the content of a the ProcedureCard. |

UNS.SmartSuite.FlexMoveControl

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, VASU/SHD, ER>*   * Control combined XY movement with a single hand in an intuitive way; * Stay clear of the head-end area for anesthesia; * Move from patient left to patient right with the stand, without moving anesthesia equipment; * Stay and work in between table and stand in lateral position; * Control all geometry movements from a single control panel; * Operate the system with a XY joystick with proportional speed-control in concurrent X-Y directions. |
| New | N.A. |

### Customization

UNS.SmartSuite.UserSpecificSettings

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR/ER>:*   * Define system specific settings; * Transfer specific settings from one system to another; * Define procedure specific settings for the hospital; * Customize hospital specific information e.g. physician list, ProcedureCards, dose in AK/DAP; * Import/export ProcedureCards. |
| New | N.A. |

### Management

UNS.SmartSuite.DeleteStudy

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Free up system storage space by deleting a study/studies and all related data from the database; * Protect a study from automatic deletion by the system; * Receive a message when the respective study cannot be deleted (e.g. study is protected or tasks are pending). |
| New | N.A. |

UNS.SmartSuite.FactoriumLogging

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas s, CR/ER>*   * Automatically log events that happened while operating the system; * Reuse this data for data-mining. |
| New | N.A. |

### Integration

UNS.SmartSuite.AuxiliarySystems

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, CR/ER>*   * Integrate and/or connect major brands of peripheral equipment and information systems; * Connect the viewing system to a wide variety of third party systems (e.g. surgical knife, injector, video screens); * View and interact with intra-vascular ultrasound (IVUS) images from table side; * View and analyse images and volumes, originating from auxiliary systems, together with the images generated by the system; * Transfer images and volumes, created by the system, to the auxiliary systems, as input for additional processing by these auxiliary systems; * Position catheters, as well as display and analyse catheter measurements; * Acquire and display physiological signals; * Use the system in a Hybrid OR environment by:   + combining a special hybrid OR patient table with the system   + creating a clean ceiling layout with the ability to position the equipment; * Couple an injector to align (timing) the contrast injection with the runs; * Control the injection of contrast fluid. |
| New | * Have flexibility in where to connect external equipment (e.g. different corners in the room, on the MCS); * Align (timing) the contrast injection with the runs. |

UNS.SmartSuite.VideoSwitching

|  |  |
| --- | --- |
| Legacy | The user needs to be able to:  *< Clinical users/Physicists/ Service users, all clinical areas , CR>*   * Easily switch X-ray and external sources across the monitors in the Exam room (non-FlexVision). |
| New | N.A. |

UNS.SmartSuite.VideoStreamIntegration

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, CR/ER>*   * Stream video output signal to other rooms for purpose of i.e. communication, teaching and recording. |
| New | N.A. |

UNS.SmartSuite.IntegratedDoseAware

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Clinical users/Physicists/ Service users, all clinical areas, CR/ER>*   * Automatically receive real-time feedback of radiation exposure to user and staff. |
| New | N.A. |

UNS.SmartSuite.ReducePatientMovement

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user wants to:  *< Clinical users/Physicists/ Service users,* all clinical areas, ER >   * Have means to compensate for the patient movements during a scan thus minimizing image artifacts. |

## Additional

UNS.SmartSuite.PowerFailure

|  |  |
| --- | --- |
| Legacy | The user needs to be able to:  *<Clinical users/Physicists/ Service users, all clinical areas , ER>*   * Prevent the table top from floating (longitudinal and lateral movements) in case of a power off situation\*; * Use limited system functionality (i.e. fluoroscopy, table and C-arc movements) during power outage; * Keep FlexVision (Pro) and FlexSpot on in case of power outage.   \*only applicable for Veterans Health Administration systems. |
| New | * All Philips workspots can be powered via the system in case of power outage allowing the user to see the x-ray video signals on all workspots and slave monitors. |

UNS.SmartSuite.ExceptionHandling

|  |  |
| --- | --- |
| Legacy | The user needs to be able to (in case of malfunctioning of (parts of) the system):  *<Clinical users/Physicists/ Service users, all clinical areas , ER>*   * Extract guide wire/ catheter/ needle(s) from the patient using fluoroscopy; * Continue performing the procedure, but with decreased level of functionality (the decrease is proportional to the severity of the failure and is understandable for the user); * Store persistently images that are already acquired; * Have access to appropriate user guidance/ manual; * Perform a warm restart of the system; * Determine from the user guidance/ manual what to do in case of a problem. |
| New | N.A. |

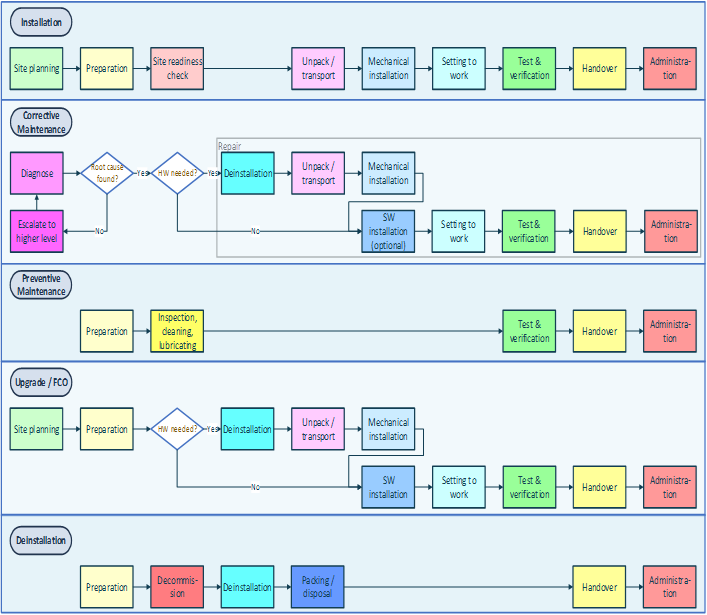
UNS.SmartSuite.Emergency

|  |  |
| --- | --- |
| Legacy | The user needs to be able to:  *<All users, all clinical areas , ER/CR>*   * In case of an emergency, unblock the use of primary system functionality by any user; * Operate the system without entering a user name and password; * Starting imaging without having entered any patient data (e.g. set-up one of the X-ray protocols as default for emergency cases); * Manually move the stand in XY out of way in emergency and/or power off situation; * Access a system emergency stop from the ER; * Perform CPR on the table without table top floating (lock table); * Free up the C-arm space around the patient manually, even in case of a power down (excluding 15”and 20” detector floor system). |
| New | N.A. |

### Service

### Service workflows

There are five service activities (installation, corrective maintenance, preventive maintenance, upgrade/field change order, and deinstallation) that each have a workflow that represents the different service activities that are performed by users from the service user group during the system life cycle. Figure 1 shows the complete set of tasks in the workflows. Most tasks have to be done in multiple service workflows; each unique task has the same color.



**Fig. 1:** Service workflows.

### Service activities

This section summarizes the unique user needs that can be encountered in the service workflows. For all tasks related to the installation activity the user should have all the information that is needed to ensure that the right preparations for the tasks can be made such as mains, network connections, remote connectivity, hospital IT impact, building construction requirements, etc. Also, other systems in the hospital need to be prepared by their provider to work correctly with the Philips Image Guided System e.g. heamo system, ultrasound or 3rd party devices.

### Site planning

UNS.SmartSuite.SitePlanning

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/BM, Installation/Upgrade/FCO>*   * Obtain all information that is needed to prepare for the installation/upgrade. |

### Preparation

UNS.SmartSuite.Preparation

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/CAS/BM, Installation/Preventive Maintenance/ Upgrade/FCO/Deinstallation>*   * Obtain information that is needed to ensure the rightful preparation for a service activity before visiting the system. |

### Site readiness check

UNS.SmartSuite.SiteReadinessCheck

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/BM, Installation>*   * Obtain information that is needed to ensure that the prerequisites of system installation are met. |

### Unpack and transport

UNS.SmartSuite.UnpackandTransport

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/BM, Installation/Corrective Maintenance/ Upgrade/FCO>*   * Have guidance to unpack (parts of) the system components. * Have options to transport\* (parts of) the system for installation at the hospital.   \*Transport is getting the equipment from unloading the truck at the hospital to the final destination in the hospital.The goal is to take all obstacles into account, like doors, elevator, corridor (bends), etc. |

### Mechanical installation

UNS.SmartSuite.MechanicalInstallation

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  <FSE/BM*, Installation/Corrective Maintenance/ Upgrade/FCO* >   * Mechanically install the system using the appropriate instruction guide in the image-guided lab. |

### Setting to work

UNS.SmartSuite.SettingtoWork

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/CAS/BM, Installation/ Corrective Maintenance/ Upgrade/FCO>*   * Perform the main tasks\* that are needed to make sure that the system is operational according to specifications in the image-guided lab.     \*power on for the first time, configuration, adjustments. |

### Test and verification

UNS.SmartSuite.TestandVerification

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/CAS/BM, Installation/Corrective Maintenance/ Upgrade/FCO>*   * Collect evidence, by performing test and verify the system in the image-guided lab, on critical parameters related to safety and performance, to indicate that the system is operational according to manufacturer specification.    \*a functional test makes sure that the system, subsystem or Field Replaceable Units functions correctly. |

### Handover

UNS.SmartSuite.Handover

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/BM, all service workflows>*   * Handover evidence indicating that the system is operational according to manufacture specification after any service activity; * Get proof that the customer accepts the system in the image-guided lab. |

### Administration

UNS.SmartSuite.Administration

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/CAS, all service workflows>*   * Do administration tasks and store evidence\* after any service activity to indicate that the system is operational according to manufacturer specification.   \*, e.g. import to the Performance Assurance tool and installed base registration. |

### Diagnosis

UNS.SmartSuite.Diagnosis

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/CAS/BM, Corrective Maintenance>*   * Diagnose problems on the system in the image-guided lab\*. * Use diagnosis to determine correct action to solve the problems.     \*All diagnostic capabilities and information that is needed to determine the corrective action to solve the (future) issue, e.g. diagnostic capabilities and information needed: correct actual lab configuration, fingerprint, logging, health status,image-guided system FRUs, tests, adjustments, EPX database, ServiceHub, heamo system, ultrasound (that can be moved to different lab), 3rd party devices, usage history (who used the device and for what reason), to enable condition/usage based preventive maintenance. |

### Escalate

UNS.SmartSuite.Escalation

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/CAS/BM, Corrective Maintenance>*   * Collect data and send to Philips Remote Service to enable remote support to be able to escalate problems to a higher support level (tier-1 to 4). |

### Mechanical deinstallation

UNS.SmartSuite.MechnicalDeinstallation

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/BM, Corrective Maintenance, Upgrade/FCO/ Deinstallation>*   * Mechanically deinstall the system in the image-guided lab based on the appropriate instructions; * Mechanically deinstall parts of the system for corrective maintenance & Upgrade/FCO. |

### Software installation

UNS.SmartSuite.SoftwareInstallation

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/BM, Corrective Maintenance/ Upgrade/FCO>*   * Install software on the system that match the workflow prerequisites\*.     \*hardware and software compatibility. |

### Inspect, clean, and lubricate

UNS.SmartSuite.InspectCleanLubricate

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/BM, Preventive Maintenance>*   * Inspect, clean, lubricate, and adjust accordingly to the critical to safety and quality aspects of the system in the image-guided lab. |

### Decomission

UNS.SmartSuite.Decommission

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/RSE/BM, Deinstallation>*   * Decommission\* the system in the image-guided lab.     \*, e.g. remove from PRS, data destruction, 'un-setting to work' of the system, Philips Remote Services, etc. |

### Packing and disposal

UNS.SmartSuite.PackingandDisposal

|  |  |
| --- | --- |
| Legacy | N.A. |
| New | The user needs to:  *<FSE/BM, Deinstallation>*   * Dispose of the system accordingly to the standards/guidelines. |

# Regulatory, Safety, Security and Legal Needs

UNS.SmartSuite.SafeSystemUse

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, CR/ER>*   * Use a system that is safe to use and complies with the applicable international standards. * Prevent harm to patients or hospital by: * Using a system that provides protection against unacceptable safety risks in hazardous situations (for example, protection against X-ray, high temperature); * Receiving guidance and instructions on minimizing the risk of causing harm in hazardous situations. |
| New | N.A. |

UNS.SmartSuite.DoorContact

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, CR>*   * Inhibit X-ray from the system while the door is open between Exam Room and adjacent rooms. |
| New | N.A. |

UNS.SmartSuite.QualityControl

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Physicist, all clinical areas, CR/ER>*   * Perform system quality control checks (in order to assure safety, regulatory compliance and validated system performance (as standardized by NEMA). |
| New | N.A. |

UNS.SmartSuite.HospitalITConformance

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Hospital IT, all clinical areas, CR/ER>*   * To bring the hospital infrastructure and associated network protocols up-to-date and connect the system to the updated configuration. |
| New | N.A. |

UNS.SmartSuite.SecurityProtection

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<Hospital IT, all clinical areas, CR/ER>*   * Protect the patient privacy as well as to prevent loss of information or inability to perform clinical procedures, as a result of security breaches; * Provide protection against all known security threats; * Receive guidance and instructions how to protect the system against security threats and how to minimize the vulnerability of the system; * Create and manage user accounts. |
| New | * Have protection over patient and personal data across the network by using user authentication and encryption protocols; * Comply with the industry security and privacy standards. |

UNS.SmartSuite.EnvironmentalCare

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, ER/CR>*   * Use a system that complies with the international environmental standards. |
| New | N.A. |

UNS.SmartSuite.VeteransAdministration

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, ER/CR>*   * Use a system that complies with the mandatory requirements from Veterans Administration (VA) |
| New | N.A. |

UNS.SmartSuite.HCA

|  |  |
| --- | --- |
| Legacy | The user wants to:  *<All users, all clinical areas, ER/CR>*   * Use a system that complies with the security requirements from HCA. |
| New | N.A. |

# Annex A: Compatibility Overview

Legacy Azurion will deliver compatibility statements for:

* Philips clinical applications (e.g. Interventional Workspot, EchoNav and Coronary tools)
* Philips Ultrasound systems; video display integration and table side control
* Philips heamo dynamic systems and applications; with table side controlPhilips information systems and multi-modality imaging clinical applications, with table side control
* Departmental Image Management Systems /PACS systems
* Measurement systems (e.g. 2D quantitative analysis)
* Export of Philips clinical applications
* Monitor booms
* Universal trolley
* Injectors
* OR tables
* Robotic steering systems
* Video distribution systems (2 ways)
* Video display integration systems, e.g. ImageStream
* EP recorders
* EP mapping, navigation and planning systems
* EM tracking systems
* PCI guidance systems (e.g. Corindus)
* Intravascular imaging systems, with table side control (e.g. TVC, IVUS, …)
* Neuro head holder
* Patient dose monitoring systems

# Annex B: List of User Need - and Claims – Tags

[CLAIM.SmartSuite.C1.ClarityIQ 10](#_Toc144194220)

[CLAIM.SmartSuite.C2.ClarityIQ 10](#_Toc144194221)

[CLAIM.SmartSuite.C3.ClarityIQ 10](#_Toc144194222)

[CLAIM.SmartSuite.C4.ClarityIQ 10](#_Toc144194223)

[CLAIM.SmartSuite.C5.ClarityIQ 10](#_Toc144194224)

[CLAIM.SmartSuite.C6.ClarityIQ 11](#_Toc144194225)

[CLAIM.SmartSuite.C7.ClarityIQ 11](#_Toc144194226)

[CLAIM.SmartSuite.C8.ClarityIQ 11](#_Toc144194227)

[CLAIM.SmartSuite.C9.ClarityIQ 11](#_Toc144194228)

[CLAIM.SmartSuite.C10.ClarityIQ 11](#_Toc144194229)

[CLAIM.SmartSuite.C11.ClarityIQ 11](#_Toc144194230)

[CLAIM.SmartSuite.C12.ClarityIQ 12](#_Toc144194231)

[CLAIM.SmartSuite.C13.ClarityIQ 12](#_Toc144194232)

[CLAIM.SmartSuite.C14.ClarityIQ 12](#_Toc144194233)

[CLAIM.SmartSuite.C15.ClarityIQ 12](#_Toc144194234)

[CLAIM.SmartSuite.C16.ClarityIQ 12](#_Toc144194235)

[CLAIM.SmartSuite.C17.ClarityIQ 12](#_Toc144194236)

[CLAIM.SmartSuite.T1.TouchScreenModule 16](#_Toc144194237)

[CLAIM.SmartSuite.T2.TouchScreenModule 16](#_Toc144194238)

[CLAIM.SmartSuite.T3.ProcedureCards 16](#_Toc144194239)

[CLAIM.SmartSuite.T4. FlexVision(Pro) 17](#_Toc144194240)

[CLAIM.SmartSuite.T5.TSMTouchpad 18](#_Toc144194241)

[CLAIM.SmartSuite.T6.FlexSpot 18](#_Toc144194242)

[CLAIM.SmartSuite.T7.ParallelWorking 19](#_Toc144194243)

[CLAIM.SmartSuite.T8.AuxiliarySystems 20](#_Toc144194244)

[CLAIM.SmartSuite.T9.DicomNetworkExporting 20](#_Toc144194245)

[CLAIM.SmartSuite.T10.ISPWorkflowIntegration 21](#_Toc144194246)

[CLAIM.SmartSuite.T11.FD12DetectorSize 21](#_Toc144194247)

[CLAIM.SmartSuite.T12.FD15DetectorSize 22](#_Toc144194248)

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