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Siemens Healthineers  
Business Area Ultrasound

## Title: K2 VA10A Design Validation and Business Confirmation Report

Part Number: 11508397-EFT-001-01

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### Revision Data

Rev	ECO #	Change Description	Printed Name
01	697335	Document Initiation	Heike Seck

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## Revision History

Rev	ECO # / Date Made	Change Description	Printed Name
01	697335	Validation Report for K2 VA10A	Heike Seck

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## 1.0 VALIDATION SUMMARY

The K2 VA10A Design Validation and Business Confirmation has been completed per the Design Validation and Business Confirmation Plan.

**Based on the results, the K2 VA10A system meets user needs and intended use and the business needs are confirmed.**

## 2.0 PURPOSE

The purpose of the K2 1.0 (VA10A) Design Validation and Business Confirmation Report is to provide a results summary.

The K2 1.0 (VA10A) Design Validation and Business Confirmation Report is a compilation of the user needs validation and business needs confirmation activities performed by testers with specific knowledge of particular requirements. This report provides results per the needs and intended uses defined in the 1.0 requirements in Requirement Specification (RS 11151404-EPH-001). The Design Validation and Business Confirmation was performed in accordance with the K2 1.0 Design Validation and Business Confirmation Plan Design (PN 111151405-EPH-001). The requirements were tested on production equivalent systems.

## 3.0 SCOPE

The K2 Design Validation and Business Confirmation Plan for Release VA10A provides comprehensive description of the design validation requirements, test methods, acceptance criteria (also referenced as “pass criteria”) and template for final report necessary to complete the K2 VA10A design validation and Business Confirmation. The Design Validation and Business Confirmation Plan consists of a list of the system user need validation requirements, a list of the system business need confirmation requirements as defined in the RS and a list of the transducer validation requirements as defined in TRS of transducers associated with K2. The validation report template provides means to record the validation or confirmation scoring of the requirements along with initials for the person completing and date. All testing described in this Design Validation and Business Confirmation Plan will be completed on production equivalent K2 Systems and all applicable transducers.

This comprehensive report of design validation and Business Confirmation is compiled by the Product Manager (or designee) and the record will be submitted to the Product Steering Group and maintained in the product design history file.

## 4.0 OBJECTIVE

The report objective is to summarize the result of the activities as defined in the plan to validate/confirm K2 with Release VA10A intended uses, user needs, business needs and applicable transducer requirements identified in the following documents:

Document Title	Document Number
K2 VA10A Requirements Specification	11151404-EPH-001
5C1 TRS	11253531-EPH-001
10L4 TRS	10787408-EPH-001
9C3 TRS	10787405-EPH-001
4V1 TRS	11014602-EPH-001
9EC4 TRS	10787409-EPH-001
14L5 TRS	11254078-EPH-001
8V3 TRS	11014604-EPH-001

10V4 TRS	11014605-EPH-001
5V1 TRS	11291793-EPH-001
18L6 TRS	10787403-EPH-001
CW2 TPS	7479533-EPH-001
CW5 TPS	7467256-EPH-001
V5Ms TPS	7706265 -EPH-001

## 5.0 REFERENCES

Document Title	Document Number or Archive Bin Number
[1] Change Control Procedure	8266240-EMU-001
[2] TFS DM Work Instruction	11150115-QMS-001
[3] Usability Validation Plan	11289348-EFT-001
[4] Usability Engineering Process	10851935-QMS-001
[5] Label, Investigational device	10436916-EZG-001
[6] Label, Non-Commercial Dist.	10437243-EZG-001
[7] Quality Records/Documentation Retention	3900789-QMS-001
[8] K2 VA10A Requirement Specifications	11151404-EPH-001
[9] K2 Transducer\Exam\Feature SSRC	11502957-EPH-001
[10] Biopsy Guide Validation Form	07859882-QMS-004
[11] Product DFX Scorecard Work Instruction	11147436-EMU-001
[12] Standards and Regulations document	7477230-QMS-002
[13] K2 Use specification	11336275-EPH-001
[14] PREP Requirements and Guidelines	11151649-AND-EHS
[15] Product Life Cycle Process	10035306-QAD-001
[16] K2 M270 Work Instruction	11502819-QMS-001
[17] K2 VA10 Product Hazard & Risk Analysis Report	11320097-EGA-001
[18] Statistical Technique Procedure	11287721-QMS-001
[19] Statistical Sampling Guidance	11507621-QMS-001

## 6.0 ABBREVIATIONS, ACRONYMS & DEFINITIONS

Term	Definition
Application	A set of features and design characteristics that support the use of the

Term	Definition
	product for a particular diagnostic use
Business Need	Implementation goals to drive commercial success. Data source for the design inputs. Business needs are confirmed.
CEUS	Contrast Enhanced Imaging
Test Challenge	A question which challenges a feature for confidence and reliability sampling strategy
Clinical User	Clinical end users of the system including Sonographers and Physicians
CRF	Case Report Form
Compounding	Steered Spatial Compounding
Console	The console is the equivalent of the control panel
Contrast	Contrast Agent Imaging
CV	Clinical Validation
DHF	Design History Folder
DoD	Department of Defense - USA
ECG	Electrocardiogram
EHS	Environmental health and safety
External	Activities performed at a clinical site external to a Siemens facility or an evaluation site external to a Siemens facility.
Phantom	A specially designed object that is scanned or imaged in the field of medical imaging to evaluate, analyze, and tune the performance of various imaging devices.
Feature	A marketable characteristic of the product
FRU	Field Replaceable Unit
Goal	The reason why the product, application or feature is to be developed and have an expected outcome
Strain	Quasi-static elasticity imaging
Internal	Activities performed at a Siemens facility
N/A	Not Applicable
NFE	New Feature Evaluation
OS	Operating System
PQ	Production Qualification
RS	Requirement Specification
S&E	See Product Life Cycle Process [15], K2 M270 Work Instruction [16]
TRS	Transducer Requirement Specification
TS	Touch Screen

Term	Definition
PRS	Purchasing Requirement Specification
PSG	Product Steering Group
pSWE	Point Shear Wave Quantification
SWE	2D Shear Wave Imaging
User Need	Expectations a clinical user has relative to the system's intended use and function. Data source for design validation. User needs are validated,
VT	Virtual Touch

## 7.0 RESULTS

During Clinical tests, the system was predominantly used in a simulated clinical environment at SUSKO office in Korea (Siemens Healthineers Ltd.; 27th Floor, KINS Tower, 25-1, Jeongja-dong Bundang-gu, Seongnam-si, Gyeonggi-do, 13558. 8 cases (404 – 411) were acquired at a clinical site in India (The Madras Medical Mission; 4-A, J J Nagar, Mogappair, Chennai, Tamil Nadu, 600037)

### 7.1 Additional documents

All documents used to generate the report and supporting memos are in the DHF, P/N 11319406-EEH-DHF-01.

## 8.0 VALIDATION SPREADSHEET DEFINITIONS

### Requirement Type Column

This column lists the type of requirement as Business Needs, Transducer or User Needs.

### RS Requirement ID Column

This column lists the requirement identification.

### RS Description Column

This column lists the requirements details as written in the corresponding document.

### Validation Criteria Column

This column provides a brief explanation of the validation item and a summary of the Pass/Fail criteria.

### Validation Method Column

This column informs what method of validation was employed as Clinical, Analysis, Usability, Business or Transducer.

### Validation Location Column

This column informs the location where activity was performed, either internal, external or a combination of internal external.

### Validation Validated or Confirmed by Column

This column informs which group or groups provided the source of validation. Individuals selected are qualified to determine that the operation or function in question meets the need or criteria based on qualification and expertise.

## Timing Column

Target milestone for confirmation completion

## Validation Results Column

This column identifies whether the requirement resulted in PASS, FAIL, DEFERRED or N/A.

## Validation ID Column

Initials of the validator who submitted the validation result for the report.

## Validation Dates Column

Date requirement was submitted for inclusion in the report.

### 8.1 Minimum Number of Studies by Transducer/Clinical Use

	Abdominal	Pediatric	Cardiac	Peripheral Vessel	Small Organ	Fetal	MSK Superficial	MSK Conventional	Transrectal	Transvaginal	TEE	Total
4V1	29	6				5						40
5C1	32	5				5						42
9C3	31	6				5		6				48
18L6		6			11		6	6				29
14L5		5		9	16		7	6				43
10L4	6	6		9	40	5	6	6				78
9EC4									5	26		31
5V1	2	6	36									44
8V3	5	7	6									18
10V4	5	7	6									18
V5Ms											14	14
CW5				5								5
CW2		5	6									11
Total	110	59	54	23	67	20	19	24	5	26	14	421

Studies Total 421

### 8.2 Transducer Specific Uses

	B Mode	Color	PW	PW DTI	CW	M-Mode	Strain	pSWE	2D SWE	Contrast	Stressecho	Speed of Sound	Panoramic	Total
4V1	24	17	18	0	0	16	0	12	0	16	0	0	0	103
5C1	26	18	18	0	0	18	0	12	0	16	0	0	17	125
9C3	32	21	21	0	0	15	0	0	0	16	0	0	23	128
18L6	29	25	24	0	0	15	11	0	0	0	0	5	17	126
14L5	43	37	34	0	0	24	13	0	0	0	0	6	20	177
10L4	62	42	41	0	0	33	19	9	20	16	0	4	34	280



9EC4	15	7	7	0	0	8	5	0	0	16	0	0	10	68
5V1	36	17	17	10	10	17	0	0	0	8	15	0	0	130
8V3	18	17	17	6	6	15	0	0	0	0	0	0	0	79
10V4	18	17	16	6	6	15	0	0	0	0	0	0	0	78
V5Ms	14	8	7	*0	7	*0	0	0	0	0	0	0	0	36
CW5	0	0	0	0	5	0	0	0	0	0	0	0	0	5
CW2	0	0	0	0	11	0	0	0	0	0	0	0	0	11
Total	317	226	220	22	45	176	45	32	20	88	15	14	121	1346

\* PW DTI and M-mode@V5Ms: V5Ms cases were supplemented by using an ultrasound phantom resembling the organ and anatomy. PW DTI and M mode is used to examine motion of tissue; which can't be resembled with a static phantom. Therefore PWDTI and M Mode are covered in verification report PN:11502870-EIT-003-01.

**Transducer Specific 1346**

### 8.3 Number of Console Uses

	Patient Registration	Annotations	Body Markers	Arrows	Dual	Physio	VVI	eSie OB	E Sie Follicle	Protocols	Mixed Modes	Cine	Hibernate	Acquire	Review	Measurement	eSie Left Heart	eSieMeasure	Clarify	Report	Total
Total	349	353	197	188	318	56	15	16	25	302	315	362	140	414	392	246	23	25	13	171	3920

**General System: 3920**

### 8.4 Minimum Number of Clinical Users

A minimum of three (3) unique clinical users performed validation activities for the clinically validated requirements, detailed in the memo called

“K2 VA10A ClinicalUsers MinimumUses Validation Memo.docx”.

The clinical user identifications are detailed in the memo called “K2 VA10A Clinical Users Validation Memo.docx”.

### 8.5 Statistical Results

Memo “K2 VA10A StatisticalEvaluation Validation Memo” reports the statistical confidence and reliability of the user needs validation

### 8.6 Clinical & Business Needs confirmation ID:

The clinical and business needs confirmation identifications are:

HJ: Hyoin; SL: Sunmi Lee; YK: YeonHwa Kim; SJ: SeongSim Jeon; MJK: MeeJeong Kong; TL: Tamy (JooYeon) Lee; SK: SoonWook Kwon; IH: InSeop Hwang; NK: NamHoon Kim; CK: ChangSeop Kim; TL: TongKeun Lee; KJ: KwanSoo Jin; YK: YeonHwa Kim; JY: JaeYoun Yoo; SY: SunChul Yoon; BH: ByunHun Hong; DR: David Roth; MS: Michael Szucs; BF: Benjamin Fritsch; HS: Heike Seck

### 8.7 Software Versions Used

K2 Production equivalent systems (“Memorandum\_form\_for\_K2\_TP\_rev04\_3rd”) were used with the following software versions: 0.1905.02; 0.1906.01; 0.1906.02; 0.1906.03; 1.0.1907.01; 1.0.1907.02; 1.0.1908.01

## 9.0 VALIDATION SPREADSHEET

Requirement Type	Requirement ID	Requirement Description	Validation Criteria	Validation Method	Validation Location	Validated or Confirmed by	Timing	Validation Result	Validation Date	Validator ID
1 : 746288 K2 Needs										
1.1 : 858770 User Needs										
1.1.1 : 859370 Transducers										
User	746129 5C1 Transducer	As a clinical user, I need the system to support a mid-frequency curved transducer.	An average score of applicable 5C1 imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746122 10V4 Transducer	As a clinical user, I need the system to support a high frequency phased array transducer.	An average score of applicable 10V4 imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746135 10L4 Transducer	As a clinical user, I need the system to support a standard footprint low frequency linear array transducer.	An average score of applicable 10L4 imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746138 9EC4 Transducer	As a clinical user, I need the system to support an endocavity	An average score of applicable 9EC4 imaging functions meets user need.	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS

		transducer.	Pass = An average score of "Meets need" or above							
User	746126 18L6 Transducer	As a clinical user, I need the system to support a wide footprint high frequency linear array transducer.	An average score of applicable 18L6 imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746124 14L5 Transducer	As a clinical user, I need the system to support a standard format high frequency linear array transducer.	An average score of applicable 14L5 imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746132 9C3 Transducer	As a clinical user, I need the system to support a high frequency curved transducer.	An average score of applicable 9C3 imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746127 4V1 Transducer	As a clinical user, I need the system to support a low frequency phased array transducer.	An average score of applicable 4V1 imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS

User	746128 5V1 Transducer	As a clinical user, I need the system to support a low frequency, small footprint phased array transducer.	An average score of applicable 5V1 imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746136 CW2 Transducer	As a clinical user, I need the system to support a non-imaging continuous wave Doppler transducer for assessment of flow states with no range ambiguity.	An average score of applicable CW2 imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746133 8V3 Transducer	As a clinical user, I need the system to support a small footprint, mid-frequency phased array transducer.	An average score of applicable 8V3 imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746137 CW5 Transducer	As a clinical user, I need the system to support a non-imaging, high frequency continuous wave Doppler transducer for assessment of flow states with no range ambiguity.	An average score of applicable CW5 imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS

User	746139 V5Ms Transducer	As a clinical user, I need the system to support a mid-frequency 2D TEE transducer	An average score of applicable V5Ms imaging functions meets user need.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746157 Biopsy	As a clinical user, I want the ability to perform ultrasound guided biopsy using a bracket with needle guide inserts for the purpose of targeting and obtaining a tissue or cell samples from a lesion or specific region of tissue.	1. Complete the In-House Biopsy Guide Evaluation for each transducer that supports a biopsy guide as described in the Biopsy Guide Validation Form - Part Number: 07859882-QMS-004-01 for biopsy guide validation in tissue mimicking material with a grade of PASS 2. Support biopsy guideline angle as defined in Biopsy Guideline Transducers Table (see PRS - Needle Guide, K2/K2 Family (M1/M2)	Clinical	Internal	Clinical Experts	S&E	PASS	5/31/2019	SL; HJ; SJ; YK
1.1.2 : 856576 Imaging										
User	746141 B Mode	As a clinical user, I need the ability to scan using B Mode so that I can visualize anatomy in real time with the ability to adjust the image display for user	1. I was able to use B Mode during the study 2. Using B-Mode, I was able to visualize anatomy in real time with the ability to adjust the image display for my preference 3. Using B-Mode, I was able to visualize	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS

		preference.	anatomy, structures and/or pathology similar to the comparison device  Pass = An average score of "Meets need" or above							
User	746142 Auto TEQ	As a clinical user, I want the ability to maintain B image uniformity across all patient body types and acoustic windows without having to change gain and focus, so that I can save time and effort.	1. I was able to use eSiImage during the study 2. Using eSiImage I was able to visualize anatomy in real time with the ability to add modes (PW; Color, CEUS) 3. Using eSiImage, I was able to visualize anatomy, structures and/or pathology similar to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746145 C Mode	As a clinical user, I need the ability to scan using C Mode so that I can visualize blood flow in real time with the ability to adjust the display for user preference.	1. I was able to use C Mode during the study 2. Using C-Mode, I was able to visualize blood flow in real time with the ability to adjust the image display for my preference 3. Using C-Mode, I was able to visualize blood flow in a similar manner as compared to the comparison	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS

			device  Pass = An average score of "Meets need" or above							
User	746147 M Mode	As a clinical user, I need the ability to scan using M Mode so that I can visualize tissue motion versus time. I require the ability to adjust the display for user preference.	1. I was able to use M Mode during the study 2. Using M-Mode, I was able to visualize tissue motion versus time with the ability to adjust the image display for my preference 3. Using angle corrected M-Mode, I was able to visualize tissue motion versus time with the ability to adjust the image display for my preference 4. Using M-Mode, I was able to visualize anatomy, structures and/or pathology in a similar manner as compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS

User	746146 PW, PW DTI and CW Mode	As a clinical user, I need the ability to scan using spectral Doppler Modes (PW, PW DTI and CW) so that I can visualize and measure the spectral display of tissue / blood flow. I require the ability to adjust the display for user preference.	1. I was able to use Doppler Mode during the study 2. Using Doppler Mode, I was able to visualize the spectral display of flow / tissue with the ability to adjust the image display for my preference 3. Using Doppler Mode, the spectral display produced a result of similar clinical performance when compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746151 E Mode	As a clinical user, I need a way to quantify or visualize relative stiffness information about the same tissue I am visualizing in B Mode.	1. I was able to use VT Mode during the study 2. Using Strain, I was able to visualize the relative tissue stiffness with the ability to adjust the image display for user preference 3. Using Strain, I was able to visualize the relative tissue stiffness in a similar manner as compared to the comparison device 4. Using pSWE, I was able to acquire stiffness quantification results in a similar	Analysis	Internal	Clinical Expert	S&E	PASS	8/26/2019	HS



			<p>manner as compared to the comparison device</p> <p>5. Using SWE, I was able to acquire parametric stiffness quantification results in a similar manner as compared to the comparison device</p> <p>Pass = An average score of "Meets need" or above</p>							
User	746152 Contrast Mode	As a clinical user, I need the ability to scan using an imaging mode so that I can visualize in real time the ultrasound contrast imaging agent.	<p>1. I was able to use Contrast Mode during the study</p> <p>2. Using Contrast Mode, I was able to visualize contrast in real time with the ability to adjust the image display for my preference</p> <p>3. Using Contrast Mode, I was able to visualize contrast in a similar manner as compared to the comparison device</p> <p>Pass = An average score of "Meets need" or above</p>	Analysis	Internal	Clinical Experts	S&E	PASS	8/31/2019	HS

User	746153 Panoramic	As a clinical user, I need a method to acquire a panoramic view of anatomy with and/or without flow information that would otherwise not fit in the transducer field of view.	<p>1. I was able to use Panoramic during the study</p> <p>2. Using Panoramic, I was able to create an image of anatomy greater than the field of view of the transducer in its widest format in a similar manner as compared to a comparison device</p> <p>3. Using Panoramic, I was able to create an image of blood flow and anatomy greater than the field of view of the transducer in its widest format in a similar manner as compared to the comparison device</p> <p>Pass = An average score of "Meets need" or above</p>	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746144 Speed of Sound	As a clinical user, I need an imaging control for linear transducers that helps reduce B-mode tissue architecture distortion in fatty tissue.	<p>1. I was able to use Speed of Sound adjustment on Linear transducers during the study</p> <p>2. I was able to use speed of sound in a similar manner as compared to the comparison device</p> <p>Pass = An average score of "Meets need" or above</p>	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS

User	746143 Clarify	As a clinical user, I need an imaging feature that enhances the visibility and conspicuity of vessels in real time.	1. I was able to use the Clarify during the study 2. Using Clarify I was able to visualize vessels in real time using in a similar manner when compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746154 Mixed Modes	As a clinical user, I need the ability to acquire B Mode image in combination with other imaging modes.	1. I was able to use mixed modes during the study 2. Using mixed modes, I was able to complete the study in a similar manner as compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746155 Dual	As a clinical user, I need the ability to view two images side-by-side so they can compare the current image against another image with different image views, modes or time.	1. I was able to use dual during the study 2. I was able to use dual in a similar manner as compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS

User	746156 Physio	As a clinical user, I need an ECG and respiratory trace to be displayed so they have access to cardiac and respiratory timing for acquisition, measurements, and analysis purposes.	1. I was able to use physio during the study 2. Using physio, I was able to complete the study in a similar manner as compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746158 CINE	As a clinical user, I need the ability to stop all imaging acquisition so I can view frozen images frame to frame in order to inspect images carefully, document images or make measurements on images.	1. I was able to use cine during the study 2. Using cine, I was able to complete the study in a similar manner as compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746193 Patient Registration	As a clinical user, I want to be able to register patients to create a patient study.	I was able to register patients using desired demographic data in a similar manner when compared to the comparison device.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS

User	746159 Acquire	As a clinical user, I need the ability to acquire images and clips to document the study and findings.	I was able to store images and clips during the study in a similar manner when compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746160 Review	As a clinical user, I want the ability to review image data stored during an active exam as well as data sets stored during a previous exam.	1. I was able to review image data stored during the study in a similar manner when compared to the comparison device. 2. I was able to review image data from previous studies in a similar manner when compared to the comparison device.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
1.1.3 : Clinical Workflow User Needs										

User	746176 Measurements	As a clinical user, I want the system to provide the ability to make measurements that support my clinical needs and organize the results and calculations into a summary.	<p>1. I was able to use the measurement functions during the study.</p> <p>2. I was able to select appropriate measurements to support my clinical need in a similar manner when compared to the comparison device.</p> <p>3. I was able to select measurement labels, make a measurement and that value was saved to the report in a similar manner when compared to the comparison device.</p> <p>4. I was able to make measurements based on cardiac and / or respiratory timing in a similar manner when compared to the comparison device.</p> <p>5. When I used a semi-automated method or VVI to generate values, those values were saved to the report in a similar manner when compared to the comparison device.</p> <p>Pass = An average score of "Meets need" or above</p>	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
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User	746176 Reports	As a clinical user, I want the system to provide the ability to make measurements that support my clinical needs and organize the results and calculations into a summary.	1. I was able to access a summary of values and results for my review in a similar manner when compared to the comparison device.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746169 Clinical Documentation Tools	As a clinical user, I want the ability to annotate images and clips to support clinical communications between the imager and reviewer and document findings directly in the imaging screen.	I was able to apply text / bodymarks / arrows to images and clips directly in the imaging screen in a similar manner when compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS

User	746170 Workflow Protocols	As a clinical user, I need the ability to work through a guided imaging exam workflow to produce study documentation.	I was able to work through a guided imaging exam workflow and produce study documentation in a similar manner when compared to the comparison device.  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746173 System Usability	As a clinical user, I need the Ultrasound system user interface to be safe to use for me and my patient.	The system risk/hazard analysis provides evidence that the device's user interface is safe and free from unreasonable risks and hazards.	Analysis	Internal	Product Manger	S&E	PASS	8/26/2019	HS
User	746212 Hibernate	As a clinical user, I want to the system startup and shutdown to support portable studies.	I was able to start and shutdown the system in a similar manner when compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746180 eSie OB	As a clinical user, I need automated biometry measurements.	1. The system automatically measures CRL, BPD, OFD, HC, AC, HL and FL 2. Using eSie OB I was able to perform biometric measurements in a similar manner when compared to the comparison device	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
1.1.4 : Clinical Application										



User	746165 VVI	As a clinical user, I want the ability to perform and display Global Longitudinal Strain using Ultrasound images so that I can analyze cardiac function.	1. I was able to use the VVI during the study 2. Using VVI, I was able to perform and display Global Longitudinal Strain using B Mode in a similar manner when compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746164 Stress Echo	As a clinical user, I need to perform exercise and pharmacologic stress echocardiograms with an application that supports the acquisition, display and review workflow.	1. I was able to perform and review a stress echo protocol 2. Using Stress Echo I was able to perform an exam in a similar manner when compared to the comparison device  Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746163 eSieLeftHeart	As a clinical user, I want automated detection of the borders for both Left Ventricle (LV) and Left Atrium (LA)	1. I was able to use eSieLeftHeart to automatically measure left ventricle 2. I was able to use eSieLeftHeart to automatically measure left atrium 3. I was able to perform the eSieLeftHeart Measurements in CINE and Review in a similar manner when	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS

			<p>compared to the comparison device.</p> <p>Pass = An average score of "Meets need" or above</p>							
User	746167 eSieMeasure	As a clinical user, I need to automatically measure frequently used 2D, M-mode and spectral Doppler Labels.	<p>1. Ability to perform eSieMeasure for 2D, M-mode and spectral Doppler measurements in Cardiac Exam.</p> <p>2. Using eSieMeasure, I was able to perform 2D, M-mode and spectral Doppler measurements in a similar manner when compared to the comparison device</p> <p>Pass = An average score of "Meets need" or above</p>	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
User	746166 eSie Follicle	As a clinical user, I need to automatically measure and record follicle.	<p>1. Ability to automatically measure follicle in GYN exam</p> <p>2. Using eSie Follicle I was able measure follicles in a similar manner when compared to the comparison device</p> <p>Pass = An average score of "Meets need" or above</p>	Clinical	Internal	Clinical Experts	S&E	PASS	8/26/2019	HS
1.2 : 858771 Business Needs										

1.2.1 : Licensing

Business	746099 Feature Licensing	As a product manager, I want the ability to configure the system by way of licenses to support customer configuration, sales, service, development and research needs for features and capabilities.	The following features are configurable with licensing: 1. Lic. Security 2. Lic. Encrypted Hard Drive 3. Lic. eSie OB, K2 4. Lic. VT Linear, K2 5 Lic. VT Endo, K2 6. Lic. Contrast, K2 7. Lic. LVO, K2 8. Lic. eSieLH, K2 9. Lic. eSie Measure, K2 8. Lic. eSie Follicle, K2 9. Lic. VT Abd 10. Lic. VT Adv Linear 11. Lic. Panoramic, K2 12. Lic. Stress Echo, K2 13. Lic. VVI, K2	Analysis	Internal	Product Management	S&E	PASS	6/21/2019	MJK
Business	746100 License Management	As a product manager, I want to manage licenses on the system.	License Management shall provide following: 1. Customer accessible license management utility 2. Customer accessible license installation utility 3. License expiration messaging is visible to the user	Analysis	Internal	Product Management	S&E	PASS	6/21/2019	MJK

1.2.2 : Imaging Features

Business	746191 Imaging System Usability	As a product manager, I want the Ultrasound system to be intuitive to learn and use.	Characterization of overall user experience regarding the system interactions and imaging performance during validation. PASS = Average score of 2 or higher.	Clinical	Internal	Product Management	S&E	PASS	8/29/2019	HS
Business	1045580 Imaging Performance	As a product manager, I want the system to be perceived as having competitive imaging performance in terms of speed of transition when interacting with the system imaging tools.	Competitive comparison of imaging transitions and imaging control transitions. PASS = Transition speed of selected parameters/functions are not more than 200 ms slower than the transitions of selected competitors.	Analysis	Internal	Engineer	S&E	FAIL	8/28/2019	HS
1.2.3 : Quality and Reliability										
Business	746291 System Reliability	As a product manager, I want the K2 system to be more reliable than the S1000 system	Confirm test results of K2 Reliability Plan PN 11336176	Analysis	Internal	Hardware	S&E	PASS	8/6/2019	CK
1.2.4 : Patient Data Management										
Business	746199 Hospital\Enterprise Workflow	As a product manager, I want the system to support IHE profiles so that potential customer know	1. IHE Scheduled Workflow profile is implemented 2. IHE Echocardiography Workflow profile is implemented	Analysis	Internal	Connectivity SME	S&E	PASS	8/7/2019	DR

		the systems can interact successfully in connected imaging environment.								
Business	746194 Patient Data Management - Local	As product manager, I want the system to locally store patient information, images, reports, and other procedure-related information obtained while performing an exam, so users can access and use it as part of the overall scheduled workflow.	1. Ability to store and organize exam data locally on the ultrasound system 2. Ability to view an inventory of the exam data stored locally on the system 3. Ability to DICOM print a prior exam from browser.	Analysis	Internal	Product Management	S&E	PASS	8/7/2019	DR
Business	746195 Data Transfer	As a product manager, I want the system to support export/transfer of images and measurement data off the ultrasound system in multiple formats including PC compatible	1. Images and report data can be exported/transferred off the system. 2. The image/clip is converted to a PC compatible format to a USB stick for inclusion in PowerPoint.	Analysis	Internal	Product Management	S&E	PASS	8/7/2019	DR

		formats, so the data can be used on other clinical systems for reporting and diagnosis, or data sharing.								
Business	746202 CEUS Quantification Support	As a product manager, I want the system to export contrast enhanced Ultrasound clips for offline quantification using Bracco CEUS quantification software.	1. Ability to open contrast enhanced Ultrasound clips with the Bracco software Vuebox and perform contrast quantification.	Analysis	Internal	Product Management	S&E	PASS	8/7/2019	DR
Business	746196 DICOM	As a product manager, I want the system to support DICOM so that the system operates in a hospital network.	1. The system conforms to the current DICOM standard. 2. The system supports DICOM Verify 3. The system supports DICOM Store 4. The system supports DICOM Storage Commitment 5. The system supports DICOM Query/Retrieve 6. The system supports DICOM MPPS 7. The system supports DICOM export to offline media and multisession export capability	Analysis	Internal	Product Management	S&E	PASS	8/29/2019	DR

			8. The system supports DICOM Modality Worklist 9. The system provides DICOM Modality Worklist query capability as defined by the IHE Scheduled Workflow Integration Profile							
Business	746201 Operating System	As a product manager I need an Operating system that is supported by the OS vendor.	1. Win10 or higher supported	Analysis	Internal	Product Management	S&E	PASS	8/14/2019	HS
1.2.5 : System Management										

Business	746174 System Configuration	As a product manager, I want system to be configurable to support user workflow.	1. Ability to change System Configuration parameters and save the changes across power cycles 2. Ability to restore System Configuration parameters to their factory default settings on a per page basis	Analysis	Internal	Product Management	S&E	PASS	8/23/2019	BF
Business	746206 Backup and Restore	As a product manager, I want the ability to backup and restore customers system settings so that the custom settings can be restored on the system without an applications specialist visit.	Ability to archive and restore following settings: 1. Imaging / exam presets 2. User defined protocols 3. Ultrasound settings (e.g. Freeze behavior) 4. Measurement and reporting configuration 5. Connectivity configuration 6. System settings (e.g. Security settings, Regional settings).	Analysis	Internal	Clinical and Service	S&E	PASS	8/21/2019	YK; SK
Business	746207 System Communication Connections	As a system administrator, I want the system to connect to facility networks and devices to facilitate data communications.	System provides connectivity: 1. To Ethernet (1Gbit) 2. To Wi-Fi (802.11ac) 3. For USB accessories	Analysis	Internal	Connectivity	S&E	PASS	8/7/2019	DR



Business	746214 Instructions for use	As a product manager, I want system operation documentation to be available in the local languages where we intend to sell the system.	1. Chinese instructions for use (after M300) 2. Danish instructions for use (R6) 3. Dutch instructions for use (R6) 4. Finnish instructions for use (R6) 5. Greek instructions for use (R6) 6. Hungarian instructions for use (R6) 7. Japanese instructions for use (R6) 8. Korean instructions for use (S&E) 9. Norwegian instructions for use (R6) 10. Polish instructions for use (R6) 11. Portuguese (Brazil) instructions for use (R6) 12. Portuguese (Portugal) instructions for use (R6) 13. Romanian instructions for use (R6) 14. Russian instructions for use (R6) 15. Slovak instructions for use (S&E) 16. Swedish instructions for use (S&E) 17. Turkish instructions	Analysis	Internal	Product Manageme nt	S&E and R6	PASS	9/2/2019	HS
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			for use (R6) 18. Vietnamese Instructions for use (R6)							
Business	746209 Peripherals	As a product manager, I want the option to configure peripheral devices such as report printers, thermal printers and a footswitch for users.	1. The clinical user can print a report on an office printer. 2. The clinical user can print an image using a thermal printer. 3. The clinical user can connect, program, and use a footswitch. 4. The clinical user can export study data to a DVD drive. 5. The clinical user can export video data via built in S-VHS	Analysis	Internal	Product Managemen t	S&E	PASS	7/8/2019	JY
Business	746210 Software Install	As a Customer service engineers want the ability to install or reinstall ultrasound software on the system and for users to perform a self- update of software.	1. I am able to install software 2. I am able to reinstall software 3. I am able to upgrade software 4. User is able to perform a self-update of software.	Analysis	Internal	Service	S&E	Fail	8/21/2019	SK

Business	746215 On-Screen Branding	As a product manager, I want branded display screens that are Siemens compliant to communicate the system state/condition to users.	1. The system displays screens on startup and shutdown that communicate the system state 2. The system displays security screens and screen savers that are configurable by the user 3. The system returns to the previous system state from the screen saver in less than 1 second	Analysis	Internal	Product Management	S&E	PASS	8/22/2019	HS
Business	746211 Video Recorder	As a product manager, I want the system to support the ability to record the study acquisition in a continuous manner.	1. Ability to start, pause and stop recording of onscreen video capture 2. Ability to record during exam workflow including image capture, clip capture and measurement 3. Ability to capture for the entire study period continuously for up to 1 hour 4. Ability to export the recording for display on a personal computer	Analysis	Internal	Product Management	S&E	PASS	7/21/2019	MJK

Business	746208 Language Support	As a product manager, I want the system and system documentation to be in the local language on a country by country basis to access sales in the specific market.	1. English on Image screen, User Interface, control panel text and operating instructions 2. French on Image screen, User Interface, control panel text and operating instructions 3. Italian on Image screen, User Interface, control panel text and operating instructions 4. German on Image screen, User Interface control, control panel text and operating instructions 5. Spanish on Image screen, User Interface, control panel text and operating instructions	Analysis	Internal	Product Management	S&E	PASS	8/15/2019	BF
Business	746213 Security	As a product manager, I want the system and data protected so that the operation of the system is not abnormally affected, and the data is not compromised.	1. Verification testing showing software meets current regulations listed in the Manufacturer Disclosure Statement for Medical Device Security (MDS2) 2. Verification testing showing software has no DoD Risk Management Framework (RMF) Category I findings.	Analysis	Internal	Security Officer	S&E	PASS	8/14/2019	SY
1.2.6 : Service										
1.2.6.1 : Service Software and Electronic										

Business	746219 Service Diagnostics	As a field service engineer, I want to run the service diagnostics to isolate the system problem(s) to its hardware and/or software components.	1. Hardware faults are locally and remotely diagnosed to the FRU level, including transducers. 2. Service accessibility to run diagnostic tests on demand when system fails to boot. 3. Software diagnostics will isolate problems to the software component level. 4. Service engineer with Siemens service level permission can access the escape to OS functionality. 5. Diagnostic output is intuitive with failures clearly distinguished and service next steps recommended.	Analysis	Internal	Service	S&E	PASS	8/29/2019	SK
Business	746220 Standardized Logging	As a field service engineer, I want a mechanism to access and capture the system logs for service diagnose and repair.  To reduce the amount of displayed log messages to the most significant ones,	1. The system shall have one service log. 2. The service log will be the central place all Service messages and exceptions are logged. 3. All error messages contain message text that shows the defect. 4. All service-relevant messages contain detailed message text with recommended service actions. 5. All messages are classified by the correct severity. 6. The system service	Analysis	Internal	Service	S&E	FAIL	8/29/2019	SK

		the Service User can filter and sort the service messages by criteria defined in the Message Handling Concept.	log shall be accessible for Siemens Service locally and remotely. 7. The system shall support a Log Analyzer. 8. Message box displayed to the user contain clear messages with useful user actions. 9. Message box errors shall have a unique Service ID (event source + ID) to the error which triggered the pop up. 10. Message box displayed to the user are also available in the service log. 11. Service log messages are limited to the most significant events.							
Business	746221 Siemens Remote Service	As a field service engineer, I want the enhanced features of Siemens Remote Service (SRS).	1. Support "Capture Log" via SRS limited permanent access to provide system information to Siemens without interrupting imaging workflow. 2. Support "System Data Collection (SDC)", provided by H CS SD, to support Siemens Asset Management 3. Support remote option delivery capability (ROD) i e license files and	Analysis	Internal	Service	S&E	FAIL	8/29/2019	SK

			presets. 4. Support remote update handling (RUH) rollback functionality							
Business	746222 Utilization Management	As a field service engineer, I want the system to collect product utilization data for supporting Service Utilization Management.	1. The system will have utilization program to collect predefined system utilization data. 2. The utilization program will be activated by service. 3. The system will enable the full functionality of the System Utilization software by service engineer. This includes continuous data collection (set at the lowest priority) locally on the ultrasound system. Daily reports (for the previous day's events) are generated once a day when the system boots up. 4. When the system is in mobile, the system will enable the data collection and report generation functionalities	Analysis	Internal	Service	S&E	PASS	8/29/2019	SK

			described above. But the reports will NOT be transferred until network connection is established. 5. The system will support the disable the System Utilization software by service engineer. 6. When it is enabled, the utilization reports are automatically transferred to the Siemens SRS backend.							
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Business	746223 Clinical Applications Support (eSie Link)	As an Application Support Specialist, I want to remotely support the end user for system and application usage.	<p>1. The system shall access the Remote Application support tool using the Remote Assistance Support button located on the System Configuration Page (SCP) &gt; Service menu.</p> <p>2. Patient information is not visible to the remote viewer during remote assistance.</p> <p>3. The system shall support audio communication through an external headset.</p> <p>4. The system shall have a fixed and movable virtual keyboard (stays on top) which will allow the remote application support specialist to control the following:</p> <p>a) All imaging knobs, toggles, and buttons</p> <p>b) Keyboard</p> <p>c) Soft Keys</p> <p>d) Trackball</p> <p>e) Picture in the picture</p> <p>f) Virtual Control Panel (VCP): Implement a combination key to launch ext VCP (Top most priority) after TeamViewer is launched.</p> <p>g) A new VCP will be</p>	Analysis	Internal	Service	S&E	PASS	8/29/2019	SK
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			manually launched remotely by a combination key (Ctrl-Alt+S+K) 5. The system shall have capability to support an external camera during Remote Assistance sessions.							
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1.2.6.2 : Service Mechanical

Business	746224 Serviceability for system and FRUs	As the Field Service Engineer, I want to perform service tasks on mechanical and electronic parts within specified time.  Note: The typical service tasks are: installation, trouble shooting, replacing hardware, reloading software, and preventive maintenance.	1. System installation can be completed within 60 minutes by a single person. 2. The system preventive maintenance interval time for all system components shall be at least 2 years. 3. Common Field Replaceable Unit replacement time shall be no more than 30 minutes by a single person. 4. Uncommon Field Replaceable Unit replacement time shall be no more than 120 minutes by single a person.	Analysis	Internal	Service	S&E	PASS	8/29/2019	SK
1.2.7 : 12267 Industrial Design / System HW										
Business	746227 Siemens Family Design	As a product manager, I want the system to conform to the Siemens Healthcare Product Design Guidelines and leverage Siemens imaging system technologies so that the system is recognized as a member of the Siemens	Confirm the system follows the Siemens Healthcare Product Design Guidelines.	Analysis	Internal	ID Engineer	S&E	PASS	6/10/2019	TL

		healthcare product family.								
Business	746228 Portability	As product manager, I want the system to have the ability to move between patient exam rooms and clinical areas so that portable studies can be performed by users.	1. The system can be moved by users between rooms and over thresholds 2. The system supports a steering lock mechanism to facilitate pushing the system from the front 3. The system can be locked into place with easy swivel castors with dual lock. 4. The monitor can be folded down for transport 5. The monitor can be secured for transport	Analysis	Internal	Mechanical Design	S&E	PASS	7/26/2019	NK
Business	746229 Ergonomic Adaptability	As a product manager, I want the system to be ergonomically adaptable so that it can be arranged for comfortable use in a variety of scanning situations when standing or sitting.	1. The user can adjust the control panel height. 2. The user can adjust the control panel lateral alignment. 3. The user can adjust the control panel swivel. 4. The user can adjust the monitor height relative to the control panel. 5. The user can adjust the monitor swivel relative to the control	Analysis	Internal	Product Manager	S&E	PASS	7/3/2019	MS

			<p>panel.</p> <p>6. The user can adjust the monitor tilt.</p> <p>7. The user can make the ergonomic adjustments.</p>							
Business	746230 On-System Peripherals	As a product manager, I want peripheral devices used in conjunction with the ultrasound system to be optional configurable.	<p>1. A black-and-white thermal printer can be configured with the system.</p> <p>2. A super drive can be configured with the system</p> <p>3. The optional peripheral devices can be configured to the system in a cosmetically integrated manner</p> <p>4. A USB two button footswitch for system control can be configured with the system</p>	Analysis	Internal	Product Management	S&E	PASS	7/8/2019	JY
Business	746231 On-System Storage	As a product manager, I want the system to support storage space on the ultrasound system so users can store and	<p>1. Storage for documents is provided.</p> <p>2. Storage for 2 extra (not connected) transducer pods is provided.</p> <p>3. Storage for extra gel, wipes, gloves, ECG leads and other</p>	Analysis	Internal	Product Management	S&E	PASS	7/11/2019	HS

		transport transducers, accessories, and supplies with the system.	ultrasound accessories is provided.4. Storage for 6 transducers is provided. 5. Storage is provided for 5cm and 8cm diameter gel bottles. 6. Storage with built in warming is provided for 5cm diameter gel bottles. 7. Cable management is provided to keep the transducers cables off the floor and out of the way. 8. Cable management is provided to keep the AC power cord off the floor and out of the way during transport 9. Storage for miscellaneous items is provided							
Business	746232 Integrated Imaging Support	As a product manager, I want integrated support for transducers of the new "M1/M2" specific design, CW transducers, and physiological monitoring so that I can access markets and intended users.	1. The user is able to connect simultaneously as many as 4 transducers of the new K2-specific design. 2. The user is able to connect a single dedicated CW transducer such as the CW2. 3. The user is able to image with any one of the connected transducers, without having to disconnect the others.	Analysis	Internal	Product Management	S&E	PASS	6/24/2019	HS

			<p>4. The user is able to monitor patient ECG and TIR with integrated capabilities of the system.</p> <p>5. The user is able to import of external physiological monitor signals for use in place of the integrated physiological monitoring.</p> <p>6. The user is able to export the integrated physiological monitor signals to external monitoring equipment.</p>							
Business	746233 Control Panel	As a product manager, I want the system to support a control panel with a touch screen.	<p>1. Includes a touch panel interface, at least 13.3"</p> <p>2. Includes a control surface with dedicated knobs, buttons, and trackball</p> <p>3. Includes a QWERTY that can be accessed on the touch panel</p>	Analysis	Internal	Product Management	S&E	PASS	7/10/2019	HS
Business	746234 Video Output	As a product manager, I want the system to support an imaging monitor with the ability to view the ultrasound image from a range of angles and in a range	<p>1. The monitor viewing angles and contrast resolution support Ultrasound imaging.</p> <p>2. Monitor brightness is appropriate for dark scan environments and bright operating room environments.</p>	Analysis	Internal	Product Management	S&E	PASS	8/5/2019	YK

		of ambient light environments.								
Business	746235 Audio Output	As a product manager, I want the system to support audio output so that Doppler audio as well as receive audible cues from the system user interface can be heard by the user.	1. I can enable and hear audible cues. 2. I can hear Doppler audio.	Analysis	Internal	Product Management	S&E	PASS	8/6/2019	HS
Business	746237 Transducers and Ports	As a product manager, I want transducers to have a new industrial design consistent with the ultrasound system industrial design so that the overall system has a cohesive design.	1. Transducer design is aligned with ultrasound system design 2. Transducers will be uniquely different from S Family and SC2000 equivalent transducers 3. Transducer name will be visible on the transducer handle 4. The name of the transducer in the currently active port is backlit	Analysis	Internal	ID Engineer	S&E	PASS	6/11/2019	TL
1.2.8 : 859360 Sys Care										
Business	746240 Production Testability	As a manufacturing engineer, I want a simplified	Confirm achievement of the DFT targets from the Siemens DFX scorecard.	Analysis	Internal	SCM	S&E	PASS	8/14/2019	BH



		means to load software that includes diagnostic tools to objectively assess system hardware quality.								
1.2.8.1 : 859368 Mechanical										
Business	746248 Manufacturability	As a manufacturing engineer, I want the system designed for manufacturability.	Confirm achievement of the target DFM Score.	Analysis	Internal	SCM	S&E	PASS	8/14/2019	BH
Business	746243 Packaging	As a packager and un-packager, I want the system shipping configuration to provide: <ul style="list-style-type: none"> <li>• Efficient packaging of the system, transducers and accessories.</li> <li>• Efficient un-packaging to promote minimal field service or contracted installation service installation time.</li> <li>• Protection of</li> </ul>	1. System package meets applicable IASTAM standards for distribution worldwide by air and land transport 2. Full system with accessories to be packaged efficiently 3. Un-packaging, installation, and power-on functional test to take less than 1 hour by a single service engineer 4. The system shall be capable, while packed for transport or storage, of withstanding environmental conditions for (transport, temperature, Relative	Analysis	Internal	SCM	S&E	PASS	8/14/2019	BH

		the system to the environments of transport (mode, temperature, humidity, elevation). • Provide all of the required labeling to deliver anywhere in the world. • Package Size complies with airline requirements lower deck shipping.	Humidity, atmospheric pressure) 5. The system packaging meets all referenced labeling standards. 6. Package height maximum of 62". This will comply with all airlines carrier lower decks except A320							
1.2.9 : 889428 PREP										
Business	746250 Regulatory Compliance	As a product manager, I want the K2 system to be compliant to all applicable regulations, both Siemens corporate and government regulatory.	System and its packaging are compliant with Standards and Regulations document 7477230-QMS-002	Analysis	Internal	Compliance	S&E	PASS	8/6/2019	TL
Business	746254 Product Related Environmental Protection Laws and Regulations	As a product manager, I want the system to comply with product related environmental protections laws and	Confirmation that PREP Requirements and Guidelines [14] have been met and adhered to.	Analysis	Internal	EHS	S&E	PASS	7/14/2019	KJ

		regulations, so that I can sell products in the EU.								
Business	746255 Shipment by Air Laws and Regulations	As a manufacturer, I want to ship the system by air even if it has lithium batteries, so that I can ship products faster.	K2 complies with ICAO Technical Instructions For The Safe Transport Of Dangerous Goods By Air (Doc 9284)	Not applicable because K2 system does not have lithium ion batteries with a capacity more than the IATA Dangerous Goods Regulations				PASS	8/22/2019	-HS
Business	868316 Acoustic Output Control and Reporting	As a product manager, I want the K2 system to be compliant to all applicable regulations relating to Acoustic Output Control and Reporting.	System is compliant with Acoustic Output Standards as documented in the Compliance Report.	Analysis	Internal	Compliance	S&E	PASS	8/6/2019	TL
1.1 : Transducers										
Transducer	5C1 - Abdominal	As a clinical user, I want the 5C1 to perform Abdominal examinations.	Average score of applicable imaging functions meets user needs for Abdominal examinations. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	5C1 - Fetal	As a clinical user, I want the 5C1 to perform Fetal examinations.	Average score of applicable imaging functions meets user needs for Fetal exams. Pass = An average score of "Meets	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS

			Needs" or above.							
Transducer	10V4 - Abdominal	As a clinical user, I want to use 10V4 to perform Abdominal examinations.	Average score of applicable imaging functions meets user needs for Abdominal examinations. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	10V4 - Cardiac	As a clinical user, I want to use 10V4 to perform routine transthoracic echocardiography (TTE) examinations	Average score of applicable imaging functions meets user needs for TTE exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	10V4 - Neonatal	As a clinical user, I want to use 10V4 to perform Neonatal examinations.	Average score of applicable imaging functions meets user needs for Fetal exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/31/2019	HS
Transducer	10V4 - Pediatric	As a clinical user, I want to use 10V4 to perform routine examinations on Pediatric patients.	Average score of applicable imaging functions meets user needs for Fetal exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	10L4 - Vascular	As a clinical user, I want to use 10L4 to perform peripheral vessel exams.	Average score of applicable imaging functions meets user needs for peripheral vessel exams. Pass = An average score of "Meets Needs" or	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS

			above.							
Transducer	10L4 - Small Organs	As a clinical user, I want to use 10L4 to perform small organ examinations.	Average score of applicable imaging functions meets user needs for Superficial Structure exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	10L4 - Abdominal	As a clinical user, I want to use 10L4 to perform Abdominal examinations.	Average score of applicable imaging functions meets user needs for peripheral vessel exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	10L4 - Fetal	As a clinical user, I want to use 10L4 to perform Fetal examinations.	Average score of applicable imaging functions meets user needs for peripheral vessel exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	10L4 - MSK Superficial	As a clinical user, I want to use 10L4 to perform MSK superficial examinations.	Average score of applicable imaging functions meets user needs for MSK superficial examinations. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	10L4 - MSK Conventional	As a clinical user, I want to use 10L4 to perform MSK	Average score of applicable imaging functions meets user needs for MSK	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS

		Conventional examinations.	Conventional examinations. Pass = An average score of "Meets Needs" or above.							
Transducer	9C3 - Abdominal	As a clinical user, I want to use 9C3 to perform Abdominal examinations.	Average score of applicable imaging functions meets user needs for Abdominal examinations. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	9C3 - Fetal	As a clinical user, I want to use 9C3 to perform Fetal examinations.	Average score of applicable imaging functions meets user needs for fetal exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	4V1 - Abdominal	As a clinical user, I want to use 4V1 to perform abdominal examinations.	Average score of applicable imaging functions meets user needs for abdominal examinations. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	4V1 - Fetal	As a clinical user, I want to use 4V1 to perform Fetal examinations.	Average score of applicable imaging functions meets user needs for fetal exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	9EC4- Transvaginal	As a clinical user, I want to use 9EC4 to perform transvaginal examinations.	Average score of applicable imaging functions meets user needs for transvaginal exams. Pass = An average score of	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS

			"Meets Needs" or above.							
Transducer	9EC4-Transrectal	As a clinical user, I want to use 9EC4 to perform transrectal examinations.	Average score of applicable imaging functions meets user needs for transrectal exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	14L5-Peripheral Vessel	As a clinical user, I want to use 14L5 to perform peripheral vessel exams.	Average score of applicable imaging functions meets user needs for peripheral vessel exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	14L5-Small Organ	As a clinical user, I want to use 14L5 to perform small organ exams.	Average score of applicable imaging functions meets user needs for Small organ exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	14L5-MSK Superficial	As a clinical user, I want to use 14L5 to perform MSK superficial examinations.	Average score of applicable imaging functions meets user needs for MSK superficial examinations. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	14L5-MSK Conventional	As a clinical user, I want to use 14L5 to perform MSK	Average score of applicable imaging functions meets user needs for MSK	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS

		Conventional examinations.	Conventional examinations. Pass = An average score of "Meets Needs" or above.							
Transducer	8V3-Cardiac	As a clinical user, I want to use 8V3 to perform Cardiac examinations.	Average score of applicable imaging functions meets user needs for Cardiac examinations. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	8V3-Abdominal	As a clinical user, I want to use 8V3 to perform Abdominal examinations.	Average score of applicable imaging functions meets user needs for Abdominal examinations. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	5V1-Cardiac	As a clinical user, I want to use 5V1 to perform Cardiac examinations.	Average score of applicable imaging functions meets user needs for Cardiac examinations. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	18L6-Small Organ	As a clinical user, I want to use 18L6 to perform small organ exams.	Average score of applicable imaging functions meets user needs for Small organ exams. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	18L6-MSK Conventional	As a clinical user, I want to use 18L6 to perform MSK	Average score of applicable imaging functions meets user needs for MSK	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS



		Conventional examinations.	Conventional examinations. Pass = An average score of "Meets Needs" or above.							
Transducer	18L6-MSK Superficial	As a clinical user, I want to use 18L6 to perform MSK superficial examinations.	Average score of applicable imaging functions meets user needs for MSK superficial examinations. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS
Transducer	V5Ms-TEE	As a clinical user, I want to use the V5Ms to perform TEE examinations	Average score of applicable imaging functions meets user needs for TEE examinations. Pass = An average score of "Meets Needs" or above.	Clinical	Internal	Clinical	S&E	PASS	8/28/2019	HS

## 10.0 EXCEPTIONS

### 746210 - Software Install

Result: FAIL

Acceptance criteria #1 "I am able to install software"– Fail: The system serial number was corrupted (set to the default serial number 900111) and the license became invalid after software re-installation (Defect 1169496).

Acceptance criteria #4 "User is able to perform a self-update of software" – Fail: User could not enter verification code after scanning the QR code, since the virtual keyboard (to enter the verification code) was inactive. This will cause endless pop-ups requiring a user to type- in the code when system boots up (Defect 1246789).

Product management recommendation is to accept this business needs exception for VA10A. This business needs failure does not impact user needs or intended use and will be fixed in VA10B before M300.

### 746220 - Standardized Logging

Result: FAIL

Acceptance criteria #-3 "All error messages contain message text that shows the defect" - Fail

Acceptance criteria #4 "All service-relevant messages contain detailed message text with recommended service actions" - Fail

Acceptance criteria # 5 "All messages are classified by the correct severity"--Fail

Above three criteria were not met due to a compatibility issue between the event viewers of Microsoft and syngo software, and some contents are not implemented yet (Defect 1243254).

Product management recommendation is to accept this business needs exception for VA10A. This business needs failure does not impact user needs or intended use and will be fixed in VA10B before M300.

#### **746221- Siemens Remote Service**

Result - FAIL

Acceptance Criteria #3 “Support remote update handling (RUH) rollback functionality” – Fail: The test package was not transferred from the server to the system while it was no problem to transfer the test package to other systems; Looking at the server log, it was found that the server kept trying to send the package, but the system was not accepting it (Defect 1248095 and 1253806).

Product management recommendation is to accept this business needs exception for VA10A. This business needs failure does not impact user needs or intended use and will be fixed in VA10B before M300.

#### **1045580 – Imaging Performance**

Result – FAIL

Analysis of imaging transition comparison with competitive systems did not confirm the business need as defined, however the performance of the system is significantly improved as compared to the predicate device and is competitive (PASS) in transition speed as compared to one competitor in 23 functions but failed in 5 functions. Transition speeds as compared to a higher-end competitive device were better than or within 200ms in 26 functions (PASS) but failed in 2 functions. Product management recommendation is to accept this business needs exception for VA10A. The goal was not reached, but the performance is significantly improved as compared to the predicate device and more competitive. This business needs failure does not impact user needs or intended use.

#### **746194 - Patient Data Management – Local**

**Result – PASS**

Defect # 1257820 for grammatical error on wireless configuration page

### **11.0 DOES NOT MEET NEED - DEFECTS CREATED**

Memo “K2\_VA10ADNMN\_Defects.docx” lists the defects created for items scored as “Does Not Meet Need” during the user needs validation. As defined in section 2.6 – Methods, of the K2 VA10A Design Validation and Business Confirmation Plan, a defect was created for a response of 1 (Does not meet need) per the TFS DM Work Instructions.

### **12.0 CLINICAL DEVELOPMENT SUMMARY**

Memo “K2\_VA10A\_ClinicalSummary\_Validation\_Memo.docx” summarizes the activities of the Clinical Development team during the validation and confirmation activity.

SAP-EDM Signature Information  
- generated automatically by SAP system P41 -

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<b>APPROVAL</b>	<b>2019-09-11T04:37:39</b>	<b>OH, HYEWON</b>