Siemens Healthineers
Business Area Ultrasound

Title: K2 VA20C Design Validation and Business Confirmation Plan

Part Number: 11575970-EPH-001-03

Revision Data

Rev	ECO #	Change Description	Printed Name
03	740729	Speed of Sound criteria added	Cho, HyunChin

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Revision History

Rev	ECO #	Change Description	Printed Name
01	720436	Initial version	Craig Williams
02	731969	Validation Spreadsheet Update	Craig Williams
03	740729	Speed of Sound criteria added	Cho, HyunChin

CONTENT

1.0 PURPOSE

The purpose of the K2 VA20A Design Validation and Business Confirmation Plan for Release VA20A is to provide the validation plan for the K2 product as defined by K2 VA20A Requirement Specifications [8]. The RS document defines the user needs and intended use, business needs for K2 with Release VA20A.
** Additional note :
At revision 03, VA20C Speed of Sound scope is added. Corresponding CRS revision is 05.

2.0 SCOPE

The K2 Design Validation and Business Confirmation Planform Release VA20A 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 VA20A 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.

The comprehensive report of design validation and Business Confirmation will be compiled by the Product Manager (or designee) who will maintain the record in the product design history file and issue the final Design Validation Report and any summary information necessary to support program activities. All requirements must have a result of Pass, Fail or Deferred in the final report.

This validation plan is an addendum (delta document) to the previous release of the K2 VA10A Design Validation and Business Confirmation Plan (11151405) and the features/functions released from VA10 will be covered by VA10 report.

2.1 Objective

The objective is to validate/confirm K2 with Release VA20A intended uses, user needs, business needs and applicable transducer requirements as identified in the following documents:

Document Title	Document Number
K2 VA20A CRS	11370958-EPH-001-05
7VC2 TRS	11289565-EPH-001
9VE4 TRS	11289564-EPH-001
9C3 TRS	10787405-EPH-001
18H6 TRS	11289567-EPH-001
9EC4 TRS	10787409-EPH-001

2.2 CLINICAL USERS / CLINICAL APPLICATIONS SPECIALISTS

For clinical activities, all scanning is conducted by sonographers that include Clinical Application Specialists at Siemens or clinical sonographers/physicians/trained technicians/trained specialists external to Siemens. All personnel conducting ultrasound scanning will be trained on the product and the features.

2.3 USER RECRUITMENT

All clinical users will provide current CV and completion certificates for human subjects' protection training to qualify as a sonographer for the clinical activities.

2.4 MODEL RECRUITMENT

Human subjects will be recruited via the volunteer database, allowable advertising or through referrals by local clinics. Current or previous employees may also be recruited as study subjects. Current employees are informed that participation/lack of participation in the study will not impact their employment with Siemens in any way.

2.5 COMPARISON

- Siemens ACUSON S3000 Ultrasound System, HELX Evolution with Touch Control VE10 (K162243) and ACUSON Sequoia 1.2
- ACUSON Juniper 1.5 for the following feature: eSieFollicle.
- Philips Affinti 70 for CEUS feature on 18H6 & 18H6

K2 VA20	Predicate device	Transducer
7VC2	S3000	7CF2
9VE4	Sequoia 1.2	9VE4
9C3	Redwood VA10A	9C3
9EC4	S3000	MC9-4
18H6	Sequoia 1.2 (BCD Modes)	18H6
18H6	Philips Affinti 70	L12-5
18L6	Philips Affiniti 70	L12-5

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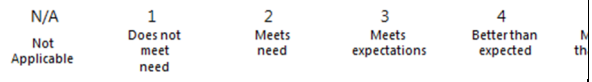
The comparison device and transducers are the functional and clinical equivalent of the K2 system and transducers. The frequency ranges, transducer formats, transducer specific functions, general system functions and indications for use are substantially equivalent.
The comparison device will be the basis for comparison and analysis of clinical uses, functions and capabilities.

2.6 METHODS

Validation of the User needs includes a composite of clinical use, simulated clinical use (Clinical), usability validation (Usability), and phantom analysis (Analysis) individually or in combination.

The Business needs confirmation (Business) of the report is accomplish through analysis and /or testing methods that confirm the success or failure of meeting the business goals.

See below for validation/confirmation methodology.

No	Validation Method	What (Description of Methodology)	How (Specific Related Tasks)
1	**Clinical**	Clinical A/B comparison between the comparison device and the device for validation using a standard image acquisition protocol for validation of clinical use in a human subject or phantom in a clinical environment or simulated clinical environment.	• A case report form is completed for each clinical A/B comparison and questions for items utilized are answered using the scale provided.  • The minimum number of Clinical uses and testers are defined in sections 6.4, 6.5, 6.6 and 6.7 in this document and includes number of performed studies and feature uses to be eligible for a pass. • A response is required for each question. • A response of N/A (Not Applicable) is selected when a question cannot be addressed (not available, not evaluated). • A response of 1 (Does not meet need) indicates that the user need has not been met. • A defect must be created for a response of 1 (Does not meet need) per the TFS DM Work Instruction [2]. • A response of 2 (Meets need) or higher indicates the user need has been met in comparison to the comparison device. • A response of 3-5 (Meets expectations – Much better than expected) indicates the degree to which the user expectation has been met in comparison to the comparison device. • Users are instructed to record defects, comments and preference feedback in the case report form in the designated section.

2	**Analysis**	A/B comparison of phantom images and data or any test method as described for a specific requirement
		
		Confirmation of business needs by analysis or testing (e.g. functional, stress, structure, material and compliance testing)
			• An Analysis test report is completed for phantom testing.
			• A summary copy of any special test record will be included with the validation report, including the pointer indicating where any detailed information is kept in the Design History File.
			• For business needs, confirmation by multiple types of testing is achieved:
			  ○ Functional testing considers whether the product is actually doing what it is supposed to do
			  ○ Structural and Material testing
			  ○ Compliance testing to make sure the system complies with specific standards as establishe by regulators
			  ○ Performance testing

No	Validation Method	What (Description of Methodology)	How (Specific Related Tasks)
3	**Usability**	Methods to validate the user interface elements identified in the Usability Validation Plan [3] in compliance with the requirements of IEC 62366 and the Usability Engineering Process [4]	• A Usability test report is completed to meet the stated goals of Usability Validation Plan. • A pointer to copy of usability test report will be included with the validation report.

3.0 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 VA20A 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

4.0 ABBREVIATIONS, ACRONYMS & Definitions

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

Term	Definition
S&E	See Product Life Cycle Process [15], K2 M270 Work Instruction [16]
TRS	Transducer Requirement Specification
TS	Touch Screen
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

5.0 VALIDATION SPREADSHEET DEFINITIONS

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

Requirement ID Column
This column lists the requirement identification.

Requirement 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 Source 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.

Validation Result Column

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

Date Column
Date requirement was submitted for inclusion in the report.

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

6.0 VALIDATION PROCEDURE

The User Needs Validation will be documented by the assigned Validation Tester(s) for the various validation requirements defined on the attached template Validation report in Section 8. The Validation Tester documents the production equivalent system Serial Number and Software Version on the worksheet. The Validation Tester determines that the trace tag requirement listed on the worksheet is present and functioning on the system as defined in the acceptance criteria. The Validation Tester summarizes all test results on the worksheet, initials and dates the line item tested. Line items not tested on the date of the activity will be marked “Not Tested”, initialed and dated.

Prior to beginning testing, the Validation Tester will verify that the documentation for the test machine configuration (production configuration) and comparison system (s) have been filed in the DHF and the Validation Tester will record the serial number and exact software version on the test spreadsheet. For each requirement listed, the Validation Tester will operate the system in a manner that will allow pass/fail decision of the requirement and document the outcome in CRFs as objective evidence.

6.1 Operating Conditions

For Clinical tests, the system will be used in simulated or routine clinical environment. The scanning room must fit a scanning bed and the system. Specific Environmental conditions will be noted in addition to the system ID number to the CRF:

- Ambient temperature (without OEM’s). Note how temperature was determined.
- Lighting conditions during scanning

6.2 Labeling Requirements

For the purpose of the Validation Production equivalent equipment must be used and documented evidence of Product Equivalent HW for validation needs to be located in the DHF. In case the system does not have 510(k) market clearance an Investigational Device Label is required. (p/n 10436916). If the system is 510K cleared but pre-released it will be labeled as “Not for commercial distribution” (p/n 10437243)

6.3 Additional documents

All documents used to generate reports and memos must be kept in the DHF. These are auditable therefore must follow retention period as defined in Quality Records/Documentation Retention [7].

6.4 Minimum Number of Studies by Transducer/Clinical Use

	Abdominal	Pediatric	Obstetric	Gynecological	MSK	Total
7VC2	5	N/A	6	5	N/A	16
9VE4	N/A	N/A	5	5	N/A	10
9C3	N/A	N/A	6	N/A	N/A	6
9EC4	N/A	N/A	N/A	5	N/A	5
18H6	N/A	5	N/A	N/A	5	10
5C1 – SoS	8	N/A	N/A	N/A	N/A	8
Total	13	5	17	15	5	55

Studies
Total 55

6.5 Minimum Transducer Specific Uses

	Auto TEQ	Freehand 3D	Contrast	Panoramic	Speed of Sound	Total
7VC2	5	N/A	N/A	5	N/A	10
9VE4	5	N/A	N/A	5	N/A	10
9C3	5	N/A	N/A	N/A	N/A	5
18L6	N/A	N/A	5	N/A	N/A	5
18H6	5	N/A	5	5	N/A	15
9EC4	N/A	5	N/A	N/A	N/A	5
5C1	N/A	N/A	N/A	N/A	8	8
Total	20	5	10	15	8	58

Transducer Specific 58

6.6 Minimum Number of Console Uses

Console Uses	Patient Registration	Annotations	Body Markers	Arrows	Dual	eSie OB	eSie Follicle	Workflow Protocols	Mixed Modes	Cine	Acquire	Review	Measurement	Clarify	Report	Total
Console	15	15	15	15	15	5	10	15	15	15	15	15	15	15	15	210
Total	15	15	15	15	15	5	10	15	15	15	15	15	15	15	15	210

General System: 210

6.7 Minimum Number of Clinical Users

The minimum unique clinical users that perform validation activities for the clinically validated requirements are 3.

6.8 Statistical Rationale

The Validation minimum sample will be based on the severity level of the validation item and follow the "Risk based Attribute sampling guideline for Process Verification and Validation "as outlined in the Statistical Sampling Guidance (PN 11507621-QMS-001). A question in the CRF is considered as one challenge; one CRF has multiple (26) challenges; a conservative assumption is that a minimum of three challenges (samples) are being executed per CRF. Based on the R&H file, the average severity for the clinical and transducer needs is 2 except Biopsy and TEE transducer, which have a risk severity of 3. A severity of 2 requires a minimum of 14 challenges to achieve 95% Confidence and 80 % Reliability with validation. A risk severity 3 requires a sample size of 29 (95% Confidence & 90% Reliability) for validation. Assuming a minimum of 3 challenges per case, a minimum of 5 respectively 10 validation cases are necessary.

Severity Risk & Hazard	Severity	Sample Size	Cases*
4	Catastrophic	59	20
3	Critical	29	10
2	Moderate	**14**	**5**
1	Negligible	11	3

(3 challenges per CRF)

This Design validation scope are not included for Biopsy and TEE transducer which have a risk severity of 3. Therefore, the sample size of design validation is selected to 14.

This plan will conduct Individual Test Challenges in Test Groups of 5. The user needs are being challenged in a robust fashion to determine that the needs are met or exceeded. The decision of the A&B comparison will be that the Score Average from 1 through 5. A PASS of each user need will be greater than or exceeds a score of 2, "Meets Expectation".
The Accept or Reject-Fail for the "A"(S3000, Sequoia, K2 VA10, Affiniti70 or Juniper) & "B"(K2 VA20)" comparison is based on average of the rating scored by the users comparing S3000, Sequoia, K2 VA10, Affiniti70 or Juniper with K2 VA20.

7.0 CONFIRMATION PROCEDURE

The Business Needs Confirmation will be documented by the assigned Tester(s) for the various confirmation requirements defined on the attached template Validation report in Section 8. The Tester documents the production equivalent system Serial Number and Software Version on worksheet. The Tester determines that the trace tag requirement listed on the worksheet is present and functioning on the system as defined in the acceptance criteria. The Tester summarizes all test results on the worksheet, initials and dates the line item tested. Line items not tested on the date of the activity will be marked "Not Tested", initialed and dated.

Prior to beginning testing, the Tester will verify that the documentation for the test machine configuration (production configuration) and comparison system (If needed) have been filed in the DHF and the Tester will record the serial number and software version on the test spreadsheet. For

each requirement listed, the Tester will operate the system in a manner that will allow pass/fail decision of the requirement and document the outcome in CRFs as objective evidence.

7.1 Labeling Requirements

For the purpose of the Confirmation, Production equivalent equipment must be used and documented evidence of Product Equivalent HW for validation needs to be located in the DHF. In case the system does not have 510(k) market clearance an Investigational Device Label is required. (p/n 10436916). If the system is 510K cleared but pre-released it will be labeled as “Not for commercial distribution” (p/n 10437243)

7.2 Additional documents

All documents used to generate reports and memos must be kept in the DHF. These are auditable therefore must follow retention period as defined in Quality Records/Documentation Retention [7].

Validation Tester ID: _____System SN#_____SW Version: _____Date: ___
Transducer SNs:_____

8.0 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 : K2 Category PIMS User Needs										
User	1350744 CRS_K2_3DReview	As a clinical user, I want the ability to review data sets 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 predicate device. 2. I was able to review image data from previous studies in a similar manner when compared to the predicate device. Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E			
User	1131911 CRS_K2_User DocAppend	As a product manager, I want the additional feature and transducers to be documented	The following Instruction for use are available 1. Chinese instructions for use 2. Croatian instructions for use 3. Czech instructions	Clinical	Internal	Technical communication	S&E			

		in an appendix, to append to existing user documentation for 1.0 release	for use 4. Danish instructions for use 5. Dutch instructions for use 6. Finnish instructions for use 7. Greek instructions for use 8. Hungarian instructions for use 9. Japanese instructions for use 10. Korean instructions for use 11. Lithuanian instructions for use 12. Norwegian instructions for use 13. Polish instructions for use 14. Portuguese (Brazilian) instructions for use 15. Portuguese (European) instructions for use 16. Romanian instructions for use 17. Russian instructions for use 18. Serbian instructions for use 19. Slovak instructions for use 20. Slovenian instructions for use 21. Swedish instructions for use 22. Turkish instructions for use 23. Ukrainian instructions for use							

			24. Vietnamese instructions for use 25. Bulgarian instructions for use 26. Indonesian instructions for use							
User	1350733 CRS_K2_3DCapture	As a clinical user, I need the ability to acquire image and clips and volumes to document the study and findings.	1. I was able to use capture during the study 2. Using image and clip and volume capture, I was able to complete the study in a similar manner as compared to the predicate device	Clinical	Internal	Clinical Experts	S&E			
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 eSieImage during the study 2. Using eSieImage I was able to visualize anatomy in real time with the ability to add modes (PW; Color, CEUS) 3. Using eSieImage, 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			

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.	1. I was able to use Contrast Mode during the study 2. Using Contrast Mode, I was able to visualize contrast in real time with the ability to adjust the image display for my preference 3. Using Contrast Mode, I was able to visualize contrast in a similar manner as compared to the comparison device Pass = An average score of "Meets need" or above	Analysis	Internal	Systems Engineering	S&E			
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.	1. I was able to use Panoramic during the study 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 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	Clinical	Internal	Clinical Experts	S&E			

			compared to the comparison device Pass = An average score of "Meets need" or above							
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			
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			
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	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	Clinical	Internal	Clinical Experts	S&E			

		against another image with different image views, modes or time.	Pass = An average score of "Meets need" or above							
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			
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			
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			

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			
User	1671723 CRS_K2_SpeedofSound	As a clinical user, I want to use Speed of Sound.	1. I was able to use Speed of Sound adjustment on transducers during the study 2. Using speed of sound, I was able to visualize anatomy in real-time with helping to reduce B mode tissue architecture distortion in fatty tissue, comparing to the feature off. Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E			

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.	1. I was able to use the measurement functions during the study. 2. I was able to select appropriate measurements to support my clinical need in a similar manner when compared to the comparison device. 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. Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E			
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			

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			
User	746170 Workflow Protocols	As a clinical user, I need the ability to work through a guided imaging exam workflow to produce study documentation.	Using workflow protocol, I was able to work through a guide imaging exam workflow and produce study documentation more efficiently Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E			
User	746180 eSie OB	As a clinical user, I need automated biometry measurements.	1. The system automatically measures BPD, 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			

User	746166 eSie Follicle	As a clinical user, I need to automatically measure and record follicle.	1. Ability to automatically measure follicle in GYN exam 2. Using eSie Follicle I was able to measure follicles 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			
1.1.6 : 3D4DMode										
User	1131949 CRS_K2_Freehand_EV	As a clinical user, I want the ability to scan Freehand 3D for endometrial reconstruction with the regular EV transducer Notes: Rocked acquisition only.	. I was able image a volume of the endometrium for endometrial reconstruction 2. I was able to do visualize image planes not available in 2D imaging 3. I was able to adjust the volume display for my preference in a similar manner as compared to the predicate device.	Clinical	Internal	Clinical Experts	S&E			

User	746149 CRS_K2_3D4D Mode	As a clinical user, I want the ability to scan using 3D/4D Mode to visualize in real time scan planes not achievable in 2D imaging alone, and to assess surface anatomy and structural relationships with a volume rendered image.	1. I was able to perform a 3D exam in a similar manner when compared to the comparison (S3000) device 2. I was able to perform a 4D exam in a similar manner when compared to the comparison device (S3000) 3. I was able to use a Curved VOI is set up Mode 4. Using 3D4D I was able to and to better analyze surface anatomy and structural relationships with a volume rendered image in a similar manner when compared to the comparison device (S3000) Pass = An average score of "Meets need" or above	Clinica	Internal	Systems Engineering	S&E			
User	1350735 CRS_K2_3DMeasurements	As a clinical user, I want the system to provide the ability to make measurements that support my clinical needs.	1. I was able to use the measurement functions during the study. 2. I was able to select appropriate measurements to support my clinical need in a similar	Clinical	Internal	Clinical Experts	S&E			

			manner when compared to the predicate device. 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 predicate device. 4. I was able to make measurements and label measurements in the MPRs Pass = An average score of "Meets need" or above							
User	1350736 CRS_K2_3DAnnotation	As a clinical user, I want the system to provide the ability to annotate that support my clinical needs.	1. I was able to use the annotation functions in 3D mode 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			
User	746131 CRS_K2_7VC2	As a clinical user, I need the system to support an abdominal volume transducer.	An average score of applicable 7VC2 imaging functions meets user need. Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E			

User	746134 CRS_K2_9VE4	As a clinical user, I need the system to support an endovaginal volume transducer.	An average score of applicable 9VE4 imaging functions meets user need. Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E			
User	1325322 CRS_K2_18H6	As a clinical user, I want the system to support a high frequency linear transducer in a hockey stick from factory. NOTES: exams supported General and MSK (Default)	An average score of applicable 18H6 imaging functions meets user need. Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E			
User	1351795 CRS_K2_18H6 -Contrast	As a clinical user I want the ability to use contrast feature with the 18L6	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			

User	1345515 CRS_K2_18L6-Contrast	As a clinical user I want the ability to use contrast feature with the 18L6	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			
User	746138 9EC4 Transducer	As a clinical user, I need the system to support an endocavity transducer.	An average score of applicable 9EC4 imaging functions meets user need. Pass = An average score of "Meets need" or above	Clinical	Internal	Clinical Experts	S&E			
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			
1.2 : 858771 Business Needs										
1.2.1 : K2 Category Platform										
Business	1350746 CRS_K2_3DFreehandLicense	As a clinical user, I want the ability to scan Freehand 3D for endometrial reconstruction with the regular EV	1. I was able image a volume of the endometrium for endometrial reconstruction 2. I was able to do visualize image planes not available in 2D imaging 3. I was able to	Clinical	Internal	SYT	S&E			

		transducer Notes: Rocked acquisition only	adjust the volume display for my preference in a similar manner as compared to the predicate device.							
1.2.2 : K2 Category PIMS Business Needs										
Business	1350748 CRS_K2_3DDICOM	As a product manager, I want the system to support DICOM capabilities 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 Print 6. The system supports DICOM Query/Retrieve 7. The system supports DICOM Modality Worklist query capability as defined by the IHE Scheduled Workflow Integration Profile 8. The system supports DICOM MPPS 9. The system supports DICOM export to offline media. 10. The system	Analysis	Internal	SYT	S&E			

			support DICOM Grayscale standard display function (GSDF). Validated by Product Management based on connectivity test							
Business	1350749 CRS_K2_3DDataTransfer	As a product manager, I want the ability to export/transfer images and measurement data off the ultrasound machine in multiple formats including PC format, so the data can be used on other clinical systems for reporting and diagnosis, or data sharing	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	SYT	S&E			
1.2.3 : K2 Category Environmental Requirements										
Business	1527984 RS_Plastic_Labeling	As a customer I want the system to be able to identify plastic materials so that decisions concerning handling, waste recovery or	All thermoplastic parts greater than 500 grams are marked as recyclable.	Analysis	Internal	Mechanical team	S&E			

		disposal is properly implemented at end-of-life.								
Business	1528062 RS_Environmental_and_Hazardous_Labeling	As a manufacturer I want the system to comply with country-specific environmental and hazardous material requirements so the system can be shipped	Labels, manual, and other documentations meet country-specific environmental and hazardous material requirements	Analysis	Internal	Material compliance	M300			
Business	1528070 RS_Reduced_Electricity_Usage	As a manufacturer I want the system to comply with country-specific energy requirements so the system can be shipped.	As a manufacturer, I want peripherals to comply with Directive 2005/32/EC of the European Parliament and Council with regard to ecodesign requirements for standby and off mode.	Analysis	Internal	Material compliance	M300			
Business	1528071 RS_Impact_on_Environment_and_Health	As a manufacturer, I want the system to meet customer request to restrict the use of certain substances so	Threshold levels of Mercury - Display and backlighting in materials used in the system is less than 900ppm Latex - Materials used in the system do not contain latex.	Analysis	Internal	Material compliance	M300			

		that the system will have less impact on environment and health.								

Comments (for Fail and NT):
The following requirement ID's are planned for testing prior to R6
1527984RS_Plastic_Labeling1528062 RS_Environmental_and_Hazardous_Labeling
1528070RSReducedElectricityUsage1528071 RS_Impact_on_Environment_and_Health

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APPROVAL	**2022-01-13T05:18:19**	**CHOI, JAEHO**