Siemens Healthineers
Business Area Ultrasound

Title: K2 2.0 Design Validation Report

Part Number: 11652988-EPT-001-03

Revision Data

Rev	ECO #	Change Description	Printed Name
03	742355	**PREP final Update**	**Cho, HyunChin**

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Revision History

Rev	ECO #	Change Description	Printed Name
01	731969	Validation Regression Report for K2 VA20	Craig Williams
02	740729	Added Speed of Sound Validation	Cho, HyunChin
03	742355	PREP final update	Cho, HyunChin

CONTENT

1.0   REGRESSION SUMMARY

The K2 VA20A Design Validation Regression Test has been completed per the Plan. Additionally, Speed of Sound validation is added at VA20C release.

User Need 746288 was tested for regression and the result is PASS. The K2 VA20A system Validation of user needs, intended uses and business need confirmation is equivalent to the validation result of K2 VA10A.

2.0   PURPOSE

The purpose of the K2 2.0 Design Validation Report is to provide a results summary.

The K2 2.0 Design Validation Report is a compilation of the user needs regression test(s) performed by testers with specific knowledge of particular requirements. This report provides results per the needs and intended uses defined in the 2.0 requirements in K2 2.0 VA20 CRS (CRS PN 11370958-EPH-001-05). The Design Validation Regression Test was performed in accordance with the K2 Design Validation and Business Plan (PN 11575970-EPH-001-03).The requirements were tested on production equivalent systems.

Rev.03 update should have been done due to PREP update by M300. All document is same from rev.02 and PREP update had been done.

3.0   SCOPE

The K2 VA20 Design Validation Regression Test Plan provides a description of the scope of change requiring regression testing, test methods, acceptance criteria (also referenced as "pass criteria") and template for final report. The K2 VA20 Design Validation Regression Test Plan consists of a list of system changes from VA10A and a list of the potentially impacted user needs as defined in the requirements specification.The report template provides a means to record the regression scoring of the requirements along with initials for the person completing and date. All testing described in the Plan were completed on production equivalent K2 Systems and applicable transducers.

The report of design validation regression testing 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.

3.1   Objective

The report objective is to summarize the result of the activities as defined in the plan and to confirm by regression testing the user needs identified in the plan.

4.0   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 Engineering Plan	11574267-EPH-001
[4] Label, Investigational device	10436916-EZG-001
[5] Label, Non-Commercial Dist.	10437243-EZG-001
[6] Quality Records/Documentation Retention	3900789-QMS-001
[7] K2 2.0 (VA20) Customer Requirement Specification	11370958-EPH-001
[8] K2 2.0 VA20 Transducer SSRS	EPH 11504038 001
[9] Product Design Evaluation and Validation	07859882-QMS-004
[10] Product DFX Scorecard Template	11147436-EMU-001
[11] Standards and Regulations document	7477230-QMS-002
[12] CRS&SRS/TERS PREP Req & Guidelines	11151649-AND-EHS
[13] PLP R and M Quality Gate Checklists	10035306-QAD-001
[14] K2 VA20 Design Validation and Business Confirm Plan	11575970-EPH-001

5.0 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
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
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.

Term	Definition
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	Safety & Effectiveness
SVI	Shear Velocity Imaging
TRS	Transducer Requirement Specification
TS	Touch Screen
PRS	Purchasing Requirement Specification
PSG	Product Steering Group
SoS	Speed of Sound
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.

6.0 REGRESSION 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.

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

Regression Method Column
This column informs what method of regression was employed as Clinical, Analysis, Usability, Business or Transducer.

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

Tested by Column
This column informs which group or groups provided the source of testing. 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

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

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

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

7.0   RESULTS

7.1   Additional documents

All documents used to generate the report and supporting memos are in the DHF, P/N 11370895-EEH-DHF-01.

7.2   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 shall be noted in the summary report per site.

Items	Condition	Remark
Name Site	SUSKO	N/A
Site Address	27F KINS Tower, 331-8 Seongnamdaero, Bundang-gu, Seongnam-si, South Korea	N/A
Period(Date)	18 Mar 2020 – 26 Mar 2020	N/A
Outdoor Max Temperature	N/A	In-house system test
Outdoor Low Temperature	N/A	In-house system test
Indoor Temperature	23 'c	N/A
Lighting condition	Dim	N/A

For Speed of Sound validation, Following environment was used.

Items	Condition	Remark
Name Site	SUSKO	N/A
Site Address	First Town, SeoHyunDong 266-1, Bundang, SeongNamsi. Kyunggido	N/A
Period(Date)	6-Dec-2021	N/A
Outdoor Max Temperature	N/A	In-house system test
Outdoor Low Temperature	N/A	In-house system test
Indoor Temperature	23 'c	N/A
Lighting condition	Dim	N/A

7.3 Number of Studies by Transducer/Clinical Use

Total Transducer	Clinical Use Obstetric	Gynecology	Pediatric	Abdomen	MSK	Small Part	Total
7VC2	7	6		5			18
9VE4	5	8					13
9C3	7						7
9EC4		5					5
18H6			7		9		16
18L6					1	4	5
5C1 – SoS				8			8
Total	19	19	7	13	10	4	72

7.4 Transducer Specific Uses

Transducer	Auto TEQ	3D/4D&Freehand 3D	Contrast	Panoramic	SoS	Total
7VC2	15	15		13		43
9VE4	10	10		9		29
9C3	7			2		9
9EC4	1	5				6
18H6	15		5	11		31
18L6	5		5			10
5C1 SoS					8	8
Total	53	30	10	35	8	136

7.5   Minimum Number of Console Uses

Transducer	Patient Registration	Annotations	BodyMarkers	Arrows	Dual	Protocols	eSie OB	eSie Follicle
7VC2	17	18	17	18	16	14	5	5
9VE4	12	10	10	10	10	7	/////	9
18H6	16	16	14	12	16	9	/////	/////
Total	45	44	41	40	42	30	5	14

Mixed Mode	Cine	Acquire	Review	Measurement	Clarify	Report	Total
16	15	18	16	15	15	15	220
10	9	13	11	10	9	10	140
11	16	16	16	8	11	8	169
37	40	47	43	33	35	33	529

7.6   Minimum Number of Clinical Users

Total 9 unique clinical users performed regression activities for the clinically tested requirements, detailed in the "Redwood VA20_ICV_Validation Report_Memo_Number of CaseClinicalSummary_Regression_Memo_Pivot table". The identification of clinical user abbreviations as recorded in the case report form:

☐   LINK :
https://kr001s1843srv.ad005.onehc.net/tfs/susko/Ultrasound/Shared%20Documents/Forms/AllItems.aspx?RootFolder=%2Ftfs%2Fsusko%2FUltrasound%2FShared%20Documents%2FK2%202%2E0%20%281%2E05%29%2FVA20%2FValidation%2FValidation%20Result&FolderCTID=0x0120002773C25BE565C349812C1F77572435EE&View=%7BD7C0238B%2D1A4B%2D49F9%2DA5EF%2DD3D2D3E5DAE3%7D

SL: SunMi Lee, JC: JinYoung Choi, JP: JinHee Park, SY: SeoBin Yun, HJ: HaNa Jeong, AJ: AYoung Jo
JK: JaeHee Kim, KS: KwangHee Seong, YN: YeonJoo NohHJ: HyoIn Jeon

For Speed of Sound,
https://kr001s1843srv.ad005.onehc.net/tfs/susko/Ultrasound/Shared%20Documents/Forms/AllItems.aspx?RootFolder=%2Ftfs%2Fsusko%2FUltrasound%2FShared%20Documents%2FK2%202%2E0%20%281%2E05%29%2FVA20%2FValidation%2FVA20C%5FSOS&FolderCTID=0x0120002773C25BE565C349812C1F77572435EE&View=%7BD7C0238B%2D1A4B%2D49F9%2DA5EF%2DD3D2D3E5DAE3%7D

SL :SunMi Lee, JP, JinHee Park, HJ : HaNa Jeong, SC : SooBin Choi
Tested SW version : 2.0.2112.1
**Note : 2.0.2112.1 is final version of VA20C, however the SoS test has been done via 2.0.2111.1 candidate version.
        There has been no SW change through 2.0.2112.1 for SoS functionality.

Transducer	Clinical Use	# of users	Users
18H6	MSK (Musculoskeletal)	7	JK(JaeHee Kim)
			SY(SeoBin Yun)
			JP(JinHee Park)
			JC(JinYoung Choi)
			SL(SunMi Lee)
			AJ(Ayoung Jo)
			HJ(Hana Jeong)
	Pediatric	6	SL(SunMi Lee)
			JP(JinHee Park)
			HJ(Hana Jeong)
			JC(JinYoung Choi)
			JK(JaeHee Kim)
			SY(SeoBin Yun)
18L6	CEUS (All Clinical Use has same PPC for CEUS)	5	HJ(Hana Jeong)
			SL(SunMi Lee)
			JP(JinHee Park)
			JC(JinYoung Choi)
			SY(SeoBin Yun)
7VC2	Abdominal	5	SL(SunMi Lee)
			JC(JinYoung Choi)
			HJ(Hana Jeong)
			JP(JinHee Park)
			SY(SeoBin Yun)
	Gynecology	4	SL(SunMi Lee)
			JK(JaeHee Kim)
			JC(JinYoung Choi)
			HJ(Hana Jeong)
	Obstetric (Fetal)	4	JC(JinYoung Choi)
			HJ(Hana Jeong)
			KS(KwangHee Seong)
			YN(YeonJoo Noh)
9C3	Obstetric (Fetal)	4	SL(SunMi Lee)
			HJ(Hana Jeong)
			KS(KwangHee Seong)
			YN(YeonJoo Noh)
9EC4	Gynecology	3	SL(SunMi Lee)
			JC(JinYoung Choi)
			HJ(Hana Jeong)
9VE4	Obstetric (Fetal)	3	SL(SunMi Lee)

			JC(JinYoung Choi)
			HJ(Hana Jeong)
	Gynecology	3	SL(SunMi Lee)
			JC(JinYoung Choi)
			HJ(Hana Jeong)

			SL(SunMi Lee)
5C1 SoS	Abdominal	8	JP(JinHee Park)
			HJ(Hana Jeong)
			SC (SooBin Choi)

7.7 Statistical Rationale

K2 VA20 patch release includes the software defects items.

Base on the confidence and reliability level of Table 11287721-QMS-001-02 Statistical Technique, Minimum number of exam sample size determined.

Table 1: Risk Based Approach for Sample Size selection (minimum)

Severity *	AQL [9]	Confidence Level	x Reliability
Catastrophic	0.65	95%	95%
Critical	1.00	95%	90%
Moderate	1.50	95%	80%
Negligible	2.50	90%	80%

- *see Produce Risk Management Procedure, 7859486-QMS-001-15*

Calculate the sample size for each feature based on C & R by using Bayes Success-Run Theorem.

The Bayes Success-Run Theorem is implemented as follows: $n = \ln(1-C)/\ln(R)$

- R = Reliability (or probability of success)
- C = confidence level
- n = sample size for "0" failures allowed on test
- Transposed the formula becomes $R = (1-C)^{(1/n)}$

Features risk severity level decided to moderate through risk analysis.
So, These features validation sample size are all determined to 14.

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 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

The actual statistical confidence and reliability will be reported in the Design Validation and Business Confirmation Report.

This plan will conduct Individual Test Challenges similar to validation peformed in VA10A focusing on the B Mode changes. The decision of the A&B comparison will be that the Score is from 1 through 5. A PASS of each user need tested will be greater than or exceeds a score of 2, "Meets Need".

The Accept or Reject-Fail for the "A"(Redwood VA10A/C) & "B"(Redwood VA20)" comparison is based rating scored by the users comparing S3000, Sequoia, Juniper and Affiniti 70 with Redwood.

N/A	1	2	3	4	5
Not Applicable	Does not meet need	Meets need	Meets expectations	Better than expected	Much better than expected

Average Score for each Transducer/Exam

Memo "Redwood VA20 ICV_Validation Report_Memo_Scoring Tag_Pivot table" summarizes each average score for each Transducer/Exam. This summary is complying with the Validation Plan (PN11509028)

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8.0   REGRESSION SPREADSHEET

Regression Tester ID: SL, JC, JP, AJ, HJ, SY, KS, YN, JK System SN 900349, 900350 SW Version: 2.0.2101.1~2.0.2102.1
Date: 14 Jan 2021~ 4 Mar 2021
Transducer SNs   : The used transducer serial numbers are documented on the Memo "Redwood_VA20_Production equivalent units for validation test.pdf"

LINK :
https://kr001s1843srv.ad005.onehc.net/tfs/susko/Ultrasound/Shared%20Documents/Forms/AllItems.aspx?RootFolder=%2Ftfs%2Fsusko%2FUltrasound%2FShared%20Documents%2FK2%202%2E0%20%281%2E05%29%2FVA20%2FValidation%2FICV%20System%20and%20Transducer%20list&FolderCTID=0x0120002773C25BE565C349812C1F77572435EE&View=%7BD7C0238B%2D1A4B%2D49F9%2DA5EF%2DD3D2D3E5DAE3%7D

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	*PASS Sample# : 59 Avg.Score= 2.88*	14Jan ~25 Feb 2021	HJ, JC, JP, KS, SL, SY, YN

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| User | 1131911 CRS_K2_UserDocAppend | As a product manager, I want the additional feature and transducers to be documented in an appendix, to append to existing user documentation for 1.0 release | The following Instruction for use are available 1. Chinese instructions for use 2. Croatian instructions for use 3. Czech instructions 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 | Clinical | Internal | Technical communication | S&E | Pass Chinese which is not inlcuded in the following languages list will be released after the country registration is complete upon China country approval. | Jun 28, 2021 | KKM |

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			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	*PASS Sample # : 30*	14Jan~25 Feb 2021	HJ, JC, JP, KS, SL, SY, YN
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	Clinical	Internal	Clinical Experts	S&E	*PASS Sample # : 150 Avg. Score 2.58*	14 Jan ~ 4 Mar 2021	SL, JC, JP, AJ, HJ, SY, KS, YN, JK

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			Pass = An average score of "Meets need" or above							
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	*PASS Sample # : 30 Avg. Score 2.30*	14 Jan ~ 4 Mar 2021	SL, JC, JP, AJ, HJ, SY
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	Clinical	Internal	Clinical Experts	S&E	*PASS Sample # : 89 Avg. Score 2.60*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK

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			transducer in its widest format in a similar manner as 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	*PASS Sample # : 81 Avg. Score 2.39*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK
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 Sample # : 84 Avg. Score 2.87*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK
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	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	Clinical	Internal	Clinical Experts	S&E	*PASS Sample # : 106 Avg. Score 2.93*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK, AJ

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		image with different image views, modes or time.	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	*PASS Sample # : 51 Avg. Score 2.81*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK, AJ
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 Sample # : 60 Avg. Score 2.92*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK, AJ
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 Sample # : 63 Avg. Score 2.82*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK, AJ

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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 Sample # : 111 Avg. Score 2.96*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK, AJ
User	1671723 CRS_K2_Speed ofSound	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	*PASS Sample # : 8 Avg Score : 3.125*	06-Dec-2021	SL, JP, HJ, SC

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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	*PASS Sample # : 124 Avg. Score 2.91*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK
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 Sample # : 40 Avg. Score 2.89*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK, AJ
User	746169 Clinical Documentatio n Tools	As a clinical user, I want the ability to annotate images and clips to support clinical communications	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	Clinical	Internal	Clinical Experts	S&E	*PASS Sample # : 155 Avg. Score 2.78*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK, AJ

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		between the imager and reviewer and document findings directly in the imaging screen.	Pass = An average score of "Meets need" or above						
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	*PASS Sample # : 35 Avg. Score 2.71*	14 Jan ~ 4 Mar 2021	SL, JC, JP, HJ, SY, KS, YN, JK, AJ
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	*PASS Sample # : 20 Avg. Score 3.2*	14 Jan ~ 4 Mar 2021	SL, JC, HJ, KS, YN
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	Clinical	Internal	Clinical Experts	S&E	*PASS Sample # : 25 Avg. Score 2.88*	14 Jan ~ 4 Mar 2021	SL, JC, HJ

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			Pass = An average score of "Meets need" or above							
			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	*PASS Sample# = 15. Avg. Score = 2.13*	20 Jan~ 8 Feb 2021	HJ, JC, SL
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	Clinica	Internal	Systems Engineering	S&E	*Pass Sample# = 89 Avg. Score = 2.57*	14Jan ~25 Feb 2021	HJ, JC, JP, KS, SL, SY, YN

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			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							
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 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	Clinical	Internal	Clinical Experts	S&E	*PASS Sample#= 131 Avg. Score = 2.84*	14Jan ~25 Feb 2021	HJ, JC, JP, KS, SL, SY, YN

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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	*PASS(Yes) Sample # = 30*	14th Jan 2021- 25th Feb	HJ, JC, JP, KS, SL, SY, YN
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	*Pass Sample # =316 Avg. Score = 2.79*	14th Jan 2021 – 4th March 2021	SL, JC, HJ,SY,JP
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	*Pass Sample# =206 Avg. Score = 2.72*	14th Jan 2021 – 4th March 2021	SL, JC, HJ,SY,JP
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	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	*Pass Sample # =149 Avg. Score = 2.64*	14th Jan 2021 – 4th March 2021	SL,JP,JC,HJ,SY,

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		General and MSK (Default)								
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	*Pass Sample # =15 Avg. Score = 2.00*	18th Jan 2021 – 4th March 2021	SL, JC, HJ,SY,JP
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	*Pass Sample # =15 Avg. Score = 2.6*	01 Jan 2021	SL, JC, HJ,SY,JP
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	*Pass Sample # =35 Avg. Score =2.57*	14th Jan 2021 – 4th March 2021	SL, JC, HJ,SY,JP

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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* *Sample# =84* *Avg. Score =2.75*	14th Jan 2021 – 4th March 2021	SL, JC, HJ,SY,JP
			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 transducer Notes: Rocked acquisition only	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 adjust the volume display for my preference in a similar manner as compared to the predicate device.	Clinical	Internal	SYT	S&E	Pass STR 11574725-EIT-003-02_K2 2.0 VA20 System Test Report 19.0 Regression License	25th Jun, 2021	Kim, JiMIn
			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	Analysis	Internal	SYT	S&E	Pass STR 11574725-EIT-003-02_K2 2.0 VA20 System Test Report	11th May, 2021	Hwang,DongGyu

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			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 support DICOM Grayscale standard display function (GSDF). Validated by Product Management based on connectivity test					63.0 Connectivity&Network DICOM		
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	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	Pass 11574725-EIT-003-02_K2 2.0 VA20 System Test Report	12th Oct 2020	Hwang,DongGyu

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		including PC format, so the data can be used on other clinical systems for reporting and diagnosis, or data sharing						62.0 DIMAQ		
1.2.3 : K2 Category Environmental Requirements										
Business	1527984 RS_Plastic_Lab eling	As a customer I want the system to be able to identify plastic materials so that decisions concerning handling, waste recovery or disposal is properly implemented at end-of-life.	All thermoplastic parts greater than 500 grams are marked as recyclable.	Analysis	Internal	Mechanical team	S&E	Pass K2 R1.0 Mechanica l SSTR (11343437 -ETP-003- 01) 7.1.34. ID: SSTS_K2_P lastic part recycle	5th Sep, 2018	Kim, NamHoon
Business	1528062 RS_Environme ntal_and_Haza rdous_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	Pass 11411092- PRQ-001- 06(PREP plan and report for K2 2.0 VA20) Please refer to "Appendix 12 - EHS Regulatory Informatio n	14th Jan, 2022	Jin, KwanSoo

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							Verification"		
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	Pass Peripherals which is used on K2 2.0 VA20 are non-relevant with EU EuP regulation	14th Jan, 2022	Jin, KwanSoo
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 that the system will have less impact on environment and health.	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	Pass 11411092-PRQ-001-06(PREP plan and report for K2 2.0 VA20) Please refer to "Appendix 12 - EHS Regulatory Information Verification"	14th Jan, 2022	Jin, KwanSoo

9.0   Exceptions

The following requirement ID's have not been tested and planned prior to R6
1527984RS_Plastic_Labeling1528062 RS_Environmental_and_Hazardous_Labeling
1528070RSReducedElectricityUsage1528071 RS_Impact_on_Environment_and_Health

10.0 Does Not Meet Need – Defects Created

11.0 Clinical Development Summary

- The memos in the LINK summarizes the activities of the Clinical Development team during the regression test activity. This summaries are complying with the Validation Plan (PN11509028)
  - Redwood VA20 ICV_Validation Report_Memo_Number of Case_Pivot table
  - Redwood VA20 ICV_Validation Report_Memo_Scoring Tag_Pivot table
- LINK :
  https://kr001s1843srv.ad005.onehc.net/tfs/susko/Ultrasound/Shared%20Documents/Forms/A
  llItems.aspx?RootFolder=%2Ftfs%2Fsusko%2FUltrasound%2FShared%20Documents%2FK
  2%202%2E0%20%281%2E05%29%2FVA20%2FValidation%2FValidation%20Result&Folder
  CTID=0x0120002773C25BE565C349812C1F77572435EE&View=%7BD7C0238B%2D1A4B
  %2D49F9%2DA5EF%2DD3D2D3E5DAE3%7D

12.0 SW Changes Summary

Build Acceptance Test Spec & Report, K2 R1.0 details the summary of software changes. BAT
sepc and reports in share point :
\Document\K2_VA10A\SQA.Docs\BAT.Result

Appendix to Document: **11652988 EPT 001 03 , ECO: 742355**
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Meaning	UTC date and time	surname, given name of signee
AUTHOR	**2022-02-21T05:15:24**	**KIM, JONGSUK**
APPROVAL	**2022-02-21T05:28:22**	**CHOI, JAEHO**