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TEST REPORT
IEC 60601-2-37
Medical electrical equipment
Part 2: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

Report Number. .....:	**211100746SHA-002**
Date of issue .....:	**2021-12-31**
Total number of pages.....:	**19**
Name of Testing Laboratory preparing the Report.....:	**Intertek Testing Services Shanghai** **Building 86, 1198 Qinzhou Road (North), 200233 Shanghai, China**
Applicant's name.....:	**VINNO Technology (Suzhou) Co., Ltd.**
Address .....:	**5F Building A, 4F Building C, No.27 Xinfa Rd., Suzhou Industrial Park, Suzhou, Jiangsu 215123, China**
Test specification:	
Standard .....:	IEC 60601-2-37 (ed.2), am1 for use in conjunction with IEC60601-1 (ed.3), am1 with Corr1 and Corr2
Test procedure .....:	CB Scheme
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_2_37F
Test Report Form(s) Originator.....:	UL(US)
Master TRF.....:	Dated 2016-03

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.
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Test item description ..... :	Ultrasound Diagnostic Systems
Trade Mark ..... :	VINNO
Manufacturer ..... :	Same as applicant
Model/Type reference ..... :	VINNO E20, VINNO E10, VINNO E10E, VINNO E10P, VINNO X3, VINNO X2, VINNO X2E, VINNO X2P, VINNO X1, VINNO X1E, VINNO X1P
Ratings ..... :	100-240V~, 50/60Hz, 400VA, Class I

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):

☒	**CB Testing Laboratory:**	Intertek Testing Services Shanghai	
Testing location/ address ..... :		Building 86, 1198 Qinzhou Road (North), 200233 Shanghai, China	
Tested by (name, function, signature) ..... :		Kay Luo / Yann Yan (Engineer)	Kay Luo Yann Yan
Approved by (name, function, signature) ... :		Jack Cheng (Mandated Reviewer)	Jack Cheng
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Approved by (name, function, signature) ... :			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) . :			
Approved by (name, function, signature) ... :			
☐	**Testing procedure: CTF Stage 3**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) . :			
Approved by (name, function, signature) ... :			
Supervised by (name, function, signature) :			

List of Attachments (including a total number of pages in each attachment):
None

Summary of testing:

From the result of our examination and tests in the submitted samples, conclude they comply with the requirements of the standard IEC 60601-2-37:2007 + A1:2015.

Tests performed (name of test and test clause):	**Testing location:**
201.11.3 Excessive Surface Temperatures	Intertek Testing Services Shanghai Building 86, 1198 Qinzhou Road (North), 200233 Shanghai, China

Summary of compliance with National Differences (List of countries addressed):

None

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Refer to 211100746SHA-001 part of this report.

Test item particulars ..... :	
Classification of installation and use ..... :	See 211100746SHA-001 report
Clinical application of ULTRASONIC DIAGNOSTIC EQUIPMENT ..... :	See general product information
MODE of operation ..... :	non-scanning mode; scanning mode; combined-operating mode
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement ..... :	Pass (P)
- test object does not meet the requirement ..... :	Fail (F)
Testing:	
Date of receipt of test items ..... :	2021-12-01
Date(s) of performance of tests ..... :	2021-12-01 to 2021-12-31

General remarks:

The test results presented in this report relate only to the object tested.
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"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

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Determination of the test conclusion is based on IEC Guide 115 in consideration of measurement uncertainty.

This Test Report Form contains the particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment according to IEC 60601-2-37. It can only be used together with IEC 60601-1 Test Report.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided..... : ☐ Yes ☒ Not applicable When differences exist; they shall be identified in the General product information section.
Name and address of factory (ies) ..... : **VINNO Technology (Suzhou) Co., Ltd.** **5F Building A, 4F Building C, No.27 Xinfa Rd., Suzhou Industrial Park, Suzhou, Jiangsu 215123, China**
General product information: Refer to 211100746SHA-001 part of this report.

IEC 60601-2-37			
Clause	Requirement + Test	Result - Remark	Verdict

201.4	**GENERAL REQUIREMENTS**		P
201.4.1	The product is ULTRASOUND ENDOSCOPE where the imaging means is limited to ultrasound and is considered an ULTRASOUND TRANSDUCER meeting the requirements of this particular standard		N/A
	The product is ULTRASOUND ENDOSCOPE having imaging means in addition to ultrasound and it also meets the requirements of 201.11.6.5 of IEC 60601-2-18:2009.		N/A
201.4.3.101	Table 201.102 applied to the potential sources of unacceptable risk identified to characterize the ESSENTIAL PERFORMANCE of ULTRASONIC DIAGNOSTIC EQUIPMENT	Essential performance addressed as part of the RM effort; see RISK MANAGEMENT Table 201.10.101 for results	P

201.7	**IDENTIFICATION, MARKING AND DOCUMENTS**		P
201.7.2.9	Marking of the IPX code on the transducer assembly is not required, for partial IPX classification of the transducer assembly		P
201.7.2.13	Physiological effects		N/A
	Description of means used to limit the surface heating of ULTRASONIC INVASIVE TRANSDUCER ASSEMBLIES to no more than 43 °C in the event of single fault condition	No such means	N/A
201.7.2.101	Acoustic output		P
	Action to directly increase or decrease output levels is clear to the OPERATOR of ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to 201.12.4.2		P
	This marking is an active DISPLAY		P
	THERMAL and MECHANICAL INDICES displayed per 51.2 together with declaration of accuracy per 201.7.9 and 201.12.....:	Active displayed on screen	P
	Ultrasound output level display is clearly visible from the OPERATOR'S position with name(s) or abbreviation(s) of the index (indices) displayed .:		P
201.7.9.2.2	Warning and safety notices		P
	Information on how to interpret the displayed ultrasonic exposure parameters, THERMAL INDEX (TI) and MECHANICAL INDEX (MI) according to annex CC	Described in chapter 2.5.1 of the user manual	P
	Procedure necessary for safe operation, pointing out possible safety hazards due to inadequate electrical installation when APPLIED PART of ULTRASONIC DIAGNOSTIC EQUIPMENT is TYPE B	Applied part is not type B	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Information on safe use of TRANSDUCER ASSEMBLIES indicating ULTRASONIC DIAGNOSTIC EQUIPMENT is of the correct type for its intended application	Described in chapter 11 probes and biopsy of user manual	P
	- Warning against activation of TRANSDUCER ASSEMBLY intended for intra-corporeal use outside PATIENT'S body if TRANSDUCER ASSEMBLY does not comply with EMC requirements (may cause harmful interference with other equipment)	Comply with EMC requirement when outside patient's body	N/A
	- Identification of interference with other equipment and mitigation techniques included in the INSTRUCTIONS FOR USE when a reduction in test levels is claimed by the MANUFACTURER	No reduction in test levels	N/A
	A notice that the ULTRASONIC DIAGNOSTIC EQUIPMENT or parts are provided with protective means against burns to PATIENT when used with HF surgical equipment	NOT for use with HF surgical equipment.	N/A
	- ACCOMPANYING DOCUMENTS caution against lack of protective means, and describe location and use of TRANSDUCER ASSEMBLY to reduce hazard of burns in the event of a defect in HF surgical neutral electrode connection		N/A
	A PRUDENT-USE STATEMENT for ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to 201.12.4.2	Described in chapter 2.5.1 of the user manual Safety statement	P
	Descriptions of DISPLAYS and means OPERATOR may use to modify operation of EQUIPMENT relevant to ultrasound output	Described in chapter 1.7 of the user manual Display annotation	P
	Description of DISPLAYS and means OPERATOR may use to modify operation of EQUIPMENT relevant to surface temperature for INVASIVE TRANSDUCER ASSEMBLIES intended for trans-oesophageal use	No probe for trans-oesophageal use	N/A
	A description of TRANSDUCER ASSEMBLY parts which may be immersed in water or other liquids for NORMAL USE or performance assessment purposes	Described in chapter 14.2.1 of the user manual Safety classification	P
	A recommendation calling the OPERATOR'S attention to the need for regular testing and periodic maintenance including inspection of the TRANSDUCER ASSEMBLY for cracks which allow the ingress of conductive fluid	Described in chapter 15.1 of the user manual "Before each use, inspect the lens, the probe housing and the cable"	P

IEC 60601-2-37			
Clause	Requirement + Test	Result - Remark	Verdict
	Instructions regarding the avoidance of unintended control settings and acoustic output levels	Described in chapter 2.5.1 of the user manual "Always be aware of the acoustic output level by observing the acoustic output display"	P
	Output limits selected according to 201.12.4.5.1 declared, and output limits declared for each application for MULTI-PURPOSE ULTRASONIC EQUIPMENT	Described in chapter 1.2 "Acoustic Output Data" of Advanced manual	P
	Instruction for transesophageal probes to be removed from the PATIENT prior to application of a defibrillator.	No probe for trans-oesophageal use	N/A
	The outer surface of the portions of TRANSDUCER ASSEMBLY which is intended to be inserted into a PATIENT should be checked to ensure that there are no unintended rough surfaces, sharp edges or protrusions which may cause harm.	Described in chapter 2.5.3 of the user manual "The operator needs to frequently inspect the probe…"	P
	For ULTRASONIC DIAGNOSTIC EQUIPMENT intended for the home care use, information provided to address this type of user.	Not for home care use	N/A
201.7.9.2.10	List of all system messages, error messages and fault messages unless these messages are self-explanatory	Self-explanatory messages	N/A
201.7.9.2.12	List of the pertinent parts, components and/or functions that should be checked after each cleaning, disinfection or sterilization cycle, and method(s) of inspection.	Described in chapter 14 operator maintenance and technical data of user manual	P
201.7.9.3	Technical description		P
201.7.9.3.101	aa) OPERATOR'S manual includes technical data on acoustic output levels .....:	Described in chapter 1.2 "Acoustic Output Data" of Advanced manual	P
	For each mode the Acoustic Output Reporting Table provides the maximum value of each index		P
	For a TRANSDUCER ASSEMBLY and ultrasound instrument console satisfying all of the exemption conditions cited in 201.12.4.2 a) & b), information declared in the ACCOMPANYING DOCUMENTS that the THERMAL INDICES and the MECHANICAL INDEX are 1.0 or less for all device settings.	TI and MI exceed 1.0	N/A
201.8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		P
201.8.7.4.7	aa) The TRANSDUCER ASSEMBLY tested with the APPLIED PART immersed in a 0.9 % saline solution		P

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Clause	Requirement + Test	Result - Remark	Verdict
201.8.7.4.8	The TRANSDUCER ASSEMBLY tested with the APPLIED PART immersed in a 0.9 % saline solution	0,9 % saline solution used	P
201.8.8.3	The TRANSDUCER ASSEMBLY tested with the APPLIED PART immersed in a 0.9 % saline solution		P
201.8.9.3.4	Thermal cycling		P
201.8.10.4	Requirements of cord-connected HAND-HELD parts and cord-connected foot-operated control devices are not applied to ULTRASONIC TRANSDUCER ASSEMBLIES		P
201.10	**PROTECTION AGAINST UNWANTED & EXCESSIVE RADIATION HAZARDS**		P
201.10.101	Ultrasonic energy		P
	RISKS associated with ultrasonic energy in the RISK MANAGEMENT PROCESS is addressed by MANUFACTURER	See RISK MANAGEMENT Table 201.10.101	P
	Acoustic output switched off when image freeze facility is enabled	Acoustic output is switched off when in freeze state	P
201.11	**PROTECTIVE AGAINST EXCESSIVE TEMPERATURES & OTHER HAZARDS**		P
201.11.1.2.2	Contact surface temperature of TRANSDUCER ASSEMBLY measured under test conditions of 201.11.1.3.1.1 did not exceed 43 (°C).....:	See Table 201.11.1.3	P
	Contact surface temperature of TRANSDUCER ASSEMBLY measured under test conditions of 201.11.1.3.1.2 did not exceed 50 (°C).....:	See Table 201.11.1.3	P
201.11.1.3	For the applied part of TRANSDUCER ASSEMBLY compliance with the requirements of 11.1.1 and 11.1.2 is checked by inspection of the RISK MANAGEMENT FILE	See RISK MANAGEMENT Table 201.11.1.3	P
201.11.1.3.1.1	Simulated use		P
	For TRANSDUCER ASSEMBLY intended for external use, thermal and acoustical properties mimicking those of a skin layer		P
	For soft tissue, the material of TRANSDUCER ASSEMBLY has specific heat capacity, thermal conductivity, and special attenuation at 5 MHz ..:		P
	For TRANSDUCER ASSEMBLY intended for external use, the initial temperature of the surface at the object-transducer interface was not less than 33°C at ambient 23 °C ± 3°C when using test method a) (°C) .....:	Test method b) was conducted	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	For INVASIVE TRANSDUCER ASSEMBLY, the initial temperature of the surface at the object-transducer interface was not less than 37°C at ambient 23 °C ± 3°C when using test method a) (°C) .....:		N/A
	Initial temperature of surface test object measured using method b) of this sub-clause was not less than the ambient temperature of 23±3 (°C)		N/A
	The surface of the APPLIED PART did not exceed 43 °C		N/A
	For TRANSDUCER ASSEMBLIES intended for external use, the initial temperature of the surface of the test object at the object transducer interface was between 20° C and 33° C, and the surface temperature rise of the APPLIED PART did not exceed 10 °C	See Table 201.11.1.3	P
	For INVASIVE TRANSDUCER ASSEMBLIES, the initial temperature of the surface of the test object at the object-transducer interface was between 20°C and 37°C, and the surface temperature rise did not exceed 6 °C		P
	For TRANSDUCER ASSEMBLIES intended for external use, the temperature measured under the test conditions of 201.11.1.3.1.1 method b) was equal to the sum of 33 °C plus the measured temperature rise (°C) .....:	See Table 201.11.1.3	P
	For INVASIVE TRANSDUCER ASSEMBLIES the temperature measured under the test conditions of 201.11.1.3.1.1 method b) was equal to the sum of 37 °C plus the measured temperature rise (°C).....:	See Table 201.11.1.3	P
	The calculated temperature did not exceed 43°C		P
201.11.1.3.1.2	Still air		P
	Initial temperature of radiating surface of TRANSDUCER ASSEMBLY was equivalent to the ambient temperature of 23 ± 3 (°C) .....:		P
	Temperature rise of radiating surface of TRANSDUCER ASSEMBLY did not exceed 27 (°C) ..:	See Table 201.11.1.3	P
	To meet the requirements of not exceeding a surface temperature of 50 °C, sum of the surface temperature rise obtained under test conditions of this sub-clause and 23 °C was regarded as the surface temperature (°C) .....:		P

IEC 60601-2-37			
Clause	Requirement + Test	Result - Remark	Verdict
201.11.1.3.2	The ULTRASONIC DIAGNOSTIC EQUIPMENT operated at a setting that gives the highest surface temperature of APPLIED PART of the TRANSDUCER ASSEMBLY (°C).....:	See Table 201.11.1.3	P
	Transmit parameters recorded in the test report	See RISK MANAGEMENT Table 201.11.1.3.2	P
201.11.1.3.3	Test according to 201.11.1.3.1.1 conducted with ULTRASONIC DIAGNOSTIC EQUIPMENT operating continuously for 30 min	Considered	P
	Test according to 201.11.1.3.1.2 conducted for 30 min or twice the time period limited by an automatic output freezing capability, whichever was shorter (minutes).....:		P
201.11.1.3.4	Surface temperature of TRANSDUCER ASSEMBLY measured on areas having achieved highest surface temperature		P
	Measurement uncertainty recorded in the test report		P
201.11.1.3.5	Test criteria and conditions required by sub-clause 201.11.1.3 were according to Table 201.104		P
201.11.6.5	Parts of TRANSDUCER ASSEMBLY likely to come into contact with OPERATOR or PATIENT meet the requirements of DRIP-PROOF EQUIPMENT (IPX1)		P
	This requirement not applied to connectors of TRANSDUCER ASSEMBLY		P
	Parts of TRANSDUCER ASSEMBLY intended to be immersed in NORMAL USE meet the necessary requirements of WATERTIGHT EQUIPMENT (IPX7) and this standard	Parts of the probes which are to be immersed are IPX7	P

201.12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		P
201.12.1	Accuracy of data and controls unique to acoustic output are specified, including		P
	- Accuracy of display indicating the THERMAL INDEX (***TI***) and MECHANICAL INDEX (***MI***) (201.7.9.2.2, 201.7.2.101 and 201.12.4.2.).....:	Described in chapter 2.5.1 of the user manual	P
	- Technical data (201.7.9.3.101).....:	Described in chapter 14.2 of the user manual basic measurement accuracy	P

IEC 60601-2-37			
Clause	Requirement + Test	Result - Remark	Verdict
	Accuracy of data and controls unique to surface temperature of ULTRASONIC TRANSDUCER intended for trans-esophageal use is specified and includes accuracy of any display of surface temperature .....:	No probe for trans-oesophageal use	N/A
201.12.4.2	c) For EQUIPMENT capable of exceeding SOFT TISSUE or BONE THERMAL INDEX of 1.0, in any mode, OPERATOR can display, but not simultaneously, both the SOFT TISSUE INDEX (***TIS***) and BONE THERMAL INDEX (***TIB***) (when a value of 0.4 is exceeded)	TI is displayed	P
	d) THERMAL INDEX display for EQUIPMENT intended solely for adult cephalic applications includes the CRANIAL-BONE THERMAL INDEX when it exceeds a value of 0,4 and can exceed a value of 1,0	ME equipment is not only for adult cephalic application	N/A
	e) MECHANICAL INDEX ≥ 0.4 displayed for EQUIPMENT capable of exceeding MECHANICAL INDEX of 1.0 in real-time B-mode operation (when no other mode is active)	MI is displayed	P
	f) OPERATOR can display both THERMAL and MECHANICAL INDICES, simultaneously	TI and MI are displayed	P
	g) The increments for the display of THERMAL INDICES, if display required, are no more than 0.2 over the entire range	TI is displayed at an increment of 0.1	P
	h) Increment for each display of MECHANICAL INDICES is no more than 0.2 over the entire range	MI is displayed at an increment of 0.1	P
	i) For trans-oesophageal ULTRASONIC TRANSDUCERS, capable of exceeding 41°C on surface temperature, a display or other means indicate when surface temperatures is over 41 °C	No probe for trans-oesophageal use	N/A
201.12.4.3	a) ULTRASONIC DIAGNOSTIC EQUIPMENT, allowing FULL SOFTWARE CONTROL OF ACOUSTIC OUTPUT, switches to an appropriate DEFAULT SETTING upon power-up, entry of new PATIENT identification data, or change from a non-foetal to a foetal application	Acoustic output level is set to default setting	P
	DEFAULT SETTING levels established by the MANUFACTURER but can be changed by OPERATOR	Default settings are established by the manufacturer and cannot be configured by operator	N/A
	b) In MULTI-PURPOSE ULTRASONIC DIAGNOSTIC EQUIPMENT, without FULL SOFTWARE CONTROL OF ACOUSTIC OUTPUT, means provided to remind OPERATOR to verify or change acoustic output and MECHANICAL and/or THERMAL INDEX displayed:	Acoustic output level is adjusted by software control	N/A
201.12.4.5.1	Limits		P

IEC 60601-2-37			
Clause	Requirement + Test	Result - Remark	Verdict
	Acoustic output is limited based on RISK ASSESSMENT and RISK MANAGEMENT following ISO 14971 using the safety related parameters specified in this standard and other relevant information such as clinical experience.	See RISK MANAGEMENT Table 201.12.4.5.1	P
201.13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		N/A
201.13.1.2	For TRANSDUCER ASSEMBLIES intended for external use, the APPLIED PART temperature exceed by up to 5 °C during a SINGLE FAULT CONDITION; an alarm provided to the OPERATOR signalled the occurrence of a SINGLE FAULT CONDITION causing the temperature to rise	No such exemption	N/A
201.17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		N/A
	ULTRASONIC DIAGNOSTIC EQUIPMENT complied with IEC 60601-1-2, as modified in 202.6	Not evaluated in this report	N/A
202.6	**ELECTROMAGNETIC COMPATIBILITY**		N/A
	ULTRASONIC DIAGNOSTIC EQUIPMENT complied with IEC 60601-1-2, except as follows:	Not evaluated in this report	N/A
202.6.1.1.1	ULTRASONIC DIAGNOSTIC EQUIPMENT classified as Group 1 and Class A or B based on CISPR 11 and based on its intended use as specified in INSTRUCTIONS FOR USE. .....:		N/A
202.6.2.1.10	IMMUNITY COMPLIED WITH IEC 60601-1-2 and modifications indicated in this subclause and in subclauses 202.6.2.3 and 202.6.2.6		N/A
202.6.2.7	a) ULTRASONIC DIAGNOSTIC EQUIPMENT complied with the requirements of 202.6.2.10 at the IMMUNITY TEST LEVELS specified in Table 10 of IEC 60601-1-2		N/A
	ULTRASONIC DIAGNOSTIC EQUIPMENT remained safe with no component failures and was restored to pre-test state by the OPERATOR when requirements of 202.6.2.10 and IMMUNITY TEST LEVELS specified in Table 10 of IEC 60601-1-2 were deviated		N/A
	Deviations from IMMUNITY TEST LEVELS for voltage dips specified in Table 10 of IEC 60601-1-2.....:		N/A

IEC 60601-2-37			
Clause	Requirement + Test	Result - Remark	Verdict

201.10.101	RM RESULTS TABLE: Protection against unwanted and excessive radiation hazards		P
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2	A series products intended use and safety feature analysis (Doc#: SFA-TSUGA, VER#: 2) Chapter 4	Intended use and identification of characteristics related to the safety.	P
4.3	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.31-1.33	Identification of hazards.	P
4.4	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.31-1.33	Estimation of the risk(s) for each hazardous situation.	P
5	risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.31-1.33	Risk evaluation.	P
6.2	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.31-1.33	Risk control option analysis.	P
6.3	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.31-1.33	Implementation of risk control measure(s).	P
6.4	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.31-1.33	Residual risk evaluation.	P
6.5	-	No any unacceptable risk.	N/A
6.6	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.31-1.33	No other hazards generated after implanting the risk control measures.	P

201.11.1.3	TABLE: Excessive Surface Temperatures					P
Supply voltage.....:		264V				
Ultrasound System	Transducer Model	TMM (Method A or B) or Still Air	Operating Condition (Mode)	Ambient (°C)	Initial Temp. (°C)	Final Radiating Surface Temp. (TF) and/or Temp. Rise (TR), (°C)
VINNO E20	F2-5C	Method B	B+M	24.1	24.1	TF=28.9 TR=4.8
		Still Air	B+M	24.1	24.1	TF=34 TR=9.9
		Method B	Colour Flow	24.1	24.1	TF=28.8 TR=4.7
		Still Air	Colour Flow	24.1	24.1	TF=34 TR=9.9
		Method B	Pulsed Doppler	24.1	24.1	TF=29.3 TR=4.9
		Still Air	Pulsed Doppler	24.1	24.1	TF=34.1 TR=10

IEC 60601-2-37			
Clause	Requirement + Test	Result - Remark	Verdict

	D3-6C	Method B	B+M	24.5	24.5	TF=30.8 TR=6.3
		Still Air	B+M	24.5	24.5	TF=34.3 TR=9.8
		Method B	Colour Flow	24.5	24.5	TF=31.2 TR=6.7
		Still Air	Colour Flow	24.5	24.5	TF=35 TR=10.5
		Method B	Pulsed Doppler	24.5	24.5	TF=30.4 TR=5.9
		Still Air	Pulsed Doppler	24.5	24.5	TF=34.2 TR=9.1
	D3-6CE	Method B	B+M	24.3	24.3	TF=27.5 TR=3.2
		Still Air	B+M	24.3	24.3	TF=31.2 TR=6.9
		Method B	Colour Flow	24.3	24.3	TF=28.5 TR=4.2
		Still Air	Colour Flow	24.3	24.3	TF=30.3 TR=6
		Method B	Pulsed Doppler	24.3	24.3	TF=28.2 TR=5.2
		Still Air	Pulsed Doppler	24.3	24.3	TF=31.3 TR=7
	F4-9E	Method B	B+M	24.3	24.3	TF=29.2 TR=4.9
		Still Air	B+M	24.3	24.3	TF=39.9 TR=15.6
		Method B	Colour Flow	24.3	24.3	TF=28.4 TR=4.1
		Still Air	Colour Flow	24.3	24.3	TF=35.2 TR=10.9
		Method B	Pulsed Doppler	24.3	24.3	TF=28.8 TR=4.5
		Still Air	Pulsed Doppler	24.3	24.3	TF=35.5 TR=11.2
	G4-9E	Method B	B+M	24.3	24.3	TF=27.5 TR=3.2
		Still Air	B+M	24.3	24.3	TF=31.2 TR=6.9
		Method B	Colour Flow	24.3	24.3	TF=30.1TR=5.8
		Still Air	Colour Flow	24.3	24.3	TF=38 TR=13.7
		Method B	Pulsed Doppler	24.3	24.3	TF=28.2 TR=3.9
		Still Air	Pulsed Doppler	24.3	24.3	TF=32.4 TR=8.1
	G4-9M	Method B	B+M	24.5	24.5	TF=27.3 TR=2.8
		Still Air	B+M	24.5	24.5	TF=29.1 TR=4.6
		Method B	Colour Flow	24.5	24.5	TF=31.9 TR=7.4
		Still Air	Colour Flow	24.5	24.5	TF=41 TR=16.5
		Method B	Pulsed Doppler	24.5	24.5	TF=33.6 TR=9.1
		Still Air	Pulsed Doppler	24.5	24.5	TF=45 TR=20.5
	F4-12L	Method B	B+M	24.3	24.3	TF=29.5 TR=5.2
		Still Air	B+M	24.3	24.3	TF=36.7 TR=12.4
		Method B	Colour Flow	24.3	24.3	TF=30 TR=5.7
		Still Air	Colour Flow	24.3	24.3	TF=38.3 TR=14
		Method B	Pulsed Doppler	24.3	24.3	TF=29.3 TR=5
		Still Air	Pulsed Doppler	24.3	24.3	TF=37 TR=12.7
	X4-12L	Method B	B+M	24.3	24.3	TF=32.1 TR=7.8
		Still Air	B+M	24.3	24.3	TF=41.2 TR=16.9
		Method B	Colour Flow	24.3	24.3	TF=32.5 TR=8.2
		Still Air	Colour Flow	24.3	24.3	TF=42.9 TR=18.6
		Method B	Pulsed Doppler	24.3	24.3	TF=32.3 TR=8
		Still Air	Pulsed Doppler	24.3	24.3	TF=41.9 TR=17.6
	G1-4P	Method B	B+M	24.2	24.2	TF=28.1 TR=3.9
		Still Air	B+M	24.2	24.2	TF=31.2 TR=7
		Method B	Colour Flow	24.2	24.2	TF=28.6 TR=4.4
		Still Air	Colour Flow	24.2	24.2	TF=31.6 TR=7.4
		Method B	Pulsed Doppler	24.2	24.2	TF=29 TR=4.8
		Still Air	Pulsed Doppler	24.2	24.2	TF=33.3 TR=9.1
	D2-6C	Method B	B+M	21.1	21.1	TF=25.9 TR=4.8
		Still Air	B+M	21.1	21.1	TF=28.7 TR=7.6
		Method B	Colour Flow	21.1	21.1	TF=27.5 TR=6.4
		Still Air	Colour Flow	21.1	21.1	TF=31.3 TR=10.2

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		Method B	Pulsed Doppler	21.1	21.1	TF=27.3 TR=6.2
		Still Air	Pulsed Doppler	21.1	21.1	TF=31 TR=9.9
VINNO X1	F2-5C	Method B	B+M	24.2	24.2	TF=31.3 TR=7.1
		Still Air	B+M	24.2	24.2	TF=35.9 TR=11.7
		Method B	Colour Flow	24.2	24.2	TF=30.7 TR=6.5
		Still Air	Colour Flow	24.2	24.2	TF=34.5 TR=10.3
		Method B	Pulsed Doppler	24.2	24.2	TF=29.6TR=5.4
		Still Air	Pulsed Doppler	24.2	24.2	TF=34.1 TR=9.9
	D3-6C	Method B	B+M	24.5	24.5	TF=29.8 TR=5.3
		Still Air	B+M	24.5	24.5	TF=34.3 TR=9.8
		Method B	Colour Flow	24.5	24.5	TF=31.3 TR=6.8
		Still Air	Colour Flow	24.5	24.5	TF=37.8 TR=13.3
		Method B	Pulsed Doppler	24.5	24.5	TF=31.2 TR=6.7
		Still Air	Pulsed Doppler	24.5	24.5	TF=38.2 TR=13.7
	D3-6CE	Method B	B+M	24.2	24.2	TF=31.3 TR=7.1
		Still Air	B+M	24.2	24.2	TF=34 TR=9.8
		Method B	Colour Flow	24.2	24.2	TF=33.5 TR=9.3
		Still Air	Colour Flow	24.2	24.2	TF=36.5 TR=12.3
		Method B	Pulsed Doppler	24.2	24.2	TF=33.3 TR=9.1
		Still Air	Pulsed Doppler	24.2	24.2	TF=37.7 TR=13.5
	F4-9E	Method B	B+M	24.3	24.3	TF=29.2 TR=5.7
		Still Air	B+M	24.3	24.3	TF=39.9 TR=17.4
		Method B	Colour Flow	24.3	24.3	TF=30.1 TR=5.8
		Still Air	Colour Flow	24.3	24.3	TF=39.4 TR=15.1
		Method B	Pulsed Doppler	24.3	24.3	TF=28.6 TR=4.3
		Still Air	Pulsed Doppler	24.3	24.3	TF=36.1 TR=11.8
	G4-9E	Method B	B+M	24.1	24.1	TF=27.2 TR=3.1
		Still Air	B+M	24.1	24.1	TF=31.4 TR=7.3
		Method B	Colour Flow	24.1	24.1	TF=28.9TR=4.8
		Still Air	Colour Flow	24.1	24.1	TF=36.3 TR=12.2
		Method B	Pulsed Doppler	24.1	24.1	TF=27.7TR=3.6
		Still Air	Pulsed Doppler	24.1	24.1	TF=33.1 TR=9
	G4-9M	Method B	B+M	24.5	24.5	TF=30.3 TR=5.8
		Still Air	B+M	24.5	24.5	TF=37.9 TR=13.4
		Method B	Colour Flow	24.5	24.5	TF=33.9 TR=9.4
		Still Air	Colour Flow	24.5	24.5	TF=47.1 TR=22.6
		Method B	Pulsed Doppler	24.5	24.5	TF=30.5 TR=6
		Still Air	Pulsed Doppler	24.5	24.5	TF=35.4 TR=10.9
	F4-12L	Method B	B+M	24.1	24.1	TF=25.9 TR=1.8
		Still Air	B+M	24.1	24.1	TF=28.4 TR=4.3
		Method B	Colour Flow	24.1	24.1	TF=27.3 TR=3.2
		Still Air	Colour Flow	24.1	24.1	TF=31.3 TR=7.2
		Method B	Pulsed Doppler	24.1	24.1	TF=27.2 TR=3.1
		Still Air	Pulsed Doppler	24.1	24.1	TF=30.4 TR=6.3
	X4-12L	Method B	B+M	24.2	24.2	TF=28.3 TR=4.1
		Still Air	B+M	24.2	24.2	TF=36.6 TR=12.4
		Method B	Colour Flow	24.2	24.2	TF=27.5 TR=3.3
		Still Air	Colour Flow	24.2	24.2	TF=32.1 TR=7.9
		Method B	Pulsed Doppler	24.2	24.2	TF=27 TR=2.8
		Still Air	Pulsed Doppler	24.2	24.2	TF=30.8 TR=6.6
	G1-4P	Method B	B+M	24.3	24.3	TF=28.7 TR=4.4
		Still Air	B+M	24.3	24.3	TF=32.6 TR=8.3

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		Method B	Colour Flow	24.3	24.3	TF=30.9 TR=6.6
		Still Air	Colour Flow	24.3	24.3	TF=36 TR=11.7
		Method B	Pulsed Doppler	24.3	24.3	TF=28.4 TR=4.1
		Still Air	Pulsed Doppler	24.3	24.3	TF=31.3 TR=7
Supplementary information: 1) All the probe is for external use except for F4-9E, G4-9E 2) Test condition: operating continuously for 30 min.						

201.11.1.3	**RM RESULTS TABLE: Excessive Surface Temperatures**		**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2	A series products intended use and safety feature analysis (Doc#: SFA-TSUGA, VER#: 2) Chapter 4	Intended use and identification of characteristics related to the safety.	P
4.3	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.34-1.36	Identification of hazards.	P
4.4	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.34-1.36	Estimation of the risk(s) for each hazardous situation.	P
5	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.34-1.36	Risk evaluation.	P
6.2	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.34-1.36	Risk control option analysis.	P
6.3	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.34-1.36	Implementation of risk control measure(s).	P
6.4	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.34-1.36	Residual risk evaluation.	P
6.5	-	No any unacceptable risk.	N/A
6.6	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC, H1.34-1.36	No other hazards generated after implanting the risk control measures.	P

201.11.1.3.2	**RM RESULTS TABLE: Transmit parameters**		**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**

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Clause	Requirement + Test	Result - Remark	Verdict

201.11.1.3.2	RM RESULTS TABLE: Transmit parameters		P
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2	Risk assessment and control Doc#: RMM-TSUGA, VER#: 2 SOP-AMP-01, VER# 3	The transmit parameters to measure the probe temperature are record.	P

201.11.1.3.4	RM RESULTS TABLE: Measurement uncertainty		P
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2	Risk assessment and control Doc#: RMM-TSUGA, VER#: 2 SOP-AMP-01, VER# 3	MI TI: U = k*uc =t.95*uc = 56% Temperature: U = k*uc =t.95*uc = 5.2%	P

201.12.4.5.1	RM RESULTS TABLE: Acoustic output limits		P
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2	A series products intended use and safety feature analysis (Doc#: SFA-TSUGA, VER#: 2) Chapter 4	Intended use and identification of characteristics related to the safety.	P
4.3	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC	Identification of hazards.	P
4.4	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC	Estimation of the risk(s) for each hazardous situation.	P
5	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC	Risk evaluation.	P
6.2	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC	Risk control option analysis.	P
6.3	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC	Implementation of risk control measure(s).	P
6.4	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC	Residual risk evaluation.	P
6.5	-	No any unacceptable risk.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

201.12.4.5.1	**RM RESULTS TABLE: Acoustic output limits**		**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
6.6	Risk assessment and control (Doc#: RMM-TSUGA, VER#: 2) Section RAC	No other hazards generated after implanting the risk control measures.	P