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TEST REPORT
IEC 60601-1-6
Medical electrical equipment - Part 1-6:
General requirements for basic safety and essential performance - Collateral standard: Usability

Report Number. ..... :	**211100746SHA-003**
Date of issue ..... :	**2021-12-31**
Total number of pages ..... :	**15**
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 60601-1-6:2010, AMD1:2013, AMD2:2020 for use in conjunction with IEC 62366-1:2015, AMD1:2020, and IEC 60601-1:2005, AMD1:2012, AMD2:2020
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
TRF template used ..... :	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No. ..... :	IEC60601_1_6K
Test Report Form(s) Originator .... :	TÜV Rheinland of North America
Master TRF ..... :	Dated 2020-11-23

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved IECEE 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.
This report shall not be reproduced, except in full, without the written approval of the Issuing NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description ..... :	Ultrasound Diagnostic Systems
Trade Mark(s) ..... :	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 No. 86, 1198 Qinzhou Road (North), 200233 Shanghai, China	
Tested by (name, function, signature).....:		Kay Luo / Yann Yan (Engineer)	
Approved by (name, function, signature)...:		Jack Cheng (Mandated reviewer)	
☐	**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 + 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):
ANNEX I – IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist (Pages: 8)

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
Process standard only, no testing	N/A

Summary of compliance with National Differences (List of countries addressed):
None

Statement concerning the uncertainty of the measurement systems used for the tests
(may be required by the product standard or client)

☒ **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

Procedure number, issue date and title:

GMS-QC-12 estimation of measurement is Uncertainty ,1-July-2012 initial release.

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

☐ **Statement not required by the standard used for type testing**

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
Supply Connection.....:	See 211100746SHA-001 report
.....:	
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement.....:	P (Pass)
- test object does not meet the requirement.....:	F (Fail)
Testing.....:	
Date of receipt of test item .....:	No test required.
Date (s) of performance of tests.....:	No test required.

General remarks:

"(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.

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 and other remarks:

Refer to IEC 60601-1 Report No. 211100746SHA-001 part of this report.

IEC 60601-1-6:2010, AMD1:2013, AMD2:2020			
Clause	Requirement + Test	Result - Remark	Verdict

4.0	**GENERAL REQUIREMENTS**		P
4.2	USABILITY ENGINEERING PROCESS complies with IEC 62366-1 including amended definitions. Excludes production and post-production monitoring, and maintenance of the USABILITY ENGINEERING PROCESS	See attached IEC 62366-1 ANNEX I	P
	Inspection of the USABILITY ENGINEERING FILE verified that the MANUFACTURER		P
	– established a USABILITY ENGINEERING PROCESS	Usability engineering process: Doc#: SDDS-TSUGA-001, SDDS-TSUGA-002, VAP-TSUGA-005, VAS-TSUGA-002, VER-TSUGA-049, Risk management file: Doc#: QP7.1-01, RMP-TSUGA, RMR-TSUGA, RMM-TUSGA, SFA-TUSGA	P
	– established acceptance criteria for USABILITY; and	Series usability validation plan (Doc#:VAP-TSUGA-005) section 6	P
	– demonstrated that the acceptance criteria for USABILITY have been met.	Series validation of usability (Doc#: VAS-TSUGA-002)	P

5	**ME EQUIPMENT ACCOMPANYING DOCUMENTS**		P
	The instructions for use shall contain a summary of the USE SPECIFICATION as specified in IEC 62366-1:2015, AMD1:2020, Clause 5.1	Described in chapter 1 general of user manual.	P
	The same information is also included in the technical description, if this is provided as a separate document from instructions for use		N/A

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
4	**PRINCIPLES**		P
4.1.1	The MANUFACTURER has established, documented and maintains a USABILITY ENGINEERING PROCESS addressing USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT	Created usability engineering process and recorded in below files: SDDS-TSUGA-001, SDDS-TSUGA-002, VAP-TSUGA-005, VAS-TSUGA-002, VER-TSUGA-049	P
4.1.2	The USABILITY ENGINEERING PROCESS complies with this standard and the acceptance criteria in the USABILITY VALIDATION plan have been met	Series usability validation plan (Doc#:VAP-TSUGA-005) section 6; Series validation of usability (Doc#: VAS-TSUGA-002)	P
4.1.3	Information for SAFETY used as a RISK CONTROL measure has been evaluated according to the USABILITY ENGINEERING PROCESS	RMM-TSUGA	P
4.2	The results of the USABILITY ENGINEERING PROCESS are recorded in the USABILITY ENGINEERING FILE .....:	VAS-TSUGA-002	P
4.3	The USABILITY ENGINEERING PROCESS is scaled-up or scaled-down based on the significance of the modification as determined by the results of the RISK ANALYSIS .....:	No evidence the usability engineering process was scaled.	N/A

5	**USABILITY ENGINEERING PROCESS**		P
5.1	The MANUFACTURER shall prepare a USE SPECIFCATION. The USE SPECIFICATION shall include the following.....:	SDDS-TSUGA-001	P
	– intended medical indication	SDDS-TSUGA-001, section 1.1.1	P
	– intended PATIENT population	SDDS-TSUGA-001, section 1.1.2	P
	– intended part of the body or type of tissue applied to or interacted with	SDDS-TSUGA-001, section 1.1.3	P
	– intended USER PROFILE	SDDS-TSUGA-001, section 1.1.4	P
	– intended USE ENVIRONMENT	SDDS-TSUGA-001, section 1.1.5	P
	– operating principle	Described in chapter 1 general of user manual.	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
5.2	The MANUFACTURER shall identify USER INTERFACE characteristics that could be related to SAFETY as part of a RISK ANALYSIS performed according to ISO 14971:2019, Clause 5.3	Document Reference No. in usability engineering file: SDDS-TSUGA-001, section 1.2.1	P
5.3	As part of this RISK ANALYSIS, the MANUFACTURER shall identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS which could affect PATIENTS, USERS or others, related to the use of the MEDICAL DEVICE.	See Appended Table 5.3	P
5.4	The RISK ANALYSIS includes a description of all the reasonably foreseeable HAZARD-RELATED USE SCENARIOS associated with the identified HAZARD and HAZARDOUS SITUATIONS.	Document Reference No. in usability engineering file: SDDS-TSUGA-001, section 2.2	P
	The description of each identified HAZARD-RELATED USE SCENARIO includes all TASKS and their sequences	RMM-TSUGA	P
	The SEVERITY of the possible resulting associated HARM was determined	RMM-TSUGA	P
5.5	The MANUFACTURER shall select the HAZARD-RELATED USE SENARIOS to be included in a SUMMATIVE EVALUATION as part of the USABILITY FILE. This SUMMATIVE EVALUATION shall include:	Document Reference No. in usability engineering file: RMM-TSUGA	P
	- all HAZARD-RELATED USE SCENARIOS;	RMM-TSUGA	P
	- a subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM that could be caused by USE ERROR (e.g. for which medical intervention would be needed); or	RMM-TSUGA	P
	- a subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM and based on other circumstances specific to the MEDICAL DEVICE and the MANUFACTURER	RMM-TSUGA	P
	A summary of any selection scheme, the rationale for its use and the results of applying it shall be stored in the USABILITY ENGINEERING FILE	Document Reference No. in usability engineering file: VAP-TSUGA-005, VAS-TSUGA-002	P
5.6	The MANUFACTURER shall establish and maintain a USER INTERFACE SPECIFICATION	See Appended Table 5.6	P
5.7	The MANUFACTURER shall establish and maintain a USER INTERFACE EVALUATION plan for the USER INTERFACE	See Table 5.6 need to update to/for 5.7	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
5.8	The MANUFACTURER shall design and implement the USER INTERFACE, including the ACCOMPANYING DOCUMENTATION if needed, and training capability, if needed, as described in the USER INTERFACE SPECIFICATION .....:	Document References in USABILITY ENGINEERING FILE, including any FORMATVE EVALUATION or required training strategy	P
	Where new USE ERRORS, HAZARDS, HAZARDOUS SITUATIONS or HAZARD-RELATED USE SCENARIOS are discovered during this step the MANUFACTURER shall repeat the steps of Clause 5 as appropriate		N/A
	If training on the specific MEDICAL DEVICE is required for the safe us of the MEDICAL DEVICE by the intended USER, the MANUFACTURER shall design and implement a training capability for the EXPECTED SERVICE LIFE of the MEDICAL DEVICE by doing at least one of the following:		N/A
	- provide the materials necessary for training;		N/A
	- ensure the materials necessary for training are available;		N/A
	- make the training available; or		N/A
	- make training available to the RESPONSIBLE ORGANIZATION that enables it to train its USERS		N/A
5.9	The MANUFACTURER shall perform a SUMMATIVE EVALUATION of each HAZARD-RELATED USE SCENARIO selected in Clause 5.5	Document Reference No. in usability engineering file: RMM-TSUGA	P
	All USE ERRORS and use difficulties that occurred shall be identified		N/A
	Where USE ERROR or use difficulty can lead to a HAZARDOUS SITUATION the root causes should be determined		N/A
	If new USE ERRORS, HAZARDS, HAZARDOUS SITUATIONS or HAZARD-RELATED USE SCENARIOS are discovered during this data analysis:		–
	- if yes, then the MANUFACTURER shall repeat the activities of Clause 5 as appropriate;		N/A
	- if not, then the MANUFACTURER determine whether further improvement of the USER INTERFACE design as it relates to SAFETY is necessary and practicable		N/A
	1) If yes, then the MANUFACTURER shall re-enter the USABILITY ENGINEERING PROCESS at Clause 5.6		N/A
	2) If not then the MANUFACTURER shall:		N/A
	i) Document why improvement is not necessary or not practicable;		N/A

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict
	ii) Identify the data from the USABILITY ENGINEERING PROCESS needed to determine the RESIDUAL RISK related to use; and	No residual risk	N/A
	iii) Evaluate the RESIDUAL RISK according to ISO 14971:2019, Clause 7.3		N/A
5.10	USER INTERFACE OF UNKNOWN PROVENANCE (UOUP) was evaluated according to Annex C rather than the requirements of 5.1 through 5.9.	See Appended Annex C below	N/A

Annex C	**Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)**		N/A
C.2.1	The MANUFACTURER shall establish a USE SPECIFICATION as required in 5.1.		N/A
C.2.2	The MANUFACTURER of a device with UOUP shall review POST-PRODUCTION information including complaints and field reports for incidents and near incidents. All identified cases of USE ERROR shall be stored in the USABILITY ENGINEERING FILE and addressed in C.2.3 and C.2.4		N/A
C.2.3	The MANUFACTURER shall review the RISK ANALYSIS of the MEDICAL DEVICE with UOUP and ensure that all HAZARDS and HAZARDOUS SITUATIONS associated with USABILITY have been identified and documented		N/A
C.2.4	The MANUFACTURER shall verify and document that adequate RISK CONTROL measures have been implemented for all identified HAZARDS and HAZARDOUS SITUATIONS identified in C.2.3 and that all RISKS are reduced to an acceptable level as indicated by the RISK ASSESSMENT		N/A
C.2.5	Based on any new information identified in performing steps C.2.3 and C.2.4 the MANUFACTURER re-evaluated the overall RESIDUAL RISK according to ISO 14971:2019, Clause 7.3 and documented the results in either the USABILITY ENGINEERING FILE or RISK MANAGEMENT FILE		N/A

Table 5.3	**USABILITY ENGINEERING FILE RESULTS TABLE: RISK ANALYSIS**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3	**USABILITY ENGINEERING FILE RESULTS TABLE: RISK ANALYSIS**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
An identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS which could affect PATIENTS, USERS or others, related to the use of the MEDICAL DEVICE. was performed according to ISO 14971:2019, Clause 5.3	RMM-TSUGA	Comprehensive residual is acceptable. All residual risk of acceptable standards within limits and be benefited more than risk.	P
During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered:			—
– USE SPECIFICATION, including USER PROFILE(S) (See 5.1)	SDDS-TSUGA-001, section 1.1	Acceptable according to IEC 62366-1	P
– information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available; and	SDDS-TSUGA-001, section 1.3.8	Acceptable according to IEC 62366-1	P
– identified USE ERRORS (see 5.2).	SDDS-TSUGA-001, section 1.3.3	Acceptable according to IEC 62366-1	P

Table 5.6	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE SPECIFICATION**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
USER INTERFACE SPECIFICATION	SDDS-TSUGA-001, section 2	Acceptable according to IEC 62366-1	P
The USER INTERFACE SPECIFICATION shall consider:			—
– the USE SPECIFICATION (See 5.1)	SDDS-TSUGA-001, section 2	Acceptable according to ISO 14791	P
– the known or foreseeable USE ERRORS associated with the medical device (See 5.2); and	SDDS-TSUGA-001, section 1.3.3 b	Acceptable according to IEC 62366-1	P
– the HAZARD-RELATED USE SCENARIOS (See 5.4)	SDDS-TSUGA-001, section 2.2	Acceptable according to IEC 62366-1	P
Inputs to the USER INTERFACE SPECIFICATION shall include the following:			—

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.6	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE SPECIFICATION**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– testable technical requirements relevant to the USER INTERFACE, including the requirements for those parts of the USER INTERFACE associated with the selected RISK CONTROL measures;	SDDS-TSUGA-001, section1	Acceptable according to IEC 62366-1	P
– an indication as to whether ACCOMPANYING DOCUMENTATION is required; and	SDDS-TSUGA-001, section1	Acceptable according to IEC 62366-1	P
– an indication as to whether MEDICAL DEVICE specific training is required	SDDS-TSUGA-001, section1	Acceptable according to IEC 62366-1	P

Table 5.7	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
The manufacturer shall establish and maintain a USER INTERFACE EVALUATION plan for the USER INTERFACE	VAP-TSUGA-005	Acceptable according to IEC 62366-1	P
The USER INTERFACE EVALUATION plan shall document:			—
a) the objective and identify the method of any planned FORMATIVE EVALUATIONS and SUMMATIVE EVALUATIONS	VAP-TSUGA-005, section 3	Acceptable according to IEC 62366-1	P
b) if USABILITY TESTS are employed, – document which USER GROUPS are intended to be included in the test;	VAS-TSUGA-002	Acceptable according to IEC 62366-1	P
– document the test environment and other conditions of use, based on the USE SPECIFICATION;	VAP-TSUGA-005, section 3	Acceptable according to IEC 62366-1	P
– specify whether ACCOMPANYING DOCUMENTATION is provided during the test; and	VAS-TSUGA-002	Acceptable according to IEC 62366-1	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.7	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– specify whether MEDICAL DEVICE-specific training is provided prior to the test and the minimum elapsed time between the training and the beginning of the test.	VAS-TSUGA-002	Acceptable according to IEC 62366-1	P
The USER INTERFACE evaluation plan for FORMATIVE EVALUATION shall address:			—
a) the evaluation methods being used;	VAP-TSUGA-005	Acceptable according to IEC 62366-1	P
b) which part of the USER INTERFACE is being evaluated; and	VAP-TSUGA-005	Acceptable according to IEC 62366-1	P
c) when in the USABILITY ENGINEERING PROCESS to perform each of the USER INTERFACE EVALUATIONS.	VAP-TSUGA-005	Acceptable according to IEC 62366-1	P
For each selected HAZARD-RELATED USE SCENARIO (see 5.5), the USER INTERFACE EVALUATION plan for SUMMATIVE EVALUATION shall specify:			—
a) the evaluation method being used and a rationale that the method produces OBJECTIVE EVIDENCE;	VAP-TSUGA-005 VAS-TSUGA-002	Acceptable according to IEC 62366-1	P
b) which part of the USER INTERFACE is being evaluated;	VAP-TSUGA-005 VAS-TSUGA-002	Acceptable according to IEC 62366-1	P
c) where applicable, the criteria for determining whether the information for SAFETY is perceivable, understandable and supports CORRECT USE of the MEDICAL DEVICE (4.1.3);	VER-TSUGA-049	Acceptable according to IEC 62366-1	P
d) the availability of the ACCOMPANYING DOCUMENTATION and provision of training during the SUMMATIVE EVALUATION; and	VAS-TSUGA-002	Acceptable according to IEC 62366-1	P
e) for a USABILITY TEST, – how the characteristics of the test participants are representative of the intended USER PROFILES;	VER-TSUGA-049	Acceptable according to IEC 62366-1	P

ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.7	**USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan**		**P**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– justifying how the test participants are grouped into distinct USER GROUPS for the purpose of determining the number of test participants;			N/A
– the test environment and conditions of use and a rationale for how they are adequately representative of the intended USE ENVIRONMENT;	VER-TSUGA-049	Acceptable according to IEC 62366-1	P
– the definition of CORRECT USE for each HAZARD-RELATED USE SCENARIO; and	VER-TSUGA-049	Acceptable according to IEC 62366-1	P
– the method of collecting data during the USABILITY TEST for the subsequent analysis of observed USE ERRORS and use difficulties.			N/A