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Siemens Healthineers
Business Area Ultrasound

Title: Temperature Measurement Software Verification and Validation Plan

Part Number: 11344281-FPV-001-04

Revision Data

Rev	ECO #	Change Description	Printed Name
04	702365	1) CAPA update(voltage sequence) 2) To modify and add control parameter for rev4.0	Hwang, InSeop

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Revision History

Rev	Change Description	Author/Printed Name	Date Made/ECO#
04	1) CAPA update(voltage sequence) 2) To modify and add control parameter for rev4.0	Hwang, InSeop	2019.09.17 / 702365
03	To add VTx control, the automation mode change for WF3 on temperature measurement software rev 3.0	Hwang, InSeop	2017.01.31 / 660066
02	To add transmit channel modulation control on temperature measurement software rev 2.0	Hwang, InSeop	2017.01.22 / 660065
01	Initial SAP released on temperature measurement software rev 1.0	Hwang, InSeop	2017.01.20 / 657217

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1.0 PURPOSE

This document describes the test plan for verification and validation of transducer temperature measurement software, and provides the form for testing the software.

2.0 SCOPE

The plan requires a series of transducer temperature measurements, supporting calculations, and comparisons with results stored in the acoustic database.

3.0 DETERMINATION OF TEST PLAN PATH

The validation and verification for the Temperature Measurement Software follows one of three paths. Examples of criteria for choosing the method for validation and verification are provided in this section. The responsible engineer should explain reasoning for verification method in verification report notes.

3.1 Criteria for Full Verification

Full verification is defined as completing all tests described in Sections 5.1 to 5.2 and shall be performed for the initial release of the software. Full verification should also be performed for revisions where major changes occur to the software logic or major changes occur to several measurement routines and algorithms.

3.2 Criteria for Partial Detailed Verification

Partial Verification is defined as performing only applicable parts of Section 5 and shall be performed for revisions where changes are made only to specific components of the software. The responsible engineer will define the appropriate test sections in the verification report notes.

3.3 Criteria for Verification by Comparison

Verification by comparison (Section 5.3) is defined as making automatic temperature measurements with both the previous and new versions of the software with the same test setup and then comparing the results. This method of verification is indicated for minor changes to the software, such as (but not limited to) formatting and default value changes, upgrading the source code to a new version of LabView, adding minor improvements (for instance, to decrease setup, ambient temperature and measurement time) to the setup or measurement routines, modifying a setup routine to adhere to a changed menu path or name in the ultrasound system DUI, *etc.* Since automatic temperature measurements use software components tested individually for full verification procedure, performing a verification by comparison exercises all aspects of program for one simpler comparison of final results.

In these situations, the measurements with the old and new versions of the software should give results which are the same within expected measurement deviation. Typical allowed deviations vary depending on transducer model and test condition chosen for the comparison, but are on the order of 10% for temperature rise. The responsible engineer should state the criterion for pass / fail in the verification report notes.

4.0 TEST PLAN

4.1 Qualification of a Test Person

4.1.1 Familiarity with temperature measurements;

4.1.2 Experience with operating acoustic measurement system;

4.1.3 Experience with using acoustic database (Reference no. 4).

4.2 Test Equipment

4.2.1 An IBM PC or compatible equipped with Temperature Measurement Software package;

4.2.2 Thermometer with thermocouples;

4.2.3 Z system with released transducer;

4.2.4 Infrared Thermometer.

4.2.5 Manual Translation

4.3 Preparation for the test

4.3.1 Connect the transducer-under-test to available transducer interface port of the system.

4.3.2 Turn on the system and let it boot up (if system is not “on”).

4.3.3 Place the transducer-under-test in the appropriate transducer-housing holder (reinforcement by some other materials is accepted to keep the transducer locked into place if transducer-housing holder is not fitted properly) and lock the holder into the translation/positioning system.

4.3.4 Turn on the IR (infrared) thermometer. Adjust the height of the transducer-under-test so the target light is tightly focused and in the approximate center of the transducer face.

4.3.5 Configure the ultrasonic diagnostic system so that it could be running for at least 30 minutes without changing the transmit activity once the system operating is set. For example, disable the screen saver/ power saver function.

4.3.6 Set system to the desired operating condition by temperature measurement program.

4.3.7 Allow system transmits to run under the desired operation condition for approximately about 5 minutes or until the temperature rise becomes stable and begin to locate the hottest spot on transducer's surface using manual translation.

4.3.8 [Way: After four minutes (time = 4), search for the hottest spot on the transducer face. At the five-minutes (time = 5), the stable temperature is represented at the hottest spot.]

4.3.9 Mark the hottest spot with an inked pen.

4.3.10 Secure the thermocouple of digital thermometer onto the hot-spot mark of the transducer.

4.4 List of The Programs to be Tested for Full Verification

First, several of the procedures which control devices or acquire data will be tested. Then, the main program will be run, and its results will be checked using the already-verified procedures. The first group of procedures to be tested is:

4.4.1 Ultrasound control program

: setZForInte_modify_Bmode_temperature_PRF&Volt

: setZForInte_modify_Bmode_temperature_SA test

4.4.2 Temperature measurement program

: Thermal PRF check by PID

: Thermal measure Volt&SA

Next, the automatic temperature measurement program will be run, and the results in the database will be verified using the procedures listed above.
(For the automatic section 5.1)

4.5 List of the Programs to be tested for Verification by Comparison

For verification by comparison the automatic temperature program will be run for the previous and new versions of the software and the results in the database will be compared.

4.6 Acceptance Criteria(Temperature deviation: ±10%)

Each tested program does what it is designed for, and gives all of the required outputs correctly.

5.0 TEST REPORT FORM

5.1 Ultrasound control program

5.1.1 Set the system and align the probe.

5.1.2 Using Temperature measurement program set condition and record. Print out the set condition.

5.1.3 After the program finishes running, check transmit parameters in the DUI.

Does mode match the given value? Yes ____ No ____

Does frequency match the given value? Yes ____ No ____

Does inTxAperModulationEn match the given value?

Yes ____ No ____

Does wave style match the given value? Yes ____ No ____

Does FOV size match the given value? Yes ____ No ____

Does ROI size match the given value? Yes ____ No ____

Does PRF match the given value? Yes ____ No ____

Does focus match the given value? Yes ____ No ____

Does depth match the given value? Yes ____ No ____

Does number of elements match the given value?

Yes ____ No ____

Does number of cycles match the given value?

Yes ____ No ____

Does voltage supply match the given value?

Yes ____ No ____

Does elevation aperture match the given value?

Yes ____ No ____

Test person (initial) _____ Test date _____

5.2 Temperature Measurement

5.2.1 Set the system and align the probe.

5.2.2 Turn on the IR (infrared) thermometer. Adjust the height of the transducer-under-test so the target light is tightly focused and in the approximate center of the transducer face.

5.2.3 Configure the ultrasonic diagnostic system so that it could be running for at least 30 minutes without changing the transmit activity once the system operating is set. For example, disable the screen saver/ power saver function.

5.2.4 Set system to the desired operating condition by temperature measurement program.

5.2.5 Allow system transmits to run under the desired operation condition for approximately about 5 minutes or until the temperature rise becomes stable and begin to locate the hottest spot on transducer's surface using manual translation.

5.2.6 [Way: After four minutes (time = 4), search for the hottest spot on the transducer face. At the five-minutes (time = 5), the stable temperature is represented at the hottest spot.]

5.2.7 Mark the hottest spot with an inked pen.

5.2.8 Secure the thermocouple of digital thermometer onto the hot-spot mark of the transducer.

5.2.9 Compare Infrared Thermometer and Thermometer with thermocouples and write Table 2.

5.3 Temperature Measurement by comparison

The steps in this section are only performed for verification by comparison as described in Section 3.3.

5.3.1 Set the ultrasound system with the transducer.

5.3.2 For the previous version of the intensity measurement program, run "TopTemperatureMeasure". Use the same measSetId as for measurement with the previous version of the software. Also use the same test setup, including Z system, probe SN, thermometer type and serial resource. When the program finishes running, print the temperature measurement data by SQL database and record measSetId(=tempSSId) and temperatureId.

MeasSetId(tempSSId) _____

TemperatureId _____

5.3.3 For the new version of the intensity measurement program, run "TopTemperatureMeasure". Use the same measSetId as for measurement with the previous version of the software. Also use the same test setup, including Z system, probe SN, thermometer type and serial resource. When the program finishes running, print the temperature measurement data by SQL database and record measSetId(=tempSSId) and temperatureId.

MeasSetId(tempSSId) _____

TemperatureId _____

5.3.4 Compare the data for the two measurements. Use the data stored in the database.

Are the pulseVoltages same?	Yes ____	No ____
Are the numTxCycles same?	Yes ____	No ____
Are the numTxElements same?	Yes ____	No ____
Are the txFrequencyHzs same?	Yes ____	No ____
Are the inTxAperModulationEns Same?	Yes ____	No ____
Are the txpgWaveformStyle same?	Yes ____	No ____
Are the pulseRepetRates same?	Yes ____	No ____
Are the scanRanges same?	Yes ____	No ____
Are the roomTempC values within +/-10%?	Yes ____	No ____
Are the temperatureC values within +/-10%?	Yes ____	No ____

Are the temperature rise C values within +/-10%?

Yes ____ No ____

* temperature rise C = temperatureC value – roomTempC value

If the comparisons show good correspondence between measurement with the previous and new versions of the software, then the result by database and write a summary(Table 3) in the verification notes.

5.4 Test Result Summary Sheet

Table 1: Record of test equipment

Equipment	Model	S/N	Calibration Date
Infrared Thermometer			
Thermometer with thermocouples			
Transducer			
Ultrasound Diagnostic system			

Test person(Initial): _____ Test Date: _____

Table 2: Summary of test results between IR and Thermometer

Program (Version:)	Infrared Thermometer	Thermometer with thermocouples	Difference	Pass/Fail	Ambient
degree(°C)					/

Table 3: Summary of test result comparison between previous and new version.

Program (Version:)	Previous version	New version	Difference	Pass/Fail	Ambient
degree(°C)					/

5.5 Verification Notes and Summary

5.6 Discrepancies

5.7 Test Approval

Authored by:	_____	_____	_____
	Print Name	Signature	Date
Reviewed by:	_____	_____	_____
	Print Name	Signature	Date
Reviewed by:	_____	_____	_____
	Print Name	Signature	Date

Engineering Manager

_____	_____	_____
Print Name	Signature	Date

Quality Assurance

_____	_____	_____
Print Name	Signature	Date

6.0 Traceability Matrix

SRS Doc. Index	SRS Description	Verification and validation Doc. Index	Test Case Description
3.1	User interaction subroutines	5.1	Ultrasound control program
3.2	Control subroutines	5.1	Ultrasound control program
3.3	Database subroutines	5.3	Temperature Measurement by comparison
3.4	Z system communication subroutines	5.3	Temperature Measurement by comparison
3.5	Temperature meter subroutines	5.2	Temperature Measurement

7.0 REFERENCE

No.	Document Name	Doc. No.
1	Temperature Measurement Software Requirements Specification	11344281-EPH
2	Temperature Measurement Software Detailed Design Description	11344281-EPH
3	Temperature Measurement Software	11344281-ESK
4	Acoustic Database Description	4848375
5	IEC 60601-2-37	IEC Standard
6	National Instruments Professional Development Suite documentation, (includes LabVIEW, Database Connectivity, Application Builder, and other pertinent information)	Public document - filed reference copy available.

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Appendix to Document: **11344281 FPV 001 04 , ECO: 702365**
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