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Siemens Healthineers
Business Area Ultrasound

Title: Temperature Measurement Software Failure Modes and Effects Analysis

Part Number: 11344281-EGA-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	2017.04.14 / 660066
02	To add transmit channel modulation control on temperature measurement software rev 2.0	Hwang, InSeop	2017.04.13 / 660065
01	Initial SAP released on temperature measurement software rev 1.0	Hwang, InSeop	2017.04.05 / 657217

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1.0 PURPOSE

This document describes the computer system failure modes and effects analysis(FMEA) of temperature measurement software.

2.0 SCOPE

The computer system failure modes and effects analysis(FMEA) is to cover effects and analysis for failure mode for temperature measurement software.

3.0 FMEA Rating Guide

SEV

Designation	Rating	Criteria
5	Critical	System failure, data corruption or data integrity resulting in SUSKO, or customers, left unable to do business. Major application downtime. No work around, business at risk for financial losses. System violation(s) of regulatory requirements resulting in death or severe injury (loss of limbs, etc) to the patient, user, or field service personnel.
4	High	System failure, data corruption or data integrity resulting in shortcomings leading to the loss of good will and long-term effects. Product failures resulting in severe injury (e.g. lost work days, immediate or subsequent) to the patient, user, or field service personnel.
3	Moderate	System failure, data corruption, or data integrity resulting in a part of a process not working. No loss of data, short-term effects. Available work around. Product failures resulting in minor injury (e.g. no lost workday) to the patient, user, or field service personnel).
2	Low	System failure, data corruption, or data integrity resulting in non-critical problems, remedy can wait. Loss of work efficiencies. Product failures resulting in damage to the system, other property, or the environment.
1	Negligible	System failure, data corruption, or data integrity resulting in minor inconvenience transparent to cost. Negligible resources required to correct the issue. Product failure may result in adversely affecting associated/peripheral equipment or the process, but will not result in injury, or system and/or environmental damage.

OCC

Designation	Assessment	Occurrence ability
5	Very frequent	A very high number of similar occurrences already on record has occurred a very high number of times at the system.
4	Frequent	A significant number of similar occurrences already on record has occurred a significant number of times at the system.
3	Occasional	Several similar occurrences on record has occurred more than once at the system.
2	Rare	Only very few similar incidents on record when considering a large traffic volume or no records on a small traffic volume.
1	Extremely rare	Has never occurred yet throughout the total lifetime of the system.

RPN

Risk Category	Lower RPN Limit	Upper RPN Limit
Broadly acceptable	1	5
ALARP	6	15
Intolerable	16	25

4.0 Computer Systems Failure Modes and Effects Analysis(FMEA)

Software Name:	**Temperature Measurement Software**
Version Number	**4**

Prepared by: Hwang, InSeop
FMEA Date (Orig): 2019-09-18 (Rev): 4

Software function	Function Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	Current Controls	OCC	RPN	Actions Recommended	Resp.	Actions Taken	SEV	OCC	RPN
What is the software function	*What is the key Input to this software function?*	*In what ways does the Key Input go wrong?*	*What is the impact to the customer and or users?*	*How Severe is the effect to the customer?*	*What causes the Key Input to go wrong?*	*What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode?* ***Should include an SOP number.***	*How many times an event occur?*	*Risk Priority Number*	*What are the actions for reducing the occurrence of the Cause, or improving detection?* ***Should have actions only on high RPN's or easy fixes.***	*Whose Responsible for the recommended action?*	*What are the completed actions taken with the recalculated RPN?* ***Be sure to include completion month/year***			
Data lose	Measurement AOP value	data delete	data lose	10	data lose	database data back up to local disk	1	10	N/A	N/A	N/A	10	1	**10**
	Measurement date													
	Measurement person													
	Measurement S/W revision													
	Measurement sample information													

	Measurement Instrument information													
Data Input	Measurement date Measurement person Measurement S/W revision Measurement Instrument information Measurement sample information Measurement function	data typo (Text and function)	wrong input data	5	wrong input data	modify wrong input data	2	**10**	operation training	administration	operation training	5	1	**5**
Data calculation and Output	Measurement AOP value Measurement calculation Measurement date Measurement person Measurement S/W revision Measurement sample information Measurement Instrument information	different output data	User refers wrong input data	10	1. The user selects wrong input data 2. Original data from database is modified by some reasons 3. The problem in user network occurs system dis-connection.	1. To ask input data again to user 2. To set up that only administrator account can modify data in database. 3. To share the status of network before data calculation and output delivery.	2	**20**	By software validation Report: 11344281-FPV-002-04	administration	By software validation Report: 11344281-FPV-002-04	10	1	**10**

RPN

Risk Category	Lower RPN Limit	Upper RPN Limit
Broadly acceptable	1	5
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