Siemens Healthineers
Business Area Ultrasound

Title: RADIX 2.5 Reliability Demonstration Test Report

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Revision Data

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02	**753429**	***Update @ RADIX 2.5 PRR***	**Holland Crook**

REVISION HISTORY

Rev	ECO #	Change Description
02	753429	*Update @ RADIX 2.5 PRR*
01	753428	*Initial Release @ RADIX 2.5 S&E*

CONTENT

1.0 PURPOSE

This document describes the results for the Reliability Demonstration Test (RDT) of the ACUSON Sequoia RADIX 2.5.

2.0 SCOPE

This plan applies to the ACUSON Sequoia RADIX 2.5. The audience of this document is the hardware and systems teams responsible for development of the Sequoia ultrasound system.

This plan defines the testing that must be executed in order to demonstrate the expected life of the Sequoia System.

3.0 DEFINITIONS

AF – Acceleration Factor

ALT – Accelerated Life Test

Compass – Development name for Sequoia product

RDT – Reliability Demonstration Test

RE – Reliability Engineer

4.0 RESPONSIBILITIES

The Reliability Engineer is responsible creating and executing this plan.

5.0 RDT BACKGROUND AND MODELS

An RDT is aimed at statistically demonstrating the expected life of the product based on an established Use Case Model. The Use Case Model should be representative of how the system will be used by the customer (or how a module will be used in a completed product).

All conditions are based on nominal operating use and environment.

As it is not practical to determine times-to-failure data under normal operating conditions for the expected life of the product, ALT methodologies will be applied. The goal of ALT is to accelerate the time to failure by applying higher usage frequency or stress levels than the product would experience under normal customer use in order to predict the characteristics of the product under normal use conditions.

It is essential to ensure that we do not expose the product to unrealistic stresses that will create failures we would not see in the field under normal use case. Refer to the Compass HALT Report 11149229-EPT-003 for established Operational Limits that cannot be exceeded.

The following quantitative accelerated testing methodologies will be used:

- **Usage Rate Acceleration** – for scenarios where the product isn't used continuously, the product will be continuously tested (increased frequency) in order to observe a failure event
- **Overstress Acceleration** – for scenarios where the product is used continuously, the product will be exposed to higher stress levels in order to observe a failure event

5.1 System Process Flow Use Case Model

Table 1 lists the assumed process flow of how an ultrasound system will be used by the customer (as viewed from a functionality standpoint). The two scenarios depicted are

- A mobile ultrasound system that is moved from one location to another
- An ultrasound system that is fixed in one location

Since the mobile ultrasound system is exposed to more dynamic mechanical stresses and requires more functionality, we will design the mechanical demonstration test around the mobile ultrasound system use case. Since most of these activities do not involve continuous use, we will use the Usage Rate Acceleration method to demonstrate the reliability of these functions.

For the imaging duration demonstration, the stationary use case systems will be exposed to a higher duty cycle and so we will design the demonstration test around this scenario. Since this activity involves continuous use, we will use the Overstress Acceleration method to demonstrate the reliability of this function.

ID	how a user will use a mobile system	how a user will use a stationary system	Duration (mins)
1	transport it from scanning room to patient room (monitor in transport position)	NA	15
2	connect System power cable to wall outlet	NA	
3	adjust CP and Monitor to desired setting	adjust CP and Monitor to desired setting	10
4	press the CP power switch to power the system on	press the CP power switch to power the system on (NA if system is left powered on)	
5	connect a transducer (or multiple transducers)	connect a transducer (or multiple transducers)	
6	apply gel to transducers	apply gel to transducers	
7	set up patient data and select workflow	set up patient data and select workflow	
8	***perform ultrasound imaging***	***perform ultrasound imaging***	30
10	perform micro adjustments of CP and Monitor	perform micro adjustments of CP and Monitor	10
11	use of peripherals & accessories to perform support functions (print pictures, save to DVD, etc)	use of peripherals & accessories to perform support functions (print pictures, save to DVD, etc)	10
9	create patient report	create patient report	
12	clean gel from transducers	clean gel from transducers	
13	disconnect transducers (no implications if transducers stays connected)	disconnect transducers (if transducers are connected, system will be in imaging mode)	
14	press the CP power switch to power the system off	systems stays powered on (in imaging mode if transducers are connected)	
15	Adjust CP and Monitor to “transport” position	NA	15
16	disconnect EMAC power cable from wall outlet	NA	
17	transport it from patient room to scanning room	NA	

Table 1: System process flow

Based on the scenarios described in Table 1, the total exam length (including all supporting activities) is 90 minutes for the Mobile Use Case and 60 minutes for the Stationary Use Case.

5.2 Diagnostic Exam Use Case Model

Table 2 lists the assumed exam length and frequency of use over the designed life of the ultrasound system. Since the assumption is that imaging is continuously performed, we will use the Overstress Acceleration method to demonstrate the reliability of this function.

	stationary	mobile	China
length of exam (hour)	1	1.5	0.25
Imaging hours/exam	.5	.5	.20
hours per day	12	12	8
exams per day	12	8	48
use days per week	5	5	5
use weeks per year	50	50	50
design life (years)	6	6	6
exams over life	18,000	12,000	72,000
hours over life	18,000	18,000	18,000
imaging hours over life	9,000	6,000	14,400

Table 2: Diagnostic exam length and frequency over design life

Exams over life = exams per day*use days per week*use weeks per year*design life

Hours over life = exams over life*length of exam(hour)

Imaging hours over life = exams over life*imaging hours/exam

Note that China uses mainly the stationary scenario

6.0 RELIABILITY DEMONSTRATION TEST RESULTS

From the use case scenarios detailed in Table 1 and Table 2, we can derive the following Reliability Demonstration Tests.

All demonstrated reliability targets can be traced to RADIX 2.5 System HW Design Reliability Test Plan 11658349-EFT-001.

6.1 Monitor and Main Cable Harness Articulation RDT

Three RADIX 2.5 systems, 800886, 801048, and 803745 were used for this RDT.

6.1.1 For the stationary system (worst case for this function), perform articulation of the CP and Monitor per movement category/direction over 18,000 cycles each (this assumes one cycle of movement per movement category/direction per exam)

6.1.2 Usage rate acceleration shall be applied to demonstrate the reliability requirements

6.1.3 The reliability requirements are listed below:

- Monitor articulation and associated cables shall have a demonstrated reliability of 80% with 80% Confidence Interval after 18,000 exams (all joints run through their complete range of motion, minus 5° before each end stop, once per exam). To demonstrate this, we will need to use a sample size of 3 systems and perform 33,350 movements for without any failures.
- The Main Harness and associated connection ports shall have a demonstrated reliability of 80% with 80% Confidence Interval after 18,000

exams (all joints run through their complete range of motion, minus 5° before each end stop, once per exam). To demonstrate this, we will need to evaluate the main harness after completion of the CP and Monitor Articulation tests.

6.1.4 All observations and recommendations shall be recorded in this report.

Monitor and Main Cable Harness Articulation RDT Summary:

PASS. RADIX 2.5 systems 800886, 801048, and 803745 were subjected to and have completed this RDT. The monitor tilt joint weakness captured in TFS Defect 1810784 which was reproduced on all systems.

The monitor joint was able to be tightened and the weakness resolved.

On the completed systems, the cables and other joints tested were inspected and found to be passing and in good condition.

Note: 33,350 adjustments or cycles from the reliability requirement was rounded up to 33,500 during testing for simplicity. This technically demonstrated 80% Reliability with 90% Confidence Interval.

7.0 QUALITY RECORDS - N/A

8.0 FLOW CHART - N/A

9.0 REFERENCES

RADIX 2.5 HW Reliability Demonstration Test Plan (11658349-EFT-001)

10.0 APPENDIX - N/A

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