Siemens Healthineers
Business Area Ultrasound

# Title: Compass RDT Report

## Part Number: 11149229-EPT-004_01

## Revision Data

| Rev | ECO # | Change Description | Printed Name |
|---|---|---|---|
| 01 | 675306 | Initial release | Ganesh Sivananthan |

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# CONTENT

## 1.0 PURPOSE

This document details the results of the Compass System VA10A Reliability Demonstration Test (RDT).

This test report is based on the Compass RDT Plan 11149229_EFT_004.

## 2.0 SCOPE

This report applies to the Compass System VA10A. The audience of this document is the hardware and systems teams responsible for development of the Compass ultrasound system. It will also be useful to the SCM organization as it supports the Compass ultrasound system in forward production.

This report defines the verification testing that was executed in order to demonstrate the expected life of the Compass System.

## 3.0 DEFINITIONS

| Acronym or Abbreviation | Definition |
|---|---|
| AF | Acceleration Factor |
| ALT | Accelerated Life Test |
| RDT | Reliability Demonstration Test |
| RE | Responsible Engineer |

**Table 1: Acronyms**

## 4.0 RELIABILITY DEMONSTRATION TEST (RDT) RESULTS

All demonstrated reliability targets can be traced to Compass System HW Design Reliability Test Plan 11149229 EFT 001 (summarized table shown in Appendix A: Reliability Targets).

| | | |
|---|---|---|
| 4.1 | System Mobility RDT | PASS, defect 816495 |
| 4.2 | EMAC Power Cable RDT | PASS |
| 4.3 | CP and Monitor Articulation RDT | PASS, defect 700050, 816499 |
| 4.4 | System Power Cycle RDT | PASS, defect 760336 |
| 4.5 | Transducer Connect-Disconnect RDT | PASS, defect 733870 |
| 4.6 | Diagnostic Exam Length RDT | PASS |
| 4.7 | E-Mode RDT | PASS, defect 736420 |

**Table 2: RDT Results Summary Table**

**System Process Flow RDT**

### 4.1 System Mobility RDT

4.1.1 In the systems default transportation position, we assumed that the mobile system (worst case for this function)

- travels a distance of 2000ft and over 4 thresholds per exam ($24x10^6$ ft and $48x10^3$ thresholds after 12,000 exams)
- has 4 applications of the brake mechanism pedals per exam ($48x10^3$ applications after 12,000 exams)

4.1.2 Usage rate acceleration would need to be applied to demonstrate the reliability requirements.

4.1.3 The reliability targets were determined as listed below

- Casters shall have a demonstrated reliability of 85.60% at 90% Confidence Interval after 12,000 exams. To demonstrate this, we will need to use a sample size of 9 systems and travel a distance of 30,786,032 ft and go over 61,572 thresholds without any failures.
    - Castor reliability was demonstrated by the supplier based on Castor Requirement Specification 11288244-EPH-001-01. The test results were verified by Mechanical Engineering Expert and deemed to be equivalent to the requirements listed in this test plan.
    - Refer to Appendix B: Mechanical Engineering Expert Memo detailing why the risk of not statistically demonstrating this requirement is acceptable.
- Brake Mechanisms shall have a demonstrated reliability of 92.80% at 90% Confidence Interval after 12,000 exams. To demonstrate this, we will need to use a sample size of 9 systems and actuate the pedals 88,818 times without any failures.
    - Brake Mechanism reliability was demonstrated on a single assembly. Refer to Compass Mechanical RDT Test Report 11290640-EPT-001 for test details.
    - Refer to Appendix B: Mechanical Engineering Expert Memo detailing why the risk of not statistically demonstrating this requirement is acceptable.

**System Mobility RDT Summary**:
PASS.
The activation forces on the central lock function showed notable change (50%) around 16K cycles, although the function remained operational. Details are logged in defect 816495.

## 4.2 EMAC Power Cable RDT

4.2.1 In the mobile system use case (worst case for this function), the female end of the cable will be held stationary since it will be held in place by a bracket (except during service events). The male end will need to be plugged in and pulled out. We assumed that per exam

- male end is plugged in and pulled out once (12,000 cycles after 12,000 exams)
- female end experiences 1 yank (12,000 yanks after 12,000 exams)
- cable experiences 2 twists (24,000 twists after 12,000 exams)
- cable experiences 2 bends (24,000 bends after 12,000 exams)
- cable experiences 1 occasion of being rolled over by a gurney (12,000 rolls after 12,000 exams)

4.2.2 Usage rate acceleration was applied to demonstrate the reliability requirements

4.2.3 The reliability requirements were determined as listed below

- AC cable shall have a demonstrated reliability of 74.80% at 90% Confidence Interval after 12,000 exams. To demonstrate this, we will need to use a sample size of 10 cables and
    - Plug in and pull out the male end 10,686 times without any failures
    - Yank the female end while connected 10,686 times without any failures
    - Twist the cable 21,373 times without any failures
    - Bend the cable 21,373 times without any failures
    - Simulate rolling over the cable with a gurney 10,686 times without any failures

- We will obtain the cable reliability report from the supplier to demonstrate that the cable requirement (or an equivalent requirement) is met

4.2.4 To meet the requirement of the EMAC Power Cable RDT,

- Analysis method was applied based on testing performed by the supplier and the suppliers field performance.
- Refer to Appendix C: AC Power Cable Reliability Tests Memo detailing why the risk of not statistically demonstrating this requirement is acceptable.

**EMAC Power Cable RDT Summary**:
PASS, no design weaknesses were observed. Based on the tests and analysis performed by the supplier, the cable was deemed reliable to perform through the 6 year service life to meet the reliability targets.

## 4.3 CP and Monitor Articulation RDT

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

4.3.2 Usage rate acceleration was applied to demonstrate the reliability requirements

4.3.3 The reliability requirements are listed below

- CP articulation and associated cables shall have a demonstrated reliability of 90.64% at 90% Confidence Intervals after 18,000 exams (3 movements per exam). To demonstrate this, we will need to use a sample size of 9 systems and perform 87,129 movements without any failures.
- Monitor articulation and associated cables shall have a demonstrated reliability of 92.80% after 18,000 exams (3 movements per exam). To demonstrate this, we will need to use a sample size of 9 systems and perform 99,920 movements without any failures.
- The Main Harness and associated connection ports shall have a demonstrated reliability of 89.92% after 18,000 exams (3 movements per exam). To demonstrate this, we will need to evaluate the main harness after completion of the CP and Monitor Articulation tests (note that evaluation may be performed after 83,795 cycles as this is all that is required to prove the 89.92% reliability).
  - CP and Monitor Articulation reliability was demonstrated on a single assembly. Refer to Compass Mechanical RDT Test Report 11290640-EPT-001 for test details.
  - Refer to Appendix B: Mechanical Engineering Expert Memo detailing why the risk of not statistically demonstrating this requirement is acceptable.

**CP and Monitor Articulation RDT Summary**:
PASS.
It was observed that excessive force was required to adjust CP elevations. Details are captured in defect 700050.
Also, it was noted that the Mechanical RDT for VA10A release was performed on systems with some early versions of various components. Significant changes have been made to the component designs to address on-going improvements. The RDT should be performed again on the final VA10A, once all changes are incorporated on final production quality processes. This has been captured in defect 816499.

## 4.4 System Power Cycle RDT

4.4.1 This demonstration will be for the mobile system use case (worst case for this function). With a PCD connected, SysCare PowerOnOff RDT Diagnostic script was executed (refer to Appendix D: SysCare PowerOnOff RDT Diagnostic Script). The mobile system is expected to experience 12,000 power cycles over a 6 year use life.

4.4.2 Usage rate acceleration was applied to demonstrate the reliability requirements.

- A constant failure rate was assumed over 6 years of service life
- This means that the first years performance shall be representative of the following 5 years' performance (only the first years performance was demonstrated)

4.4.3 The reliability requirements are listed below

- The system shall have a demonstrated reliability of 53.32% at 90% Confidence Intervals after 2,000 power cycles
- To demonstrate this, we will need to use a sample size of 9 systems power cycled for 1276 cycles without failure

4.4.4 Results of systems with System ID numbers are listed below

| RDT test | reliability goal | Cycles per year | #004 | #008 | #015 | #024 | #025 | #026 | #028 | #027 | #022 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| System Power Cycle (cycles) | 53.32% | 1,276 | 1513 | 1963 | 1473 | 1998 | 1998 | 1998 | 1582 | 1682 | 1856 |

**System Power Cycle RDT Summary**:
PASS.

BP ID Prom corruption occurred at cycle 1582. Since passing the test required all 9 systems to complete 1276 cycles, the reliability requirement was met. The failure is still a concern since Constant Failure Rate is being assumed. Root cause efforts will be detailed in defect 760336. Once root cause has been determined, the test will need to be repeated through 6 years of use.

*Note that the reason why Systems #004, #008, #015, #22 and #27 weren't tested up to 1998 cycles (as the other 3 systems) was due to schedule limitations.*

## 4.5 Transducer Connect-Disconnect RDT

4.5.1 For the stationary system (worst case for this function), it is expected that a transducer is connected and disconnected once per exam. In order to verify the reliability of the TPM ports (and associated electronics) over the life of the system, PCDs were connected and disconnected via the TPM ports 18,000 cycles per port.

- A PCD was inserted into one of the TPM ports
- The port was latched
- Verification was done that the PCD was recognized by the system with the use of diagnostics
- Unlatch the port and use diagnostics to confirm that the PCD had been unlatched.
- Repeat for the rest of the TPM ports
- At every 750 cycles (equivalent to 3 months of use life)
    - Manually connect-disconnect the PCDs to determine "feel
    - Visually inspect mating surfaces of transducer and TPM ports
    - Introduce gel and lint (or other representative contaminants) to the mating surface prior to restarting the next 750 cycles

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

4.5.3 The reliability requirements are listed below

- Each TPM port shall have a demonstrated reliability of 89.92% at 90% Confidence Intervals after 18,000 cycles
- The test plan required this to be demonstrated on 2 TPM ports (4 ports each); 1 sample from the P1 build and the second from the PPQ build. The test was performed only on the P1 build TPM since PQ builds were delayed.
- Each port of the P1 build TPM was exposed to 30,000 (29,626 was needed for the requirement) connect-disconnect cycles without failure to prove the 89.92% reliability after 18,000 exams

*Note that transducer reliability shall not be evaluated as it is out of the scope of this RDT. The test may be conducted concurrently but results shall be mutually exclusive*

4.5.4 Results of P1 TPM ports

| RDT test | reliability goal | Cycles requirement | Port 0 | Port 1 | Port 2 | Port 3 |
|---|---|---|---|---|---|---|
| Transducer Connect-Disconnect RDT (cycles) | 89.92% | 29626 | 2 bent pin; knob doesn't actuate smoothly after 13,200 cycles (but still functional) | 1 bent pin | 5 bent pins | 7 bent pins |

**Transducer Connect-Disconnect RDT Summary**:
PASS, with a few observations.

4.5.4.1 When gel is applied to the XBB boards and allowed to dry up, it takes about 800 cycles prior to passing the RF Test (indicating no contact between the pins of the TPM port to the pads on the XBB board). This was an extreme case but when XBB is cleaned up, full functionality was returned

4.5.4.2 Multiple ground pins broke off (refer to defect 733870 for details of the failure).Refer to Appendix E: PodPlugger Cycle Observations for details of test observations.

4.5.4.3 Port 1 knob doesn't actuate smoothly after 2.8 years of use but still retains functionality

Based on the tests and analysis of the system logs, the system was deemed reliable to perform through the 6 year service life to meet the reliability targets.

## Diagnostic Exam RDT

### 4.6 Ultrasound Diagnostic Exam Length RDT

The system in the stationary use case is subjected to higher constant thermal stress levels than the system in the mobile use case (9000 vs 6000 imaging hours over life).

4.6.1 With an Emulator connected, the "auto sequence test" was executed to cycle through workflows and image modes.

4.6.2 A constant failure rate was assumed over 6 years of service life. This means that the first years performance (1500 hours) will be representative of the following 5 years' performance (7500 hours)

4.6.3 Overstress acceleration (using the Arrhenius Model) was applied to demonstrate 1500 imaging hours over the first years service life. The system was run at 40C (nominal operating temperature 25C) in order to create the overstress acceleration.
*The initial plan was to run at 50C but the system will power off due to over-temperature conditions (built in safety mechanism by design)*

With an activation energy of 0.6eV (which is the same constant that is used by Delta on the EMAC), we obtained an Acceleration Factor of 3.06.This reduced the required demonstration time from 1,500 imaging hours at 25C to 490 imaging hours at 40C (i.e. operating at 40C for 490 hours is equivalent to operating at 25C for 1,500 hours).

4.6.4 The reliability requirements are listed below

- System shall have a demonstrated reliability of 53.32% after 1 year of use life
- In order to demonstrate a System Reliability of 53.32% at 25C for 1,500 imaging hours (at 40C for 490 hours),
  - we will use a sample size of 9 systems continuously running the “auto sequence” test at 40C ambient
  - for 312.7 hours each without failure (at 90% CI)

Refer to Appendix F: Arrhenius Acceleration Factor Calculations for Imaging RDT for the calculation details

4.6.5 Results of systems with System ID numbers are listed below

| RDT test | reliability goal | Hours per year | #004 | #008 | #015 | #024 | #025 | #026 | #028 | #027 | #022 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Diagnostic Exam Length (hours) | 53.32% | 490.27 | 313 | 313 | 313 | 313 | 313 | 313 | 313 | 313 | 313 |

**Diagnostic Exam Length RDT Summary**:
PASS, with a few observations.

4.6.5.1 Fan speed had to be increased from 2500rpm max to 2850 rpm to compensate for the 40C ambient. While this increases the noise while system is operational, it is unlikely for the system to be operated in this environment in the field. This was incorporated into the production firmware in case the system was ever operated in a 40C ambient

4.6.5.2 “Thermal Warning” message pop up threshold was increased from 75C to 84C (at 85C, the system will automatically power off). This change was not incorporated into the production firmware as we want to warn the user not to exceed the safe operating area of the system

## 4.7 E-Mode RDT

4.7.1 This demonstration was for the stationary system use case (worst case for this function), With an emulator configured as a DAX probe connected to Port 1, E-Mode was set to SWE and max depth of 40. Acquisitions were repeated using a script (refer to Appendix G: E-Mode Test Script) . The stationary system is expected to experience 15,000 exams over a 6 year use life.

4.7.2 The reliability requirements are listed below

- The System shall have a demonstrated reliability of 89.92% at 90% Confidence Intervals after 15,000 exams
- To demonstrate this, we will need to use a sample size of 9 Systems and execute 23277 E-Mode acquisitions

4.7.3 Results of systems with System ID numbers are listed below

| RDT test | reliability goal | Acquisitions (6 years) | #004 | #008 | #015 | #024 | #025 | #026 | #028 | #027 | #022 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| E-Mode RDT (acquisitions) | 89.92% | 15,000 | 23,277 | 23,277 | 23,277 | 23,277 | 23,277 | 23,277 | 23,277 | 23,277 | 23,277 |

**E-Mode RDT Summary**:
PASS, with one defect.

4.7.3.1 When the region of interest (ROI) was skewed from the default position, the Software would freeze. Defect 736420 captures all the details.

A reset was added to the script to enable testing to continue (regardless of ROI position)

# 5.0 Appendix

## 5.1 Appendix A: Reliability Targets

Table 3 below summarizes the RDT goals for the Compass System from Table 3 in Compass System HW Design Reliability Test Plan 11149229 EFT 001

| Component | Compass Target (Requirement) | | | |
|---|---|---|---|---|
| | % Good after life | Life (Years) | CFR/mth | RDT plan |
| **Imaging Electronics** | | | 0.71% | |
| TPM | 89.92% | 6 | 0.14% | In this plan |
| TRAM | 97.12% | 6 | 0.04% | In this plan |
| TRAM | 97.12% | 6 | 0.04% | In this plan |
| TRAM | 97.12% | 6 | 0.04% | In this plan |
| CPP | 89.92% | 6 | 0.14% | In this plan |
| EMAC | 89.92% | 6 | 0.14% | In this plan |
| IOM | 94.24% | 6 | 0.08% | In this plan |
| CC (BP) | 93.52% | 6 | 0.09% | In this plan |
| **Computer** | | | 0.60% | |
| CEM | 56.80% | 6 | 0.60% | In this plan |
| **Control Panel** | | | 0.84% | |
| CP | 89.92% | 6 | 0.14% | OEM RDT |
| Buttons/Caps/Keys/Knobs | 56.80% | 6 | 0.60% | OEM RDT |
| Keyboard | 92.80% | 6 | 0.10% | OEM RDT |
| **Display** | | | 0.10% | |
| SMM | 92.80% | 6 | 0.10% | OEM RDT |
| **Infrastructure** | | | 0.70% | |
| AC Cable | 74.80% | 6 | 0.35% | In this plan |
| Cooling | 89.92% | 6 | 0.14% | In this plan |
| Ethernet | 96.40% | 6 | 0.05% | No demonstration planned |
| WiFi | 99.28% | 6 | 0.01% | No demonstration planned |
| Audio | 99.28% | 6 | 0.01% | No demonstration planned |
| Main Harness | 89.92% | 6 | 0.14% | In this plan |
| **Mechanical** | | | 0.73% | |
| Casters | 85.60% | 6 | 0.20% | In this plan |
| Brake Mechanism | 92.80% | 6 | 0.10% | In this plan |
| Covers and Panels | 85.60% | 6 | 0.20% | No demonstration planned |
| CP Articulation | 90.64% | 6 | 0.13% | In this plan |
| Monitor Articulation | 92.80% | 6 | 0.10% | In this plan |
| **Peripherals & Acc.** | | | 0.21% | |
| DVD | 96.40% | 6 | 0.05% | No demonstration planned |
| DVR | 100.00% | 6 | 0.00% | No demonstration planned |
| ECG Cable | 99.28% | 6 | 0.01% | No demonstration planned |
| Footswitch | 95.68% | 6 | 0.06% | No demonstration planned |
| Gel Warmer | 99.28% | 6 | 0.01% | No demonstration planned |
| Physio | 97.12% | 6 | 0.04% | No demonstration planned |
| Printers | 97.12% | 6 | 0.04% | No demonstration planned |
| Probe Holder | 100.00% | 6 | 0.00% | No demonstration planned |
| **Full System** | | | **3.89%** | |

**Table 3: Compass System Reliability Targets**

## 5.2 Appendix B: Mechanical Engineering Expert Memo

Compass_RDT_Mech
anical Engineer_Memo

## 5.3 Appendix C: AC Power Cable Reliability Tests Memo

AC Power Cable
Reliability Tests Memo

## 5.4 Appendix D: SysCare PowerOnOff RDT Diagnostic Script

System_ESS_RDT_1
0.xml

System_ESS_RDT_1
1.xml

System_ESS_RDT_1
2.xml

## 5.5 Appendix E: PodPlugger Cycle Observations

POD Plugger.xlsx

## 5.6 Appendix F: Arrhenius Acceleration Factor Calculations for Imaging RDT

Arrhenius
Exceleration Factor1.

## 5.7 Appendix G: E-Mode Test Script

RunEModeLoopTest.
bat

RunEModeLoopTest.
bat

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Appendix to Document: **11149229 EPT 004 01 , ECO: 675306**
Sheet generated at : **2018-04-27T03:33:27-02:00**
Originator **: SIEMENS Healthcare, P41**
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| **AUTHOR** | **2018-04-27T03:32:09-02:00** | **Burke, Laurel** |
| **APPROVAL** | **2018-04-27T03:32:51-02:00** | **Burke, Laurel** |