Document number	0000986 Rev. 1
Document name	Test Report Analysis of Eurofins Environmental Stress Test on DCiS / DC-Air
Product(s)	Wireless intra oral sensor WIOS-S2
Author(s)	Konstantinos Spartiotis
Created	2.6.2023 11.12
Last Modified By	(M-Files Server), 2.6.2023 11.12

Test Report

Version:	Author:	Date:	Description:
1.0	Konstantinos Spartiotis Markku Eräluoto	1.6.2023	First version

TABLE OF CONTENTS

1 INTRODUCTION

1.1 Purpose and Scope

Athlos performed severe environmental stress tests of its DCiS / DC-Air direct conversion, wireless intraoral sensor to prove the robustness of the product.

The direct conversion, wireless intraoral sensor consists of the Application Specific Integration Circuit (ASIC) and the Si detector, are bonded to the Printed Circuit Board (PCB) via wire bonds. The PCB contains the required transceiver for wireless communication.

1.2 Scope of Testing

The scope of the testing is to verify by severe environmental tests that DCiS / DC-Air is effective and withstrands the most extreme cases of use and storage. The environmental tests simulate the worst-case storage and operational conditions for the sensor. Testing was performed with three sensors and done by Eurofins, an independent test laboratory.

1. Temperature shock (EN 60068-2-14:2009)
2. Random free fall (EN 60068-2-6:2008)
3. Human bite force (no reference standard)

1.3 Terms and Abbreviations

Term, Abbreviation:	**Definition:**
WIOSS	Wireless IntraOral Sensor System
IOS	IntraOral Sensor
DS	Docking Station
WIOS	Wireless IntraOral Sensor

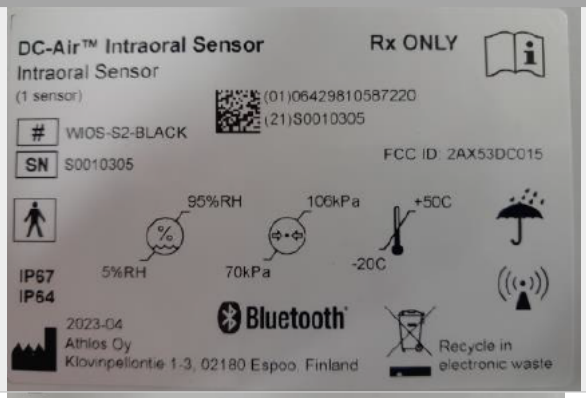
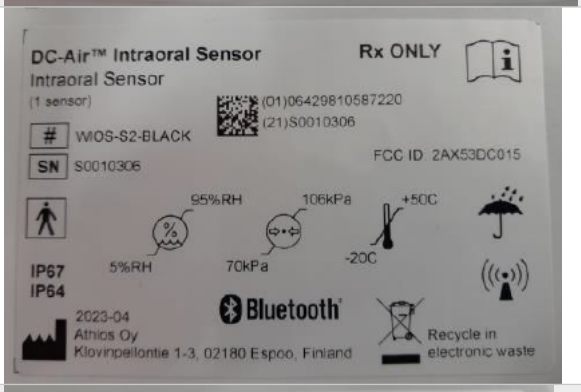
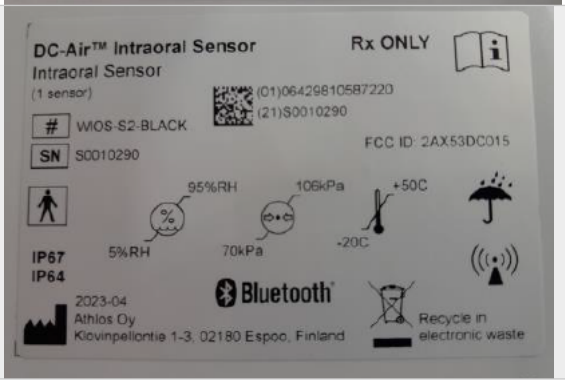
2 PRODUCT UNDER TEST

2.1 General Description

The DCiS / DC-Air sensor is described in detail in 0000486 - Device Description (Wireless intra oral sensor WIOS-S2) WIOS-S2 Device Description.

2.2 Devices Under Test

Three WIOS sensors were sent to Eurofins, an external and independent test laboratory for environmental testing.

Devices to be tested		
Device #1	S/N S0010305	
Device #2	S/N S0010306	
Device #3	S/N S0010290	

3 TEST DESCRIPTION

Three sensors were used in the test with all three going through the temperature shock test, two of the three through the random fall test on a steel plate from 1m, 10 times, and finally one sensor out of the three went through also the average human maximum bite force test.

All three sensors were found to be operational after the test and in the same condition as before the test.

The sensor that went through all three tests was recalibrated and analyzed in detail.

3.1 Temperature Shock

The temperature shock test will be performed for all three test samples. This test simulates the worst-case transportation, storage, and operating temperatures that the sensors are exposed to.

Test Parameters	
Number of sensors to be tested	3 (sensors #1, #2 and #3)
Minimum temperature	-30 °C
Maximum temperature	+50 °C
Time at each extreme	30 min
Number of full cycles	20
Reference standard	IEC 60068-2-14:2009

3.2 Random Free Fall

The random free fall test will be performed for two of the test samples. The test is meant to simulate the worst-case handling at a dental office. In the test, the sensor is dropped on a steel surface from a height of 1 meter and the test is repeated 10 times for both sensors. Dropping on a steel surface is much worse than any floor material used at dental offices.

Test Parameters	
Number of sensors to be tested	2 (sensors #2 and #3)
Drop height	1 m
Number of drops per sensor	10
Drop target	Steel
Reference standard	IEC 60068-2-31:2008

3.3 Human Bite Force Resistance

The human bite force resistance test is performed for one of the test samples. The test simulates the worst-case scenario, where the patient bites the sensor. Human bite force of 160 PSI is reported in the literature and is used for this test.

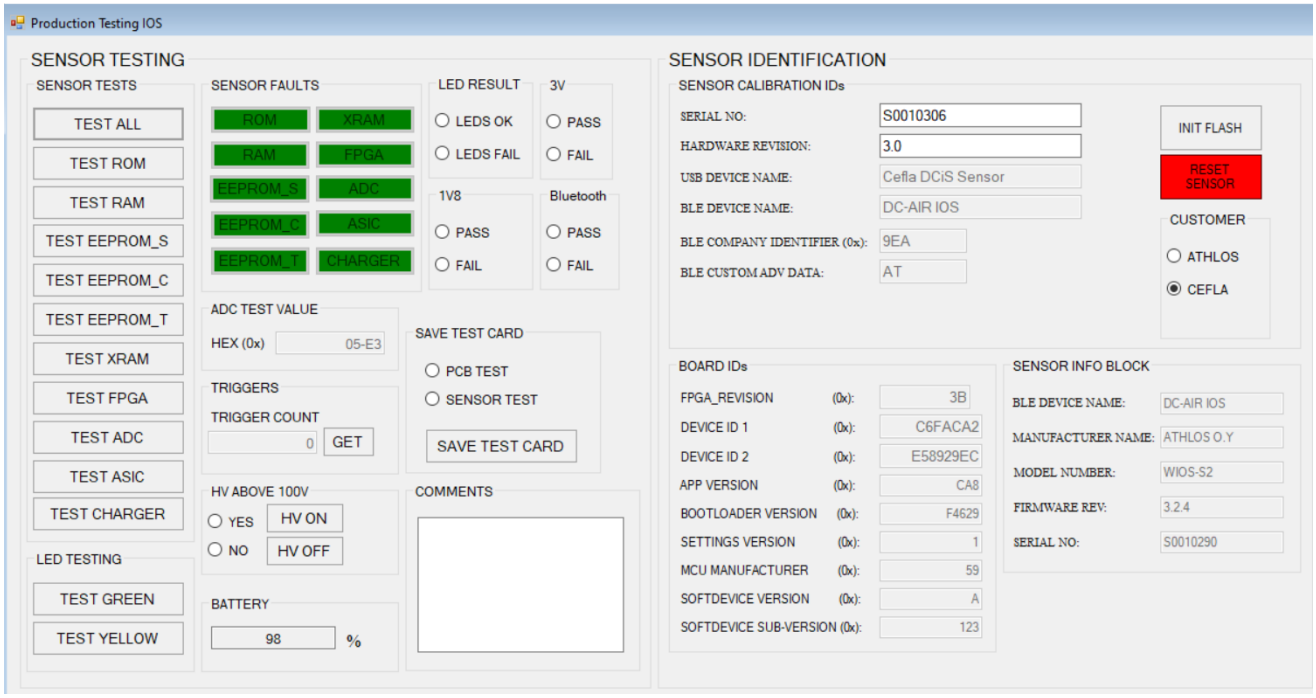
Test Parameters	
Number of sensors to be tested	1 (sensor #3)
Bite force	160 PSI

	110 N/cm^2
Test points per sensor	3
Maximum force duration	2
Reference standard	No reference standard available

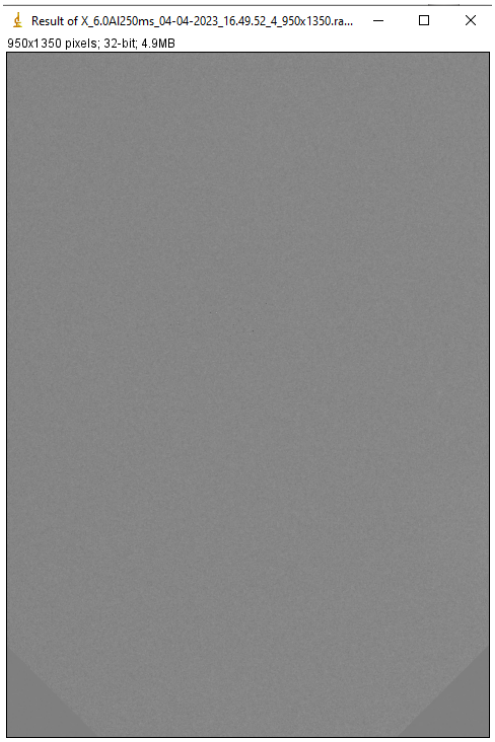
4 RESULTS & ANALYSIS OF DEVICE #3

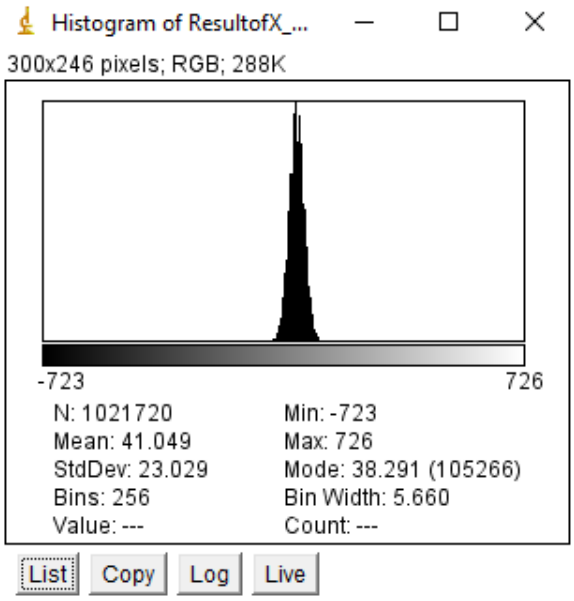
Front and back side photos of the three devices after the tests at Eurofins. There is no evidence externally that any of the three devices would have been damaged.

EUT #3 → S0010290, underwent all three severe tests: the thermal shock test, the random free fall test, 10 times, from 1m onto a steel surface and maximum average human bite force of 160PSI. The results presented are after all three tests:



Athlos production test program run after the tests indicates that all elements of the devices perform as expected.





Raw frames before and after the tests are subtracted: 70kV, 8mA, 30cm SID, 6.0mm Al filter and 250ms exposure time. The resulting subtracted image gives a mean value of only 41.09 indicating full responsiveness to x-rays. The small offset is due to local temperature variations (before & after measurements) and due to small difference in the SID (before & after measurement). The key here is that the "after" irradiated frame has a value substantially the same as before and responds normally to x-rays.

Athlos WIOS QA report (Before EUROFINS severe environmental tests)

Date: 4.5.2023 Serial no.: S0010290 Status: PASSED
Calibration: Niculina Sistac
Final QA: Niculina Sistac

Signal levels

	Raw image median	Signal median	Median limits	Median step	Step limits
Dark ave	1724	0	(raw) 1400 - 1850		
Dark hot	1746	46	0 - 250	46	0
Dose 1	1819	107	50 - 200	107	30
Dose 2	1959	248	100 - 400	141	50
Dose 3	2158	447	300 - 700	199	150
Dose 4	2415	705	500 - 900	258	100
Dose 5	2913	1202	700 - 1300	497	200
Dose 6	3428	1717	1100 - 1900	515	200
Dose 7	3969	2258	1600 - 2600	541	130

Masked pixels

		Limit	Criteria	
Pixels total	3601	20000	Dark fit residual max	62,5
2 x 2	62	1000	Gain fit residual max	0,0015625
3 x 3	62	500	Gain min	0,78125
4 x 4	33	50	Gain max	1,3671875

Athlos WIOS QA report (After all three severe Eurofins environmental tests)

Date: 31/05/2023 Serial no.: S0010290 Status: PASSED
Calibration: Niculina Sistac
Final QA: Niculina Sistac

Signal levels

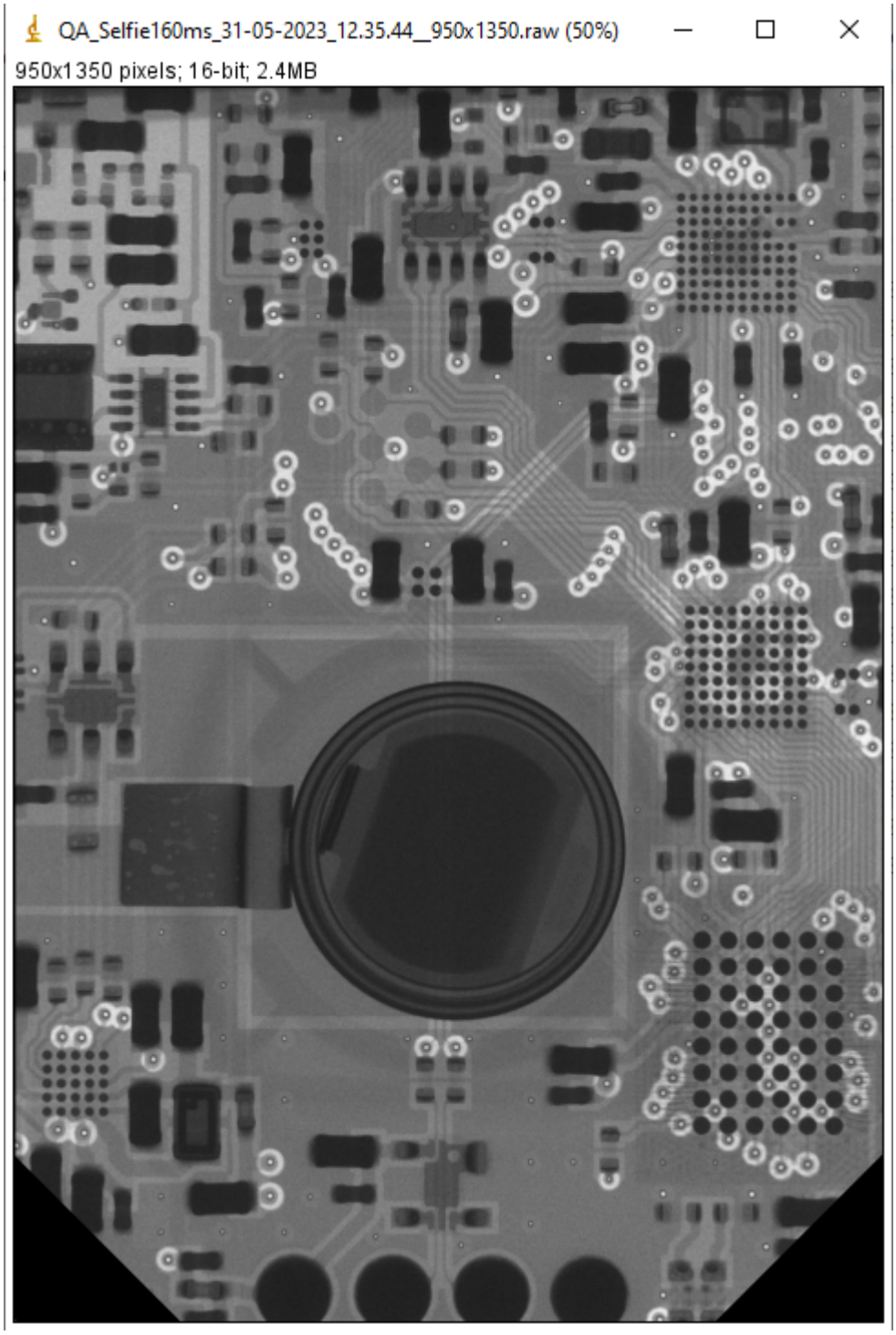
	Raw image median	Signal median	Median limits	Median step	Step limits
Dark ave	1721	0	(raw) 1400 - 1850		
Dark hot	1745	46	0 - 250	46	0
Dose 1	1813	102	50 - 200	102	30
Dose 2	1929	221	100 - 400	119	50
Dose 3	2133	425	300 - 700	204	150
Dose 4	2374	667	500 - 900	242	100
Dose 5	2849	1141	700 - 1300	474	200
Dose 6	3338	1630	1100 - 1900	489	200
Dose 7	3856	2148	1600 - 2600	518	130

Masked pixels

		Limit	Criteria	
Pixels total	4452	20000	Dark fit residual max	62,5
2 x 2	68	1000	Gain fit residual max	0,002148438
3 x 3	62	500	Gain min	0,72265625
4 x 4	30	50	Gain max	1,328125

Above we see the comparison of the Athlos QA sheet before and after the three severe environmental tests. The DCiS / DC-Air has retained substantially its original condition.

The above image is a flat field exposure of the DCiS / DC-Air after the three severe environmental tests with the following exposure parameters: 70kV, 8mA, 30cm SID, 0.6mm Cu filter and 160ms exposure time.



The above image is a selfie of the DCiS / DC-Air after the three severe environmental tests with the following exposure parameters: 70kV, 8mA, 30cm SID and 160ms exposure time.

5 SUMMARY OF VERIFICATION

This is a summary of the results found after the Eurofins severe environmental tests. A separate test report, that gives detailed test setup of each test, was prepared by Eurofins attached herein.

Test	Result
Temperature shock	PASS
Random free fall	PASS
Human bite force resistance	PASS

The DCiS / DC-Air have been shown to withstand the toughest and most severe conditions that may be encountered in normal clinical use and storage.

Signatures:

Document Reviewed:	I have reviewed the contents of this document		
Name:	**Vasileios Grammatikakis ATHLOS\vasileios.grammatika**	Title:	**Senior Electronics Engineer**
	Vasileios Grammatikakis		2023-06-02 08:12:27 (UTC+00:00)
Electronically Signed in	M-Files	Timestamp	

Document Approved:	I approve this document to be immediately released for use		
Name:	**Vasileios Grammatikakis ATHLOS\vasileios.grammatika**	Title:	**Senior Electronics Engineer**
	Vasileios Grammatikakis		2023-06-02 08:12:41 (UTC+00:00)
Electronically Signed in	M-Files	Timestamp	

Environmental Testing for

DCiS/DC-Air Intraoral Sensor

Test Report

EUFI29-23001623-T1

Test Report
Environmental Testing

Purpose of test:	RnD test
Equipment under test:	DCiS/DC-Air Intraoral Sensor

Manufacturer:	Athlos Oy
Contact information:	Klovinpellontie 1-3 02180 Espoo Finland

Customer:	Athlos Oy
Contact information:	Klovinpellontie 1-3 02180 Espoo Finland

Test laboratory:	Eurofins Electric & Electronics Finland Oy, Salo lab Eurofins Electric & Electronics Finland Oy, Oulu lab
Contact information:	Hyvoninkatu 1 24240 Salo Finland tel: +358 (0) 40 631 1311 e-mail: EEinfo@eurofins.fi

Date:	31 May 2023	**Date:**	31 May 2023
Prepared By:	Ville Räikkä	**Approved By**:	Mikko Halonen

Table of Contents:

1 Version History

Version	Description	Date
1.0	Initial release	30 May 2023
1.0.1	Correct Free Fall reference standard in test schedule	31 May 2023
1.0.2	Change EUT name from DC-Air ->DCiS/DC-Air	31 May 2023
-	-	-

2 Introduction

2.1 Scope

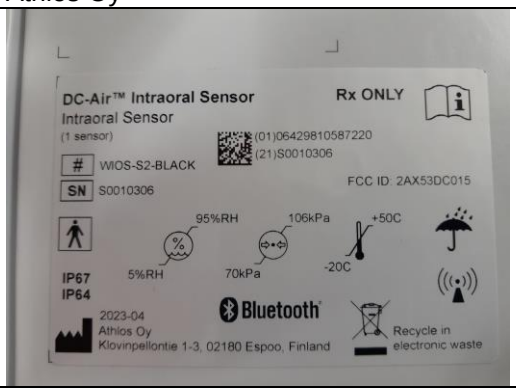
This document includes complete test results from Environmental testing to DCiS/DC-Air Intraoral Sensor(s). It describes the test schedule, test information, exceptions in test procedure / set-up, possible description of failures, test results, used test equipment and software, identification of tested units, test place and environment, test report distribution and person(s) who made the test. Document may also contain recorded monitoring data and detailed test specifications if needed.

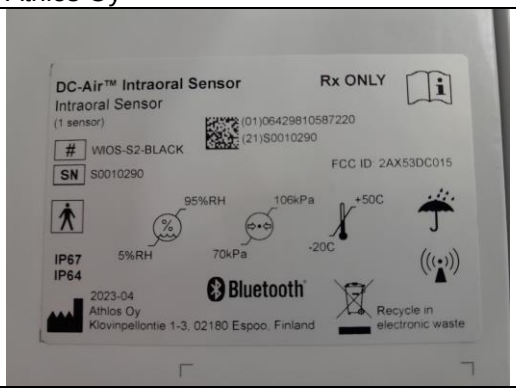
2.2 Abbreviations

Abbreviation	Description
EUT	Equipment Under Test
STD	Standard
ID	Identification
SW	Software
NC	No calibration
S/N	Serial number

3 Equipment(s) Under Test

Model name:	WIOS-S2-BLACK
S/N:	S0010290
Manufacturer:	Athlos Oy
Type label photo:	
EUT ID:	S1

Model name:	WIOS-S2-BLACK
S/N:	S0010306
Manufacturer:	Athlos Oy
Type label photo:	
EUT ID:	S2

Model name:	WIOS-S2-BLACK
S/N:	S0010290
Manufacturer:	Athlos Oy
Type label photo:	
EUT ID:	S3

4 Testing Schedule and Results

EUT has been tested for environmental tests according **Clients dedicated test plan** with test results below.

Test ref.	Test name	Reference Standard	Test Result
6.1	Temperature Shock	EN 60068-2-14:2009	**NA*1**
6.2	Random Free Fall	EN 60068-2-31:2008	**NA*1**
6.3	Human bite force resistance	NA	**NA*1**

*1) Client makes PASS/FAIL Decision basing their own analyze of the EUT(s) after the exposure.

Results in this test report are valid only for tested EUT(s) defined in Chapter 3.

5 General test information

5.1 Ambient conditions

All the testing is done under controlled temperature and humidity conditions. Unless otherwise noted ambient temperature during the testing is 21±2 °C and relative humidity 35±5 %.

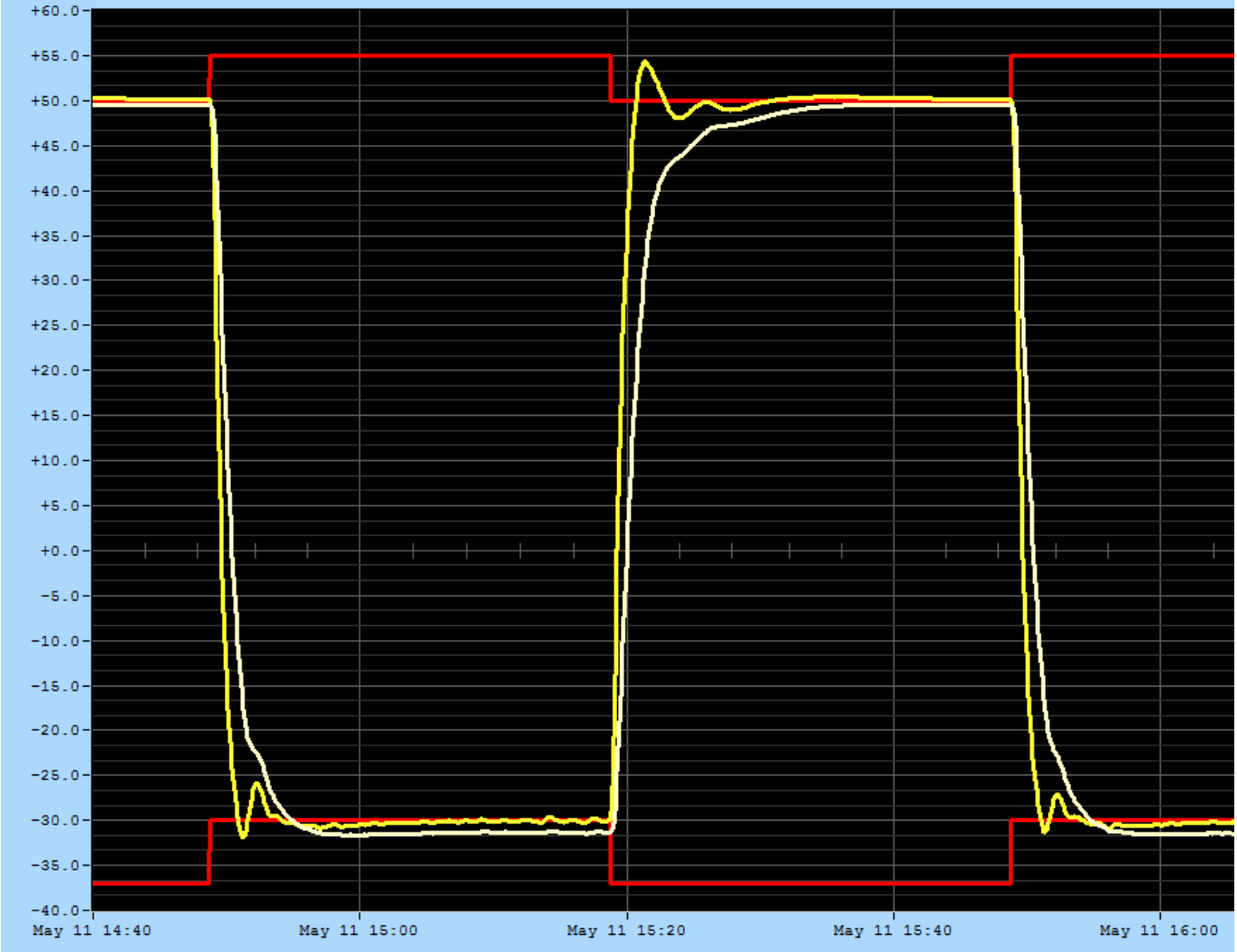
5.2 Failure definition

Only major visual mechanical failures checked during the testing. Customer checks the electrical operation of EUTs after the testing.

6 Environmental Tests

6.1 Temperature Shock

Test name and type:	Temperature Shock	**Test standard:** **Reference std:**	Customer Spec IEC 60068-2-14:2009
EUT ID in test:	S1, S2 and S3		
Test method:	Test Na: Rapid Change of temperature with prescribed time of transfer		
Test date:	11-13 May 2023	**Test laboratory:**	Eurofins E&E Finland Oy, Hyvoninkatu 1 lab, Salo
Tested by:	Ville		
Test parameters:	Test parameters: T_a = -30 °C T_b = 50 °C T_1, T_2 = 30 min Number of Cycles = 20 Picture of one full cycle in Picture 6.1.1 Setup Photo in chapter 7.		
Test result:	**NA** **Customer makes PASS/FAIL decision basing their own analyze of the product.**		
Notes in test procedure:	Setup photos in chapter 7.		
Performed initial/intermediate/ final measurements:	Visuall check before and after test.		



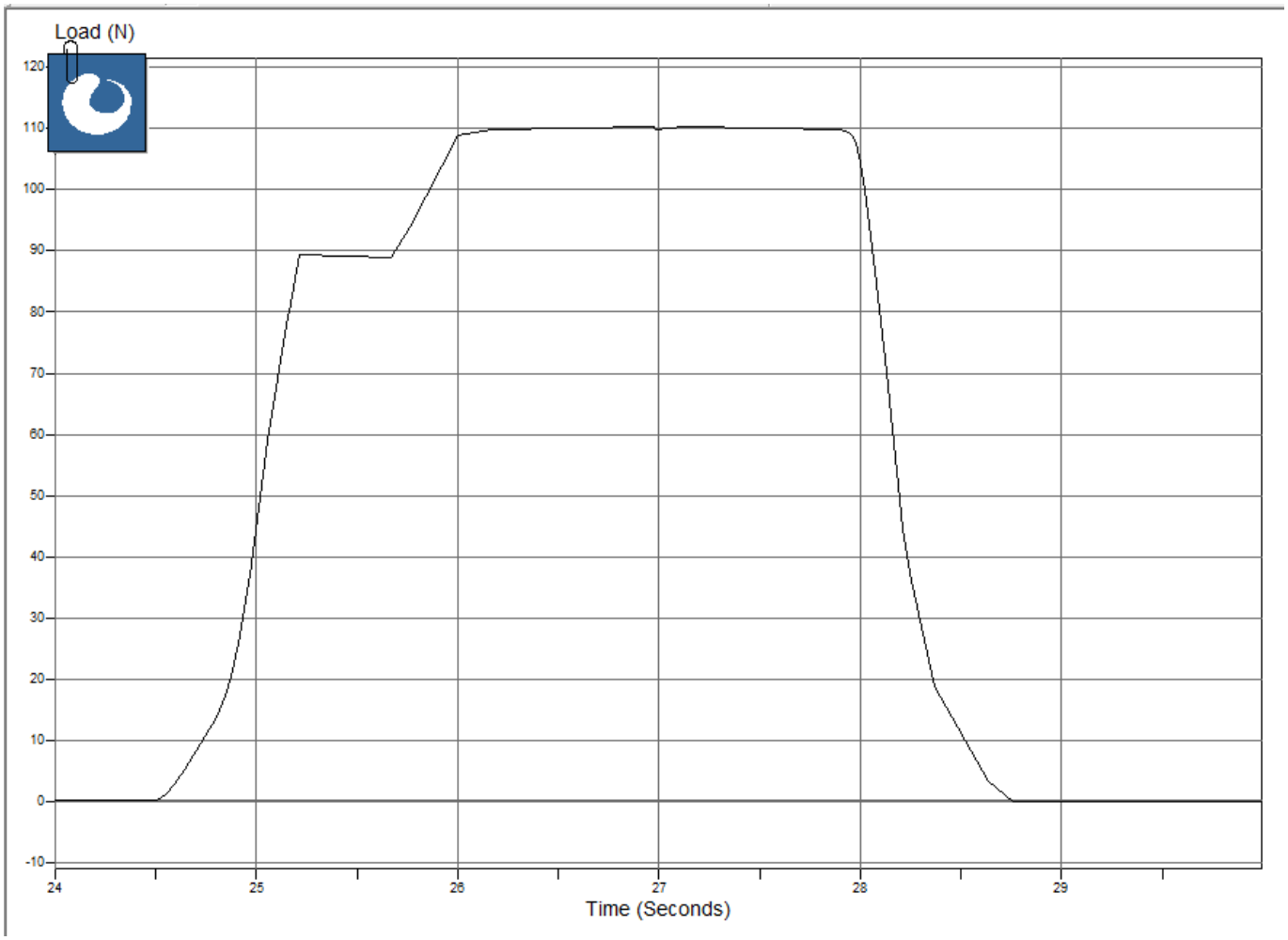
Picture 6.1.1 Log data of 1 temperature cycle

6.2 Random Free Fall

Test name and type:	Random Free Fall	**Test standard:** **Reference std:**	Customer spec IEC 60068-2-31:2008
EUT ID in test:	S2 and S3		
Test method:	Free Fall Repeated – Procedure 2		
Test date(s):	22 May 2023	**Test laboratory:**	Eurofins E&E Finland Oy, Yrttipellonkatu 6 lab, Oulu
Tested by:	Samuli		
Test parameters:	Drop Height: 1m Number of Drops:10 Drop Target: Steel		
Test result:	**NA** **Customer makes PASS/FAIL decision basing their own analyze of the product.**		
Notes in test procedure:	-		
Performed initial/intermediate/ final measurements:	Visual check before and after exposure		

6.3 Human bite force resistance

Test name and type:	Press resistance	**Test standard:** **Reference std:**	Customer spec NA
EUT ID in test:	S3		
Test method:	Press with material tester		
Test date(s):	29 May 2023	**Test laboratory:**	Eurofins E&E Finland Oy, Hyvoninkatu 1 lab, Salo
Tested by:	Ville		
Test parameters:	Target force in PSI = 160 Target force in N/cm^2 = 110 Force keep time 2 seconds. 3 test points selected see photo below:  Pressing force was applied via artificial teeth's to the EUT with script below: 60 mm/min up to 90 N 10 mm/min to 110 N Hold 2 seconds Test control and monitoring curves in picture 6.3.1 Setup photos in chapter 7.		
Test result:	**NA** **Customer makes PASS/FAIL decision basing their own analyze of the product.**		
Notes in test procedure:	-		
Performed initial/intermediate/ final measurements:	Visual check before and after each exposure		



Picture 6.3.1 Log data from material tester

7 Setup Photos

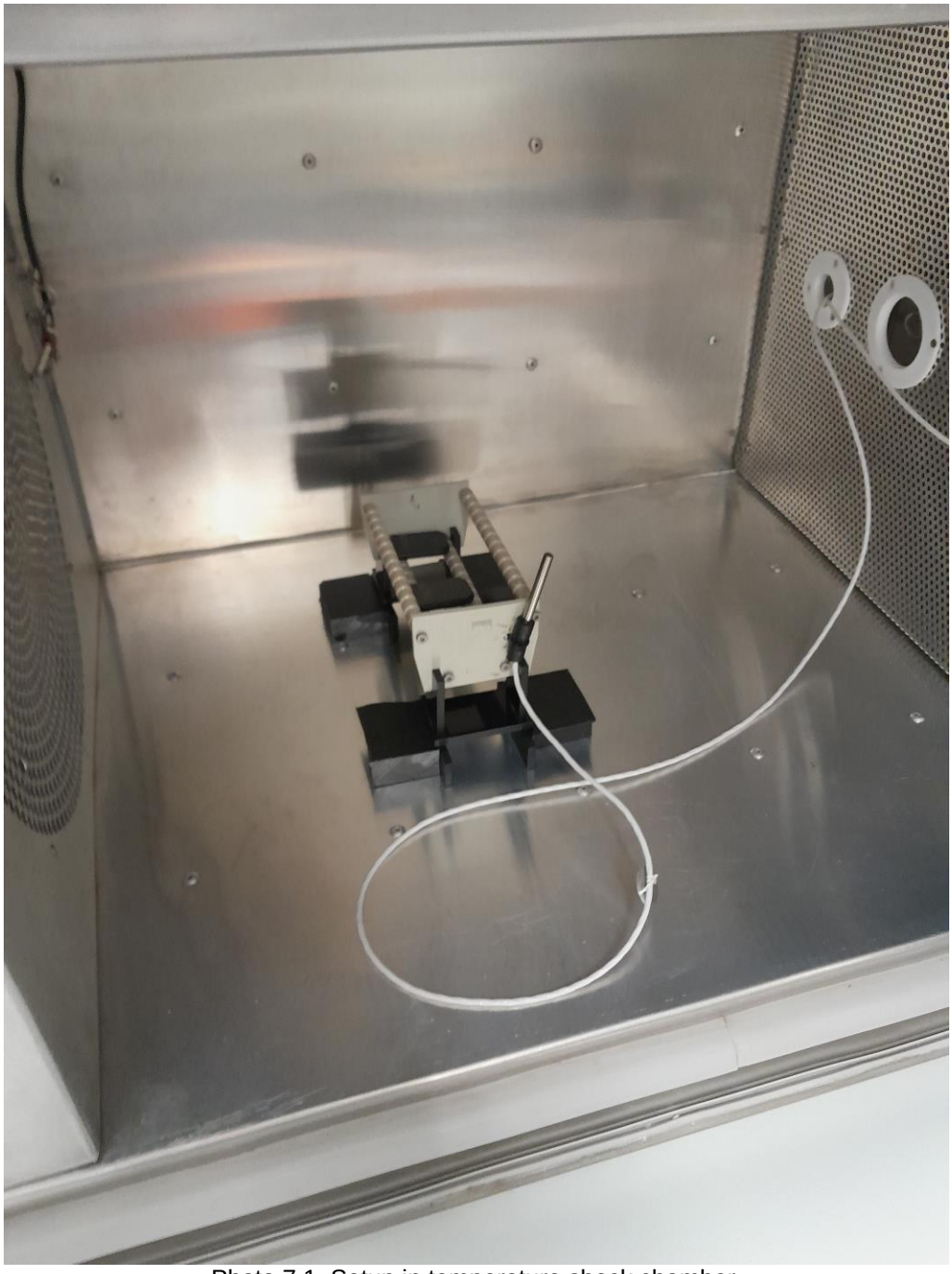


Photo 7.1. Setup in temperature shock chamber.

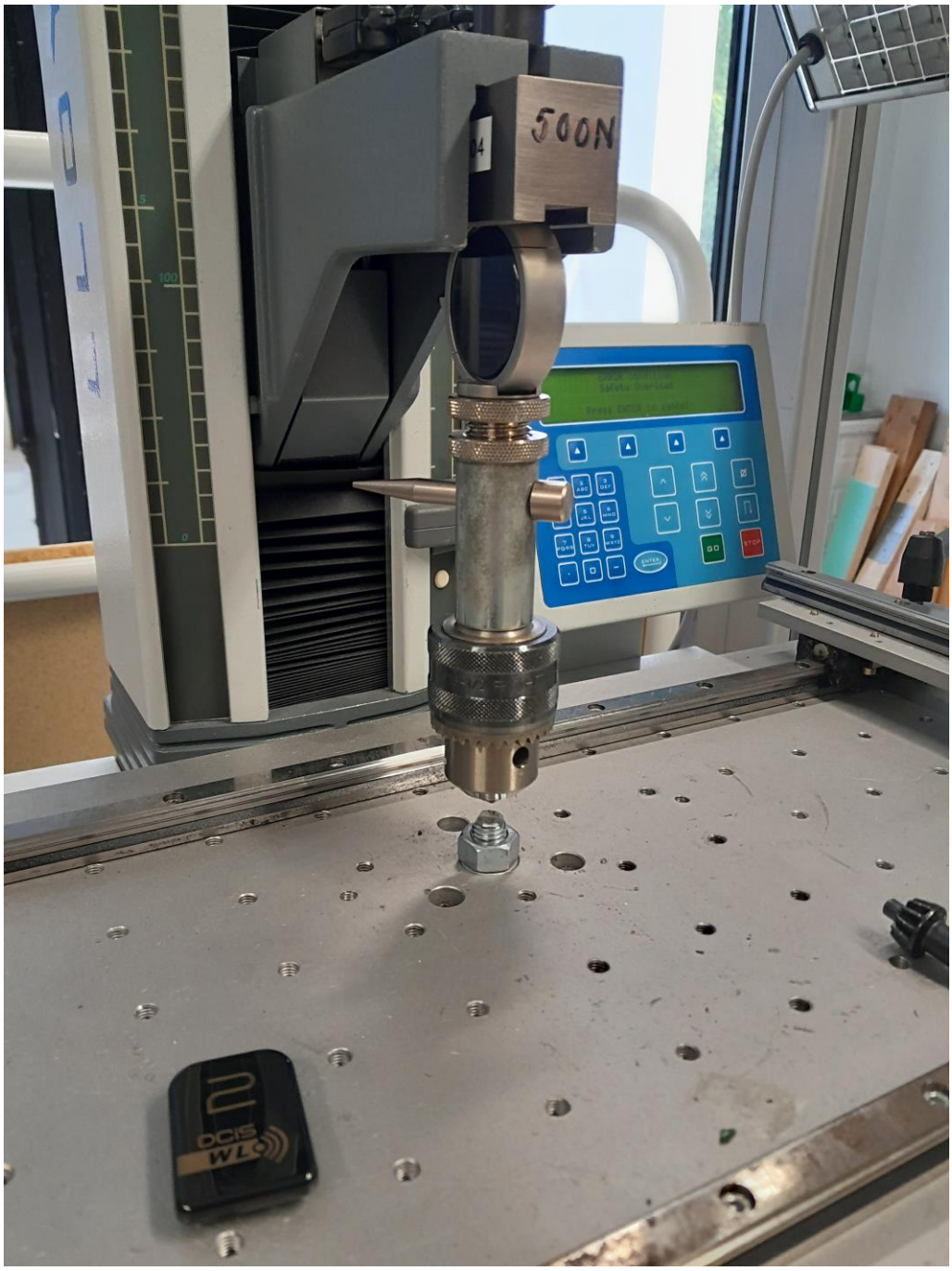


Photo 7.2. General setup in press testing.

Photo 7.3. Test point 1 setup in material tester.

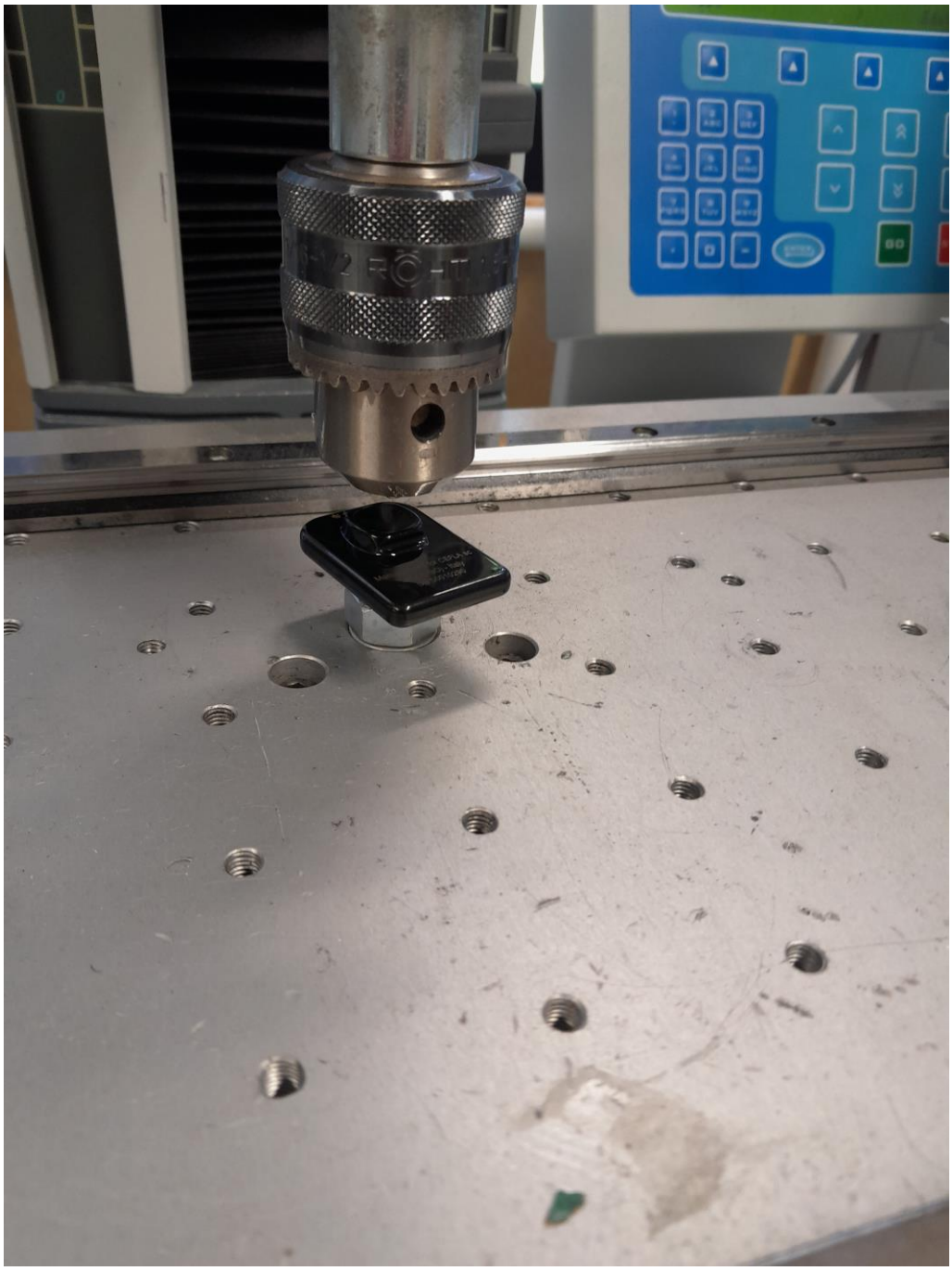


Photo 7.4. Test point 2 setup in material tester.

Photo 7.5. Test point 3 setup in material tester.

8 Observation log and failure photos

None to Report.

9 List of Test Equipment

Item code	Equipment	Manufacturer	Type	S/N	Calibration date / Calibration due
MS6517017	Shock Chamber	ATT	CST130 S	TT01892	04-2019 / 04-2024
-	Free Fall Tester	Automation Assistant	Random Free Fall Tester	4061	NCR
ENKO2103	Material Tester	Lloyd Instruments LTD	LRX (2.5kN)	104864	NC*1
ENKO2104	Force Sensor	Lloyd Instruments LTD	500N	16091	NC*1
EQM22-M29-004164	Force Reference	Mecmesin	AFG2500N	02-0088-12	03-2022 / 03-2025

NCR = No Calibration Required
NC *1 = Not Calibrated. Performance check with reference for requested Force(s)

10 Test Report Distribution

Company:	Contact person:
Athlos Oy	Konstantinos Spartiotis
Eurofins E&E Finland Oy	Mikko Halonen
Eurofins E&E Finland Oy	Ville Räikkä