

Document number Document name

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

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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:
NIOSS Wireless IntraOral Sensor System	
IOS	IntraOral Sensor
DS Docking Station	
WIOS	Wireless IntraOral Sensor

2 PRODUCT UNDER TEST

2.1 General Description

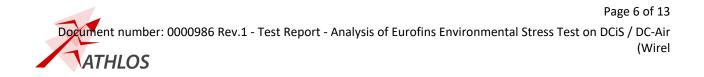
The DCiS / DC-Air sensor is described in detail in 0000486 - Device Description (Wireless intra oral sensor WIOS-S2) WIOS-S2 Device Description.

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	DC-Air™ Intraoral Sensor Rx ONLY Intraoral Sensor (1)06429810587220 (1 sensor) (21)80010305 Image: Construction of the sensor (21)80010305 Image: Construction of the sensor <t< th=""></t<>
Device #2	S/N S0010306	DC-Air TM Intraoral Sensor Rx ONLY Intraoral Sensor Image: Construction of the sensor It sensor Image: Construction of the sensor It sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image:
Device #3	S/N S0010290	DC-Air TM Intraoral Sensor Rx ONLY Intraoral Sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Construction of the sensor Image: Cons





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

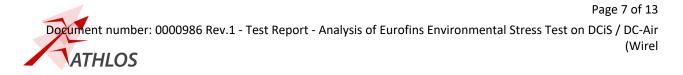
The random free fall test will be performed for two of the test samples. The test is meant to simulate the worst-case handling at a dental office. In the test, the sensor is dropped on a steel surface from a height of 1 meter and the test is repeated 10 times for both sensors. Dropping on a steel surface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

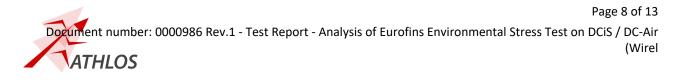
3.3 Human Bite Force Resistance

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

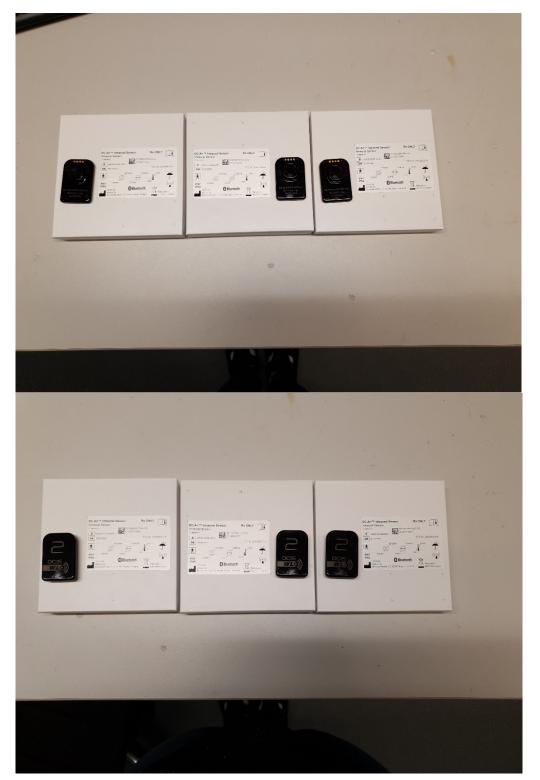
Test Parameters							
Number of sensors to be tested	1 (sensor #3)						
Bite force	160 PSI						



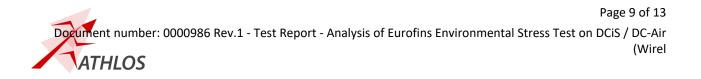
	110 N/cm ²
Test points per sensor	3
Maximum force duration	2
Reference standard	No reference
	standard available



4 RESULTS & ANALYSIS OF DEVICE #3



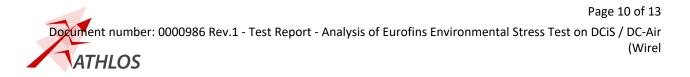
Front and back side photos of the three devices after the tests at Eurofins. There is no evidence externally that any of the three devices would have been damaged.



EUT #3 \rightarrow 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:

NSOR TESTING				SENSOR IDENTIFIC	CATIO	N			
NSOR TESTS	SENSOR FAULTS	LED RESULT	3V	SENSOR CALIBRATION	IDs				
TEST ALL	ROM XRAM	O LEDS OK O PASS O LEDS FAIL O FAIL				S0010306	INIT FLASH		
TEST ROM	RAM FPGA			HARDWARE REVISION: USB DEVICE NAME:		3.0 Cefla DCiS Senso			
TEST RAM	EEPROM_S ADC	1V8	Bluetooth	BLE DEVICE NAME:		DC-AIR IOS			
EST EEPROM_S	EEPROM_C ASIC		O PASS	BLE COMPANY IDENTIFI	ER (0x):	9EA	9EA		
EST EEPROM_C	CHARGER	○ FAIL	⊖ FAIL	BLE CUSTOM ADV DATA:		AT		 ATHLOS CEFLA 	
EST EEPROM_T	ADC TEST VALUE	SAVE TEST CARD							
TEST XRAM	HEX (0x) 05-E3	O PCB TEST		BOARD IDs			SENSOR INFO BLOCK		
TEST FPGA	TRIGGERS TRIGGER COUNT	○ SENSOR TES	SENSOR TEST	FPGA_REVISION	(0x):	3B	BLE DEVICE NAME:	DC-AIR IOS	
TEST ADC	0 GET	SAVE TEST C	ARD	DEVICE ID 1 DEVICE ID 2	(0x): (0x):	C6FACA2 E58929EC	MANUFACTURER NAME	ATHLOS O.Y	
TEST ASIC	HV ABOVE 100V	COMMENTS		APP VERSION	(0x):	CA8		WIOS-S2	
EST CHARGER	O YES HV ON			BOOTLOADER VERSION	(0x) :	F4629	FIRMWARE REV:	3.2.4	
D TESTING	O NO HV OFF			SETTINGS VERSION MCU MANUFACTURER	(0x): (0x):	59	SERIAL NO:	S0010290	
TEST GREEN	BATTERY			SOFTDEVICE VERSION	(0x):	33			
TEST YELLOW	98 %			SOFTDEVICE SUB-VERSIC	ON (0x):	123			

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 \	VIOS QA repor	t (Before EUR	OFINS severe env	/ironment	al tests)	1	Athlos V	VIOS QA repor	t (After all th	ree se	vere Eurofir	s environ	mental test
Date:	4.5.2023	Serial no.:	\$0010290	Status:	PASSED	3	Date:	31/05/2023	Serial no.:	S001	0290	Status: F	ASSED
Calibration:	Niculina Sistac					4	Calibration:	Niculina Sistac					
Final QA:	Niculina Sistac					5	Final QA:	Niculina Sistac					
						6							
						7							
Signal lev	els					8	Signal leve	els					
Ray	v image median	Signal media	n Median limits	Median step	Step limits	9	Rav	v image median	Signal med	lian	Median limits	Median step	Step limits
Dark ave	1724		0 (raw) 1400 - 1850			10	Dark ave	1721		0 (raw) 1400 - 1850		
Dark hot	1746	4	6 0 - 250	46	0		Dark hot	1745		46	0 - 250	46	0
Dose 1	1819	10	50 - 200	107	30	-	Dose 1	1813		102	50 - 200	102	30
Dose 2	1959	24	100 - 400	141	50	-	Dose 2	1929		221	100 - 400	119	50
Dose 3	2158	44	300 - 700	199	150		Dose 3	2133		425	300 - 700	204	150
Dose 4	2415	70	500 - 900	258	100	-	Dose 4	2374		667	500 - 900	242	100
Dose 5	2913	120	02 700 - 1300	497	200		Dose 5	2849		141	700 - 1300	474	200
Dose 6	3428	171	.7 1100 - 1900	515	200	_	Dose 6	3338		630	1100 - 1900	489	200
Dose 7	3969	225	1600 - 2600	541	130	-	Dose 7	3856	2	148	1600 - 2600	518	130
						19	-						
Masked p	ixels						Masked p	ixels					
		Limit	Criteria			21	-		Limit	Crite			
Pixels total	3601	20000	Dark fit residual max	62,5			Pixels total	4452	20000		fit residual max	62,5	
2 x 2	62	1000	Gain fit residual max	0,0015625		-	2 x 2	68	1000			0,002148438	
3 x 3	62	500	Gain min	0,78125			3 x 3	62	500	Gain		0,72265625	
4 x 4	33	50	Gain max	1,3671875		25	4 x 4	30	50	Gain	max	1,328125	

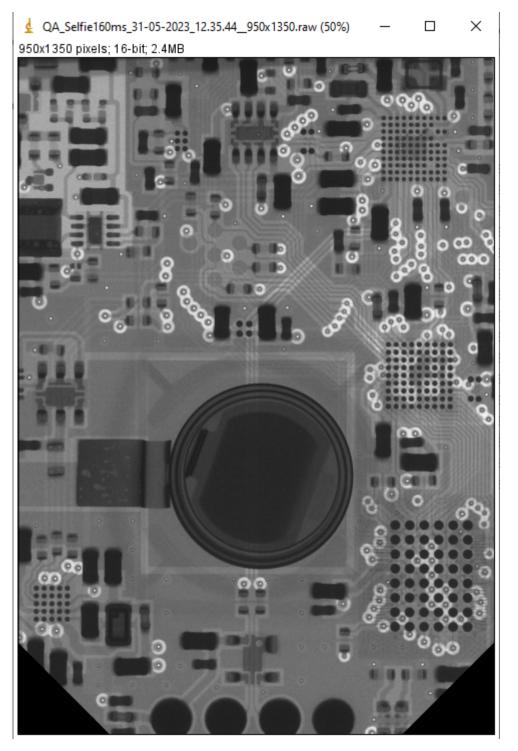
Above we see the comparison of the Athlos QA sheet before and after the three severe environmental tests. The DCiS / DC-Air has retained substantially its original condition.





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:						
Name:	Vasileios Grammatikakis ATHLOS\vasileios.grammatika	Title:	Senior Electronics Engineer			
	Vaçileios Grammat ikakis		2023-06-02 08:12:27 (UTC+00:00)			
Electronical	ly Signed in M-Files	Timestamp				
Document Approved:	I approve this document to be immediat	ely released for us	e			
Name:	Vasileios Grammatikakis ATHLOS\vasileios.grammatika	Title:	Senior Electronics Engineer			
	Vaçikeios Grammat ikakis		2023-06-02 08:12:41 (UTC+00:00)			
Electronical	ly Signed in M-Files	Timestamp				

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Environmental Testing for

DCiS/DC-Air Intraoral Sensor

Test Report

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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

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

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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
-	-	-

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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:	DC-Air [™] Intraoral Sensor Intraoral Sensor (1 sensor) WiOS-S2-BLACK WiOS-S2-BLACK SN S0010305 FCC ID: 2AX53DC015 SN S0010305 FCC ID: 2AX53DC015 FCC ID: 2AX54DC015 FCC ID:
EUT ID:	S1

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Model name:	WIOS-S2-BLACK
S/N:	S0010306
Manufacturer:	Athlos Oy
Type label photo:	DC-Air TM Intraoral Sensor Intraoral Sensor I
EUT ID:	S2

Model name:	WIOS-S2-BLACK
S/N:	S0010290
Manufacturer:	Athlos Oy
Type label photo:	DC-Air ** Intraoral Sensor Rx ONLY Image: Comparison of the sensor Intraoral Sensor (1)06429810587220 If sensor Image: Comparison of the sensor Comparison of the sensor If sensor Image: Comparison of the sensor FCC ID 2AX53DC015 Image: Comparison of the sensor Source of the sensor FCC ID 2AX53DC015 Image: Comparison of the sensor Source of the sensor Image: Comparison of the sensor Image: Comparison of the sensor Source of the sensor Image: Comparison of the sensor Image: Comparison of the sensor Source of the sensor Image: Comparison of the sensor Image: Comparison of the sensor Source of the sensor Image: Comparison of the sensor Image: Comparison of the sensor Source of the sensor Image: Comparison of the sensor Image: Comparison of the sensor Source of the sensor Image: Comparison of the sensor Image: Comparison of the sensor Source of the sensor Image: Comparison of the sensor Image: Comparison of the sensor Source of the sensor Image: Comparison of the sensor Image: Comparison of the sensor Source of the sensor Image: Comparison of the sensor Image: Comparison of the sensor Image: Comparison of t
EUT ID:	\$3

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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.

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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.

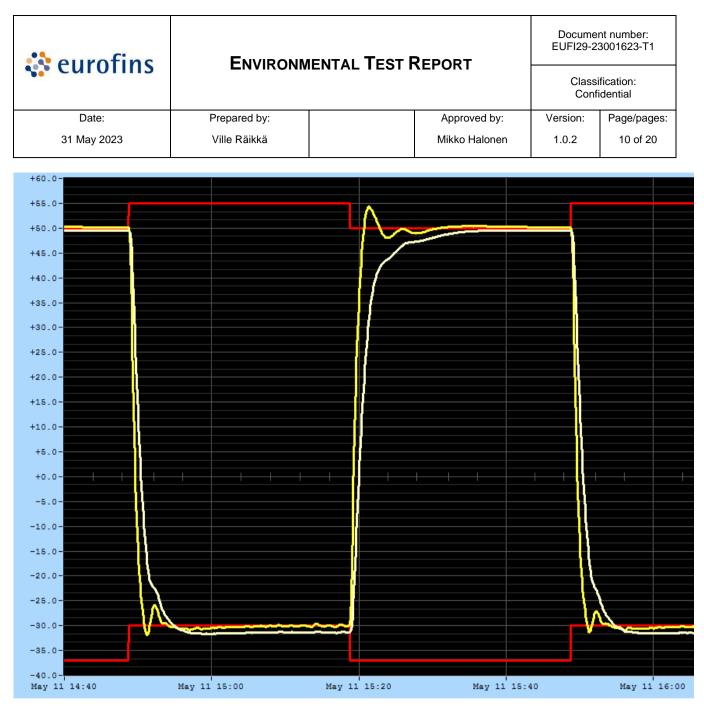
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6 Environmental Tests

6.1 Temperature Shock

Test name and type:	Tempe	erature Shock	Test standard: Reference std:	Customer Spec IEC 60068-2-14:2009		
EUT ID in test:	S1, S2	and S3	•			
Test method:	Test N	a: Rapid Change of temp	erature with prescri	bed 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 pa	arameters:				
T	Numbe					
Test result: NA Customer makes PASS/FAIL decision basing their own analyze the product.						
Notes in test procedure:		Setup photos in chapter				
Performed initial/intermediate/ Visuall check before and after test. final measurements: Visuall check before and after test.						



Picture 6.1.1 Log data of 1 temperature cycle

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6.2 Random Free Fall

Test name and type:	Rando	m Free Fall	Test standard: Reference std:	Customer spec IEC 60068-2-31:2008			
EUT ID in test:	S2 and	1 S3					
Test method:	Free F	all Repeated – Procedure	2				
Test date(s):	22 Ma	y 2023	Test laboratory:	Eurofins E&E Finland Oy, Yrttipellonkatu 6 lab, Oulu			
Tested by:	Samul	i					
Test parameters:	Numbe	leight: 1m er of Drops:10 Farget: Steel	r of Drops:10				
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					

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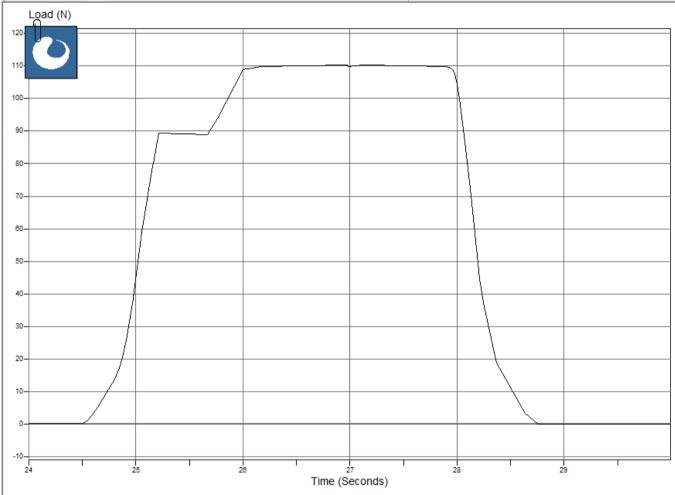
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6.3 Human bite force resistance

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Test name and type:	Press	resistance	Test standard: Reference std:	Customer spec
EUT ID in test:	S3			
Test method:		with material tester		
Test date(s):	29 Ma		Test laboratory:	Eurofins E&E Finland Oy, Hyvoninkatu 1 lab, Salo
Tested by:	Ville			
Test parameters:	Target Force 3 test p	force in PSI = 160 force in N/cm ² = 110 keep time 2 seconds. points selected see photo	rtificial teeth's to th	e EUT with script below:
Test result:		NA		
		Customer makes PASS the product.	6/FAIL decision ba	asing their own analyze of
Notes in test procedure		-		
Performed initial/interm final measurements:	ediate/	Visual check before and	after each exposu	re

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Picture 6.3.1 Log data from material tester

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7 Setup Photos

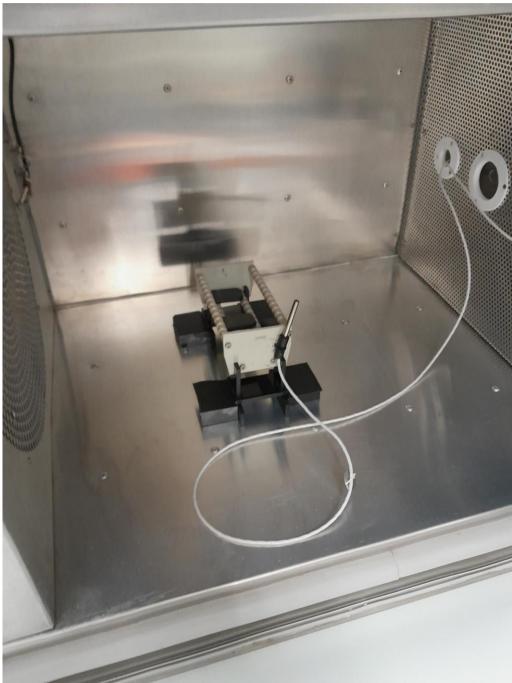


Photo 7.1. Setup in temperature shock chamber.

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Photo 7.2. General setup in press testing.

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Photo 7.3. Test point 1 setup in material tester.

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Photo 7.4. Test point 2 setup in material tester.

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		INVIKONMENTAL TEST REPORT		Classification: Confidential			
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Photo 7.5. Test point 3 setup in material tester.

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	ENVIRONMENTAL LEST REPORT			ification: idential
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8 Observation log and failure photos

None to Report.

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9 List of Test Equipment

Item code	Equipment	Manufacturer	Туре	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