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LAB N° 1347 L

RAPPORTO DI PROVA

TEST REPORT

Rif. / Ref. n.	**FCCTR_179304-1_NovoNordisk**	Data Emissione /Issue Date:	**14/01/2022**	Pagine / Pages:	**19**

Scopo delle prove *Test object*	Prove di tipo in accordo alla Norme *Type test according to Standards* **FCC Cfr 47 part 15 - Subpart B - §15.109** **ICES-003 Issue 6**
Richiedente *Applicant*	**Novo Nordisk A/S** Novo Allé 1 Bagsværd 2880 - Denmark
Marchio commerciale *Trade mark*	DIALOG
Fabbricante *Manufacturer*	Novo Nordisk A/S
Prodotto *Product*	Add-on for Insulin Pen-Injector
Modello testato *Testing model*	**DV samples (project Revival)**
Data ricevimento campioni *Date of test samples receipt*	15/02/2021
Campioni verificati *No. of tested samples*	1 – Sampled by the manufacturer
Data verifiche *Testing date*	15/02/2021
Sito di prova *Testing site*	PRSLAB S.r.l. Unipersonale - Via Campagna 92 - 22020 Faloppio - Como - Italy
Esito delle valutazioni *Assessment results*	**CONFORME / COMPLIANT**
Verifiche effettuate da *Verifications carried out by*	**Daniele AOSANI** Tecnico laboratorio *Test Engineer*
Approvato *Approved by*	**Riccardo PFEIFFER** Responsabile laboratori *Laboratory manager*

I risultati delle prove riportati nel presente rapporto di prova si riferiscono solo ai campioni esaminati.
The test results reported in this test report shall refer only to the samples tested.
Il campione è stato fornito dal cliente ed i risultati si riferiscono al campione così come ricevuto
The sample has been provided by the customer and the results apply to the sample as received

CONTENUTO

TABLE OF CONTENTS

0. RELEASE CONTROL RECORD 3
1. DECISION RULE 3
2. INFORMATION PROVIDED BY CUSTOMER 3
3. GENERAL REMARKS 3
4. TECHNICAL INFORMATION OF EQUIPMENT UNDER TEST (EUT) 4
4.1 EUT Identification 4
4.2 Bluetooth module technical data 5
4.3 Ports identification 6
4.4 Modifications incorporated in E.U.T. 6
4.5 Auxiliary equipment 6
5. REFERENCE STANDARDS 7
6. OPERATING TEST MODES AND TEST CONDITIONS 7
7. UNITS OF MEASUREMENTS 7
8. SUMMERY OF TEST RESULTS 8
8.1 Emission tests 8
9. LIST OF INSTRUMENTS USED 8
10. TEST RESULTS 8
11. PHOTOGRAPHIC DOCUMENTATION 18

0. RELEASE CONTROL RECORD

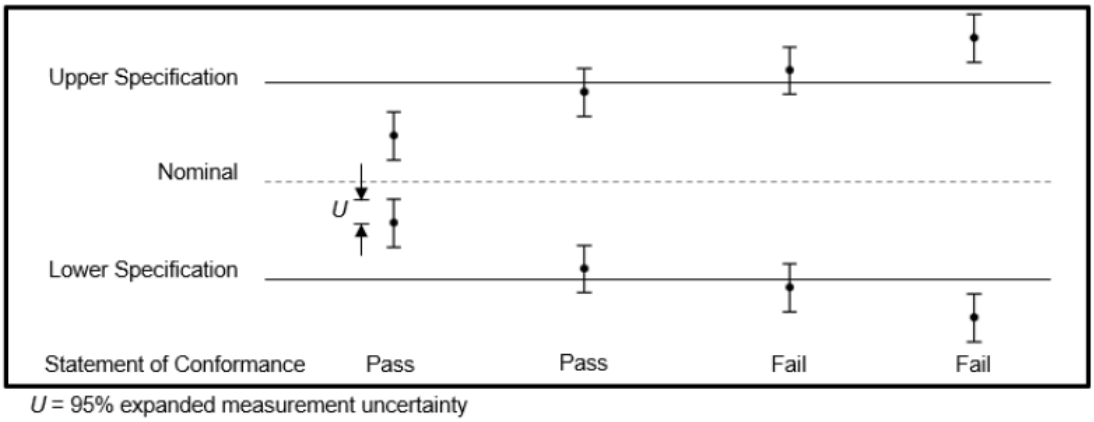
TEST REPORT NUMBER	REASON OF CHANGE	DATE OF ISSUE
FCCTR_179304_0_NovoNordisk	Original release	14/05/2021
FCCTR_179304_1_NovoNordisk	Modified section 11. Photographic documentation	14/01/2022

This document is valid in last revision that deletes and replaces the previous one

1. DECISION RULE

PRS LAB specifies that, if the decision rules of conformity of the test results are not indicated in detail in the standard/s object of tests, it takes as a decision rule for the declaration of conformity the simple binary system (w = 0) stated in the ILAC-G8-09:2019 document.

The decision rule is applicable for all parts of standard



U = 95% expanded measurement uncertainty

Statements of conformity are reported as:

- Pass: the measured value is below the acceptance limit, $AL{=}TL$.
- Fail: the measured value is above the acceptance limit, $AL{=}TL$.

Definitions

- Guard Band (w): interval between a tolerance limit and a corresponding acceptance limit where length $w{=}|TL{-}AL|$.
- Tolerance Limit (TL) (Specification Limit): specified upper or lower bound of permissible values of a property.
- Acceptance Limit (AL): specified upper or lower bound of permissible measured quantity values.

2. INFORMATION PROVIDED BY CUSTOMER

- Customer own protocol:
  NND020428-801 Revival Design Verification ESD EMC RF and Airborne Equipment Tests Protocol, Rev. A

3. GENERAL REMARKS

- None

4. TECHNICAL INFORMATION OF EQUIPMENT UNDER TEST (EUT)

4.1 EUT Identification

DESCRIPTION	Add-on for Insulin Pen-Injector
MODEL NAME	DV samples (project Revival)
SERIAL NO.	1043
PRS LAB INTERNAL REFERENCE	BC 44/2021 3/20
TRADEMARK	DIALOG
MANUFACTURER	Novo Nordisk A/S
COUNTRY OF MANUFACTURER	Denmark
SINGLE UNIT OR SYSTEM	Single
POWER SOURCE	Internal lithium battery, Coincell CR1632
SUPPLY VOLTAGE	3V⎓
MAX POWER or MAX ABSORBED CURRENT	11mA
SW VERSION (MAIN and BLE)	FW: CSS_EMI_TEST_00.04.00
OPERATING TEMPERATURE	+5°C ~ +40°C
DIMENSIONS	See photography documentation
EUT STANDING	On insulin pen

4.2 Bluetooth module technical data

CHIP MANUFACTURER	NXP
CHIP TYPE	**QN9083**
FREQUENCY BAND	2400 – 2483.5MHz
NUMBER OF CHANNELS	40
CHANNEL BANDWIDTH	2MHz
CHANNEL SEPARATION	2MHz
TRANSFER RATE	1Mbps
SENSITIVITY	-94dBm
TYPE OF MODULATION	GFSK
ANTENNA	Chip antenna
ANTENNA GAIN	1dBi
ANTENNA TYPE	**2450AT07A0100**
ANTENNA MANUFACTURER	JOHANSON TECHNOLOGY

4.3 Ports identification

	PORT	DESCRIPTION	CONNECTION	NOTES
☒	Enclosure	Plastic	Snaps	---
☐	AC Power input	Port not present	---	---
☐	DC Power input	Internal battery	---	---
☐	Signal/Control port	Port not present	---	---
☐	Telecomm. port	Port not present	---	---
☐	Antenna Port	Internal	---	---

Note:
During the tests all cables must be what provided the manufacturer or the same that used in the real employment of the EUT.

4.4 Modifications incorporated in E.U.T.

The following items are the modifications introduced in the equipment under test:

- None

4.5 Auxiliary equipment

- Auxiliary injection pen with SN U100-41555.

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5. REFERENCE STANDARDS

CODE OF FEDERAL REGULATIONS	DESCRIPTION
Title 47 Part 15 Subpart B	Radio frequency devices - General
Title 47 Part 15 Subpart B § 15.109	Radio frequency devices – Unintentional Radiators Radiated Emissions Limits
ICES-003 Issue 6	Information Technology Equipment (ITE) — Limits and Methods of Measurement
ANSI C63.4: 2014	American National Standard for Methods of Measuring of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz – 40 GHz

6. OPERATING TEST MODES AND TEST CONDITIONS

In the following table there are the operating conditions adopted during tests identified by an indicator (#) at which has been referred the item "Operating condition of the equipment under test"

OPERATING CONDITION	DESCRIPTION
#1	EUT with injection pen in "Active mode", all functions enable
#2	EUT with injection pen in "Standby mode", ready to receive in input

7. UNITS OF MEASUREMENTS

Conducted EMI Data is in dBµV; dB referenced to one microvolt
Radiated EMI Data is in dBµV/m; dB/m referenced to one microvolt per meter

Sample Calculation:
RFS = Radiated Field Strength,
FSM = Field Strength Measured,
A.F. = Receive antenna factor,
Gain = amplification gains and/or cable losses.

RFS (dBµV/m @ 3m) = FSM (dBµV) + A.F. (dB/m) - Gain (dB)

8. SUMMERY OF TEST RESULTS

8.1 Emission tests

SUMMARY OF TEST RESULTS				
Port	**Test**	**Reference Standard**	**Operating Condition[1]**	**Results**
Enclosure	Radiated emission	Title 47 Part 15 Subpart B § 15.109 ICES-003 Issue 6	#1, #2	Within the limits
AC main	Conducted emission	Title 47 Part 15 Subpart B § 15.107 ICES-003 Issue 6	Not applicable[2]	

[1] Ref. Tab. of Section 6

[2] Port not present

9. LIST OF INSTRUMENTS USED

Instrument	Manufacturer	Model	Serial n°	Calibrated on	Due to
MXE Emi Receiver	Keysight	N9038A	MY57290150	06/2020	06/2021
Bi-log antenna	Chase	CBL6111C	2717	03/2019	03/2022
Horn antenna	Electro Metrics	EM-6961	100437	10/2020	10/2023
Semi-Anechoic Chamber	Siemens	B83117-D6019-T232	003-005-134/94C	02/2021	02/2022
Software EMC	Rohde & Schwarz	EMC32-E	V 8.40.0	N.A.	

10. TEST RESULTS

RADIATED EMISSIONS..... 9

TEST **1.**	**RADIATED EMISSIONS**
REFERENCE DOCUMENT	**FCC Cfr 47 part 15 - Subpart B - §15.109** **ICES-003 Issue 6**

• **TEST SETUP**	Acc. To ref. Std.
• **TEST LOCATION**	Semi-anechoic chamber [Measure distance 3 meters]
• **TEST EQUIPMENT USED FOR TEST**	MXE Emi Receiver Keysight mod. N9038A Bi-Log antenna Chase mod. CBL6111C Horn antenna Electro Metrics mod. EM-6961 Software Rohde & Schwarz EMC32-E
• **TESTED PORT**	Enclosure
• **FREQUENCY RANGE**	30MHz – 12.75GHz
• **LIMITS**	Class A - Acc. To ref. Std.
• **UNCERTAINTY OF MEASURE**	Level of confidence = 95% (k=2) Expanded uncertainty 30MHz – 1GHz = 5,86 dB Expanded uncertainty 1GHz – 12.75GHz = 5,3 dB

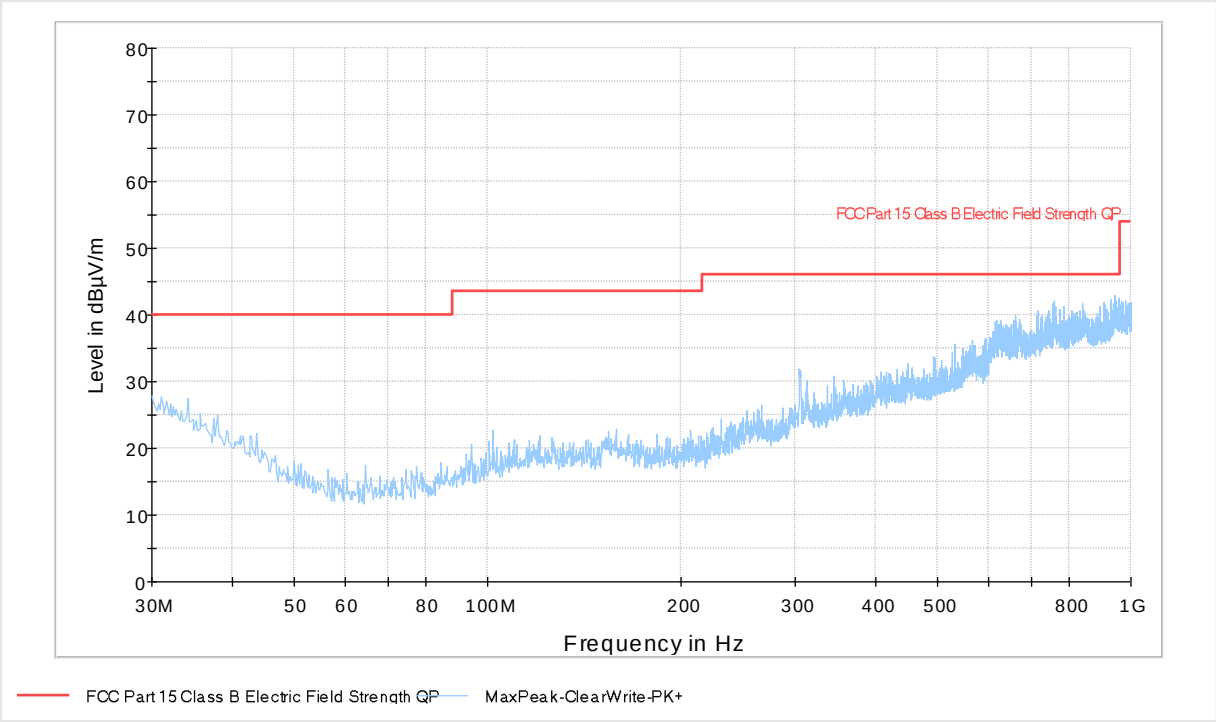
TEST CONDITIONS	REQUIRED	MEASURED
Ambient temperature	**23°C ± 5°C**	24 °C
Ambient humidity	**25 - 75%rH**	45%
Pressure	**85 - 106kPa (860mbar - 1060mbar)**	960 mbar
Voltage		3Vdc Internal battery

OPERATING CONDITION: **#1, #2**

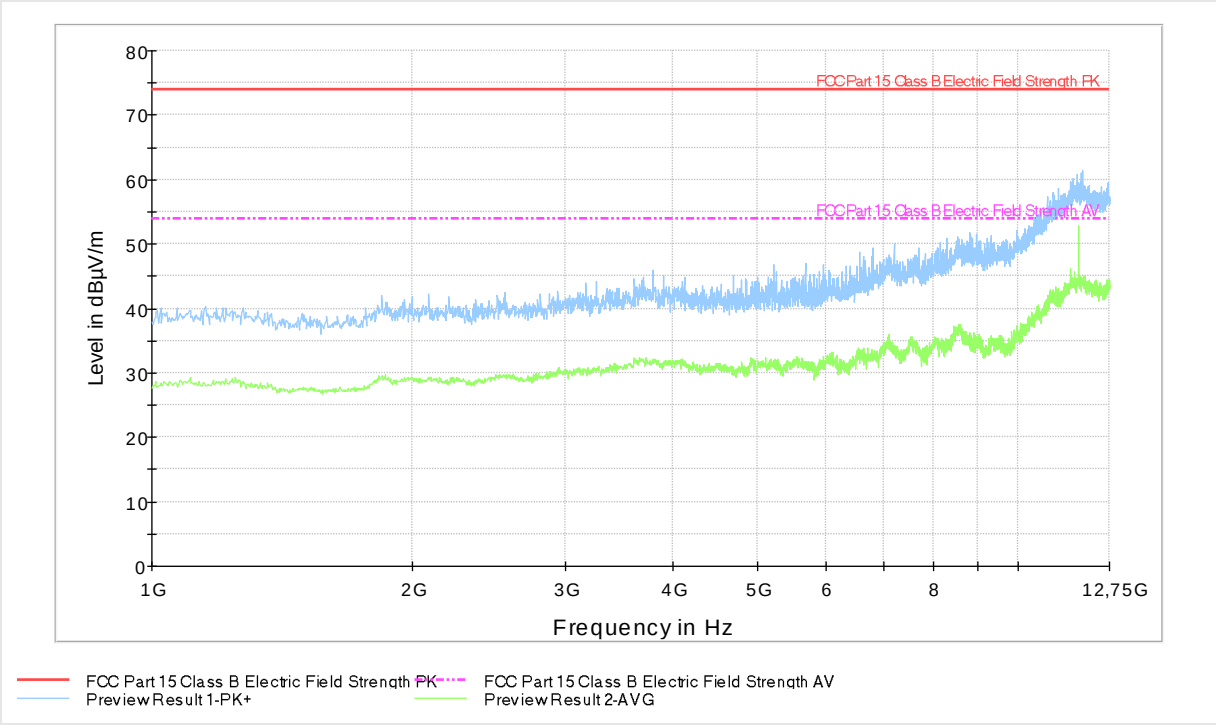
RESULT: **WITHIN THE LIMITS**

TEST RESULTS

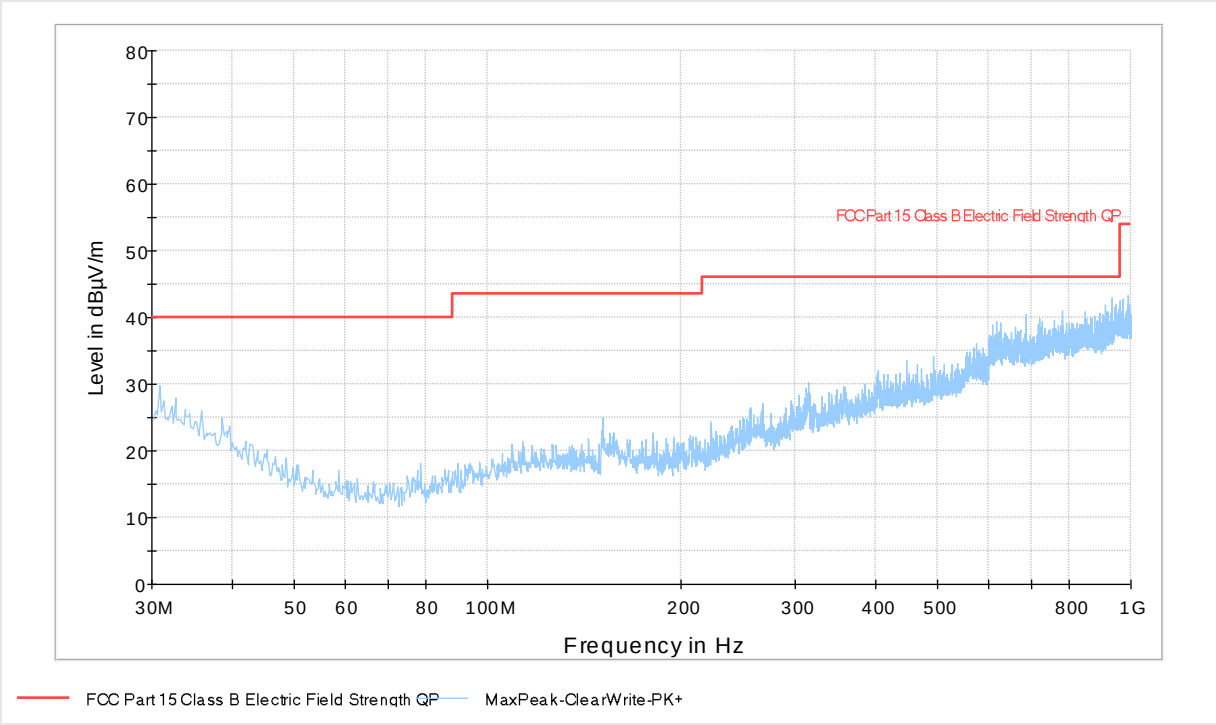
OPERATING CONDITION #1	
Frequency Range	30MHz – 1GHz
Polarization	Vertical



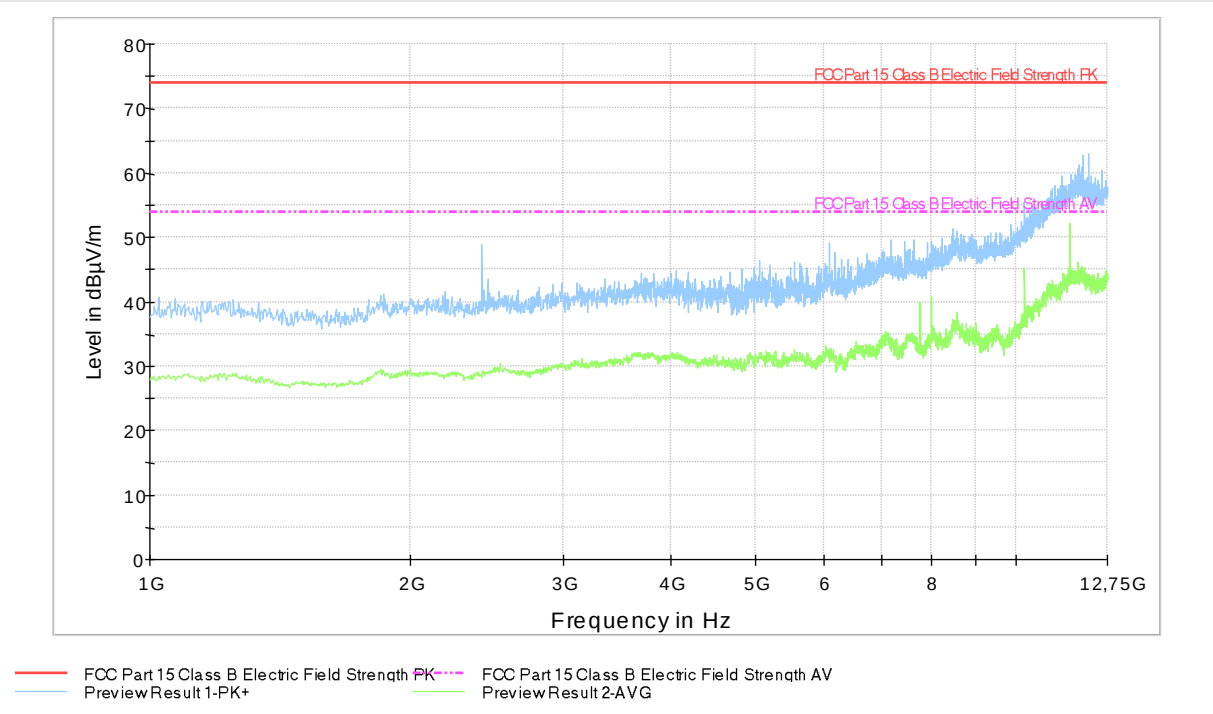
Frequency Range	1GHz – 12.75GHz
Polarization	Vertical



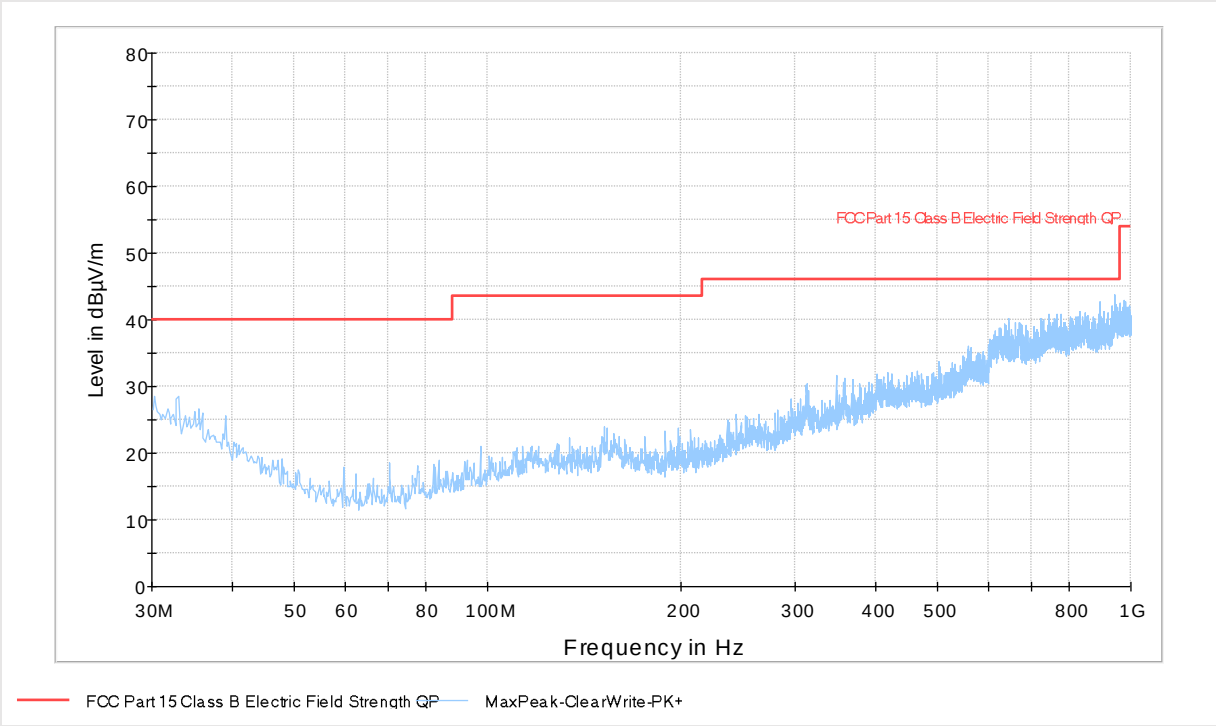
Frequency Range	30MHz – 1GHz
Polarization	Horizontal



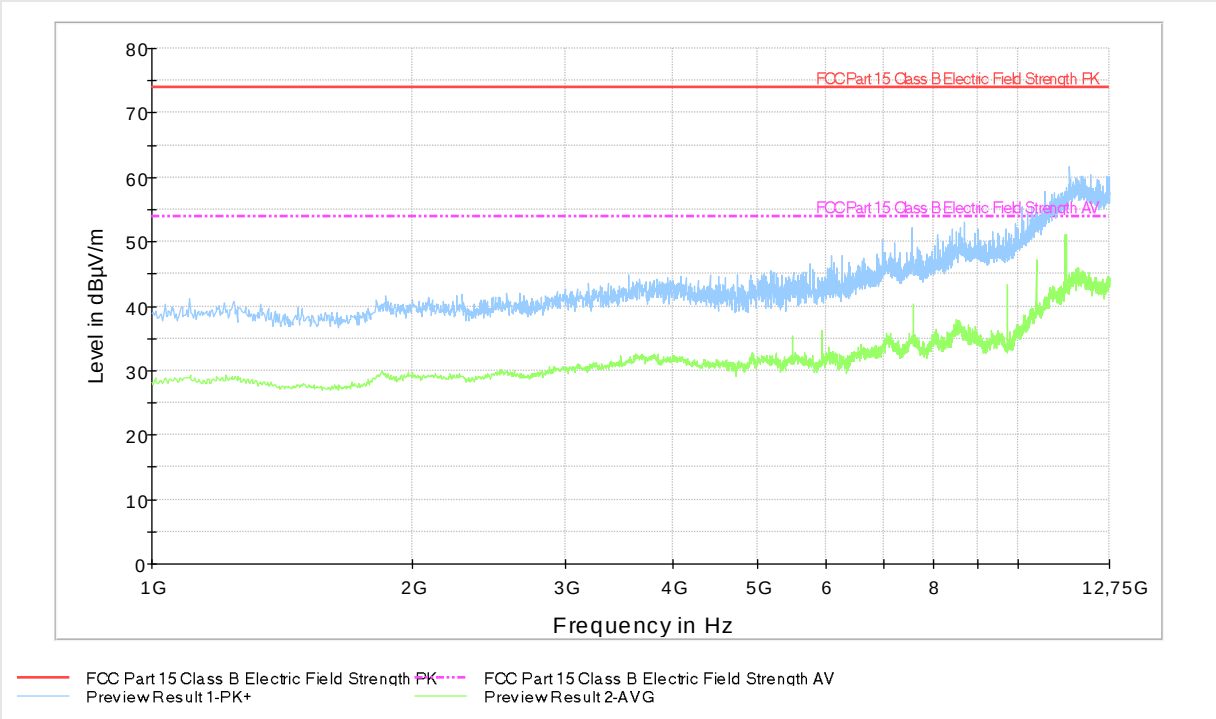
Frequency Range	1GHz – 12.75GHz
Polarization	Horizontal



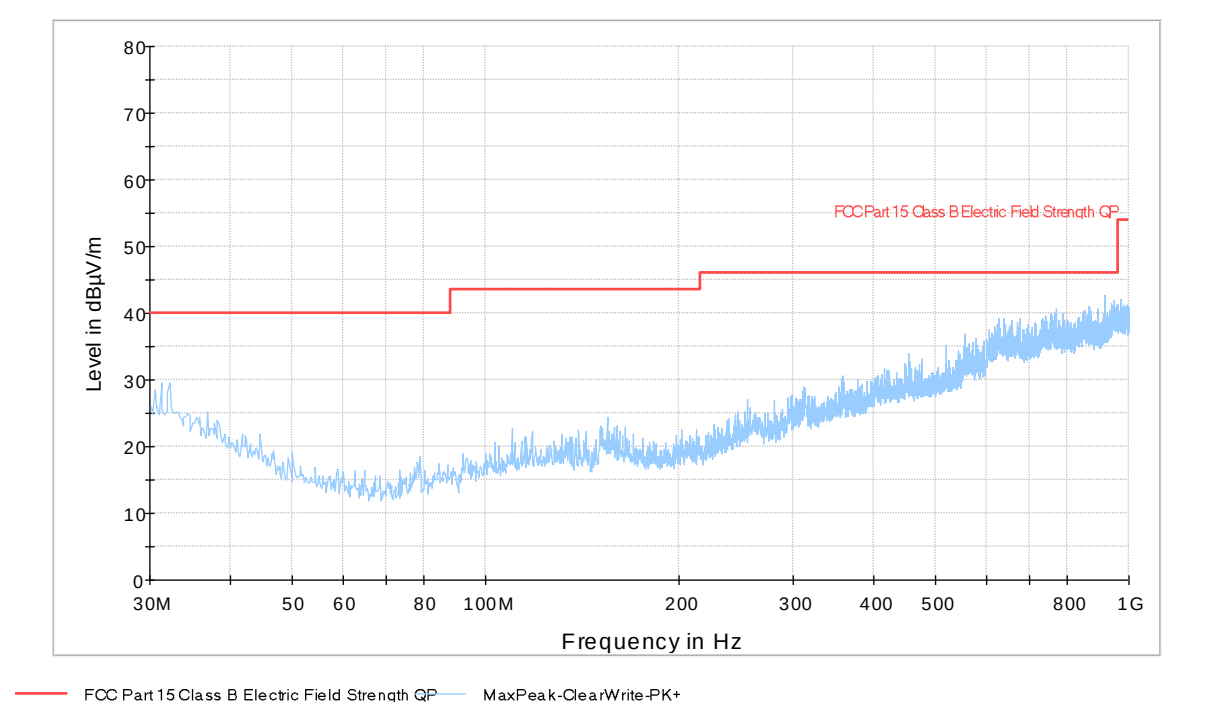
OPERATING CONDITION #2	
Frequency Range	30MHz – 1GHz
Polarization	Vertical



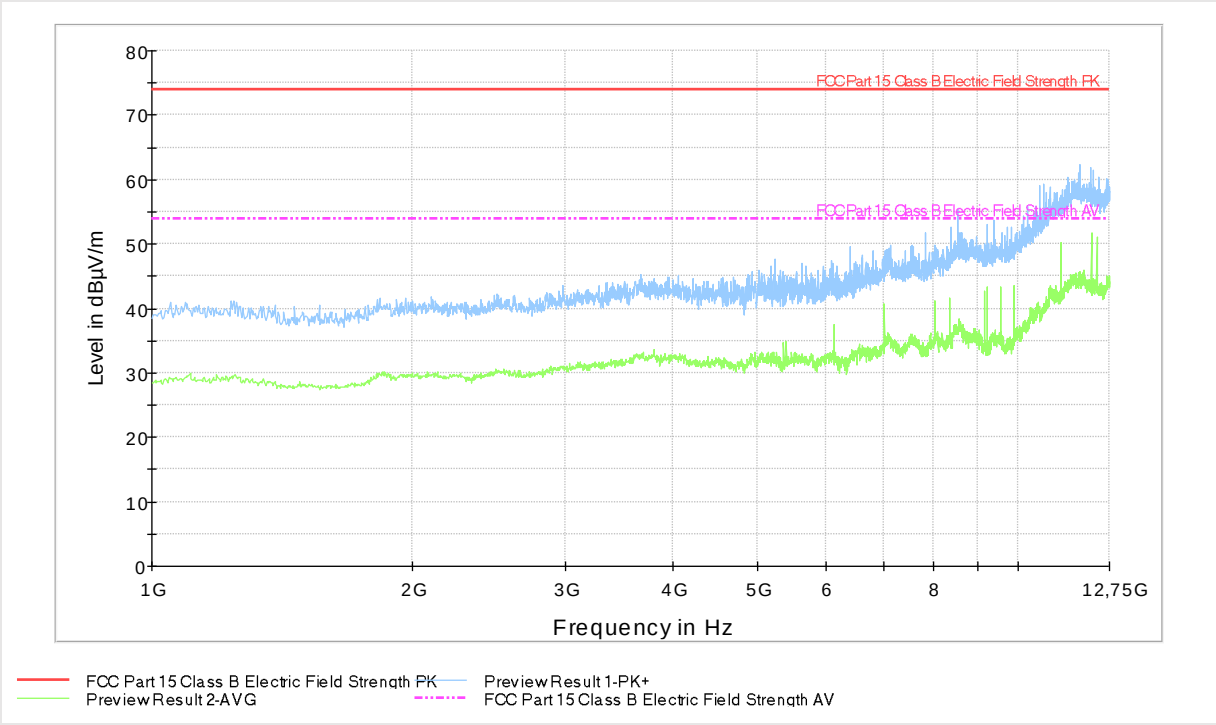
Frequency Range	1GHz – 12.75GHz
Polarization	Vertical



Frequency Range	30MHz – 1GHz
Polarization	Horizontal

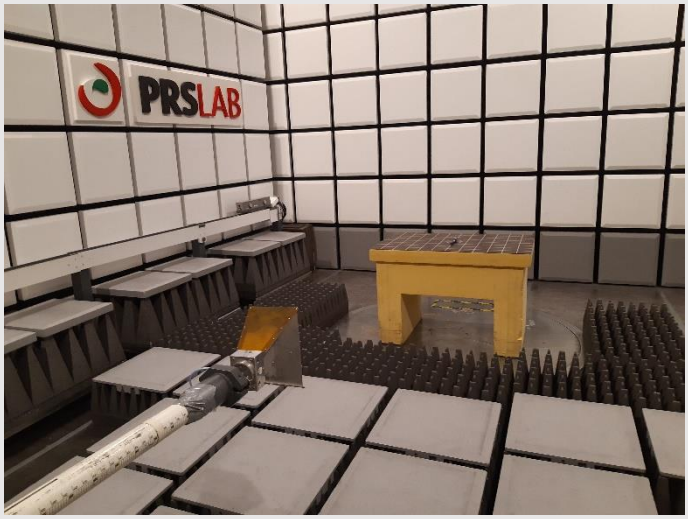


Frequency Range	1GHz – 12.75GHz
Polarization	Horizontal



11. PHOTOGRAPHIC DOCUMENTATION

PHOTO N° 1 - RADIATED EMISSIONS SETUP



END OF TEST REPORT