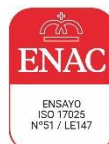


Test report No:
 NIE: 71079REM.001A1

Test report

FCC Rules and Regulations CFR 47, Part 15, Subpart B & Subpart C (10-1-20 Edition) ICES-003 Issue 7 (October 2020) & RSS-Gen Issue 5 (April 2018)

(*) Identification of item tested	<p>The SPICA analyzer is used to determine analytes concentrations by colorimetric and turbidimetric measurements of several kinds of samples from a wide range of industries. There are two clear business divisions: IVD & non-IVD.</p> <p>The SPICA IVD analyzer is used to determine analyte concentrations by in vitro colorimetric, turbidimetric, and electrolyte measurements of different human body fluids or samples (for example serum, urine, plasma, cerebrospinal fluid, total blood, seminal plasma, and fecal samples). For in vitro professional use only in the clinical laboratory.</p> <p>The SPICA non-IVD analyzer determines analytes concentrations by colorimetric, turbidimetric, and electrolyte measurements of different kinds of food (for example, meat or fish) and beverage samples (for example, wines, juices, milk), veterinary samples, and/or samples of biological cultures. For professional use in analytical laboratories only.</p>
(*) Trademark	BioSystems
(*) Model and /or type reference	Spica Hightrouput
Other identification of the product	<p>HW version: Hightrouput Spica HW SW version: BTS Platform FCC ID: 2A5PS000083100 IC: --</p>
(*) Features	Bluetooth LE, , 802.11a/b/g/n20
Manufacturer	<p>BioSystems S.A. C/ Costa Brava, 30 08030 BCN (SPAIN)</p>
Test method requested, standard	<p>FCC Rules and Regulations CFR 47, Part 15, Subpart B & Subpart C (10-1-20 Edition) ICES-003 Issue 7 (October 2020) & RSS-Gen Issue 5 (April 2018)</p>
Summary	IN COMPLIANCE
Approved by (name / position & signature)	<p>José Manuel Gómez Industrial & Automotive EMC Lab. Manager</p>
Date of issue	2022-08-25
Report template No	<p>FDT08_24 (*) "Data provided by the client"</p>



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Acronyms

Acronym ID	Acronym Description
Code	EMC Test Code
Freq Rng	Frequency Range
Line	Conducted Emissions - Tested Line
OM	Operation Mode
S/	Sample
V	Verdict

Competences and guarantees

DEKRA Testing and Certification S.A.U. is a testing laboratory accredited by the National Accreditation Body (ENAC -Entidad Nacional de Acreditación), to perform the tests indicated in the Certificate No. 51/LE 147.

In order to assure the traceability to other national and international laboratories, DEKRA Testing and Certification S.A.U. has a calibration and maintenance program for its measurement equipment.

DEKRA Testing and Certification S.A.U. guarantees the reliability of the data presented in this report, which is the result of the measurements and the tests performed to the item under test on the date and under the conditions stated on the report and, it is based on the knowledge and technical facilities available at DEKRA Testing and Certification S.A.U. at the time of performance of the test.

DEKRA Testing and Certification S.A.U. is liable to the client for the maintenance of the confidentiality of all information related to the item under test and the results of the test.

The results presented in this Test Report apply only to the particular item under test established in this document.

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General conditions

1. This report is only referred to the item that has undergone the test.
2. This report does not constitute or imply on its own an approval of the product by the Certification Bodies or competent Authorities.
3. This document is only valid if complete; no partial reproduction can be made without previous written permission of DEKRA Testing and Certification S.A.U.
4. This test report cannot be used partially or in full for publicity and/or promotional purposes without previous written permission of DEKRA Testing and Certification S.A.U. and the Accreditation Bodies.

Uncertainty

Uncertainty (factor $k=2$) was calculated according to the DEKRA Testing and Certification S.A.U. internal document PODT000.

The total uncertainty of the measurement system for the measured conducted disturbance characteristics of EUT from 150 kHz to 30 MHz is $I = \pm 3,9$ dB for quasi-peak measurements, $I = \pm 3,2$ dB for peak measurements ($k = 2$).

The total uncertainty of the measurement system for the measured radio disturbance characteristics of EUT from 30 MHz to 1000 MHz is $I = \pm 4,9$ dB for quasi-peak measurements, $I = \pm 4,6$ dB for peak measurements ($k = 2$).

The total uncertainty of the measurement system for the measured radio disturbance characteristics of EUT from 1000 MHz to 12.75 GHz is $I = \pm 2,6$ dB for peaks and average measurements ($k = 2$).

Data provided by the client

The following data has been provided by the client:

1. Information relating to the description of the sample ("Identification of the item tested", "Trademark", "Model and/or type reference tested")
2. The sample consists of a SPICA Analyzer is used to determine analytes concentrations by colorimetric and turbidimetric measurements of several kinds of samples from a wide range of industries. There are two clear business divisions: IVD & non-IVD.

The SPICA IVD analyzer is used to determine analyte concentrations by in vitro colorimetric, turbidimetric, and electrolyte measurements of different human body fluids or samples (for example serum, urine, plasma, cerebrospinal fluid, total blood, seminal plasma, and fecal samples). For in vitro professional use only in the clinical laboratory.

The SPICA non-IVD analyzer determines analytes concentrations by colorimetric, turbidimetric, and electrolyte measurements of different kinds of food (for example, meat or fish) and beverage samples (for example, wines, juices, milk), veterinary samples, and/or samples of biological cultures. For professional use in analytical laboratories only.

DEKRA Testing and Certification S.A.U. declines any responsibility with respect to the information provided by the client and that may affect the validity of results.

Usage of samples

Samples undergoing test have been selected by: The client.

Id	Control Number	Description	Model	Serial N°	Date of Reception	Application
S/01	70829_1.1	SPICA	SPICA	831000005	2022-01-05	Element Under Test
S/01	70829_1.2	Power Supply Cable	--	--	2022-01-05	Element Under Test
S/01	70829_4.1	Ethernet Cable	--	--	2022-01-10	Auxiliary Element

Notes referenced to samples during the project.

Test sample description

Test Sample description (compulsory information for EMC and RF testing services)

Ports..... :	Port name and description	Cable					
		Specified max length [m]	Attached during test	Shielded	Coupled to patient ⁽³⁾		
	ETHERNET	>3m	[X]	[X]	[]		
	USB	Not provided data	[X]	[]	[]		
	[]	[]	[]		
	[]	[]	[]		
	[]	[]	[]		
	[]	[]	[]		
Supplementary information to the ports..... :						
Rated power supply	Voltage and Frequency		Reference poles				
			L1	L2	L3	N	PE
[]	AC:	[]	[]	[]	[]	[]	
[X]	AC: 115V -50Hz	[X]	[]	[]	[X]	[X]	
[]	DC:						
[]	DC:						
Rated Power	450 VA						
Clock frequencies.....	Not provided data						
Other parameters	Not provided data						
Software version	BTS Platform						
Hardware version	Hightrought Spica HW						
Dimensions in cm (W x H x D)	Not provided data						

Mounting position	<input checked="" type="checkbox"/>	Table top equipment		
	<input type="checkbox"/>	Wall/Ceiling mounted equipment		
	<input type="checkbox"/>	Floor standing equipment		
	<input type="checkbox"/>	Hand-held equipment		
	<input type="checkbox"/>	Other:		
Modules/parts.....	Module/parts of test item		Type	Manufacturer
	Not provided data	

Accessories (not part of the test item)	Description		Type	Manufacturer
	Not provided data	

Documents as provided by the applicant	Description		File name	Issue date
	Not provided data	

⁽³⁾ Only for Medical Equipment

Identification of the client

BioSystems S.A.
C/ Costa Brava, 30 08030 BARCELONA (SPAIN)

Testing period and place

Test Location	DEKRA Testing and Certification S.A.U.
Date (start)	2022-01-26
Date (finish)	2022-02-09

Document history

Report number	Date	Description
71079REM.001	2022-05-17	First release
71079REM.001A1	2022-08-25	Second release: Including references to standards Part 15.207 – Subpart C and RSS-Gen. This test report cancels and replaces the report: 71079REM.001

Environmental conditions

In the control chamber, the following limits were not exceeded during the test:

Temperature	Min. = 15 °C Max. = 35 °C
Relative humidity	Min. = 30 % Max. = 75 %
Air pressure	Min. = 860mbar Max. = 1060mbar

In the semianechoic chamber, the following limits were not exceeded during the test.

Temperature	Min. = 15 °C Max. = 35 °C
Relative humidity	Min. = 30 % Max. = 75 %
Air pressure	Min. = 860mbar Max. = 1060mbar

In the chamber for conducted measurements, the following limits were not exceeded during the test:

Temperature	Min. = 15 °C Max. = 35 °C
Relative humidity	Min. = 30 % Max. = 60 %
Air pressure	Min. = 860mbar Max. = 1060mbar

Remarks and comments

The tests have been performed by the technical personnel: Jaime Barranquero Gómez and Victoria Olmedo Villalba.

Testing verdicts

Fail	F
Inconclusive	I
Not applicable	N/A
Not measured	N/M
Pass	P

List of equipment used during the test

Control No.	Equipment	Model	Manufacturer	Next Calibration
7762	ACTIVE LOOP ANTENNA 9kHz-30MHz	FMZB 1519B	SCHWARZBECK	2022-11-06
7853	EMI RECEIVER 10Hz-30MHz	PMM 9010F	NARDA	2023-12-03
7817	EMI TEST RECEIVER 2Hz-44GHz	ESW44	ROHDE AND SCHWARZ	2023-12-30
7763	HORN ANTENNA 1-18GHz	BBHA 9120D	SCHWARZBECK MESS-ELEKTRONIK	2022-11-15
6495	HORN ANTENNA 18-40GHz	BBHA 9170	SCHWARZBECK	2024-03-19
7862	PRE-AMPLIFIER G>30dB 18-40GHz	BLMA 1840-3G	BONN ELEKTRONIK	2023-02-15
7769	PREAMPLIFIER 30dB 500MHz-18GHz	BBV 9718 C	SCHWARZBECK	2023-02-10
7859	THREE-PHASE ARTIFICIAL NETWORK 32A	PMM L3-32	NARDA	2024-01-14
7826	ULTRALOG ANTENNA 30MHz-6GHz	HL562E_UPG	ROHDE AND SCHWARZ	2022-10-15

Summary

Test Specification.	Requirement – Test case	Verdict	Remark
FCC 47 CFR Part 15B	RE Radiated emission. Electromagnetic field measure	Pass	--
FCC 47 CFR Part 15B FCC 47 CFR Part 15C ICES-003 RSS-Gen	CE Continuous conducted emission	Pass	--
<u>Supplementary information and remarks:</u> None			

Appendix A: Test results

Appendix A content

DESCRIPTION OF THE OPERATION MODES	15
TEST STANDARDS VERSION APPLIED	16
TEST CASES DETAILS	17
FCC 47 CFR PART 15B	17
RE RADIATED EMISSION. ELECTROMAGNETIC FIELD MEASURE	17
CE CONTINUOUS CONDUCTED EMISSION	22

Description of the operation modes

The operation modes described in this paragraph constitute a functionality of the sample under test for itself. Every operation mode takes a failure criteria for the immunity test that they were applying to it and a monitoring to guarantee performance of the same ones.

The operation modes used by the samples to which the present report refers, are shown in the following table:

Id	Description
OM/01	EUT ON. Continuous analyzing samples, dispensing and stirring arms in continuous movement. Wifi 2.4GHz and Bluetooth active without transmission. Power supply:115 Vac.
OM/02	EUT ON. Continuous analyzing samples, dispensing and stirring arms in continuous movement. Wifi 2.4GHz and Bluetooth active and established communication with auxiliary device. Power supply:115 Vac.

Test standards version applied

The product standards and test standards applied for each test cases are shown in the following table:

Product Test Standard	Test standard	Requirement – Test case
FCC CFR 47, Part 15, Subpart B (10-1-20 Edition) & ICES-003 Issue 7 (October 2020)	ANSI C63.4 (2014)	RE Radiated emission.
FCC CFR 47, Part 15, Subpart B and Subpart C (10-1-20 Edition) & ICES-003 Issue 7 (October 2020) RSS-Gen Issue 5 (April 2018)	ANSI C63.4 (2014)	CE Continuous conducted emission

Test Cases Details

FCC 47 CFR Part 15B

RE Radiated emission. Electromagnetic field measure

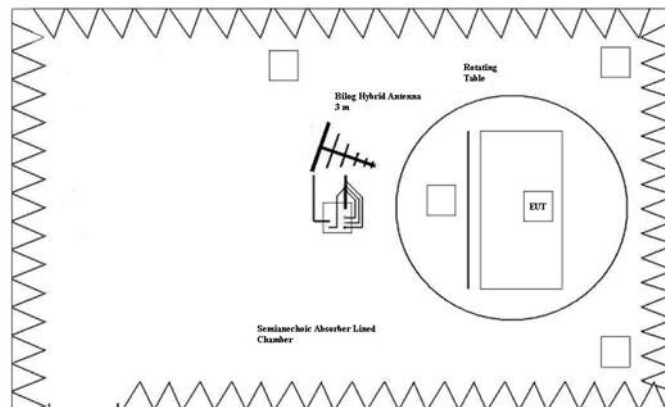
Limits of interference Class B

The applied limit for radiated emissions, 3 m distance, according to the requirements of FCC Rules and Regulations 47 CFR Part 15, Subpart B (10-1-20 Edition), Secs. 15.109 & ICES-003 Issue 7 (October 2020)

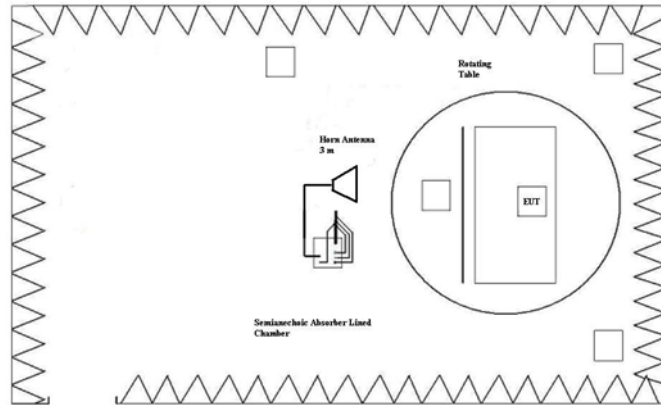
Frequency range (MHz)	FCC Part 15B		ICES-003 Issue 7		FCC Part 15B & ICES-003 Issue 7	
	QP Limit for 3 m		QP Limit for 3 m		PK Limit for 3 m	AVG Limit for 3 m
	($\mu\text{V/m}$)	($\text{dB}\mu\text{V/m}$)	($\mu\text{V/m}$)	($\text{dB}\mu\text{V/m}$)	($\text{dB}\mu\text{V/m}$)	($\text{dB}\mu\text{V/m}$)
30 to 88	100	40	100	40	---	---
88 to 216	150	43.5	150	43.5	---	---
216 to 230	200	46	200	46	---	---
230 to 960	200	46	224	47	---	---
960 to 1000	500	54	500	54	---	---
Above 1000	---	---	---	---	74	54

NOTE: FCC QP and AVG limits are in concordance with RSS-Gen Issue 5 (March 2019), Secs. 7.1 and 7.3. Limits according to FCC Part 15B, are equal or more stringent than those of ICES-003 Issue 7.

Setup for measurements



Setup for measurements < 1GHz.



Setup for measurements > 1GHz.

Results

S/	OM	Code	Freq Rng (MHz)	Comments	V
01	OM/01	RE0101LR	[30, 1000]		P
01	OM/01	RE0101HR	[1000, 12750]		P

Verdict

Pass

Attachments

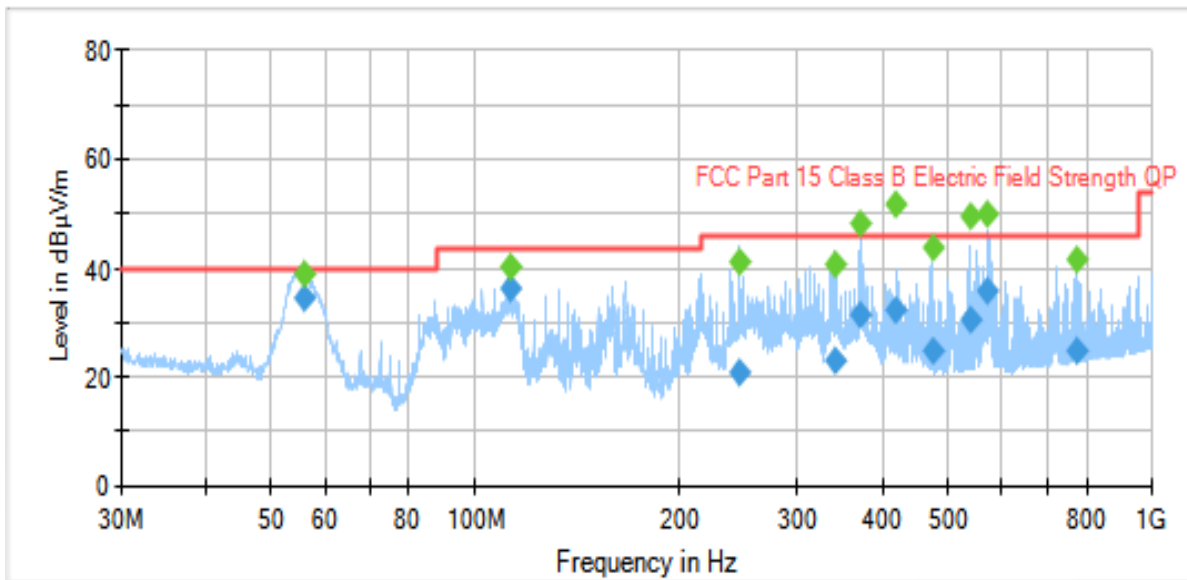
EMC Test Code = RE0101LR, Frequency Range MHz = [30, 1000]

Sample ID: S/01

Operation Mode: OM/01. EUT ON. Continuous analyzing samples, dispensing and stirring arms in continuous movement. Wifi and Bluetooth in RX mode. Power supply:115 Vac..

Images:

Full Spectrum



◆ Preview Result 1-PK+ Final_Result QPK
 ◆ FCC Part 15 Class B Electric Field Strength QP Final_Result PK+

Documents:

Frequency(MHz)	QuasiPeak(dBµV/m)	MaxPeak(dBµV/m)	Limit(dBµV/m)	Margin(dB)	Height(cm)	Pol	Azimuth(deg)
55.999000	---	38.90	---	---	133.0	V	38.0
55.999000	34.47	---	40.00	5.53	133.0	V	38.0
112.510000	36.26	---	43.52	7.26	251.0	V	244.0
112.510000	---	40.07	---	---	251.0	V	244.0
246.259000	---	40.95	---	---	139.0	V	347.0
246.259000	20.72	---	46.00	25.28	139.0	V	347.0
340.489000	---	40.61	---	---	160.0	H	319.0
340.489000	23.11	---	46.00	22.89	160.0	H	319.0
370.424000	31.32	---	46.00	14.68	167.0	H	294.0
370.424000	---	48.00	---	---	167.0	H	294.0
418.585000	---	51.77	---	---	164.0	V	302.0
418.585000	32.07	---	46.00	13.93	164.0	V	302.0
473.666000	---	43.55	---	---	264.0	H	315.0
473.666000	24.74	---	46.00	21.26	264.0	H	315.0
538.316000	---	49.43	---	---	100.0	H	289.0
538.316000	30.63	---	46.00	15.37	100.0	H	289.0

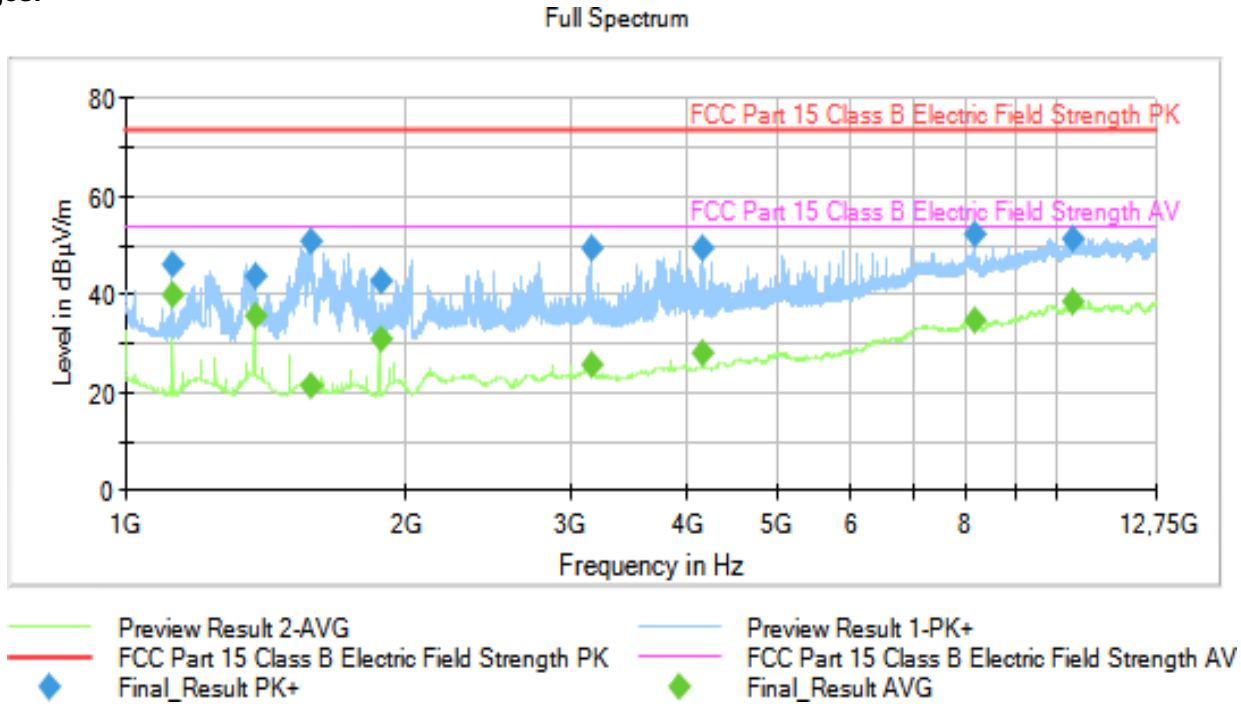
Frequency(MHz)	QuasiPeak(dB μ V/m)	MaxPeak(dB μ V/m)	Limit(dB μ V/m)	Margin(dB)	Height(cm)	Pol	Azimuth(deg)
572.249000	---	50.05	---	---	107.0	H	261.0
572.249000	35.87	---	46.00	10.13	107.0	H	261.0
772.799000	24.62	---	46.00	21.38	255.0	H	214.0
772.799000	---	41.66	---	---	255.0	H	214.0

EMC Test Code = RE0101HR, Frequency Range MHz = [1000, 12750]

Sample ID: S/01

Operation Mode: OM/01. EUT ON. Continuous analyzing samples, dispensing and stirring arms in continuous movement. Wifi and Bluetooth in RX mode. Power supply:115 Vac..

Images:



Documents:

Frequency(MHz)	MaxPeak(dBµV/m)	Average(dBµV/m)	Limit(dBµV/m)	Margin(dB)
1125.200000	---	39.96	53.97	14.01
1125.200000	45.97	---	73.97	28.00
1375.200000	---	35.89	53.97	18.08
1375.200000	43.58	---	73.97	30.39
1578.000000	---	21.45	53.97	32.52
1578.000000	50.77	---	73.97	23.20
1875.200000	42.65	---	73.97	31.32
1875.200000	---	31.11	53.97	22.86
3166.400000	---	25.81	53.97	28.16
3166.400000	49.44	---	73.97	24.53
4159.200000	49.54	---	73.97	24.43
4159.200000	---	28.16	53.97	25.81
8134.000000	---	34.88	53.97	19.09
8134.000000	52.16	---	73.97	21.81
10408.800000	---	38.45	53.97	15.52
10408.800000	51.59	---	73.97	22.38

CE Continuous conducted emission

Limits of interference Class B

The applied limit for continuous conducted emissions in power leads, according with the requirements of FCC Rules and Regulations 47 CFR Part 15, Subpart B (10-1-20 Edition) Secs. 15.107 and Subpart C (10-1-20 Edition) Secs. 15.207 & ICES-003 Issue 7 (April 2020) & RSS-Gen Issue 5 (April 2018) in the frequency range 0,15 to 30 MHz, for Class B equipment was:

Frequency range (MHz)	Limit (dB μ V)	
	Quasi-Peak	Average
0,15 to 0,5	66 - 56	56 - 46
0,5 to 5	56	46
5 to 30	60	50

Results

S/	OM	Code	Freq Rng (MHz)	Line	Comments	V
01	OM/02	CE01020N	[0.15, 30]	N		P
01	OM/02	CE0102L1	[0.15, 30]	L1		P

Verdict

Pass

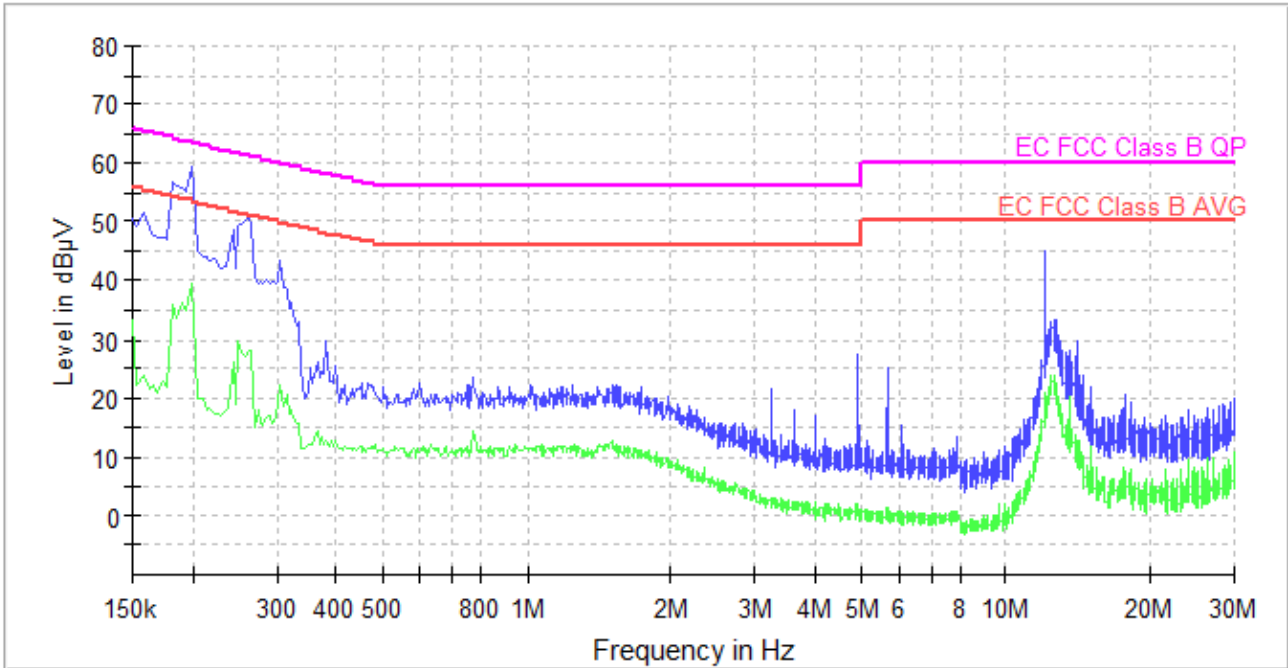
Attachments

EMC Test Code = CE01010N, Frequency Range MHz = [0.15, 30], Conducted Emissions - Tested Line = N

Sample ID: S/01

Operation Mode: OM/01. EUT ON. Continuous analyzing samples, dispensing and stirring arms in continuous movement. Wifi and Bluetooth in RX mode. Power supply:115 Vac..

Images:



- AVG_CLRWR
- PK+_CLRWR
- EC FCC Class B QP
- EC FCC Class B AVG

Documents:

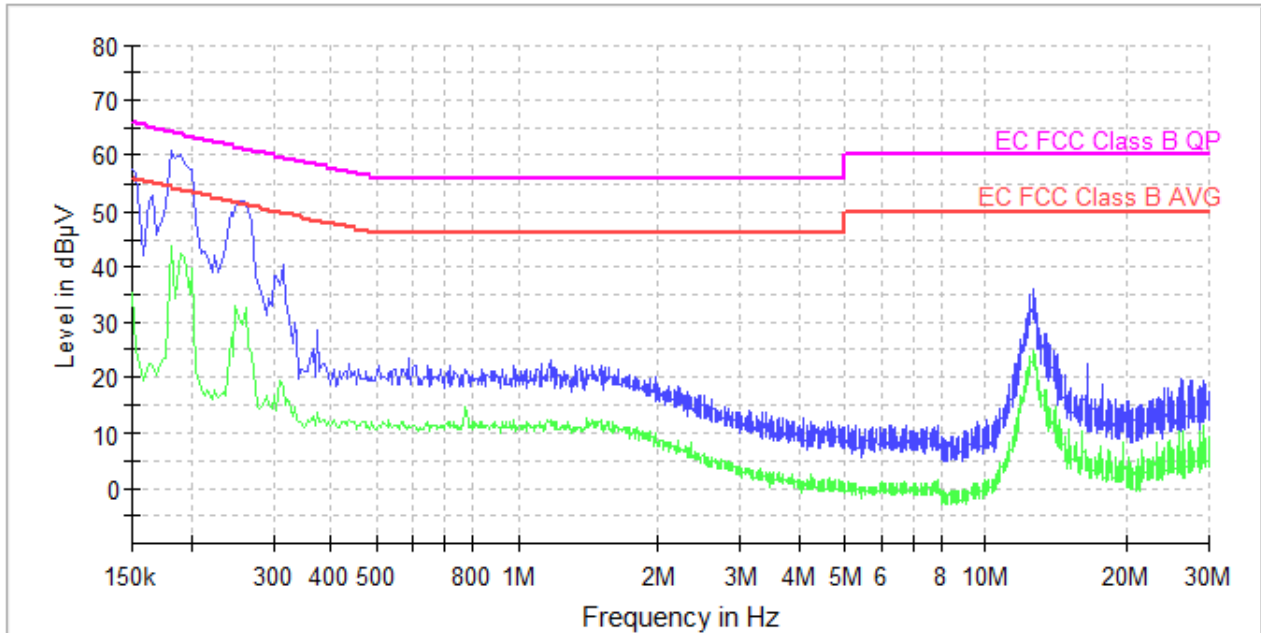
Frequency (MHz)	PK+_CLRWR (dBµV)	AVG_CLRWR (dBµV)	Line
0.182000	61.1	43.8	L1
0.258000	51.8	29.8	L1
0.582000	23.2	11.4	L1
1.170000	23.1	11.9	L1
1.446000	22.4	12.1	L1
2.198000	18.3	8.4	L1

EMC Test Code = CE0101L1, Frequency Range MHz = [0.15, 30], Conducted Emissions - Tested Line = L1

Sample ID: S/01

Operation Mode: OM/01. EUT ON. Continuous analyzing samples, dispensing and stirring arms in continuous movement. Wifi and Bluetooth in RX mode. Power supply:115 Vac..

Images:



— AVG_CLRWR — PK+_CLRWR
— EC FCC Class B QP — EC FCC Class B AVG

Documents:

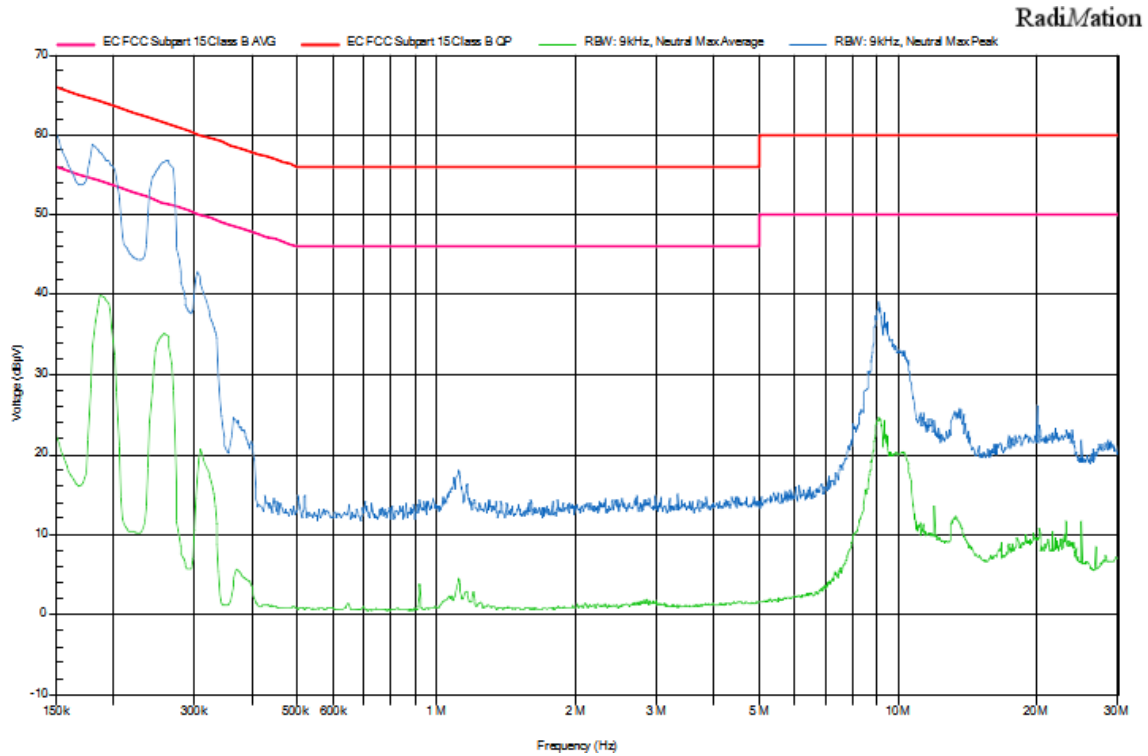
Frequency (MHz)	PK+_CLRWR (dBµV)	AVG_CLRWR (dBµV)	Line
0.182000	61.1	43.8	L1
0.258000	51.8	29.8	L1
0.582000	23.2	11.4	L1
1.170000	23.1	11.9	L1
1.446000	22.4	12.1	L1
2.198000	18.3	8.4	L1
3.694000	12.7	2.3	L1
10.074000	12.2	0.4	L1
12.602000	35.7	24.5	L1
26.190000	19.8	5.0	L1

EMC Test Code = CE01020N, Frequency Range MHz = [0.15, 30], Conducted Emissions - Tested Line = N

Sample ID: S/01

Operation Mode: OM/02. EUT ON. Continuous analyzing samples, dispensing and stirring arms in continuous movement. Wifi 2.4GHz and Bluetooth active and established communication with auxiliary device. Power supply:115 Vac.

Images:



Documents:

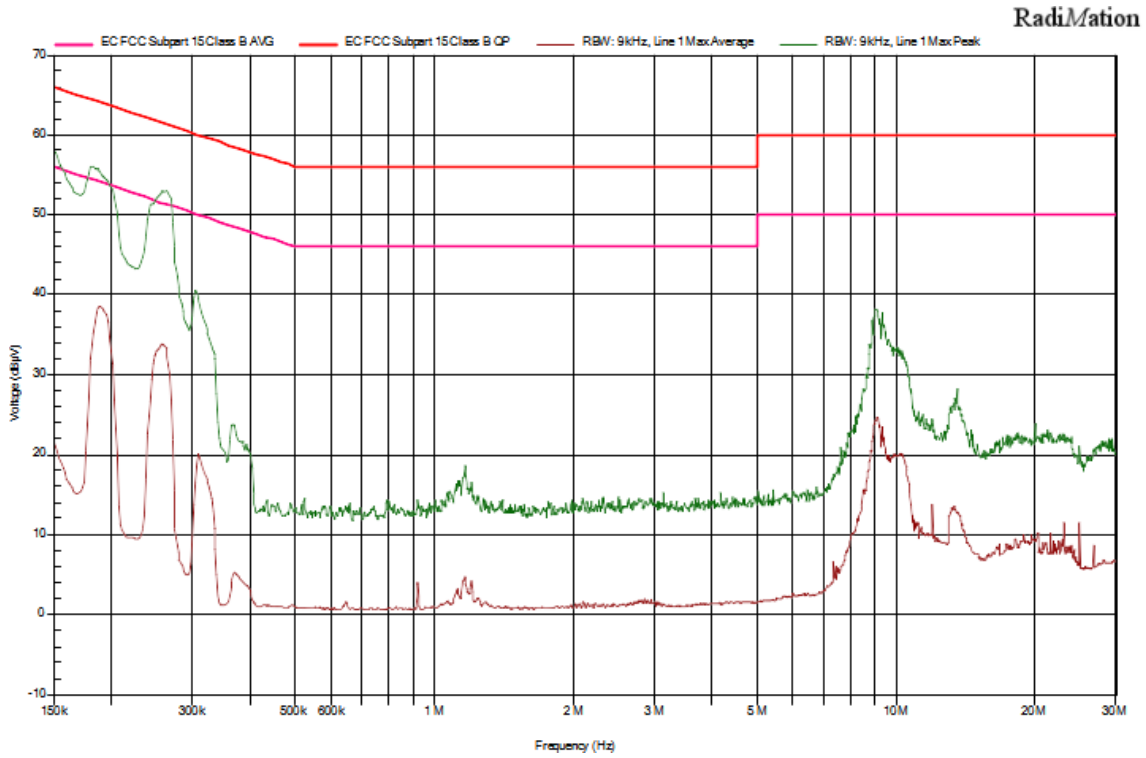
Frequency(MHz)	Average(dBµV)	Peak(dBµV)	Line
0,15 MHz	22,3 dBµV	60,1 dBµV	N
0,185 MHz	38,7 dBµV	58 dBµV	N
0,26 MHz	35,1 dBµV	56,8 dBµV	N
0,305 MHz	19,4 dBµV	42,4 dBµV	N
9,095 MHz	24,5 dBµV	39,2 dBµV	N
9,359 MHz	23 dBµV	37,9 dBµV	N

EMC Test Code = CE0102L1, Frequency Range MHz = [0.15, 30], Conducted Emissions - Tested Line = L1

Sample ID: S/01

Operation Mode: OM/02. EUT ON. Continuous analyzing samples, dispensing and stirring arms in continuous movement. Wifi 2.4GHz and Bluetooth active and established communication with auxiliary device. Power supply:115 Vac.

Images:



Documents:

Frequency(MHz)	Average(dBµV)	Peak(dBµV)	Line
0,15 MHz	21,4 dBµV	58,2 dBµV	L1
0,185 MHz	37,4 dBµV	55,6 dBµV	L1
0,26 MHz	33,7 dBµV	52,9 dBµV	L1
0,305 MHz	18,8 dBµV	40,2 dBµV	L1
9,081 MHz	24,6 dBµV	38,1 dBµV	L1
9,359 MHz	22,3 dBµV	37,5 dBµV	L1