

**EN 301 489-1 V2.2.0,
EN 301 489-17 V2.2.1
EN 300 328 V2.1.1
Radio Equipment Directive (2014/53/EU)
pre-compliance evaluation report**

Report No. 9042020
Product: VentilatorPAL Pro
Model:

CONTENTS:

EMC and radio pre-compliance evaluation report according to:

EN 301 489-1 V2.2.0; Common technical requirements; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU.

EN 301 489-17 V2.2.1; Specific conditions for Broadband Data Transmission Systems

EN 300 328 V2.1.1: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum

Title VentilatorPAL Pro Pre-compliance EMC and Radio evaluation report

Keywords EMC; Wireless

Abstract This report describes the EMC and Radio pre-compliance evaluations which were performed for the VentilatorPAL Pro according to:
EN 301 489-1 V2.2.0;
EN 301 489-17 V2.2.1;
EN 300 328 V2.1.1:

The Stogger B.V.; VentilatorPAL Pro complies with the requirements of these standards .

Number of Pages 14

Applicant : Stogger B.V.

Evaluation Date : 09-04-2020

Evaluated by : R. Brett

Date : 09-04-2020

Signature :

A handwritten signature in blue ink, appearing to be 'R. Brett', written over a horizontal line.

Table of contents

1	Introduction	4
1.1	Equipment classification	4
2	Evaluation Report Information.....	5
3	Applied standards	6
3.1	Reference documents	6
4	Applied performance criteria	7
5	SPECIFICATIONS	7
6	Evaluation:	8
7	Wireless module and antenna implementation:	9
8	Conclusions	10
8.1	Radiated emission at the transmission frequency (2400 – 2483.5MHz)	11

1 Introduction

This report describes the EMC measurements which are performed for the VentilatorPAL Pro according to the 2014/35/EU Directive. This apparatus is from now on called the EUT (Equipment Under Test).



Figure 1: Photo of the VentilatorPAL Pro

FreeBreathing started with the mission to provide a high-quality, low-cost and open-source solution to the shortage of medical ventilators during the coronavirus pandemic.

The VentilatorPAL Pro was developed to meet the requirements of healthcare workers at the forefront of the COVID-19 crisis. The device makes it possible to treat patients when conventional ventilators are not available.

1.1 Equipment classification

Equipment for use in professional healthcare facilities or home healthcare environments.

2 Evaluation Report Information

Equipment Under Test (EUT):

Equipment:	VentilatorPAL Pro		
Model #:	1032-455-00	Serial #:	M0056200
Software & Firmware #:	N/A	Mains configuration	N/A
Supply voltage	24V d.c.		D.C.
AC/DC power cords are:	Adapter	N/A	N/A
Equipment is:	Medical and Wireless (WiFi/Bluetooth)		
Wireless Class	Class 1		

Company:

Company name:	Stogger B.V.		
Address:	Haagveld 1a	Zip:	5981PK
City:	Panningen	Country:	Netherlands

Optional Equipment (OE): AC/DC adapter

Model #:	MeanWell GSM25E24-P1J	Compliance test report
Input voltage:	80-264Vac, 47 - 63Hz; 0.35A (230V)	Report No. S4C-M020-1304-409
Output voltage	24V 1.04A	

Integrated Wireless Module

Model #:	ESP-Wroom-32	Compliance certificate to RED
Max output Bluetooth RF power	9dBm (specification) see note	Certificate No. B1803062

Note: The parameter setting for the Bluetooth RF power is 3dBm.

3 Applied standards

The following EMC standards were used:

EN 301 489-1 V2.2.0; Common technical requirements; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU.

EN 301 489-17 V2.2.1; Specific conditions for Broadband Data Transmission Systems

EN 300 328 V2.1.1: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum

EN61000-4-2:2009	Electrostatic Discharge Immunity test
EN61000-4-3:2006	Radiated, radio-frequency electromagnetic field immunity test
EN 61000-4-4:2004	AC/DC adapter configuration
EN 61000-4-5:2006	AC/DC adapter configuration
EN 61000-4-6:2009	AC/DC adapter configuration
EN 61000-4-8:2010	Power frequency magnetic field immunity test
EN 61000-4-11:2004	AC/DC adapter configuration
EN/IEC 61000-3-2:2014	Harmonic current emissions
EN 61000-3-3 :2013	Voltage fluctuations and Flicker

3.1 Reference documents

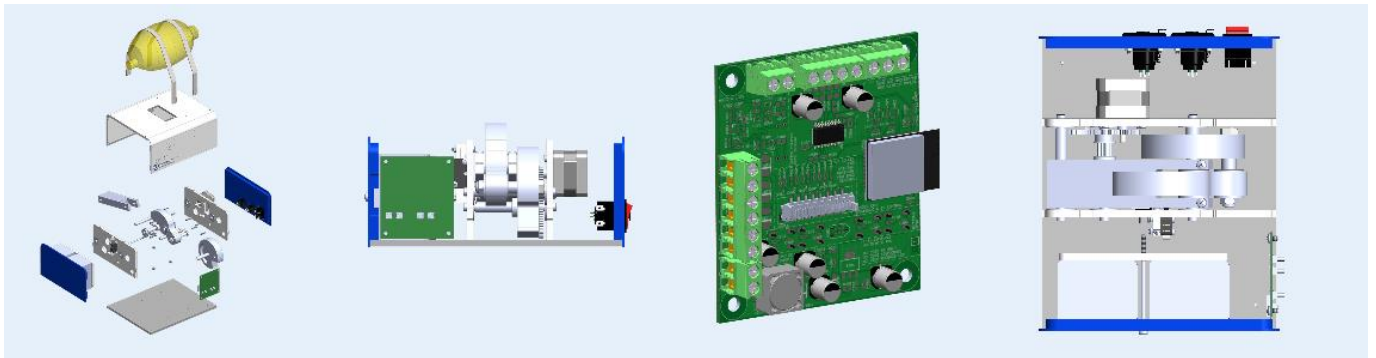
- RED Compliance Association© REDCA TGN 01 Version 1.0 (November 2018)
- 8042020 VentilatorPAL Pro EMC pre-assessment EN60601-1-2

4 Applied performance criteria

Reference: Annex A of EN-IEC 60601-1-2:2016+ A:12013:.

If it is required that during or after the test the equipment continue to operate as intended, the test should be included in an EMC IMMUNITY standard (or clause) of a product (product family).

5 SPECIFICATIONS



Size (LxWxH): 250x200x110

Operating voltage: 18-24 Vdc

Power options:

Mains Power supply -and/or- External battery -and- Internal emergency battery

Human interface: Machine -and/or- mobile app

Control, Machine:

- Tidal Volume (TV)
- Inhale/Exhale ratio (I/E)
- Respiratory Rate (RR)

Aux port I/O:

- 4x digital I/O
- 2x Analog inputs

Control, Mobile app:

- Tidal Volume (TV) ml/kg
- Inhale/Exhale ratio (I/E)
- Respiratory Rate (RR)
- Automatic calculation of tidal volume by Gender and length

Future optional features:

- Air pressure sensor
- SPo2 sensor
- O2 Inlet valve

6 Evaluation:

In general, there is a desire to avoid unnecessarily repeating the performance assessment, if compliance can be justified on the basis of technical analysis, test data and information. However, if the assessment indicates that a measurement is required, then this must be performed to demonstrate compliance.

The wireless module used is the ESP-Wroom-32 which complies with the Radio Equipment Directive requirements as well as the EMC Directive requirements.

According to the REDCA TGN (see chapter 3.1), chapter 5.2 (Final Radio Product Assessment): Radio performance according to Article 3.2 of the RED applies to the final radio product and a full assessment will be required at the final radio product level; but that does not necessarily mean full radio testing must be performed on the final radio product. Some radio tests performed on the radio module may provide confidence of radio compliance of the final radio product.

Therefore for this evaluation reliance is made on the radio performance test results/data from the radio module to demonstrate compliance of the final radio product to Article 3.2 of the RED. For this the test data for Article 3.2 of the RED must be made available provide the final radio product manufacturer with the information needed to state compliance with the RED.

At present the certificate No. B1803062 is available. Due to the rush to get this equipment onto the market as quickly as possible, we must for the time being rely on this certificate. Later on we need to get the test data from the module supplier.

Note that installation of a radio module into a host product may cause reflections or shielding of radio signals. Reflections can increase radiated levels, which can increase e.i.r.p. or field strength levels. Shielding can decrease radiated levels, which can affect the input levels to the radio receiver. Due to this risk, RF emissions were measured at the Wideband Data Transmission Frequency as described in this report.

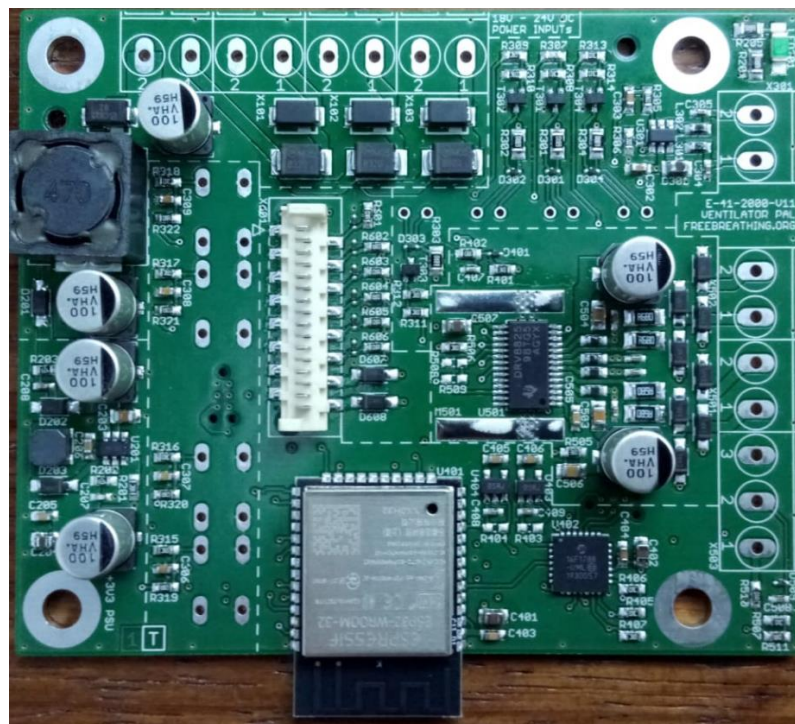
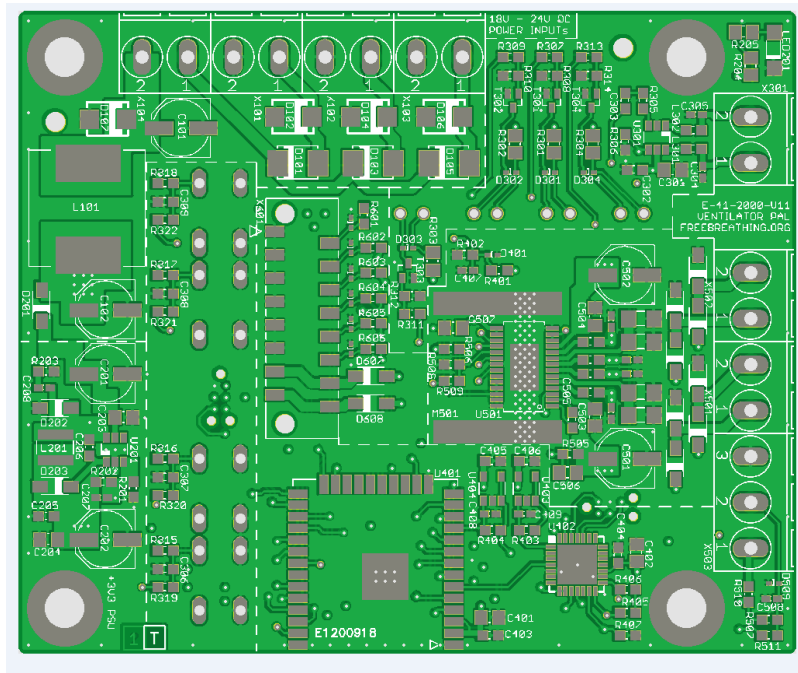
7 Wireless module and antenna implementation:

The implementation of the Wireless module and antenna into the host system was evaluated.

The recommended PCB Land Pattern described in the ESP32-WROOM-32 Datasheet V2.9 was implemented in the PCB layout, therefore ensuring that the radio functions and characteristics comply with the manufacturers specifications.

The antenna is a permanent construction which is fixed (soldered) at the edge of the host board as shown in the photo below.

The RF-power setting of the wireless module is set to 3dBm



8 Conclusions

The EUT complies with the requirements in EN 301 489-1 V2.2.0 based on the EMC evaluation report No. 8042020¹

Note: There are some small differences between the EMC technical requirements in EN 301 489-1 V2.2.0 in comparison with the EN/IEC 60601-1.

- EN 301 489-1 V2.2.0 specifies RF immunity from 10-6GHz (3V/m)
 - EN/IEC 60601-1 requires immunity to telecommunication bands up to 5.8GHz (28V/m)
- EN 301 489-1 V2.2.0 includes 0.5 period >95% voltage dip.
 - The power supply (see chapter 2) has a wide-range input so therefore there is no risk of non-compliance.

EN 300 328 V2.1.1: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard.

EN 301 489-17 V2.2.1; Specific conditions for Broadband Data Transmission Systems

Regarding the above Radio/wireless standards a presumption of conformity is assumed for the implemented wireless module based on the ESP32-WROOM-32 certification as described in chapter 2.

The evaluation and measurements which were performed were necessary to verify that after installation of radio module into the host product that reflections of radio signals do not increase radiated levels due to the host shielding structure, and to ensure that the radio signals are not dampened to much that the wireless function does not work.

Reflections can increase radiated levels, which can increase e.i.r.p. or field strength levels. Shielding can decrease radiated levels, which can affect the input levels to the radio receiver.

Due to this risk, RF emissions were measured at the Wideband Data Transmission Frequency as described in this report.

The measurements demonstrate that the host complies with the Class 1 requirements specified in "Publication in accordance with Article 1(3) of Commission Decision 2000/299/EC (version January 2020 of indicative and non-exhaustive list)"

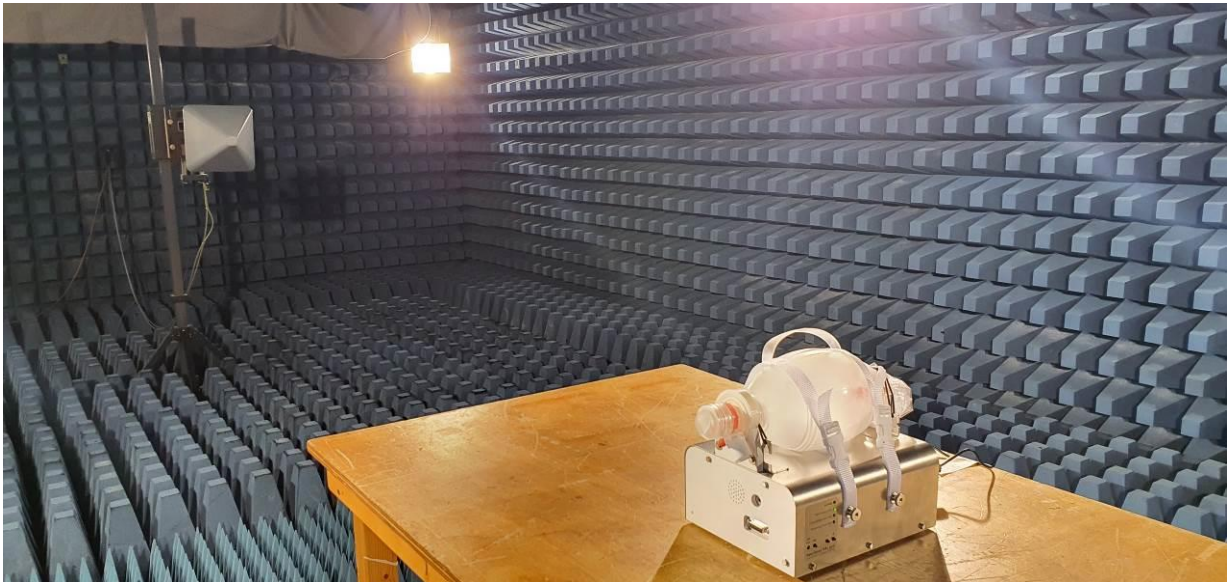
The antenna evaluation (PCB layout) demonstrates that the recommended PCB Land Pattern described in the ESP32-WROOM-32 Datasheet V2.9 was implemented in the PCB layout, therefore ensuring that the radio functions and characteristics comply with the module manufacturers specifications.

The antenna is a permanent construction which is fixed (soldered) at the edge of the host board. Therefore it is highly unlikely that it will be interchanged with another antenna type (i.e. with a higher gain factor).

¹ EN 301 489-1 V2.2.0; Common technical requirements; Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU.

8.1 Radiated emission at the transmission frequency (2400 – 2483.5MHz)

Report title:	EN 60601-1-2
Company Name:	Canon production Printing
Date of test:	07 April 2020
Testers:	R. Brett; W. Ophelders
Standard used:	EN-IEC 60601-1-2:2016
Customer:	Stogger B.V.
Mains supply voltage:	AC/DC adapter (230V)
Ambient Temperature:	22.7°C
Humidity:	44%RH
E. U. T.:	VentilatorPAL



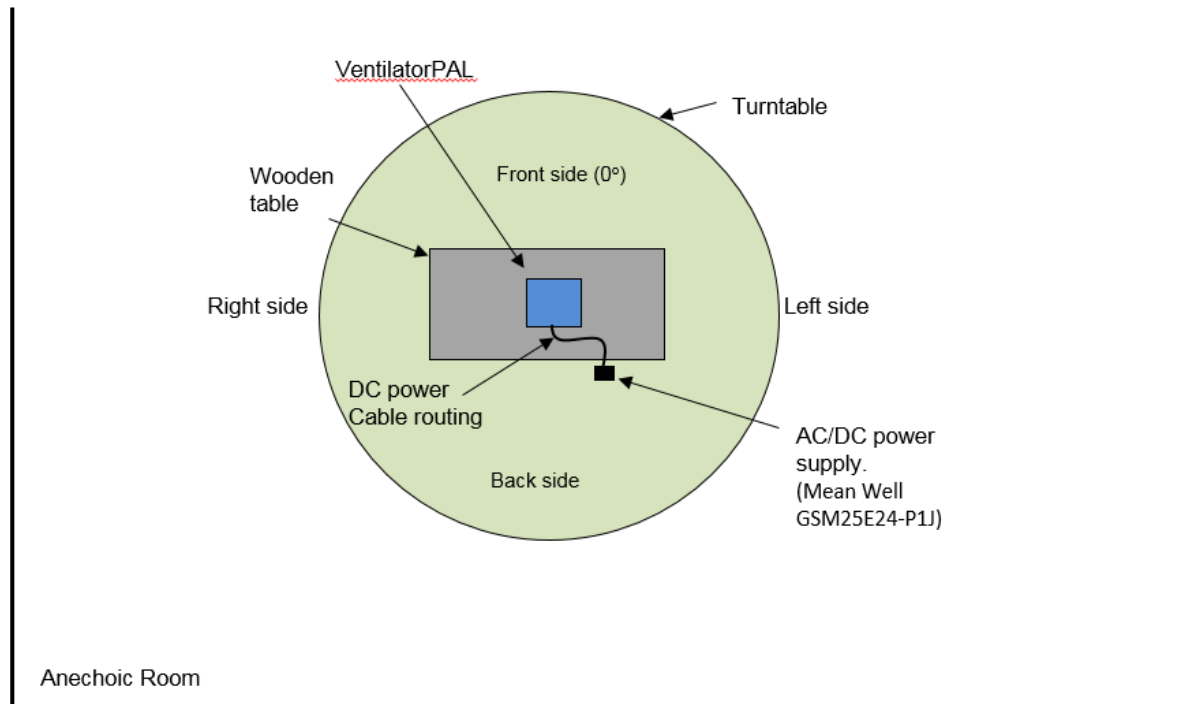
Test Result

Result:	With the wireless module set to a maximum RF power transmission of 9dBm the system will not increase e.i.r.p. or field strength levels a level which is above the Class 1 requirement.
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A.1 Used equipment

Used equipment. For calibration dates see Chapter 6.				
Reg. No.	Equipment	manufacturer	Type	Used in this test
22637	EMI test receiver 1	Rohde & Schwarz	ESIB 7	Y
22879	EMI test receiver 2	Rohde & Schwarz	ESPI 7	
24442	EMI test receiver 4	Rohde & Schwarz	ESU 26	
22540	Spectrum analyser	Rohde & Schwarz	FSP 3	
19949	Biconilog antenna 26MHz-2GHz	EMCO	3141	
22576	Biconilog antenna 26MHz-2GHz	EMCO	3142C	
21528	Biconilog antenna 26MHz-2GHz	Schaffner	CBL 6141A	
17596	Biconical antenna 20MHz – 200MHz	EMCO	3104	
17598	Log-per antenna 200MHz – 2GHz	EMCO	3146	
22759	Log-per antenna 1GHz-20GHz	Schwarzbeck	STLP9148	Y
21566	Full Anechoic Room (lxwxh = 10mx6mx3m)	Rainford	30MHz – 18GHz	Y
22966	OATS	Océ		

A.2 Measurement method



The EUT was placed on a wooden table 0.8, height as shown in the figure. The turntable was rotated so that all 4 sided were measured. The Wideband WiFi levels were investigated by rotating the turntable to the worst-case angle. The angle found to give the highest transmission levels is the right-side of the apparatus.

Equipment information:

Overview of receiver settings	
Attenuator	0 dB
RBW	1 MHz
Step frequency	500 kHz
Measure time	1 ms
Reference level	100 dB μ V
Internal Preamp.	20 dB

A.1 Measurement uncertainty

The uncertainty for radiated emission (enclosure port) 1 - 6GHz is 4.31dB. . This value lies beneath the CISPR requirement of 5.2dB. Report 1010261850_01 describes the complete analysis.

A.2 Applied limits

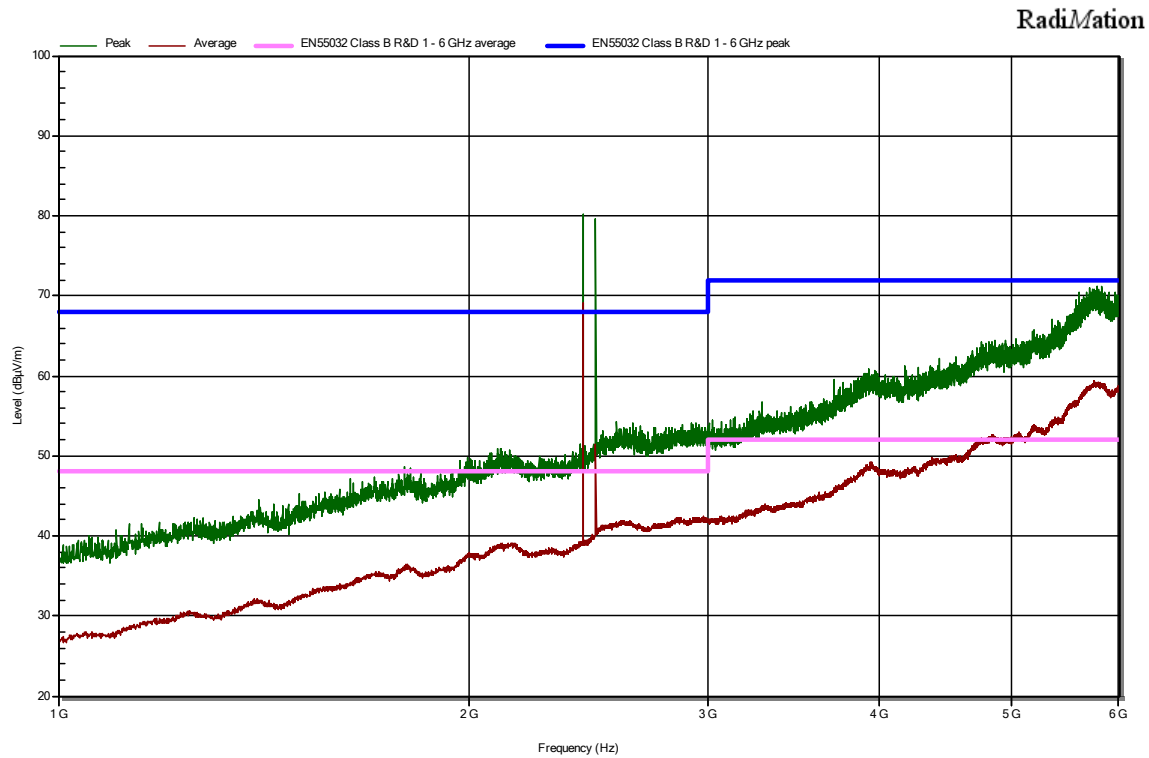
For extra margin the applied limits are 2dB below limits in standard.

A.3 Antenna correction factor and cable loss correction factors

Due to the antenna correction factor, the Anechoic room factor and cable loss correction factor, the EMI noise floor exceeds the average limits near 6GHz using the vertical antenna correction factor.

A.4 Vertical, right 90°

VentilatorPAL Pro: Class B; Vertical antenna, right side.
Operational
Mobile communication in the FAR



Nr	Frequency (MHz)	PK Value (dBµV/m)	AVG Value (dBµV/m)	PK Limit (dBµV/m)	AVG Limit (dBµV/m)	Result	Angle (degrees)	Height (m)	H/V
1	2426	83,129	43,147	68	48	Note	0	1,5	V
2	2480,5	82,486	42,334	68	48	Note	0	1,5	V

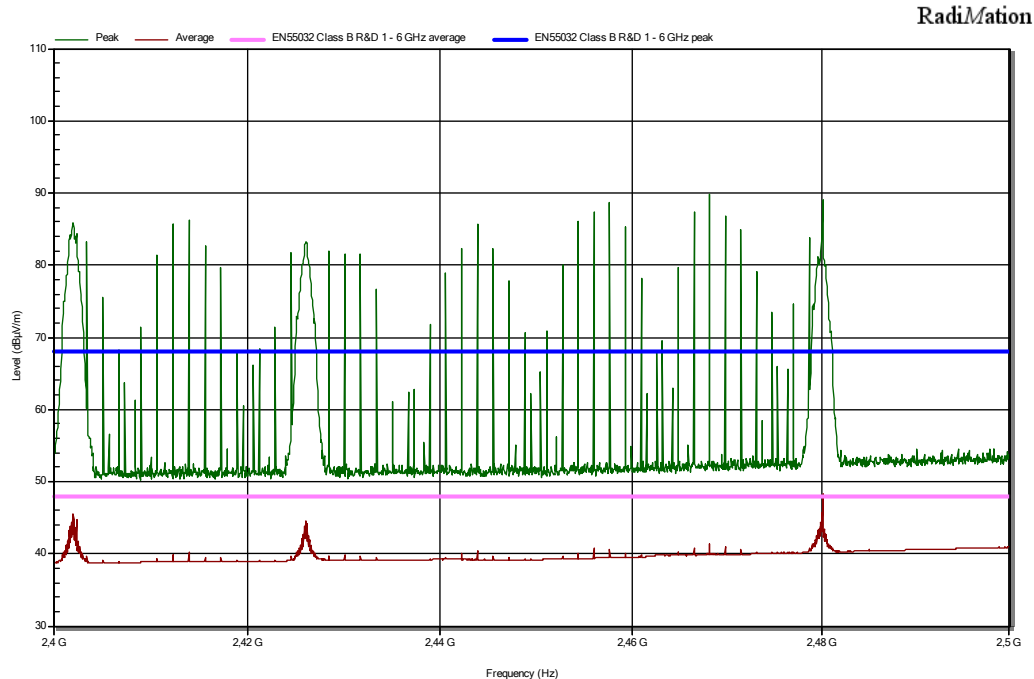
NOTE: This is the WiFi frequency

A.5 Vertical, right 90°

VentilatorPAL Pro: Class B; Vertical antenna, right side.

Operational

Mobile communication in the FAR; Zoom 4 - 5GHz



Nr	Frequency (MHz)	PK Value (dBμV/m)	AVG Value (dBμV/m)	PK Limit (dBμV/m)	AVG Limit (dBμV/m)	Result	Angle (degrees)	Height (m)	H/V
1	2468,2	52,613	39,881	NA	NA	NOTE	0	1,5	V
2	2480,15	84,337	43,64	NA	NA	NOTE	0	1,5	V

NOTE:

The measurements show the RF wideband spectrum of the WiFi module using frequency hopping modulation.

The module has a maximum Bluetooth RF power output of 9dBm.

The parameter setting for the Bluetooth RF power is 3dBm.

Converting from dBm to dBuV:

$$\text{dB}\mu\text{V} = \text{dBm} + 90 + 10\log_{10}(Z) \quad (Z: \text{impedance of air} = 377 \, \Omega)$$

Then 3dBm is equivalent to approx.. 120dBuV (at the source)

This is equivalent to approx. 100dBuV/m at 3m and 89dBuV/m at 10m using the 1/d falloff rule.

The max. measured peak RF field strength at 3m = 84.4 dBuV/m which is approx. 6dB lower than the calculated value (note that the radiated field measurements in the Anechoic Room are relative to a 10m OATS). This attenuation is likely caused by the shielding of the conductive housing of the apparatus. The Frequency band is within the specified frequencies of 2400 – 2483.5MHz.

With the wireless module set to a maximum RF power transmission of 9dBm the system will not increase e.i.r.p. or field strength levels a level which is above the Class 1 requirement.

Therefore the system can be classified as a Class 1 product with the modular transmitter module implemented.

This complies with the “Publication in accordance with Article 1(3) of Commission Decision 2000/299/EC (version January 2020 of indicative and non-exhaustive list)”