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RF Radiation Exposure Evaluation

In accordance with:

CFR47 FCC Part 2, Subpart J, 2.1093

FCC KDB 447498 D01 v06

Adherium (NZ) Limited

NF0108

Hailie for GSK pMDI

FCC ID: PN2-MDI2

REPORT: E2202-1515-6 Rev1

DATE: November, 2022



RF Radiation Exposure Evaluation Report

EMC Bayswater Test Report: E2202-1515-6 Rev1
Issue Date: November, 2022

Product: Hailie for GSK pMDI
Model No: NF0108
Serial No: Beta 05, Beta 16
FCC ID: PN2-MDI2

Client Details: Mr Iqbal Syre
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Standard(s): CFR47 FCC Part 2, Subpart J, 2.1093
Radiofrequency radiation exposure evaluation: portable devices.
FCC KDB 447498 D01 v06
RF EXPOSURE PROCEDURES AND EQUIPMENT AUTHORIZATION POLICIES
FOR MOBILE AND PORTABLE DEVICES

Results Summary: RF Radiation exposure requirements **Complied**

Test Date(s): 7th March 2022

Test House (Issued By) EMC Bayswater Pty Ltd
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FCC Accredited Test Firm Registration number: 527798
FCC Accredited Test Firm Designation number: AU0004

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The Adherium (NZ) Limited, NF0108, Hailie for GSK pMDI, measured EIRP is below the SAR exception threshold (5mm distance) and the calculated power density level at a distance of 20cm are below the maximum levels allowed by regulations therefore complied with the requirements of CFR47 FCC Part 2, Subpart J, 2.1093.

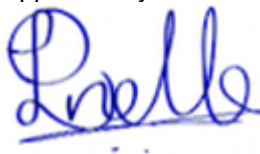
This is to certify that the necessary evaluations were made by EMC Bayswater Pty Ltd, and that the Adherium (NZ) Limited, NF0108, Hailie for GSK pMDI, has been tested in accordance with requirements contained in the appropriate commission regulations.

Prepared by:



Adnan Zaman
(EMC Test Engineer)

Approved by:



Neville Liyanapatabendige
(Manager)

02/11/2022 16:46

Date

**RF Radiation Exposure Evaluation
for
Adherium (NZ) Limited**

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1. Introduction

RF Radiation Exposure evaluation was performed on a Adherium (NZ) Limited, NF0108, Hailie for GSK pMDI in accordance with CFR47 FCC Part 2, Subpart J, 2.1093.

2. Test Report Revision History

ISSUE	DATE	Description	AUTHORISED BY
E2202-1515-6	2022-09-29	Original	Neville Liyanapatabendige (Manager)
E2202-1515-6 Rev1	2022-11-02	<ul style="list-style-type: none">Updated the customer's addressCorrected the antenna gain as per customer request. RF exposure analysis was updated accordingly.	Neville Liyanapatabendige (Manager)

3. Report Information

EMC Bayswater Pty Ltd reports apply only to the specific samples tested under the stated test conditions. All samples tested were in good operating condition throughout the entire test program unless otherwise stated. EMC Bayswater Pty Ltd does not in any way guarantees the later performance of the product/equipment. It is the manufacturer's responsibility to ensure that additional production units of the tested model are manufactured with identical electrical and mechanical components. EMC Bayswater Pty Ltd shall have no liability for any deductions, inference or generalisations drawn by the clients or others from EMC Bayswater Pty Ltd issued reports. This report shall not be used to claim, constitute or imply product endorsement by EMC Bayswater Pty Ltd. This report shall not be reproduced except in full, without the written approval of EMC Bayswater Pty Ltd. This document may be altered or revised by EMC Bayswater Pty Ltd personnel only, and shall be noted in the revision section of the document. Any alteration of this document not carried out by EMC Bayswater Pty Ltd will nullify the document.

4. Product Details

4.1. Product Sample Details

The device, as supplied by the client, is described as follows:

Product:	Hailie for GSK pMDI	
Model No:	NF0108	
Variant:	None	
Serial No:	Beta 05, Beta 16	
Firmware Version:	Emission: GSK_PMDI_EMCC_V8.7.dev_B60361.hex	
Software Version:	SoftDevice S112 v6.1.1	
Power Specifications:	Battery Powered 1 x CR2032 coin cell and 1 x CR1620 3.0V coin cell	
Dimensions	37mm x 40mm x 83 mm (Length x Width x Height)	
Weight:	37g	
Transmitter:	Description:	Bluetooth Low Energy
	Part Number:	NRF52832-QFAA-R7
	Frequency of Operation:	2402 MHz to 2480 MHz
	Max Transmit Power:	0 dBm
	Modulation Scheme:	GFSK
	Channels:	40 channels with 2 MHz spacing (3 advertising channels/37 data channels).
	Antenna Details:	Custom PCB trace antenna on flex tail
	Peak Antenna Gain:	+2.7 dBi

(Customer supplied product information)

4.2. Product description

The device has been described by the customer as follows:

“The Hathaway product has two variants – Hathaway Short (NF0107) and Hathaway Tall (NF0108). The device is a small hand-held battery-powered electronic module which an inhaler is inserted into.

The product variations are to be used with a short and tall inhaler respectively. It reminds the user when medication is due and logs when medication is taken.

It is powered by two-coin cell batteries and can transfer log data via Bluetooth Low Energy (BLE) for later analysis by a health professional.”

(Customer supplied product description information)

5. SAR and RF Exposure exception evaluation

5.1. SAR exception evaluation

As per Appendix A of KDB 447498 D01 General RF Exposure Guidance v06

SAR Test Exclusion Thresholds for 100 MHz – 6 GHz and ≤ 50 mm

Approximate SAR Test Exclusion Power Thresholds at Selected Frequencies and Test Separation Distances are illustrated in the following Table. The equation and threshold in 4.3.1 must be applied to determine SAR test exclusion.

MHz	5	10	15	20	25	mm
150	39	77	116	155	194	<i>SAR Test Exclusion Threshold (mW)</i>
300	27	55	82	110	137	
450	22	45	67	89	112	
835	16	33	49	66	82	
900	16	32	47	63	79	
1500	12	24	37	49	61	
1900	11	22	33	44	54	
2450	10	19	29	38	48	
3600	8	16	24	32	40	
5200	7	13	20	26	33	
5400	6	13	19	26	32	
5800	6	12	19	25	31	

SAR test exclusion threshold for 2402MHz transmitter is 10.16mW for 5mm distance.

- The measured maximum peak conducted power is 0.089mW (-10.5dBm)*
(*The measurement uncertainty was calculated at ± 1.4 dB. The reported uncertainty is an expanded uncertainty calculated using a coverage factor of approximately $k=2$ which gives a level of confidence of approximately 95%)
- Customer declared antenna gain is +2.7dBi
- Therefore the maximum EIRP is 0.165mW (Worst-case, Without Duty Cycle correction factor).

The measured EIRP is below the SAR exception threshold.

Note: The customer declared nominal transmit power is 0dBm (1mw), assumed worst-case output power variation is 0.4dBm therefore nominal power with tune up tolerance is 0.4dBm (1.10mW) and antenna gain is +2.7dBi. The nominal maximum EIRP will be 3.1dBm (2.04mW) which is below the SAR exception threshold.

5.2. RF Exposure Evaluation (MPE)

As per section 1.1310 of CFR 47 following Maximum Permissible Exposure (MPE) limits are applicable.

Frequency range (MHz)	Electric field strength (V/m)	Magnetic field strength (A/m)	Power density (mW/cm ²)	Averaging time (minutes)
(A) Limits for Occupational/Controlled Exposure				
0.3-3.0	614	1.63	*100	6
3.0-30	1842/f	4.89/f	*900/f ²	6
30-300	61.4	0.163	1.0	6
300-1,500			f/300	6
1,500-100,000			5	6
(B) Limits for General Population/Uncontrolled Exposure				
0.3-1.34	614	1.63	*100	30
1.34-30	824/f	2.19/f	*180/f ²	30
30-300	27.5	0.073	0.2	30
300-1,500			f/1500	30
1,500-100,000			1.0	30

f = frequency in MHz * = Plane-wave equivalent power density

Limits for Maximum Permissible Exposure (MPE) to radiofrequency electromagnetic fields for 2402 to 2480MHz as per Table 1 of Section 15.1310 is 1 mW/cm² (General Population/Un-controlled).

Prediction Worst case:

Using equation

$$S = PG / 4\pi R^2$$

where: S = Power density

P = Power input to the antenna

G = Antenna gain

R = Distance to the center of radiation of the antenna

Band	Maximum Conducted Power @ Antenna (dBm)*	Antenna Gain (dBi)	Maximum EIRP (dBm)	Maximum EIRP (mW)	Distance (cm)	Calculated Power Density at 20cm (mW/cm ²)	Power Density Limit** (mW/cm ²)
2.4GHz BLE	-10.5	+2.7	-7.8	0.165	20	0.000033	1

*Worst-case, Without Duty Cycle correction factor

** MPE limit for General Population/Un-controlled exposure

Table 1: Results for MPE Evaluation

6. Conclusion

The measured EIRP is below the SAR exception threshold (5mm distance) and the calculated power density level at a distance of 20cm are below the maximum levels allowed by regulations.