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RF Radiation Exposure Evaluation

In accordance with:

FCC KDB 447498 D01 v06

SomnoMed Limited

Elite

Rest Assure Appliance

FCC ID: 2BBTC-1154412

REPORT: E2305-1655-2 Rev1

DATE: September, 2023

*This report replaces the previously issued report E2305-1655-2
Please refer to section 2 of this report for details of any previously issued reports*



RF Radiation Exposure Evaluation Report

EMC Bayswater Test Report: E2305-1655-2 Rev1
Issue Date: September, 2023

Product: Rest Assure Appliance
Model No: Elite
Serial No: RA-CCM62LN, RA-CCM62M6 & RA-CCM3ZNT
FCC ID: 2BBTC-1154412

Customer Details: Mr. Mark Smyth
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Standard(s): FCC KDB 447498 D01 v06
RF EXPOSURE PROCEDURES AND EQUIPMENT AUTHORIZATION POLICIES
FOR MOBILE AND PORTABLE DEVICES
CFR47 FCC Part 2, Subpart J, 2.1091
Radiofrequency radiation exposure evaluation: mobile devices.
CFR47 FCC Part 2, Subpart J, 2.1093
Radiofrequency radiation exposure evaluation: portable devices.

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

Test Date(s): 15th of May, 2023

Test House (Issued By): EMC Bayswater Pty Ltd
18/88 Merrindale Drive
Croydon South
Victoria, 3136
Australia

FCC Accredited Test Firm Registration number: 527798
FCC Accredited Test Firm Designation number: AU0004

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The SomnoMed Limited, Elite, Rest Assure Appliance, 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, 2.1091.

This is to certify that the necessary evaluations were made by EMC Bayswater Pty Ltd, and that the SomnoMed Limited, Elite, Rest Assure Appliance, has been tested in accordance with requirements contained in the appropriate commission regulations.

Prepared by:

Approved by:



27/09/2023 14:55

Adnan Zaman
(EMC Test Engineer)

Neville Liyanapatabendige
(Manager)

Date

RF Radiation Exposure Evaluation *for* SomnoMed Limited

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1. Introduction

RF Radiation Exposure evaluation was performed on a SomnoMed Limited, Elite, Rest Assure Appliance in accordance with FCC KDB 447498 D01 v06.

2. Test Report Revision History

ISSUE	DATE	SECTIONS AFFECTED	AUTHORISED BY
E2305-1655-2	30/06/23	Original	Neville Liyanapatabendige (Manager)
E2305-1655-2 Rev1	27/09/23	Removed photo from page 6, Figure 1: Customer supplied photo of Rest Assure Appliance (EUT) and Charging Dock (for Illustration Purposes Only)	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:	Rest Assure Appliance	
Model No:	Elite	
Part No:	SPC-0804-D	
Serial No:	RA-CCM62LN, RA-CCM62M6 & RA-CCM3ZNT	
Firmware:	472_1335_01	
Power Specifications:	Varta CP9440 A4 lithium battery	
Dimensions:	Customized to patient	
Weight:	Customized to patient	
EUT Type:	Tested as table-top	
Transmitter:	Description:	Bluetooth Low Energy (BLE)
	Type:	Transceiver
	Part Number:	STM32WB55VGY6
	Manufacturer:	ST Microelectronics
	Max Transmit Power:	+6 dBm (max possible by the radio chipset)
	Modulation Scheme:	GFSK
	Frequency of Operation:	2402 MHz to 2480 MHz
	Antenna Details:	Integrated Antenna (SMD ceramic chip antenna), P/N 2450AT07A0100T (Johanson Technology)
	Peak Antenna Gain:	1.0dBi

(Customer supplied product information)

4.2. Product description

The device has been described by the customer as follows:

“The Rest Assure product is a Medical Electrical System based around an Oral Appliance used in the treatment of mild to moderate Obstructive Sleep Apnea, in a Home Healthcare Environment. The treatment (clinical benefit) is achieved by mechanically preventing the lower jaw from rearwards movement.

The system has the capability to monitor parameters associated with Obstructive Sleep Apnea, as determined from raw data collected by sensors embedded within the Appliance electronics. However, the aspects relating to the monitoring capabilities of the Rest Assure system are unrelated to the clinical benefit of the Oral Appliance.”

The system comprises the following main hardware components:

- An Appliance (This is the Equipment Under Test as it contains the transmitter)
- A Charging Dock (It is an auxiliary equipment for the transmitter testing)

(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	SAR Test Exclusion Threshold (mW)
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 10.08mW for 5mm distance.

SAR test exclusion threshold for 2480MHz transmitter is 9.94mW for 5mm distance.

- The measured maximum EIRP is 1.8mW (Worst-case, Without Duty Cycle correction factor).

The measurement uncertainty was calculated at ± 4.83 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%.

The measured EIRP is below the SAR exception threshold for 5mm distance.

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 EIRP (dBm)	Maximum EIRP (mW)	Distance (cm)	Calculated Power Density at 20cm (mW/cm ²)	Power Density Limit** (mW/cm ²)
2.4GHz BLE	+2.5	1.8	20	0.000354	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.