RF-EXPOSURE REPORT

FCC 47 CFR Part 2.1093

RF-Exposure evaluation of portable equipment

Report Reference No	G0M-2311-2313-TFC093PE-V02
Testing Laboratory	Eurofins Product Service GmbH
Address	Storkower Str. 38c 15526 Reichenwalde Germany
Accreditation	A2LA Accredited Testing Laboratory, Certificate No.: 1983.01 FCC Test Firm Designation Number: DE0008
Applicant	Phillips-Medisize A/S
Address	Gimsinglundvej 20 7600 Struer DENMARK
Test Specification	According to FCC rules
Standard	FCC 47 CFR 2.1093
Non-Standard Test Method	None
Equipment under Test (EUT):	
Product Description	IDA0097 Auto-lnjector
Model(s)	IDA0097 Auto-lnjector, Model 02
Additional Model(s)	None
Brand Name(s)	None
Hardware Version(s)	2089879486
Software Version(s)	11.04.00
FCC ID	2AAGY-SKYT2
Test Result	**PASSED**

Possible test case verdicts:		
required by standard but not tested	N/T	
not required by standard	N/R	
test object does meet the requirement	P(PASS)	
test object does not meet the requirement	F(FAIL)	
Testing:		
Test Lab Temperature	20 °C - 30 °C	
Test Lab Humidity	25 % - 55 %	
Date of performance	2024-08-30	
Date of receipt of test item	See test sample identification table on page 6	
Report:		
Compiled by	Stephan Liebich	
Tested by (+ signature) (Responsible for Test)	Stephan Liebich	 .....
Approved by (+ signature) (Test Lab Engineer)	Radwan Jaafar	 .....
Date of Issue	2024-09-05	
Total number of pages	17	
General Remarks:		
The test results presented in this report relate only to the object tested. **The results contained in this report reflect the results for this particular model and serial number. It is the responsibility of the manufacturer to ensure that all production models meet the intent of the requirements detailed within this report.** This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.		
Additional Comments:		
None		

VERSION HISTORY

Version History			
Version	Issue Date	Remarks	Revised By
01	2024-08-13	Initial Release	--
02	2024-08-30	Replaced document: G0M-2311-2313-TFC093PE-V01 Replaced by: G0M-2311-2313-TFC093PE-V02 Changes: • Add of LE 1M PHY and LE 2M PHY • Re-calculation Page 8: • Add of SAR test exclusion power threshold acc. to FCC KDB 447498 D01 Page 15: • Add of Duty Cycle Plots	St. Liebich

ABBREVIATIONS AND ACRONYMS

Acronyms	
Acronym	Description
EIRP	Equivalent Isotropic Radiated Power
ERP	Effective Radiated Power
EUT	Equipment Under Test
LPE	Low Power Exclusion

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1 Equipment (Test Item) Under Test

Description	IDA0097 Auto-Injector			
Model	IDA0097 Auto-Injector, Model 02			
Additional Model(s)	None			
Brand Name(s)	None			
Sample Identification	EUT #	Sample-ID	Serial Number	Date of receipt
	EUT 1	48528	24030040002450	2024-05-15
Hardware Version(s)	2089879486			
Software Version(s)	11.04.00			
FCC ID	2AAGY-SKYT2			
Equipment type	End Product			
Environment	General public			
Use case	Extremities			

1.1 Reference Documents

Document Type	Document No.	Issued by	Date
RADIO REPORT	G0M-2311-2313-TFC247BL-V02	Eurofins Product Service GmbH	2024-09-05

1.2 Standalone radiation sources

Standalone radiation sources					
Mode	**Operating Frequency [MHz]**	**Maximum conducted power [dBm]**	**Maximum radiated power [dBm EIRP]**	**Maximum duty cycle [%]**	**Antenna distance to body [mm]**
Bluetooth LE 1 Mbps	2402	6.717	2.869	88.7	5.0
Bluetooth LE 2 Mbps	2402	6.662	2.814	82.0	5.0
Comment: SAR test exclusion power threshold acc. to FCC KDB 447498 D01 is max. 1.6 ≤ 3.0 1g SAR					

1.3 Concurrent Sources

No concurrent radiation sources

2 Result Summary

Standalone sources - FCC KDB 447498				
Product Standard Reference	**Requirement**	**Reference Method**	**Mode**	**Verdict**
KDB 447498	SAR Test Exclusion	KDB 447498 4.3.1	Bluetooth LE 1 Mbps	PASS
KDB 447498	SAR Test Exclusion	KDB 447498 4.3.1	Bluetooth LE 2 Mbps	PASS
Comment: --				

3 RF-Exposure classification

RF-Exposure Categories	
Fixed	A fixed device is defined as a device physically secured at one fixed location and cannot be easily re-located.
Mobile	A mobile device is defined as a transmitting device designed to be used in other than fixed locations and to generally be used in such a way that a separation distance of at least 20 centimeters is normally maintained between the transmitter's radiating structure(s) and the body of the user or nearby persons.
Portable	A portable device is defined as a transmitting device designed to be used so that the radiating structure(s) of the device is/are within 20 centimeters of the body of the user.

RF-Exposure Categories	
Occupational / Controlled	Limits apply in situations in which persons are exposed as a consequence of their employment provided those persons are fully aware of the potential for exposure and can exercise control over their exposure. Limits for occupational/controlled exposure also apply in situations when an individual is transient through a location where occupational/controlled limits apply provided he or she is made aware of the potential for exposure.
General population / Uncontrolled	Exposures apply in situations in which the general public may be exposed, or in which persons that are exposed as a consequence of their employment may not be fully aware of the potential for exposure or cannot exercise control over their exposure.

4 RF-Exposure limits and exclusion thresholds

4.1 SAR limits

SAR Limits		
Type	**Occupational SAR values [W / kg]**	**General population SAR values [W / kg]**
Whole-body SAR averaging mass = entire body	0.4	0.08
Partial-body Localized Head, Neck and Trunk SAR averaging mass = 1g	8.0	1.6
Hands, Wrists, Feet and Ankles Localized Limbs SAR averaging mass = 10g	20.0	4

4.2 SAR standalone test exclusion threshold

SAR test exclusion power acc. to FCC KDB 447498 D01 – Standalone operation

Unless specifically required by the published RF exposure KDB procedures, standalone 1-g head or body and 10-g extremity SAR evaluation for general population exposure conditions, by measurement or numerical simulation, is not required when the corresponding SAR Exclusion Threshold condition, listed below, is satisfied. These test exclusion conditions are based on source-based time-averaged maximum conducted output power of the RF channel requiring evaluation, adjusted for tune-up tolerance, and the minimum test separation distance required for the exposure conditions.

The minimum test separation distance is determined by the smallest distance from the antenna and radiating structures or outer surface of the device, according to the host form factor, exposure conditions and platform requirements, to any part of the body or extremity of a user or bystander

The 1-g and 10-g SAR test exclusion thresholds for 100 MHz to 6 GHz at test separation distances ≤ 50 mm are determined by:

a) For 100 MHz to 6 GHz and test separation distances ≤ 50 mm

$$\frac{max.\ power\ of\ channel\ [mW]}{min.\ test\ separation\ distance\ [mm]} \cdot \sqrt{f[GHz]} \leq \begin{cases} 3.0 & 1g\ SAR \\ 7.5 & 10g\ SAR \end{cases}$$

b) For 100 MHz to 6 GHz and test separation distances > 50 mm

1) For 100 to 1500 MHz

$$\left\{Power\ allowed\ at\ numeric\ threshold\ for\ 50\ mm\ in\ step\ a + (\text{test separation distance} - 50\text{mm}) \cdot \frac{f(MHz)}{150}\right\}, mW$$

2) for > 1500 MHz and ≤ 6 GHz

$$\{Power\ allowed\ at\ numeric\ threshold\ for\ 50\ mm\ in\ step\ a + (\text{test separation distance} - 50\text{mm}) \cdot 10\}, mW$$

c) for frequencies below 100 MHz:

1) test separation distances > 50 mm and < 200 mm:

the power threshold at the corresponding test separation distance at 100 MHz in step b) is multiplied by

$$\left(1 + \log\left(\frac{100}{f(MHz)}\right)\right)$$

2) test separation distances ≤ 50 mm:

the power threshold determined by the equation in c) 1) for 50 mm and 100 MHz is multiplied by ½

4.3 SAR concurrent test exclusion threshold

SAR test exclusion acc. to ISED RSS-102 + FCC KDB 447498 D01 – Concurrent operation
When the sum of 1-g or 10-g SAR of all simultaneously transmitting antennas in an operating mode and exposure condition combination is within the SAR limit, SAR test exclusion applies to that simultaneous transmission configuration. For the test exclusion to apply, the maximum output power, duty factor, and other applicable parameters used in the standalone SAR tests, must be the same or more conservative than those required for simultaneous transmission. When an antenna qualifies for the standalone SAR test exclusion of 4.3.1 and also transmits simultaneously with other antennas, the standalone SAR value must be estimated according to the following to determine the simultaneous transmission SAR test exclusion criteria: 1) $\frac{\text{max.power of channel,including tune-up tolerance,mW}}{\text{min.test separation distance,mm}} \cdot \frac{\sqrt{f(GHz)}}{x}$, for test separation distances ≤ 50 mm where x = 7.5 for 1-g SAR and x = 18.75 for 10-g SAR 2) 0.4 W/kg for 1-g SAR and 1.0 W/kg for 10-g SAR, when the test separation distance is > 50 mm

5 RF-Exposure Evaluation

Evaluation procedure acc. to FCC KDB 447498
Standalone operational modes 1) For each standalone operational mode the associated frequencies, radiated output power values, duty cycles and antenna separation distances to the human body are specified 2) From the radiated power and the duty cycle the source-based time averaged radiated output power is calculated 3) The transmission frequency, average power and separation distance is used to determine the SAR test exclusion power threshold value acc. to FCC KDB 447498 D01 4) If the time averaged output power of the transmission mode is lower than the SAR test exclusion power threshold value, the mode clarifies for SAR test exclusion and no further SAR evaluation is needed Concurrent operational modes 1) For each operational mode that participates in the concurrent operational mode, the estimated SAR is calculated from the source-based time average conducted output power and the separation distance to the human body for each transmission frequency of the operation mode 2) The maximum estimated SAR value for each operational is determined 3) The sum of SAR values of the maximum estimated SAR values for each operational mode is calculated 4) If the sum of SAR values is below the corresponding SAR limit, the concurrent operational mode clarifies for SAR test exclusion and no further evaluation is needed

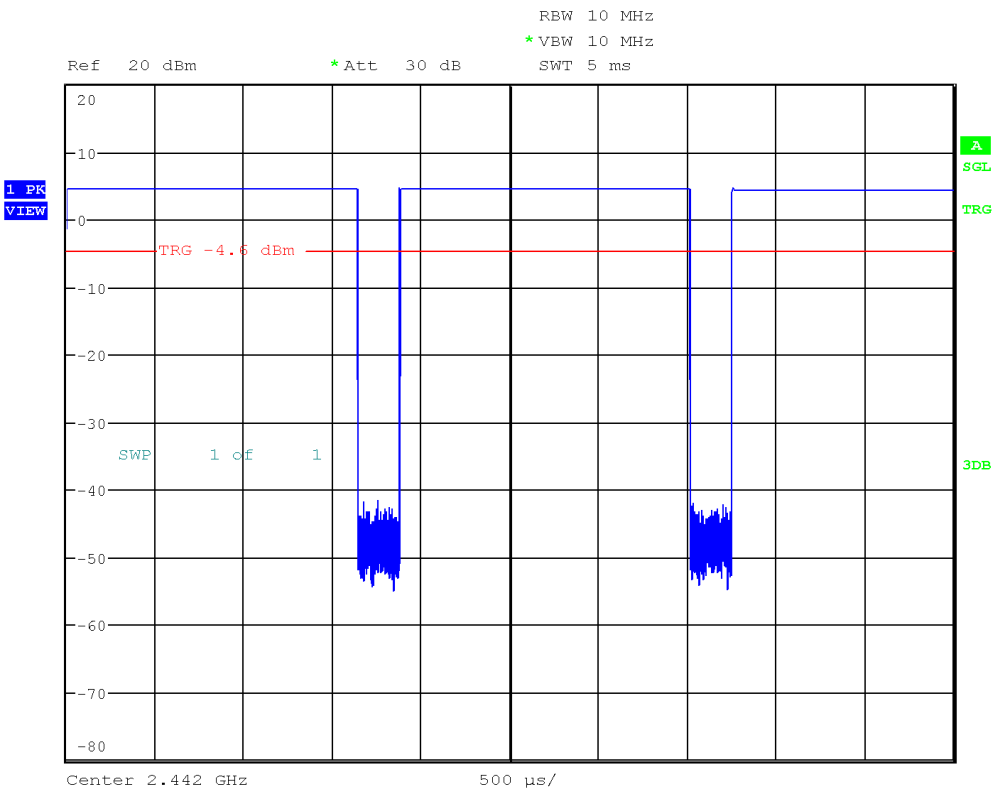
6 Single Source Evaluation Results - FCC

Results – Standalone Operational Modes							
Mode	Frequency [MHz]	Power [mW]	Duty Cycle	Average Power [mW]	Distance [mm]	Power Limit [mW]	Verdict
Bluetooth LE 1 Mbps	2402	4.70	0.89	4.17	5.0	10	PASS
Bluetooth LE 2 Mbps	2402	4.64	0.82	3.80	5.0	10	PASS
Comment: --							

ANNEX A Duty Cycle Plots

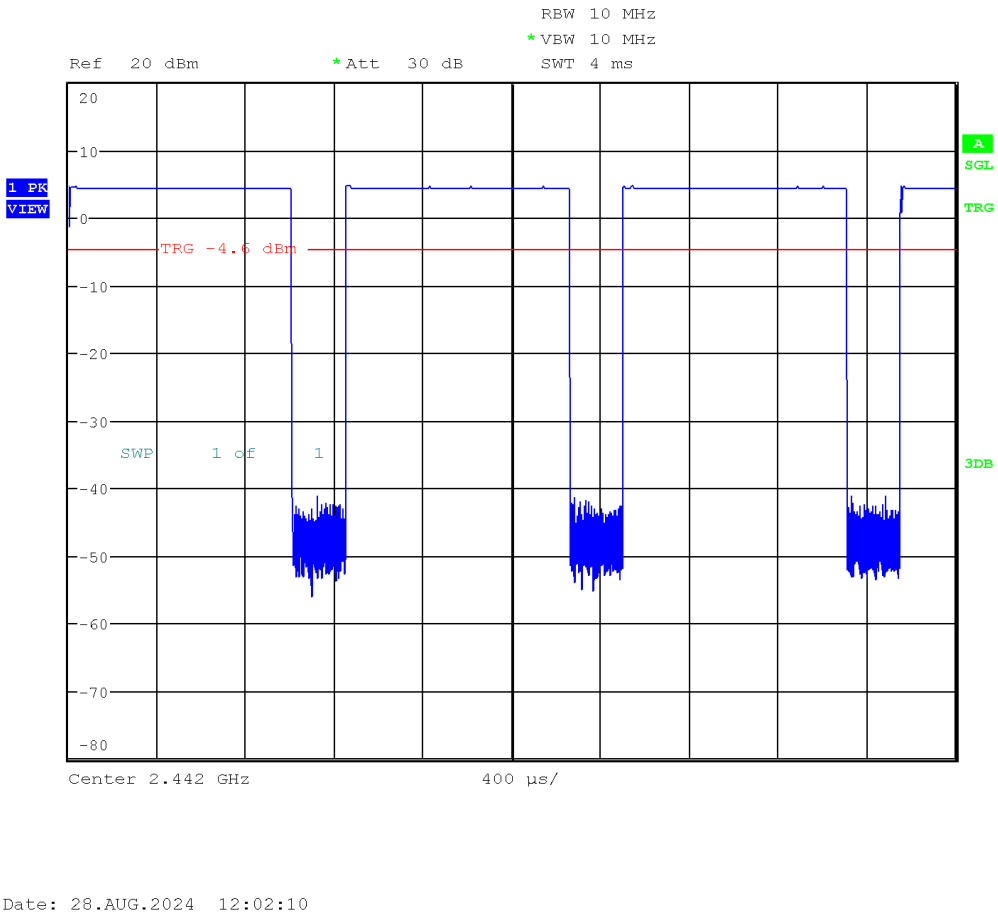
Duty Cycle

Project Number:	G0M-2311-2313
Applicant:	Phillips-Medisize A/S
Model Description:	Auto-Injector
Model:	IDA0097
Test Sample ID:	48528
Reference Standards:	ANSI C63.10:2013
Reference Method:	ANSI C63.10:2013, Section 7.5
Operating Frequency:	2442 MHz
Operating Conditions:	Tnom/Vnom
Operator:	Burkhard Pudell
Test Site:	Eurofins Product Service GmbH
Test Date:	2024-08-28
Duty Cycle Period [ms]:	4
Maximum Duty Cycle:	0.88
Maximum Duty Cycle [%]:	88
Duty Cycle Correction [dB]:	-1.11



Duty Cycle

Project Number:	G0M-2311-2313
Applicant:	Phillips-Medisize A/S
Model Description:	IDA0097 Auto-Injector
Model:	IDA0097 Auto-Injector, MODEL 02
Test Sample ID:	48528
Reference Standards:	ANSI C63.10:2013
Reference Method:	ANSI C63.10:2013, Section 7.5
Operating Frequency:	2442 MHz
Operating Conditions:	Tnom/Vnom
Operator:	Burkhard Pudell
Test Site:	Eurofins Product Service GmbH
Test Date:	2024-08-28
Duty Cycle Period [ms]:	4
Maximum Duty Cycle:	0.82
Maximum Duty Cycle [%]:	82
Duty Cycle Correction [dB]:	-1.72



=== End of test report ===