

Test report No:
NIE: 75285RAN.002

Assessment report

RF EXPOSURE REPORT ACCORDING TO

FCC 47 CFR Part 2.1093
FCC 47 CFR Part 1.1307

(*) Identification of item under evaluation	Photometric reader for lateral flow test
(*) Trademark	QASSAY
(*) Model and /or type reference	Q1A-DUO-USB (Qassay Lateral Flow Reader Dual)
(*) Other variants/model not evaluated	Qassay Lateral Flow Reader Visible
(*) Other identification of the product	FCC ID : 2BD3B 13EA2BD3B IC ID : 31782-13EA2BD3B HW version : Ver 0x201 SW Version : Ver 3
(*) Features	Bluetooth LE
(*) Manufacturer	P4Q Health S.L.U. Calle Nuestra Señora de la Guía, Número 19, Arbuio 48810 ALONSOTEGI, Bizkaia - España
Test method requested, standard	FCC 47 CFR Part 2.1093. Radiofrequency radiation exposure evaluation: portable devices. FCC 47 CFR Part 1.1307: Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.
Summary	IN COMPLIANCE
Approved by (name / position & signature)	Miguel Lacave Antennas Lab Manager
Date of issue	2024-03-13
Report template No	FAN24_02 <small>(*) "Data provided by the client"</small>

Index

Competences and guarantees	3
General conditions	3
Data provided by the client.....	3
Identification of the client.....	5
Document history	5
Appendix A: FCC RF Exposure assessment result	6
General description of the device under evaluation.....	7
Evaluation Results	8
Appendix B: FCC RF Exposure information	9
RF Exposure determination of exemption	10

Competences and guarantees

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 Assessment Report apply only to the particular item under test established in this document.

IMPORTANT: No parts of this report may be reproduced or quoted out of context, in any form or by any means, except in full, without the previous written permission of DEKRA Testing and Certification, S.A.U.

General conditions

1. This report is only referred to the item that has undergone the assessment.
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

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 under evaluation", "Trademark", "Model and/or type reference", "Other variants/model not evaluated", "General description of the device", "Other identification of the product").
2. Maximum output power, maximum antenna gain, use distance and duty cycle information,
3. The device under evaluation consists of a photometric reader for lateral flow test for visible and UV strips with the purpose of qualification, semi-quantification and quantification of specific analyses.
4. Other variants/models not evaluated: Qassay Lateral Flow Reader Visible. On the following page, the models have been declared by the supplier as equivalent.



Dear Ladies and Gentlemen,

I, Aitor Alapont, CEO of P4Q Health, S.L.U. hereby declare through this letter the product design similarities for the Qassay Lateral Flow Reader DUAL and VISIBLE models. Qassay Lateral Flow Reader DUAL and VISIBLE models are photometric lateral flow test analyzers.

Radio and EMC test results from the worst-case configuration (DUAL) are applicable to all models indicated below.

According to the strip type, must be required to excite it with White or UV light. Qassay Lateral Flow Reader DUAL model can illuminate the strip using White or UV light and the VISIBLE model can illuminate the strip only using the White light.

The schematics for both models are the same, the only difference is that the DUAL model mounts both LEDs, D300 (UV) and D301 (White), plus two transistors (Q300 and Q301) to activate one or another, and the VISIBLE model just mounts the D301 (White).

Due to this minimal difference on the schematics, Radio and EMC test results are applicable to both models.

Yours sincerely,

Aitor Alapont (CEO)

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.

Identification of the client

P4Q Health S.L.U.
Calle Nuestra Señora de la Guía, Número 19, Arbuio
48810 ALONSOTEGI, Bizkaia - España

Document history

Report number	Date	Description
75285RAN.002	2024-03-13	First release

Appendix A: FCC RF Exposure assessment result

General description of the device under evaluation

Table 1 shows information used for the RF Evaluation, taking into account the following declared specifications for the device:

Description and technologies: the device under evaluation consists of a photometric reader for lateral flow test for visible and UV strips with the purpose of qualification, semi-quantification and quantification of specific analyses with the following features: Bluetooth LE. For RF Exposure evaluation, only transmission technologies: Bluetooth LE are taken into account.

Evaluation Distance: according to the manufacturer, during its normal use, the separation distance between the radiating structures of the device and nearby users will be greater than 0 cm. In order to perform the assessment a conservative evaluation distance of 0 cm has been used.

Maximum output power:

Values corresponding to Maximum conducted output power have been measured and stated into DEKRA Testing and Certification, S.A.U. test report num. 75285RRF.002.

Antennas: the device supports one antenna for the Bluetooth LE transmitting technology:

- “Type F PCB antenna” antenna for Bluetooth transmissions.

The duty cycle has been declared by the client in a declaration of conformity.

Maximum peak antenna gain values have been declared by the device manufacturer (maximum peak gain stated in antenna manufacturer's datasheet)

The following table shows the information provided above:

Technology / Mode	Operating Band	Frequency under evaluation (MHz)	Maximum Conducted Output Power (dBm)	Duty Cycle (%)	Time Averaged Conducted Power (dBm)	Antenna peak gain (dBi)	Maximum Averaged E.R.P (dBm)	Maximum Averaged E.R.P (mW)	Maximum Averaged E.I.R.P (dBm)	Maximum Averaged E.I.R.P (mW)
Bluetooth LE 1Mb	2.4 GHz	2402 - 2480	3.10	10.00	-6.90	3.80	-5.25	0.30	-3.10	0.49
Bluetooth LE 2Mb	2.4 GHz	2402 - 2480	3.27	10.00	-6.73	3.80	-5.08	0.31	-2.93	0.51

Table 1: Equipment specifications

Evaluation Results

Determination of Exemption according to FCC 47 CFR Part 1.1307:

The evaluation according to the minimum intended use distance of 5 mm will be as follow:

Technology / Mode	Operating Band	Frequency under evaluation (MHz)	Distance (cm)	Time Averaged Conducted Power (mW)	§1.1307(b)(3).i.(A) Exposure Limit (mW)	Verdict
BTLE 1Mb	2.4 GHz	2402 - 2480	0.50	0.20	1.00	Pass
BTLE 2Mb	2.4 GHz	2402 - 2480	0.50	0.21	1.00	Pass

Table 2: FCC Exemption Evaluation Result

The computed value(s) are below the exemption limit(s), so these modes meet the requirements stated in FCC 47 CFR Part 1.1307.

Appendix B: FCC RF Exposure information

RF Exposure determination of exemption

According to FCC 47 CFR §1.1307 (b)(3) Determination of exemption:

(i) For single RF sources (i.e., any single fixed RF source, mobile device, or portable device, as defined in paragraph (b)(2), a single RF source is exempt if:

(A) The available maximum time-averaged power is no more than 1 mW, regardless of separation distance. This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(ii)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(ii)(A);

(B) Or the available maximum time-averaged power or effective radiated power (ERP), whichever is greater, is less than or equal to the threshold P_{th} (mW) described in the following formula. This method shall only be used at separation distances (cm) from 0.5 centimeters to 40 centimeters and at frequencies from 0.3 GHz to 6 GHz (inclusive). P_{th} is given by:

$$P_{th} \text{ (mW)} = \begin{cases} ERP_{20 \text{ cm}}(d/20 \text{ cm})^x & d \leq 20 \text{ cm} \\ ERP_{20 \text{ cm}} & 20 \text{ cm} < d \leq 40 \text{ cm} \end{cases}$$

Where

$$x = -\log_{10} \left(\frac{60}{ERP_{20 \text{ cm}} \sqrt{f}} \right) \text{ and } f \text{ is in GHz;}$$

and

$$ERP_{20 \text{ cm}} \text{ (mW)} = \begin{cases} 2040f & 0.3 \text{ GHz} \leq f < 1.5 \text{ GHz} \\ 3060 & 1.5 \text{ GHz} \leq f \leq 6 \text{ GHz} \end{cases}$$

d = the separation distance (cm);

(C) Or using Table 1 and the minimum separation distance (R in meters) from the body of a nearby person for the frequency (f in MHz) at which the source operates, the ERP (watts) is no more than the calculated value prescribed for that frequency. For the exemption in Table 1 to apply, R must be at least $\lambda/2\pi$, where λ is the free-space operating wavelength in meters. If the ERP of a single RF source is not easily obtained, then the available maximum time-averaged power may be used in lieu of ERP if the physical dimensions of the radiating structure(s) do not exceed the electrical length of $\lambda/4$ or if the antenna gain is less than that of a half-wave dipole (1.64 linear value).

TABLE 1 TO §1.1307(b)(3)(i)(C)—SINGLE RF SOURCES SUBJECT TO ROUTINE ENVIRONMENTAL EVALUATION

RF Source frequency (MHz)	Threshold ERP (watts)
0.3-1.34	$1,920 R^2$.
1.34-30	$3,450 R^2/f^2$.
30-300	$3.83 R^2$.
300-1,500	$0.0128 R^2 f$.
1,500-100,000	$19.2 R^2$.

(ii) For multiple RF sources: Multiple RF sources are exempt if:

(A) The available maximum time-averaged power of each source is no more than 1 mW and there is a separation distance of two centimeters between any portion of a radiating structure operating and the nearest portion of any other radiating structure in the same device, except if the sum of multiple sources is less than 1 mW during the time-averaging period, in which case they may be treated as a single source (separation is not required). This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(i)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(i)(A).

(B) in the case of fixed RF sources operating in the same time-averaging period, or of multiple mobile or portable RF sources within a device operating in the same time averaging period, if the sum of the fractional contributions to the applicable thresholds is less than or equal to 1 as indicated in the following equation.

$$\sum_{i=1}^a \frac{P_i}{P_{th,i}} + \sum_{j=1}^b \frac{ERP_j}{ERP_{th,j}} + \sum_{k=1}^c \frac{Evaluated_k}{Exposure\ Limit_k} \leq 1$$

Where:

a = number of fixed, mobile, or portable RF sources claiming exemption using paragraph (b)(3)(i)(B) of this section for Pth, including existing exempt transmitters and those being added.

b = number of fixed, mobile, or portable RF sources claiming exemption using paragraph (b)(3)(i)(C) of this section for Threshold ERP, including existing exempt transmitters and those being added.

c = number of existing fixed, mobile, or portable RF sources with known evaluation for the specified minimum distance including existing evaluated transmitters.

Pi = the available maximum time-averaged power or the ERP, whichever is greater, for fixed, mobile, or portable RF source i at a distance between 0.5 cm and 40 cm (inclusive).

Pth,i = the exemption threshold power (Pth) according to paragraph (b)(3)(i)(B) of this section for fixed, mobile, or portable RF source i.

ERPj = the ERP of fixed, mobile, or portable RF source j.

ERPth,j = exemption threshold ERP for fixed, mobile, or portable RF source j, at a distance of at least $\lambda/2\pi$ according to the applicable formula of paragraph (b)(3)(i)(C) of this section.

Evaluated,k = the maximum reported SAR or MPE of fixed, mobile, or portable RF source k either in the device or at the transmitter site from an existing evaluation at the location of exposure.

Exposure Limit,k = either the general population/uncontrolled maximum permissible exposure (MPE) or specific absorption rate (SAR) limit for each fixed, mobile, or portable RF source k, as applicable from §1.1310 of this chapter.

The available maximum time-averaged power or effective radiated power (ERP), can be calculated using the following formula to assess compliance with the Exemption Limits:

$$P_{E.I.R.P.} = P_T + G_T - L_c$$

Where:

P_T = transmitter time-averaged output power (including Duty Cycle and tune-up tolerance, if applicable)

G_T = gain of the transmitting antenna

L_c = signal attenuation in the connecting cable between the transmitter and the antenna if applicable

$$P_{E.R.P.} = P_{E.I.R.P.} - 2.15 \text{ dB}$$