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Test report No:
NIE: 71079RAN.001A2

Assessment report
RF EXPOSURE REPORT ACCORDING TO
FCC 47 CFR Part 2.1091; FCC 47 CFR Part 1.1307
FCC 47 CFR Part 1.1310

(*) Identification of item under evaluation	The SPICA Analyzer
(*) Trademark	BioSystem
(*) Model and /or type reference	Spica Hightrouput
(*) Other identification of the product	HW version: Hightrought Spica HW SW Version: BTS Platform FCC ID: 2A5PS000083100 IC ID: Data not provided
(*) Features	Bluetooth LE, , 802.11a/b/g/n20
(*) Manufacturer	BioSystems S.A. C/ Costa Brava, 30 08030 BCN (SPAIN)
Test method requested, standard	FCC 47 CFR Part 2.1091 Radiofrequency radiation exposure evaluation: mobile devices. FCC 47 CFR Part 1.1307: Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared. FCC 47 CFR Part 1.1310: Radiofrequency radiation exposure limits.
Summary	IN COMPLIANCE
Approved by (name / position & signature)	Miguel Lacave Antennas Lab Manager  2022.06.16 10:06:20 +02'00'
Date of issue	2022-06-16
Report template No	FAN36_02 (*) "Data provided by the client"

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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 identification of the product”, “Features”, “Manufacturer” and “General description of the device”).
2. Maximum output power, maximum antenna gain and use distance information.

   The sample consists of a SPICA Analyzer is used to determine analytes concentrations by colorimetric and turbidimetric measurements of several kinds of samples from a wide range of industries. There are two clear business divisions: IVD & non-IVD.

   The SPICA IVD analyzer is used to determine analyte concentrations by in vitro colorimetric, turbidimetric, and electrolyte measurements of different human body fluids or samples (for example serum, urine, plasma, cerebrospinal fluid, total blood, seminal plasma, and fecal samples). For in vitro professional use only in the clinical laboratory.

   The SPICA non-IVD analyzer determines analytes concentrations by colorimetric, turbidimetric, and electrolyte measurements of different kinds of food (for example, meat or fish) and beverage samples (for example, wines, juices, milk), veterinary samples, and/or samples of biological cultures. For professional use in analytical laboratories only.

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

Company name: BioSystems S.A.

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Document history

Report number	Date	Description
71079RAN.001	2022-03-29	First release
71079RAN.001A1	2022-06-16	Second release: It was corrected minor typos and more detailed description of the equipment under test was included. This test report cancels and replaces the report: 71079RAN.001
71079RAN.001A2	2022-06-16	Third release: It was corrected minor typos This test report cancels and replaces the report: 71079RAN.001A1

Appendix A: FCC RF Exposure assessment result

General description of the device under evaluation

The device under evaluation consists of an analyzer is used to determine analyte concentrations by flin vitrofl biochemical, turbidimetric, and electrolyte measurements of different human body fluids or samples (for example serum, urine, plasma, cerebrospinal fluid, total blood, seminal plasma, and fecal samples). For in vitro professional use only in the clinical laboratory.

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 20 cm. In order to perform the assessment a conservative evaluation distance of 20 cm has been used.

The equipment specifications declared by the manufacturer for each supported technology and band are:

Technology / Mode	Band	Frequency (MHz)	Maximum Conducted Output Power (Incl. Tune-Up) (dBm)	Antenna peak gain (dBi)	Maximum E.I.R.P. (dBm)	Maximum E.I.R.P. (mW)
802.11 b/g/n	2.4 GHz	2400 - 2483.5	15.00	3.00	18.00	63.10
BT EDR	2.4 GHz	2400 - 2483.5	5.00	3.00	8.00	6.31
BTLE	2.4 GHz	2400 - 2483.5	5.00	3.00	8.00	6.31

Table 1: Equipment specifications

Evaluation Results

Technology / Mode	Band	Frequency (MHz)	Distance (cm)	Maximum E.R.P. output power (mW)	Limit (mW)	Verdict
802.11 b/g/n	2.4 GHz	2400 - 2483.5	20.00	38.46	768.00	**Pass**
BT EDR	2.4 GHz	2400 - 2483.5	20.00	3.85	768.00	**Pass**
BTLE	2.4 GHz	2400 - 2483.5	20.00	3.85	768.00	**Pass**

Table 2: FCC Evaluation Results

The computed value(s) are below the 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 Pth (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). Pth is given by:

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

Where

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

and

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

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 λ/2π. 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 λ/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^2f.
1,500-100,000	19.2R^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 is 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 λ/2π 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.

RF Exposure evaluation

Limits for Maximum Permissible Exposure (MPE) for RF sources are defined in FCC 47 CFR "§1.1310 Radiation Exposure limits. paragraph (e)":

TABLE 1 TO §1.1310(E)(1)—LIMITS FOR MAXIMUM PERMISSIBLE EXPOSURE (MPE)

Frequency range (MHz)	Electric field strength (V/m)	Magnetic field strength (A/m)	Power density (mW/cm^2)	Averaging time (minutes)
(i) 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
(ii) 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.

Each supported transmission technology will be evaluated to determine if it is in compliance with limits for Maximum Permissible Exposure (MPE) to radiofrequency electromagnetic fields.

In order to perform the assessment. the following equations have been used for the calculations; these equations are accurate in the far-field of an antenna and will over-predict power density in the near field. where they could be used for making a "worst-case" or conservative prediction:

Power density: $S[mW/cm^2] = \frac{P_{E.I.R.P.}[mW]}{4\Pi R[cm]^2}$

Where:

S = power density

$P_{E.I.R.P.}$ = Equivalent isotropically radiated power

R = distance to the center of radiation of the antenna (evaluation distance)

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

Where:

P_T= transmitter output power (including tune-up tolerance)

G_T= gain of the transmitting antenna

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