

Test report No:
NIE: 76077RAN.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	Receiver-In-The-Canal Hearing Aid (air-conduction, wireless)
(*) Trademark	Phonak
(*) Model and /or type reference	Phonak Audéo I90-Sphere Phonak Audéo I70-Sphere Phonak Audéo ISphereTrial See section "Data provided by the client".
(*) Other identification of the product	FCC ID : KWC-IRP IC ID : 2262A-IRP HW version : 050-1029 SW Version : 067-1602
(*) Features	DM, Flora, Bluetooth Classic, Bluetooth Low Energy
(*) Manufacturer	Sonova AG Laubisrütistrasse 28 8712 Stäfa, Switzerland
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	2024-06-13
Report template No	FAN24_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", "General description of the device", "Other identification of the product").
2. Maximum output power, maximum antenna gain and use distance information
3. The device under evaluation consists of a hearing aid that is intended to amplify and transmit sound to the ear and thereby compensate for impaired hearing.
4. The data used for the evaluation are from the device Phonak Audéo I90-Sphere. On the following page, the models have been declared by the supplier as equivalent.

To whom it may concern

Stäfa (Switzerland), April 2024 / David Sooprayen, Interim Head of Regulatory Affairs

Product Equality Declaration

We, Sonova AG, hereby declare under our own responsibility that the products listed below as “Hardware Equivalent Products” are in all relevant parts and hardware construction identical to the corresponding product identified as “Products with basis Hardware”. The following standards and/or technical regulations and corresponding test reports fully apply accordingly:

Standards
Hearing aid standards: ACUSTIC: IEC (International Electroacoustic Commission) 60118-0 and NSH 7.0 (including Annex A); EMC (Electromagnetic Compatibility): IEC 60118-13; EMC immunity: ANSI (American National Standards Institute) C63.19; SW: IEC/EN 62304:2006 + A1:2015; UNE EN 62304:2007 + Corr:2009 + A1:2016; Europe: HEALTH & SAFETY: IEC/EN 60601-1; IEC/EN 60601-1-6; IEC/EN 60601-1-11; IEC/EN 60601-2-66; IEC/EN 62133-2; UN 38.3 Test 7; IEC/EN 62479; EMC: IEC/EN 60601-1-2; EN ETSI 301 489-1, -17 ; SPECTRUM: EN 300 328; USA: 47 CFR Part 15 (B); Part 15 (C):15.249, 15.209; Part 2: 2.1093; 2.1091 Canada: RSS-Gen, ICES-003, RSS-210, RSS-102 Japan: ARIB T66, Ordinance regulating Radio Equipment (2005-08) Ar12 item 19

The only difference between the listed equivalent and corresponding basis models is the model's name, a separate set of audiological features per performance level.

Products with basis Hardware (tested representative model)	Hardware Equivalent Products
Phonak Audéo I90-Sphere (with S/M/P/UP/MAV receivers) HW version: 050-1029-xx FW version: 067-1602 SW version: Target 10	Phonak Audéo I70-Sphere (with S/M/P/UP/MAV receivers) HW version: 050-1060-xx SW version: Target 10.0 FW version: 067-1603 Phonak Audéo ISphereTrial (with S/M/P/UP/MAV receivers) HW version: 050-1030-xx SW version: Target 10.0 FW version: 067-1602

where xx – means colour identification

Place and date

Staefa, 23. April 2024



David Sooprayen
Interim Head of Regulatory Affairs

Staefa, 24. April 2024



Lora Braun
Regulatory Affairs Manager

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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

Sonova AG
Laubisrütistrasse 28 8712 Stäfa, Switzerland

Document history

Report number	Date	Description
76077RAN.002	2024-06-13	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 hearing aid that is intended to amplify and transmit sound to the ear and thereby compensate for impaired hearing with the following features: DM, Flora, Bluetooth Classic, Bluetooth EDR, Bluetooth Low Energy. For RF Exposure evaluation, only transmission technologies: DM, Flora, Bluetooth Classic, Bluetooth EDR, Bluetooth Low Energy 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 (5mm applied for the evaluation) has been used.

Maximum output power:

Values corresponding to maximum output power have been declared by the device manufacturer (maximum output power values stated in manufacturer's technical description document).

The duty cycle of each transmission technology has been declared by the client in the Operational Description document.

Antennas: the device supports one antenna for the DM, Flora, Bluetooth Classic, Bluetooth EDR, Bluetooth Low Energy transmitting technologies:

- "FPCB 02 ANT RIC, 006-0649-03" antenna for Bluetooth Classic, Bluetooth EDR, Bluetooth Low Energy transmissions.
- "FPCB 02 ANT RIC, 006-0649-03" antenna for DM and Flora transmissions.

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 (Incl. Tune-Up) (dBm)	Duty Cycle (%)	Time Averaged Conducted Power (dBm)	“FPCB 02 ANT RIC, 006-0649-03” 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)
Proprietary DM	2.4 GHz	2402 - 2483.5	6.00	4.00	-7.98	-9.20	-19.33	0.01	-17.18	0.02
Proprietary Flora	2.4 GHz	2400 - 2483.5	6.00	60.00	3.78	-9.20	-7.57	0.18	-5.42	0.29
Bluetooth Classic	2.4 GHz	2400 - 2483.5	6.00	31.00	0.91	-9.20	-10.44	0.09	-8.29	0.15
Bluetooth EDR 2 Mb	2.4 GHz	2400 - 2483.5	2.00	31.00	-3.09	-9.20	-14.44	0.04	-12.29	0.06
Bluetooth EDR 3 Mb	2.4 GHz	2400 - 2483.5	2.00	31.00	-3.09	-9.20	-14.44	0.04	-12.29	0.06
Bluetooth Low Energy 1Mb	2.4 GHz	2400 - 2483.5	6.00	38.00	1.80	-9.20	-9.55	0.11	-7.40	0.18
Bluetooth Low Energy 2Mb	2.4 GHz	2400 - 2483.5	6.00	38.00	1.80	-9.20	-9.55	0.11	-7.40	0.18

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 **0** mm (5mm applied for the evaluation) will be as follow:

Technology / Mode	Operating Band	Frequency under evaluation (MHz)	Distance (cm)	Time Averaged Conducted Power (mW)	§ 1.1307(b)(3).i.(B) Exposure Limit (mW)	Verdict
Proprietary DM	2.4 GHz	2402 - 2483.5	0.50	0.16	2.71	Pass
Proprietary Flora	2.4 GHz	2400 - 2483.5	0.50	2.39	2.71	Pass
Bluetooth Classic	2.4 GHz	2400 - 2483.5	0.50	1.23	2.71	Pass
Bluetooth EDR 2 Mb	2.4 GHz	2400 - 2483.5	0.50	0.49	2.71	Pass
Bluetooth EDR 3 Mb	2.4 GHz	2400 - 2483.5	0.50	0.49	2.71	Pass
Bluetooth Low Energy 1Mb	2.4 GHz	2400 - 2483.5	0.50	1.51	2.71	Pass
Bluetooth Low Energy 2Mb	2.4 GHz	2400 - 2483.5	0.50	1.51	2.71	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 P_{th}, 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.

P_i = 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).

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

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

ERP_{th,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.

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

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