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Parque Tecnológico de Andalucía,
c/ Severo Ochoa nº 2 · 29590 Campanillas · Málaga · España
C.I.F. A29 507 456

Test report No:
NIE: 79371RAN.001

Assessment report
RF EXPOSURE REPORT ACCORDING TO
FCC 47 CFR Part 2.1093
FCC 47 CFR Part 1.1307

(*) Identification of item under evaluation	Air conduction Hearing Aids
(*) Trademark	Phonak
(*) Model and /or type reference	Phonak Virto I90-R (Left) & Phonak Virto I90-R (Right)
(*) Derived model not tested	Phonak Virto I70-R, Phonak Virto I50-R, Phonak Virto I30-R
(*) Other identification of the product	HW version: 063-0526-01 SW Version: 068-1500 FCC ID (Left): KWC-VTI IC (Left): 2262A-VTI FCC ID (Right): KWC-VTJ IC (Right): 2262A-VTJ
(*) Features	Bluetooth, Bluetooth LE, DM, Flora
(*) Manufacturer	SONOVA AG Laubisrutisstrasse 28, CH-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)	Manuel García Antennas Laboratory Technical Responsible 74862741H MANUEL GARCÍA (C:A29507456) 74862741H MANUEL GARCÍA (C:A29507456) 2024.07.15 12:16:40 +02'00'
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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 an in-the-ear hearing instrument powered by a Li-Ion rechargeable battery. Integrated wireless connectivity over BLE, BT and a proprietary modulation.

sonova
HEAR THE WORLD

ID: PDL-14003
Version: 4

Product Equality Declaration DoE Phonak Virto I

To whom it may concern

Stäfa (Switzerland), June 2024 / Regulatory Affairs

Product Equality Declaration

We, Sonova AG, hereby declare under our own responsibility that the products listed below as "Products with equivalent Hardware and Software" are in all relevant parts and hardware and software construction identical to the corresponding product identified as "Products with basis Hardware and Software".

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; Degrees of protection provided by enclosures (IP Code): IEC 60529 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 name, a separate set of audiological features per performance level.

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ID: PDL-14003
Version: 4

Products with basis Hardware and Software (tested representative model)	Products with equivalent Hardware and Software
Phonak Virto I90-R (with Receiver M/P/SP/UP) HW version: 063-0526-01 FW version: 068-1500 SW version: Target 10 or higher	**Phonak Virto I70-R** (with Receiver M/P/SP/UP) HW version: 063-0527-01 FW version: 068-1501 SW version: Target 10 or higher **Phonak Virto I50-R** (with Receiver M/P/SP/UP) HW version: 063-0528-01 FW version: 068-1502 SW version: Target 10 or higher **Phonak Virto I30-R** (with Receiver M/P/SP/UP) HW version: 063-0529-01 FW version: 068-1503 SW version: Target 10 or higher
Phonak Virto I90-10 NW O (with Receiver M/P/SP) HW version: 063-0530-01 FW version: 068-1414 SW version: Target 10 or higher	**Phonak Virto I70-10 NW O** (with Receiver M/P/SP) HW version: 063-0531-01 FW version: 068-1415 SW version: Target 10 or higher **Phonak Virto I50-10 NW O** (with Receiver M/P/SP) HW version: 063-0532-01 FW version: 068-1416 SW version: Target 10 or higher **Phonak Virto I30-10 NW O** (with Receiver M/P/SP) HW version: 063-0533-01 FW version: 068-1417 SW version: Target 10 or higher
Phonak Virto I90-Titanium (with Receiver M/P/SP) HW version: 063-0534-01 FW version: 068-1418 SW version: Target 10 or higher	**Phonak Virto I70-Titanium** (with Receiver M/P/SP) HW version: 063-0535-01 FW version: 068-1419 SW version: Target 10 or higher

Place and date

Staefa,

Staefa,

Shokoufeh Khodabandeh

Director Regulatory Affairs

David Sooprayen

Senior Regulatory Affairs Manager

Document is signed and dated electronically with SmartSolve

Sonova AG
Laubisrütistrasse 28
8712 Stäfa, Switzerland

Phone +41 58 928 01 01
Fax +41 58 928 20 11
info@sonova.com // www.sonova.com

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1

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PDL-22655 [1]	Lifetime Performance Test Plan Prince ITE-R	DOCUMENT	Related

Approvals

Level	Actor	Job Title	Sign-off Date	Sign-off By
1	Nataya Jaiman	Regulatory Affairs and Quality Coordinator	27-Jun-2024	11NJAIMAN
2	David Sooprayen	Senior Regulatory Affairs Manager	27-Jun-2024	22DSOOPRAYEN
2	Shokoufeh Khodabandeh	Director Regulatory Affairs	27-Jun-2024	11SKHODABAND

Revision Notes

Access Activity	Note	Accessed By	Accessed Date
Remark	Reference to additional standards added and transfer into new version of the template.	22DSOOPRAYEN	25-Jun-2024

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: SONOVA AG

Postal address: Laubisrutisstrasse 28, CH-8712 Stäfa, Switzerland

Contact person: Andrei Goia

Telephone / e-mail: +15198950100 / andrei.goia@sonova.com

Document history

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79371RAN.001	2024-07-15	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:

The following information is going to be taken into account for the evaluation of the both models declared on the cover of this document, due to both ones implement the same radio specifications.

Description and technologies: the device under evaluation consists of an in-the-ear hearing instrument powered by a Li-Ion rechargeable battery. Integrated wireless connectivity over BLE, BT and a proprietary modulation with the following features: Bluetooth, Bluetooth LE, DM, Flora. For RF Exposure evaluation, only transmission technologies: Bluetooth, Bluetooth LE, DM, Flora 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 and duty cycle have been declared in module manufacturer´s datasheet.

Antennas: Antennas: the Bluetooth, Bluetooth LE, DM, Flora transmitting radios both use the same antenna.

Maximum peak antenna gain values have been extracted from the 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)	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	2.4 GHz	2400 - 2483.5	6.00	31.00	0.91	-13.10	-14.34	0.04	-12.19	0.06
BTLE	2.4 GHz	2400 - 2483.5	6.00	38.00	1.80	-13.10	-13.45	0.05	-11.30	0.07
BT EDR	2.4 GHz	2400 - 2483.5	2.50	31.00	-2.59	-13.10	-17.84	0.02	-15.69	0.03
Proprietary DM	2.4 GHz	2402 - 2480	0.50	4.00	-13.48	-13.10	-28.73	0.00	-26.58	0.00
Proprietary Flora	2.4 GHz	2402 - 2480	6.00	60.00	3.78	-13.10	-11.47	0.07	-9.32	0.12

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
Bluetooth	2.4 GHz	2400 - 2483.5	0.50	1.23	2.71	**Pass**
BTLE	2.4 GHz	2400 - 2483.5	0.50	1.51	2.71	**Pass**
BT EDR	2.4 GHz	2400 - 2483.5	0.50	0.55	2.71	**Pass**
Proprietary DM	2.4 GHz	2402 - 2480	0.50	0.04	2.72	**Pass**
Proprietary Flora	2.4 GHz	2402 - 2480	0.50	2.39	2.72	**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 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.

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

$P_{E.R.P.} = P_{E.I.R.P.} – 2.15$ dB