

DOC_TITLE

Labelling and Packaging Information

Phonak Audéo I-R (90/70/50/30/Trial)
ampli-energy R L R PH (5/4/3/2/Trial)

Product Family:

Phonak Audéo I-R	Phonak Audéo I90-R Phonak Audéo I70-R Phonak Audéo I50-R Phonak Audéo I30-R
Phonak Audéo I-R Trial	N/A
ampli-energy R I R PH	ampli-energy R 5 I R PH ampli-energy R 4 I R PH ampli-energy R 3 I R PH ampli-energy R 2 I R PH
ampli-energy R trial I	N/A

1. Product pictures and Labelling on the product

1.1 Labelling on the product:

Model name: Phonak Audéo I-R (90/70/50/30/Trial), ampli-energy R I R PH (5/4/3/2/Trial)

Brand labeling : “Phonak” on the side of the product, “amplifon” on the side of the product

Product Line: “Audéo” on the bottom of the housing for Phonak Audéo I-R products, “ampli-energy” on the bottom of the housing for ampli-energy R I R PH products.

CE 0459: CE 0459 on the bottom of the housing.

UKCA (if applicable): N/A

Serial number, platform, performance level and model name: on the serial number plate e.g. 2436H0ELT

Serial number: 2 lines, e.g. YYWW
IABCD

The serial number contains **Manufacturing Date** within the number:

Y	Y	W	W	I	A	B	C	D
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YY = year (Example: 18 for 2018)

WW = number of the current production week (example: 35 for the week 35)

I = SAP Site ID

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ABCD = incremental serial number

Phonak Audéo I-R (Side, back and front views)

Side	Back* (representative model)	Front
		

*The hearing aids shown in the pictures are red marked (right hearing aid). Left hearing aid has a blue mark instead.

Phonak Audéo I-R Trial (Side, back and front views)

Side	Back* (representative model)	Front
		

*The hearing aids shown in the pictures are red marked (right hearing aid). Left hearing aid has a blue mark instead.

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ampli-energy R I R PH (Side, back and front views)

Side	Back* (representative model)	Front

*The hearing aids shown in the pictures are red marked (right hearing aid). Left hearing aid has a blue mark instead.

ampli-energy R Trial I (Side, back and front views)

Side	Back* (representative model)	Front

*The hearing aids shown in the pictures are red marked (right hearing aid). Left hearing aid has a blue mark instead.

Example of a serial number plate:



1.2 Labelling on the product: software

N/A

1.2.1 About screen

N/A

1.2.2 US labelling requirements to software related to prescription hearing aids 21 CFR 801.422

N/A.

2. Labelling on the package

2.1 Labelling sticker:

Products of the product line Phonak Audéo I-R can be presented in different colors.

A pre-defined color can be applied to all models. The identification of a product model and its specific color is done by the last two or four digits in the REF number (part number) which is placed on the packaging label.

The table below represents all available colors for the product line and the related two digits of the REF number:

Color code	Color name	Phonak Audéo I-R	ampli-energy R I R PH
1A	Copper	X	
8A	Sienna Red	X	
9A	Atlantic Green	X	

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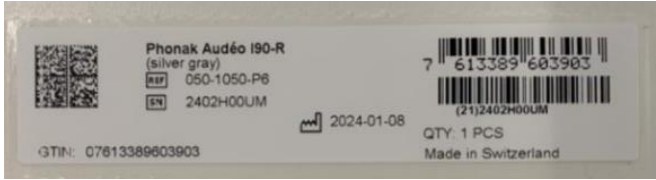
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Color code	Color name	Phonak Audéo I-R	ampli-energy R I R PH
P1	Sand beige	X	X
P3	Sandalwood	X	Level 5,4,3 only
P4	Chestnut	X	
P5	Champagne	X	
P6	Silver Grey	X	X
P7	Graphite Grey	X	
P8	Velvet Black	X	Level 5,4,3 only
H0	Beige	Level 90 only	

Phonak Audéo I90-R

Model Name	Color	SAP number	Representative illustration
Phonak Audéo I90-R	(sand beige)	050-1050-P1	
Phonak Audéo I90-R	(sandalwood)	050-1050-P3	
Phonak Audéo I90-R	(chestnut)	050-1050-P4	
Phonak Audéo I90-R	(champagne)	050-1050-P5	
Phonak Audéo I90-R	(silver grey)	050-1050-P6	
Phonak Audéo I90-R	(graphite grey)	050-1050-P7	
Phonak Audéo I90-R	(velvet black)	050-1050-P8	
Phonak Audéo I90-R	(copper)	050-1050-1A	
Phonak Audéo I90-R	(sienna red)	050-1050-8A	
Phonak Audéo I90-R	(atlantic green)	050-1050-9A	
Phonak Audéo I90-R	(beige)	050-1050-H0	

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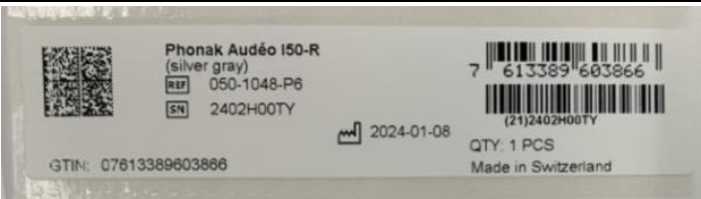
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Phonak Audéo I70-R

Model Name	Color	SAP number	Representative illustration
Phonak Audéo I70-R	(sand beige)	050-1049-P1	
Phonak Audéo I70-R	(sandalwood)	050-1049-P3	
Phonak Audéo I70-R	(chestnut)	050-1049-P4	
Phonak Audéo I70-R	(champagne)	050-1049-P5	
Phonak Audéo I70-R	(silver grey)	050-1049-P6	
Phonak Audéo I70-R	(graphite grey)	050-1049-P7	
Phonak Audéo I70-R	(velvet black)	050-1049-P8	
Phonak Audéo I70-R	(copper)	050-1049-1A	
Phonak Audéo I70-R	(sienna red)	050-1049-8A	
Phonak Audéo I70-R	(atlantic green)	050-1049-9A	

Phonak Audéo I50-R

Model Name	Color	SAP number	Representative illustration
Phonak Audéo I50-R	(sand beige)	050-1048-P1	
Phonak Audéo I50-R	(sandalwood)	050-1048-P3	
Phonak Audéo I50-R	(chestnut)	050-1048-P4	
Phonak Audéo I50-R	(champagne)	050-1048-P5	
Phonak Audéo I50-R	(silver grey)	050-1048-P6	
Phonak Audéo I50-R	(graphite grey)	050-1048-P7	
Phonak Audéo I50-R	(velvet black)	050-1048-P8	
Phonak Audéo I50-R	(copper)	050-1048-1A	

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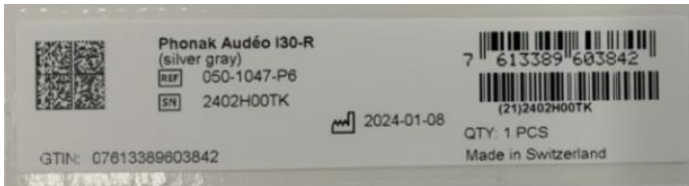
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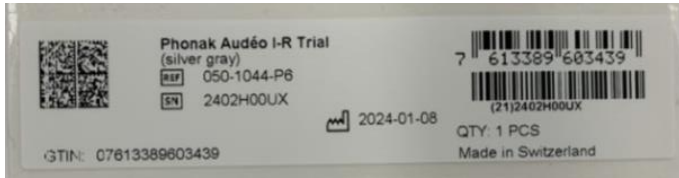
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Model Name	Color	SAP number	Representative illustration
Phonak Audéo I50-R	(sienna red)	050-1048-8A	
Phonak Audéo I50-R	(atlantic green)	050-1048-9A	

Phonak Audéo I30-R

Model Name	Color	SAP number	Representative illustration
Phonak Audéo I30-R	(sand beige)	050-1047-P1	
Phonak Audéo I30-R	(sandalwood)	050-1047-P3	
Phonak Audéo I30-R	(chestnut)	050-1047-P4	
Phonak Audéo I30-R	(champagne)	050-1047-P5	
Phonak Audéo I30-R	(silver grey)	050-1047-P6	
Phonak Audéo I30-R	(graphite grey)	050-1047-P7	
Phonak Audéo I30-R	(velvet black)	050-1047-P8	
Phonak Audéo I30-R	(copper)	050-1047-1A	
Phonak Audéo I30-R	(sienna red)	050-1047-8A	
Phonak Audéo I30-R	(atlantic green)	050-1047-9A	

Phonak Audéo I-R Trial

Model Name	Color	SAP number	Representative illustration
Phonak Audéo I-R Trial	Atlantic Green	050-1044-9A	
Phonak Audéo I-R Trial	Silver Grey	050-1044-P6	

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ampli-energy R 5 I R PH

Model Name	Color	SAP number	Representative illustration
ampli-energy R 5 I R PH	Sand Beige	050-1050-P167	
ampli-energy R 5 I R PH	Silver Grey	050-1050-P667	
ampli-energy R 5 I R PH	Sandalwood	050-1050-P367	
ampli-energy R 5 I R PH	Velvet Black	050-1050-P867	

ampli-energy R 4 I R PH

Model Name	Color	SAP number	Representative illustration
ampli-energy R 4 I R PH	Sand Beige	050-1049-P167	
ampli-energy R 4 I R PH	Silver Grey	050-1049-P667	
ampli-energy R 4 I R PH	Sandalwood	050-1049-P367	
ampli-energy R 4 I R PH	Velvet Black	050-1049-P867	

ampli-energy R 3 I R PH

Model Name	Color	SAP number	Representative illustration
ampli-energy R 3 I R PH	Sand Beige	050-1048-P167	
ampli-energy R 3 I R PH	Silver Grey	050-1048-P667	
ampli-energy R 3 I R PH	Sandalwood	050-1048-P367	
ampli-energy R 3 I R PH	Velvet Black	050-1048-P867	

ampli-energy R 2 I R PH

Model Name	Color	SAP number	Representative illustration
ampli-energy R 2 I R PH	Sand Beige	050-1047-P167	
ampli-energy R 2 I R PH	Silver Grey	050-1047-P667	

ampli-energy R 5 I R PH

Model Name	Color	SAP number	Representative illustration
Ampli-energy R Trial I	Silver Gray	050-1044-P667	

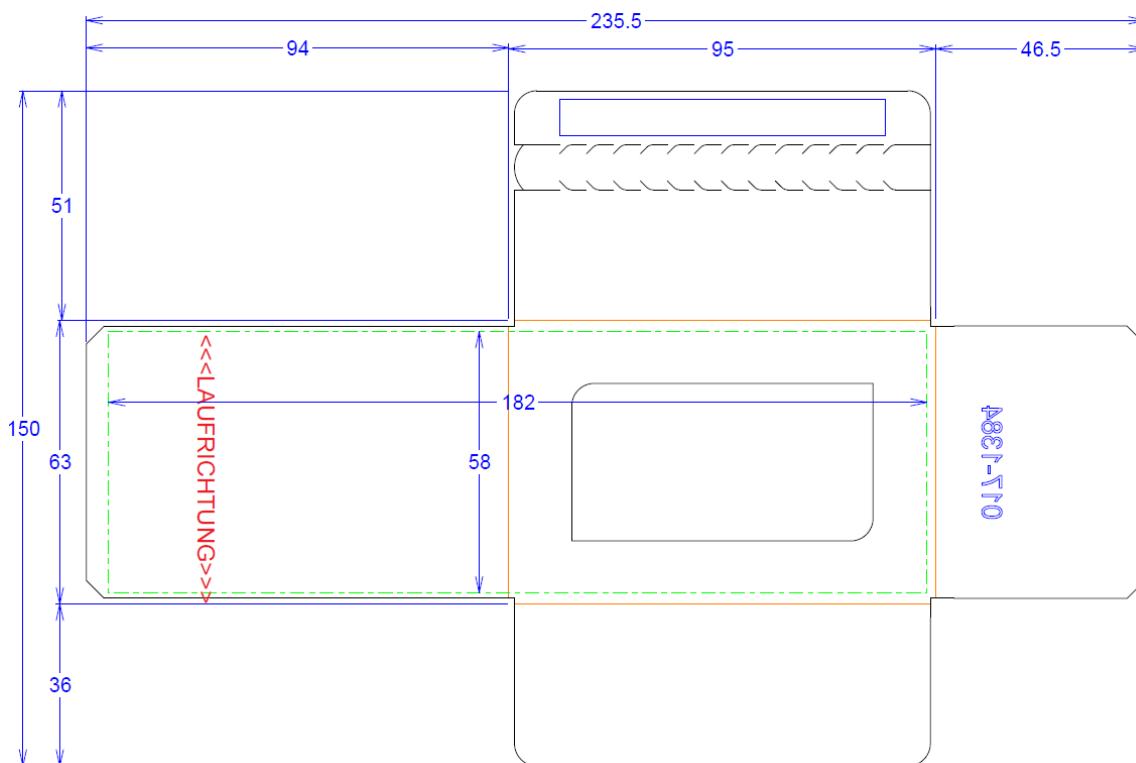
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2.2 Inner cardboard box:



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Phonak Audéo I-R (I90/I70/I50/I30/Trial)

Material Type(s): PAWI – Duo Fix (SRFIXT60-1) / Toan Pat – Polyethylene / Suzhou Meidi Package - Polyethylene

Material part number(s): 017-1384

Supplier: PAWI, Switzerland / Toan Phat Printing & Packaging, Vietnam / Suzhou Meidi Package Design Material, China

Datasheet for material types: ISIR 191253, 190597, 190562

2.3 Outer cardboard box:

The products are manufactured, packed and shipped individually in labelled cardboard cartons, refer to photos below. The same cardboard box model is used for all hearing aid products. However, the labelling

sticker on the box is unique for the products. The labelling stickers with complete product model name, color, article number, serial number and bar code can be seen in the representative pictures below.

Phonak Audéo I-R:

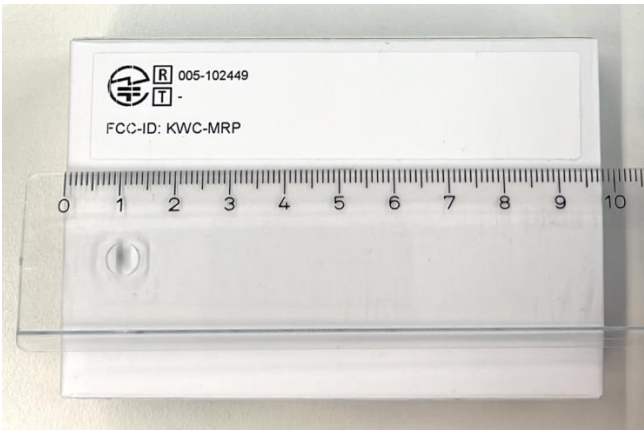
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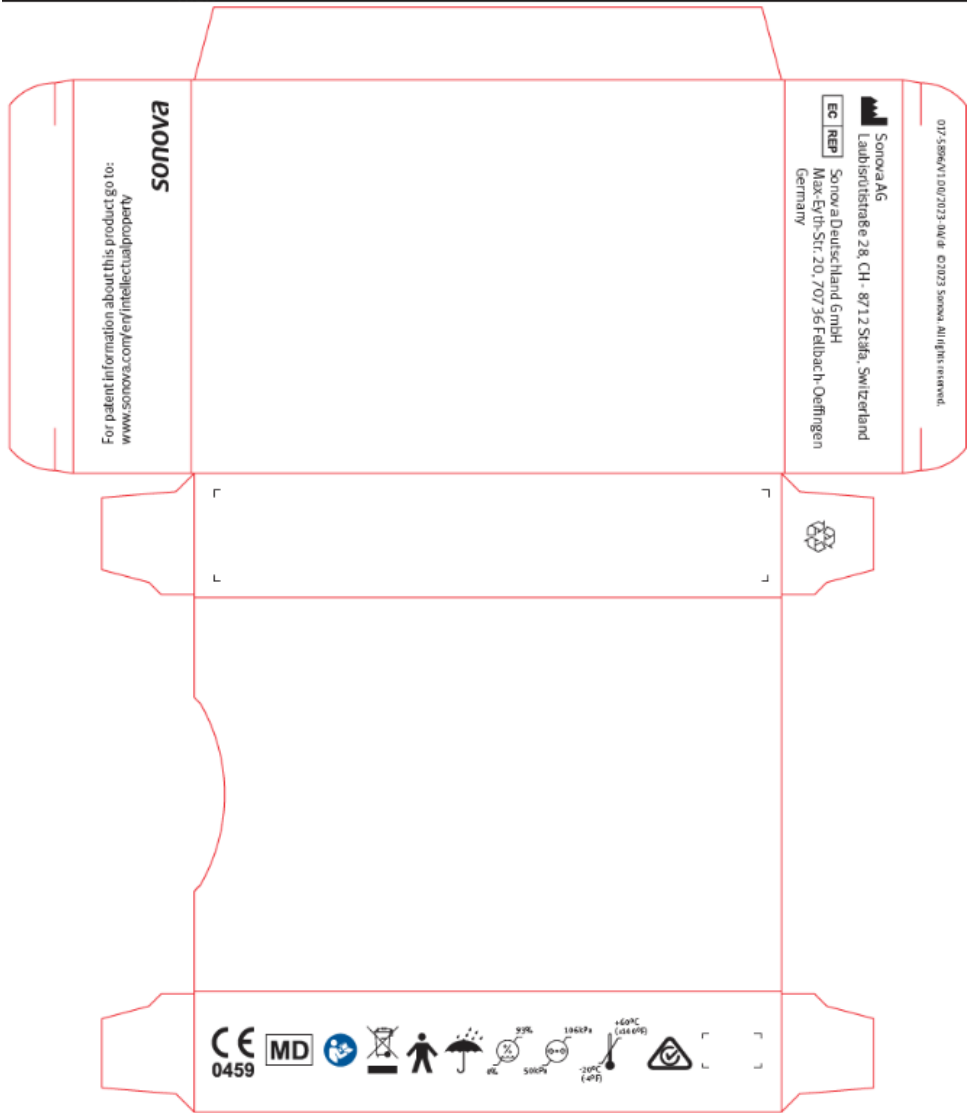
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Picture showing the dimension of FCC ID and Giteki symbol (this is only an EXAMPLE)

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Ampli-energy R I R PH



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Name and address of the “legal manufacturer” in the sense of the MDR 2017/475 completed with the address of the manufacturer, and the corresponding pictogram.



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www.phonak.com

2.4 US labelling requirements to prescription hearing aids 21 CFR 801.422

The following information will be applied as sticker to the packaging of prescription hearing aids entering the US market.

- Prescription hearing aid with integrated Lithium-ion battery

WARNING - Medical evaluation for people younger than 18:

The use of a hearing aid in people younger than 18 years old without a medical evaluation may worsen impairment or disability. A prospective hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Prior to purchase, a doctor should determine that the person is a candidate for the use of a hearing aid.

Note: Ask about trial-rental or purchase-option programs.

If you're unsure about your ability to get used to using a hearing aid, you should ask about a trial-rental or purchase-option program. Many hearing instruments specialists offer programs that allow you to wear a hearing aid for a short time, at a nominal fee, before you decide to buy a hearing aid.

Battery information: One hearing aid contains one rechargeable Lithium-Ion battery.

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months.
- Your ear feels painful or uncomfortable.
- You have a lot of ear wax, or you think something could be in your ear.
- You get really dizzy or have a feeling of spinning or swaying (called vertigo).
- Your hearing changed suddenly in the past 6 months.
- Your hearing changes: it gets worse then gets better again.
- You have worse hearing in one ear.
- You hear ringing or buzzing in only one ear.



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3. Placement of remaining mandatory symbols

The mandatory markings required by the applicable standards, that are not affixed to the hearing aids, because the size of the device does now allow it, are recorded in full in the user guide, see:

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Symbol	Placement in the user guide
Type B applied part 	This user guide is valid for: Wireless hearing aids  Phonak Audéo I90-R Phonak Audéo I70-R Phonak Audéo I50-R Phonak Audéo I30-R Phonak Audéo I-R Trial Simple to follow instructions videos and further support can be found online: https://www.phonak.com/en-int/support.html Note that instructions for the activity functions can be found in the myPhonak User Guide.    Your hearing care professional:   EC REP Sonova Deutschland GmbH Max-Eyth-Strasse 20 70736 Fellbach-Oeffingen Germany Australian Sponsor: Sonova Australia Pty Ltd 12 Inglewood Place, Norwest NSW 2153 Australia Manufacturer: Sonova AG Laubisrütistrasse 28 CH-8712 Stäfa Switzerland www.phonak.com      029-1357-02/V1.00/2023-10/Im © 2023 Sonova AG All rights reserved

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Symbol	Placement in the user guide

4. QR code card with information on how and where to access the user guide in electronic format

The QR code card is accompanying the hearing aid in the packaging and provides the link to Phonak.com web site, where the applicable user guide can be accessed in electronic format.



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