





CLASSIFICATION

IEC 60645-1: Type 2 Class A/AE ANSI S3.6: Type 2A/2AE

AVAILABLE SIGNALS

Stimulus: pure tone, warble tone 2 external inputs for speech audiometry MIC input for live speech audiometry Internal input (flash memory) for speech audiometry (Harp Plus only) Masking: NBN, WN, SN

SIGNALS SPECIFICATION

Attenuator step: 1 and 5 dB

Presentation: Continuous, Pulsed (0.5, 1 and 2 Hz) Warble: 5 Hz sin wave modulating signal

AVAILABLE OUTPUTS AND TRANSDUCERS

AC: TDH-39 / DD45 headphones, ER-3 / IP30 insert earphones

BC: B-71 bone vibrator

Free field

Insert masking earphone: IME-100

AVAILABLE TESTS

- Pure Tone audiometry
- Auto threshold (modified Hughsone-Westlake)
- Speech audiometry (2 channels)
- ABLB
- SISI: automatic score; 1 dB increment (5 dB for familiarization)
- $\bullet\,$ Stenger, with pure tone or speech stimulation
- Tone decay, with 60 or 120 sec. duration
- DLI, with increments between 0 and 5 dB
- 2 independent channels Master Hearing Aid

Only on Harp Plus:

- TEN test (optional)
- QuickSIN® test (optional)

4

PURE TONE: FREQUENCIES AND MAXIMUM LEVELS (dB HL)

40

TDH-39 DD45	ER-3 IP30	AC ER-5(*)	ВС	FF (**)
80	90	90	-	75
100	105	100	45	85
110	110	110	65	95
115	115	120	70	95
120	120	120	75	95
120	120	120	80	95
120	120	115	80	95
120	120	115	75	95
120	110	110	75	95
105	95	100	55	90
95	90	90	50	85
	TDH-39 DD45 80 100 110 115 120 120 120 120 120 120	TDH-39 DD45 ER-3 IP30 80 90 100 105 110 110 115 115 120 120 120 120 120 120 120 120 120 120 120 110 105 95	TDH-39 DD45 ER-3 IP30 AC ER-5(*) 80 90 90 100 105 100 110 110 110 115 120 120 120 120 120 120 120 115 120 120 115 120 120 115 120 110 110 105 95 100	TDH-39 DD45 ER-3 IP30 AC ER-5(*) BC 80 90 90 - 100 105 100 45 110 110 110 65 115 115 120 70 120 120 120 75 120 120 120 80 120 120 115 80 120 120 115 75 120 110 110 75 105 95 100 55

^(*) Transducer supported but no more available for purchasing

SPEECH AUDIOMETRY: MAXIMUM LEVELS (dB HL)

AC (*) TDH-39 DD45	AC ER-3 IP30	AC ER-5	ВС	FF
100	400	100	60	Normal: 75
100	100	100		Extended: 85

(*) Reduce by 20dB in case of free field equivalent filter activation.

PATIENT - OPERATOR COMMUNICATION

Talk over: built-in or external microphone

Talk back: through built-in speaker or monitor headset (included); patient microphone included

Patient response trigger

MONITOR SIGNAL

Both channels monitored through the built-in speaker or monitor headset (included)

INTERNAL FLASH MEMORY (only Harp Plus)

Used to store the speech material (.wav format)
Capacity: 4 GB (more than 6 hours of speech)
Speech material upload: through ATIT software (incl.)

PRINTER

Optional integrated thermal printer

Paper size: 112 mm

INTERNAL DATABASE

Up to 100 patients both AC and BC thresholds (only pure tone exams)

CALIBRATION

Validity: 12 months

All the parameters set through the device software

COMPUTER INTERFACE

Connection: USB (driverless)

Compatible software: Inventis Maestro

HYBRID TECHNOLOGY

Description: Harp can be controlled either as a stand-alone or as a PC-controlled audiometer

It requires Inventis Maestro software

DISPLAY

Live display of the graph of all the tests Type: Graphical colour TFT LCD Size: diagonal 4.3", 95 mm x 54 mm

Resolution: 480 x 272

POWER SUPPLY

Without integrated printer:

Maximum consumption: 8 Watts

Power supply: 6V, 2A cont., through an external medical grade 100-240 Vac 50/60 Hz power supply

With integrated printer:

Maximum consumption: 25 Watts

Power supply: 6V, 4,16A cont., through an external medical grade 100-240 Vac 50/60 Hz power supply

^(*) The values refer to "normal" range; add 10 dB to each value in case of "extended range" option selected



MECHANICS

Without integrated printer:

Size (WxDxH): 32 x 32 x 9 cm / 12.6 x 12.6 x 3.5 in

Weight: 1.8 Kg / 4.0 lbs *With integrated printer*:

Size (WxDxH): 32 x 39 x 9 cm / 12.6 x 15.4 x 3.5 in

Weight: 2.3 Kg / 5.0 lbs

FREIGHT PACKING

Size (WxDxH): $47 \times 40 \times 35$ cm / $18.5 \times 15.8 \times 13.8$ in Gross weight (without printer): 4.2 Kg / 9.3 lbs Gross weight (with printer): 4.7 Kg / 10.4 lbs

APPLICABLE STANDARDS

Pure tone audiometry: IEC 60645-1, ANSI S3.6 Speech audiometry: IEC 60645-1, ANSI S3.6

Calibration: ISO 389-1 (TDH 39 and DD45), ISO 389-2 (ER-3, IP30,

ER-5), ISO 389-3 (B71), ISO 389-7 (FF) Electrical safety: IEC 60601-1, Class I type BF

EMC: IEC 60601-1-2

CE CERTIFICATE

MDR 2017/745/EU Classification: Class IIa Classification rule (Annex VIII, 2017/745): 10

Notified body: TÜV SÜD Product Service GmbH (0123)

PRODUCT CODES

10145: Harp model Basic – Diagnostic audiometer

10162: Harp model Basic – Diagnostic audiometer – with integrated thermal printer

10146 Harp model Plus – Diagnostic audiometer

10163: Harp model Plus – Diagnostic audiometer – with integrated thermal printer

INCLUDED PARTS

- TDH-39 or DD45 supra-aural headphones
- B71 bone vibrator
- Patient response switch
- Monitor headset with boom microphone
- Clip-on microphone for patient-to-operator communication
- Plastic cover sheet
- Medical grade power supply
- USB connection cable
- User manual

OPTIONAL PARTS (with order code)

- 10833: ER-3C insert earphones
- 11748: IP30 insert earphones
- 10177: IME-100 insert masking earphone
- 10181: Desktop, battery operated microphone for live speech tests
- 10179: Amplivox Audiocups noise excluding enclosures for TDH-39 / DD45 headphones
- 10180: Cable set for sound booth
- 10182: Soft carrying case
- 10293: Thermal paper for Harp and Piano audiometers (box of 5)
- 10266: One active speaker FBT J-5A
- 10534: TEN test license
- 10533: QuickSIN® test license

Harp is developed by:

INVENTIS S.r.l.

CORSO STATI UNITI, 1/3 35127 PADOVA – ITALY PHONE: +39.049.8962 844 FAX: +39.049.8966 343 info@inventis.it www.inventis.it

Follow us on Linkedin

https://www.linkedin.com/company/inventis-srl

The Inventis Quality System complies with ISO 13485 standard

 $\label{eq:local_state} Invent is {}^{\circledcirc} is a registered trademark of INVENTIS S.r.l.$