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A Clinician's Primer on How and Why to Perform the 'ANSI Test'

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Joshua Alexander is a professor at Purdue University, located in West Lafayette, Indiana. For the last 15 years, he has been responsible for instructing first- and second-year Au.D. students in hearing aids. Professor Alexander participates in the Working Group on Hearing Aids for the ANSI Standards Committee and represents ASHA as the voting member for ANSI standards pertinent to bioacoustics and noise. Today, he will present the most recent proposed modifications to the ANSI standard regarding electroacoustic measurements of hearing aids. He will also provide a refresher on the standard's content and offer valuable tips and tricks for performing these measures efficiently.

Disclosures

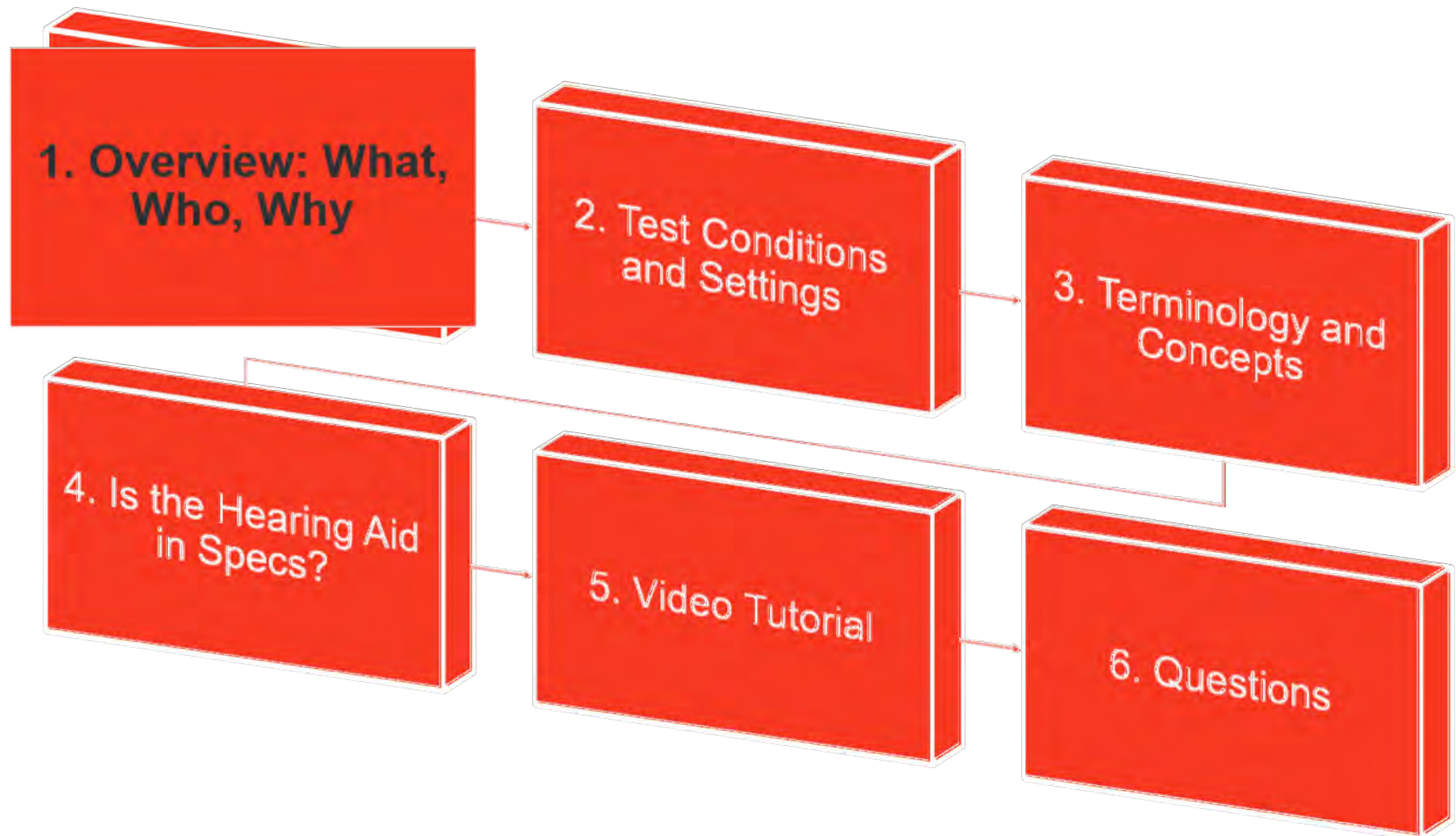
- **Presenter Disclosure:** Financial: Joshua Alexander is an employee of Purdue University and has past research support from: The National Institutes of Health; The Indiana Clinical and Translational Sciences Institute; The William Demant Holding Group; Sonova Holding AG. He is the holder of two patents on a method of frequency lowering and has a recent invention disclosure on another method. He is a paid consultant for Create, LLC on an NIH SBIR project to develop an open-source, master hearing aid. Dr. Alexander is the recipient of speaker honoraria from Signia, Oticon, Phonak, Starkey, and ReSound hearing aid companies, and received an honorarium for presenting this course. Non-financial: Joshua Alexander has no relevant non-financial relationships to disclose.
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Learning Outcomes

After this course, participants will be able to:

- Describe the importance of using a standardized procedure for measuring the electroacoustic characteristics of a hearing aid.
- Identify key terms and measurements associated with the 'ANSI Test.'
- Identify strategies for finding the ANSI test setting and specifications for different manufacturer's hearing aids.

Roadmap



What is a Standard?

- *“A prescribed set of rules, conditions, or requirements concerning definitions of terms; classification of components; specification of materials, performance, or operations; delineation of procedures; or measurement of quantity and quality in describing materials, products, systems, services, or practices.”*
 - National Standards Policy Advisory Committee
- They help **simplify life** and increase the **reliability** and **effectiveness** of goods and services
- They are **voluntary** and do not impose any regulations. However, laws and regulations may refer to certain standards making compliance compulsory.

Who Decides These Things?

- Voluntary committees help establish standards
 - Members include **professionals** who use the products, expert **scientists** who help develop them, and **representatives** from business and industry who sell them
 - **ANSI**: American National Standards Institute
 - **ISO**: International Standards Organization
 - **IEC**: International Electrotechnical Commission
 - Standards from different committees often overlap
 - Attempts are made to **harmonize**: *why reinvent the wheel?*
 - Cooperation between countries is obviously good

Accredited Standards Committees Operating Under ANSI Procedures

- S1- Acoustics
- S2- Mechanical Vibration and Shock
- S3- Bioacoustics
 - ANSI S3.22: Specification of Hearing Aid Characteristics
- S12- Noise

What is ANSI S3.22?

- **General Purpose of all standards:** quality control, product certification, and conformity assessment
- Hearing aid manufacturers use the ANSI S3.22 standard to define **terms and performance parameters**
 - Provides a common set of definitions and tests that allows agreement throughout the industry
- **S3.22 is for quality control purposes**
 - **Purpose:** check to see if the main components (mic, receiver, and circuit module) are functional

History

- The U.S. Food and Drug Administration (FDA) uses the ANSI S3.22 as *the labeling document* for hearing aids
 - ANSI S3.22-**2009/2014** is a recognized standard by the FDA but is **not yet mandatory**
 - Manufacturers **must 2003** for reporting test data
 - Other versions: 1976 (original), 1987, 1996
 - Latest revision is **2014 (re-affirmed in 2020)**

Why is this Topic Relevant Today?

- A new revision of ANSI S3.22 is being circulated for comment and approval
- Balloting at the end of March 2024

Proposed S3.22 Changes Affecting What We Do

- **Sound source and sound field calibration**

- Since the loudspeaker used to generate the acoustical input to the hearing aid does not have a uniform response at all frequencies, a frequency-by-frequency adjustment of the input level to the loudspeaker based upon a prior calibration measurement is employed. (NOT NEW)
- **NEW:** the calibration procedure will be either *uncompensated* or *compensated* with respect to the presence of the hearing aid and coupler assembly
- **NEW:** the reference microphone is removed when testing the hearing aid

Uncompensated Calibration

- **Calibration is performed WITHOUT the hearing aid and coupler assembly in the sound field**
 - Does not compensate for the obstacle effect and diffraction caused by the presence of the hearing aid and coupler assembly
 - Results in small increases in level at higher frequencies
- **Advantages**
 - Only one microphone is required
 - The reference microphone and the hearing aid are both positioned at the reference point
 - Results in the **most readily reproducible test condition**
 - As the sound source remains stable, the same calibration can be used for multiple tests, and hearing aids can be removed and carefully repositioned **without requiring a new calibration**

Compensated Calibration

- **The hearing aid and coupler assembly are positioned in the sound field during calibration**
 - Compensates for the obstacle effect and diffraction caused by the presence of the hearing aid and coupler assembly
- **Disadvantages**
 - Requires two mics, each with its own calibration
 - The reference microphone and the hearing aid are not at the same point in the sound field (or at the reference point)
 - Relies on careful positioning about the reference point
 - If the hearing aid or coupler assembly is moved (e.g., to change hearing aid programs or if a different hearing aid is tested), the sound source **must be recalibrated**

Why Clinicians Don't Run ANSI Tests

- The ANSI tests are outdated
- They were taught in school and never used again
- They were NEVER taught or used during training
- All that matters is how the hearing performs in the patient's ear

Why Clinicians Don't Run ANSI Tests

- The ANSI S3.22 document is expensive
- The test (document) is confusing
- They take too long
- ANSI test settings for a hearing aid are hard to find
 - DO NOT CONDUCT TEST WITH **USER** SETTINGS
- The manufacturer spec sheets are hard to find

Why Perform the ANSI Test?

*“Current **best practice guidelines** recommend that all hearing aids (new and repaired) be assessed electroacoustically to provide a **benchmark against which future quality control measures** can be made (AAA, 2006; ASHA, 1998).*

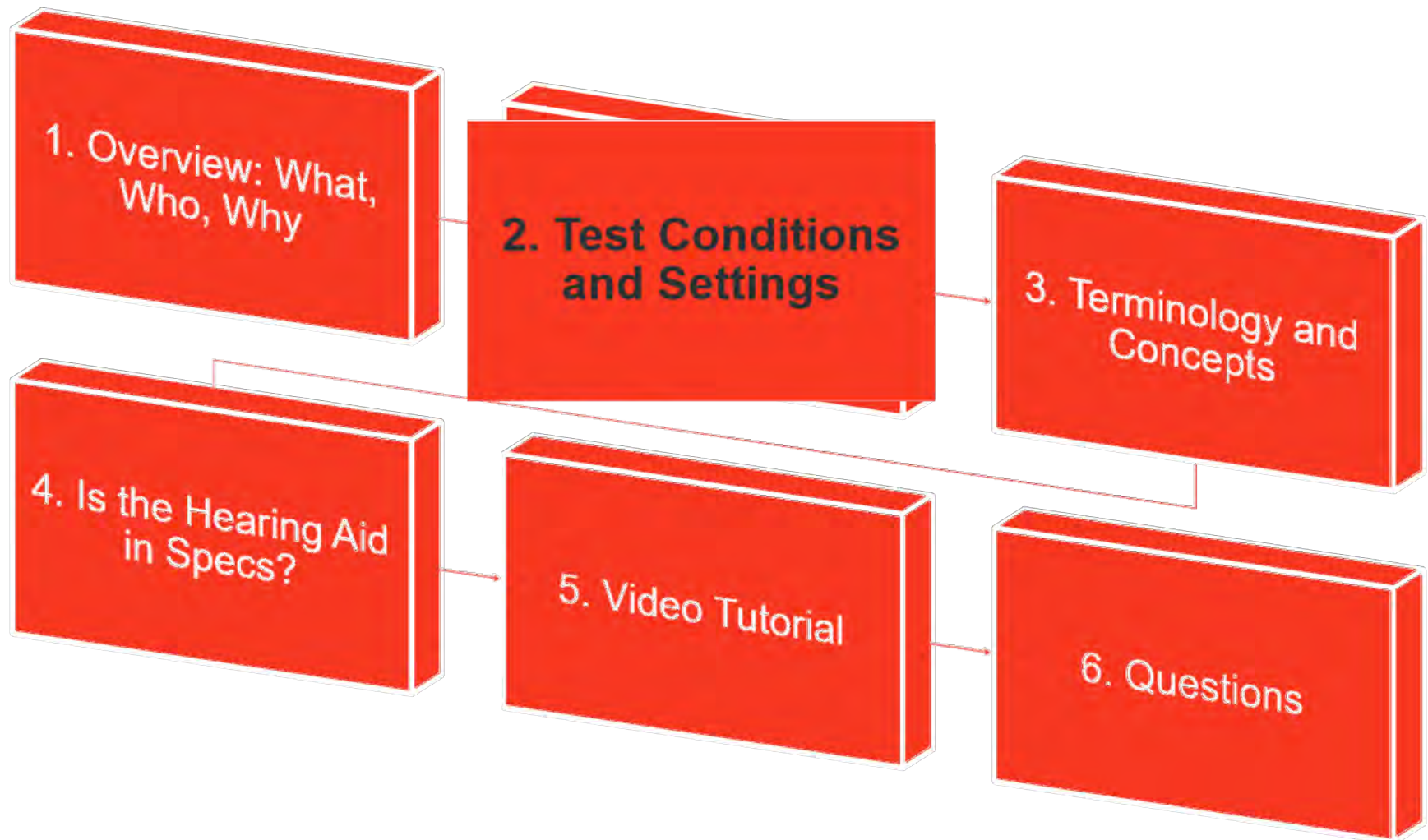
Ricketts, Bentler, & Mueller (2019)

Why Perform the ANSI Test

- Practical Reason:

- Evaluate the *electromechanical functioning* of the microphone and receiver *while minimizing contributions from the DSP*
 1. Incoming measurement for new hearing aids
 2. Before/after sending in for repair (or drying)
 3. Identify patient complaints related to the DSP
 - Eliminate mic/receiver issues as a possible cause

Roadmap



Test Conditions

- Results are **valid only** for the test signals, test conditions, hearing aid settings, hooks, tips, filters, wax guards, and accessories employed **when they were obtained**
 - Unless specified in the standard, these are to be specified by the manufacturer
- Test signals are always **pure-tone signals**
 - **Not representative** of everyday sounds
 - Used because professional engineers agree more closely on what to expect when the analysis is done
 - When complex signals are analyzed, the answers obtained are dependent on the method of analysis
 - With a pure tone, it is more likely that all forms of analysis will give the same answer

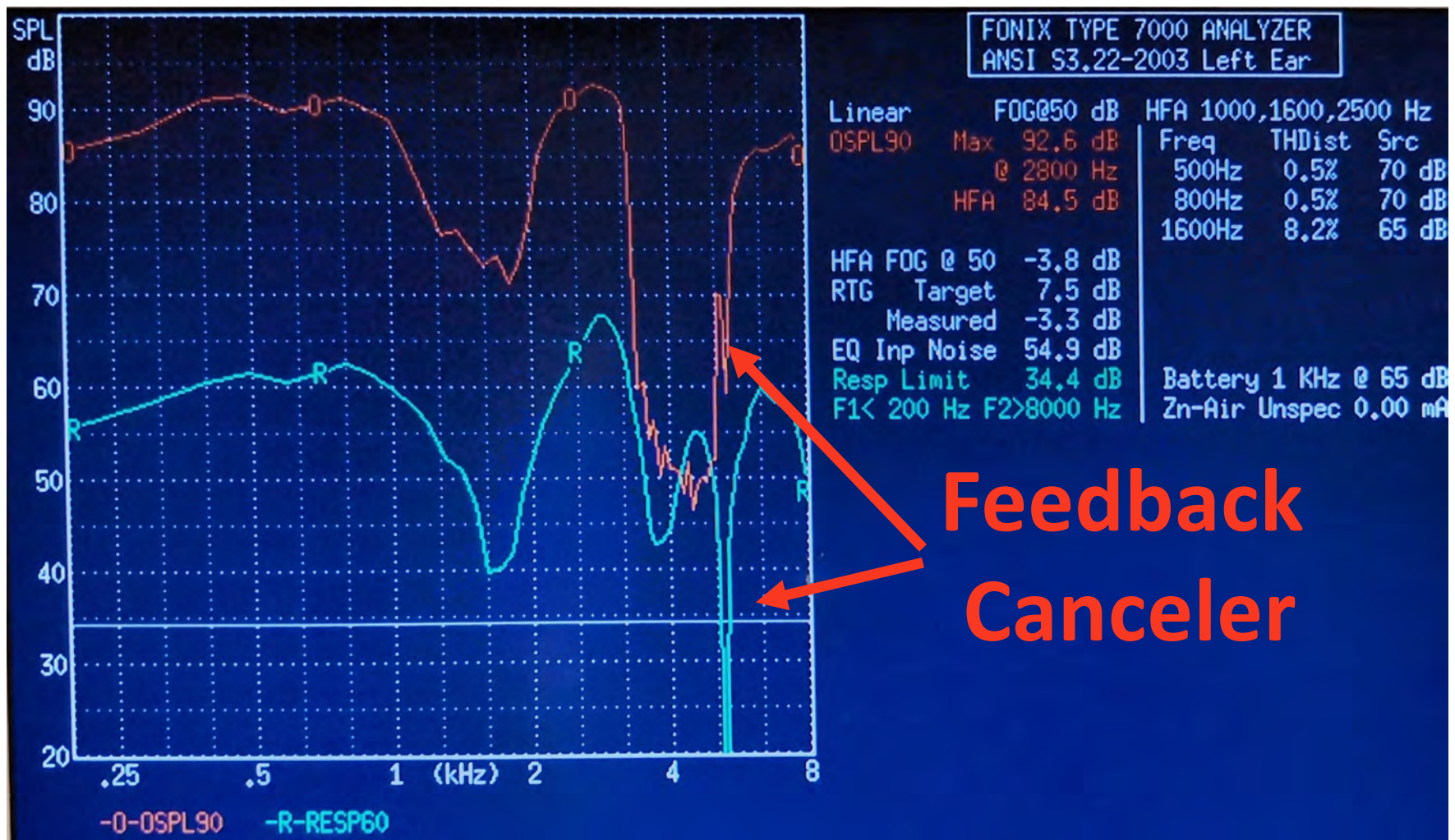
ANSI Test Hearing Aid Setting

- Requires that the hearing aid be programmed in a way that **does NOT reflect how it actually functions** in a user's ear or how it will perform under real-world conditions
- Use the programming software and select a **special mode** used only when performing ANSI tests
 - Differs for all manufacturers
 - Should be set to omnidirectional mode, its widest frequency response range, greatest output and gain
 - All advanced features (noise reduction, feedback suppression) should be deactivated

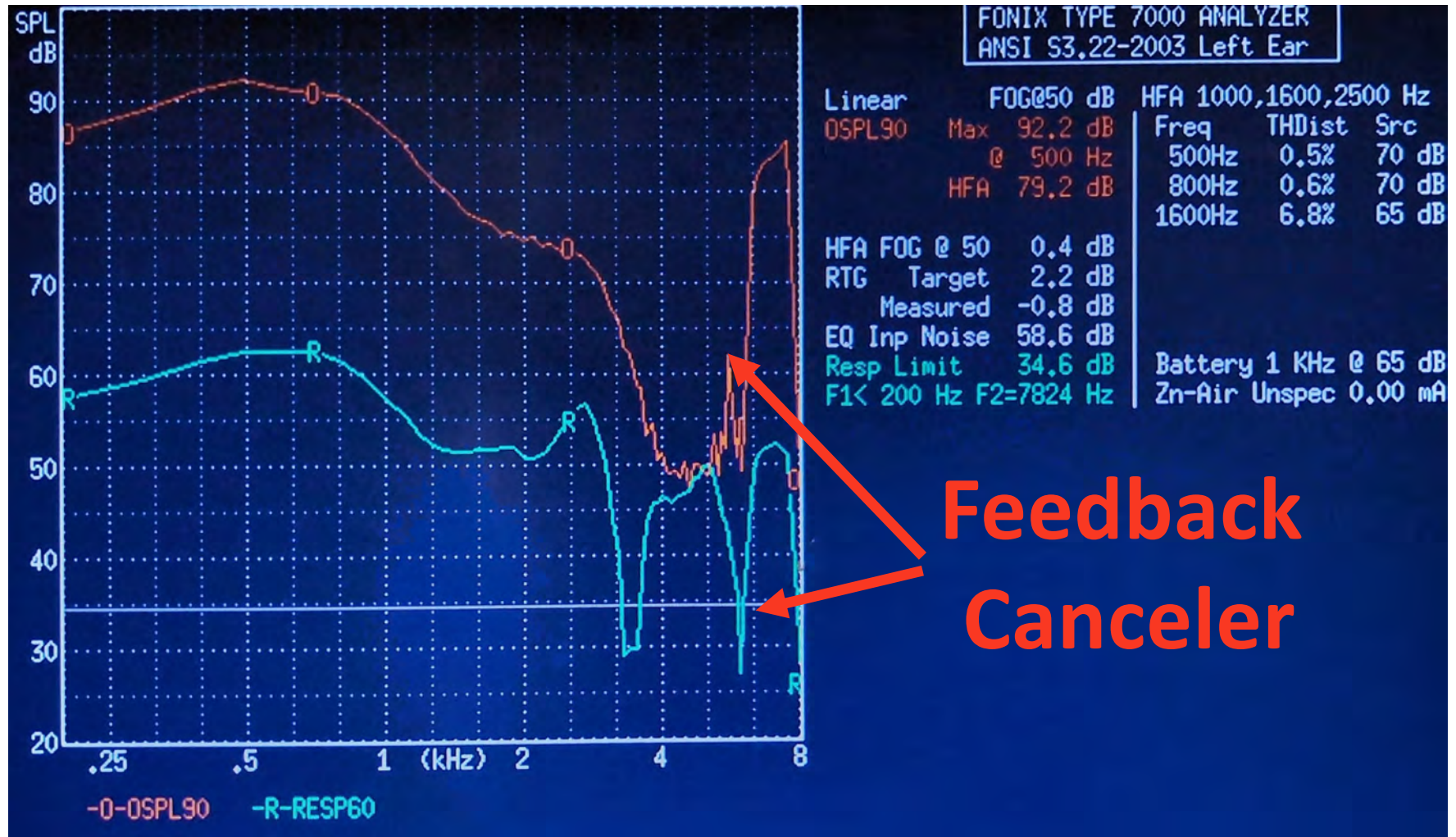
ANSI Test Hearing Aid Setting

- **DO NOT RUN THE 'ANSI TEST' AT USER SETTINGS**
- The premise behind standards is repeatability
- Problems with modern digital hearing aids
 - **Alter incoming sounds** in an attempt to reduce noise and feedback and/or alter how they amplify sounds depending on the relative speech and noise levels

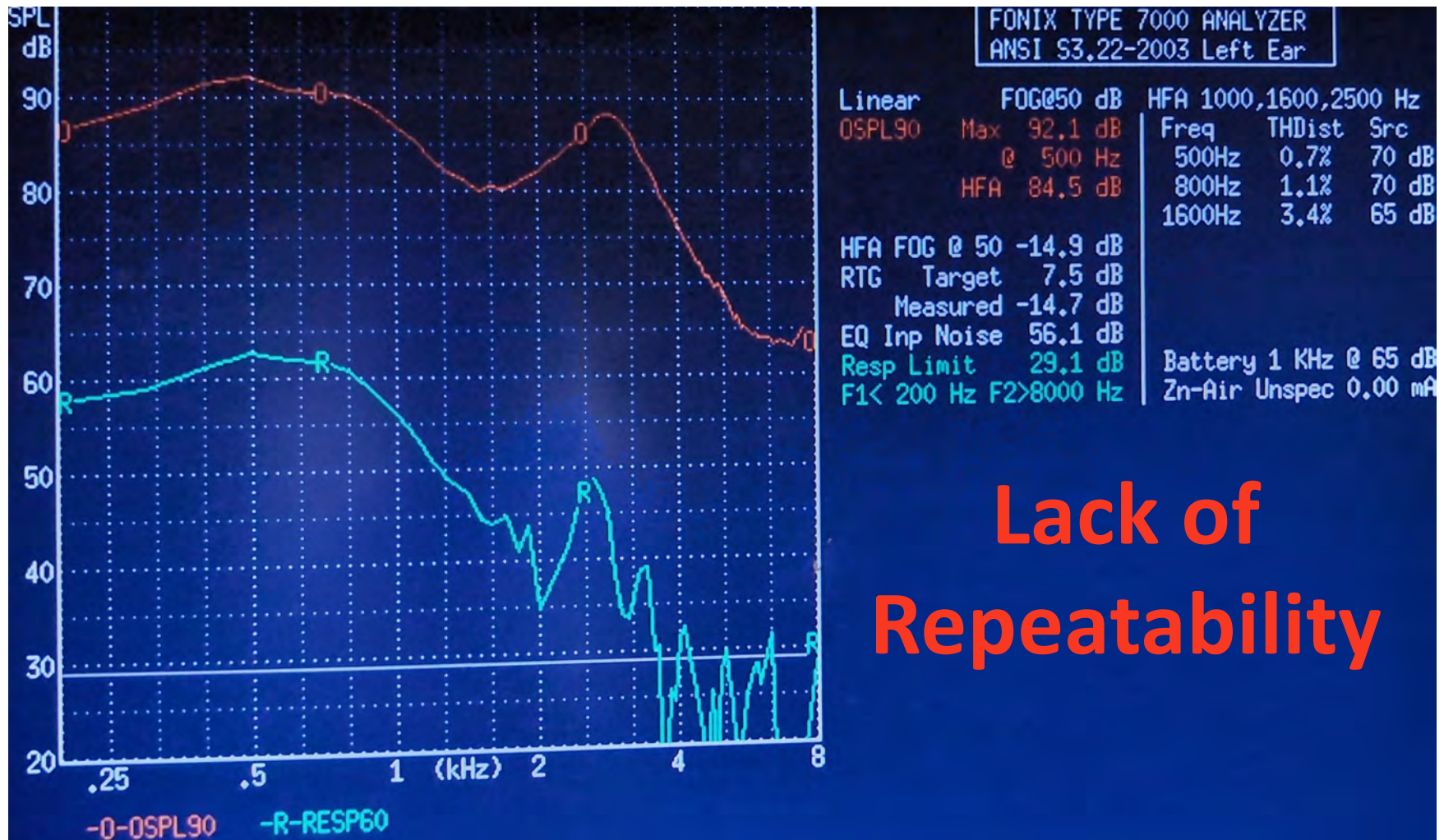
HA 1 at USER Setting



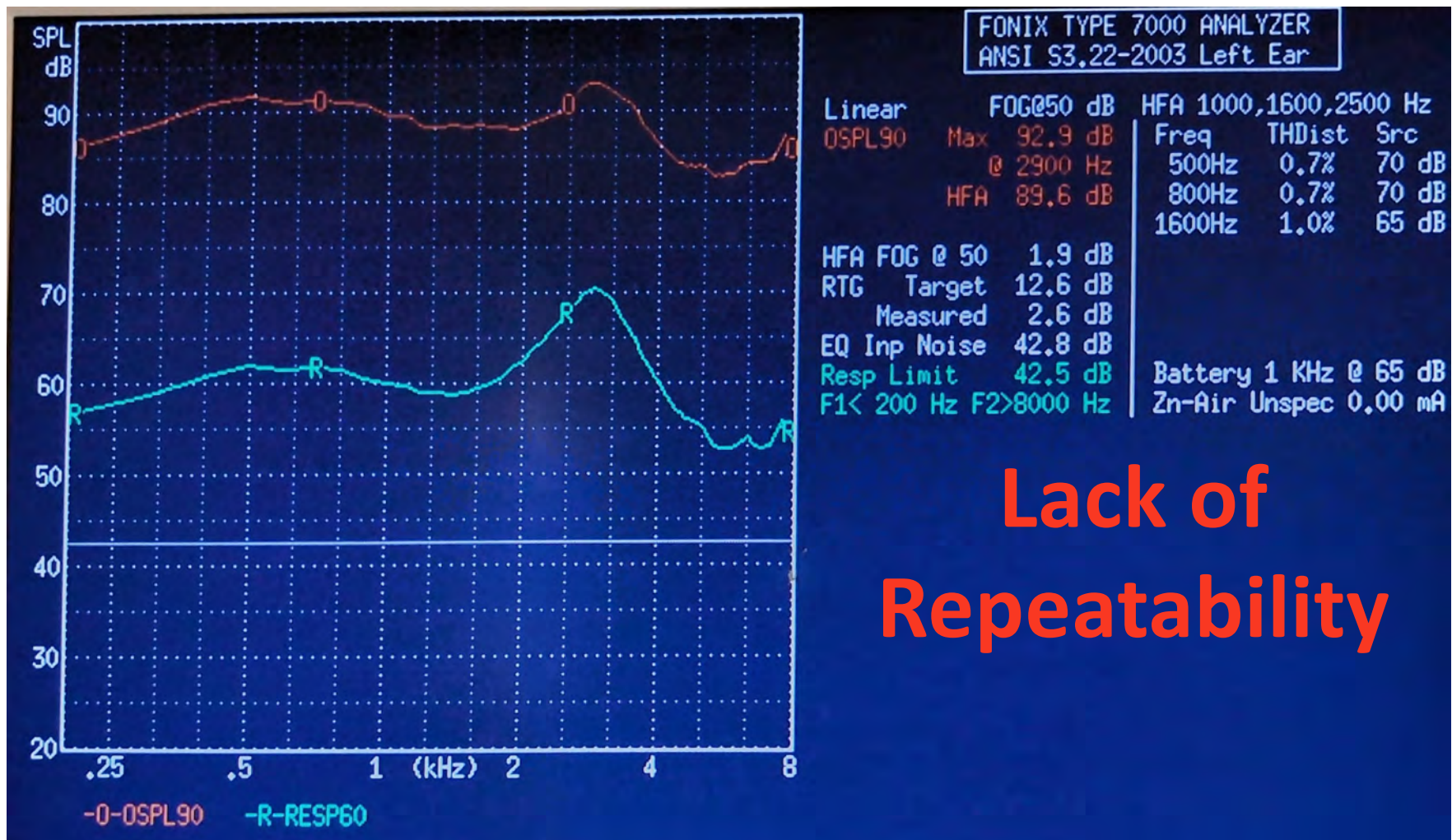
HA 2 at USER Setting, Run 1



HA 2 at USER Setting, Run 2



HA 2 at USER Setting, Run 3



ANSI Test Hearing Aid Setting

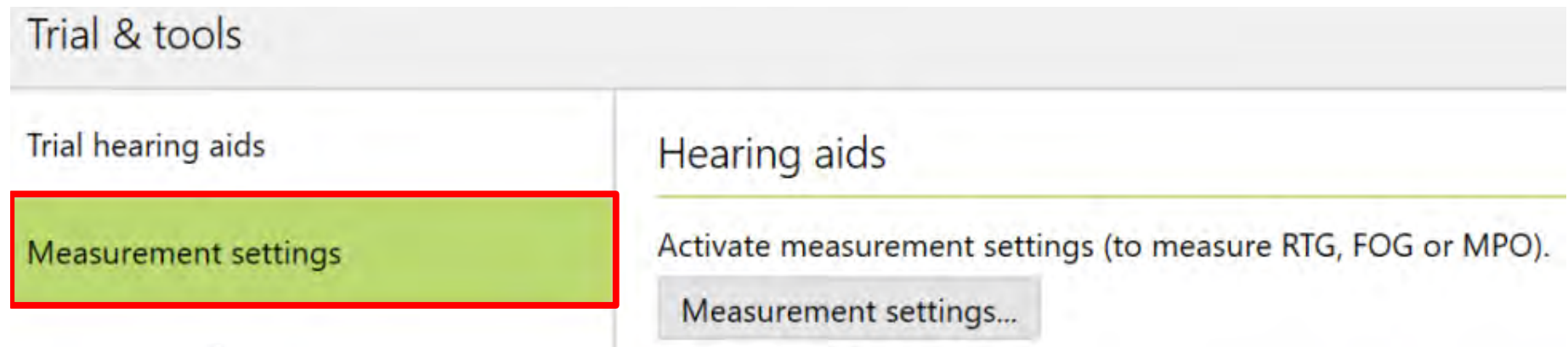
- **Full-On Gain (FOG)**
 - Volume control at its maximum setting

- **Reference Test Gain (RTG)**
 - The HFA gain for an input SPL of 60 dB with the gain control at the **Reference Test Setting** (*more later*)
 - More representative of **typical usage**

Finding Manufacturers' ANSI Test Setting

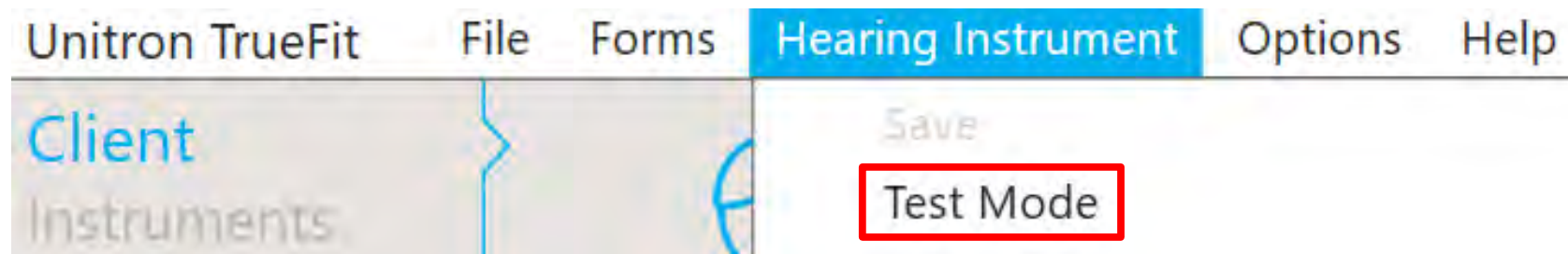
Phonak (Target v9.0)

No client is necessary. Open the Target module, then click the **Trials & tools** icon at the bottom. Then select **Measurement settings** on the left menu.



Unitron (TrueFit v5.5)

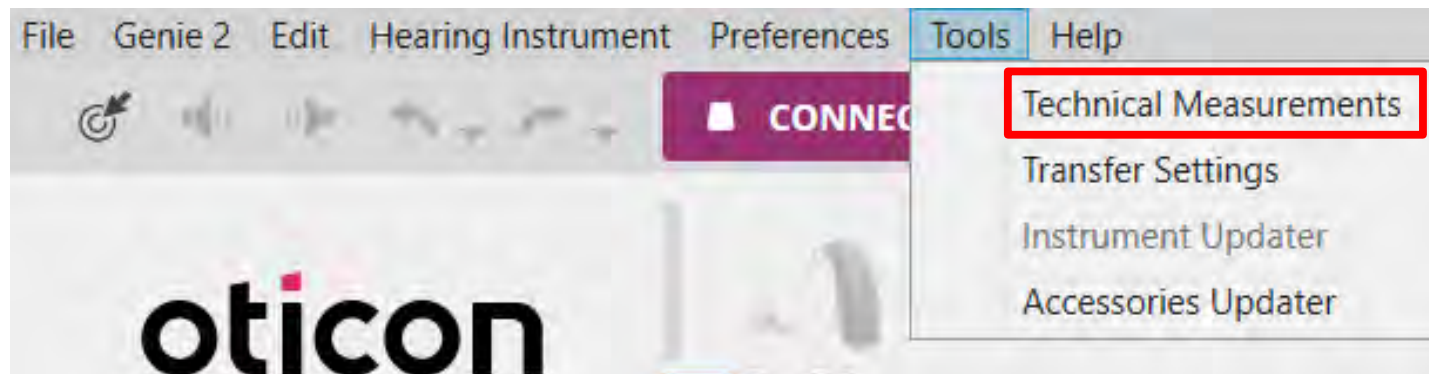
No client is necessary. Select **Test Mode** under the **Hearing Instrument** menu at the top.



Finding Manufacturers' ANSI Test Setting

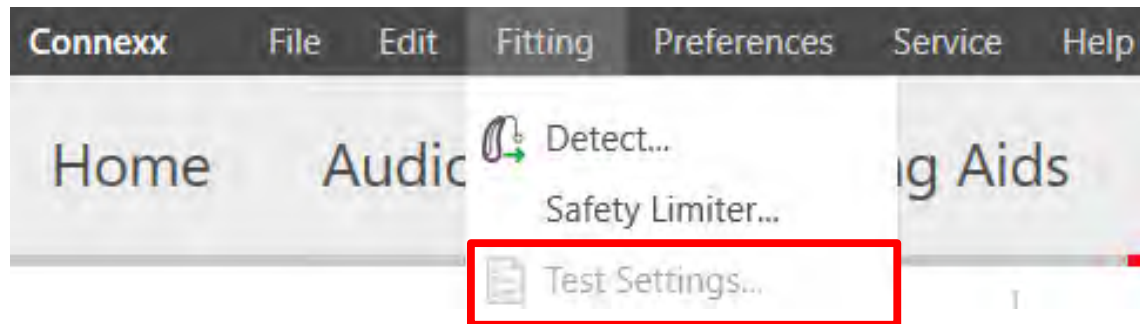
Oticon Genie 2 (v2023.2)

After loading the client, select **Technical Measurements** under the **Tools** menu.



Signia (Connexx 9.11)

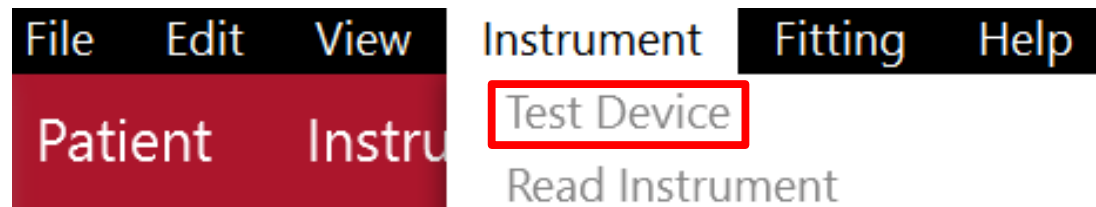
After loading the client, click the **Fitting** menu on the top of the screen. Then, select “**Test Settings.**”



Finding Manufacturers' ANSI Test Setting

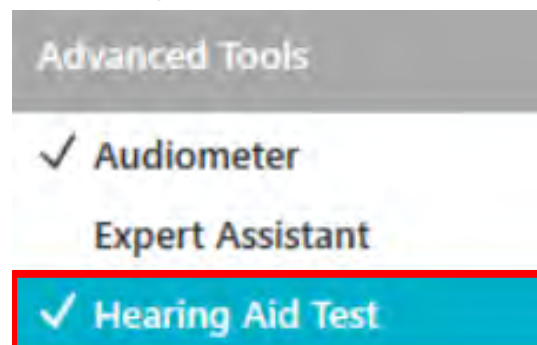
ReSound (Smart Fit 1.17)

After loading the client, select **Test Device** under the **Instrument** menu.



Starkey (Inspire X 2023.1)

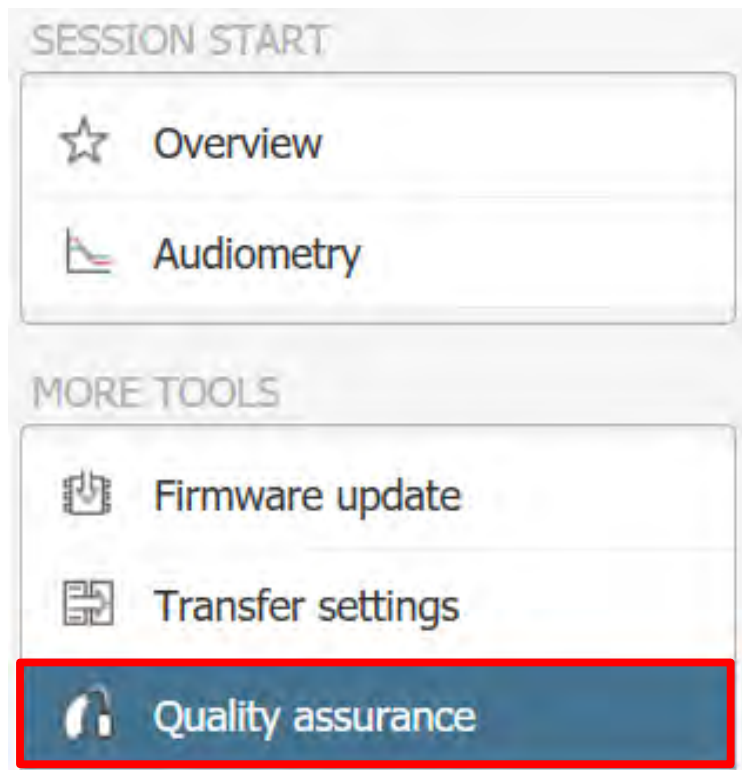
After loading the client, click the **Advanced Tools** menu on the left side of the screen. Then, select "Hearing Aid Test."



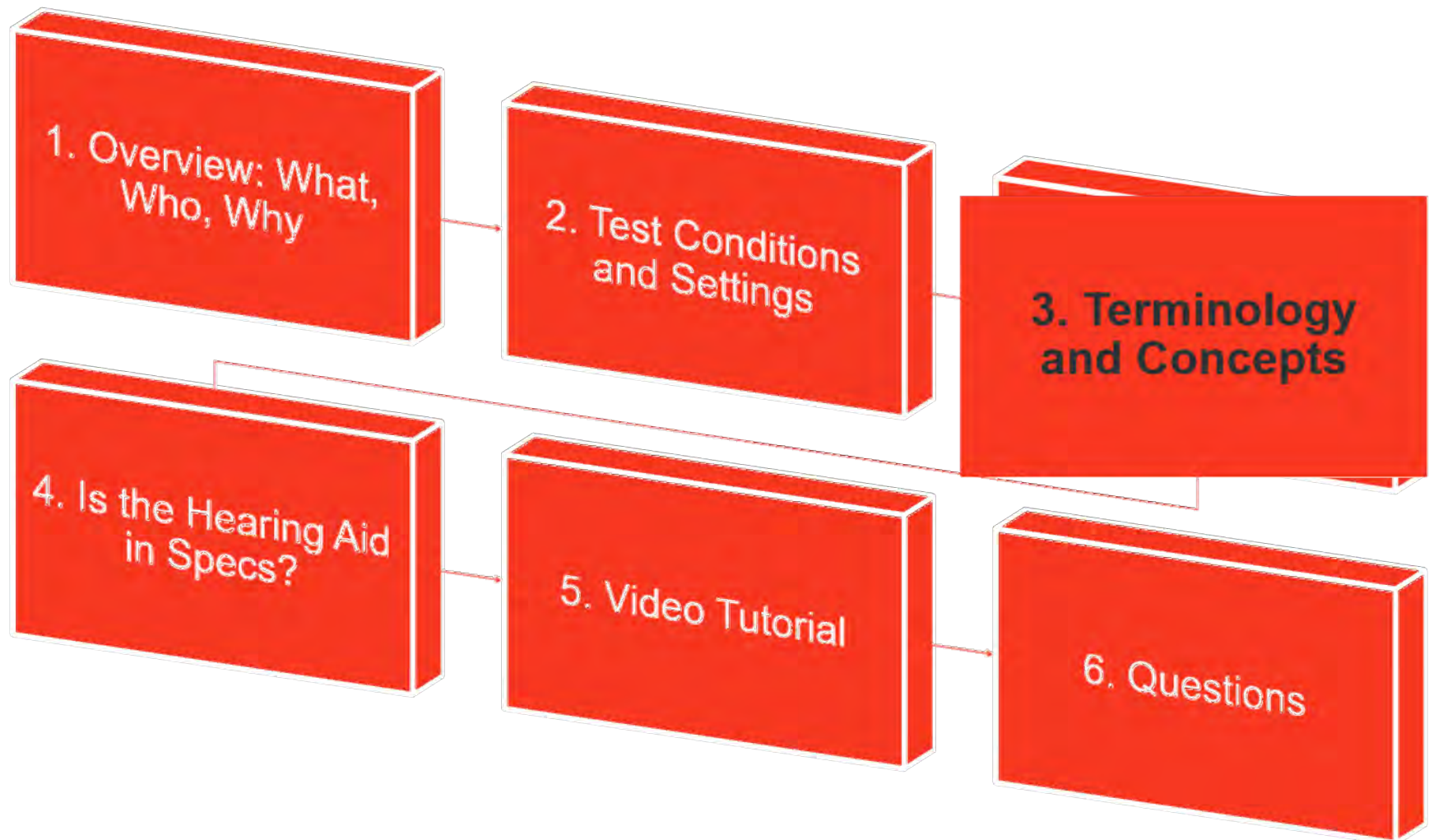
Finding Manufacturers' ANSI Test Setting

Widex (COMPASS GPS 4.5)

After loading the client, click the **Quality assurance** option on the left side of the screen.



Roadmap



General Purpose of ANSI S3.22

- Provides a method of ascertaining whether a hearing aid, after being manufactured and shipped, meets the specifications and design parameters stated by the manufacturer for a particular model, within the tolerance stated by the standard
- (1) Make a measurement, (2) compare it to the manufacturer's measurement, (3) check to see if the difference is within the tolerance

Interpretation of Tolerances

- **Tolerances:** the range that the measurements can be in and still be considered to be '**within specs**'
- The allowable tolerances **must be increased by the accuracy** of the measuring equipment
 - Clause 6.15: To be within specs, the difference between measurements must be
$$< \text{tolerance} + \text{accuracy}$$
 - For example, if measurement equipment accuracy is ± 1 dB, and the tolerance given in the table for a particular test is ± 3 dB, a measured value within ± 4 dB of the value listed by the manufacturer would be considered to be within specification

Verifit 1 Accuracies

Verifit 1 User's Guide v3.26, January 2022

- Measurement accuracy (200-5000 Hz): ± 1.0 dB
- Measurement accuracy (5000-8000 Hz): ± 2.5 dB
- Harmonic distortion accuracy: ± 1.0
- Battery drain accuracy: $\pm 5.0\%$

Verifit 2 Accuracies

Verifit2 User's Guide 2023.2

- Measurement accuracy (200-5000 Hz): ± 1.0 dB
- Measurement accuracy (5000-12,500 Hz): ± 3.0 dB
- Harmonic distortion accuracy:
 - 250 Hz = 3.5-5.5%
 - 1000 & 2000 Hz = 3.5-5.5%
 - 4000 Hz = 2.2-4.2%
- Battery drain accuracy: $\pm 5.0\%$

Frye Fonix 7000 Accuracies

Frye 7000 Operators Manual v1.64, rev. 3-2009

- Measurement accuracy (300-5000 Hz): ± 1.0 dB
- Measurement accuracy (all other freq.): ± 2.0 dB
- Harmonic distortion accuracy: $\pm 0.1\%$
- Battery drain accuracy: $\pm 5.0\%$
- Attack/release: larger of $\pm 10\%$ or ± 2 ms

Averages

- **High-Frequency Average (HFA)**
 - The average gain or SPL at 1000, 1600, and 2500 Hz
- **Special Purpose Average (SPA)**
 - The average gain or SPL at three 1/3 octave band frequencies (ANSI S1.6-1984, R2006), each separated by 2/3 octave selected by the manufacturer
- Throughout the standard, wherever the term high-frequency average or HFA appears, special-purpose average or **SPA may be substituted**

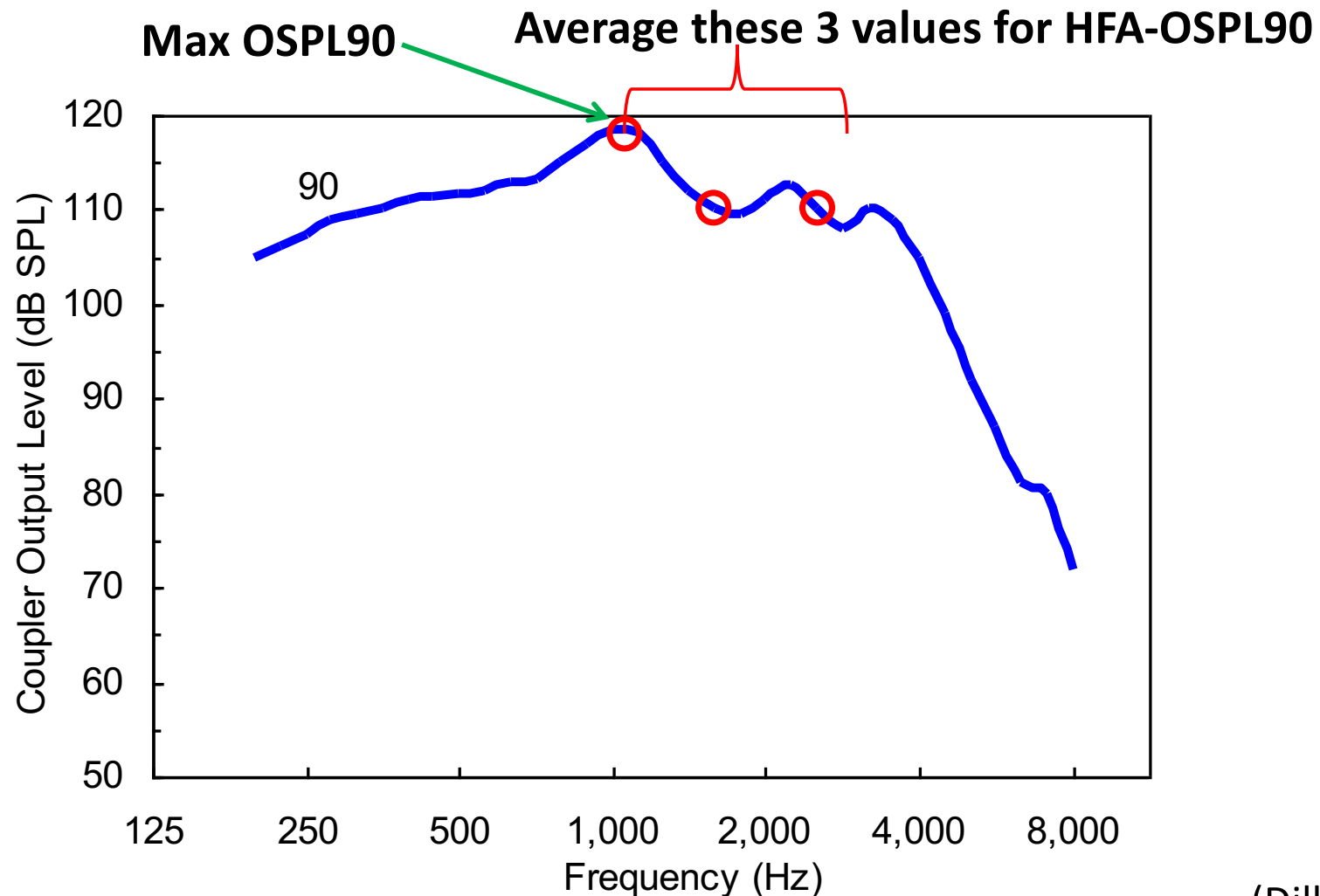
OSPL90

- **Output SPL for 90-dB input SPL**
 - Run with the hearing aid at full-on gain (**FOG**)
 - SPL developed in coupler when the input SPL is 90 dB
- **Purpose:** approximate the **maximum output** level the hearing aid can produce
 - Maximum output may occur with a slightly higher or lower input than 90 dB SPL, but the differences are usually small
 - A single value makes automatic recording very *convenient*
- Test signal is a **pure-tone sweep**
 - All the energy of the signal at one instant is concentrated around **one frequency** region, which will give the maximum output at that region

HFA-OSPL90 and Max OSPL90

- **HFA-OSPL90: High-frequency average OSPL90**
 - The high-frequency average of the OSPL90 levels
 - OSPL90 is a curve, HFA-OSPL90 is a number
 - **Tolerance = +/- 4dB** of the manufacturer's specified value
- **Maximum OSPL90**
 - Maximum SPL from the OSPL90 curve between 200-5000 Hz (not necessarily one of the HFA frequencies)
 - **Tolerance = +3dB** of the manufacturer's specified value

OSPL90, HFA-OSPL90, and Max OSPL90



(Dillon, 2001)

HFA-FOG

- Full-on gain (FOG) shall be determined with the gain control of the hearing aid set to its full-on position and with an **input SPL of 50 dB**
 - HFA: average FOG at 1000, 1600, and 2500 Hz
- **Tolerance = +/- 5dB** of the manufacturer's specified value
- **Purpose** is to approximate the **greatest gain** the hearing aid is capable of
 - *Hearing aids with WDRC amplify (add gain) soft sounds more than loud sounds, hence input level is low*

Reference Test Gain (RTG)

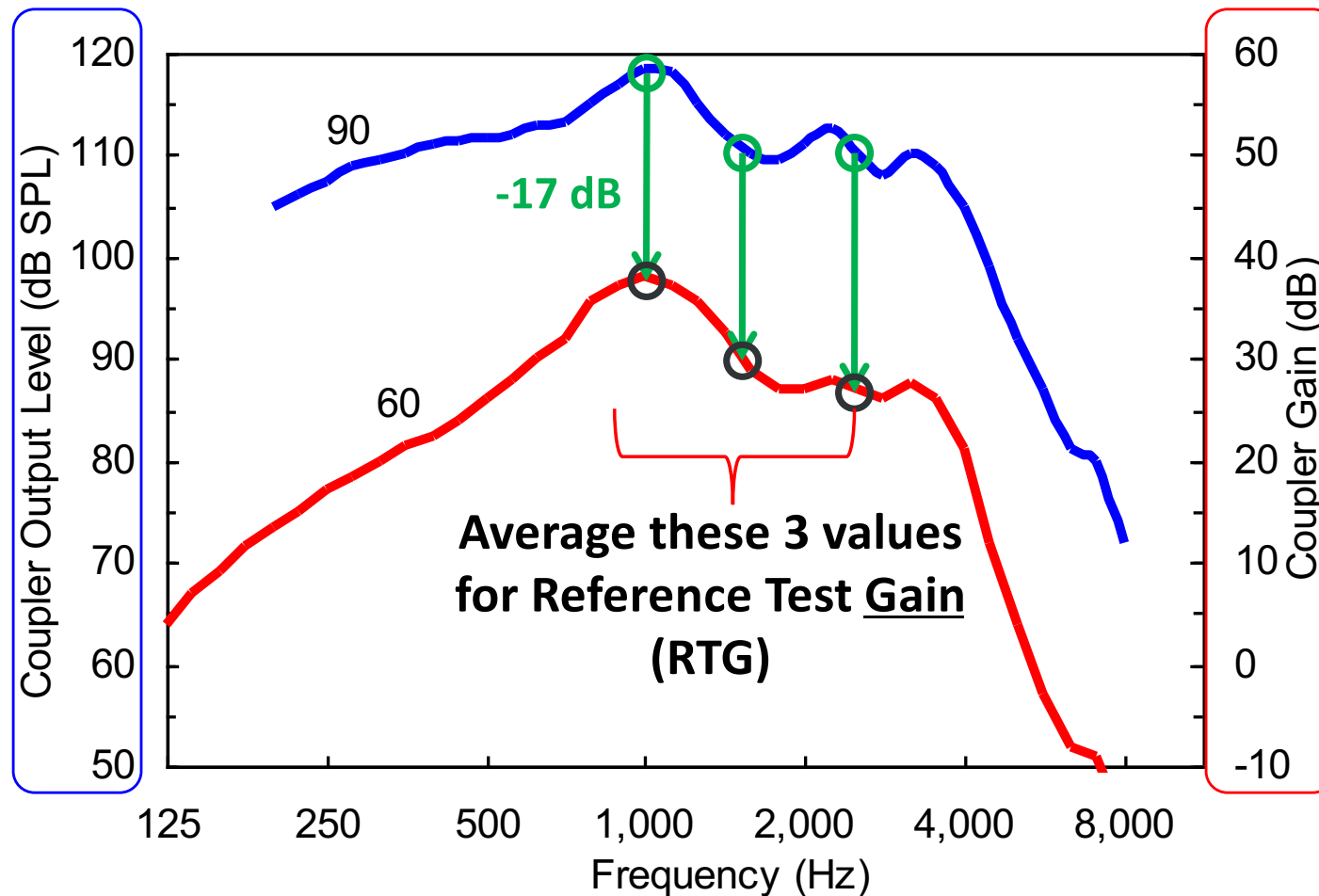
- **Reference Test Setting (RTS)** of gain control
 - “For a 60 dB input SPL, the setting of the gain control required to produce an HFA-gain within +/- 1.5 dB of the **HFA-OSPL90 minus 77 dB**. If the full-on HFA gain for a 60 dB input SPL is less than the HFA OSPL90 minus 77 dB, the RTS is the full-on position of the gain control.” (Clause 3.2.4)
- **Rationale:** more representative of **typical usage**
 - LTASS (**L**ong-**T**erm **A**verage **S**peech **S**pectrum) at 1 meter is about 65 dB SPL with peaks 12 dB above this or 77 dB SPL

Reference Test Gain (RTG)

What you need to know

- For a 60 dB SPL test signal, it is the hearing aid gain needed to turn down the OSPL90 by 17 dB
- **RTG = HFA-OSPL90 – 77 dB** (Clause 3.2.4)
 - Input + Gain = Output
 - Speech_Peaks + Typical_Gain = Max_Output
 - 77 + RTG = HFA-OSPL90
 - RTG = HFA-OSPL90 – 77
 - RTG = HFA-OSPL90 – (60+17)

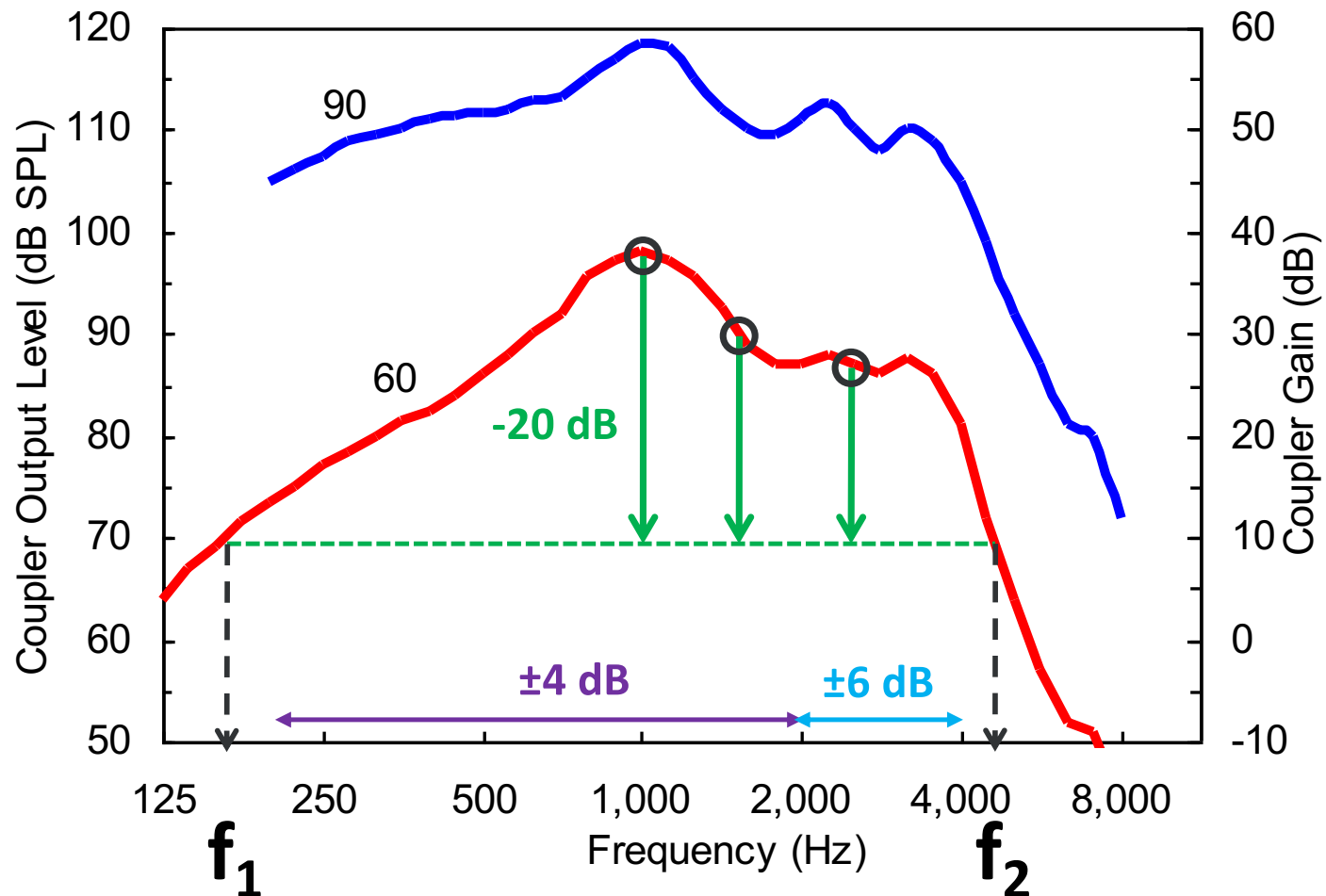
Reference Test Gain (RTG)



Frequency Response Range

- Range between the lowest and highest frequency at which the frequency response curve is **20 dB below its HFA value**
 - Subtract 20 dB from HFA on the reference test curve
 - Draw a horizontal line parallel to the frequency axis at this point
 - Note the lowest and highest frequencies (f_1 and f_2 , respectively) at which the response curve **intersects the horizontal line**
 - The low-frequency limit shall be the **higher of f_1 or 200 Hz**
 - The high-frequency limit shall be the **lower of f_2 or 5000 Hz**

Frequency Response Range and Curve



Tolerances: Gain on the frequency response curve must be ± 4 dB from the greater of $1.25f_1$ or 200 Hz to 2kHz and ± 6 dB from 2kHz to the lesser of 4kHz or $0.8f_2$

(Dillon, 2001)

Frequency Response Curve

- **Important:** this does NOT actually represent the usable frequency range of the hearing aid
 - It is a procedural definition
 - It **does not consider what is audible** for a hearing loss
 - Using this standard, some manufacturers will report a wider bandwidth than can be practically achieved for a person with **significant hearing loss**

Total Harmonic Distortion (THD)

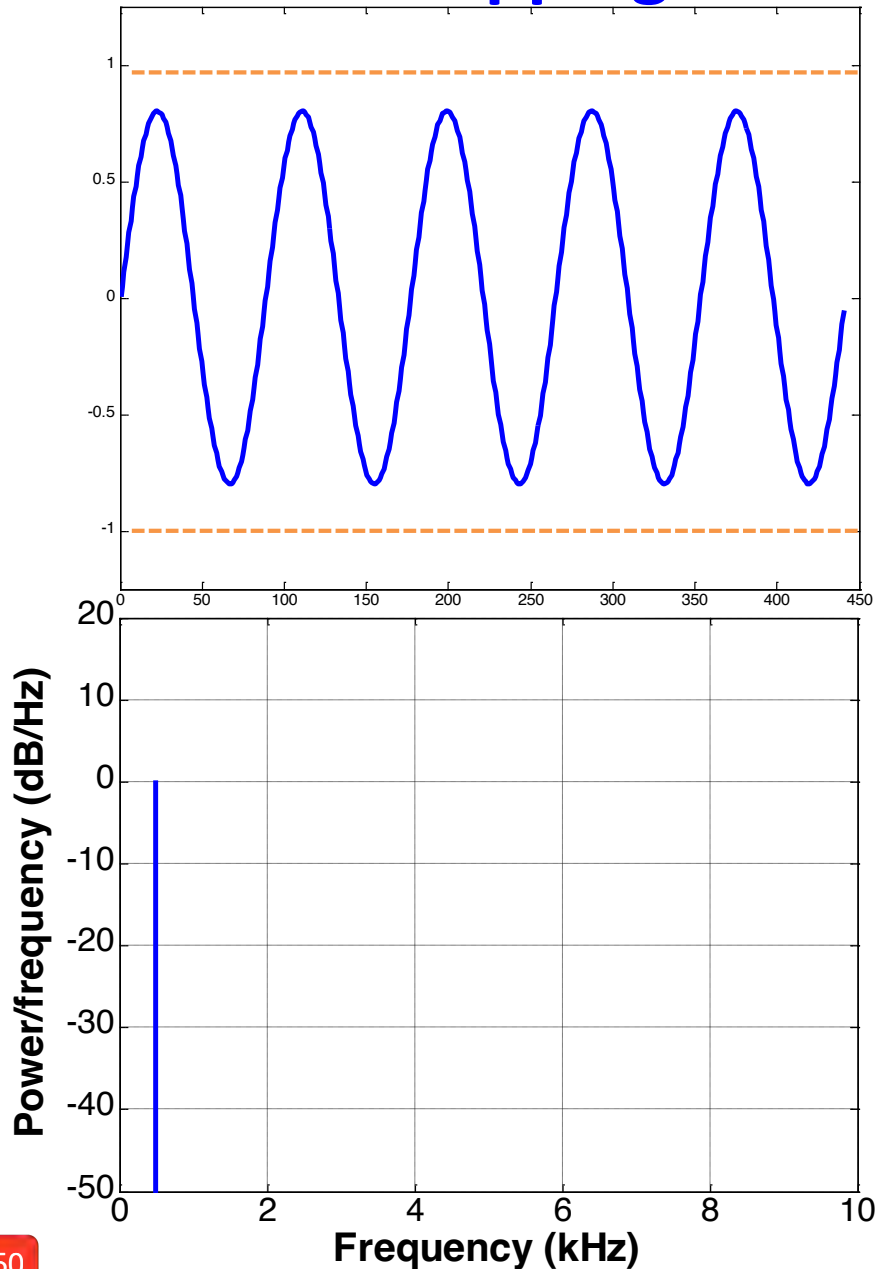
- **Hearing aid volume:** RTG
- **Test tone frequencies:** 500, 800, 1600 Hz or the SPA frequencies divided by 2
- **Signal input levels:** 70 dB SPL for the two lowest test frequencies and 65 dB SPL for the highest frequency
- % THD is ratio of sum of the powers of all the harmonics (**non-test frequencies**) to the power of the fundamental (p_1 is the **test frequency**)

$$\%THD = 100 \sqrt{(p_2^2 + p_3^2 + p_4^2 + \dots) / p_1^2}$$

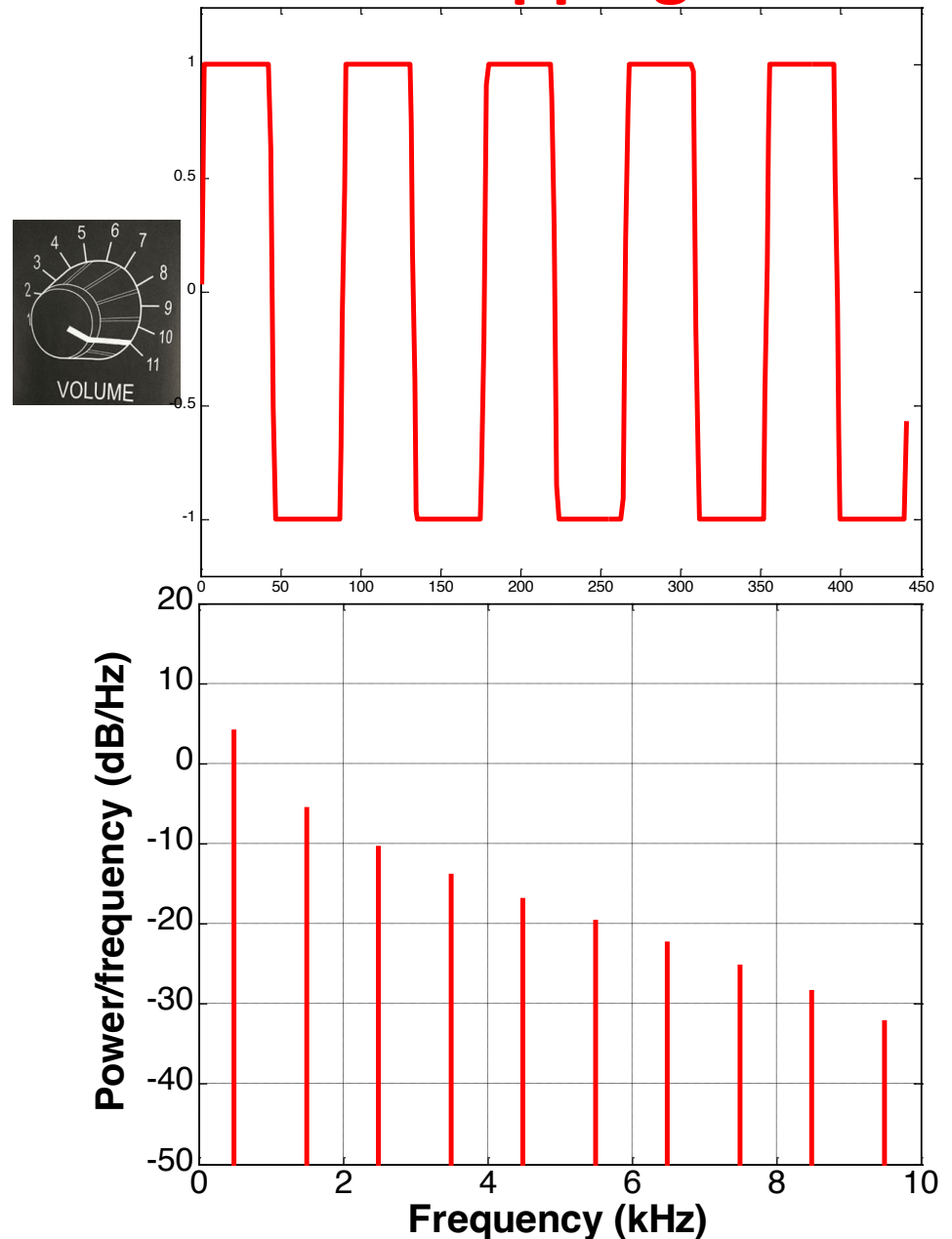
- **Tolerance = +3%** of manufacturer's specified value

Example: Peak Clipping

No Clipping



Clipping



Total Harmonic Distortion Example

- Total Harmonic Distortion (THD)
 - Compares the power of the non-signal harmonics (p_2 and above), to the total power of the signal (the 1st harmonic, p_1)

$$THD = 100 \sqrt{\frac{p_2^2 + p_3^2 + p_4^2 + \dots}{p_1^2}} \%$$

Harmonic	Level	Power
500	4.2	2.630
1500	-5.5	0.282
2500	-10.3	0.093
3500	-13.8	0.042
4500	-16.8	0.021
5500	-19.6	0.011
6500	-22.3	0.006
7500	-25.2	0.003
8500	-28.4	0.001
9500	-32.1	0.001

$$\sqrt{\frac{0.46}{2.63}} = 42\%$$

Internal Noise

- Noise that is **not** present in the acoustic input signal, but is added by the hearing aid itself as an unintentional by-product of its design and/or processing
- Internal noise is added to any external signal processed by the hearing aid, potentially **degrading the fidelity** of the sound
- Can arise anywhere along the hearing aid processing path, but **most of it is from the microphone**

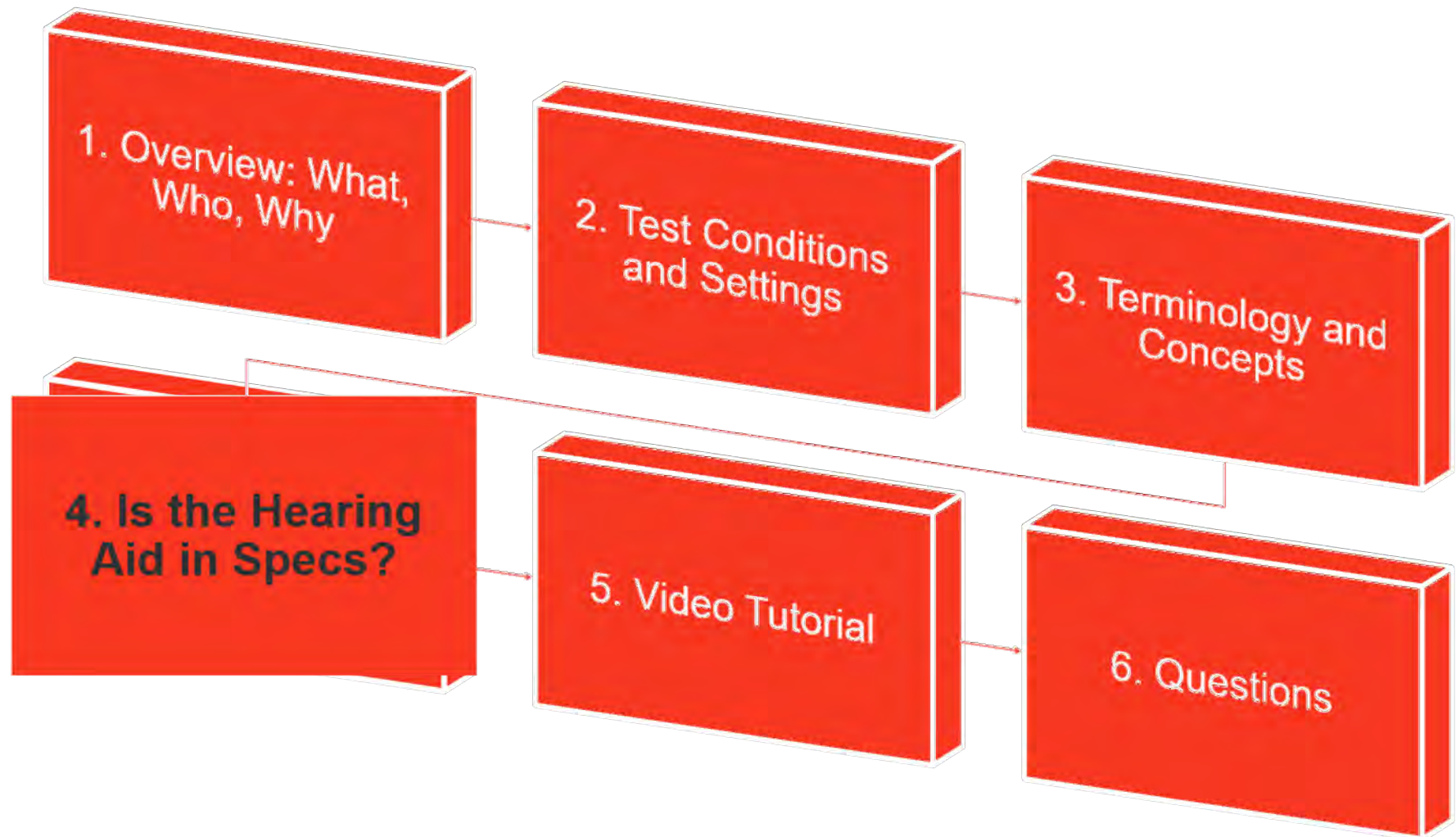
Equivalent Input Noise Level (EIN)

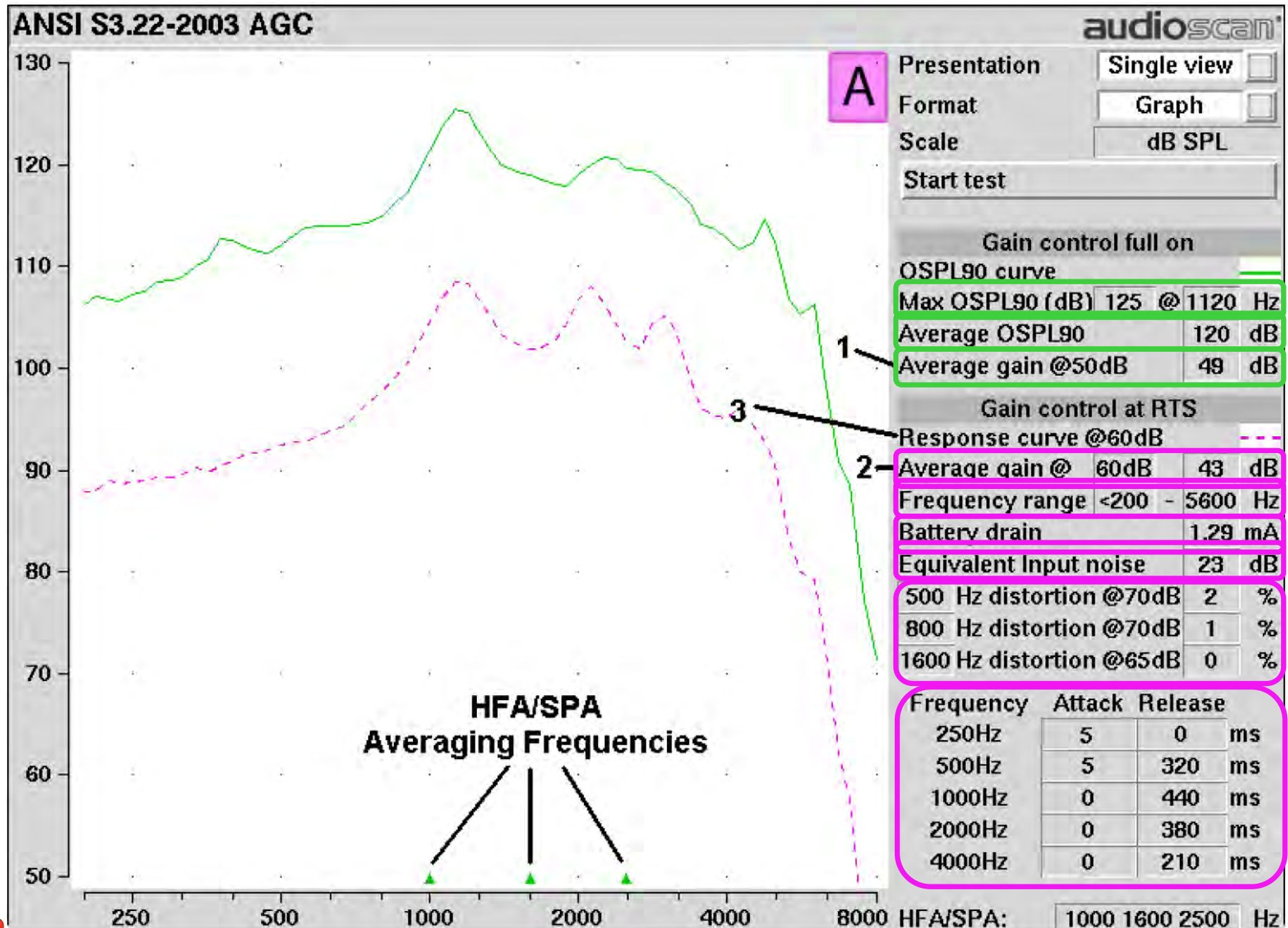
- With the hearing aid gain set to RTG, it measures the coupler SPL with the sound source **turned off** and then subtracts the gain (RTG)
 - **Equivalent Input Noise (EIN) =**
(Hearing aid output SPL with no input) - RTG
- **Tolerance = +3 dB** of manufacturer's specified value

Equivalent Input Noise Level (EIN)

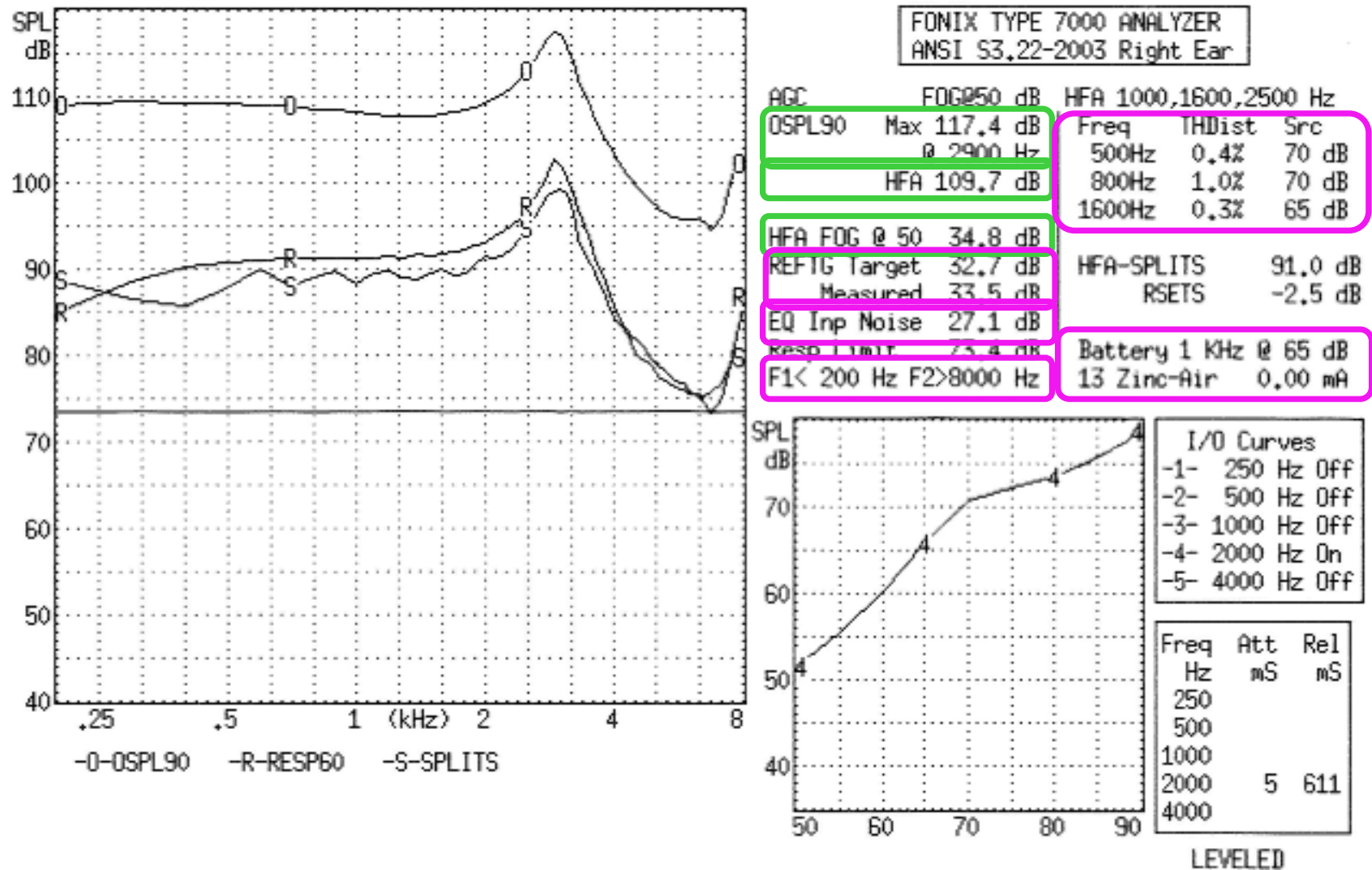
- **Cannot** be used to compare the ‘noisiness’ between hearing aids since this measure depends on their frequency responses
 - If one of the HFA reference frequencies falls in the peak of the response it will be high, if they all fall in the ‘troughs’ it will be low
- **Feedback will cause excessive EIN**
 - If using an HA1 coupler (for RICs and custom products), be sure the receiver is adequately sealed to the coupler (e.g., with putty)

Roadmap





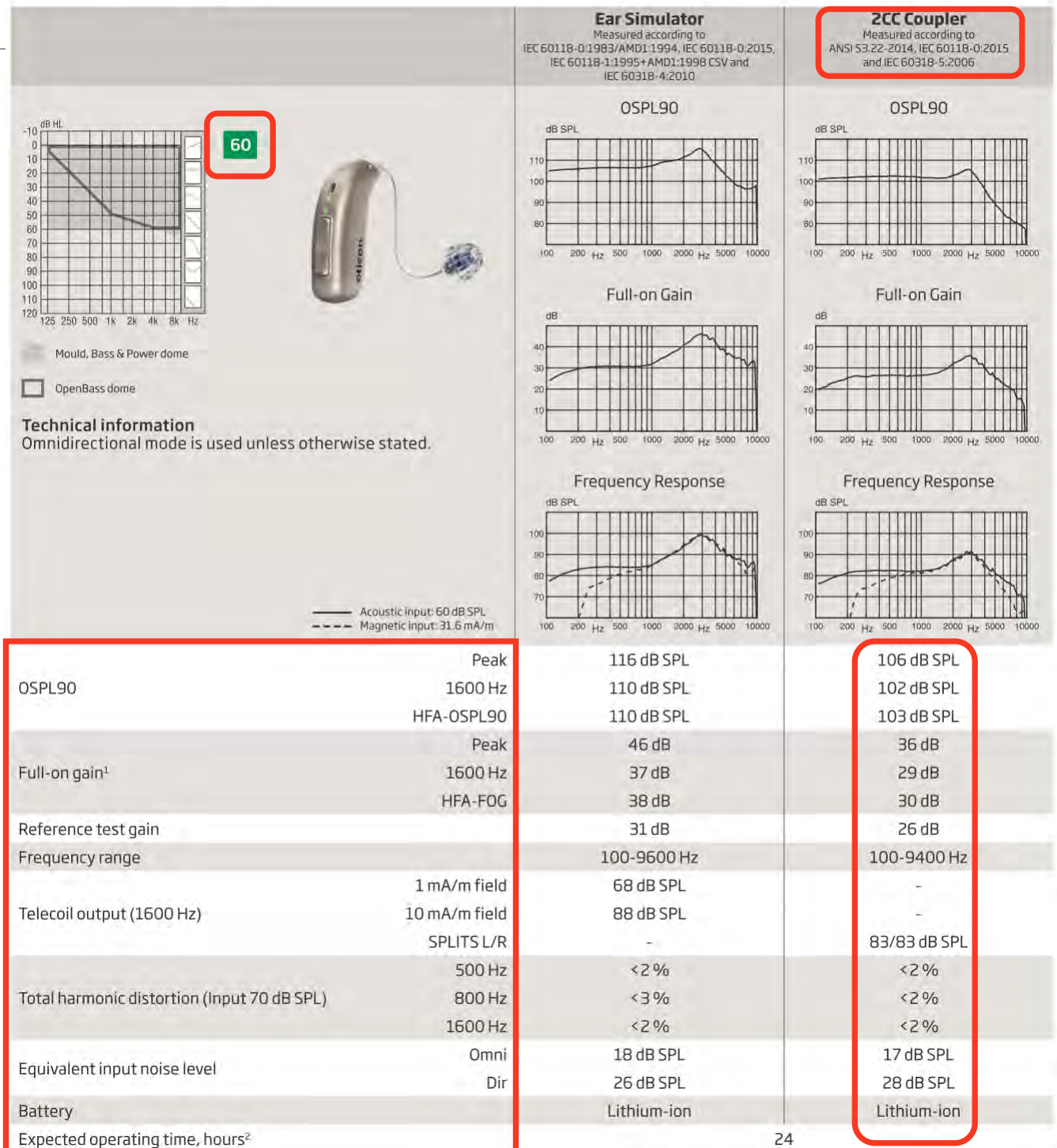
Fonix 7000



ANSI Spec Sheet

Double Check

- Model
- Technology level
- Receiver power
- 2 cc coupler



Double Check

- Model
- Technology level
- Receiver power
- 2 cc coupler

ANSI Spec Sheet

Technical specifications

		LP		MP		
		IEC 60118-0:1983_AMD1:1994 IEC 60118-0:2015 IEC 711 Ear Simulator	ANSI S3.22-2014 IEC 60118-0:2015 JIS C 5512: 2015 2cc coupler	IEC 60118-0:1983_AMD1:1994 IEC 60118-0:2015 IEC 711 Ear Simulator	ANSI S3.22-2014 IEC 60118-0:2015 JIS C 5512: 2015 2cc coupler	
Reference test gain (60 dB SPL input)	1600 Hz/HFA	41	32	46	37	dB
Full-on gain (50 dB SPL input)	Max. 1600 Hz/HFA	63 54	53 46	69 60	58 52	dB
Maximum output (90 dB SPL input)	Max. 1600 Hz/HFA	123 116	113 108	126 121	116 114	dB SPL
Total harmonic distortion	500 Hz 800 Hz 1600 Hz	0.6 0.6 0.5	0.5 0.2 0.4	0.8 1.3 0.8	0.6 0.6 0.7	%
Telecoil sensitivity (1 mA/m input)*	Max.	93	83	98	90	
HFA - SPLIV @ 31.6 mA/m (ANSI)	HFA	102	92	107	97	dB SPL
Full-on telecoil sensitivity @ 1mA/m	1600 Hz/HFA	83	76	89	83	
Equivalent input noise, w/o noise reduction		21	20	21	20	dB SPL
1/3 Octave Equivalent input noise, w/o noise reduction	1600 Hz	5	7	6	7	dB SPL
Frequency range IEC60118-0:2015**		100-9640	100-9410	100-9560	100-9160	Hz
Battery Lifetime (Battery type Rechargeable)***		30	30	30	30	Hours
Current Drain (Quiescent / Operating) (Model 61-DRW, 62-DRW)		0.81 / 1.03	0.81 / 1.04	0.81 / 0.91	0.81 / 1.04	mA

* Telecoil is only for the RTx62-DRW models.

** Measured according to IEC 60118-0:2015, with 711 Ear Simulator coupler.

*** Expected operating time of the rechargeable battery depends on active features, the use of wireless accessories, hearing loss, battery age and sound environment.

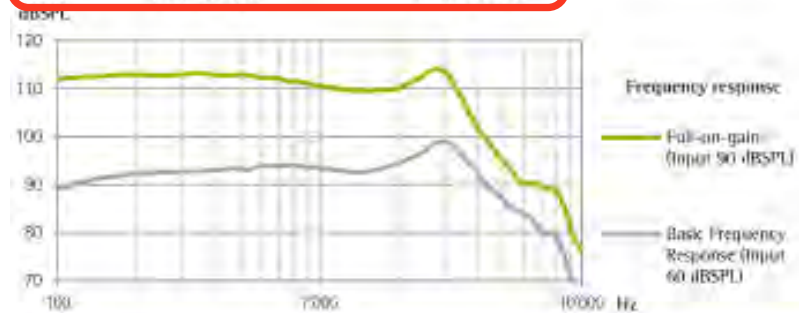
ANSI Spec Sheet

M Receiver 2 cm³ coupler data

ANSI / ASA S3.22-2014
IEC 60118-0 : 2015

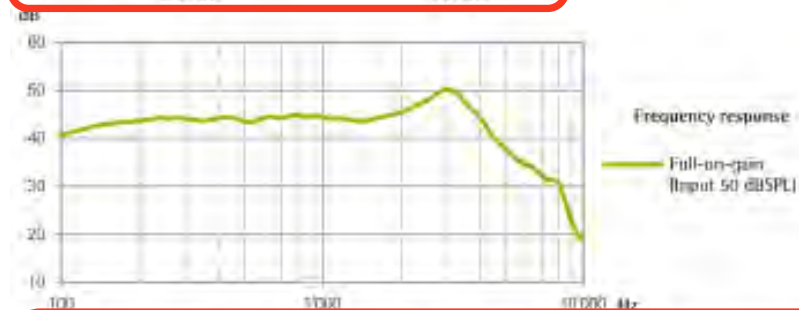
Output sound pressure level

Maximum 114 dB SPL HFA 111 dB SPL



Acoustic gain

Maximum 50 dB HFA 45 dB



Frequency range	<100 Hz - >8000 Hz			
Total harmonic distortion	500 Hz	800 Hz	1600 Hz	3200 Hz
	1.5%	2.0%	2.0%	1.0%
Expected operating time*	18	h		
Equivalent input noise level	19	dB SPL		

Strategies for Finding Manufacturer ANSI Specifications

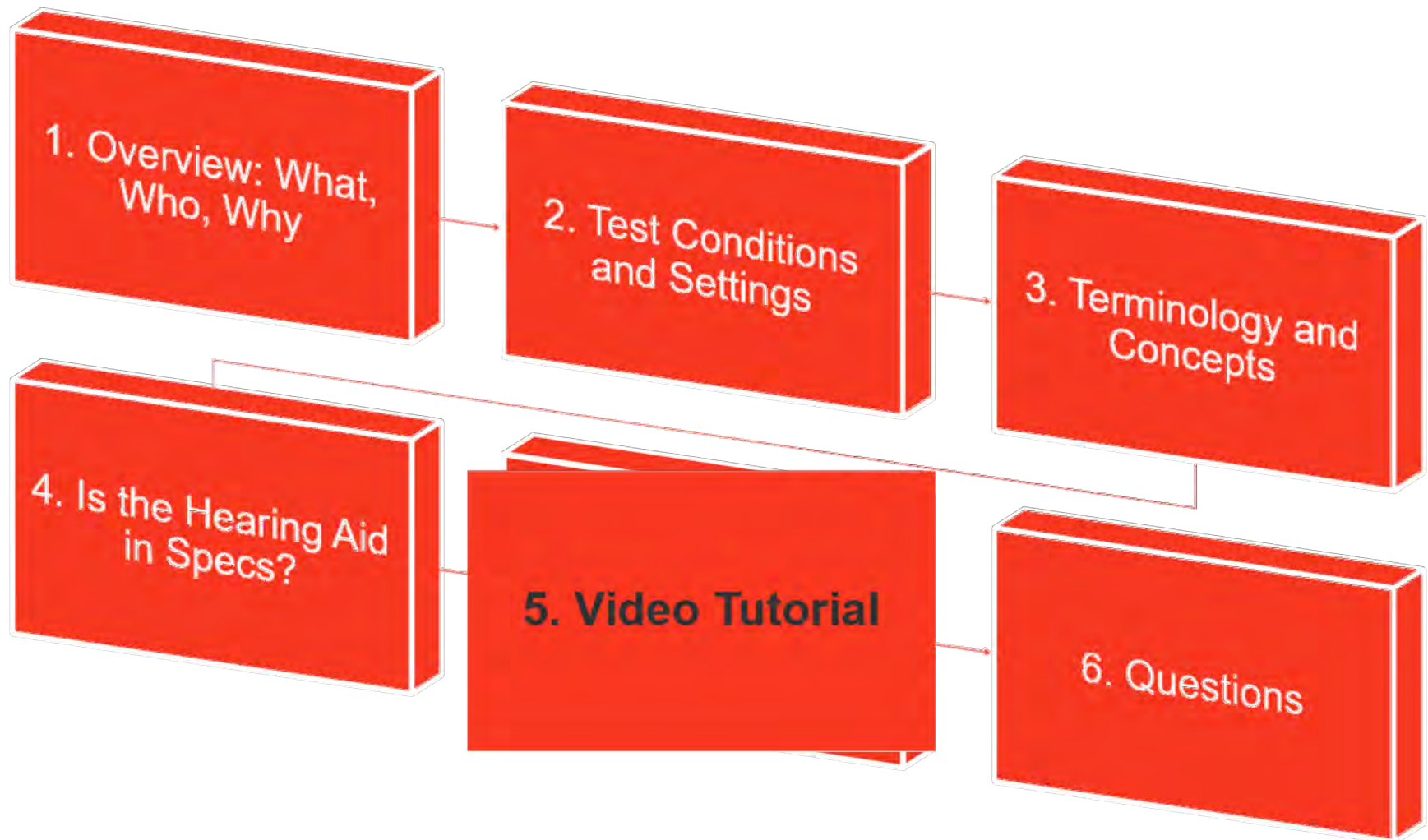
- The product packaging
- The programming software
- The internet
 - Manufacturer's website
 - Search Google, **Perplexity.AI**
 - “ANSI Technical Data Sheet [Make Model]”

A Useful Tool for Recording Results

Hearing Aid:			Date:		Tester(s):		
Serial #:							
ANSI S3.22-2014 Measure	Tolerance	Verifit Accuracy	Manufacturer's Measurement	Lowest Acceptable	Highest Acceptable	Clinician's Measurement	In Specs?
Max OSPL90 (dB)	3	1	126	122	130	125	Yes
HFA-OSPL90 (dB)	4	1	120	115	125	120	Yes
HFA-FOG (dB)	5	1	45	39	51	46	Yes
f1 (Lower Freq. Limit, Hz)	-	-					
f2 (Higher Freq. Limit, Hz)	-	-					
Current Drain (mA)	20%	5%	1.35	1.0125	1.6875	1.29	Yes
EIN (dB)	3	1	22	18	26	23	Yes
THD @ 500 Hz (%)	3%	1.0%	1%	0.0%	5.0%	2%	Yes
THD @ 800 Hz (%)	3%	1.0%	1%	0.0%	5.0%	1%	Yes
THD @ 1600 Hz (%)	3%	1.0%	1%	0.0%	5.0%	0%	Yes
HFA/SPA Frequencies (Hz)	1000, 1600, 2500						
(Accuracies from Verifit User's Guide v3.26)							

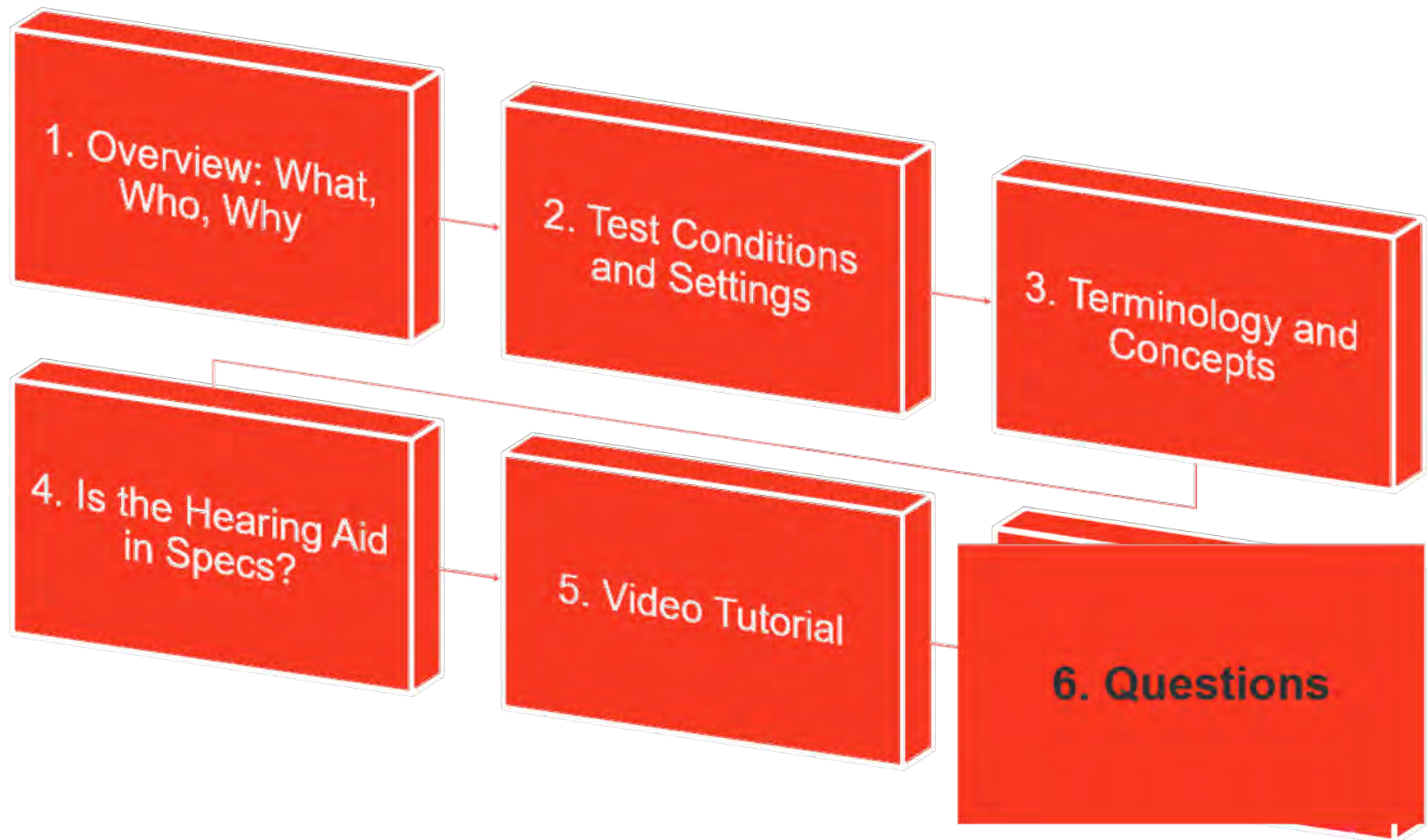
https://web.ics.purdue.edu/~alexan14/Downloads/ANSI_Table

Roadmap



Video Tutorial

Roadmap



References

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- Dillon, H. (2001). Hearing Aids (New York: Thieme).
- Frye, G. J. (2005). “Understanding the ANSI Standard as a Tool for Assessing Hearing Instrument Functionality,” Hearing Review, 12(5), pp. 22, 24, 25, 26, 27, & 79.
- Lewis, J. D., Goodman, S. S., and Bentler, R. A. (2010). “Measurement of hearing aid internal noise,” The Journal of the Acoustical Society of America, 127(4), 2521-2528.
- Ricketts, T. A., Bentler, R. A., and Mueller, H. G. (2019). Essentials of Modern Hearing Aids (San Diego: Plural).

Thank you

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