PREMIUM

8.0
8.0T
Tcoil

KIRKLAND Signature™ / MC / MR

DIGITAL

Hearing

INSTRUMENTS

SAFETY MANUAL

Content

Safety information

This safety manual provides safety information and other important information about your hearing instruments. It covers several instrument types and optional features.

- Refer to the user guide of your hearing instruments, to check the instrument type and the activated features.

Intended use

Hearing instruments are intended to improve the hearing of hearing impaired persons. Diagnosis and prescription of a hearing instrument must be performed by hearing health specialists, e.g. acousticians, audiologists or ENT doctors.

Use the hearing instruments and accessories only as described in the respective user guides.

Explanation of symbols

Symbols used in this document	
	Points out a situation that could lead to serious, moderate, or minor injuries.
	Indicates possible property damage.

Symbols on the device or packaging	
	CE compliance label, confirms compliance with certain European Directives, refer to section "Conformance information".

Symbols on the device or packaging	
	EMC and radio communications compliance label Australia, refer to section "Conformance information".
	Indicates the legal manufacturer of the device.
	Do not dispose of the device with general domestic waste. Read more in section "Disposal information".
	Read and follow the instructions in the user guide.

General warnings

WARNING

Risk of impairing the residual hearing of the user.

- Use only hearing instruments that have been fitted especially for your needs.

WARNING

Risk of injury!

- Do not use obviously damaged devices and return them to point of sale.

WARNING

Note that any unauthorized changes to the product may cause damage to the product or cause injury.

- Use only approved parts and accessories. Ask your Hearing Care Professional for support.

WARNING

Your hearing instruments may reduce certain background sounds, potentially also traffic or warning signals.

WARNING

Risk of explosion!

- Do not use your hearing instruments in explosive atmospheres (e. g. in mining areas).

WARNING

Choking hazard!

Your hearing instruments contain small parts which can be swallowed.

- Keep hearing instruments, batteries and accessories out of reach of children and mentally disabled persons.
- If parts have been swallowed consult a physician or hospital immediately.

NOTICE

- Protect your hearing instruments from high humidity. Do not wear them in the shower or when you apply make-up, perfume, aftershave, hairspray or suntan lotion.

NOTICE

- Protect your hearing instruments from extreme heat. Do not expose them to direct sunlight.

NOTICE

- Do not dry your hearing instruments in the microwave oven.

NOTICE

Different types of strong radiation, e. g. during X-ray or MRI head examinations, may damage hearing instruments.

- Do not wear the hearing instruments during these or similar procedures.

  Weaker radiation, e. g. from radio equipment or airport security, does not damage the hearing instruments.

NOTICE

Your devices comply with international standards.

However, it cannot be guaranteed that all products on the market work interference-free, for example some induction cookers may cause audible interference.

Contraindications

WARNING

Consult a Hearing Care Professional if you experience any unusual side effects like skin irritation, excessive accumulation of ear wax, dizziness, change in your hearing, or if you think there may be a foreign object in your ear canal.

WARNING

A Hearing Care Professional should advise a prospective hearing instrument user to consult a licensed physician before using the hearing instrument if the Hearing Care Professional determines that the prospective user has any of the following conditions:

- Visible congenital or traumatic deformity of the ear.
- History of active drainage from the ear within the previous 90 days.
- History of sudden or rapidly progressive hearing loss within the previous 90 days.
- Acute or chronic dizziness.

WARNING

A Hearing Care Professional should advise a prospective hearing instrument user to consult a licensed physician before using the hearing instrument if the Hearing Care Professional determines that the prospective user has any of the following conditions:

- Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1,000 Hz, and 2,000 Hz.
- Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- Pain or discomfort in the ear.

For hearing instruments with wireless functionality

In some countries restrictions for the usage of wireless equipment exist.

- ▶ Refer to local authorities for further information.

WARNING

Risk of affecting electronic equipment!

- ▶ In areas where the use of electronics or wireless devices are restricted, verify if your device has to be turned off.

NOTICE

Your hearing instruments are designed to comply with international standards on electromagnetic compatibility but interference with nearby electronic devices could occur. In this case, move away from the source of interference.

For certain instrument types

RIC models

The receiver is placed within the ear canal and connected to the instrument via a receiver cable.

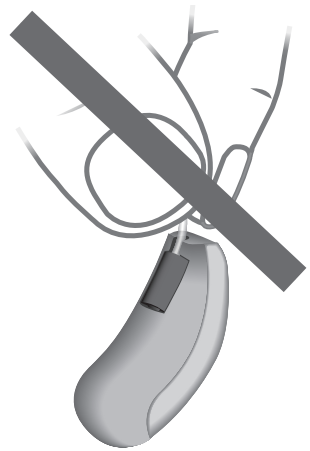
CAUTION

Risk of injury!

- Always wear the receiver cable with an ear piece.
- Make sure that the ear piece is completely attached.

NOTICE

- Do not pull the receiver connection as this could damage your hearing instruments.



For certain battery types

NOTICE

Only use zinc-air batteries or nickel-metal hydride (NiMH) rechargeable batteries.

Do not use e.g. silver-zinc or lithium-ion rechargeable batteries.

NOTICE

Leaking batteries damage the hearing instruments.

- ▶ Turn the hearing instruments off when not in use to preserve the battery.
- ▶ Remove batteries when the instruments are not in use for a prolonged period of time.

When using remote control apps

When using an app for controlling hearing instruments:

WARNING

Risk of hearing damage!

The device with the app for controlling hearing instruments generates short control signals which may be audible. If the device running the app has a very high audio output there is the risk of hearing damage.

While using the app:

- Do not hold the loudspeaker of the device to your ears or the ears of others.
- Do not use the device with headphones, headsets or other audio playback devices.

For Hearing Care Professionals

WARNING

For hearing instruments with an output sound pressure level of 132 dB SPL or more:

Risk of impairing the residual hearing of the user.

- ▶ Take special care when fitting this instrument.

Important information

Operating, transport and storage conditions

Operating conditions	
Temperature	0 to 50 °C (32 to 122 °F)
Relative humidity	5 to 93 %

During extended periods of transport and storage, please observe the following conditions:

	Storage	Transport
Temperature	10 to 40 °C (50 to 104 °F)	-20 to 60 °C (-4 to 140 °F)
Relative humidity	10 to 80 %	5 to 90 %

For other parts, such as batteries, other conditions may apply.

Disposal information

- Recycle hearing instruments, accessories and packaging according to local regulations.
- To avoid environmental pollution, do not throw batteries into household trash.
- Recycle or dispose of batteries according to local regulations or return them to your Hearing Care Professional.

Conformance information

The CE mark indicates conformity with the following European directives:

- 93/42/EEC concerning medical devices
- 2011/65/EU RoHS concerning the restriction of hazardous substances
- Only for products with wireless functionality: 2014/53/EU RED concerning radio equipment

The full text of the declaration of conformity can be obtained from www.sivantos.com/doc.

The ACMA compliance mark  indicates conformity with the electromagnetic interference standards set by the Australian Communications and Media Authority (ACMA).

Devices with the FCC marking comply with the standards of the FCC regarding electromagnetic interference (only for products with wireless functionality).

Notices

This Class B digital apparatus complies with Canadian ICES-003.

Changes or modifications made to this equipment not expressly approved by the legal manufacturer may void the FCC authorization to operate this equipment.

This device complies with Part 15 of the FCC Rules and with ISED's licence-exempt RSSs.

Operation is subject to the following conditions:

- this device may not cause harmful interference, and
- this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed

and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

For body worn operation, this device has been tested and meets the FCC RF exposure guidelines when used with the legal manufacturer’s accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

For US and Canadian markets only

For prospective hearing instrument users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing instrument. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing instrument is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for hearing instruments. The physician will refer you to a Hearing Care Professional for a hearing instrument evaluation.

The Hearing Care Professional will conduct a hearing instrument evaluation to assess your ability to hear with and without hearing instruments. The hearing instrument evaluation will enable the Hearing Care Professional to select and fit hearing instruments to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a

trial-rental or purchase-option program. Many Hearing Care Professionals now offer programs that permit you to wear hearing instruments for a period of time for a nominal fee after which you may decide if you want to purchase them.

U.S. federal law restricts the sale of hearing instruments to those individuals who have obtained a medical evaluation from a licensed physician. U.S. federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

For hearing instrument users

Hearing instruments will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases infrequent use of hearing instruments prohibits the wearer from attaining the full benefit from it. The use of hearing instruments is only part of hearing rehabilitation and may need to be supplemented by auditory training and instruction in lip reading.

Health considerations

If soreness or skin irritation develops, discontinue wearing your hearing instruments, and bring the instruments and earmolds to your Hearing Care Professional. Minor fit adjustments or earmold modification can often correct this

condition. If soreness persists, discontinue wearing the hearing instrument and see your physician. If excessive earwax accumulates when wearing your hearing instruments, consult your Hearing Care Professional.

Battery tips

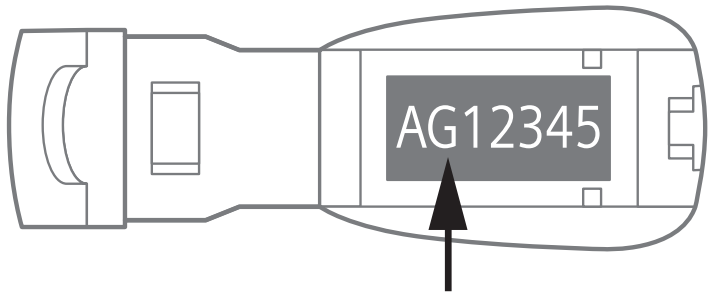
If a battery is accidentially swallowed, seek medical attention immediately, or call the National Battery Hotline collect at **(202) 625-3333**.

Identification information

Your hearing instruments have a serial number imprinted on them. The location of the serial number will vary according to the style of hearing instrument you have chosen. Record the serial number in your user guide for future reference.

The year of manufacture is incorporated into the serial number.

For RIC instruments, the year of manufacture is derived from the second digit:



Code (second digit)	Year
D, E, F	2013
G, H	2014

Code (second digit)	Year
L, M	2015
N, P	2016
Q, R	2017
S, T	2018

Please note the warranty is based upon the date of purchase, not the date of manufacture.

Your Audiologist or Hearing Care Professional can answer any questions you may have about the identifying code on your hearing instrument.

Wireless functionality

The following tables summarizes the technical details of the wireless technology:

Wireless technology	Nearfield magnetic induction
Antenna type	Inductive antenna
Antenna dimensions	Ø: 1.9 mm, L: 6.5 mm, respectively, Ø: 2.3 mm, L: 5.7 mm, respectively, Ø: 2.8 mm, L: 4.4 mm
Modulation	PSK (Phase Shift Key)
Magnetic field strength	0.07 A/m, (1 cm^2 coil; average)

Output power (EIRP)	53 µW
EIRP = Equivalent isotropically radiated power	
Range	< 20 cm between hearing instruments
Center frequency	3.28 MHz
Channel	Single channel radio
Bandwidth	140 kHz
Data rate	324 kbit/sec (raw channel capacity)
Data flow	Simplex or semi-duplex capability
Protocol	Random access, no collision avoidance
S.A.R.	2.36 nW/kg
S.A.R. = Specific Absorption Rate (S.A.R.) based on 10 g ICNIRP testing.	

Bluetooth® low energy*

Wireless technology	Radio frequency - Bluetooth low energy
Antenna type	Electromagnetic dipole antenna
Antenna dimensions	H: approx. 4 mm, L: approx. 15 mm
Magnetic field strength	not applicable
Output power (EIRP)	150 µW
EIRP = Equivalent isotropically radiated power	

* The Bluetooth word mark and logos are owned by the Bluetooth SIG, Inc., and any use of such marks by the legal manufacturer of this product is under licenses. Other trademarks and trade names are those of their respective owners.

Range	< 10 m between smartphone/ accessory and hearing instruments
Center frequency	2.45 GHz
Channel	40 channel radio
Bandwidth	2 MHz per channel
Data rate	1 Mbit/sec, respectively, 2 Mbit/sec
Data flow	Simplex or semi-duplex capability
Protocol	Bluetooth network FHSS (Frequency Hopping Spread Spectrum)
S.A.R.	1.31 nW/kg
S.A.R. = Specific Absorption Rate (S.A.R.) based on 10 g ICNIRP testing.	

EMI/EMC compliance

Wireless hearing instruments comply with the following EMC/EMI standards:

Standard	Test Type	Note
47 CFR Part 15, Subpart C	RF emissions	U.S. FCC requirements for intentional radiators.
EN 300 330	RF emissions including spurious emission	EMC and radio spectrum matters for short range devices in the frequency range 9 kHz - 25 MHz.

Standard	Test Type	Note
EN 301 489-1/3/17	Immunity, RF and ESD	Standard for low power transmitters in the frequency range 9 kHz - 40 GHz.
EN 300 328	Signal integrity and emissions	Wideband transmission systems; data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques

Standard	Test Type	Note
IEC 60118-13	RF immunity	International product standard for hearing instruments to ensure adequate immunity to radio interference from mobile telephones.
ANSI C63.19	RF immunity	American National Standard method of measurement of compatibility between wireless communication devices and hearing instruments.

Standard	Test Type	Note
ANSI/AAMI PC69	RF emissions	Implantable medical device EMC immunity.
ISO 14117	RF emissions	Implantable medical device EMC immunity.
EN 45502-2-1	RF emissions	Particular requirements for pacemakers.

Wireless security measures

Wireless signal security is assured through the device system design that includes:

- A built-in pairing table which specifies valid and legitimate pairing among units.
- A proprietary communication protocol which checks the package numbers during each transmission.
- A Cyclic Redundancy Check (CRC) to check data validity.
- A convolutional encoder/decoder (Viterbi) to correct errors.

The Bluetooth low energy connection uses the security measures that are defined in the Bluetooth low energy standard.

For children with hearing loss

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

Warranty and service

Your hearing instrument, with the exception of the battery, is covered by a comprehensive warranty. All covered instrument parts received for warranty service at an

authorized service center will be repaired or replaced with new or reconditioned components, without charge, to meet the performance specifications for that model.

This warranty does not cover malfunctions due to unusual wear and tear or mistreatment of the instrument such as physical shock, excessive wax build-up, or tampering with the instrument, any of which voids all warranties. Your Hearing Care Professional may charge a service fee for processing warranty service.

Warranty service must only be performed by an authorized service center. Service performed by unauthorized service depots voids this warranty, and repairs so necessitated will be done on a parts and labor cost basis.

Please refer to the warranty card included with your hearing instruments for warranty period effective dates.

Your hearing instruments may have additional loss and damage coverage. Please consult your Hearing Care Professional to determine if this is applicable to your hearing instruments.

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Master Rev01, 01.2018

CE
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KS 8.0 · Technical Data

Type	S-Receiver		M-Receiver	
				
	2 ccm coupler	Ear simulator	2 ccm coupler	Ear simulator
Output sound pressure level				
at 1.6 kHz	–	109 dB SPL	–	123 dB SPL
Peak	108 dB SPL	119 dB SPL	119 dB SPL	129 dB SPL
HFA-OSPL 90	101 dB SPL	–	113 dB SPL	–
Gain				
Full on gain (FOG) at 1.6 kHz	–	43 dB	–	55 dB
Full on gain (peak)	45 dB	56 dB	60 dB	70 dB
HFA-FOG	37 dB	–	50 dB	–
Reference test gain	24 dB	34 dB	36 dB	48 dB
Frequency, noise and directivity				
Frequency range	100 - 10000 Hz	100 - 10000 Hz	100 - 9400 Hz	100 - 10000 Hz
Equivalent input noise	19 dB SPL	20 dB SPL	19 dB SPL	23 dB SPL
Total harmonic distortion at 500 / 800 / 1600 / 3200 Hz	1 / 1 / 1 / 1 %	1 / 1 / 2 / – %	1 / 2 / 1 / 1 %	2 / 3 / 2 / – %
AI-DI	4.0 dB		4.0 dB	

KS 8.0 · Technical Data

Type	S-Receiver		M-Receiver	
Inductive coil sensitivity	2 ccm coupler	Ear simulator	2 ccm coupler	Ear simulator
MASL (1 mA/m) at 1.6 kHz	–	–	–	–
HFA MASL (1 mA/m)	–	–	–	–
HFA SPLITS (left/right)	–	–	–	–
RSETS (left/right)	–	–	–	–
HFA SPLIV	–	–	–	–
Battery				
Battery voltage	1.3 V		1.3 V	
Battery current drain	1.2 mA	1.2 mA	1.4 mA	1.4 mA
Battery life (cell zinc air)	~70 h		~67 h	
Battery life (rechargeable)	–		–	
IRIL IEC 60118-13:2016 Ed. 4.0				
700-960 MHz (rating)	user		user	
1400-2000 MHz (rating)	user		user	
2000-2700 MHz (rating)	user		user	
ANSI C63.19-2011				
800-950 MHz (rating)	M4		M4	
1600-2500 MHz (rating)	M4		M4	

KS 8.0 · Technical Data

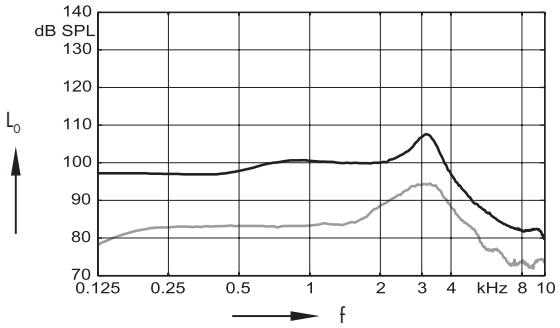
Type	P-Receiver		HP-Receiver	
				
	2 ccm coupler	Ear simulator	2 ccm coupler	Ear simulator
Output sound pressure level				
at 1.6 kHz	–	128 dB SPL	–	137 dB SPL
Peak	124 dB SPL	134 dB SPL	130 dB SPL	138 dB SPL
HFA-OSPL 90	119 dB SPL	–	123 dB SPL	–
Gain				
Full on gain (FOG) at 1.6 kHz	–	70 dB	–	82 dB
Full on gain (peak)	70 dB	80 dB	75 dB	82 dB
HFA-FOG	63 dB	–	68 dB	–
Reference test gain	42 dB	53 dB	46 dB	62 dB
Frequency, noise and directivity				
Frequency range	100 - 7500 Hz	100 - 8100 Hz	100 - 7300 Hz	250 - 6100 Hz
Equivalent input noise	18 dB SPL	21 dB SPL	16 dB SPL	12 dB SPL
Total harmonic distortion at 500 / 800 / 1600 / 3200 Hz	1 / 2 / 1 / 1 %	3 / 4 / 2 / – %	1 / 2 / 1 / 1 %	2 / 2 / 1 / – %
AI-DI	4.0 dB		4.0 dB	

KS 8.0 · Technical Data

Type	P-Receiver		HP-Receiver	
Inductive coil sensitivity	2 ccm coupler	Ear simulator	2 ccm coupler	Ear simulator
MASL (1 mA/m) at 1.6 kHz	–	–	–	–
HFA MASL (1 mA/m)	–	–	–	–
HFA SPLITS (left/right)	–	–	–	–
RSETS (left/right)	–	–	–	–
HFA SPLIV	–	–	–	–
Battery				
Battery voltage	1.3 V		1.3 V	
Battery current drain	1.3 mA	1.3 mA	1.3 mA	1.3 mA
Battery life (cell zinc air)	~67 h		~67 h	
Battery life (rechargeable)	–		–	
IRIL IEC 60118-13:2016 Ed. 4.0				
700-960 MHz (rating)	user		user	
1400-2000 MHz (rating)	user		user	
2000-2700 MHz (rating)	user		user	
ANSI C63.19-2011				
800-950 MHz (rating)	M4		M4	
1600-2500 MHz (rating)	M4		M4	

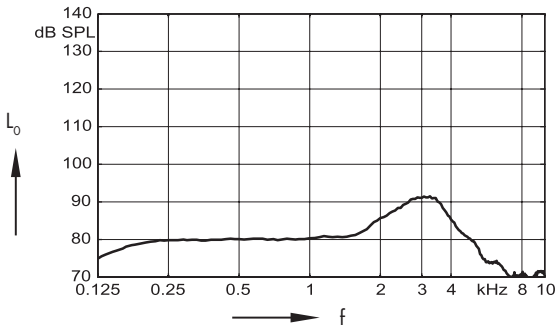
S-Receiver (Closed Click Dome) · Basic Data

2 ccm coupler



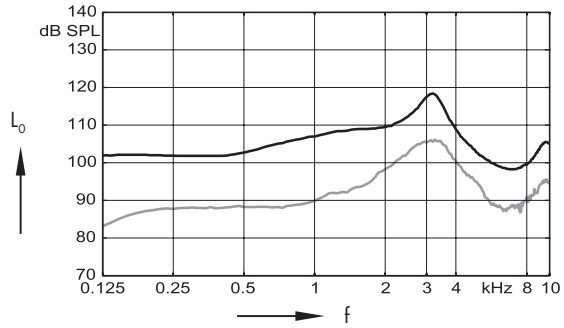
Output sound pressure level
(L_I = 90 dB)

Full on gain
(L_I = 50 dB)



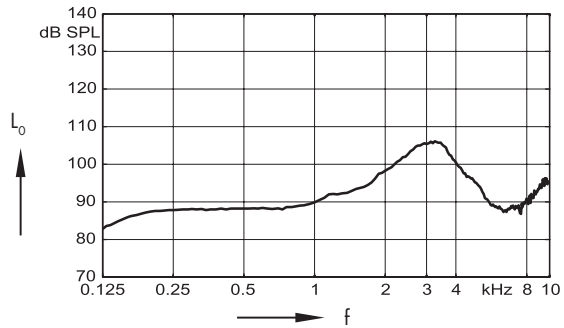
Frequency response
(L_I = 60 dB)

Ear simulator



Output sound pressure level
(L_I = 90 dB)

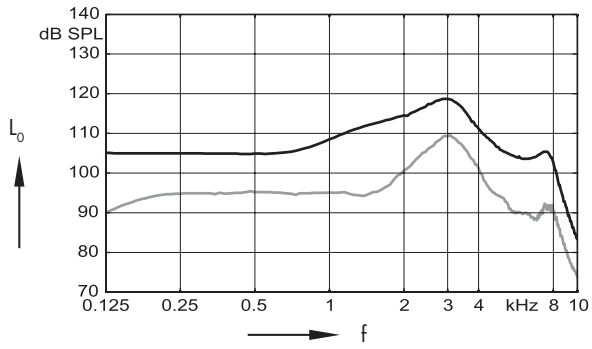
Full on gain
(L_I = 50 dB)



Basic acoustic response
(L_I = 60 dB)

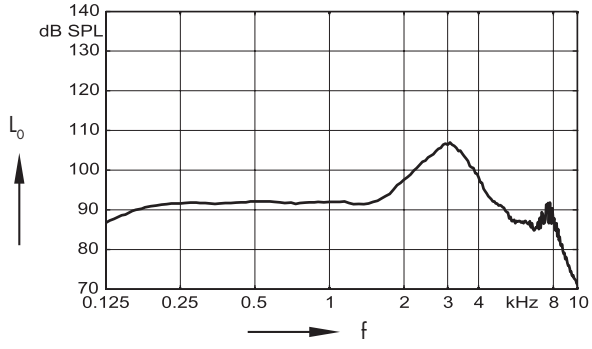
M-Receiver (Closed Click Dome) · Basic Data

2 ccm coupler



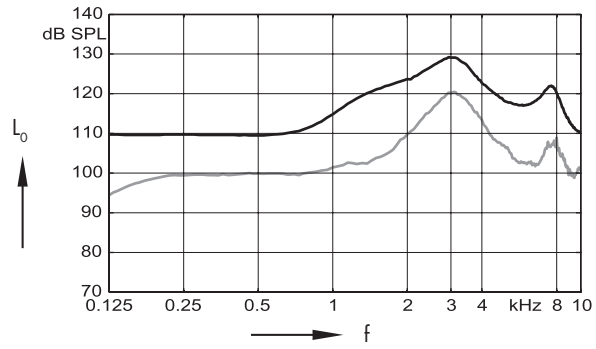
Output sound pressure level
(L_I = 90 dB)

Full on gain
(L_I = 50 dB)



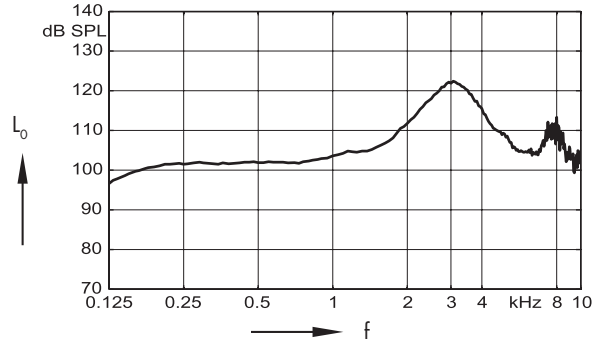
Frequency response
(L_I = 60 dB)

Ear simulator



Output sound pressure level
(L_I = 90 dB)

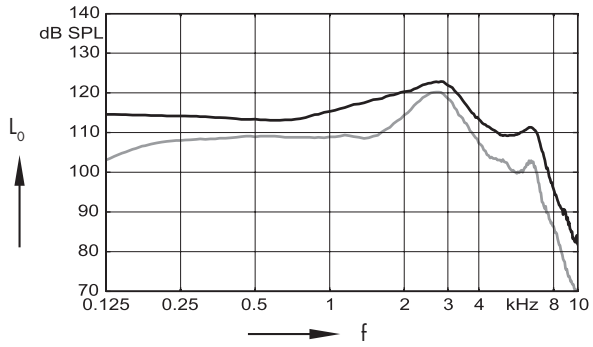
Full on gain
(L_I = 50 dB)



Basic acoustic response
(L_I = 60 dB)

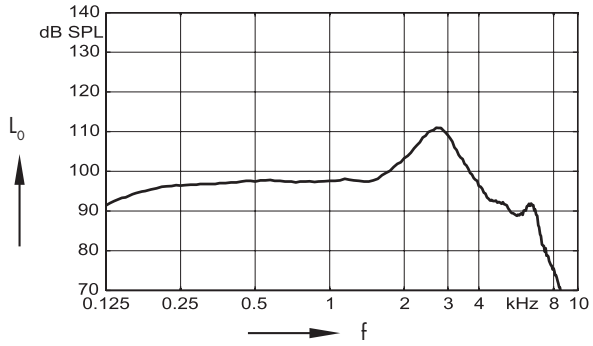
P-Receiver (Closed mold) · Basic Data

2 ccm coupler



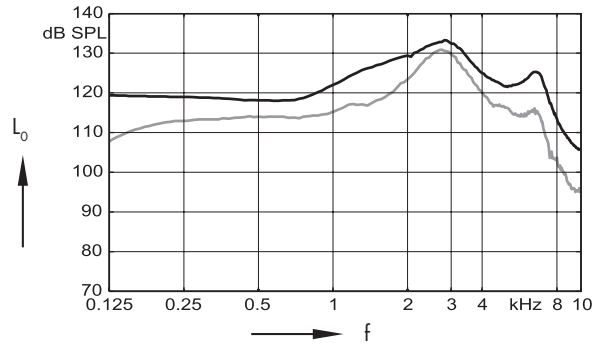
Output sound pressure level
(L_I = 90 dB)

Full on gain
(L_I = 50 dB)



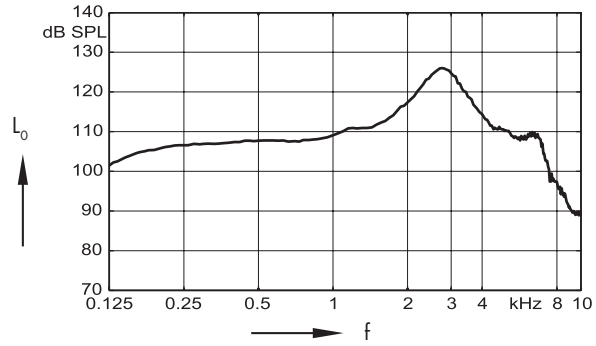
Frequency response
(L_I = 60 dB)

Ear simulator



Output sound pressure level
(L_I = 90 dB)

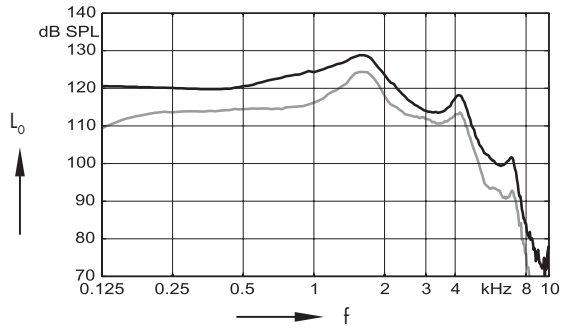
Full on gain
(L_I = 50 dB)



Basic acoustic response
(L_I = 60 dB)

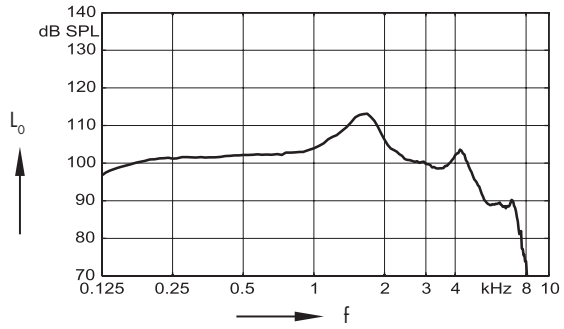
HP-Receiver (Custom Shell) · Basic Data

2 ccm coupler



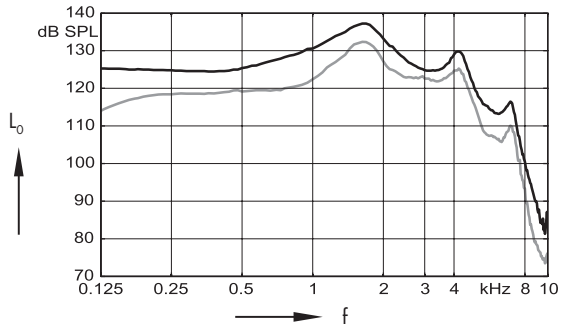
Output sound pressure level
(L_I = 90 dB)

Full on gain
(L_I = 50 dB)



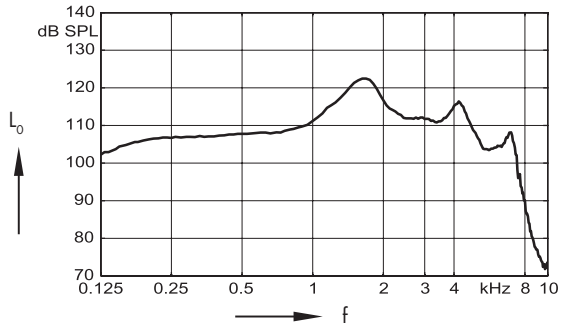
Frequency response
(L_I = 60 dB)

Ear simulator



Output sound pressure level
(L_I = 90 dB)

Full on gain
(L_I = 50 dB)



Basic acoustic response
(L_I = 60 dB)

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