Study author, year	Setting	Study design	Participants, Sampling method	Device(s) and transducers used, administratio n method	Reference <i>l</i> gold standard	Outcomes	Definition of hearing loss used for sensitivity/spe cificity analysis	Test frequen cies (kHz)	Calibration performed	Result summary
	alidating uHe			1	1		1	r	1	
Abu- Ghanem et al. (2015)	Retirement facility. Israel, urban	Within subjects	N=26 Age: 65-94 years; mean 84.4 years Gender: 31% (M) 69% (F) Sampling: Voluntary participation.	Single iPhone 4S Sennheiser CX300 headphones in three available sizes with replaceable rubber covers Self- administered in quiet room	Conventional PTA on portable audiometer in quiet room (ambient noise 41- 42dBA) with audiologist	Sensitivity/ Specificity; Mean difference in thresholds; Pearson's correlation coefficient (for validity of uHear questionnaire); Test duration	PTAv>40dB HL at 500, 1000, 2000 and 4000Hz in better ear	0.25, 5, 1, 2, 4, 6	No Single device and headphone combination was used to test all participants in order to avoid potential inter-device variability	Sensitivity=100% Specificity=60% Mean difference in thresholds varied from 0.38- 17.02dB HL greater for uHear depending on the frequency. Difference statistically significant at all frequencies except 2000Hz.
Khoza- Shanga ze et al. (2013)	School. South Africa, urban	Within subjects	N=86 Age: 8-10 years; mean 9.0 years Gender: 49% (M) 51% (F) Sampling: Quota	Single iPod touch Standard earbud headphones Administered by audiologist in a quiet room	Conventional PTA in quiet room with audiologist	Mean difference in thresholds – greater than 10dB was considered a significant shift in thresholds	Hearing level >15dB HL	0.25, 5, 1, 2, 4, 6, 8	No Single device and headphone combination was used to test all participants in order to avoid potential inter-device variability	Mean difference in thresholds: Varied from 9.2 to 23.4dB HL greater for uHear depending on the frequency (standard deviation 9.4-21.9dB). Differences statistically significant at all frequencies.

Appendix 3: Summary of selected peer-reviewed studies included in the review

Study author, year	Setting	Study design	Participants, Sampling method	Device(s) and transducers used, administration method	Reference/ gold standard	Outcomes	Definition of hearing loss used for sensitivity/spe cificity analysis	Test frequenc ies (kHz)	Calibration performed	Result summary
	validating uHe		 	1		1		1	1	
Peer et al. (2015)	ENT clinic South Africa, urban	Within subjects	N=25 patients Age: 15-80 years; mean 43 years Gender: 52% (M) 48% (F) Sampling: Consecutive	Single iPhone 4 Standard earbud headphones Self-administered in 3 different settings: quiet room, waiting room, soundproof room. Investigator was present to ensure test was completed.	Conventional PTA in soundproof room with an audiologist	Sensitivity/Spe cificity; Cohen's kappa comparing agreement between thresholds at different frequencies	PTAv>40dB HL at 500, 1000, 2000 and 4000Hz in either ear	0.25, 5, 1, 2, 4, 6	Single device and headphone combinatio n was used to test all participants in order to avoid potential inter-device variability	Waiting room: Sensitivity=100% Specificity=64% Cohen's kappa: Low frequencies: poor to moderate High frequencies: moderate Quiet room: Sensitivity=100% Specificity=74% Cohen's kappa: Low frequencies: poor to moderate High frequencies: Moderate to good Soundproof room: Sensitivity=100% Specificity=88% Cohen's kappa Low frequencies: Poor to good High frequencies: Moderate to very good

Study author, year	Setting	Study design	Participants, Sampling method	Device(s) and transducers used, administration method	Reference <i>l</i> gold standard	Outcomes	Definition of hearing loss used for sensitivity/spe cificity analysis	Test frequenc ies (kHz)	Calibration performed	Result summary
	validating uHe		N. 400	Oissals in I		0	DTA - 40 ID III	0.05.5	NI-	Out at ma
Szudek et al. (2012)	Single otology practice within hospital. Canada, urban	Within subjects	N=100 Age: 20-91 years; mean 46 years Gender: 33% (M) 67% (F) Sampling: Not reported	Single iPod touch Standard earbud headphones Self-administered in soundproof room and quiet room (ambient noise <50dBA) under supervision of clinician/resear cher	Conventional PTA in a soundproof room with a single audiologist	Sensitivity/ Specificity; Mean difference in thresholds – within 10dB considered normal variation; Test duration	PTAv>40dB HL at 500, 1000, 2000 and 4000Hz Ear was unit of analysis	0.25, 5, 1, 2, 4, 6	No Single device and headphone combinatio n was used to test all participants in order to avoid potential inter-device variability	Quiet room: Sensitivity=98% (95%CI=89-100) Specificity=82% (95%CI=75-88) Mean difference in thresholds: 14dB HL greater with uHear for all ears compared to PTA, 6dB HL for ears with a hearing loss (p<0.001) Soundproof room: Sensitivity=100% (95%CI=92-100) Specificity=90% (95%CI=83-94) Mean difference in thresholds: 8dB greater with uHear for all ears compared to PTA, 4dB for ears with a hearing loss (p<0.001)

Study author, year	Setting	Study design	Participants, Sampling method	Device(s) and transducers used, administration method	Reference <i>l</i> gold standard	Outcomes	Definition of hearing loss used for sensitivity/spe cificity analysis	Test frequenc ies (kHz)	Calibration performed	Result summary
Studies v	alidating uHe									
Handzel et al. (2013)	Emergency department Israel, urban	Within subjects	N=32 Age: 20-82 years; mean 51.4 years Gender: 75% (M) 25% (F) Sampling: Consecutive	Single iPod touch Creative EP 630 earbud speakers with replaceable rubber covers. Self-administered in a quiet room (ambient noise varied between 41-42dBA) supervised by researcher	Conventional PTA in soundproof room	Sensitivity/Spe cificity	Sudden sensorineural hearing loss: hearing loss of 2 or more hearing grades in 3 consecutive test frequencies.	0.25, 5, 1, 2, 4, 6	No Single device and headphone combinatio n was used to test all participants in order to avoid potential inter-device variability	Sensitivity=76% (53-92) Specificity=91% (59-99)
	alidating Ear									
Foulad et al. (2013) ^a	Medical USA, urban	Within subjects	N=42 Age: 20-85 years; mean 58 years Gender: 55% (M) 45% (F) Sampling: Consecutive	Either an iPhone or iPod (multiple devices used) Standard earbud headphones Self-administered in soundproof room and quiet room	Conventional pure tone audiometry in soundproof room	Percent of thresholds falling within 0-5dB, 0-10dB and 0-20dB of standard audiometry; Paired threshold differences; iOS device compatibility (how the output varies across devices)	None given	0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 6, 8	iOS based hearing test was designed and calibrated with Apple's earbuds connected to a soundmeter through 1" tube simulating ear canal	Quiet room: Percent of thresholds falling with 10dB of standard audiometry =94% (87-100) Soundproof room: Percent of thresholds falling with 10dB of standard audiometry =96% (91-100)

Study author, year	Setting	Study design	Participants, Sampling method	Device(s) and transducers used, administration method	Reference <i>l</i> gold standard	Outcomes	Definition of hearing loss used for sensitivity/spe cificity analysis	Test frequenc ies (kHz)	Calibration performed	Result summary
Studies v	validating sho	eBOX audi	ometry		•	•		,	•	
Yeung et al. (2013) ^a	Audiology clinic. Canada, urban	Within subjects	N=70 children Age: 3-13 years; mean 5.2 years Gender: Not described Sampling: Consecutive	Single iPad Calibrated TDH-39 headphones Soundproof room with two audiologists	Traditional play audiometry in soundproof room	Sensitivity/ Specificity; Repeated measures analysis (model); Participant performance – including time to completion, feedback from the audiologists	Threshold greater than 25dB HL in any of 4 test frequencies (500, 1000, 2000 and 4000Hz)	0.5, 1, 2,	Professiona lly calibrated by Genie Audio Inc to ANSI S3.6- 2004 standards.	Sensitivity =93.3% (95%CI=71.7- 99.6) Specificity =94.5% (95%CI=88.6- 96.3)
Yeung et al. (2015) ^a	Audiology clinic. Canada, urban	Within subjects	N=79 Age: 5-17 years; mean 9.5 years Gender: Not described Sampling: Consecutive	Single iPad 2 Apple In Ear Headphones or Apple Earbud Headphones Self- administered by child in quiet room supervised by an adult and a communication disorders assistant	Traditional play audiometry in sound proof room	Sensitivity/ Specificity; Receiver Operating Curve (ROC) curve to determine optimum discrimination threshold	Threshold greater than 25dB HL in any of 4 test frequencies, but changed to 30dB HL in analysis stage.	0.5, 1, 2, 4	Professiona Ily calibrated by Genie Audio Inc to ANSI S3.6- 2004 standards using non- standard RETSPLs derived using the TDH39 headphone s as a reference (no standard exists for ear-bud headphone s in ANSI	Sensitivity =91.2% (95% CI=78.5-97.6) Specificity =57.8% (95%CI=48.2-62.6)

				S3.6-2010	
				document).	

Study author, year	Setting	Study design	Participants, Sampling method	Device(s) and transducers used, administration method	Reference <i>l</i> gold standard	Outcomes	Definition of hearing loss used for sensitivity/spe cificity analysis	Test frequenc ies (Hertz)	Calibration performed	Result summary
Studies v	alidating Aud									
Larrosa et al. (2015)ª	9 ENT clinics. Spain, urban	Within subjects	N=110 Age: 18-91 years; mean 43.9 years Gender: 54% (M) 46% (F) Sampling: Consecutive	Various apple devices (iPhone 4, 5, 5c, 5s, iPad 2) Standard earbud headphones Audiologist administered in "minimal ambient noise level sound conditions"	Conventional pure tone audiometry in soundproof room	Cohen's kappa coefficient (agreement between both methods); Threshold compared using: Cronbach's alpha (reliability of application), Intraclass correlation coefficient (concordance), mean difference in thresholds	PTA>20dB HL at 500, 1000, 2000, 4000Hz	0.5, 1, 2, 3, 4, 8	Calibrated by researchers using iPhone 5 and EarPod (human sensitivity model – manual comparison between audiometer and standard headphone s and EarPod headphone s coupled with iPhone)	Kappa coefficient = 0.894 Cronbach's alpha: All cases 0.96 (≥0.80 considered excellent) Intraclass correlation coefficient (concordance) All cases 0.93 (≥0.90 considered excellent) Mean difference in thresholds: 0.21±6.38dB
	alidating hea									
Swanep oel et al. (2014)ª	School. South Africa, urban	Within subjects	N=162 Age: 5.6 – 7.7 years; mean 6.5 years Gender: Not described Sampling: Convenience	Two Samsung Galaxy pocket plus S5301 smartphones Sennheiser HD202 supra- aural headphones Administered by audiology student in quiet	Conventional screening audiometry	Agreement between smartphone and conventional screening; Referral rate; Validity of smartphone calibration; Validity of environmental noise	Threshold >25dB HL at 1000, 2000, or 4000Hz	1, 2, 4	Calibrated professiona lly coupled to Sennheiser HD202 headphone s. Calibration within +/- 3dB of RESPLs	Smartphone and conventional hearing screening methods were in agreement in 97.8% of cases. hearScreen had a referral rate of 4.3% whilst conventional screening 3.7%.

	room.	monitoring;			
	Supervised by	Test duration			
	audiologist.				

Study author, year	Setting	Study design	Participants, Sampling method	Device(s) and transducers used, administration method	Reference/ gold standard	Outcomes	Definition of hearing loss used for sensitivity/spe cificity analysis	Test frequenc ies (Hertz)	Calibration performed	Result summary
Studies v	alidating Cell	Scope								
Richard s et al. (2015)	Academic paediatric emergency department USA, urban	Within subjects	N=51 Age: mean 5.1 years Gender: 53% (M) 47% (F) Sampling: Convenience.	CellScope otoscopy	Traditional otoscopy with camera attachment	Ear examination findings were grouped as normal, abnormal with effusion, abnormal with erythema of TM, abnormal (other not listed), cerumen impaction, and unable to visualise. Inter and intrarater diagnostic agreement.	N/A	N/A	N/A	Intrarater agreement resident physicians: Right ear: k=0.74 (95% CI, 0.58-0.89) Left ear: k=0.74 (95% CI, 0.58- 0.89) Intrarater agreement attending physicians: Right ear: k=0.86 (95% CI, 0.72-0.98) Left ear: k=0.79 (95%CI,0.65- 0.94)

a=conflict of interest declared

PTAv=Pure Tone Average

ENT= Ear Nose and Throat

RETSPLs=Reference Equivalent Threshold Sound Pressure Level

ANSI= American National Standards Institute

CI=Confidence Interval

k=Kappa Hz=Hertz

dB=Decibels