

## Datasheet

# Hearing Assessment and **Fitting Unit** Auditdata

#### Classification: Public

Standards	General Regulation	Medical Device Regulation MDR (EU) 2017/745
	Audiometry	IEC 60645-1:2017 / ANSI S3.6:2018 Type 1; IEC 60645-1:2017 / ANSI S3.6:2018 Type A or A-E
	REM	IEC 61669:2015; ANSI S3.46:2013;ISO 12124:2001
	Safety	IEC 60601-1:2005+A1:2012; class 2, type B
	EMC	IEC 60601-1-2:2014+A1:2020
	Usability	EN 60601-1-6:2010+A1:2013+A2:2020
	Software	IEC 62304:2006+A1:2015
	Calibration	ISO 389-7:2005
	Other standards	IEC 62366-1:2015; FCC 47 CFR, Part 15 Subpart B, Class A; ICES 003, Issue 7:2020, Class A; ISC 14971:2019; ISO 13485:2016
Tone Testing	Tests	HTL, MCL, UCL, BCL, FF, FF-A, Weber test, SISI test, Hughson-Westlake method, TEN test (CD required), Stenger test
	Output	AC, BC, and Free Field
	Transducers	Insert Earphone, Bone Conductor - B71, DD45 w. HBA headband, DD45 w. RE-7 headband, DD450, DD65 v2, ER-3C Insert, Free Field Speaker, and Loudspeaker Small, Cambridge Audio
	Frequency Range	125 Hz to 16 kHz
	Hearing Levels	-10 dB HL up to 120 dB HL (max. output is limited by transducer capability)
	Stimuli Distortion	Less than 1%
	Stimuli	Pure tone, pulsed pure tone, warble, pulsed warble, narrowband noise, and pulsed narrowband noise
	Masking Noise	Narrowband noise, white noise, speech noise
	Extended Range	+20 dB
	Tone Switch	Manual or 0.1 - 5 sec. tone duration
	Client Response System	Handheld push button
	Monitoring	Operator Monitor for talk-back and stimuli monitoring
	Talk Over / Talk Back	Full bi-directional client communication with two-channel operator microphones
	Client Safety	Max. level limiter (max 100 dB w/o extended range, UCL limiter)
Speech	Tests	SRT, MCL, UCL, SD, SD-A, SDN, SDN-A, and QuickSIN (CD required)
Testing	Output	AC, BC, and Free Field
	Transducers	Insert Earphone, Bone Conductor - B71, TDH39, DD45 w. HBA headband, DD45 w. RE-7 head- band, DD450, DD65 v2, ER-3C Insert, Free Field Speaker, and Loudspeaker Small, Cambridge Audio
	Stimuli	CD, Sound Library, or Live voice using operator microphone
	Masking Noise	Speech noise, white noise, CD and sound files
	Monitoring	Operator Monitor for talk-back and stimuli monitoring
	Talk Over / Talk Back	Full bi-directional client communication with two-channel operator microphones

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Instrument	Power Supply	USB-powered. External power supply unit needed for elevated outputs
	Dimensions	5.5 x 5.5 x 2.1 in (140 x 140 x 55 mm)
	Weight	415 g
	Connections	AC1 (HF), AC2 (HF), BC, Client Response, Option Connector (RECD), S/PDIF optical output, Left/Right Loudspeaker, Operator Monitor, Operator Monitor Talk Over/Live Speech, Talk Back Microphone, Free Field (Line Out), USB-C, DC input for external power supply
PC Minimum	CPU	Minimum 2 GHz processor (recommended 2 GHz or higher multi core) with 2 GB system RAM (4 GB or more)
Requirements	Hard Disk Space	2 GB free hard disk space for Measure Software
	Operating System	Windows 10 (32 & 64-bit), and Windows 10 Anniversary Update (recommended Windows 11)
	Screen Resolution	1280 x 1024 (1600 x 1200 recommended)
	Graphics Card	XVGA (dual monitor output recommended)
	Connections	CD drive required for speech test CD's. USB 2.0 connection required.
	Noah Compatibility	Noah 4

## Standard & optional parts

Standard	100.010	2000-1 Fitting Unit
Accessories	100.110	Client Response
	100.111	Power Supply (EU+US+UK+AUS)
	100.112	USB-C Cable (2000-1)
	1010.406	Loudspeaker cable with black plug
	100.115	Measure software
	100.118	Quick Installation Guide
Software	40.0005	Audiometry – SW module
Modules	40.0022	Audiometry ST – SW module
	40.0023	Audiometry HF – SW module
	40.0006	Real Ear Measurement – SW module
	40.0009	Speech Mapping – SW module
Optional	100.056	Insert Earphone (2000-1)
Parts	100.051	REM Probe (2000-1)
	100.052	REM Probe Flex (2000-1)
	100.050	B71 Bone Conductor (2000-1)
	100.053	DD45 Headphone w. HBA Headband (2000-1)
	100.058	DD45 Headphone w. RE-7 Headband (2000-1)
	100.055	DD450 HF Headphone (2000-1)
	100.054	DD65v2 Headphone (2000-1)
	100.057	ER-3C Insert Earphone (2000-1)
	100.114	Talk Forward Operator Headset (2000-1)

#### Specifications are subject to change without notice. Copyright $\textcircled{\sc opt}$ Auditdata A/S. 2024/11. ID: PN00886.100

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#### Classification: Public

100.113Talk Back Client Microphone (2000-1)100.040REM/Free Field Speaker (2000-1)100.119USB-C Cable Isolation Kit91.0115Loudspeaker Small, Cambridge Audio
100.119   USB-C Cable Isolation Kit     91.0115   Loudspeaker Small, Cambridge Audio
91.0115 Loudspeaker Small, Cambridge Audio
100.042Sound Booth Cable Kit (2000-1)
100.551   Wireless REM Probe Complete Package
100.554   Wireless REM Probe Base Package
100.041 Transducer Extension Cable, 3m (2000-1)
Consumables   90.4015   Ear Hanger (4 Pieces)
91.0202 E-A-RLINK 3B (Small, 50 pcs)
91.0203 E-A-RLINK 3A (Medium, 50 pcs)
91.0204 E-A-RLINK 3C (Large, 24 pcs)
91.0205 Insert Tube with Nipples
91.0302 Probe tube guide (8 pcs)
91.0303 Probe tubes (36 pcs)

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