SHOEBOX Consult & Remote Supported Accessories

SHOEBOX Consult & Remote software requires accessories to fulfill its Intended Use. The following establishes requirements for the different types of compatible accessories.

Audiometric Transducers	Note: Audiometric transducers must be paired with a Digital to Analog Converter (DAC) (see DAC below). The Transducer-DAC pair must be calibrated together and remain together during use. Note: Follow transducer manufacturer IFU for proper use.
Audiometric Circumaural Transducer	● Audio Jack: 3.5mm Stereo ● Compliance: ○ IEC-60645-1 ○ ANSI S3.6 ○ Local medical device regulations, as applicable ● Nominal Impedance: 10 ohm or 40 ohm (100 Hz to 8 kHz) ● Sensitivity: > 100 dB SPL @ kHz 1mW ● Distortion: < 1% THD @ 1mW ● Headband Tension:10 N ± 0.5N
Audiometric Insert Phone Transducer	● Audio Jack: 3.5mm Stereo ● Compliance: ○ ANSI S3.6 2010 ○ Local medical device regulations, as applicable ● Nominal Impedance: 10 ohm (125 Hz to 8 kHz) ● Sensitivity: > 103 dB SPL @ 1kHz, 0.2Vrms using HA-2 coupler (IEC 60318-5, 2006) ● Distortion: < 3% THD @ 500 Hz, 118.5 dB SPL
Audiometric Transducers - Insert Air	Part of: 21H-0004-C RadioEar IP30 Specifications ● Audio Jack: 3.5mm Stereo ● Compliance: ○ ANSI S3.6 2010 ○ Local medical regulations, as applicable ● Nominal Impedance: 10 ohm (125 Hz to 8kHz) ● Sensitivity: > 103 dB SPL @ 1kHz, 0.2Vrms using HA-2 coupler (IEC 60318-5, 2006) ● Distortion: < 3% THD @ 500 Hz, 118.5 dB SPL
Audiometric Transducers - Bone	● Audio Jack: 3.5mm Stereo ● Compliance: ○ ANSI S3.6-2010 ○ IEC 60645-1:2012 ○ Local medical device regulations, as applicable ● Nominal impedance: 10 ohm ● Frequency response: 250 Hz to 4kHz ● Distortion: <5.5% THD @ 250 Hz, 20 dBHL & 500 Hz to 4kHz, 50 fBHL
Headband for Bone Transducer	● Approved for clinical use ● Compatibility with bone transducer in use ● Adjustable headband tension ● Force: 5.4 + 0.5 N for full range of head circumferences as required by ANSI S3.6 and ISO 389-3
Digital to Analog Converter (DAC)	Note: DACs must be paired with transducers for calibration and use.
DAC (Air)	● USB-A Male ● 3.5mm Stereo Female ● OS Compatibility: Windows PC, Mac ● Ability to disable volume control in OS ● Queryable unique identifier in OS ● Output voltage: > 1.4 Vrms (125 Hz to 16 kHz) ● Sampling rate: > 96 kHz ● Crosstalk: < 70 B (125 Hz to 16 kHz) ● Distortion: < 0.5% THD @ 0 dBFS (125 Hz to 16 kHz) ● Compliance: ○ EN 55022 ○ EN 55024
DAC (Bone and Free Field)	● USB-A Male ● 3.5mm Stereo Female ● OS Compatibility: Windows PC, Mac ● Ability to disable volume control in OS ● Queryable unique identifier in OS ● Output voltage: > 1.2 Vrms (125 Hz to 16 kHz) ● Sampling rate: > 96 kHz

	• Crosstalk: < 70 dB (125 Hz to 16 kHz)
	• Distortion: < 0.5% THD @ 0 dBFS (125 Hz to 16 kHz)
	• Compliance:
	  ○ EN 55022
	  ○ EN 55024

Microphone	• USB-A or USB-C Male
	• Type: Electret condenser
	• OS Compatibility: Windows PC, Mac
	• Principle of operation: Pressure
	• Sensitivity: > -27 dBFS (94 dB SPL @ 1kHz)
	• Frequency response: 20 Hz to 20 kHz
	• SNR: > 62 dB
	• Compliance:
	  ○ EN 55032
	  ○ EN 55035
	  ○ IEC 61000-4-3
	  ○ IEC 61000-4-8
	• ANSI S1.4 / IEC 61672 Class II

Speakers	• Adjustable volume • Frequency response: > 125 Hz to 16 kHz • Output wattage: > 4.4W per speaker • SNR: > 86 dB • Compliance ○ IEC 62368-1 / IEC 60950-1 (for externally powered speakers or amplifier)

Video Otoscope	• USB-A Male
	• OS Compatibility: Windows PC, Mac
	• Compliance:
	  ○ Local medical device regulations, as applicable
	  ○ EN 55032
	  ○ EN 55035
	
	Note: Follow otoscope manufacturer IFU for proper use.

Disposable Specula Tips	• Recommended by Video Otoscope manufacturer Note: Disposable specula tips are single use and should not be reused as per manufacturer's recommendations.

Computer	• OS Compatibility: Windows PC, Mac
	• Web Browser: Google Chrome
	• Internet connection: > 2Mb/s
	• Screen: > 1280 px wide (1920 x 1080 recommended)
	• Memory: > 8 GB
	• Processor: 64-bit architecture with minimum 50% availability after launching Google Chrome
	• Sound output: Functioning stereo sound device
	• Compliance:
	  ○ IEC 62368-1 / IEC 60950-1
	  ○ Local EMC standards, as applicable (e.g. EN 301 489-1, EN 301 489-17)
	  ○ Local Radio Spectrum standards, as applicable (e.g. EN 300 328, EN 301 893, EN 300 440)

USB-A Response Button	• USB-A Male connector
	• OS Compatibility: Windows PC, Mac
	• 2m cable
	• Programmable
	• Compliance:
	  ○ EN 55032
	  ○ EN 55035

4-port USB-A to 4xUSB-A Hub (USB v3.2)	• Backward compatibility with USB 3.0, 2.0, and 1.1
	• OS Compatibility: OS independent
	• Performance: 5 Gbps (USB 3.2 Gen 1)
	• Power: Bus Powered (5V DC input voltage)
	• Compliance:
	  ○ EN 55032
	  ○ EN 55035
	  ○ IEC 61000-4-3
	  ○ IEC 61000-4-8

USB Interconnect	• USB extender cables, USB adapter, or another unpowered USB interconnect may be required for the specific configuration. • These USB interconnect components must comply with applicable EMC and safety standards for the component type.