



Viola Basic - Plus

COMBO UNIT: MIDDLE EAR ANALYZER / AUDIOMETER



CLASSIFICATION

IEC 60645-5 / ANSI S3.39: Type 2 middle ear analyzer
IEC 60645-1 / ANSI S3.6: Type 3 audiometer (Viola Basic), Type B/BE audiometer (Viola Plus)

AVAILABLE TESTS

- Tympanometry (automatic)
- Acoustic Reflex Threshold (automatic)
- 2 Automatic test sequences (tympanometry + reflex test)
- Pure Tone Audiometry

Only Viola Plus

- Acoustic Reflex Decay
- Speech Audiometry
- QuickSIN® test (optional)

MIDDLE EAR ANALYZER SPECIFICATIONS

PROBE TONE

Frequency: 226 Hz
Level: 85 dB SPL (@ 226 Hz)

COMPLIANCE MEASUREMENT SYSTEM

Volume range: 0.2 ÷ 8.0 ml (@ 226 Hz)

PRESSURE SYSTEM

Rotary type pump with endless flow

TYMPANOMETRY

Viewing mode: absolute or compensated
Single scan
User selectable pressure range
Maximum range: -600 to +400 daPa
Safety limits: -800 daPa and +600 daPa
Available rates: 50, 100, 200, 300 daPa/sec and AUTO (100-300 daPa/sec)
Auto start feature

ACOUSTIC REFLEX TEST

Ipsilateral and contralateral stimulation
Stimulus ON-Time: selectable from 0.5s to 2.5s
Stimulus OFF-Time: selectable from 0.5s to 2.5s
Three different tests available:

- Automatic threshold
- Fixed intensity
- Growing intensity

ACOUSTIC REFLEX DECAY TEST (Viola Plus only)

Ipsilateral and contralateral stimulation
Test duration: 10 sec or 20 sec (selectable)

QUICK TESTS

Two user programmable Quick tests available
Each test consists of a sequence of

- Tympanometry
- Reflex test (Fixed intensity or Automatic threshold, with user defined parameters)

AVAILABLE STIMULI AND MAXIMUM LEVELS

Attenuator step: 5 dB

Stimulus	IPSI (dB HL)	CONTRA TDH39 / DD45 headphone (dB HL)	CONTRA IME-100 earphone (dB HL)
250 Hz	-	100	-
500 Hz	100	120	110
1,000 Hz	110	120	115
2,000 Hz	105	120	110
4,000 Hz	100	120	110

AUDIOMETER SPECIFICATIONS

AVAILABLE SIGNALS

- Stimulus: pure tone, warble tone
 - Masking: NBN, WN, SN
- Only Viola Plus:
- 2 external inputs for speech audiometry
 - MIC input for live speech audiometry
 - Internal input (flash memory) for speech audiometry

SIGNALS SPECIFICATION

Attenuator step: 5 dB
Presentation: Continuous, Pulsed (0.5, 1 and 2 Hz)
Warble: 5 Hz sin wave modulating signal

AVAILABLE OUTPUTS AND TRANSDUCERS

AC: TDH-39 / DD45 headphones, ER-3C/ IP30 insert earphones
BC: B-71 bone vibrator
Insert masking earphone: IME-100

PURE TONE: FREQUENCIES AND MAXIMUM LEVELS (dB HL)

Freq. (Hz)	AC TDH-39 DD45	AC ER-3C IP30	BC B71
125	80	90	-
250	100	105	45
500	110	110	65
750	115	115	70
1.000	120	120	75
1.500	120	120	80
2.000	120	120	80
3.000	120	120	75
4.000	120	110	75
6.000	105	95	55
8.000	95	90	50

SPEECH AUDIOMETRY: MAXIMUM LEVELS (dB HL)

AC (*) TDH-39 DD45	AC ER-3C IP30	BC B71
100	100	55

(*) Reduce by 20dB in case of free field equivalent filter activation.

PATIENT – OPERATOR COMMUNICATION

Talk over: built-in or external microphone
Talk back (Viola Plus only): through built-in speaker or monitor headset (included); patient microphone included
Patient response trigger

MONITOR SIGNAL (only Viola Plus)

Both channels monitored through the built-in speaker or monitor headset (included)

PRINTER

Optional integrated thermal printer
Paper size: 112 mm

CALIBRATION

Validity: 12 months
All the parameters set through the device software

COMPUTER INTERFACE

Connection: USB (driverless)
Compatible software: Inventis Maestro

DISPLAY

Type: Graphical color TFT LCD
Size: diagonal 4.3", 95 mm x 54 mm
Resolution: 480 x 272

POWER SUPPLY

Without integrated printer:
Main Unit: 6Vdc, 1.3A
External adapter: 100-240 Vac 50/60 Hz 0.9-0.34A medical grade, responding to IEC 60601-1 standard

With integrated printer:
Main Unit: 6Vdc, 3.2A,
External adapter: 100-240 Vac 50/60 Hz 0.9-0.34A medical grade, responding to IEC 60601-1 standard

MECHANICS

Without integrated printer:
Size (WxDxH): 32 x 32 x 9 cm / 12.6 x 12.6 x 3.5 in
Weight: 1.9 Kg / 4.19 lbs

With integrated printer:
Size (WxDxH): 32 x 39 x 9 cm / 12.6 x 15.4 x 3.5 in
Weight: 2.4 Kg / 5.29 lbs

FREIGHT PACKING

Size (WxDxH): 47 x 42 x 35 cm / 18.5 x 15.8 x 13.8 in
Gross weight (without printer): 4.3 Kg / 9.48 lbs
Gross weight (with printer): 4.8 Kg / 10.58 lbs

APPLICABLE STANDARDS

Impedance: IEC 60645-5 / ANSI S3.39
Pure tone audiometry: IEC 60645-1 / ANSI S3.6
Speech audiometry (Viola Plus): IEC 60645-1 / ANSI S3.6
Calibration: ISO 389-2 (IPSI), ISO 389-1 (CONTRA TDH 39, DD45) ISO 389-2 (CONTRA IME-100)
Electrical safety: IEC 60601-1
EMC: IEC 60601-1-2

CE CERTIFICATE

MDR 2017/745/EU Classification: Class IIa
Classification rule (Annex VIII, 2017/745): 10
Notified body: TÜV SÜD Product Service GmbH (0123)

PRODUCT CODES

10343: Viola Basic
10344: Viola Basic – with integrated thermal printer
10374: Viola Plus
10375: Viola Plus – with integrated thermal printer

INCLUDED PARTS

- Main unit
- Control box with probe
- Shoulder strap for probe control box
- Wrist strap for probe control box
- Single TDH-39 or DD45 contralateral headset (IME-100 contralateral earphone for -INS models)
- Calibration cavities
- Assorted ear tips box
- 3pcs heat-sensitive paper rolls (only for models with printer)
- TDH-39 or DD45 supra-aural headphones
- B71 bone vibrator
- Patient response switch
- Monitor headset with boom microphone (Viola Plus only)
- Clip-on microphone for patient-to-operator communication (Viola Plus only)
- Plastic cover sheet
- Medical grade power supply
- USB connection cable
- User manual

OPTIONAL PARTS (with order code)

- 10833: ER-3C insert earphones
- 11748: IP30 insert earphones
- 10177: IME-100 insert masking earphone
- 10342: IME-100 Insert earphone for contra reflex testing
- 10181: Desktop, battery operated microphone for live speech tests (Viola Plus only)
- 10182: Soft carrying case
- 11672: Handheld support for Inventis tympanometers probe
- 10179: Amplivox Audiocups noise excluding enclosures for TDH-39 and DD45 headphones
- 10533: QuickSIN® test license (Viola Plus only)
- 10180: Cable set for sound booth with Jack sockets
- 10557: Cable set for sound booth with RCA sockets

DISPOSABLES (with order code)

- 10293: Thermal paper for printer (box of 5)
- 10488: White tips (diam. 6 mm) – Set of 30
- 10489: Pink tips (diam. 7 mm) – Set of 30
- 10490: Violet tips (diam. 8 mm) – Set of 30
- 10491: Green tips (diam. 10 mm) – Set of 30
- 10492: Red tips (diam. 12 mm) – Set of 30
- 10493: Blue tips (diam. 14 mm) – Set of 30
- 10494: Orange tips (diam. 16 mm) – Set of 30
- 10495: Light blue tips (diam. 18 mm) – Set of 30
- 10496: Yellow tips (diam. 21 mm) – Set of 30
- 10511: Box with assorted tips – Set of 160
- 10554: Cleaning brushes for the tympanometers probe

SUMMARY

	Viola Basic	Viola Plus
Automatic tympanometry	✓	✓
Reflex test		
<i>Fixed intensity</i>	✓	✓
<i>Growing intensity</i>	✓	✓
<i>Automatic threshold</i>	✓	✓
Acoustic reflex decay	-	✓
Quick tests (tymp. + reflex seq.)	✓	✓
Probe tones	226 Hz	226 Hz
Pure Tone audiometry	✓	✓
Speech audiometry	-	✓

Viola is manufactured by:

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