



# Viola Basic - Plus

COMBO UNIT: MIDDLE EAR ANALYZER / AUDIOMETER



## DESCRIPTION

Viola is a combo unit that integrates a screening middle ear analyzer offering ultrafast and reliable tympanometry and reflex tests with a diagnostic audiometer capable of performing threshold and speech examinations in AC and BC.

## 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**

	<b>Viola Basic</b>	<b>Viola Plus</b>
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:

**INVENTIS S.r.l.**

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