



# 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<br>TDH39 /<br>DD45<br>headphone<br>(dB HL) | CONTRA<br>IME-100<br>earphone<br>(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.<br>(Hz) | AC<br>TDH-39<br>DD45 | AC<br>ER-3C<br>IP30 | BC<br>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 (*)<br>TDH-39<br>DD45 | AC<br>ER-3C<br>IP30 | BC<br>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
- Electronic IFU

#### 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 100
- 10489: Pink tips (diam. 7 mm) – Set of 100
- 10490: Violet tips (diam. 8 mm) – Set of 100
- 10491: Green tips (diam. 10 mm) – Set of 100
- 10492: Red tips (diam. 12 mm) – Set of 100
- 10493: Blue tips (diam. 14 mm) – Set of 100
- 10494: Orange tips (diam. 16 mm) – Set of 100
- 10495: Light blue tips (diam. 18 mm) – Set of 100
- 10496: Yellow tips (diam. 21 mm) – Set of 100
- 10511: Box with assorted tips – Set of 160
- 10554: Cleaning brushes for the tympanometers probe

**SUMMARY**

|                                   | Viola<br>Basic | Viola<br>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:

**INVENTIS S.r.l.**

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The Inventis Quality System complies with ISO 13485 standard.

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