



Flute Basic – Plus – HF

DIAGNOSTIC MIDDLE EAR ANALYZER



CLASSIFICATION

Flute is a diagnostic middle ear analyzer, capable of performing incredibly fast and reliable automatic sequences of tympanometry and reflex threshold tests.

CLASSIFICATION

IEC 60645-5 / ANSI S3.39: Type 2

PROBE TONE

Frequency: 226 Hz

1000 Hz (Flute Plus w/optional license and Flute HF)

Level: 85 dB SPL (@ 226 Hz)

75 dB SPL (@ 1000 Hz)

COMPLIANCE MEASUREMENT SYSTEM

Volume range: .0.2 ÷ 8.0 ml (@ 226 Hz)

0.9 ÷ 15 mmho (@ 1000 Hz)

PRESSURE SYSTEM

Rotary type pump with endless flow

Manual pressure adjustment available in the tympanometry and reflex tests (Flute Plus only)

AVAILABLE TESTS

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

Only Flute Plus

- Tympanometry (manual)
- Acoustic Reflex Threshold (manual)
- Acoustic Reflex Decay
- Eustachian Tube Function (intact TM)

Only Flute HF

- Eustachian Tube Function (intact and perforated TM)

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)

Manual pressure adjustment (Flute Plus only)

Auto start feature

ACOUSTIC REFLEX TEST

Ipsilateral and contralateral stimulation

Non-acoustic stimulation (Flute Plus only)

Stimulus ON-Time: selectable from 0.5s to 2.5s

Stimulus OFF-Time: selectable from 0.5s to 2.5s

Four different tests available:

- Automatic threshold
- Fixed intensity
- Growing intensity
- Manual mode (Flute Plus only)

ACOUSTIC REFLEX DECAY TEST (FLUTE PLUS ONLY)

Ipsilateral and contralateral stimulation

Non-acoustic stimulation

Test duration: 10 sec or 20 sec (selectable)

EUSTACHIAN TUBE FUNCTION TEST

ETF with TM intact: Williams test

ETF with perforated TM: Toynbee test, with customizable duration and pressure range

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
3,000 Hz*	105	120	110
4,000 Hz	100	120	110
6,000 Hz*	100	105	100
8,000 Hz*	-	100	-
BBN*	95	115	105
LPN*	95	115	105
HPN*	95	115	105

(*) available only on Flute Plus model

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, 1.2A

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 / 5.29lbs

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

Calibration: ISO 389-2 (IPSI), ISO 389-1 (CONTRA TDH 39, CONTRA 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

10337: Flute model Basic

10338: Flute model Basic – with integrated thermal printer

10340: Flute model Plus

10341: Flute model Plus – with integrated thermal printer

10409: Flute model HF

10410: Flute model HF – 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 contralateral headset or single DD45 contralateral headset or insert contralateral earphone
- Calibration cavities
- Assorted ear tips box
- 3pcs heat-sensitive paper rolls (only for models with printer)
- Plastic cover sheet
- Medical grade power supply
- USB connection cable
- Electronic IFU

OPTIONAL PARTS (with order code)

- 10342: Insert earphone for contra reflex testing
- 10182: Soft carrying case for audiometers/tympanometers
- 10864: 1KHz Probe tone license for Flute Plus
- 11672: Handheld support for Inventis tympanometers probe

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

	Flute Basic	Flute Plus	Flute HF
Automatic tympanometry	✓	✓	✓
Manual tympanometry	-	✓	-
Reflex test			
<i>Fixed intensity</i>	✓	✓	✓
<i>Growing intensity</i>	✓	✓	✓
<i>Automatic threshold</i>	✓	✓	✓
<i>Manual</i>	-	✓	-
Acoustic reflex decay	-	✓	-
Quick tests (tymp. + reflex seq.)	✓	✓	✓
ETF			
<i>TM intact</i>	-	✓	✓
<i>TM perforated</i>	-	-	✓
Probe tones	226 Hz	226 Hz 1000 Hz(*)	226 Hz 1000 Hz

(*) Available through optional activation license

Flute is manufactured by:

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