



FLUTE & VIOLA

MIDDLE EAR ANALYZERS



QUICK START GUIDE

IT - Guida Rapida

EN - Quick Start Guide

DE - Kurzanleitung

FR - Guide de Démarrage Rapide

ES - Guía de Inicio Rápido

PT - Guia de Início Rápido

QUICK START GUIDE: ENGLISH

INTENDED USE

Flute and Viola middle ear analyzers are medical devices intended to measure biomechanical characteristics of the patient's middle ear to aid the operator to evaluate its functional condition for diagnostic purposes.

Viola is also an audiometer. An audiometer is a device that helps the operator in defining the patient's auditory sensitivity by generating and delivering to the patient sound stimuli of different types and intensities for diagnostic purposes.

INDICATION FOR USE AND END USERS

Flute and Viola are intended for use by healthcare ENT professionals in hospitals, ENT clinics and audiology offices in conducting hearing evaluations and assisting in diagnosis of possible otologic disorders. There is no patient population restriction in the use of the device; always be sure to perform an otoscopy before using the device.

These tests – especially the audiometric tests – must be conducted in a quiet environment to avoid artifacts and to ensure that errors are not committed when determining the hearing threshold.

PRECAUTIONS



Users are entirely responsible for any malfunction caused by improper use, or by maintenance or repair operations performed by any party other than Inventis srl or an authorized Service Centre.

Installation



If the middle ear analyser is connected to other devices, making up an electromedical system, the resulting system must comply with IEC standard 60601-1.



Avoid installing and using Flute & Viola instruments close to any sources of strong electromagnetic fields: these could interfere with the operation of the device.

Calibration



The calibration is valid only for the transducers supplied with the device. If a transducer is replaced, the audiometer must be recalibrated.

Use



Be sure to set a suitable intensity of stimulus before presenting it to the patient.



The ear tips of the middle ear analyzer probe are disposable, likewise that of the insert earphone for contralateral stimulus, and those of ER-3 and ER-5 earphones; do not use the same ear tips for different patients. Dispose of ear tips after use.



Disinfect the cushions of headphones between one patient and the next.

REAR PANEL CONNECTIONS

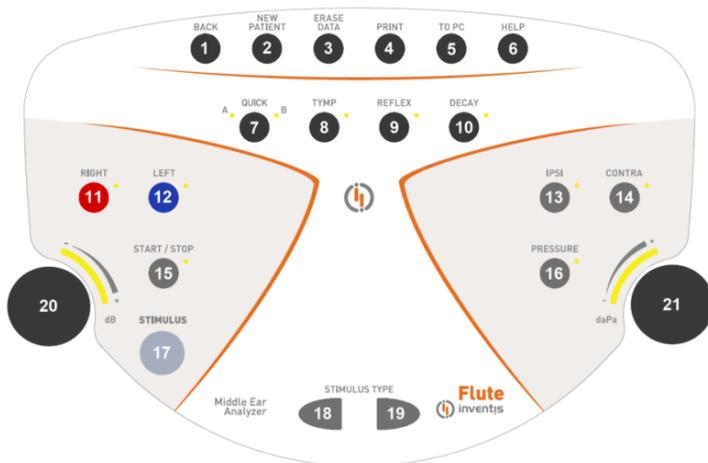


Rear Panel of Viola combo unit.

Viola Basic and Flute may not have some of these connectors.

Connector	Description
1	Power switch (0: Off, 1:on)
2	Power supply connection
3	USB cable for the connection to the PC
4	Patient response switch
5	Microphone for operator to patient communication
6	Monitor headphones
7	External input 1 for speech audiometry
8	External input 2 for speech audiometry
9	Operator microphone for live speech tests
10	Patient microphone
11	Free field speaker: Left L
12	Free field speaker: Right R
13	AC headphones - Right R
14	AC headphones - Left L
15	Insert earphone for masking
16	Bone vibrator

KEYBOARD OF THE FLUTE MIDDLE EAR ANALYZER



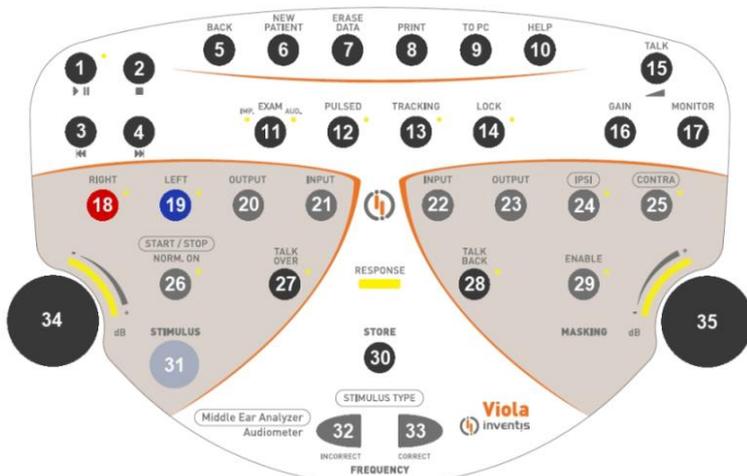
*Keyboard of the Flute Plus middle ear analyzer.
Certain buttons are not present on the Flute Basic model.*

Button		Function
1	BACK	Pressed to go back to the previous window.
2	NEW PATIENT	Cancels all examinations conducted in the current session.
3	ERASE DATA	Deletes the current data.
4	PRINT	Starts the printout of the current test (if the audiometer is equipped with the thermal printer).
5	TO PC	Sends the current examination to a computer.
6	HELP	Opens a context-sensitive help window.
7	QUICK	Accesses Quick tests. Pressing repeatedly, the instrument toggles between Quick A and Quick B tests.
8	TYMP	Accesses the tympanometry test window.
9	REFLEX	Accesses the acoustic reflex test window.
10	ETF / DECAY	Accesses the Eustachian Tube Function test window (HF version only) or the acoustic reflex decay test window (Plus version only).
11	RIGHT	Selects the stimulation side.
12	LEFT	
13	IPSI	Selection of output for acoustic reflex and reflex decay tests: ipsilateral or contralateral.
14	CONTRA	
15	START / STOP	Used to start and stop the test currently selected.
16	PRESSURE	Accesses the screen allowing adjustment of the pressure at which acoustic reflex and decay tests are conducted.
17	STIMULUS	During acoustic reflex and reflex decay examinations, can be pressed to run (or repeat) the test relative to the box currently selected.

18	STIMULUS TYPE	Selects the type of stimulus used for the acoustic reflex test.
19		
20	<i>Left hand knob</i>	Adjusts the output strength of the stimulus. This knob is also used to select the various items of the Settings menu.
21	<i>Right hand knob</i>	Adjusts the pressure at which acoustic reflex and decay tests are conducted (Flute Plus only) Also used to change the values of parameters when the Settings menu is activated.

KEYBOARD OF THE VIOLA ‘COMBO’ IMPEDANCE-AUDIOMETER

Certain buttons on the keyboard of Viola models (e.g. number 26) have more than one function, depending on the examination selected. If the window currently displays an impedance-related test, the button will have the function inscribed in the border, whereas if the screen is displaying an audiometric test page, the other function indicated will be the active function.



Keyboard of the Viola Pus ‘combo’

Certain buttons are not present on the Viola Basic impedance-audiometer.

Button		Function
1	▶	Starts or pauses the playback of word list.
2	■	Terminates playback of the current list.
3	◀◀	If audio material is not playing: brings up the list preceding the current list. If audio material is playing: jumps back to the previous word, if the list is indexed, or by 5 seconds if not indexed.

4		If audio material is not playing: brings up the list that follows the current list. If audio material is playing: jumps forward to the next word, if the list is indexed, or by 5 seconds if not indexed.
5	BACK	Pressed to go back to the previous window.
6	NEW PATIENT	Cancels all examinations conducted in the current session.
7	ERASE DATA	Deletes the current data.
8	PRINT	Starts the printout of the current test (if the audiometer is equipped with the thermal printer).
9	TO PC	Sends the current examination to a computer.
10	HELP	Opens a context-sensitive help window.
11	EXAM	Allows direct access (without going through the main menu) to impedance and audiometry tests.
12	PULSED	For pure tone audiometry, allows selection of pulsed mode for presentation of the stimulus.
13	TRACKING	If enabled, the difference between the intensity of the stimulus and masking signals is maintained constant, changing the intensity of the stimulus signal.
14	LOCK	When the lock option is selected, the masking tone will be switched on and switched off together with the stimulus tone (the masking tone <i>Enable</i> button is deactivated).
15	TALK	Shows a volume control window for communications between patient and operator.
16	GAIN	(Only for Speech audiometry) Shows a gain control window for the speech material.
17	MONITOR	Shows a volume control window for monitor signals used by the operator.
18	RIGHT	Selects the stimulation side. For stimulation on both sides, press the two keys simultaneously.
19	LEFT	
20	OUTPUT	Selects the transducer for the stimulus channel.
21	INPUT	Selects the input signal for the stimulus channel.
22	INPUT	Selects the input signal for the masking channel.
23	OUTPUT	Selects the transducer for the masking channel.
24	IPSI	Selects the output for acoustic reflex and reflex decay tests: ipsilateral or contralateral.
25	CONTRA	
26		For impedance examinations, used to start and stop the test currently selected. For audiometric tests, can be used to keep the output of

		the stimulus channel permanently active, as long as the stimulus button (31) is not depressed.
27	TALK OVER	When pressed and held, allows operator-to-patient communication.
28	TALK BACK	Allows patient-to-operator communication.
29	ENABLE	Switches the masking signal on or off
30	STORE	For audiometric tests, stores the current threshold level.
31	STIMULUS	During acoustic reflex examinations, can be pressed to run (or repeat) the test relative to the box currently selected, without having to repeat the entire test. During audiometric tests, switches on the stimulus signal.
32		During reflex tests, used for selection of the stimulus to be presented to the patient.
33	STIMULUS TYPE FREQUENCY	During pure tone audiometry, used to select the previous or next frequency. During speech audiometry, used to count the words the patient is either able to recognize (CORRECT , 33) or unable to recognize (INCORRECT , 32)
34	Knobs	Regulates the output volume or scrolls a list of settings.
35		
	RESPONSE	Lights up whenever the patient presses the response button.

REMOTE CONTROL UNIT (RCU) AND PROBE STATUS

The remote control unit (RCU) designed for use with Flute and Viola middle ear analyzers is illustrated below.



There are two buttons on the RCU: the first (START) has the same function as the START/STOP button on the keyboard; the second button can be pressed to select the side on which the stimulus is presented.

There are also two LEDs, one of which indicates the ear being tested (red: right ear; blue: left ear), the other indicating the status of the probe. This information is also shown on the display of the instrument, and can be summarized in the table below.

<i>Indication in display</i>	<i>LED status</i>	<i>Explanation</i>
READY	Green blinking	The examination is ready to start

OPEN	Yellow permanently alight	Probe open: the compliance measured is above the upper limit of the measurement range
CLOSED	Yellow blinking	Probe blocked: the compliance measured is below the lower limit of the measurement range
PRESSURIZATION / DEPRESSURIZATION	Green permanently alight	Pressurization / depressurization of ear canal in progress
COMPLIANCE CHECK	Green permanently alight	Compliance is verified before starting an acoustic reflex test. The stimulus will be presented only when compliance is stable
IN PROGRESS	Green permanently alight	Test in progress
PRESSURE LEAKAGE	Yellow permanently alight	Lack of airtight seal between probe and ear canal

OPERATING INSTRUCTION

* To select those functions marked with the asterisk, press the corresponding key, placed below the display.

** Referred only to Flute Plus, Flute HF

Access to examinations

Flute: There are four buttons (7, 8, 9, 10) in the top half of the keyboard, giving direct access to examinations. To bring up the screen for a given examination, accordingly, press the corresponding button.

Viola: From the main window of the instrument, scroll the list of tests with the left hand knob (34) and, having made the selection, access the relative window by pressing OK* or the stimulus button (31).

Impedance / reflex tests

The first step in ensuring that an impedance or reflex will be performed correctly is to select the earpiece best suited to the patient being examined, and introduce the probe together with the earpiece into the patient's ear canal, to the point at which a tight pressure seal is assured.

Tympanometry

- Select the ear being examined, left side or right side;

- select the rate at which the pressure sweep occurs during the course of the test (P. RATE *);
- select the preferred probe tone (226 / 1000 Hz)*,**
- start the test (START/STOP button). The test will start only if the status of the probe is indicated as *READY*.
- on completion of the examination, the results of the test will be calculated and displayed.

Acoustic Reflexes

- Select the ear being examined, left side or right side;
- select the mode of performing the reflex test (MODE*);
- check the types of stimulus — box by box — to be presented to the patient. Change the characteristics of the stimuli, if necessary, by accessing the settings window (SETTINGS*), for preconfigured modes (*Fixed intensity, Threshold search*); for *Growing intensity* and *Manual* modes, select the output (ipsilateral or contralateral), the type, and the intensity of the stimulus;
- (on Flute Plus only) if necessary, access the window allowing adjustment of the pressure at which the test is to be conducted (16), the default value being the peak value of the tympanogram; start the test.
- To examine all of the boxes, press the START/STOP button. To examine a single box, select it with the right hand knob and press the STIMULUS button.

Reflex Decay

- select the ear being examined, left side or right side;
- using the right hand knob, select the box in which to create the graph;
- select the output of the stimulus: ipsilateral or contralateral;
- select the type and intensity of the stimulus;
- (on Flute Plus only) if necessary, access the window allowing adjustment of the pressure at which the test is to be conducted (16), the default value being the peak value of the tympanogram; start the test by pressing the START/STOP button. The ear canal will be pressurized to the value appearing in the display;
- Press the STIMULUS button to present the stimulus to the patient.

For safety reasons, if the intention is to present a stimulus signal stronger than 100 dB HL, the instrument will prompt for confirmation.

Eustachian Tube Function test (ETF) with eardrum intact

- Select the ear being examined, left side or right side;
- select the rate at which the pressure sweep occurs during the course of the test (P. RATE *);

- start the test (START/STOP button). The test will start only if the status of the probe is indicated as *READY*;
- a first tympanogram is generated and the pressure in the ear canal is raised automatically to +400 daPa;
- invite the patient to swallow several times, as indicated in the pop-up message, and press the CONTINUOUS* function button;
- a second tympanogram is generated and the pressure in the ear canal is lowered automatically to -400 daPa;
- invite the patient to swallow several times, as indicated in the pop-up message, and press the CONTINUOUS* function button;
- a third tympanogram is generated and all three graphs are shown in the display.

Eustachian Tube Function test (ETF) with perforated eardrum

- Select the ear being examined, left side or right side.
- Select the maximum pressure (PRESS. MAX* function buttons), or, the pressure that will be established in the middle ear of the patient for the purposes of assessing Eustachian tube function;
- select the duration of the test by pressing the DURATION* function button (selectable values are 20, 30, 40 or 50 seconds);
- start the test (START/STOP button). The test will start only if the status of the probe is indicated as *READY*.
- ask the patient to swallow so that a variation of pressure can be induced in the examined ear, and functionality of the Eustachian tube thus evaluated.

Quick A / Quick B

Quick A and Quick B are sequential tests in which the tympanometry examination and then the acoustic reflex examination (configurable on the Settings page of the instrument) are run automatically one after the other.

- access the window relative to the tympanometry examination;
- select the ear being examined, left side or right side;
- select the rate at which the pressure sweep occurs during the course of the test (P. RATE *);
- start the test (START/STOP button). The test will start only if the status of the probe is indicated as *READY*.
- once the test has been concluded, press the scroll button (<<* or >>*) to change the type of test displayed.

Pure-tone audiometry (Viola only)

- select the type of threshold to examine (HL/UCL*);
- select the stimulus input signal (21);
- select the masking input signal (22);

- select the transducer for the stimulus canal (20) and the masking canal (23);
- Select the mode of presenting the stimulus (12) between continuous or pulsed and, where appropriate, change the pulse frequency by pressing the appropriate key below the display;
- Select the stimulation side: R (18), L (19) or Bilateral (18+19); the masking signal is automatically set to contralateral;
- Select the frequency (32), (33) and the intensity (34) of the stimulus; to select an intensity above 100 dB HL, press the *HIGHER dB** button;
- If masking is required, select the intensity (35) and enable (29);
- Deliver the stimulus (31);
- When the threshold is identified, store it (30) or press *NO RESP.** if the patient cannot hear the tone at its maximum intensity.

Speech audiometry (Viola Plus only)

- Select the type of speech test to be conducted (TEST: ---*)
- Select the input signal for Channel 1: (21); the INT input refers to the internal flash memory;
- Select the masking signal: (22);
- Adjust the inputs gains: play the calibration tone (if the input is EXT or INT), press (16) and regulate the gains through (34), (35);
- select the transducer for the stimulus canal (20) and the masking canal (23);
- Select the stimulation side: R (18), L (19), or Bilateral (18+19); the masking signal is automatically set to contralateral;
- Select the intensity of stimulus (34) and masking signal (35);
- Play the words list (in case of INT input, use (1), (2), (3) and (4)) or say the words (in case of MIC input);
- Update the score, by pressing (32) or (33), depending on the Speech score mode and the correct or incorrect answer given by the patient;
- To save the score, press (30).

For uploading a word list onto the internal flash memory, use the *Audio Tracks Indexing Tool (ATIT)* software, supplied with the audiometer. With this software you can also *index* the lists, so that you can see on the device display the word being pronounced.

For a detailed description of the ATIT software, refer to the relative manual, which will be found on the “Software Suite” CD.

TECHNICAL SPECIFICATIONS

Classification

All:

Type 2 middle ear analyzer (IEC 60645-5 / ANSI S3.39)

Viola Basic:

Type 3 pure tone audiometer (IEC 60645-1 / ANSI S3.6)

Viola Plus:

Type 3B/BE pure tone audiometer (IEC 60645-1)

Type 3C/3CE audiometer (ANSI S3.6)

Tympanometer specifications

Probe Tone

Frequency: 226 Hz Level: 85 dB SPL

Frequency: 1000 Hz Level: 75 dB SPL

Compliance measurement system

Volume range: 0.2 ÷ 8.0 ml (@ 226 Hz)
0.9 ÷ 15 mmho (@ 1000 Hz)

Pressure measurement system

User selectable range

Maximum range: -600 to +400 daPa

Available rates: 50, 100, 200, 300 daPa/sec and AUTO (100-300 daPa/sec)

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

Acoustic reflex tests

Ipsilateral and contralateral stimulation

ON-Time and OFF-Time: selectable from 0.5s to 2.5s

Reflex Decay (only Flute Plus and Viola Plus)

Test duration: 10 sec or 20 sec (selectable)

ETF with perforated eardrum (only Flute HF)

Customable pressure range (max. absolute value: -600 daPa ÷ +400 daPa)

Test duration: 20s, 30s, 40s, 50s (customable)

Available stimuli and maximum levels (dB HL)

Freq. (Hz)	IPSI	CONTRA TDH-39 headphone	CONTRA DD45 headphone	CONTRA IME-100 earphone
250	--	100	100	--
500	100	120	120	110
1,000	110	120	120	120
2,000	105	120	120	120
4,000	100	120	120	110

Audiometer specifications

Available signals

Stimulus: pure tone, warble tone.

Masking: NBN, WN, SN (only Viola Plus).

Speech audiometry inputs: EXT1, EXT2, MIC, INT (flash memory, only Viola Plus).

Signals specifications

Attenuator step: 5dB.

Presentation: Continuous, Pulsed (0.5, 1, 2 Hz).

Warble: 5 Hz sin wave modulating signal

Available outputs and transducers

AC: TDH-39 headphones, DD45 headphones, ER-3 or ER-5¹ insert earphones

BC: B-71 bone vibrator

Insert masking earphone: IME-100

Pure tone: available frequencies and maximum levels (dB HL)

Freq. (Hz)	AC TDH-39	AC DD45	AC ER-3	AC ER-5	BC
125	80	80	90	90	--
250	100	100	105	100	45
500	110	110	110	110	65
750	115	115	115	120	70
1.000	120	120	120	120	75
1.500	120	120	120	120	80
2.000	120	120	120	115	80
3.000	120	120	120	115	75
4.000	120	120	110	110	75
6.000	110	110	95	100	55
8.000	100	100	90	90	50

Speech audiometry: maximum levels (dB HL)

AC TDH-39 ANSI S3.6 Type C, IEC 60645-1 Type B (*)	AC TDH-39 ANSI S3.6 Type CE, IEC 60645-1 Type BE (**)	AC DD45 ANSI S3.6 Type C, IEC 60645-1 Type B (*)	AC DD45 ANSI S3.6 Type CE, IEC 60645-1 Type BE (**)	AC ER-3 / ER-5	BC
100	80	100	80	100	55

(*) Free Field Equivalent filter OFF

(**) Free Field Equivalent filter ON

¹ Supported but not available for purchase

Patient – operator communication and monitoring

Talk over: via built-in or external microphone.

Talk back: patient microphone input.

Monitor signal (only Viola Plus)

Both channels can be monitored through built-in speakers on the chassis or monitor headphones.

Internal flash memory (only Viola Plus)

Used to store the speech material (*wav* format); *Capacity:* 4 GB.

Speech material upload: through ATIT software (incl.)

Display

Type: Graphical color TFT LCD; *Size:* diagonal 4.3”, 95 mm x 54 mm;

Resolution: 480 x 272

Available tests

	<i>Flute Basic</i>	<i>Flute Plus</i>	<i>Flute HF</i>	<i>Viola Basic</i>	<i>Viola Plus</i>
Tympanometry	•	•	•	•	•
Acoustic reflex					
<i>Fixed intensity</i>	•	•	•	•	•
<i>Growing intensity</i>	•	•	•	•	•
<i>Automatic threshold</i>	•	•	•	•	•
<i>Manual</i>	-	•	-	-	-
Reflex Decay	-	•	-	-	•
ETF					
<i>TM intact</i>	-	•	•	-	-
<i>TM perforated</i>	-	-	•	-	-
Probe tone	226 Hz	226 Hz / 1000 Hz (opt)	226 Hz / 1000 Hz	226 Hz	226 Hz
Quick A	•	•	•	•	•
Quick B	•	•	•	•	•
Pure tone audiometry	-	-	-	•	•
Speech audiometry	-	-	-	-	•

Printer

Optional integrated thermal printer; *Paper size:* 112 mm.

Calibration

Validity: 12 months.

ISO 389-2 (IPSI, CONTRA IME-100, ER-3, ER-5, IME-100),

ISO 389-1 (CONTRA TDH-39, TDH-39, CONTRA DD45, DD45), ISO 389-3 (B71)

Computer interface

Connection: USB (driverless); *Compatible software:* Inventis Maestro.

Power supply

Without integrated printer: Consumption (max.): 7.8W. Power supply: 6V, 1.3A cont., through an external medical grade 100-240 Vac 50/60 Hz power supply

With printer: Consumption (max.): 19.2W. Power supply: 6V, 3.2A cont., through an external medical grade 100-240 Vac 50/60 Hz power supply

Mechanics

Without integrated printer: Size (WxDxH): 32x32x9 cm. Weight: 1.9 kg

With integrated printer: Size (WxDxH): 32x39x9 cm. Weight: 2.4 kg

Applicable standards

Electrical safety: IEC 60601-1. *EMC:* IEC 60601-1-2