

MADSEN OTOflex 100 Specifications

MADSEN OTOflex 100 & OTODiagnostics Suite

Application specification

Tympanometry

Probe tones:	226, 1000 Hz
Pressure range:	<ul style="list-style-type: none">• Standard: Fixed to -400 to +200 daPa• Custom: Negative pressure: -600 to -50 (in 50 daPa steps) Positive pressure: +50 to +400 daPa (in 50 daPa steps)
Pump speed:	<ul style="list-style-type: none">• 50, 100, 200, 400 daPa/s,• AFAP (As Fast As Possible, >500 daPa/s in 2cc)
Sweep direction:	Negative or Positive

Graphical presentation

- Features:
- Multi-layered tympanograms with 1-3 curves (ETF-I)
 - Component tympanometry (B/G)^{ODS}

- Automation:
- Auto next curve
 - Auto start on seal

- Baselines:
- None (absolute admittance)
 - Magnitude compensated
 - Component compensated (B/G)^{ODS}

Tymp characteristics: TPP, ECV, SC/SA, TW

Norm & classification: Adult, 226 Hz

Scaling: Manual settings or Automatic

Admittance units: mmho, ml, cm³, cc

Pressure units: daPa

Reflex screening

Probe tones:	226, 1000 Hz
Pressure compensation:	TPP from latest tympanometry at same probe tone
Stimuli:	<ul style="list-style-type: none">• 500, 1000, 2000, 4000 Hz, BBN• Selectable stimuli in any order• Ipsi, Contra, Ipsi then Contra, Contra then Ipsi (OTOflex 100 Diagnostic only)
Stimulus intensities:	<ul style="list-style-type: none">• Customizable up to 100 dB HL• 1, 2, or 3 increasing intensities (in 10, 15, or 20 dB steps)
Pause and resume test:	<ul style="list-style-type: none">• Pause manually, on leak, and on intensity warning• Optional skip to next stimulus• Manual or automatic resume
Detection levels:	<ul style="list-style-type: none">• 226 Hz probe tone: 0.01-0.10 mmho• 1000 Hz probe tone: 0.04-0.43 mmho

Graphical presentation:

- Features:
- Multiple deflection curves per stimulus type
 - Detection level visualized in deflection graph
 - Tabular results (present/not-present or intensity)

Reflex threshold (Diagnostic version only)

Probe tones:	226, 1000 Hz
Pressure compensation:	<ul style="list-style-type: none">• TPP from latest tympanometry at same probe tone• TPP offset -50 to +50 daPa• Optional pumping during stimulus
Stimuli:	<ul style="list-style-type: none">• 500, 1000, 2000, 3000, 4000 Hz, BBN, LBN, HBN• Ipsi: Pulsed, Contra: Steady at 226 Hz probe tone, pulsed at 1000 Hz probe tone• Configurable pre-stim, stim, post-stim, and pause timing
Auto threshold search:	<ul style="list-style-type: none">• Selectable stimuli in any order• Ipsi, Contra, Ipsi then Contra, Contra then Ipsi• Customizable intensity start, max, and increment (1, 2, 5, 10 dB)• Max intensity: up to 105 dB HL• Increasing or decreasing search according to reflex responses• Manual threshold override
Semi-auto threshold search:	<ul style="list-style-type: none">• Manually selected stimulus• Otherwise follows Auto threshold settings• Manual threshold override
Manual threshold search:	<ul style="list-style-type: none">• Manual presentation and threshold marking
Pause and resume testing:	<ul style="list-style-type: none">• Pause manually, on leak, and on intensity warning• Optional skip to next stimulus• Manual or automatic resume
Detection levels:	226 Hz probe tone: 0.01-0.10 mmho 1000 Hz Probe tone: 0.04-0.43 mmho

Graphical presentation:

- Features:
- Multiple deflection curves per stimulus type
 - Detection level visualized in deflection graph
 - Tabular thresholds (customizable table)
 - Acoustic reflex thresholds plotted in audiogram

With NOAH compatible database: Pure tone audiogram^{ODS} imported and plotted together with the acoustic reflexes

Reflex decay (Diagnostic version only)

- Probe tones: 226 Hz
- Pressure compensation:
- TPP from latest tympanometry at same probe tone
 - TPP offset -50 to +50 daPa
 - Optional pumping during stimulus
- Stimuli:
- 500, 1000 Hz
 - Steady tone
 - Default stimulus intensity: Threshold + 10 dB
 - Configurable pre-stim, stim, post-stim, and pause timing
- Auto decay test:
- Selectable stimuli in any order
 - Ipsi, Contra, Ipsi then Contra, Contra then Ipsi
- Manual decay test:
- Manual presentation
- Pause and resume testing:
- Pause manually, on leak, and on intensity warning
 - Optional skip to next stimulus
 - Manual or automatic resume

Graphical presentation:

- Features:
- Deflection curves w/100% and 50% deflection markers
 - Tabular half-lives (customizable table)

Reflex decay (Quick-check version)

- Probe tones: 226 Hz
- Pressure compensation:
- TPP from latest tympanometry at same probe tone
 - TPP offset -50 to +50 daPa
 - Optional pumping during stimulus
- Stimuli:
- 1000 Hz
 - Steady tone
 - Configurable pre-stim, stim and post stim timing
- Manual decay test:
- Manual presentation

Graphical presentation:

- Features:
- Deflection curves w/100% and 50% deflection markers
 - Tabular half-lives (customizable table)

ETF-P (OTOflex 100 Diagnostic only)

- Pressure control:
- Range: -600 to +400 daPa
 - Auto pressure build-up 50, 100, 200, 400 daPa/s
 - Manual pressure build-up^{OTOflex}
 - Positive and negative pressure testing

Graphical presentation:

- Features: Pressure recorded as function of time
- Time window: Auto expansion 30-60 s
- ET open/close pressures:
- Auto detect^{ODS}
 - Manual graphical adjustments^{ODS}

Test sequences

- Sequences:
- Tympanometry + Reflex Screening
 - Tympanometry + Reflex Threshold
 - Tympanometry + Reflex Threshold + Reflex Decay
- Dynamically selectable with any test setting
- Automation:
- Auto start on seal
- Pause and resume testing:
- Pause manually, on leak, and on intensity warning
 - Manual or automatic resume

Technical specifications – OTOflex 100

Admittance measuring system

Probe tone intensities: • 226 Hz @ 85dB SPL \pm 1.5dB
• 1000 Hz @ 75dB SPL \pm 1.5dB

Total Harmonic Distortion: < 3% in 2 cc

Frequency accuracy: \pm 0.5%

Range: 0.1 ml to 8.0 ml \pm 5% or 0.1 ml whichever is greater

Air pressure system

Pressure range: -600 to 400 daPa (50 daPa steps)

Pump speed: • 50, 100, 200, 400 daPa/s,
• AFAP (As Fast As Possible, >500 daPa/s in 2cc)

Pressure accuracy: \pm 10% or \pm 10 daPa whichever is greatest

Pressure accuracy: -650 \pm 70 daPa to 450 \pm 70 daPa

Software safety limits: -650 \pm 70 daPa to 450 \pm 70 daPa

Hardware safety limits: -730 \pm 70 daPa to 530 \pm 70 daPa

Ipsilateral stimulation (Immittance probe)

Pure tones: • 500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz
(\pm 0.5%)

Noise: • Broad Band Noise according to IEC 1027
• Low Band Noise 400 to 1600 Hz.
• High Band Noise 1600 to 4000 Hz.
• Roll off >12 dB/Octave.

Intensity range: • 500 Hz: 50 to 105 dB HL \pm 3dB
• 1, 2 kHz: 50 to 120 dB HL \pm 3dB
• 3, 4 kHz: 50 to 115 dB HL \pm 3dB
• BBN, HBN, LBN 50 to 100 dB HL \pm 3dB

Total Harmonic Distortion: < 3% in 2 cc (measured 5 dB below max output)

Stimulus presentation: • Pulsed

Contralateral stimulation (E-A-RTone® 3A)

Pure tones: • 500Hz, 1000Hz, 2000Hz, 3000Hz, 4000Hz
(\pm 0.5%)

Noise: • Broad Band Noise according to IEC 1027
• Low Band Noise 400 to 1600 Hz.
• High Band Noise 1600 to 4000 Hz.
• Roll off >12 dB/Octave.

Intensity range: • 500 Hz: 50 to 115dB HL \pm 3dB
• 1, 3, 4 kHz 50 to 120dB HL \pm 3dB
• 2 kHz 50 to 110dB HL \pm 3dB
• BBN, HBN: 50 to 110dB HL \pm 3dB
• LPN: 50 to 110 dB HL \pm 3dB

Total Harmonic Distortion: < 3% in 2 cc (measured 5 dB below max output)

Stimulus presentation: • Steady or pulsed tone

OTOflex 100 details

Communication: • Wireless Bluetooth data transfer to PC or printer
• Output power: 1 mW (range up to 10 m (33 ft.))

Display: High contrast OLED, 128x128 pixels

Clock & calendar: Automatic time stamping of test results

Batteries

Rechargeable: Ni-MH, size AA (R6) 1.2V, 4 pcs
Use only rechargeable batteries supplied by GN Otometrics A/S

Alkaline: Size AA (R6) 1.5V, 4 pcs.

Estimated battery life: 4 hours without charging

Charger unit

Type 1012 Charger: Charger unit is Type 1012 Charger from GN Otometrics A/S

Power: 100 – 240 VAC 50/60 Hz

Power consumption: < 10 VA

2 cc coupler: Built-in for probe checks

Environment requirements - operation

Temperature: +15°C to +35 °C (59 °F to 95 °F)

Warning: Operation at temperatures below -20°C or above +60°C may cause permanent damage.

Relative humidity: 30 to 90 % (non-condensing)

Warm-up time: < 2 min

Barometric pressure: 600 hPa to 1060 hPa

Environment requirements - storage and handling

Temperature: -20 °C to +60 °C (-4°F to 140°F)

Rel. Humidity: < 90 % (non-condensing)

Barometric pressure: 500 hPa to 1060 hPa

Dimensions

OTOflex 100 (HxWxD): 20 cm x 4.9 cm x 7.8 cm (7.9" x 1.9" x 3.0")

Charger Unit (HxWxD): 18 cm x 4.9 cm x 7.8 cm (6.9" x 1.9" x 3.0")

Weight

OTOflex 100: 0.60 kg, 1.3 pounds

Charger Unit: 0,23 kg, 0,5 pounds

Calibration

- Equipment should be calibrated regularly according to EN 61027 and ANSI S3.39.
- Notifications when probe calibrations exceed 1 year.
- Run a probe check at least once a day to get the ECV reading adjustment to the environment

Classification

Type 1012: OTOflex 100 is Type 1012 from GN Otometrics A/S

EN 61027: Immittance instrument type 1

OTOflex 100 complies with regulations and standards regarding safety and EMI for medical devices with Bluetooth® interface:

- Medical devices: Directive 93/42/EEC, FDA 21 CFR, Canadian Medical Devices Regulations, EN/UL 60601-1 and CAN/CSA-C22.2 NO 601.1-90, EN 60601-1-2
- Bluetooth® devices: RTTE Directive 1999/5/EC, FCC part 15, Canadian RSS-210, EN 300 328-2 and EN 301 489-17.

Technical specifications – OTODiagnostics Suite

Requirements

- PC hardware minimum requirements:
- Pentium® III 500 MHz
 - 128 MB RAM
 - 200 MB free disk space for installation of this software
 - A USB port for connection of a Bluetooth® device for communication with OTOflex devices

PC software requirements:

- Operating system:
- Windows® 2000 with Service Pack 3
 - Windows® XP Professional with Service Pack 1

Service Packs are available from Microsoft at www.microsoft.com.

The English versions of the service packs are can be found also on the installation CD in the prerequisites folder.

Internet Explorer 6 with Service Pack 1 (included on the CD, will automatically be updated)

NOAH mode operation: OTODiagnostics Suite stores data through the NOAH 3 interface which is available only when running ODS as a NOAH measurement module from one of the following applications:

- NOAH 3.1™ or higher (refer to HIMSA at www.himsa.com)
- Auditbase from GN Otometrics A/S
- Mirage from GN Otometrics A/S

ODS Specifications applying to OTODiagnostics Suite only (not available in OTOflex 100)

OTOflex Specifications applying to OTOflex 100 only (not available in OTODiagnostics Suite)

Data management Hearing assessment Fitting & Testing Balance assessment

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GN Otometrics

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