MADSEN Capella

Cochlear Emissions Analyzer

User Manual

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1   Introduction

The *CAPELLA Cochlear Emissions Analyzer* is the most recent addition to the comprehensive line of audio diagnostic instrumentation from GN Otometrics. *Capella* is a PC-based system which runs under Microsoft® Windows™, either together with the NOAH/PAX software platform, or as a self-contained program. In addition to the main unit containing the hardware, *Capella* consists of separate software modules, this documentation and accessories.

Capella evaluates both of the two broad classes of emissions, Spontaneous and Evoked, and two of the evoked emission types, Transient and Distortion Product. Two separate modes are incorporated for Transient emissions, Echo-Screen for rapid neo-natal and infant screening, and TEOAE for clinical and diagnostic testing of all patients. Tests include amplitude and input/output determinations of Evoked emissions, as well as spectral averages of Spontaneous emissions. A Tympanometry module is included for identifying hearing problems arising in the middle ear.

CAPELLA Cochlear Emissions Analyzer is operated by an IBM or compatible personal computer via the built-in RS232C connection, and offers the following unique features:

- Windows-based software running under NOAH or PAX.

- Small, lightweight combination probe tip.

- Separate Echo-Screen probe especially suited to infants and new-born babies.

- Each probe is individually calibrated for maximum probe measurement accuracy.

- Mounting options for probe assembly: shoulder harness, standard sized headband or children´s headband.

- Significantly reduced noise floor for threshold detection and Input/Output tests.

- Screening Tympanometry module.

- Echo-Screen baby screening module.

1.1   Applications of *Capella*

CAPELLA Cochlear Emissions Analyzer is designed to measure the low-amplitude audio frequencies transmitted from the cochlea through the middle ear to the external ear canal and known as otoacoustic emissions. Otoacoustic emissions (OAE's) were first identified at the Royal National TNE Hospital, London, and have been shown to be the result of an active mechanical process in the cochlea. This process enhances the sound-induced motion of cochlear structures and increases the sensitivity and frequency selectivity of the ear. OAE's are typically classified into two broad classes based on the type of acoustic stimulation that evokes them, as described below.

1.1.1   Spontaneous Otoacoustic Emissions

Spontaneous Otoacoustic Emissions (SOAE's) are low-level narrow-band signals measured in the absence of deliberate acoustic stimulation. They occur in only about one half of normal-hearing ears, and at only a few frequencies for ears in which they do occur. Consequently, they are thought to have limited clinical utility although they may have research implications.

1.1.2   Evoked Otoacoustic Emissions

Evoked emissions, which occur in nearly all normal-hearing ears, are further divided into three sub-types according to the nature of the acoustic stimulus used to elicit them. Transient Evoked Otoacoustic Emissions (TEOAE's) occur in response to brief acoustic signals (clicks, tone bursts, etc.). It has been suggested that they may be particularly well-suited to detection of cochlear disorders, especially in screening applications.

Stimulus-Frequency Otoacoustic Emissions (SFOAE's) are elicited by swept pure tone signals and show characteristics similar to those of transient emissions. However, because their detection is more complicated and time-consuming than the measurement of TEOAE's, they have not yet been incorporated into clinical tests.

Distortion Product Otoacoustic Emissions (DPOAE's or DP's) are evoked by two simultaneously presented pure tones of different frequencies. They represent the ear's nonlinear response to the stimulus tones, and consist of new frequencies not present in the eliciting stimuli. Although DPOAE's are somewhat more complex to elicit and analyze than TEOAE's, they may have greater clinical utility for some applications.

Capella currently measures Spontaneous, Transient, and Distortion Product Otoacoustic Emissions, using synchronous time averaging (where applicable), correlation techniques and FFT frequency analy-

sis to measure emissions whose sound pressure level is below that of extraneous and body sounds and (where applicable) the evoking stimuli. Echo-Screen uses statistical analysis to perform rapid measurement and classification of Transient Otoacoustic Emissions.

Capella also incorporates a Tympanometry module to diagnose or eliminate middle ear disorders as a cause of hearing loss or potential hearing problems identified by OAE measurement. This module records the changes in the immittance of the middle ear associated with changing static pressure in the ear canal. This pressure is swept through a predetermined range by means of a digitally driven pump.

The measurement techniques employed in *Capella* have several distinct advantages over more traditional audiologic tests:

1. *Objectivity*
    No behavioural response is required from the patient.

2. *Time-efficiency*
    Some tests can be accomplished in less than a minute for both ears.

3. *Non-invasiveness*
    No electrodes are required. No discomfort to the patient. Signal delivery and OAE response measurement are achieved using a small probe held in place by a soft, disposable eartip.

4. *Sensitivity to cochlear function*
    Useful in the differential diagnosis of cochlear and retrococh-

lear disorders. Capable of distinguishing sensory (cochlear) hearing loss from neural hearing loss in site-of-lesion testing.

5.   *Sensitivity to disorders of the middle ear and Eustachian tube*

CAPELLA Cochlear Emissions Analyzer is intended for the following applications:

- Hearing screening
  -Difficult-to-test patients, including infants
  -Industrial (occupational hearing loss)
  -Schools and itinerant patients
  -Geriatric patients

- Clinical evaluation
  -Differential diagnosis (middle ear versus cochlear versus retrocochlear)

  -Monitoring: progressive hearing loss, ototoxicity, noise-induced hearing loss

- Research

Measured properties of cochlear function include signal detection threshold and response amplitude, frequency content, and growth.

- Outer hair cells (OHC)
- Basilar membrane
- Efferent innervation

Capella complies with the following international standards:

- Patient Safety: Complies with EN 60601-1.

- Immittance testing: Comparative tympanometry according to EN 61027 and ANSI S3.39.

1.2   The NOAH fitting platform

The *Capella* OAE application module may be integrated with HIMSA's NOAH program for fitting hearing instruments. NOAH uses a common software platform and central database to integrate hearing instrument fitting systems, test equipment, and office management software systems. NOAH integrates client records, audiological data and the dedicated fitting modules from various hearing instrument manufacturers.

Digitally programmable hearing instruments using different technologies and different programming devices are available from a number of manufacturers. NOAH provides a common software

platform for fitting different brands of programmable hearing instruments. Alternatively, *Capella* can also run under PAX, HIMSA's new software standard for ENT professionals.

Please read the NOAH or PAX User's Guide for detailed instructions on how to install and run these programs.

1.3   About this manual

The Windows-based application software of *Capella* is so user-friendly that we are convinced that you will find operation of *Capella* a very straightforward process. The simplicity of the screen layouts together with online Help make the program very easy to use.

This manual describes *Capella*'s hardware and accessories, and also includes an Operation Guide to the application software. Familiarity with Windows is assumed.

Note:
Program diskette is located at the back of this manual!

1.4   System requirements

Recommended

IBM® or IBM compatible PC with the following:

> 32 MB RAM
> Microsoft Windows 95 or 98
> Pentium processor
> VGA graphics adapter
> Mouse
> Color printer
> 1 free COM port
> PC noise level under 35 dB (A)

1.5   Software installation

The *Capella* software is supplied on the diskette(s) enclosed in a plastic pocket at the back of this User Manual.

To install *Capella* on your PC, proceed as follows:

1.   Insert the diskette (or diskette #1 if there are more than one) into your diskette drive.

2.   Use the Windows **Run** function to locate and run **Setup** on the diskette.

3.   Windows will now start the Installation program. Just follow the on-screen instructions.

4.   By default, the program will install *Capella* under the path for NOAH.

5.   If you are not using NOAH, you may specify another path. The *Capella* software is represented by a **NOAH** icon. You can simplify start up by creating a short cut to *Capella* on the Windows desktop.

1.6   Starting up the system

If *Capella* is running under NOAH, first access NOAH´s Client Module. On the toolbar, only the first icon (Client Module) and the last icon (Help) are active until a client has been selected - all the others are greyed (inactive). Before proceeding to any of the application modules, it is first necessary to access the Client Module, and then to either select an existing client or to add a client to the database.

You are referred to the NOAH or PAX User's Guide for detailed navigation instructions.

After having selected or added a client, click on the Selection of Measurement Module icon which opens the NOAH/PAX Measurement Selection Screen. Double-click on the **Capella** button. The *Capella* software will now be loaded, and the program will start by trying to connect with the *Capella* hardware platform - see next chapter.

If not running NOAH, start *Capella* by double-clicking on the **NOAH** icon in the directory where you have installed *Capella*, or on the Windows desktop if you have made a short cut.

2 The *Capella* Hardware

2.1 Safety

2.1.1 Symbols

This User Manual contains information and warnings which must be followed to ensure the safe performance of the *CAPELLA Cochlear Emissions Analyzer*. Local government rules and regulations, if applicable, should also be followed at all times.

Special note should be made of the following:

⚠	The *Capella* carries this symbol when it is important that the user refer to associated warnings in this guide.
$C\epsilon$ xxxx	The *Capella* and this manual are CE-marked according to the Medical Devices Directive 93/42/EEC.
c UL us CLASSIFIED	Classified with respect to electrical shock, fire, mechanical and other specified hazards in accordance with UL2601-1 and CAN/CSA-C22.2 NO 601.1-90
🧍	*Capella* is marked with this symbol to indicate compliance with Type B requirements of EN 60601-1. This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.

2.1.2   Safety precautions

Capella has been designed and tested in compliance with EN 60601-1 "Safety of Medical Electrical Equipment".

To ensure safe performance, *Capella* must be correctly installed and the following safety requirements must be complied with.

Only the original power cable supplied with *Capella* must be used. This must be fitted with an approved 3-pole mains (line) plug, which has a protective earth conductor.

Capella should only be connected to an AC power supply which has a protective earth conductor in accordance with EN requirements.

Caution:
Grounding continuity should be checked periodically.

Avoid using extension cables. The increased length of the cable may increase the resistance of the protective earth conductor beyond an acceptable level.

When assembling an electro-medical system, the person carrying out the assembly must take into account that other connected equipment which does not live up to the same safety requirements as this product may lead to a reduction in the overall safety level of the system.

When selecting accessories connected to the RS232 socket, the following points must be considered:

* Use of connected equipment in a patient environment.

* Evidence that connected equipment has been tested in accordance with EN60601-1 and/or EN 60601-1-1.

2.2   Installing the *Capella* hardware

2.2.1   Unpacking *Capella*

Capella is shipped in its own custom-made carton together with this User Manual, a Packing Specification and standard accessories. Please keep and store this carton in case you need to return the instrument to your supplier or to the factory for service or repair.

If the shipping carton is visibly damaged upon delivery, ask the carrier's agent to be present when the instrument is unpacked. If the instrument is damaged or fails to operate, please notify the carrier and your supplier immediately. Your supplier will arrange for the repair

or replacement of the instrument prior to settlement of any claim against the carrier.

Please refer to the Packing Specification sheet enclosed with the instrument to ensure that all accessories are complete and intact.

2.2.2   Storage and shipment

See Section 3.1.9, 'Storage & Shipment Environment" on page 27 for specification of storage and shipment environment.

To protect the instrument and accessories during storage or shipment, always use the best packaging available. If it becomes necessary to return the instrument to your supplier or to the factory for service or repair, please use the original shipping cartons, as recommended above. All products returned to GN Otometrics or its representatives must be shipped prepaid and insured, or you must assume the risk of loss or damage in transit.

When shipping *Capella*, please remember to:

1.   Seal the shipping container securely.

2.   Mark the container *FRAGILE* to ensure careful handling.

3.   Refer to the instrument by make, model, and serial number in any correspondence.

4.   Specify the problem and your preferred return shipping address and arrangements.

Always store *Capella* in a clean, dry environment, and never leave the power on when the instrument is in an enclosed container!

2.2.3   Inspection

Capella is a modular system which may be assembled from accessories chosen to meet the needs of different countries and practices.

The following lists are for general guidance and purposes of identification.

2.2.3.1   Equipment supplied

Capella Instrument

1.   Hardware platform
2.   Probe Assembly, including preamplifier
3.   Probe
4.   Eartip Assortment
5.   Shoulder Harness (standard) or Headband (optional)
6.   *Capella* application module (software)
7.   RS232C Serial Interface Cable
8.   Probe Connector Cable
9.   Power Cord
10.   *Capella* User Manual including program diskette
11.   Calibration Adaptors
12.   Fuse Kits

Note:
Program diskette is located at the back of this manual!

2.2.3.2   Optional accessories

Echo-Screen probe
Eartip box with 2cc cavity
Carrying Case
Inkjet, or laser printer
Children´s Headband
M.E. Coupler
B & K Calibrator
8m Serial Interface Cable
Service Manual

2.2.4   Installation

Locate *Capella* in a well-ventilated room away from all liquids and sources of heat (see for detailed specifications of operating environment). Test-

ing will be facilitated by a moderately quiet room, although a sound-treated booth is not necessary.

Note:

Capella is *NOT* suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

Connect the Probe Connector Cable and personal computer (PC) to their respective ports on the Connection Panel at the back of *Capella*.

Before connecting the power cord, please make sure that the voltage from the electrical outlet matches the voltage shown on the identification label stuck over the power inlet.

Caution!

Operating at the wrong voltage may blow the fuses!

Plug one end of the supplied power cord into the power inlet on the back of *Capella* (see Fig. 1 below) and plug the other end directly into a three-wire, protective ground, AC power outlet.
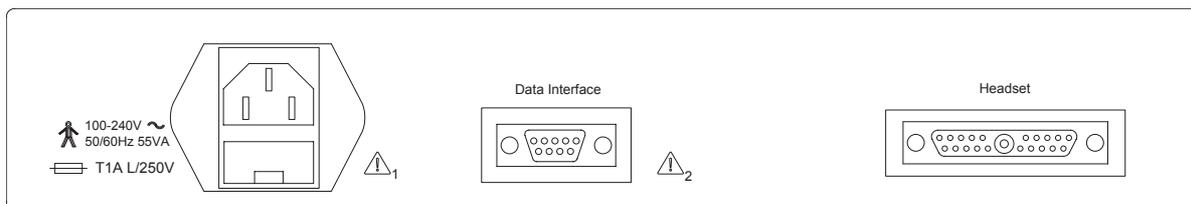
Figure 1

For more information about installation, set up the *Capella* software on your PC (Section 3.3, 'Starting up the system" on page 28) and then refer to the section on "Installation" in the on-line help.

2.3   Care and maintenance

The probe, headset and parts are in constant contact with your patients so care should be taken to ensure that they are kept clean.

2.3.1   Probe

Proper treatment of the *Capella* combination probe is important. It contains delicate transducers, precisely calibrated to work with your

instrument. It should not be dropped, brought in contact with liquids, or otherwise maltreated.

However, the probe tip should be inspected periodically for foreign matter at the end of the tip. To clear cerumen, vernix and other debris from the tip, follow the instructions below:

1. Brush the probe every time after use with the cleaning tool supplied. If cerumen or vernix is pushed up inside the probe housing, the probe will be damaged. Brush in a direction away from the probe housing, towards the tip of the probe.

2. The probe should never be placed directly in water or other cleaning liquids. Liquids seeping into the housing will damage the probe.

3. When fitting a new eartip to the probe, ensure it is pushed all the way to the probe casing, so there is no gap between the eartip and the casing. The top should be flush with the end of the probe tip.

4. ***Caution!***
   Do not allow the probe body, which contains the acoustic transducers, to come in contact with any liquids.

5. The probe cannot be dismantled - this is not necessary for cleaning if the care instructions are followed.

6. Do not fit the probe by holding on to the cable as you could damage the pin connector by doing this.

Probe body · Probe tip · Eartip

Probe cable
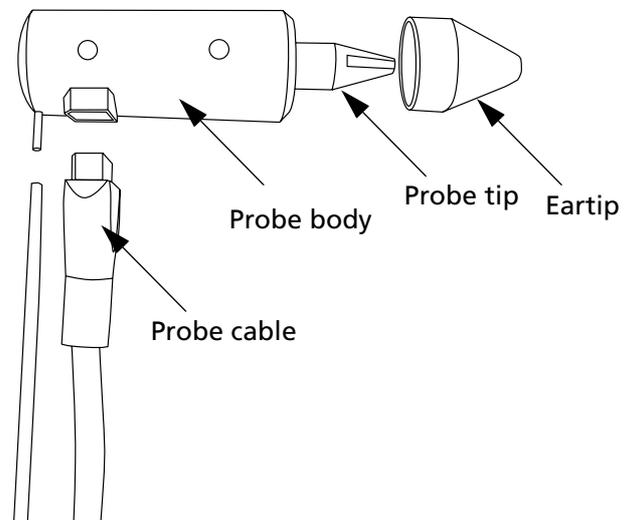
2.3.2 Eartips

Capella eartips are designed to fit over the end of the probe and per-mit a tight seal in the patient's external ear canal. Please see the in-structions on the eartip assortment box for proper attachment on the probe tip.

Use a new eartip for every patient. Select an appropriately sized ear-tip for the patient's ear canal - the eartip should fit snugly. Use only the eartips supplied with this probe.

Eartips should be used on only one patient. The eartips are in direct contact with your patients, and you should therefore observe strict hygienic precautions to prevent passing infections from one patient to another. It is therefore recommended that you use only disposable eartips.

Most eartips are disposable, and should not be cleaned or re-used. Always throw away disposable eartips after use on a patient.

2.3.2.1 Disposal

There are no special requirements for disposal of the rubber eartips, i.e. they may be discarded in any regular waste bin.

2.3.2.2 Portable use

Capella is a fully portable system, but the optional carrying case is recommended for safe transportation. Before packing the system,

ensure that the probe assemblies, eartips, etc., are not loose in the case.

Note:
Eartips for *Capella* and Madsen´s Zodiac 901 Middle-Ear Analyzer are interchangeable.

2.3.3   Hardware platform

Capella requires no preventative maintenance. However, it is recommended that the following guidelines be observed:

The instrument should be kept clean and as free of dust as possible:

- Remove dust using a soft cloth or brush.

- To clean, use a soft, slightly damp cloth with a small amount of mild detergent on it. *Do not allow any moisture inside the instrument or probe.*

Caution!
Chemical agents containing ammonia or alcohol will damage the cabinet.

Avoid exposing the instrument to direct sunlight, and keep it well-ventilated at all times to prevent overheating.

2.4   Fuse replacement

Two identical fuses are located in the connection panel between the power inlet and the on/off switch. To replace a fuse, please proceed as follows.

1. Disconnect *Capella* from mains/line power supply.

2. The black plastic fuse holder may be extracted from the fuse compartment using a small screwdriver to press back the clip in the middle left of the holder.

3. When loose, extract the holder and change fuses - refer to the fuse specifications marked above the on/off switch.

Warning!
When replacing the fuses there is a risk of fire. For continued protec-

tion against fire hazard, replace fuses with the same type and rating only.

4. Replace the fuse holder by pushing it firmly into place - an audible click can be heard (the holder cannot be replaced back to front).

2.5 Equipment failure

If you believe the correct function or operating safety of *Capella* is impaired in any way, disconnect it from the power supply and secure it against further use.

Caution:
Under no circumstances remove the Hardware Platform's cover! Contact your local representative that supplied *Capella*.

2.6 Battery powered version

The optional battery powered version of *Capella* utilizes a rechargeable Ni-MH battery pack. The battery pack is located inside the *Capella* cabinet, and is NOT to be accessed by unauthorized personnel.

If you experience any problems with recharging the battery pack, or operation on battery power only, please contact your local supplier.

2.6.1 Battery replacement

For authorized personnel only:

1. Disconnect *Capella* from AC power source.

2. Unscrew the 4 screws which secure the cabinet to the baseplate.

3. Replace the battery pack with a new one, type HHR-380A/L2x3 (7.2V, 3800mAh).

4. Dispose of the battery pack by sending it to an authorized Ni-MH battery destruction facility.

Do not attempt to disassemble the battery pack.

Do not incinerate the battery pack, or expose to fire.

2.6.2   Battery operation

When connected to an AC power source, the battery version of *Capella* will automatically recharge the battery pack, whether *Capella* is powered on or off. When powered on, the Power LED (see Figure 3) will light continuously green, and the AC/Charge LED will light as follows:

>   Yellow = charging
>   Green = fully charged

If the battery is allowed to become exhausted, the AC/Charge LED will not indicate charging until about five minutes after AC power has been applied. When not connected to an AC power source, the Power LED will light green when *Capella* is powered on, and the AC/Charge LED will not light. *Capella* cannot be operated if the battery pack is dead, not even when connected to the mains (line).

Note:
In order to disengage the battery pack of *Capella* completely from an AC power source, it is not sufficient to power the instrument off. The power cable must be detached from the power source.

2.6.3   Battery life

When fully charged, *Capella* can operate for approximately 5 to 7 hours of constant use, up to 22 to 24 hours´ "typical" usage, and up to 38 hours´ stand-by, i.e. powered on, but not in use.

The life of the rechargeable battery pack depends on too many variables to be estimated, but you are advised to follow the normal rules for maximizing battery life: *avoid constant recharging* when not in use, and *completely exhaust* the batteries periodically (once every 6 months).

A memory effect will occur when a user repeatedly recharges the battery before it is fully drained. For example, if you use the battery for 20 minutes at a time and then recharge it, the battery will tend to "remember" that it needs to operate only 20 minutes per charge. As a result, during the charging process, the declining battery will receive only a portion of its charge capacity. The declining battery will also exhibit some characteristics of a fully charged battery. For example, during charging, the battery temperature will rise, prompting the system to stop charging.

The memory effect also has a direct impact on the battery's life span. Ni-MH batteries have a typical life (charge/drain cycles) of up to 800 cycles. If the battery is used an average of 30 minutes per cycle, you can expect a total life of 400 hours. If you use the battery 6 hours per

cycle, you can expect a total life of 4800 hours. Therefore, it is advantageous to use the battery as much as possible during each cycle.

Ni-MH batteries should not be subjected to longer periods of *deep discharging*, to prevent polarity reversal of individual cells. The worst thing for a battery is to remain fully discharged for long periods of time. This causes sulfation, which is a hard lead sulfate coating on the plates. Sulfation can reduce battery capacity dramatically.

If a battery has been deep discharged, the charge LED will light green when the mains are connected, and after 3-30 seconds the green colour will change to orange. If the AC/Charge LED doesn't change colour back to green within the first 10 minutes, disconnect the mains supply for a few seconds and then reconnect it.

2.7   Service and repair

Service and repair of electro medical equipment should be carried out only by the equipment manufacturer or by authorized representatives.

The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties. Following repair, the safety of all equipment should be verified by a qualified electronics engineer.

2.8   Start-up

Power *Capella* on by means of the on/off switch. The start-up process is as follows: on power-on, the Power LED (see Figure 3) lights green, and a brief system test is made. The PC Com LED lights green once, indicating that *Capella* is ready for communication with your PC. There is no warm-up time required.
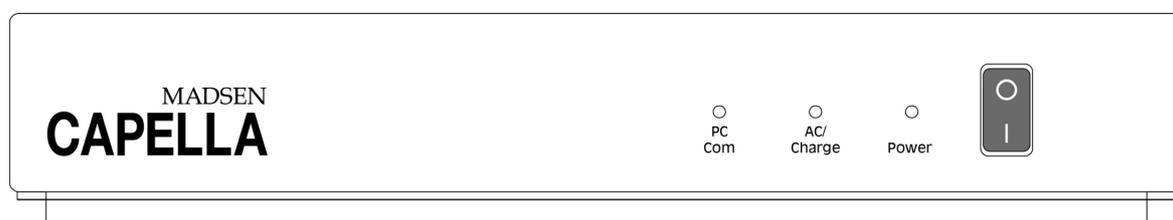
Figure 3

Communication between your PC and the Hardware Platform is indicated by the PC Com LED, which flashes green. If you attempt communication with *Capella* without powering it on, you will be ad-

vised on-screen of a timeout error: power *Capella* on, wait a few seconds and Retry.

2.9   Calibration

Your *Capella* was dispatched from the factory in Denmark together with a Test Report (Calibration Certificate). The Test Report specifies which transducers have been calibrated (i.e. those which have been supplied together with the instrument), according to which standards, and what equipment was used for calibration. Results are listed for each transducer at all standard frequencies.

For DPOAE, *Capella* is calibrated in dB SPL (1 dB SPL = 20 µPA); for TEOAE, *Capella* is calibrated in dB peak.

Calibration has been performed on the supplied probe. If you wish to use any other probe for testing with *Capella*, please contact your local supplier first.

Calibration should be performed annually by suitably qualified personnel, using the appropriate equipment.

3 General Description

The *CAPELLA Cochlear Emissions Analyzer* is an audio diagnostic instrument designed to measure two broad classes of otoacoustic emissions, Spontaneous and Evoked. *Capella* consists of the following:

1. The hardware platform, which houses the power supply and printed circuit boards for signal generation.

2. The probe assembly, which contains the preamplifier.

3. The probe body, which contains a microphone and two receivers.

4. A headset and earphone or a shoulder harness and a set of color-coded eartips to stabilize the probe and probe assembly when the probe tip is placed in the external ear canal.

5. Operating software, which delivers signal generation and other instructions to the hardware platform and collects data from the hardware platform. Includes a comprehensive on-line Help to assist the user.

6. Various cords and cable connections, including an RS232C computer interface.

7. This User Manual, which provides general information about the theory and technique involved in the measurement of otoacoustic emissions, as well as specific instruction in the use of *Capella*.

8. A laminated Quick Guide.

Some test parameters are pre-programmed and stored in non-volatile memory on the printed circuit boards of the main electronics unit. These parameters are retained when the power supply is cut off, but can be reprogrammed or upgraded from a personal computer by authorized personnel as necessary. Other test parameters are selected from the computer using the keyboard or various function keys.

The hardware platform has three LED displays indicating power on, battery status, and signal and response transmission (PC Com).

3.1   Technical specifications

3.1.1   Distortion-Product Otoacoustic Emissions (DPOAE)

Stimulus   2 sinus stimulus channels

Geometric Center Frequencies   0.5, 0.75, 1.0, 1.5, 2.0, 3.0, 4.0, 6.0, 8.0 kHz

Stimulus Level Range   0 - 70 dB SPL

Stimulus 3rd order Intermodulation< -80 dB

Input Sensitivity For Stimulus   ≥50 dB SPL: 80 to -30 dB SPL
                                          < 50 dB SPL: 60 to -50 dB SPL

PC Readout:
800 point FFT analysis

Fsample	Fmax	Resolution
26.04 kHz	10 kHz	13 Hz
13.02 kHz	5 kHz	6 Hz
6.51 kHz	2.5 kHz	3 Hz

Frequency Response Accuracy:

    Microphone   ± 3 dB from 500 to 4000 Hz
                                          ± 6 dB from 4000 to 9000 Hz

    Sound Level   711 Coupler Reference (volume compensated)
                                          ± 4 dB from 500 to 4000 Hz
                                          ± 7 dB from 4000 to 9000 Hz

                                          In Situ Sound Level Adjustment
                                          ± 4.5 dB from 500 to 4000 Hz

3.1.2   Transiently Evoked Otoacoustic Emissions (TEOAE)

Stimulus

    Non-linear: 3 clicks of the same polarity and 1 click of opposite polarity, at 3
                                          times the amplitude of the 1st click. Pulse width 40, 80, 120 µsec.

    Stimulus Level Range   30 - 80 dB p.e. SPL approx. -30 to 60 dB nHL

    Linear: Unipolar click. Pulse width 40, 80, 120 µsec.

    Stimulus Level Range   30 - 80 dB p.e. SPL approx. -30 to 60 dB nHL

    Level Accuracy   ± 4 dB

Stimulus:

Acoustical Bandwidth	500 - 4000 Hz ± 5 dB @ 1000 Hz
Input Resolution	Measurement range: Time domain: 1 μPa/div. to 1 Pa/div. Freq. domain: -30 dB to 10 dB SPL

3.1.3   Spontaneous Otoacoustic Emissions (SOAE)

Input Sensitivity	0 - 70 dB SPL
Frequency Ranges	500-5000, 500-10,000 Hz

3.1.4   Echo-Screen

Sound stimulus level:	70 to 85 dB SPL, self-calibrating to ECV (Ear Canal Volume)
Stimulus rate:	40...100 Hz
Stimulus type:	Nonlinear click
Signal bandwidth:	1.4 to 4 kHz
Max. sound pressure:	Limited to 85 dB SPL
Probe:	Eartips from 4 to 10 mm dia.
Signal processing:	Binomial statistical analysis of TEOAE sweeps for signal to noise ratio. 99% confidence-level analysis of a time window from 6 to 12 ms after the stimulus, ranked in four quality buffers
Result display:	"Pass" or "Refer", based on the acquisition of four pos. and four neg. peaks
Data display:	Elapsed time, no. of peaks, no. of sweeps in each buffer, noise, artifact rate, stimulus stability, signal quality, no. of accepted sweeps, no. of rejected sweeps, percentage of completed sweeps
Graphic display:	Pos. and neg. significance level as a function of time after stimulus

3.1.5   Tympanometry (immittance measurements)

Standards:	EN 61027, ANSI S3.39
Pump direction:	Neg. to pos. and pos. to neg. selectable
Pump accuracy:	±10% or ±10 daPa, whichever is greater. Plunger-type pump controlled digitally by stepper motor
Pressure range:	-400, -350, -300, -250, -200, -150, and -100 daPa to 100, 150 and 200 daPa
Pump speed:	50, 100, 200 and 400 daPa/sec plus As Fast As Possible
Probe tone:	226 Hz at 85 dB SPL and 1000 Hz at 75 dB SPL, selectable
Volume range:	0.1 to 8 ml
Y-axis scaling:	0.3, 0.6, 0.9, 1.5, 3, 4.5 ml and Auto
Smoothing:	On/off selectable before or after measurement
Sweep start:	From probe, from screen, or automatic when volume detected
Leak detect:	On/off selectable
Air release:	From screen or from keyboard or automatically if pressure exceeds -800 daPa or 600 daPa
Measurement status:	Pop-up box displays pump position and status messages in real time
Tympanogram characteristics displayed:	Cartesian tymp. plot; current measured volume and static pressure in real time; calculated values for ECV, MEP, SC, Grad, TW; and tymp. Type (A, AD, AS, B, C, D, E)

3.1.6   Power Supply

AC 50/60 Hz, 100-240 V AC

Fuses Type 1A T (accessible from outside the cabinet)

Power Consumption:Approx. 55 VA

Battery pack (optional):type HHR-380A/L2x3 (7.2V, 3800mAh)

3.1.7   Patient Safety

Complies with EN 60601-1, Class 1, Type B, IPX0.

Battery version complies with EN 60601-1, Class I, Internal Powered,

Type B, IPX0.

3.1.8   Operating Environment

Mode of operation: Continuous

Temperature: 10° - 35°C

Relative Humidity: 30 - 90%, non-condensing

Atmospheric Pressure: 600 - 1090 hPa

Operation in temperatures exceeding -20°C or +60°C may cause permanent damage.

3.1.9   Storage & Shipment Environment

Temperature: -20°C to +60°C

Relative Humidity: 30 - 90%, non-condensing

Atmospheric Pressure: 600 - 1090 hPa

3.1.10   EMC

EMC Emission and Immunity: Complies with EN 60601-1-2

3.1.11   Dimensions and Weight

Hardware platform: Approx. 305 x 284 x 59 mm (W x D x H),
                            12" x 11" x 2¼"

Net Weight: Approx. 1.8 kg, 4 lbs (excl. PC)

Probe assembly: 73 g, 2.6 oz.

Probe: 14 g, ½ oz.

3.2   Manufacturer

GN Otometrics A/S
9 Hoerskaetten, DK-2630 Taastrup, Denmark
Phone: +45 45 75 55 55
Fax: +45 45 75 55 59
www.gnotometrics.com

3.3   Starting up the system

First access Client Module (NOAH only)
On the NOAH toolbar, only the first icon (Client Module) and the last icon (Help) are active until a client has been selected-all the others are greyed (inactive). Before proceeding to any of the application modules, it is first necessary to access the Client Module, and then to either select an existing client or to add a client to the database.

You are referred to the NOAH or PAX User's Guide for detailed navigation instructions.

After having selected or added a client, click on the Selection of Measurement Module icon which opens the NOAH/PAX Measurement Selection Screen. Double-click on the **Capella** button. The *Capella* software will now be loaded, and the program will start by trying to connect with the *Capella* hardware platform.

If the *Capella* hardware platform has not been powered on, or if the platform has not been connected correctly to your PC, you will be prompted to retry or ignore.

The *Capella* software is delivered with a comprehensive built-in electronic assistant. Click on **Help** to obtain answers to queries about testing patients using *Capella*.

4   Operation

This manual assumes familiarity with Microsoft Windows™ and the NOAH™ or PAX™ platforms if used, and that the patient has been also prepared with visual inspection of the ear canal. For more information about using *Capella*, click on **Help**.
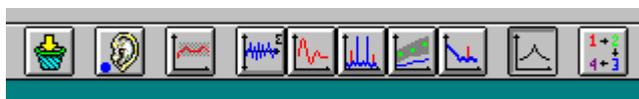
The icons above are used to navigate around *Capella*.

Note:
If any of the measurements made using *Capella* is found to have inadvertently been made with the wrong ear selected, open the **Ear** menu and choose **Swap ear data**... . Then select **This measurement only**, **All measurements for current mode (and current ear)**, **All measurements for current ear (all modes)**, or **Selected measurements**. If necessary, select the measurements to be moved from the list, and then click on **OK**.

To clear all measurement data for all modes and for both ears from the current session, select **Clear all** in the **File** menu or click on the **Clear all** icon in the toolbar. When this function is used, the Probe Fit operation will have to be repeated before any more measurements can be made.
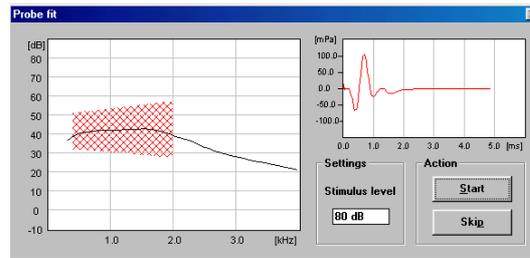
4.1   Probe fit

1.   Click on the **Ear** icon to select the ear you wish to measure, or select **Right** or **Left** in the **Ear** menu.

2.   Mount a suitable eartip on the probe and insert it into the ear canal, obtaining a tight seal with the canal wall.

3. Enter Probe fit mode by clicking on the **Probe fit** icon   or choosing **Probe fit** in the **Mode** menu.

4. Click on **Start** to check the probe fit. If necessary, adjust the probe in the ear canal until the curve falls within the red hatched area.


5. Probe fit will automatically stop when an adequate fit is obtained, and a message will appear informing you that the fit is either good or acceptable. The probe fitting process can be terminated manually by clicking on **Skip**.

6. The **Fit** dot on the lower left part of the measurement screen allows you to monitor the status of the probe fit. Green indicates a good fit, yellow indicates an acceptable fit and red indicates a poor fit (or that the probe fit procedure was not carried out).

4.2   ECHO-SCREEN

1. Click on the **Echo-Screen** icon   or choose **Echo-Screen** in the **Mode** menu.

2. Press **Start** to begin screening.

3. When the screening is complete the **Result** will display green for *Pass*, red for *Refer*, and gray if a significant result was prevented by a leak or noise.

4. Up to 6 measurements can be made for each ear. Click on the arrow keys in the **Meas. No.** box on the lower left to make a new measurement or to view other measurements made on the same ear during the session.

5. Repeat the procedure beginning with **Probe fit** for measuring the other ear.

4.3 TEOAE
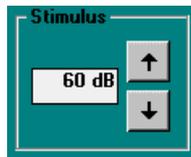
1. Click on the **TEOAE** icon   or choose **Transient (TEOAE)** in the **Mode** menu.

2. Change stimulus level by clicking on the **Stimulus** arrow keys or pressing the up and down arrow keys on the keyboard.

3. Access to additional test parameters (selection of **Linear**, **Nonlinear** or **Fast-screen** mode, **Stimulus suppression**, **Noise criteria** and **Stop criteria**) can be gained by selecting **Parameters** in the **Setup** menu. If necessary, change the **Stimulus correction** in the **Setup** menu.

4. Click on **Start** to begin measuring.

5. If you wish to halt the measurement momentarily, click on **Pause**. Click on **Continue** to resume the measurement.

6. Measurement status can be monitored by observing the **Sweeps** and **Statistics** boxes on the lower right part of the screen. The **Correlation**, **Emission strength** and **S/N ratio** are shown in each of five frequency bands as well as the broad-band values. The blue vertical bar on the right of the time response graph also indicates the noise floor during the measurement.

7. Click on **Stop** to end the measurement if you have disabled **Stop criteria**.

8. Scaling of the time response graph can be changed by using the **up** and **down** arrows in the **Scale** box on the screen or the **PgUp** and **PgDn** keys on the keyboard.

9. The cursor can be moved by clicking on the time response graph or using the right and left arrow keys in the **Cursor** box on screen or on the keyboard. The cursor's position on the time scale and the amplitude of the mean of the A and B curves are displayed in the **Cursor** box.

10. The time window for data analysis can be changed by entering different values in **Window** in the **Parameters** dialog box (**Setup** menu) but this not generally recommended as it can affect the correlation coefficient substantially. If displayed, the gray hatched area is not included in the FFT analysis. The **Scaling** of the FFT display may also be altered and its

Smoothing and or **Microphone correction** turned on or off from this dialog box.
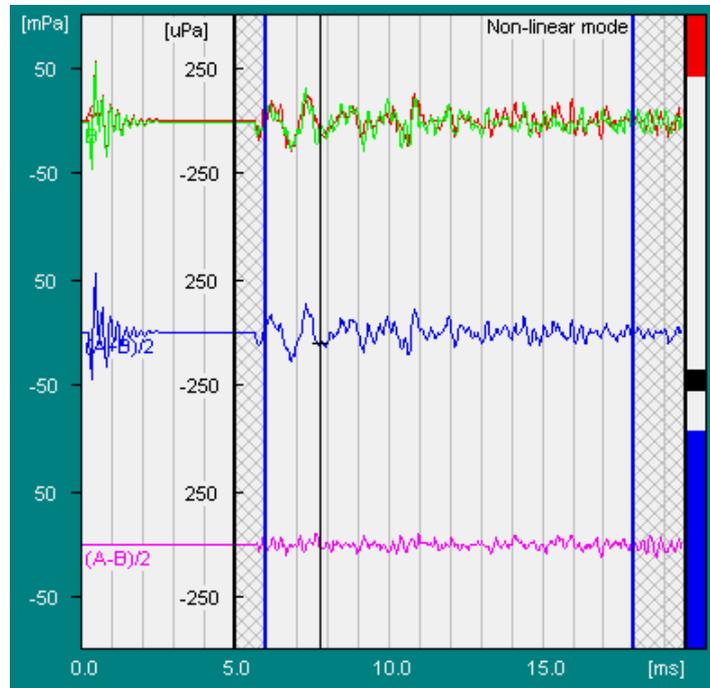
11. Up to 6 measurements can be made for each ear. Click on the arrow keys in the **Meas. No.** box on the lower left to make a new measurement or to view other measurements made on the same ear during the session.

12. Repeat the procedure beginning with **Probe fit** for measuring the other ear.

4.4 DPOAE: DP-gram

1. Click on the **DP-Gram** icon or choose **Distortion Products (DPOAE)** in the **Mode** menu and **DP-Gram** in the submenu.

2. Select **Parameters** in the **Setup** menu to define the **Level Difference** between f_1 and f_2, select either **2f_1-f_2 (DP1)** or **2f_2-f_1 (DP2)** for analysis, and if required change **Noise criteria**, **Stop criteria** and **Noise estimate**.

3. Change the stimulus level by clicking the arrow keys in the **F1 Level** box or pressing the up and down arrow keys on the keyboard.

4. Indicate the desired frequencies by clicking in the appropriate boxes under the DP-Gram.


5. Click on **Start** to begin measuring. When the stop criteria for one frequency have been met, measurement will automatically resume on the next preselected frequency.

6. Click on **Stop** to end the measurement if you have disabled **Stop criteria**. To resume measurement on the next preselected frequency, click on **Start**.

7. If you wish to halt the measurement momentarily, click on **Pause**. Click on **Cont.** to resume the measurement, at the same frequency.

8. Measurement status can be monitored by observing the **Sweeps** and **Statistics** boxes on the lower right part of the screen. The noise floor during the measurement is also indicated by the blue vertical bar to the right of the DP-Gram.
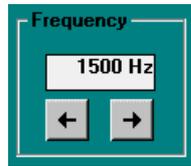
9. Use the right and left arrow keys in the **Frequency** box on screen or on the keyboard to view the amplitude spectra for different frequencies.

    Data for the selected frequency appear in the **Sweeps** and **Statistics** boxes, and in the boxes labeled **DP1** and **DP2**.
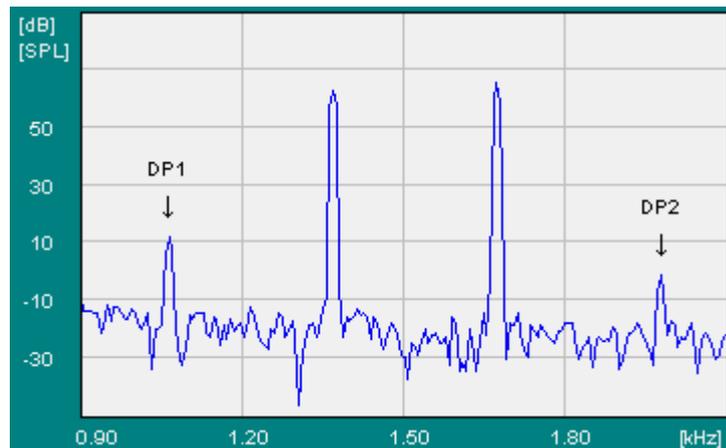

10. The DP1 and DP2 and noise values can be viewed in a tabular form by choosing **DP Tabular** on the **View** menu. Information regarding the f1:f2 ratio, primary and DP frequencies, primary levels and DP phases can be viewed by choosing **DP Info** on the **View** menu.

11. The default pattern showing normative data in the DP-Gram display is for adults, measured at the University Hospital of Copenhagen. To show the corresponding pattern for babies instead, select **Norm. data** in the **Setup** menu and click on **baby**. Amongst the other normative data patterns which may be selected from this dialog box is the **Gorga** norm. Confirm the selected norm by clicking on **OK**. The normally green DP-dot turns yellow if lower than the noise floor or outside the dynamic range of the instrument.

12. Up to 6 measurements can be made for each ear. Click on the arrow keys in the **Meas. No.** box on the lower left to make a new measurement or to view other measurements made on the same ear during the session.

13. Repeat the procedure beginning with Probe fit for measuring the other ear.

4.5   DPOAE: Input/Output

1. Click on the **DP-I/O** icon or choose **Distortion Product (DPOAE)** in the **Mode** menu and **DP-IO** in the submenu.

2. From **Parameters** in the **Setup** menu. select **DP1** or **DP2** for analysis, change if required **Noise criteria**, **Stop criteria** and **Noise estimate**, and define **Start level**, **Increment** and **Stop level**. The DP-I/O measurement will be carried out automatically only if stop criteria are defined. If this is not the case, you must click on **Stop** to end the measurement, use the **up** and **down** arrow keys on the keyboard or on screen to change the **F1 level**, and then click on **Start** to resume measuring.
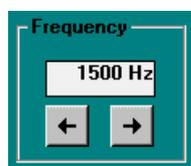
3. Select frequency by using the **right** and **left** arrow keys on the keyboard or in the **Frequency** box on screen.

4. Click on **Start** to begin measuring.

5. If you wish to halt the measurement momentarily, click on **Pause**. Click on **Continue** to resume the measurement.

6. Measurement status can be monitored by observing the **Sweeps** and **Statistics** boxes on the lower right part of the screen. The noise floor during the measurement is also indicated by the blue vertical bar to the right of the DP-Gram. The normally green DP-dot turns yellow if lower than the noise floor or outside the dynamic range of the instrument.

7. Click on **Stop** to end the measurement if you have disabled **Stop criteria**.

8. Use the **up** and **down** arrow keys on the keyboard or in the **F1 Level** box on screen to view the amplitude spectra and data for the various presentation levels.

9. Up to 6 measurements can be made for each ear. Click on the **arrow** keys in the **Meas. No.** box on the lower left to make a new measurement or to view other measurements made on the same ear during the session.

10. Repeat the procedure beginning with **Probe fit** for measuring the other ear.

4.6   SOAE

1. Click on the **SOAE** icon or choose **Spontaneous (SOAE)** in the **Mode** menu.

2. Select **Parameters** in the **Setup** menu to choose the bandwidth for the measurement, the criteria for stopping the measurement automatically (if desired), the noise reject level, and the S/N ratio for automatic identification of an SOAE. Click on **OK**.

3. Click on **Start** to begin measuring.

4. If you wish to halt the measurement momentarily, click on **Pause**. Click on **Continue** to resume the measurement. Measurement status can be monitored by observing the **Sweeps** box on the lower right part of the screen.

5. Click on **Stop** to end the measurement if you have disabled **Stop criteria**.

6. The frequency range shown in the SOAE response spectrum window extends to half of the measured frequency bandwidth. Use the scroll bar under the response spectrum to view other frequencies.

7. Move the cursor by using the left and right arrow keys on the keyboard, by clicking on the arrow keys in the Cursor box on screen, or by clicking on the response spectrum itself at the point where you want to position the cursor.

8. Click on **Next** to identify the next SOAE according to the defined S/N criteria. The spike will be marked on the graph with ↓, and data listed in the box in the upper right hand corner of the screen.

9. Click on Auto to automatically identify SOAEs according to the defined S/N criteria. These will be listed in the box, and the spikes on the graph marked with ↓.

10. SOAEs can be manually marked by double-clicking on them on the graph. These will also be listed in the upper right hand corner of the screen.

11. If any spikes have been either manually or automatically selected which you do not wish to have identified as SOAEs, they can be deleted by double-clicking them in the list or on the graph.

12. Up to 6 measurements can be made for each ear. Click on the arrow keys in the **Meas. No.** box on the lower left to make a

new measurement or to view other measurements made on the same ear during the session.

13. Repeat the procedure beginning with Probe fit for measuring the other ear.

4.7   Tympanometry

1. Click on the **Tympanometry** icon or choose **Tympanometry** in the **Mode** menu. If the patient shows signs of distress at any time, release the air pressure by clicking on **Air release (F5)** or pressing **F5** on the keyboard.

2. If required, reduce measurement time by clicking on the **up** arrow in the **Pump speed** box. **A.F.A.P.** means "As fast as possible".

3. To alter other settings (pump pressure range and sweep direction, display scaling and smoothing, auto start, measurement increment, and stop when results available), select **Parameters** in the **Setup** menu and choose different settings as required.

4. Select **probe tone** in the **Frequency** box.

5. To prevent the sweep from restarting if a leak is detected, click **Off** in the **Leak detect** box.

6. If **auto start** has not been selected, click on **Start** to begin the sweep. If a leak halts the sweep or the **Pump position** displayed during the sweep is seen to reach either of its end stops, try to improve the seal between the eartip and the ear canal, and then sweep again.

7. To compare the recorded tympanogram with norm data, click on **Setup** and then on **Norm data**. Click on the option required and then click on **OK**.

8. Up to 3 tymp. measurements can be made for each ear. Click on the arrow keys in the **Meas. No.** box on the lower left to make a new measurement (if **Enable meas. no. increment** has not been checked in **Setup**) or to view other measurements made on the same ear during the session.

4.8   Importing old Celesta files

To retrieve saved measurement results made using Celesta, proceed as follows:

1.   Go to the **File** menu.

2.   Select **Open old Celesta files...**

3.   If necessary, select **Drive**. Click on the **arrow down** icon to show the available drives and then click on the one containing the required files.

4.   If necessary, select **Directory**. Double-click on **[..]** to move down the directory tree, or double-click on one of the other displayed directories to select it or to move up the tree.

5.   There are three kinds of measurement mode: **TEOAE**, **DPOAE** and **SOAE**. Select the required patient and mode and then click on **OK**.

4.9   Comments

You can append comments by selecting **Edit comments** from the **File** menu -- 4 lines of comments can be written per session. These comments are displayed on NOAH's session list, and can be included on the printout.

4.10   User configuration

1.   From any measurement mode, all setup and test parameters can be saved as a specific user configuration. Select **User** in the **Setup** menu. Type a name or initials in the **New user** box, and click on **Save**.

2.   Confirm **Save user setup file** by clicking on **OK**. Click on **OK** again to exit.

3.   Alternatively, you can revert to the default configuration or select another configuration using this feature. Click on the desired user setup file to select, and then on **OK** to exit.

4.   You can also delete an old user setup file by selecting it, and then **Delete**. You will be prompted to confirm the deletion.

4.11   Auto sequence

To permit automatic testing, *Capella* has a built-in macro function.

1. First complete **Probe fit** for the ear to be tested, and then select **Auto sequence** from the **Setup** menu or click on the **Auto sequence** icon.

2. Select an existing Auto sequence from the box, and click on **Run** to start measurements in the predefined sequence and with the predefined parameters. The measurement can be interrupted at any time by clicking on **Pause**, or the Auto sequence can be terminated prematurely by clicking on the **Stop** button in the **Auto Sequence** run box.

3. To create a new macro, type a name into the **New Auto sequence** box and then click on **New**. Select the measurement modes you wish to test with, type the number in the sequence under **Mode order**, choose the **Number of measurements** you wish to make for each mode, and then set up each measurement mode by means of **Parameters**. If required, choose the **Break** condition for Probe fit, Echo-Screen and Tympanometry. Remember that each Auto sequence is for one ear at a time, i.e. to test both ears you must

first change ear, perform a Probe fit and then run the Auto sequence.

4. After creating a new Auto sequence, click on **Run** to execute it, or **Close** to exit from the dialog box.

5. Any existing macro can be deleted or edited from the Auto sequence box.

4.12   Compare

Use this function to compare measurements made on the same client's ear over time:

1. Select **Compare** from the **File** menu.

2. Choose **TEOAE**, **DP-Gram** or **DP-I/O** from the **Mode** menu as required.

3. Click on **Open session** in the **File** menu to find the data to be compared.

4. Click on the first session to be compared, then on **OK**, and then select another measurement if required by means of the **left** or **right** arrows in the **Session** sub-window.

5. Repeat step 4 up to five times. Each successive measurement result will be assigned a session number and superimposed on the others on the graph. To display the corresponding measurement parameters and/or statistics, select **Param.** and/or

Statistics in the **View** menu and then click on the **Session** sub-window with the corresponding session number.

4.13   Printing measurement results and comments

Capella has a very versatile printout function, which can be comprehensively configured to your own requirements.

- You can register up to four lines of comments per session by selecting **Edit comments** from the **File** menu.

- To print out measurement results (with any comments) using the default setup, select **Print** from the **File** menu, and then **This mode**, **Overview** or **All**.

- To configure a new print setup or select a different existing named setup (**Load Setup**), select **Print layout** in the **File** menu.

- Portrait or landscape format may be set up by clicking on **Select Printer**.

To add an image to the current page, proceed as follows:

1. Click on the arrow to the right of the selection bar at the top of the dialog box.

2. Click on the required image.

3. Click on **Add Image**.

4. Drag the image to the required position on the page.

5. Use the right mouse button to identify a selected image (**Show Description**), bring it to the **Top** or **Bottom**, or **Delete** it from the page.

6. The size of an image may be changed by clicking on an edge or a corner.

7. When the setup is complete, click on **Save Setup** and assign a name to it.