

PRODUCTnews

Data Management

Hearing assessment

Fitting & Testing

Balance assessment

Madsen OTOflex 100 & OTODiagnostics Suite

OTOflex was successfully launched April this year. We are proud already now to present some new powerful features that will further enhance the product and strengthen its market position.

Forward this to everybody in sales and service!

OTOflex 100 firmware release plan – overview



August – soon to come!

- Much faster test start-up
- Comprehensive new probe check feature with integrated volume readout adjustment
- Additional set of HL correction factors for improved backward compatibility

The new firmware will be part of the associated new release of the OTODiagnostics Suite CD (order number #8-49-68100). The CD will include the latest OTODiagnostics Suite software released in July (see summary notes at the end of this news letter) with no further changes.

Existing OTOflex devices can be upgraded on site via Bluetooth using the Kernel Upgrade PC software tool included on the CD. The procedure will be described in detail in the final release note.



November/December

- Additional OTOflex device languages: Spanish, French, German, and Italian
- Direct printout of the full immittance report to a standard printer via Bluetooth
- New data export feature in OTODiagnostics Suite

Further information on the November release will follow prior to the release.

Get dressed for your sales visits

- Why do I sometimes see higher reflex thresholds?
- What is the battery condition at delivery?
- Where do I find Service Packs for Microsoft Windows?



Learn more about the new features, about OTOflex, about OTODiagnostics Suite installation support, and the updated release plan in this letter.

Important product info

Delayed translation of OTODiagnostics Suite Online-Help

Due to project priorities, we face a delay in the translations of the OTODiagnostics Suite Online-Help into German, French, Italian and Spanish. The October 2004 deadline communicated in the product release cannot be met.

Note that the User guides have been translated already and that translation of the screen texts on the OTOflex 100 device is ongoing and will be released later this year.

Madsen OTOflex 100 is delivered with pre-charged batteries

To assure smooth demo of the Madsen OTOflex 100 to customers, we want to address the apparent uncertainty about the initial charging of OTOflex 100. The aim is to clarify what the battery condition is at delivery and what you can expect initially from OTOflex.

When OTOflex 100 is tested and packed in Taastrup a set of fresh rechargeable NiMH batteries are included. These batteries get charged at our factory to assure that OTOflex 100 can be demoed and used without having to await the initial full battery charging when OTOflex is delivered to the customer.

As rechargeable batteries lose their charge over time even when not used, you cannot assume that the batteries are sufficiently charged for normal clinical operation. After charging, the batteries have been stored with the OTOflex for some time before it reaches the end user. This is the reason for directing the user to charge the batteries before the first use. Also, a higher battery capacity is usually obtained after several full charges.

When bringing a new OTOflex 100 to the customer for demonstration (and delivery), take the following precautions:

- 1) Before going to the customer, check the OTOflex production date. If it is older than 1 month, you may need to unpack the OTOflex and charge the batteries over night to allow for a smooth product demo.
- 2) During the demo, explain to the customer the need for initial charging of the batteries.
- 3) Keep the OTOflex in the charger as much as possible during the product demo to prevent running low on power.

If OTOflex is sent directly from the factory to the customer, the battery charge condition will normally be sufficient for demo purposes.

Madsen OTOflex 100 demo hints

- For users operating the OTOflex 100 from its keypad, focus on the simple selection of predefined test settings from the My Settings menu. Loading of settings causes all parameters for all test types to be changed in one go. Create settings initially that match the user's preferences for various patient categories and name them accordingly.
 - Train users in how to enter the test selection mode: press and hold the select key for 1 second and then simply turn the scroll wheel to go to a test or to review all the measurement results. Exit the test selection mode by pressing the select key in the test you want.
 - When making ipsilateral measurements without using the shoulder harness - then put the long probe cable around the back of the subject's neck so that it rests on both shoulders to achieve the optimal probe placement.
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OTODiagnostics Suite installation support

The OTODiagnostics Suite software can be installed on PCs running Windows XP with Service Pack 1 and Windows 2000 with Service Pack 3 (and other selected Windows versions). The service packs are available from the Microsoft website for download in all supported languages.

As a special service to you, the English versions of the service packs are readily available on the OTODiagnostics Suite installation CD. However, this CD does not have enough space for service packs in other languages.

To further support installation, we have now created 2 CDs with the full sets of Service Packs for all 5 languages supported by OTODiagnostics Suite (English, Spanish, French, German, and Italian):

- Windows® XP Service Pack 1 for OTOdiagnostics Suite
- Windows® 2000 Service Pack 4 for OTOdiagnostics Suite

(Service Pack 4 is the latest for Windows® 2000 and is therefore supplied in stead of the minimum required Service Pack 3)

Both CDs automatically present a selection of language versions to install when the CD is inserted into the drive.

Due to Microsoft policies, these CDs are not part of the OTOdiagnostics Suite product distribution. The CDs are available from the International Sales team in Denmark. They are labelled "For internal use only". You may copy the CDs and distribute them internally to your sales and service staff as needed.

If you need other language versions than those on the CD you will still need to download them from the Microsoft website.

Clinical update

Understanding elevated reflex thresholds

- Influence from TPP offset setting

Most diagnostic immittance instruments can measure acoustic reflexes at a pressure close to the detected tympanometric peak pressure (TPP) where the most sound energy is transmitted through the middle ear and into the cochlear. However, many ears present very sharp tympanograms related to hyperflaccid tympanic membranes. In such ears it is almost impossible to get stable reflex measurements right at the peak pressure. Offsetting the pressure will stabilize the measurement and allow reflex results to be obtained. Users may choose always to offset the pressure from the peak regardless of the peak sharpness to keep uniform settings or to offset it only when needed.

The detected reflex thresholds will be influenced when offsetting the pressure from the middle ear pressure as differences in pressure across the tympanic membrane will stiffen the tympanic membrane and attenuate the applied stimulus reaching the middle ear and cochlea. The effective lower stimulus applied will be reflected as higher reflex thresholds. Even contralateral measurements will be affected as the stapedius response will also be attenuated by the stiffened mechanics in the probe ear.

Internal testing has shown that the pressure effect on reflex thresholds can elevate the results with as much as 10 dB when offsetting the pressure by 50 daPa in normal ears. In ears with steeper tympanograms, this effect shows at even lower pressure offsets. We therefore recommend that an offset of 0 daPa is used whenever possible.

The current default offset in OTOflex 100 is 25 daPa for all measurements. To change this, OTOflex 100 users should set "TPP offset" to 0 daPa in the RT and RD More Settings menus and apply it by setting "Custom TPP offset" to "On" in the RT and RD main menus. When set from OTOdiagnostics Suite: set "Custom TPP offset" to 0 daPa in the measurement settings dialog for reflex threshold and decay, and "Custom TPP offset" to "On" in the control panels.

The TPP offset defaults are changed in the August OTOflex 100 firmware release.

- Influence from applied HL corrections

The international ISO and the American ANSI standards agree almost 100% on HL corrections for insert phones. These corrections are currently used in the OTOflex probes.

Some immittance device manufactures (like GSI) traditionally use a slightly different set of correction factors based on the study "Reference thresholds for the ER-3A insert phone" by Laura Ann Wilber, Barbara Kruger, and Mead C. Killion, 1987. These correction factors differ by up to 4.0 dB from the ISO and ANSI standards for the stimulus frequencies used (2.5, 3.5, 4, 3, 1.5 dB higher for 0.5, 1, 2, 3, 4 kHz respectively) and will give slightly lower reflex threshold results when applied.

To maximize backward compatibility, the HL correction factors from the study above are now made available for selection in OTOflex as an alternative to the ISO/ANSI standards (August release).

- Influence from noise rejection and applied verification protocol

The ability to discriminate measurement artefacts from real reflex responses vary from instrument to instrument. Instruments with poor noise rejection and/or verification schemes may occasionally detect reflexes at too low levels or even in total absence of physiological reflex responses. Instruments with a good artefact rejection can usually avoid this and will consequently report the correct higher thresholds or absent reflexes.

OTOflex automatically repeats presentation of a stimulus in presence of noise. Furthermore, the user can freely select the verification scheme that matches the requirements:

- None – Stop as soon as a deflection exceeding the limit is observed.
- Repeat – Repeat the same stimulus level again to verify that it really exceeds the limit.
- Do next level – Apply the stimulus at the next higher stimulus level to confirm.
- Do next 2 levels – Apply the stimulus at the next 2 higher stimulus levels to confirm.

By default, OTOflex is set up to verify the result by applying the stimulus at the next higher intensity level.

New OTOflex 100 features - August release

Much faster test start-up

Some users have expressed a need for faster test start-up particularly in connection with auto-start and tympanometry measurements.

The start-up timing is a compromise between the ability to start right away and the risk of starting before the probe has been properly inserted into the ear canal. The criteria have been adjusted to greatly speed up testing and we believe the new compromise will work much better for the users. The following start-up situations have been made faster:

- Starting with the probe already in the ear
- Pressing start before probe placement
- With auto-start enabled

Your feedback regarding this matter following implementation in the market is appreciated.

Madsen OTOflex 100 probe check and 2 cc calibration

Before you test a patient, you need to know that the probe is ok to avoid having to retest and lose valuable test time. Also, when you sometimes get unexpected test results you will need to know if the results are real or affected by e.g. an occluded probe.

It is sometimes difficult to visually determine if the probe is clean and ready for use as wax may hide inside the tiny canals in the probe tip. Even OTOflex 100 cannot always discover such conditions during a measurement as the test conditions vary unpredictably from patient to patient and ear to ear, so some sort of help is needed.

Occluded probe tip canals can result in a variety of effects on the measurements:

- Elevated reflex thresholds
- Elevated ECV
- Noisy tympanometry and reflexes
- Shifted and broader tympanometry peaks
- Difficulties starting a measurement
- Louder probe tones

The solution is a new probe check feature in OTOflex 100. It is activated via a new entry in the OTOflex main menu with the probe placed in the cavity in the charger base. It checks that all canals in the probe tip are open and that the probe is not leaking. At the same time, the volume reading (the ECV readout) is adjusted to 2.00 cc if all probe checks are passed.

Adjustment of the volume reading to 2 cc with each probe check improves the accuracy and reliability of the ECV readings. It removes the uncertainty caused by reported ECV readings on the edge or outside the specified tolerances reported since the launch of OTOflex and it eliminates the natural variations caused by temperature, humidity and ambient pressure variations.

When taking OTOflex to other altitudes, remember to adjust the altitude setting and run a probe check!

We recommend checking the probe at least once a day to get the ECV reading adjusted to the environment. As with any other immittance instrument, a check before each patient examination or whenever probe problems are suspected will maximize the testing quality.

HL correction factors

As described earlier in this news letter, a new set of HL correction factors are added in the August release. The selectable standards are now:

- ISO
- ANSI
- Ref. ER-3A

Order the standard of your choice when ordering the OTOflex. The user can at any time switch between the standards from the OTOflex menu.

See the description in "Understanding the reasons for occasionally elevated reflex thresholds" above.

New default TPP offsets

The TPP default offsets have been adjusted to maximize the sensitivity in reflex threshold tests. See the description in "Understanding the reasons for occasionally elevated reflex thresholds" above.

OTODiagnostics Suite – what was in the July update?

A new version of OTODiagnostics Suite was released in July (8-49-68100/02) as announced in a separate release note. The new features were:

1. The OTODiagnostics Suite software texts in German, Italian, Spanish and French were updated
2. User Guides in German, Spanish and French language were included (in addition to the English one) on the CD. These are now delivered as paper copies with OTOflex 100 orders according to the language selection.
3. A compatibility issue with third party NOAH 2 fitting software modules was solved allowing these modules to read test results stored by OTODiagnostics Suite. (The problem was related to the NOAH 2 wrapper.)

The CD that will be released shortly with the new OTOflex firmware will of course include the latest version of OTODiagnostics Suite.