Otoscan

User Guide

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otometrics
a division of natus

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Technical support
Please contact your supplier.

Patents
This product is covered by one or more patents or patent applications as listed at: www.unitedsciences.com/patents:

1. U.S. Patent 8,715,173

2. U.S. Patent 8,900,126

3. U.S. Patent 8,900,125

4. U.S. Patent 8,900,129

5. U.S. Patent 8,900,128

6. U.S. Patent 8,900,127

7. U.S. Patent 8,900,130

8. U.S. Patent Application 14/040,973

9. U.S. Continuation Patent Application 14/538,994

10. U.S. Patent Application 14/041,943

11. U.S. Patent Application 14/049,542

12. U.S. Patent Application 14/049,538

13. U.S. Patent Application 14/049,666

14. U.S. Patent Application 14/049,530

15. U.S. Patent Application 14/049,687

16. U.S. Patent Application 14/049,678

17. U.S. Patent Application 14/049,504

18. U.S. Patent Application 14/049,518

19. U.S. Patent Application 14/150,863

20. U.S. Patent Application 14/462,619

21. PCT Patent Application PCT/US2012/029806

22. PCT Patent Application PCT/US2013/028347

23. Australian National Phase Patent Application 2012231140 Corresponding to PCT Patent Application PCT/US2012/029806

24. European National Phase Patent Application 12760319.9 Corresponding to PCT Patent Application PCT/US2012/029806

25. Chinese National Phase Patent Application Corresponding to PCT Patent Application PCT/US2012/029806

26. South Korean National Phase Patent Application 10-2013-7027859 Corresponding to PCT Patent Application PCT/US2012/029806

27. Japanese National Phase Patent Application Corresponding to PCT Patent Application PCT/US2012/029806

28. Canadian National Phase Patent Application Corresponding to PCT Patent Application PCT/US2012/029806

29. Hong Kong National Phase Patent Application Corresponding to PCT Patent Application PCT/US2012/029806

30. PCT Patent Application PCT/US2014/59512

31. PCT Patent Application PCT/US2014/59521

32. PCT Patent Application PCT/US2014/59535

33. PCT Patent Application PCT/US2014/59530

Table of Contents

1 Introduction

Otoscan is a comprehensive ear scanning solution that provides a new, safe and easy way to make digital impressions for earmolds or customized in-ear devices.

It eliminates clinical concerns related to traditional silicone impressions, such as risk to the patient, patient discomfort, and inconsistent outcomes.

The primary function of Otoscan is to make digital 3D scans of the patient's ear canal and pinna, to be used in the manufacture of customized in-ear devices. The scanning software transforms the scans into image files that are ready for use in 3D modeling. During the scanning process, the scanner performs video otoscopy in order to help the user navigate the scan in the patient's ear. See Intended use ▶ 5.

Scanner and software

The scanner is used in connection with Otoscan Session Manager installed on a dedicated PC.

Session Manager synchronizes data with the online application Otocloud, from where you can access, annotate and, subsequently, submit patient scans electronically as custom orders to manufacturers or ear mold laboratories.

1.1 The Otoscan system

The Otoscan system consists of:

- A dedicated laptop with pre-installed Otoscan software
- A hand-held scanner
- A cradle for secure docking of the scanner
- A headset for precise targeting of the ear and ear canal during scanning
- A training kit for practicing the scanning technique. (Optional)

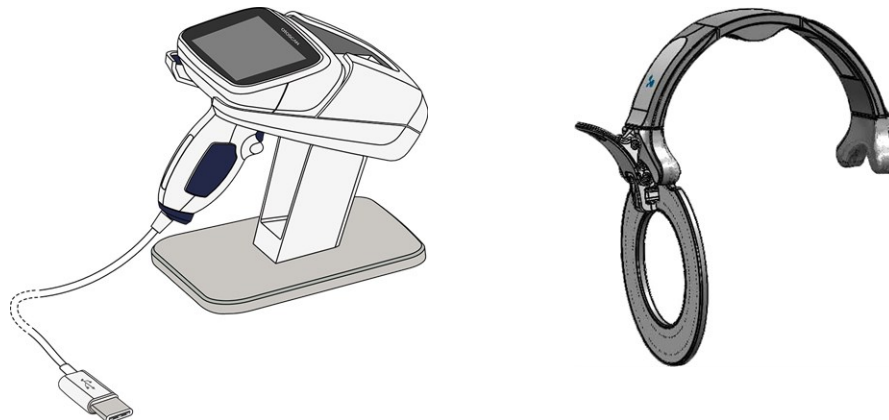The individual parts of the system are further described in the following sections.

Fig. 1   The Otoscan set

A. Scanner seated in its desktop cradle   **B.** Headset

1.2 About this manual

Read the User Guide

Read this User Guide before using the scanner for scans involving patients.

Where relevant, the procedure to be followed is listed at the beginning of the section, and a detailed description of the individual steps can be found in the sections following the procedure.

To obtain a free printed copy of the user documentation, contact Otometrics (www.otometrics.com).

The use of Warning, Caution and Note

To draw your attention to information regarding safe and appropriate use of the device or software, the manual uses precautionary statements as follows:

> ***Warning •*** *Indicates that there is a risk of death or serious injury to the user or patient.*

> ***Caution •*** *Indicates that there is a risk of injury to the user or patient or risk of damage to data or the device.*

> ***Note •*** *Indicates that you should take special notice.*

Reference to screen items in this User Guide

Menus, icons and functions to select are shown in **bold** type, as for instance:

"In this example, which displays an ongoing scan, the trigger will activate the **Pause** button."

2 Intended use

Otoscan provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for inspection.

Otoscan records and presents to the hearing professional in an image file a topology measurement of the external ear canal.

2.1 Indications for use

The primary application of the scanner and Session Manager is to make digital three dimensional (3D) impressions (scans) of the patient's ear(s) for manufacturing ear molds and customized hearing instruments.

The 3D impression can also be used for manufacturing customized noise protection headsets, ear plugs or swimming ear plugs.

The secondary application of this product is video otoscopy. The video otoscope function is mainly to help the user navigate the scan in the patient's ear.

2.2 Physical operating principle

The Otoscan scanner projects a blue ring or line of light from the probe onto the surface of the ear canal or the outer ear. This projection is converted to 3D coordinates through a complex camera system.

A 3D model is created by scanning the probe over the surfaces of the ear. The camera system also allows the operator to navigate the probe inside the ear canal, which is illuminated by a white light source.

The user can operate the scanner directly from the hand-held scanner display.

The scanner is intended for transient use.

2.3 Intended user profile

Audiologists, hearing instrument dispensers, ENT doctors and other trained personnel. Please note that local regulations may define users for video otoscopy differently. Local regulations must be complied with at all times.

2.4 Intended patient population

Otoscan is indicated for use on patients 18 years of age and older presenting for inspection of the external ear canal.

2.5 Intended part of the body or type of tissue applied to or interacted with

The external ear of the patient is the only intended body part for scanning.

2.6 Contraindications

> ***Warning*** • *If the patient experiences severe discomfort during the scanning procedure, stop the process.*

> ***Caution*** • *It is strongly recommended that you perform an otoscopic exam with a traditional or dedicated video otoscope to assess the status of the outer ear prior to performing a scan.*
> *- Cerumen should be absent, or present in only a small amount that does not interfere with the scanning process.*
> *- If excessive cerumen is present, either do not scan the ear or clean the ear before scanning.*
> *- Make sure that there is no residual fluid in the patient's ear after cleaning or wax removal.*

> ***Warning*** • *Scanning should not be performed on patients displaying the following contraindications:*
> *- If there is discharge or signs of infection in the ear*
> *- If the patient recently has undergone ear surgery*
> *- If the ear canal is occluded or cerumen is present in moderate amounts that will interfere with the scanning process*
> *- If the patient is uncooperative*
> *- If the patient is unable to be still during the scanning process due to uncontrollable or involuntary movements of the head and/or body*

- If the patient has a history of seizures, migraines, or other sensitivity to strobing lights
- If the patient experiences severe discomfort during the procedure

3 Unpacking Otoscan
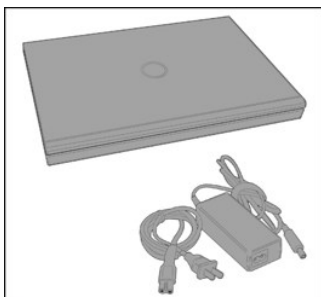
Package 1: Laptop   **Package 2: Scanner and headset**   **Optional: Training kit**
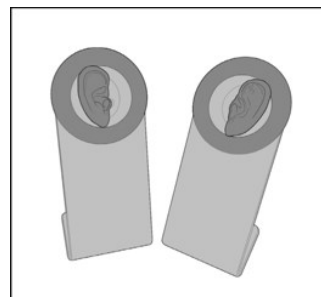
Fig. 2   The Otoscan set and optional training kit

Unpacking the PC

- Remove all packaging and make sure to store all cables and parts, including the instruction material.

- Keep the enclosed insert note at hand for reference. Possible later users may need the description of how to start the PC and find the present user guide.

Unpacking the scanner, cradle and headset

> ***Note •*** *Carefully remove all packaging and note that the scanner probe tip is fragile!*
> *Be particularly careful when removing the tape that keeps the scanner attached to the cradle and when handling the scanner once it is free.*

- When the scanner is not in use, always place it in the cradle to protect the probe tip.

Inspecting the equipment for possible damage

> ***Caution •*** *Visually inspect the equipment for possible damage.*
> *If damage has occurred, do not put the device into operation. Contact your local distributor for assistance.*
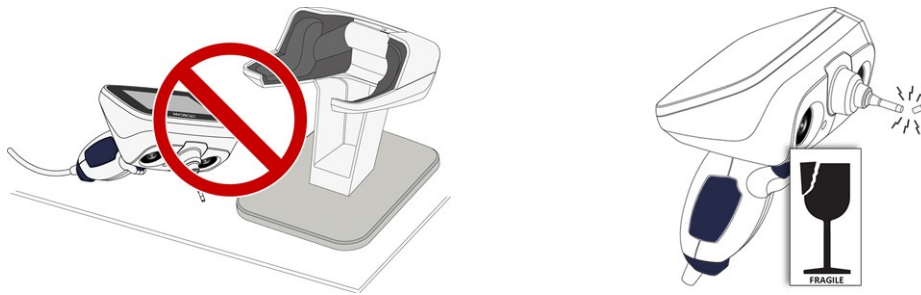
Fig. 3   To avoid damage, always leave the scanner in the cradle when it is not in use!

Checking the packing list
- Check the packing list to make sure that you have received all necessary parts and accessories. If your package is incomplete, contact your local distributor.

Storing packaging for later use
- Keep all packing materials as the original packing material will protect against damage during shipping, for example when sending the scanner in for an annual calibration check or service.

3.1   Storage of the Otoscan units

If you need to store the Otoscan devices, follow these guidelines:

- Store Otoscan and accessories in the boxes provided to protect the equipment from damage.
- Store Otoscan and accessories in a dry environment. See also Technical specifications ▶ 47.

4   Getting acquainted with Otoscan

4.1   The Otoscan PC

The PC is dedicated to be used exclusively for the Otoscan process. It powers the scanner during use, and the installed Session Manager controls the scanner and stores the data derived from the scanning process in a local database.

When online, the local patient database will be synchronized with a second database which is part of the online application Otocloud.

Installation procedure
1. Set up the PC on a suitable location. (See below).
2. Power the PC: Connect it to an electrical outlet. (See below).

Setting up the PC
- Place the PC on a suitable desktop and leave a space for the scanner nearby. Make sure that the PC's air vents are not obstructed.
- Consider placing the PC screen in full view of the patients, so they can follow the scanning process.

Otoscan Session Manager and all required accessories have been installed on the PC at the factory.

The PC is to be connected to a wired or wireless network prior to use. See Connecting to Internet ▶ 9.

To get started you need a log-in and a password which is provided by the local Otoscan administrator.

For instructions on how to use the Otoscan software units, see the sections:

- Logging into the system ▶ 14.
- Managing patient records ▶ 16.
- The scanning session ▶ 23.
- Managing patients and scans in Otocloud ▶ 35.

Powering the PC

1. Plug the external power supply into the Power socket on the PC.
2. Plug the external power supply directly to an AC electrical wall outlet with a three-wire protective ground.

Battery operation

If needed, the PC can run on its built in battery for a short period before it must be connected to an electrical outlet for recharging. To prolong battery life, do not let the PC discharge entirely before recharging it.

Further instructions

If you need further instructions on how to connect the PC to an electrical outlet or how to use general functions on the PC, see the user instructions from the PC manufacturer, which are supplied with the PC.

4.2   Connecting to Internet

The PC can be connected to a network by a wired Ethernet cable or by a wireless (Wi-Fi) connection.

Connecting to a wireless (Wi-Fi) network

1. To access the list of available wireless networks, click the **network icon** in the system tray in the lower right corner of the PC screen.
2. Locate the network to which you want to connect and click its name. If it is a network you know and you will connect to it on a regular basis, you should also check the option that says: **Connect automatically**. Then, click **Connect**.
3. After you have clicked **Connect**, Windows will do a scan for the security settings of the wireless network. When it is done, it will ask you for the security key.
4. Once you have entered the security key (password) required by the wireless network, click **Next**.

Connecting to a wired network

1. Plug the Ethernet cable into the network adapter on the PC.
2. The network connection should be established automatically.

Note • *Contact your network administrator for support with establishing or maintaining a network connection.*
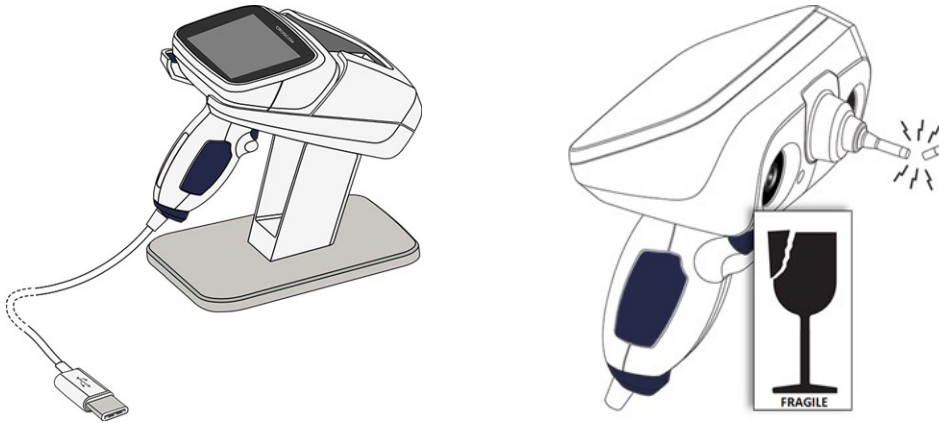

4.3 The Otoscan cradle

Fig. 4   To avoid damage, always leave the scanner in the cradle when it is not in use!

The cradle is designed for safe docking of the scanner when not in use. In addition, the inside back wall of the cradle is covered by a dotted pattern. Before each scan, the scanner will use this pattern for a self-test of the functionality of the scanner.

4.4 The scanner

The scanner is an advanced unit with built-in lasers and cameras. See Physical operating principle ► 6.

The patient headset serves as the reference point for the entire scanning process. See The headset ► 14.

During scanning, the two cameras placed on either side of the probe continuously track the position of the headset relative to the 3D data that is being collected by the scanner. This allows the system to build an accurate 3D model of the ear canal and the required parts of the pinna. See The scanner components ► 11, Fig. 5 and Fig. 6.

> **Caution •** The scanner probe tip is fragile. To avoid damage, always leave the scanner in the cradle when it is not in use!

4.4.1 Connecting the scanner

> **Warning •** The Otoscan system must always be installed in accordance with the instructions in the Otoscan User Guide.

The scanner is fully assembled on delivery, and you simply have to connect cables.

> **Caution •** To connect the scanner to the PC, use only the supplied USB cable.

- Connect the USB cable that is attached to the scanner into one of the PC's USB ports on the side of the PC.

> *Warning* • *The scanner must not be connected to PCs other than the locked-down laptop provided by Otometrics. No attempts should be made to use it with any software other than Otoscan Session Manager, Otocloud and training software.*

Place the cradle and scanner next to the PC

- Keep the scanner in the cradle and place the set on a stable desktop next to the PC.
  Choose a location where you will have convenient access to the scanner when it is parked in the cradle.
  Also, ensure that you have a clear view of the PC screen during the scanning session. This will be useful when you pause to evaluate the scanned image, if you prefer to see it on the larger screen, and when you finalize the scanning session.

4.4.2 The scanner components

The individual components of the scanner that work together to form the 3D scans are described below, as seen from the probe-side and the touchscreen side of the scanner, respectively.

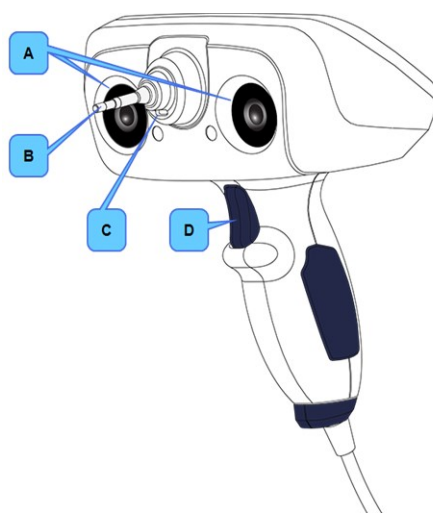**Scanner components — seen from the probe side**

A. Tracking cameras

Cameras on either side of the probe detect the tracking ring of the headset worn by the patient. The cameras track the position of the scanner in relation to the patient's ear. To function properly, the cameras' view of the tracking ring must remain unobstructed.

B. Ring laser

Scans outwards from the tip of the probe (E on Fig. 6 ► 12). Scans the canal (in **Canal Ring** mode) and the curved portions of the pinna such as the helix, sidewalls of the concha, and intertragal notch (in **Concha Ring** mode).

C. Line laser

Scans in front of the probe tip in a horizontal line (in **Pinna Line** mode), similar to a bar code scanner. It is used for scanning the flatter parts of the pinna, such as the center part of the concha bowl, and ridges at the edge of the concha..

D. Trigger button

Selects the most common next action, based on the current state of the device. If more than one action is available, the most common next action is shown highlighted on the screen. For example, you will use the trigger to set the depth gauge and start a scan. During a scan, you can press the trigger to pause the scan.

Fig. 5 The hand-held scanner, seen from the probe side.

Scanner components (continued) — seen from the touchscreen side

E. Probe

The probe is the portion of the scanner which can be inserted into the ear canal. It contains lighting, the video otoscope camera, and the Ring laser scanner. It is fragile and can break if the device is not seated in the cradle while not in use.

F. Status indicator

The color of the Otometrics logo indicates the status of the scanner. The device is on and ready when the light is green. See Legend: Status indicator colors below.

G. Touchscreen

The screen is a touchscreen. It serves as the primary interface used throughout the scanning process and can be used in combination with the trigger. All aspects of the procedure are shown on the screen, including the 3D scan image, the video otoscopic view, depth readings, and messages.

Fig. 6   The hand-held scanner, seen from the touchscreen side

Legend: Status indicator colors

Green:	Ready/Standby
Blue:	Scanner active or in scanning mode, with headset tracking
Yellow:	Scanner in scanning mode, but tracking lost Action required: Correct scanner position vs. tracking ring.
Orange:	Depth warning and any error condition. Action required: Correct the error.

4.4.3   Switching the scanner on and off

Switching the scanner on

The PC controls the power to the scanner. This means that the scanner will be switched on automatically when you initiate a scan from within a patient record in Session Manager. See Beginning the 3D scan ▶ 23.

To open Session Manager, you need a registered user name and a password. See Logging into the system ▶ 14

> **Warning** • *Do not stare into the laser, or point the laser in the direction of other people's eyes. It can damage the eyes.*

Switching the scanner off

The scanner automatically switches off a short time after completion of a scanning session.

> *Note •* *If you accidentally unplug the scanner from the PC during use, this will switch off the scanner but not the scanning application. Plug the same scanner back in and continue the scanning session.*

4.4.4 Using the Otoscan trigger and touchscreen

Operating methods

The recommended way to control the scanner is by means of its touchscreen and trigger.

Using the touchscreen

During scanning, the touchscreen on the scanner displays a duplicate of the screen on the PC. This allows you to operate the scanner by means of its touchscreen, while you can use the PC display for a larger view of the partial or completed scan. When needed, you can also make scanner selections on the PC screen by using a PC mouse or the PC's touch pad.

> *Caution •* *The Otoscan touchscreen display may get hot during heavy use. Do not touch the display surface for longer than 1 minute.*

Using the trigger

The Otoscan trigger is located on the handle of the device. See point D in The scanner components ▶ 11. It allows the user to start or pause the scan as well as proceed to next steps in the scanning process. Pressing the trigger will always select the button seen on the touchscreen. If more than one button is available, the button to be selected next will appear highlighted on the screen. Generally, the highlighted buttons on the screen will guide you through the normal scanning procedure.

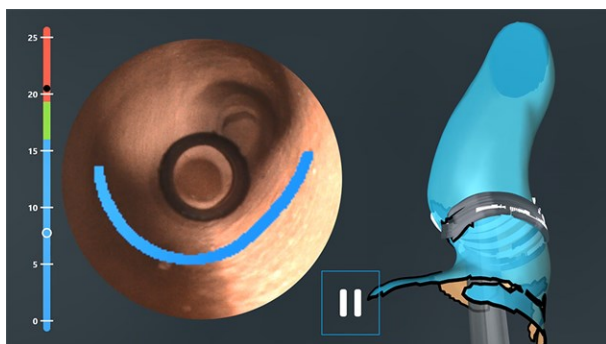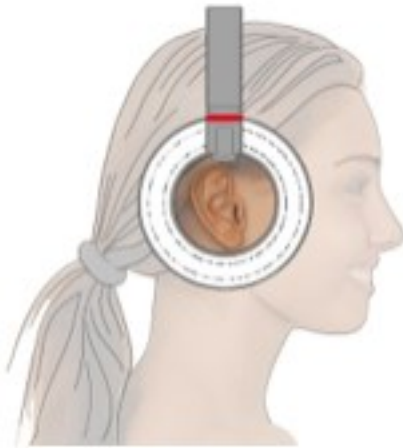In the example in Fig. 7, which displays an ongoing scan, the trigger will activate the **Pause** button.

Fig. 7   An ongoing scan. The **Pause** button is the only selection available at this point.

4.5 Accessories

Unpacking the accessories

Unpack the headset and (if relevant) the optional training kit and place them next to the scanner.

4.5.1 The headset

The headset is fitted on the head of the patient before scanning. It is essential for the scanning process, as the tracking ring of the headset serves as the reference point for the two cameras on the scanner, which keep track of the exact location of the ear during the scan.

It is, therefore, very important for a successful scan that the headset is placed correctly, and that it remains in place during the entire scan. See Placing the headset ▶ 21.

In order to facilitate correct placement, the headset is designed for scanning of one ear. When scanning the other ear (if required), reposition the headset to target that ear. This procedure is found to maximize efficiency and maintain high accuracy for both scans.

Fig. 8   The headset, with the tracking ring correctly centered over the ear

4.5.2 Training kit

A training ear stand, permanently fitted with a ring from a headset, and two interchangeable ear models are available as an optional extra for training purposes.

If the training kit was part of your order, place them in a convenient location for training such as next to the scanner.

Along with the included training software which is accessible from the desktop of the Otoscan PC, this set of ears provides a safe and convenient opportunity to experiment with the scanner until you feel that you have gained sufficient proficiency to use it with real people.

4.5.3 Otoscan training

Otoscan training sessions are arranged in order to ensure that users quickly become familiar with using the equipment in a safe and efficient manner.

Please consult your supplier for information on available training in your area.

5   Logging into the system

User ID and password

All Otoscan users must have a user ID (the user's email address) and password to access Otoscan Session Manager and the online application Otocloud. There are two ways to access Otocloud: Either through Session Manager on the Otoscan PC, or via the separate Otocloud login on any PC with internet connection. See the Otocloud User Guide for further information.

Initially, the primary administrator for a clinic receives an email with instructions on how to log into Session Manager and Otocloud. The primary administrator can then add other users who need access to the application.

5.1 Logging in

The first log-in

Otoscan administrators can set up users in the online application Otocloud.

Each new user who has been set up by the administrator, will receive an email with a user name and password for OtoscanSession Manager and Otocloud.

To log in, follow this procedure:

Start the PC and open the Otoscan software application

1. Press the **ON/OFF** button on the PC to switch it on.

2. Click the **Otoscan icon** on the desktop of your PC.

Wait while the system checks for new software

When Session Manager starts, it checks for updates to the software. If an update is available, we recommend that you let the system install it. If the update notification is shown at an inconvenient time, you can skip the update for a limited number of times. However, the system will continue in offline mode until the software has been updated.
If the update is critical for continued performance, you will not be allowed to skip the update.
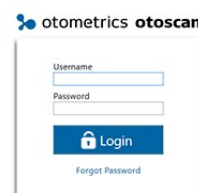
• To start the update, click the **Update** button.

> **Update available for Otoscan Session Manager**
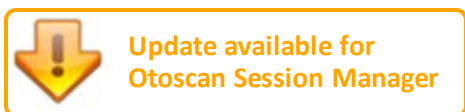
• To skip the update, just log into the system.

Log into the system

The system will prompt you to enter your user name and password:

• Enter the user name and password that you have received from the Otoscan administrator in your clinic.

• Click the button **Login**.

> **Note** • *If you leave the PC idle for 20 minutes, the system automatically logs you out.*

See for instructions on how to log out and close down after use.

Forgotten password

If you have forgotten your password, do as follows:

- Click the link below the **Login** button: **Forgot Password**
  You will be redirected to another window, where you can enter your email address.
  You will then receive an email with instructions on how to reset the password and create a new one.

5.2   Overview of the Otoscan software application

Session Manager contains a patient database, which opens automatically when you start Session Manager. Here patient data is created and kept updated. See Managing patient records ► 16.

The scanner can only be started from within a patient record. While performing a scan you can operate the scanner directly from its built-in touchscreen. See The scanning session ► 23.

5.3   Overview of Otocloud

Otocloud is Otoscan's an online application. It is used to transmit scans and images to hearing instrument manufacturers and ear mold laboratories in association with hearing instrument orders.

There are two ways to access Otocloud: Either through Session Manager on the Otoscan PC, or via the separate Otocloud login on any PC with internet connection. See the Otocloud User Guide for further information.

When the Otoscan PC is online and a user is logged in, the application will keep the patient record in the local database on the PC synchronized with the corresponding data records in Otocloud.

While you are working in Otocloud from the Otoscan PC, Session Manager on the PC remains open in background.

- To switch between Otocloud and Session Manager: press the keyboard keys **Alt** + **Tab**.

- Alternatively, click the relevant icon, that is, the **Otoscan** icon or the **browser** icon on
  the task bar at the bottom of your PC screen.

If you leave Session Manager idle in the background for 20 minutes, the system automatically logs you out. This is done to minimize the risk of unauthorized access to the data.

See Managing patients and scans in Otocloud ► 35 and the Otocloud User Guide for further information.

6   Managing patient records

Otoscan Session Manager and Otocloud store all patient data and saved scans in mutually synchronized patient records.

It is good practice to check if a patient is already in the database, before you create a new patient record.

This description covers Session Manager. For instructions on how to work with patient records within Otocloud, see the Otocloud User Guide.

Opening or adding a patient record in Session Manager

- See Opening a patient record ► 17.
- If no record exists for the current patient, create one. See Creating a new patient record ► 19.

For information on how to work with patient records in Otocloud, see the Otocloud User Guide.

More options
- Editing a patient record ▶ 18.
- Deleting a patient record ▶ 18.

6.1 Opening a patient record

When you start Session Manager, the **Patient list** appears.

To find an existing patient record in the **Patient list**, you can either use search filters or sort the list by the column headers.

Using filters to search for a patient
1. If the patient list is long, use the filter selections in the left panel to search for the patient:
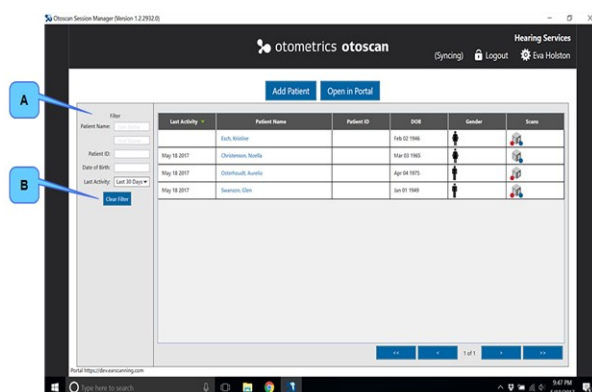
A. Enter either the patient's name, ID, Date of Birth, or date of last activity in the corresponding fields. The list will narrow down as you type.

B. If you need to reset the filter in order to make a new search, click the button **Clear Filter**.

Fig. 9 The Patient List
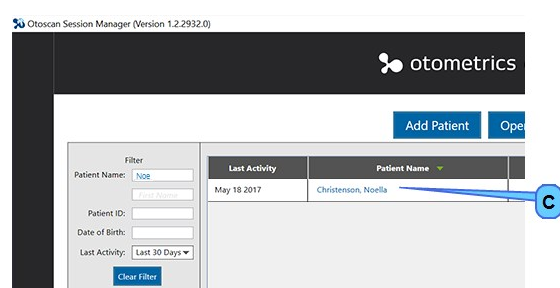
C. When the patient is found, click the patient name in the **Patient Name** column to open the record.

Fig. 10 Example: List sorted by starting to write the patient's last name in the **Patient Name** field
(**A** on Fig. 9 ▶ 17).

Using column headers to sort the list of patient records
You can click one of the column headers to have the list sorted according to the selected column:
- The first click on a column header will sort the list in ascending order.
- A second click on the column header will reverse the sorting order.

A green arrowhead next to the column name will indicate that this column was used for sorting. If the arrowhead points upward, the sorting is in ascending order; if it points downward, the sorting is in descending order.

Editing a patient record

If you need to make changes to a patient record:

1. Open the relevant patient record from the **Patient list**.

2. In the top left corner, click the **Pencil** icon.
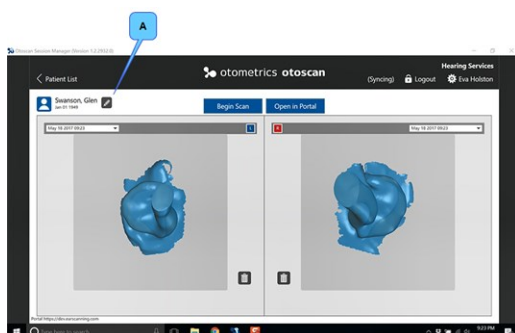
A. The **Pencil** icon.

Fig. 11   The **Pencil** icon, located in the top left corner, next to the patient name.

3. Make the required changes.

4. Click **Save** to save your changes, or **Cancel** to quit without making changes.
   You will be returned to the patient record window.
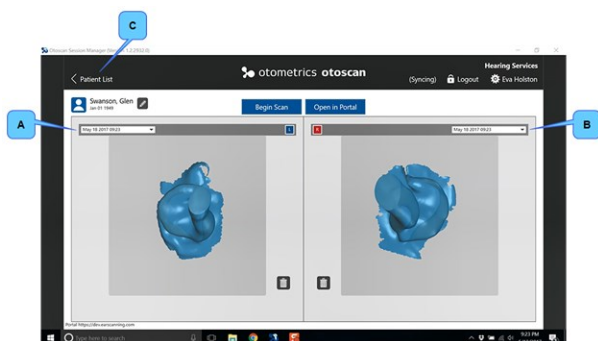
If more than one scan exist for an ear, the other scans can be found via the drop-down list at the top of each frame.

A. List of scans for the Left ear.

B. List of scans for the Right ear.

C. To return to the **Patient list**, click
   < Patient List.

Fig. 12   The patient record window. In this example, a scan of each ear has been made at an earlier stage. New scans will not overwrite earlier scans.

Closing a patient record

- To close a patient record and return to the Patient List, click the **< Patient List** button in the top left corner of the patient record.

Deleting a patient record

It is not possible to delete a patient record once it has been created.

If a patient record contains data that needs editing, use the above option Editing a patient record ▶ 18.

6.2   Creating a new patient record

If the patient record is not already in the system, a new record must be created in Session Manager (or in Otocloud) before you scan the patient.

To add a new patient in Session Manager:

1. Open the **Patient list** and click the **Add Patient** button, which is located in the Action bar at the top of the workspace.
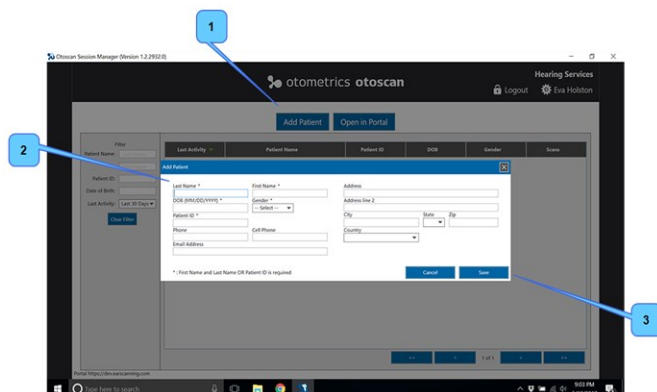

Fig. 13   The **Add Patient** dialog box.

2. Enter all relevant patient information.
    The required fields are marked with an asterisk (*). They are:

    •   **Patient Last Name**. Required if **Patient ID** not specified.

    •   **Patient First Name**. Required if **Patient ID** not specified.

    •   **Date of Birth**: Patient Date of Birth. Required.

    •   **Patient ID**: Patient identifier. Required if name not specified.

    •   **Gender** of the patient.

3. After entering at least the required data of the patient, click **Save**.

    A new patient record is now created in Session Manager. This is where patient data and scans for the new patient are stored for viewing or editing.

•   To close the dialog box without adding a new patient, click **Cancel**.

For instructions on how to add a patient record in the Otocloud database, see the Otocloud User Guide.

7   Preparing the patient for scanning

Procedure

1. Performing otoscopy and cleaning the ear canal ▶ 20.

2. Instructing the patient ▶ 21.

3. Placing the headset ▶ 21.

7.1   Performing otoscopy and cleaning the ear canal

In this User Guide, the individual parts of the pinna are referred to as indicated in Fig. 14 ▶ 20.

Fig. 14   The pinna

Before you scan a patient, perform an otoscopic exam using a traditional or dedicated video otoscope to determine if any contraindications exist:

1.   Examine the patient's ear canals in order to determine whether scanning is safe and advisable.

     A small amount of wax will not interfere with the scanning process if it does not partially occlude or change the shape of the surface of the canal. Oil and wax transferred onto the probe can distort the 3D image and can also make it difficult to clearly see into the ear canal with the scanner.

2.   If necessary, clean the patient's ears with a cotton swab dipped in 70% isopropyl alcohol to remove loose oils and wax from the canal prior to scanning.

Other elements in the ear such as hair and exostoses will have a minimal effect, and the scanning can be attempted. Also, patients with healed surgical ears can be safely scanned.

> **Warning** • If the patient experiences severe discomfort during the scanning procedure, stop the process.

> **Caution** • It is strongly recommended that you perform an otoscopic exam with a traditional or dedicated video otoscope to assess the status of the outer ear prior to performing a scan.
> - Cerumen should be absent, or present in only a small amount that does not interfere with the scanning process.
> - If excessive cerumen is present, either do not scan the ear or clean the ear before scanning.
> - Make sure that there is no residual fluid in the patient's ear after cleaning or wax removal.

> *Warning* • *Scanning should not be performed on patients displaying the following contraindications:*
> - *If there is discharge or signs of infection in the ear*
> - *If the patient recently has undergone ear surgery*
> - *If the ear canal is occluded or cerumen is present in moderate amounts that will interfere with the scanning process*
> - *If the patient is uncooperative*
> - *If the patient is unable to be still during the scanning process due to uncontrollable or involuntary movements of the head and/or body*
> - *If the patient has a history of seizures, migraines, or other sensitivity to strobing lights*
> - *If the patient experiences severe discomfort during the procedure*

7.2   Instructing the patient

It is very important that the patient remains still during the scan. If there is excessive movement of the patient this may cause errors in the scan. Slight movements will not affect the scan.

To accomplish patient cooperation, make sure that the patient is well prepared.

- Spend some time instructing the patient. Relevant subjects to include would be:
  – a short description of the process
  – an estimate of the time the scan will take per ear
  – an explanation as to why it is important that the headset does not shift from its original position
  – that the patient should minimize movements during the scan
  – that it is important that the patient does not talk or yawn during the scan.
- Ask the patient to try to indicate unavoidable moves - for example an upcoming sneeze.

7.3   Placing the headset

The headset is fitted on the head of the patient before scanning. It is essential for the scanning process, as the tracking ring of the headset serves as the reference point for the two cameras on the scanner, which keep track of the exact location of the ear during the scan.

The headset must be placed correctly on the patient's head (Fig. 15).

- Make sure that the ear is roughly centered within the tracking ring, that all parts of the pinna are free of the ring, and that no hair or other obstacles cover the dot pattern on the ring.
  If the pinna is too large to fit within the tracking ring, the ring can be adjusted to sit over the earlobe as long as the natural shape of the pinna is not changed.
- For the best fit, rest the headband cushion on the top of the patient's head. Use the hinges above the tracking ring to adjust the ring so that it sits as close as possible to the head without actually touching. If the ring is sitting too far away from the head it will limit the probe depth in the ear canal. If the ring is touching the head it may be easily moved if the patient talks or swallows.
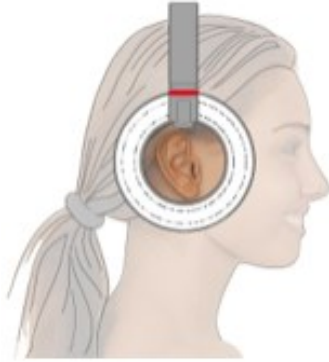 Once the scanning has started, the headset must not be bumped or moved.

Fig. 15   Correctly fitted headset

Incorrect: Pressing on pinna, thereby dis-
torting the shape of the ear.

Incorrect: Hair obstruction. The dot pattern
must remain fully visible during scanning.

Fig. 16   Examples of incorrect placement of the headset

7.4   Positioning the patient

It is important for a safe and convenient scanning procedure that you have free and easy access to the ear being scanned
and are not hampered by obstacles near the patient or on the floor, or by an impractical positioning of the patient.

1. Check the work space for possible obstacles that should be removed prior to scanning.

2. Position the patient in such a way that you have free access to the ear to be scanned. In particular, make sure that the
    shoulder of the patient is not in the way of the scanner and its cable. You can often achieve this by turning the
    patient's head toward the opposite shoulder and tilting the top of the head slightly away from you.

8   The scanning session

The procedure lists the usual steps of a scanning session. You will find detailed explanations to the individual steps in the following sections.

Procedure

> **Caution •** *Before scanning the patient's ear, make sure that you have cleaned the scanner probe tip and checked the placement of the headset.*

1. Make sure that the current patient's record is open on the PC screen. See Managing patient records ► 16.
2. Select **Begin Scan**. See Beginning the 3D scan ► 23.
3. Wait for the scanner self-test to finish. See Beginning the 3D scan ► 23.
4. Select the ear to be scanned. See Selecting ear to scan ► 24.
5. Set the depth gauge. See Setting the depth gauge ► 25.
6. Scan the ear canal (**Canal Ring** mode). See Scanning the ear canal ► 27.
7. Pause the scan to review results. See Reviewing a scan in progress ► 29.
8. Scan the relevant parts of the pinna (**Pinna Line** mode). See Scanning flat surfaces in Pinna Line mode ► 30.
9. Pause the scan to review results. See Reviewing a scan in progress ► 29.
10. Scan the curved portions of the pinna (**Concha Ring** mode). See Completing curved surfaces in Concha Ring mode ► 31.
11. Review and save the scan. See Saving the scan ► 32.
12. Mark the horizontal plane, if required. See Mark horizontal ► 32.
13. If relevant, scan the other ear after cleaning the probe. See Selecting the other ear ► 34.
14. Clean the scanner and place it in the cradle. See Ending the scanning session ► 34.

8.1   Beginning the 3D scan

Make sure that the scanner is connected to the laptop PC. See Connecting the scanner ► 10. The scanner will be activated when you start the scanning procedure from a patient record.

> **Warning •** *Do not stare into the laser, or point the laser in the direction of other people's eyes. It can damage the eyes.*

Before you start the scan

This procedure assumes that:

• You have already opened the relevant patient record from the Patient List. See Opening a patient record ► 17.

• You have examined, instructed, fit the headset, and positioned the patient. See Preparing the patient for scanning ► 19.

Initiating the scan

A. From within the patient record, click **Begin Scan** in the upper and center part of the Patient Record screen. The scanner switches on and a new window opens.
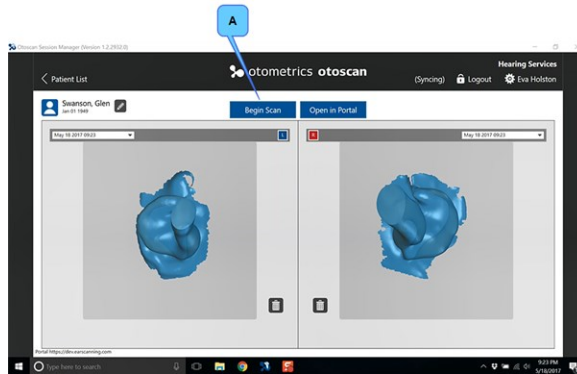

Fig. 17   A patient record, in this example already containing an earlier scan for both ears.
The **Begin Scan** button (A) is seen on the Action bar near the top of the screen.

Scanner start-up and self-test

Before each scan, the scanner performs a self-test while it is seated in the cradle. A screen message informs you accordingly:

> **Scanner self-test in progress...**
>
> **Leave scanner in cradle.**
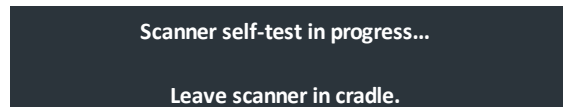
If the scanner does not pass the self-test, you will see an error message on the screen. In that case, clean the probe tip with an alcohol swab. Place the scanner in the cradle for a re-check. Before you start the re-check, make sure that the scanner is correctly seated in the cradle.

8.2   Selecting ear to scan

The screen displays a frame for the left and right ear, respectively. When you start a new session, they show corresponding drawings of a left and right ear. When you have scanned an ear, the scan is shown in the relevant frame and is available for further actions.
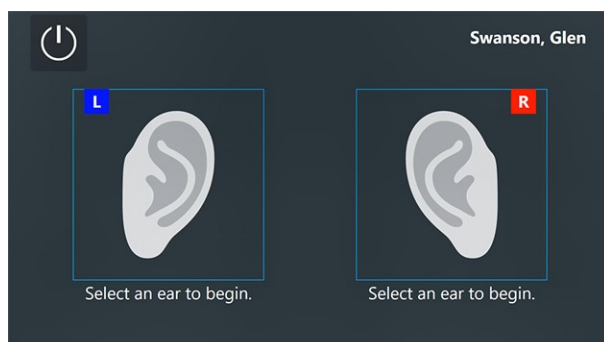
Fig. 18   Select an ear to begin.

• On the PC: Click inside the Left (L) or Right (R) ear frame to start the scan.

• On the scanner touchscreen: Tap inside the Left (L) or Right (R) ear frame.

   (If you accidentally select the wrong ear, you can swap the scan to the other ear after the scanning.)

The screen now displays the **Set Depth Gauge** view. See Fig. 21 ▶ 26.

8.3   Setting the depth gauge

The first step in the scanning procedure is to set the depth gauge. This is done in order to establish a reference zero point with which to determine the depth of the probe in the ear canal during scanning. It is very important for an accurate and safe scan that this step is carried out correctly. It is important that you observe the following warnings and cautions:

> **Caution •** *Always carefully inspect the probe before each use and do not use if there are any signs of damage to the probe, or if the unit is malfunctioning. Contact your supplier for assistance.*

> **Caution •** *To prevent cross-infection or re-infection, clean and disinfect the probe with alcohol wipes between patients and between scans of patient's ears.*

> **Warning •** *Be careful when you insert the probe into the ear of the patient - there is a risk of damaging the wall of the ear canal and/or the tympanic membrane. Do not apply excessive force to the outer ear with the probe.*

> **Note • Do not** *straighten the ear at any time during the scanning process, including during depth gauge setting. It is also important that the patient does not move their jaw. This includes talking, laughing, smiling, and other motions that would change the shape of the ear canal.*

Bracing the Scanner

The scanner is designed to allow single-handed use, but in order to improve scanning precision, minimize fatigue, and ensure patient safety, you should use a proper bracing technique.

Hold the scanner in your dominant hand. Place the finger of your other hand against the neck or jaw of the patient and then rest the scanner on the thumb of that hand as shown in Fig. 19 ► 26. Be careful not to allow your fingers to block the tracking ring or the tracking cameras.
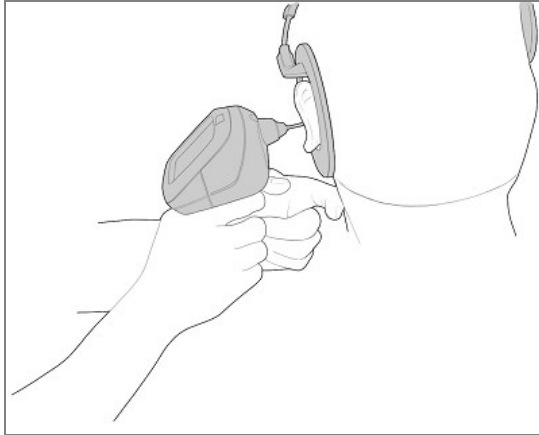

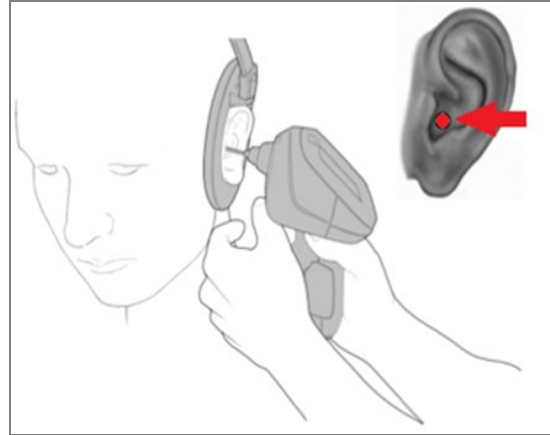**Fig. 19**   Proper bracing technique when using the scanner

Fig. 20   Where to place the scanner probe when setting the zero point.

Setting the zero point for the depth gauge

• Gently touch the flat part of the concha next to the ear canal opening with the probe tip, as shown in Fig. 20 and Fig. 21 and press the trigger on the hand-held scanner. This action marks a user specified zero reference point.

Once this action is complete, the scanning process will begin automatically. As the probe tip enters the ear canal, the depth gauge will display current estimated depth readings. The depth reading is the length of the probe inserted into the ear canal as estimated beyond the user specified zero reference point. A visual and audio warning will appear if a depth reading is detected beyond that recommended by Otometrics. The recommendations are based on an average adult ear differentiated by gender. See Scanning the ear canal ► 27.
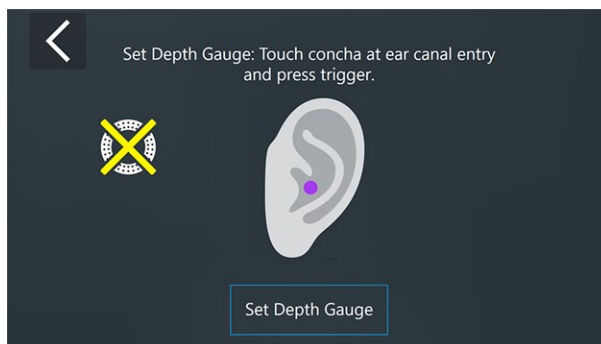

A **Headset not detected** icon is seen to the left on the screen. It will disappear as soon as the scanner comes within range of the tracking ring and detects it.

Fig. 21   Set the depth gauge.

> *Warning • The user is the sole person responsible for marking the correct reference point and for keeping the end of the probe at a safe distance from the tympanic membrane. The depth measurement and warning shown on the screen are based on the zero reference point specified by the user and average canal lengths as recommended by Otometrics, and are provided as guidelines only. The depth measurement and depth warning do NOT represent the actual safe scanning depth of the patient's ear canal.*

8.4 Scanning the ear canal

After setting the depth gauge, the scanner will automatically start scanning in the **Canal Ring** mode. In this mode it uses the Ring laser to complete a scan of the ear canal.

Procedure

• Using a suitable bracing technique, slowly insert the probe tip, while monitoring the scanning process on the screen of the scanner. The screen items that you see during scanning are explained in detail below with reference to .

• When required, press the trigger of the scanner or tap the **Pause** button on the touchscreen to pause the scanning and evaluate the result. See .

Live scanning view

To provide full control of the process, the screen displays three live items simultaneously. They are updated concurrently and show different aspects of the ongoing scanning.
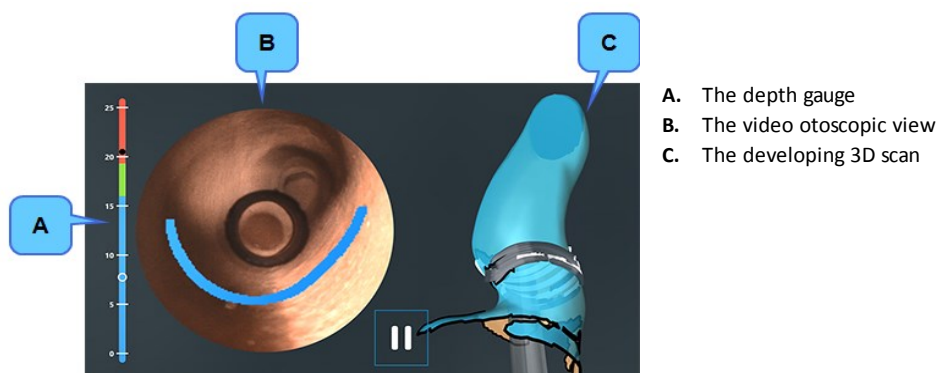

A. The depth gauge
B. The video otoscopic view
C. The developing 3D scan

Fig. 22   The live scanning view in **Canal Ring** mode

A. The depth gauge

On the left part of the scanning screen you see the ear canal depth gauge. The depth gauge provides guidance on the estimated depth of the probe tip within the ear canal. This gauge will warn you if the probe tip comes within an estimated unsafe distance of the tympanic membrane.

On the depth gauge, the current probe tip location is indicated by a white dot, and the deepest location during the current scanning pass is indicated by a black dot.

The insertion depth of the probe tip is indicated by color coding:

Green: The probe tip is within the target range (male: 16-18 mm; female: 14-16 mm)

Blue: Indicates a shallow probe tip insertion (male: 0-15 mm; female: 0-13 mm)

Red:

> **Warning** • *RED indicates a too deep probe position in the ear canal!*
> *If you reach the red area, the entire frame of the screen will also turn red as a very clear warning sign.*
> *At the same time, a warning signal will sound. The audible warning begins 2 mm into the depth warning zone.*
> *For a male the red color starts at 19 mm, but the audible warning does not start until 21 mm.*
> *For a female the red color starts at 17 mm, but the audible warning does not start until 19 mm.*
> *In that case, immediately reposition the probe to ensure proper depth in the patient's ear canal!*

B. The video otoscopy screen item

A live otoscopic view of the ear canal is seen to the right of the depth gauge. The colored lines in the video otoscopy image, called the data capture lines, indicate surfaces that are being captured in the scan. The color of the line changes between blue, green, and red according to the insertion depth and in synchrony with the color indication on the depth gauge. Hence, the blue line indicates shallow depth, green indicates target depth, and red is too deep.
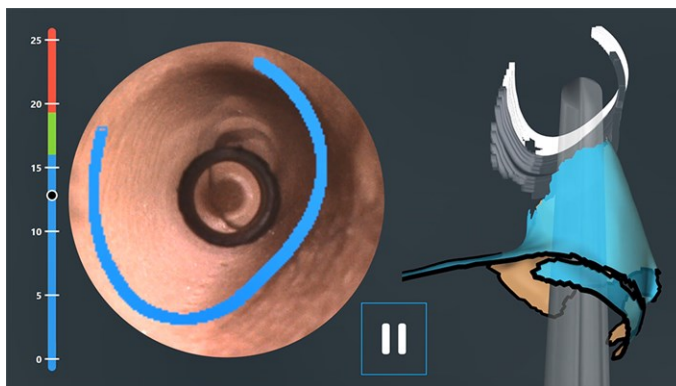

Fig. 23   In the otoscopic view, to the right of the depth gauge, the area of the ear canal that is currently being scanned is indicated by means of a bright blue line.
Further to the right, the developing 3D scan is seen. The probe tip is visible in the lower part of the image, and behind it follows trailing white and gray shadows which indicate the area that has just been scanned.

C. The developing 3D scan

On the right side of the screen, you will see the 3D image of the ear scan developing as the scanning continues. The smooth blue surface indicates the parts that have already been scanned. The data capture line shown on the video otoscopy image is also seen here as a white curve and is shown together with a faint grey image of the scanner probe. Behind the area being scanned you will see trailing shadows, indicating the area that you have just scanned.

Unfinished parts of the scan are indicated by a colored edge:

- Gaps that are so small that they do not require additional scanning are visualized by means of a black edge.

- Large gaps that need attention before the scan is complete are indicated by a yellow edge.

Fig. 24 ▶ 29 and Fig. 25 ▶ 29 show two scans seen in **Pause** mode. Gaps are indicated by means of black and yellow outlines.
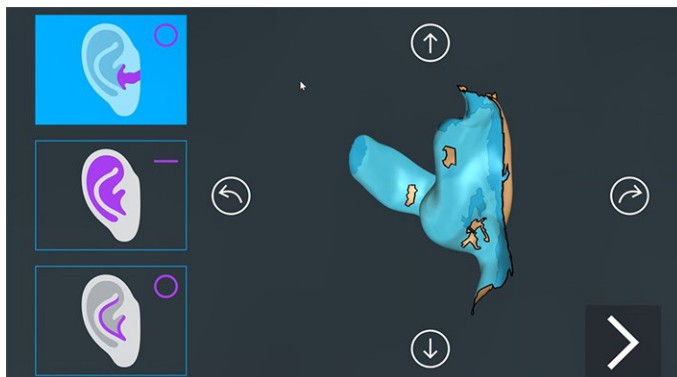

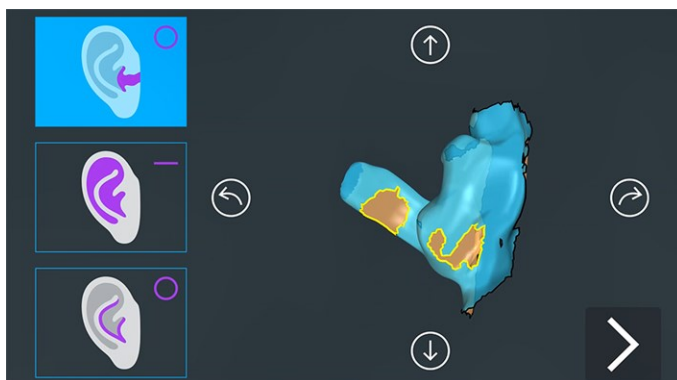**Fig. 24**   Smaller gaps that do not require additional scanning are shown with a black outline.

Fig. 25   Large gaps that need additional scanning are shown with a yellow outline.

Recommended ear canal scanning sequence

It is recommended that you concentrate on scanning the bottom of the ear canal in one pass, and the top of the ear canal in the next pass. Then, observe the 3D image for gaps that need to be filled using additional passes. Pay extra attention to the posterior wall of the ear canal, as it may be a bit tricky to scan this part. Complete the ear canal scan before moving on to scan the pinna.

8.5   Reviewing a scan in progress

During an ongoing scan, **Pause** is the only button that can be selected.

• To review a scan in progress, press the trigger to select **Pause** before removing the scanner from the ear (so as not to have the scanner inadvertently pointed at the eye) and move the scanner away from the ear canal.

The screen will now show the current 3D scan to the right, and the optional next steps to perform to the left.

Evaluating the scan

The 3D model can be rotated in multiple viewing planes to ideally visualize the preliminary scan.

• Use the arrows on the touchscreen of the scanner to rotate the scan for a better view.

Alternatively, you can view the image on the PC screen. Here you can use the mouse in two ways:

• To turn the image stepwise in a specific direction, click repeatedly near the **Arrow** symbol that points in that direction.

• To rotate the image in any direction, press and hold down the left mouse button at the center of the 3D image and drag the mouse in the intended directions.

For an accurate 3D digital impression, gaps indicated with a yellow outline should be rescanned in an attempt to fill them in. Utilize your clinical judgment regarding continuing to scan or moving on to the next step. Smaller gaps outlined in black do not require additional scanning. See Fig. 24 ▶ 29 and Fig. 25 ▶ 29.
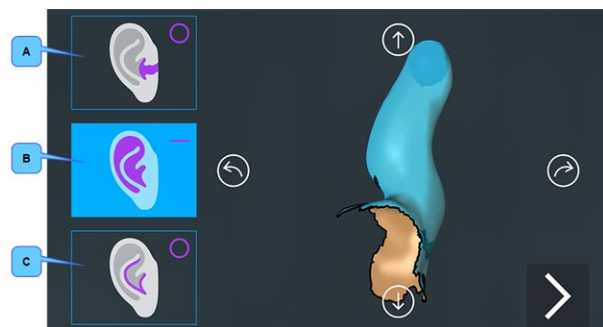
The buttons for scan mode selection shown to the left are:

A. **Canal Ring** mode,
B. **Pinna Line** mode,
C. **Concha Ring** mode.

Fig. 26   The scanner view during **Pause**.
At this point, only the canal of the patient's ear has been scanned.

Resuming scanning after a pause

The scan mode selection buttons are shown in the left part of the display.

The suggested next step has been highlighted (step B in the example above). The highlighted step is the one that will be selected when you press the trigger on the hand-held scanner.

If you want to select one of the other steps in the process, tap the relevant selection on the touchscreen.

• To continue the scanning:

   1. Select the button that shows the portion of the ear that you wish to scan next:
      A. The ear canal - **Canal Ring** mode,
      B. The flat surfaces of the pinna - **Pinna Line** mode, or
      C. The concha cavities - **Concha Ring** mode.

   2. Point the scanner probe at the ear canal and press the trigger to resume scanning.

8.6   Scanning flat surfaces in Pinna Line mode

When the ear canal scan is complete, continue by scanning the concha and other relevant parts of the pinna.

Use the Line laser to scan the flatter surfaces of the pinna and most of the visible surfaces of the ear. During Line scanning, position the probe so that it is pointing at the area to be scanned and is close to (but not touching) the surface of the skin.

• Scan the flat surfaces of the pinna using the **Pinna Line** mode:

1. Select **Pinna Line** mode. See Fig. 26 ▶ 30.

2. Press the trigger to activate the Line laser and begin scanning the pinna, starting with the flat surfaces of the concha.

3. After scanning as much as possible with the Line laser, select **Pause**.

4. Review the scan for accuracy and missing spots to be scanned. See Reviewing a scan in progress ▶ 29.
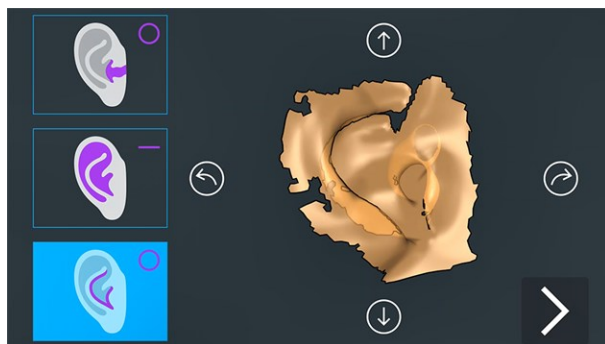

Fig. 27   Example of a scan after scanning in **Pinna Line** mode. The screen suggests that you continue in **Concha Ring** mode, in order to fill in possible missing parts.

8.7   Completing curved surfaces in Concha Ring mode

The next step is to use the Ring laser for scanning the less visible parts of the pinna, such as the curved surfaces inside the concha bowl. During the scanning, position the probe parallel to the area being scanned.

1. Select **Concha Ring** mode. (See Fig. 26 ▶ 30).

2. Press the trigger to activate the Ring laser in **Concha Ring** mode. Use the Ring laser to scan the helix, the lower part of the concha bowl, and other side surfaces of the ear.

3. Pause the scanning and review the scan.

4. If there are still gaps on the 3D image, use the **Pinna Line** mode or the **Concha Ring** mode as required to complete the scan.
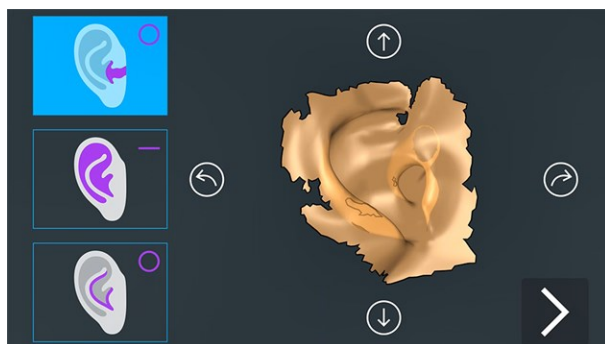

Fig. 28   Example of a finished scan, seen during **Pause**.
        The mode selector in the left side has returned to the starting point.

8.8 Saving the scan

- After reviewing the scan for completeness, start the Save procedure by selecting the **Next** icon.

You now get three options:

- **Return**. Continue scanning the same ear. See Return ▶ 32.
- **Mark Horizontal**. See Mark horizontal ▶ 32.
- **Save**. See Save ▶ 33.

Return

Use this option to cancel the Save operation and continue the scanning session with the same ear.

Mark horizontal

You can mark the horizontal plane on the 3D image. This feature is useful when ordering directional microphones with customized hearing instruments.

1. To mark the horizontal plane for the microphones, move the scanner close to the ear and select **Mark Horizontal**. The Line laser will switch on.
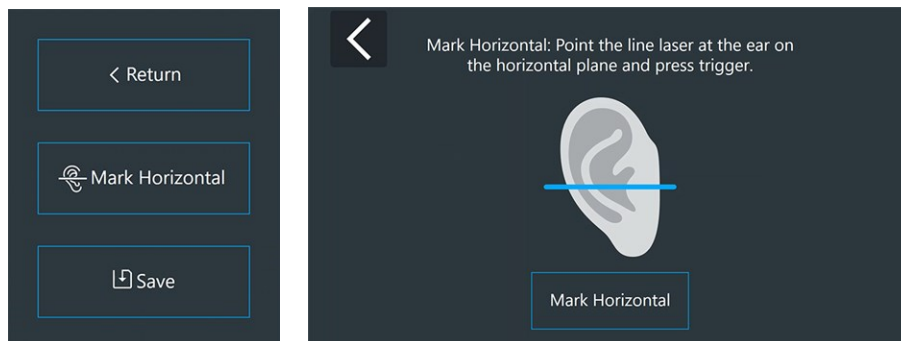

Fig. 29   Select **Mark Horizontal** on the menu to open the **Mark Horizontal** screen.

2. Point the scanner at the ear in such a way that the line marks the horizontal plane. Press the scanner trigger or select **Mark Horizontal** on the touchscreen to set the line. A green check-mark will indicate that the horizontal plane has been marked.
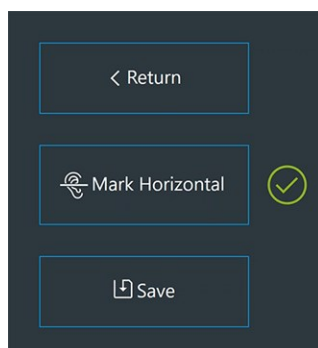
Fig. 30   The line that indicates the horizontal plane has been set.

Save

When you select **Save**, the application will begin the process of filling in any remaining gaps and save the scan. The size of the gaps will affect the accuracy of the final 3D digital impression of the ear.

The finished scan will appear in the frame corresponding to your initial selection of Left or Right ear.

Swapping ears

If you have selected the opposite ear by mistake, you can assign the digital impression to the other ear.

• To swap ear(s), click the **Swap ear** button at the bottom of the screen.

  After a moment the scan(s) will shift to display in the opposite ear frame.
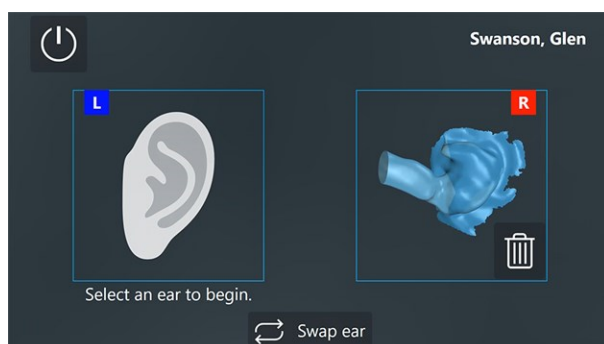
Fig. 31   The screen display after scanning of the right ear.

Accepting a scan

The saved scan is rotating slowly in its frame, allowing you to give it a final examination.

At this point, either continue to scan the other ear, or switch off the scanner:

• To continue to scan the other ear, clean the scanner probe and select that ear on the screen. See Selecting the other ear ► 34.

• To switch off the scanner and return to the patient record, click the **Power** button in the top left corner of the screen.

Deleting a scan

If the scan outcome is not acceptable (the patient moved the jaw, the headset moved, the scan is incomplete or poor quality), it should be deleted and repeated.

- Select the **Trashcan** icon for the ear to be deleted in order to delete the scan and begin again.
  You will be prompted to confirm that you want to delete the scan.

8.9   Selecting the other ear

Preparations

1. If both ears are to be scanned, reposition the headset to fit the opposite ear.
   Again, make sure to center the headset on the ear and check that no hair obstructs the dot pattern on the tracking ring. The tracking ring should be positioned close to, but not touching the head.
   If in doubt, see Placing the headset ▶ 21.

2. Place the patient at an appropriate angle for convenient scanning of this ear. See Positioning the patient ▶ 22.

Selecting the other ear

3. On the screen, select the other ear in order to begin the scanning for this ear.
   See Selecting ear to scan ▶ 24.

Caution • *After scanning the patient's first ear, make sure that you clean the probe tip to prevent cross-infection, and reposition the headset correctly before scanning the other ear.*

Scanning the other ear

4. Set the depth gauge and scan the ear.
   If required, review the steps from Setting the depth gauge ▶ 25.
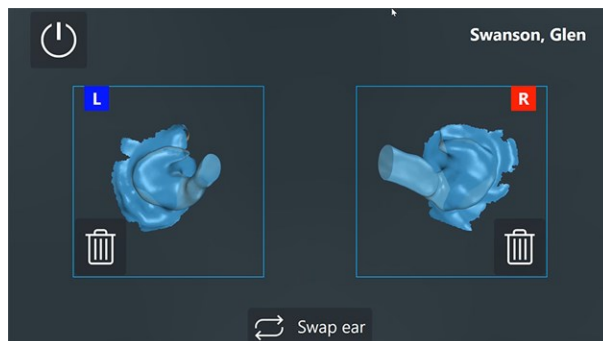

Fig. 32   The final result seen on the scanner touchscreen after scanning both ears.

8.10   Ending the scanning session

- When you have finished scanning a patient and saved the scan, clean the probe tip and place the scanner in its cradle. See Cleaning ▶ 37.

- If you have not already done so, click the **Power** icon in the top left corner to switch off the scanner and return to the patient record.

Scans will be listed in the patient record and will be automatically uploaded to Otocloud.
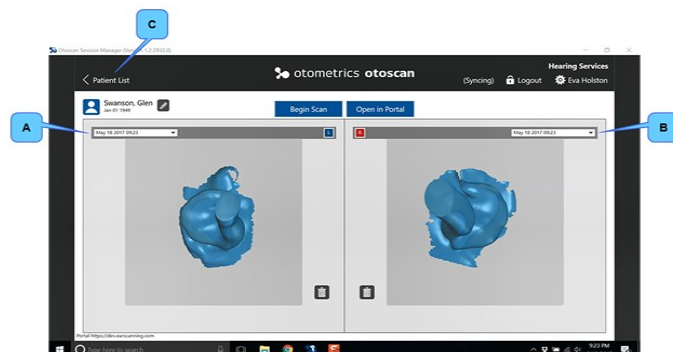

Fig. 33   The Patient record with the latest scans displayed.

To see possible earlier scans for an ear, click the drop-down list for that ear, located at the top of the frames:

A.   List for left ear
B.   List for right ear
C.   To return to the **Patient list**, click **< Patient List**.

Troubleshooting scanning results

If you find faults in the scan at this point, such as large areas that have not been scanned, consider discarding the scan and making a new scan to replace it.

9   Managing patients and scans in Otocloud

You can send the scans to your chosen manufacturer via the online application Otocloud. This section describes how you open Otocloud from Session Manager and close it after use.

It is also possible to open Otocloud directly from the PC desktop.

For further instructions on how to work with patient data in Otocloud, see the Otocloud User Guide.

9.1   Opening Otocloud

When the ear scan(s) for the current patient are completed, you can continue working with the data in Otocloud. Otocloud is a web application that allows hearing healthcare providers to access their scans and send them to hearing instrument and ear mold manufacturers.

In Otocloud you can also view details of previously sent scans.

Procedure

1.   If you have not done so already, open the patient's record in Session Manager, where you can see the scanned images. See Opening a patient record ▶ 17.

2. Click the button **Open in Otocloud** (A). The button is located at the top of the screen.
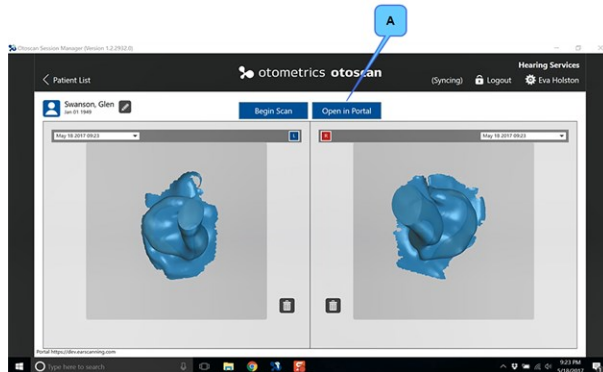

Fig. 34   Open in Otocloud (A)

3. When Otocloud becomes available, continue through the process to send scans or view sent scans for the patient's hearing instruments or , as needed.

Alternative procedure

From the **Patient list** in Session Manager, select **Open in Otocloud**.

4. When Otocloud opens, select the required patient from either the **Patients** or the **Packages** tab.

9.2   Returning from Otocloud to Session Manager after use

Session Manager remains open in the background, while Otocloud is in focus.

This means that you can shift between working in Otocloud and in Session Manager.

*   To switch between Otocloud and Session Manager: press the keyboard keys **Alt** + **Tab**.

*   Alternatively, click the relevant icon, that is, the **Otoscan** icon or the **browser** icon on the task bar at the bottom of your PC screen.

Closing Otocloud after use

1. Click the button **Log Out** at the top of the screen. This will return you to the **Login** screen.

2. To close the **Login** screen, click the **X** icon in the top right corner of the screen. You will now be back at Session Manager on the local PC.

> *Note •* *If you leave Session Manager idle in the background for 20 minutes, the system automatically logs you out. This is done to minimize the risk of unauthorized access to the data.*

If you have been away from Session Manager for more than 20 minutes, you will have to log in again if you want to resume working with Session Manager at that point.

10   Logging out

Closing Session Manager after use

A.   To close Session Manager after use, click the button **Logout** at the top of the screen. This will return you to the login screen.

B.   To close the login screen, click the **X** icon in the top right corner of the screen.

C.   If you want to turn off the PC, click the Windows **Start** button placed to the far left on the Windows task bar at the bottom of the screen, and follow the current Windows procedure to shut down.
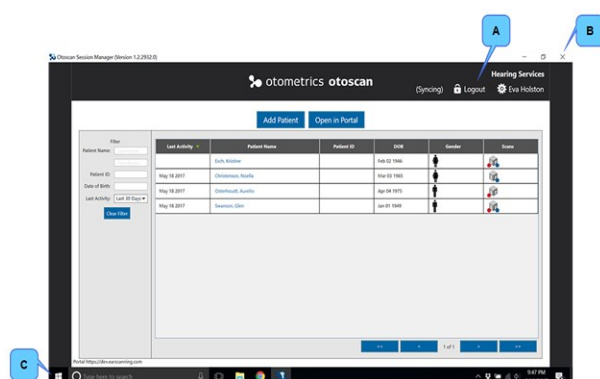
Fig. 35   The **Logout** procedure

11   Cleaning

> **Caution •** *Never use sharp or pointed objects for cleaning!*

11.1   Recommended cleaning agents

There are no specific recommended cleaning agents for this product.

The probe tip and headset are cleaned with a new, soft and slightly damp 70% isopropyl alcohol swab.

All other parts are cleaned with a new, soft and slightly damp cloth with mild cleaning detergent.

See detailed instructions for each of the scanner components and accessories in the sections Cleaning the scanner ► 38, Cleaning the cradle ► 38, and Cleaning the headset ► 38.

11.2 Cleaning the scanner

> *Warning •* *Do not clean any part of the scanner in an ultrasonic bath and do not gas-sterilize or autoclave the scanner.*

> *Warning •* *Keep the unit away from liquids. Do not allow moisture inside the unit. Moisture inside the unit can damage the instrument and it may result in a risk of electrical shock to the user or patient.*

> *Caution •* *To prevent cross-infection or re-infection, clean and disinfect the probe with alcohol wipes between patients and between scans of patient's ears.*

1. Clean the touchscreen, tracking cameras, housing, trigger button, and cable. Use a new, soft and slightly damp cloth with mild cleaning detergent. Once the touchscreen and tracking cameras are dry, wipe them with a dry cloth (such as a microfiber cloth) to remove streaks.
2. Clean and disinfect the probe tip. Use a new, soft and slightly damp 70% isopropyl alcohol swab. Be sure to wipe around all surfaces from base to tip and including the flat surface at the end of the tip.

> *Caution •* *Do not apply pressure to the probe tip.*

11.3 Cleaning the cradle

- Clean the seating for the scanner and outside surfaces of the cradle. Use a new, soft and slightly damp cloth with mild cleaning detergent.

11.4 Cleaning the headset

- Clean the headset. Use a new, soft and slightly damp 70% isopropyl alcohol swab.

> *Note •* *Alcohol wipes should be disposed of according to local regulations.*

12 Service and maintenance

> *Note •* *There are no user-serviceable parts inside the scanner housing.*

> **Warning** • *For the sake of safety and in order not to void the warranty, service and repair of electro-medical equipment should be carried out only by the equipment manufacturer or by service personnel at authorized workshops. In case of any defects, make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.*
> *Always carefully inspect the probe before use and do not use if there are any signs of damage to the probe.*

> **Warning** • *Do not disassemble the scanner housing under any circumstance. Parts inside the scanner must only be checked or serviced by authorized personnel.*

12.1 Maintenance and calibration check

Maintenance

The daily maintenance required for the scanner is correct cleaning after each scan. See Cleaning ▶ 37.

Self-test

Before each scan, the scanner performs a self-test while it is seated in the cradle.

If the scanner does not pass the test, you will see an error message on the screen. Then do as follows:

1. Clean the probe tip. Use a new, soft and slightly damp 70% isopropyl alcohol swab.

2. Place the scanner in the cradle for a re-check. Make sure that it is seated correctly in the cradle.

3. Select **Retry** on the screen to start the re-check.

4. If the error persists, see Error messages during Start-up and Update ▶ 40.

Annual calibration check

• Please contact your supplier to schedule at least one annual calibration check of the scanner.

• We recommend that the calibration should be checked, if the equipment has suffered any potential damage.

• When sending the scanner in for calibration, see the packing instructions in Packing instructions for the scanner ▶ 39.

12.2 Packing instructions for the scanner

When shipping the scanner assembly for service or repair, follow the below guidelines in order to minimize the risk of damage during transportation.

Procedure:

1. Place the scanner so that it is securely seated in its cradle.

2. Fasten the scanner to the cradle with masking tape or painter's tape. Do not use a type of tape that is difficult to remove and which may damage the device.

3. Ship the scanner in the original packing material.

13   Troubleshooting

13.1   Error messages during Start-up and Update

Error message	Cause	Solution
User name and/or Password is not valid.	Either the user name or the password was not correct. User names are case sensitive. This message will also appear if the user name has not yet been used on this PC while it was online.	Make sure that Caps lock is not activated on your keyboard. Try again. If you are logging in for the first time on this PC, be sure the PC is online. If the problem persists:Contact the clinic's Otoscan administrator.
Login failed, service not found. (404)	A network error has occurred.	Contact your supplier for technical support.
Login failed, service error. (500)	A network error has occurred.	Contact your supplier for technical support.
Login failed, unknown.	A network error has occurred.	Contact your supplier for technical support.
You must be online to use the Forgot Password process.	The PC may not be connected to the Internet.	Check your internet connection and try again.
Login failed, user account locked.	Login with incorrect data has been attempted too many times.	Contact the clinic's Otoscan administrator.
Otoscan Update cannot connect to the server. Check your internet connection or firewall.	The PC may not be connected to the Internet.	Check your internet connection or firewall. Try again. Contact your supplier for technical support if the failure persists.

Error message	Cause	Solution
Your user account has no access to any clinic.	The current user has not been set up for any clinics.	Contact your Otoscan administrator.
Error while checking for updates.	An error occurred during the update check.	Contact your supplier for technical support.
Failed to initialize Otoscan Update.	The PC may not be connected to the Internet.	• Check your internet connection and try again. • Contact your supplier for technical support if the failure persists.
Error: Failed to launch Otoscan Update.	An error prevented the Otoscan update from starting up.	Contact your supplier for technical support.
Unexpected failure while installing update.	An error occurred during the update procedure.	Contact your supplier for technical support.
Error downloading file, {0}.	A network error has occurred.	Contact your supplier for technical support.
Error downloading manifest from server.	An error occurred during the upstart procedure.	Contact your supplier for technical support.

13.2   Error messages in Session Manager

Error message	Cause	Solution
Failed to start the scanning software.	An error prevented the scanner from starting up.	Contact your supplier for technical support.
Waiting for the scanning software to shut down.	It takes an unusually long time for the application to close down.	If this process does not complete in a timely fashion, select **Force Close**.
There was an error connecting to Otocloud.	The PC may not be connected to the Internet.	Check your internet connection.
Could not load scan.		Contact your supplier for technical support.

13.3   Error messages in the scanning software

Error message	Cause	Solution
Failed to connect to scanner.	The scanning software could not detect that a scanner is connected to the PC.	• Make sure the scanner cable is connected securely in the USB port and select **Retry**. • Check the task bar to see if the Training software is open in background. If so, close it and select **Retry**.
Failed to connect to scanner. (Second attempt)	The scanning software could not detect that a scanner is connected to the PC.	Contact your supplier for technical support.
Critical Failure!	The scanning software detected a failure that prevents the application from working correctly.	Contact your supplier for technical support.
Self-test failed.	There may be several causes: • The scanner is not placed correctly in the cradle.	• Make sure that the scanner rests evenly on the cradle brackets, with the probe tip pointing directly at the back wall.Select **Retry**.
Self-test failed. (Second attempt)	• The probe or tracking cameras are not clean. • The scanner may be damaged.	• Make sure that the probe and the tracking cameras are clean and free of debris, oils, or residues. See Cleaning ▶ 37. Select **Retry**. • Inspect for any signs of visible damage.Contact your supplier for technical support.

Error message	Cause	Solution
Tracking lost (Icon):	There may be several causes: • The scanner is too far from the ear and tracking ring. • The patient may not be wearing the headset correctly. • The tracking camera view may be blocked by operator fingers, patient hair, etc. • The tracking camera lenses may not be clean. • The angle of the scanner may be too extreme.	• Move or angle the scanner closer to the tracking ring. • Make sure that the patient is wearing the headset as described in the Otoscan User Guide. • Make sure that the view of the two tracking cameras on the front of the scanner is free of any obstruction. • Make sure that the probe and the tracking cameras are clean and free of debris, oils, or residues. See Cleaning ▶ 37. • Avoid extreme angles and make sure the tracking cameras have a clear view of the tracking ring at all times.

14 Standards and warnings

14.1 Definition of symbols

![WEEE symbol]	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).
	All electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste.
	You can return your device and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.
![Consult manual symbol]	Consult user manual for warnings and cautions.
CE xxxx	Complies with Medical Devices Directive 93/42/EEC and RoHS Directive (2011/65/EC).
![Type BF symbol]	Complies with Type BF requirements of IEC60601-1.
![Class II symbol]	Complies with Class II requirements of the safety standard IEC 60601-1.
![Manufacturer symbol]	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. It also states the date of manufacture.
![Tracking lost symbol]	Used on software display to indicate that tracking is currently lost. See the manual for further reference.
![Warning symbol]	Used in error message dialogs if software program fails. See the detailed information in the dialog box.
![Laser caution symbol]	CAUTION: Laser radiation. Do not stare into beam. Class 2 laser product. Complies with class 2 requirements of the IEC 60825-1:2014 standard.

14.1.1 Warning notes

This manual contains information and warnings, which must be followed to ensure the safe performance of the devices and software covered by this manual. Local government rules and regulations, if applicable, should also be followed at all times.

1. This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.

2. Intended users: Audiologists, hearing instrument dispensers, ENT doctors and other trained personnel. Please note that local regulations may define users for video otoscopy differently. Local regulations must be complied with at all times.

3. Do not use the device for uses other than those described in the section Intended use. For example, do not use the device for examination of nasal cavities, eyes or larynx.

4. Do not stare into the light beam, or point the light beam in the direction of other people's eyes. It can damage the eyes.

5. To prevent cross-infection or re-infection, clean and disinfect the probe with alcohol wipes between patients and between scans of patient's ears.

6. Be careful when you insert the probe into the ear of the patient - there is a risk of damaging the wall of the ear canal and/or the tympanic membrane. Do not apply excessive force with the probe to the outer ear of the patient.

7. The device display can get hot during heavy use. Consequently, do not touch the display surface for longer than 1 minute.

8. Accidental damage and incorrect handling can have a negative effect on the functionality of the device. Contact your supplier for advice.

9. Do not use the device if there are any signs of damage to the probe.Contact your supplier.

10. If the device has been dropped, return the device to your supplier for safety inspection.

11. For the sake of safety and in order not to void the warranty, service and repair of electro-medical equipment should be carried out only by the equipment manufacturer or by service personnel at authorized workshops. In case of any defects, make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.

12. It is recommended to install the unit in an environment that minimizes the amount of static electricity. For example, anti-static carpeting is recommended.

13. Do not store or operate the device at temperatures and humidity exceeding those stated in the Technical Specifications, Storage and handling.

14. Keep the unit away from liquids. Do not allow moisture inside the unit. Moisture inside the unit can damage the instrument and it may result in a risk of electrical shock to the user or patient.

15. Do not use the instrument in the presence of flammable agents (gases) or in an oxygen-rich environment.

16. No parts may be eaten, burnt, or in any way used for purposes other than the applications defined in the Intended Use section of this manual.

17. For safety reasons and due to effects on EMC, accessories connected to the equipment's outlet fittings must be identical to the type supplied with the system.

18. We recommend that the device should not be stacked with other equipment or placed in a poorly ventilated space as this may affect the performance of the device. If it is stacked or placed adjacent to other equipment, make sure that the operation of the device is not affected.

19. Unwanted noise may occur if the device is exposed to a strong radio field. Such noise may interfere with the performance of the device. Many types of electrical devices, e.g. mobile telephones, may generate radio fields. We recommend that the use of such devices in the vicinity of Otoscan be restricted.
    Likewise, we recommend that the instrument is not used in the vicinity of devices sensitive to electromagnetic fields.

20. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

21. RF emissions from Otoscan are very low and are not likely to cause any interference in nearby electronic equipment. However, local devices placed in close vicinity of Otoscan may experience a negative effect or loss of functionality.

22. When assembling an electro-medical system, the person carrying out the assembly must take into account that other connected equipment which does not comply with the same safety requirements as this product (e.g. PC and/or printer) may lead to a reduction in the overall safety level of the system. The equipment must comply with UL/IEC 60950.

23. When selecting accessories connected to the device, the following points must be considered:

    • Use of connected equipment in a patient environment

    • Proof that connected equipment has been tested in accordance with IEC60601-1 and/or IEC60601-1-1 and UL60601-1 and CAN/CSA-C22.2 NO 601.1-90.

24. To comply with EN 60601-1-1 computer and printer must be placed out of reach of the client, i.e. not closer than approx. 1.5 meters/5 ft.

25. The device can be disposed of as normal electronic waste, according to local regulations.

15   Technical specifications

System requirements

- Internet access. Recommended download speed: 2 Mbit

- Included dedicated laptop Lenovo T470p with the following specifications:

Operating system	Windows 10 Professional
Graphics processor	Discrete graphics card with min. 2 GB memory
Processor	Min. Quad Core, 8 logic cores (hardware threads)
Total memory	Min. 8 GB
Display	Min. 13" Max. 15" full HD (1920x1080) Non-Touch
Wi-Fi adapters	Dual Band Wireless- b/g/n/ac
Hard drive	156 GB Solid State Drive

Type identification

The Otoscan scanner is type 1093 from Otometrics A/S.

Scanning system

Scanning modes	- Canal Ring, using 360° blue LED light - Pinna Line, using blue line laser - Concha Ring, using 360° blue LED light
Probe distal diameter	3.20 mm (0.13 inches)
Probe length	30 mm (1.18 inches)
Accuracy	Min 80% of the surface area is within a three dimensional rendering tolerance of ±200 µm, when scanning the surface of a CMM verified mechanical artifact with curvatures similar to an ear.

Device display

Size	4 inches
Type	Color TFT with LED backlight
Resolution	480 x 800 dots
User input	Capacitive touch

Scanner power supply

Input Power	5 V USB 3.0, Max. 900 mA
USB Plug	USB 3.0, Type A

Storage and handling

Storage temperature	-20°C to +60°C (-4°F to +140°F)
Relative humidity	<90%, non-condensing
Air pressure	500 hPa to 1060 hPa

Operating environment

Temperature	+10°C to +30°C (+50°F to +86°F)
Relative humidity	30% to 75%, non-condensing
Air pressure	600 hPa to 1060 hPa

Standards

Patient Safety	IEC 60601-1, Class II, Type BF.
	Applied parts are Scanner Probe and Housing.
Laser safety	Complies with class 2 requirements of the IEC 60825-1:2014 standard.
EMC	IEC 60601-1-2

15.1 Accessories

Standard accessories and optional accessories may vary from country to country - please consult your local distributor.

Accessory name	Part number
1093, Training Kit complete	8-61-20000
1093, Desktop Cradle Accessory	8-61-20100
1093, HS3 Headset Accessory	8-61-22000
1093, Laptop PC with pre-installed SW	8-35-49800-XX
1093, Alcohol swaps, 70% isopropyl	8-62-48100
User Guide	7-50-14200-XX

15.2 Notes on EMC (Electromagnetic Compatibility)

- Otoscan is part of a medical electrical system and is thus subject to special safety precautions. For this reason, the installation and operating instructions provided in this document should be followed closely.
- Portable and mobile high-frequency communication devices, such as mobile phones, may interfere with the functioning of Otoscan.

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
Otoscan is intended for use in the electromagnetic environment specified below. The user of Otoscan should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	Otoscan uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Otoscan is suitable for use in all environments, including domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
Otoscan is intended for use in the electromagnetic environment specified below. The user of Otoscan should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 16 kV air	+/- 8 kV contact +/- 16 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting			
Otoscan is intended for use in the electromagnetic environment specified below. The user of Otoscan should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	150 kHz to 80 MHz outside ISM bands 10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of Otoscan, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 80 MHz to 2.7 GHz, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with this symbol:

Note 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Otoscan is used exceeds the applicable RF compliance level above, the Otoscan should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating Otoscan.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and Otoscan

The Otoscan is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Otoscan can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Otoscanas recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

16 Other references

The latest version of the present User Guide is available from the desktop of your Otoscan PC.

For information about the online application Otocloud, see the Otocloud User Guide.

17 Manufacturer

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Denmark
☎ +45 45 75 55 55
🖷 +45 45 75 55 59
www.otometrics.com

Responsibility of the manufacturer

The manufacturer is to be considered responsible for effects on safety, reliability, and performance of the equipment only if:

- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by the equipment manufacturer or personnel authorized by the manufacturer.

- The electrical installation to which the equipment is connected complies with EN/IEC requirements.

- The equipment is used in accordance with the instructions for use.

The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties.