HearSIM™

Instructions for Use - US

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1 Introduction

1.1 About this manual

This manual is valid for the HearSIM™ revision 3. 3. The product is manufactured by:

OtoAccess A/S
Audiometer Allé 1
5500 Middelfart
Denmark

This manual describes the functions of HearSIM™. It is recommended that users of the software read the manual thoroughly before using it.

HearSIM™ 3. 0 and above requires pre-installation of the OtoAccess® Database software (version 2. 0 or higher) which supports HearSIM™. Without the OtoAccess® Database installed, the HearSIM™ application is not functional. The text in this manual will generally refer to the software as HearSIM™ but the reader should understand that the OtoAccess® database is a required supporting application for HearSIM™ to function.

The OtoAccess® Database has its own user manual. This HearSIM™ manual may refer you to the OtoAccess® manual for descriptions of certain functions and settings that are available only within the OtoAccess® Database application. This HearSIM™ manual will focus only on the functions available in HearSIM™.

Menus, icons and functions that are selectable are shown in **bold** font.

1.1.1 Supported models

HearSIM™ version 3. 0 and above support two device types in the product line. In most cases HearSIM™ functions described in the manual are relevant for both devices. However there are some functions that are specific to one of these device types and are not supported for the other device. In this case the manual will display a graphic representing the supported device type as seen below:

	This graphic will be used to indicate that a HearSIM™ function is only available for this model which is a touchscreen device with a Home button that supports both AABR and OAE technology.
	This graphic will be used to indicate that a HearSIM™ function is only available for this device type which is an OAE only instrument (screener model) with a small LCD screen and several function buttons used to maneuver through the menus.

1.2 General

Thank you for purchasing a system supported by the HearSIM™ screening information manager software. Your device is fully functional for performing hearing screening without the use of HearSIM™.

HearSIM™ with the OtoAccess® Database is an accessory software tool that allows you to:

- Store, view and manage patient information
- Store, view and manage test data transferred from a supported device
- Transfer names of patients requiring testing to a supported device
- Print test results on a standard PC-compatible printer
- Export patient and test data (HiTrack, OZ eSP™, XML and CSV formats supported)
- Customize the device settings to your preferences
- Manage device users
- Manage device custom lists (e. g. Screening facility names, risk factors, etc)
- Manage user accounts
- Back up and restore the patient database and custom lists
- Import patient lists from other 3rd party databases
- Export & Import HearSIM settings to share among multiple PCs
- Set user preferences for display of patient fields and mandatory status of fields
- Audit changes made to patient demographics and test details

1.3 Intended use

The software is intended to be used as an accessory for compatible hearing screening devices to customize device settings and manage screening data. Contact your local representative for a list of HearSIM-compatible devices.

2 HearSIM™ installation

2.1 Pre-installation notes

2.1.1 PC requirements

- OtoAccess® version 2. 0 or higher installed
- . NET framework 4. 6. 2

Refer to the OtoAccess® Database Instruction for Use for detailed information about installation of that software and the minimum PC hardware requirements.

2.2 HearSIM™ installation

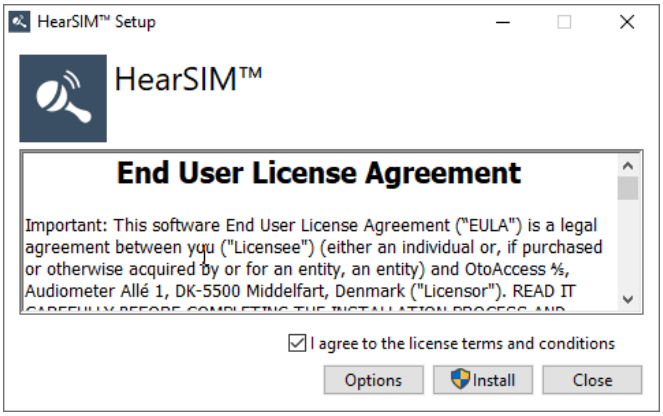
NOTE: Make sure that the device is not connected to your computer while installing the software.

Close all open or running programs.

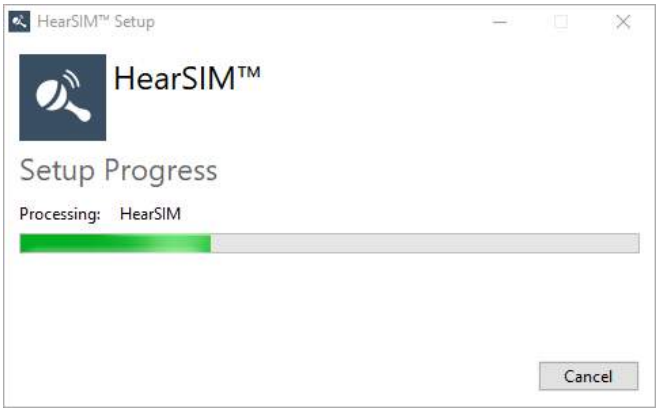
HearSIM™ is provided on a USB drive for installation. The software must be installed by a Windows Administrator.

Insert the USB drive in the PC. Locate and run the “HearSIM Setup. exe” file.

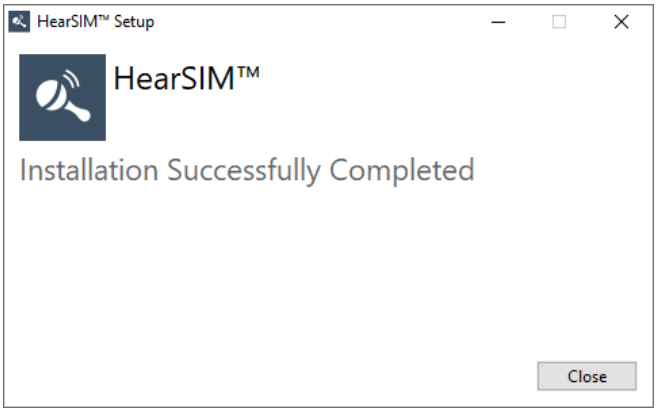
Agree to the license terms and **Install**



Setup in progress

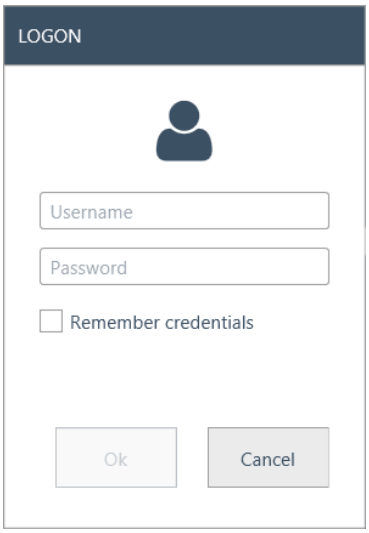


Installation complete. **Close.**



2.3 HearSIM™ launch and logon

Each time you launch HearSIM™ you will be required to logon based on your user account established in the OtoAccess® Database Adminstration tool. Refer to the OtoAccess® Instructions for Use in order to setup and manage user accounts.



Defaults are: Username = admin; Password = password.

It is highly recommended that the user name and password for the default user be changed as soon as possible within the OtoAccess® Database Administration program. While this user cannot be deleted, the user name and password can be changed. Refer to the OtoAccess Instructions for Use to setup users.

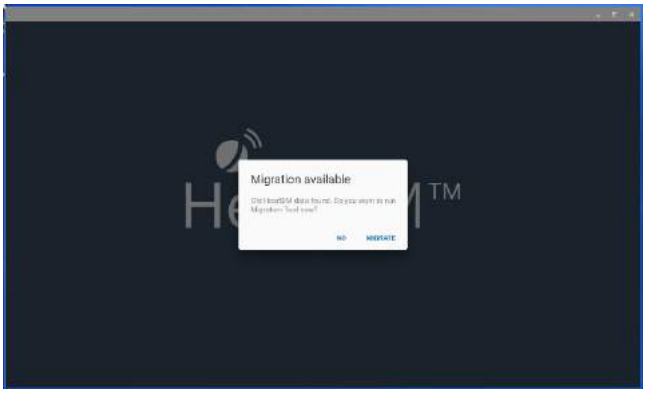
2.4 Data migration upon first launch

If your PC had a previous version of HearSIM™ installed (version 2. 1 or earlier), then the first time you launch HearSIM 3. 2 you will be queried about migration of the existing HearSIM™ database to make it compatible with OtoAccess®.

Migration available query

Choose **MIGRATE** if you wish to convert your existing HearSIM™ database into a format compatible with OtoAccess®.

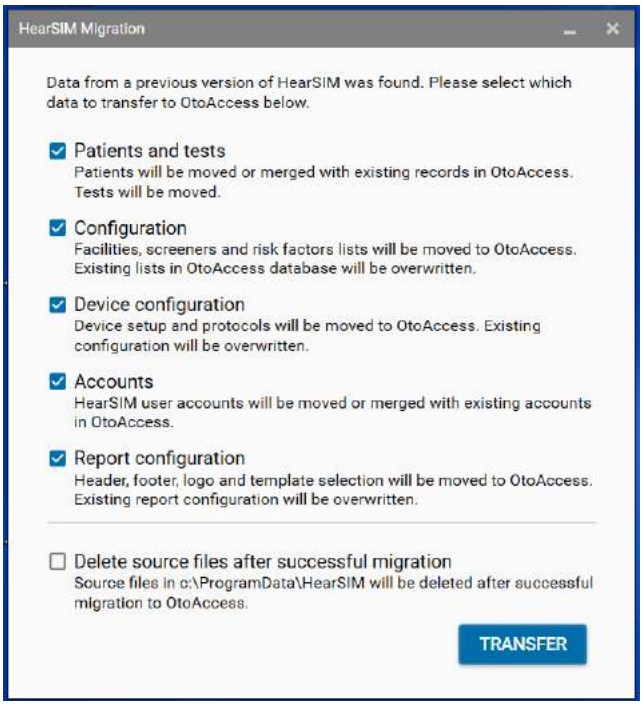
Choose **NO** if you do not want to convert your existing database.



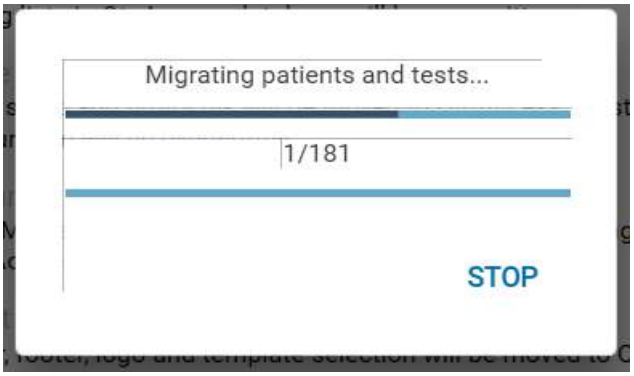
Choose your preferences for which data in HearSIM™ will be converted and transferred into OtoAccess® by checking/unchecking the appropriate checkboxes.

Choose your preference regarding deleting the source files from the original HearSIM™ folder after migration by checking/unchecking the “Delete source files after successful migration” checkbox.

Select **Transfer** when the checkboxes are set according to your preferences.



Migration in progress



Migration Success

Choose **EXIT**

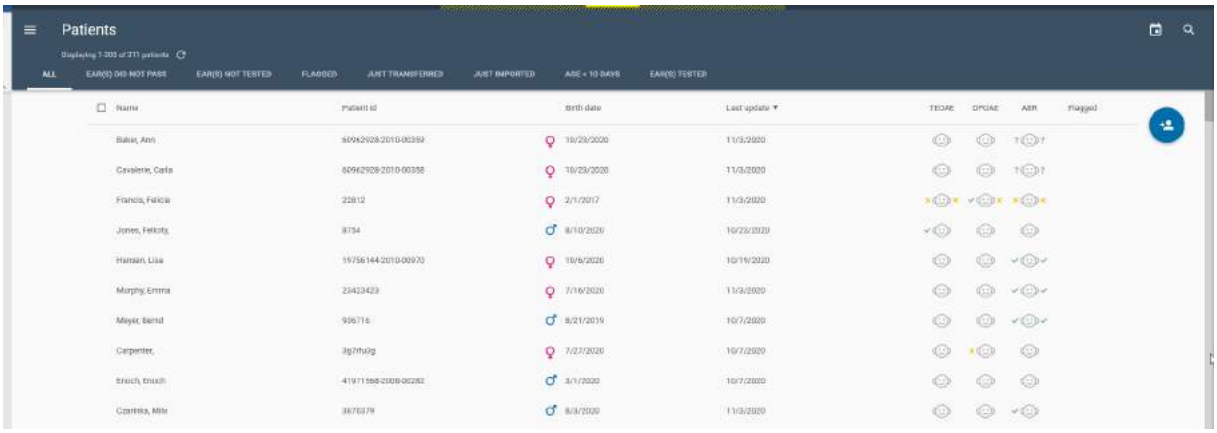
2.5 Device driver installation

The device driver will be automatically installed the first time that a compatible device is connected after Otoaccess® and HearSIM™ installation and HearSIM™ is launched.

3 Patient & test management

3.1 Patient lists

Upon launch of the HearSIM™ software the Patient list view is displayed.



3.1.1 Displayed patients

To save time populating the screen with data, 100 of the most recent patients will be displayed by default. This is indicated by the information seen in the upper left corner of the patient list as outlined below.

As you scroll down to the bottom of the list, more patients will be added to the display and the information about number of displayed patients will update automatically.

3.1.2 List format

Each row in the list represents a patient. Column headers describe the data in the columns.

- Name – last, first
- Patient ID
- Sex (symbol)
- Birth date
- Last update
- Test summary – TEOAE / DPOAE / ABR
- Flagged status

3.1.2.1 Sex symbols

♂ Male ♀ Female

Absence of a symbol indicates that gender is unspecified.

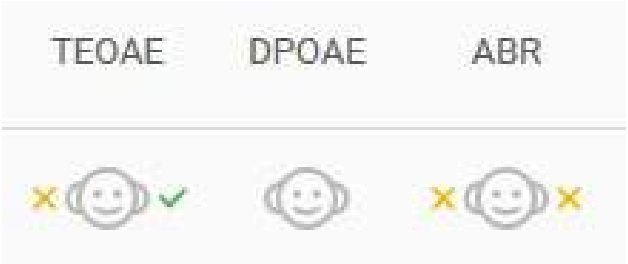
3.1.2.2 Last update date

The Last Update column in the Patient List displays the date on which the patient's record was most recently modified. For a patient newly added in HearSIM™, the last update date will be the creation date. Otherwise the last update date will reflect whichever occurred most recently:

- Edit date on which any of the patient fields were added or edited; or
- Data transfer date on which data (patient or test information) was last transferred from the device to HearSIM™

3.1.2.3 Test summary

Three columns in the patient list provide summary information regarding the last test performed of each test type for the patient. The symbols and position represent:



Pass

Refer

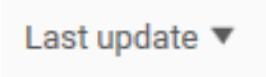
Incomplete

Right ear result Left ear result

3.1.3 Sorting lists

Patient lists can be sorted by Name, Patient ID, Birth date or Last update by selecting the different column headers. The default sort order is based on the Last update date.

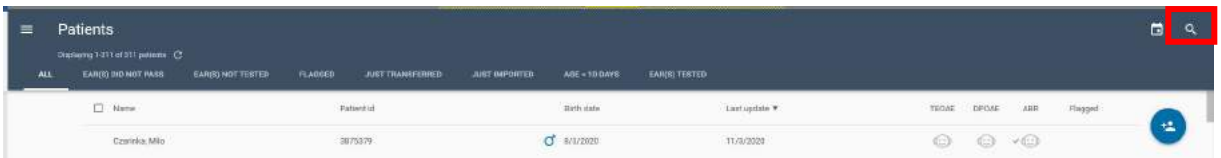
An arrow symbol appears next to the active sort order column.



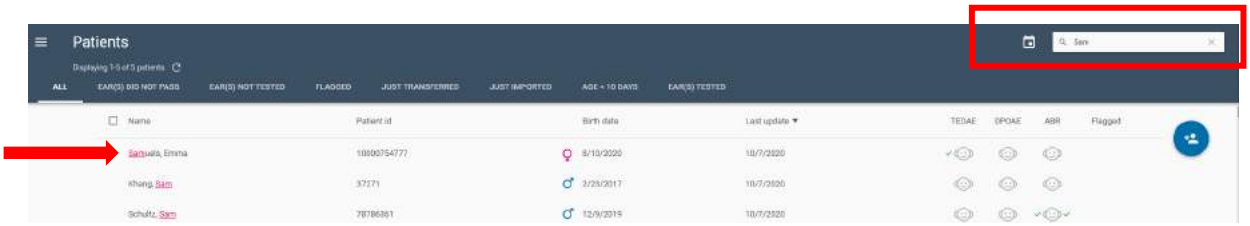
Clicking once on the column header activates the sorting of the list by the selected criteria. Clicking again changes the sort order from first to last and reverse.

3.1.4 Search for a patient

The **Search** icon in the upper right corner opens a Search field.



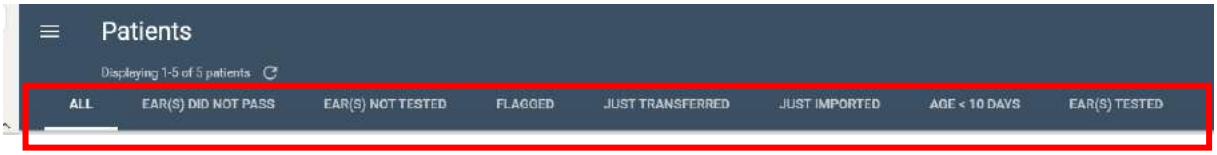
Searching can be performed based on Patient ID, Last name or First name. As you type in characters in the Search field, the patient list will be shortened to reflect only patients who match the search characters. The matching characters in the patient record are displayed in red font as seen below.



Clear the Search field by clicking on the **X** on the right side of the field to return to the full patient list.

3.2 Filtered lists

The default patient list upon launching HearSIM™ displays 100 of the most recently updated patients in the full (**ALL**) database.



Pre-defined options are available that filter the patient database to display only a subset of patients who meet the filter criteria. The filtered lists that can be selected are:

- **All (default)**
- **Ear(s) Did Not Pass**
- **Ear(s) Not Tested**
- **Flagged**
- **Just Transferred**
- **Just Imported**
- **Age < 10 days**
- **Ear(s) Tested**

3.2.1 All

Select this choice to return to the full patient list view from one of the filtered lists.

The list of All patients is impacted by use of the **Search** function as well as he modified date range filter . When either of these functions is in use, the full patient list is shortened to match your search or filter criteria.

To revert back to the full list of All patients, close these tools.

3.2.2 Ear(s) did not pass

Patients displayed in this list meet these criteria:

- Have at least one test record saved
- The last test performed for one or both ears was not a Pass for any test type

These are patients who are likely to need a rescreen or follow-up.

NOTE: This is not intended to be a comprehensive list of all patients that may need follow-up based on your screening program's protocol. It is merely one tool you can use to identify patients who did not have a Pass test result in each ear for at least one test type the last time they were screened.

3.2.3 Ear(s) not tested

Patients displayed in this list meet this criterion:

- Have no test records for one or both ears in at least one measurement type (TE, DP, ABR)

These are patients in the data manager who need to be screened for the first time for at least one ear.

3.2.4 Flagged

Patients displayed in this list meet this criterion:

- Have been flagged by the user.

3.2.5 Just transferred

Patients displayed in this list meet this criterion:

- Were transferred from the device the last time a device was connected and an import of data was performed.

The names in the Just Transferred list will be overwritten when the next import of data from a device is performed.

The names in the Just Transferred list will be cleared when the application is closed.

3.2.6 Just Imported

Select this choice to display only a list of the patients that were imported through the HearSIM™ Import patients function which takes a file exported from a 3rd party database and places the patient information into the HearSIM™ & OtoAccess® database. This list remains until a new file is imported when the list will be overwritten with the new patients or until the HearSIM application is closed when the list will be cleared.

3.2.7 Age < 10 days

Patients displayed in this list meet this criterion:

- According to the birth date entered, the baby is less than 10 days old

This filtered list allows you to view a subset of babies most likely to have been seen for screening recently.

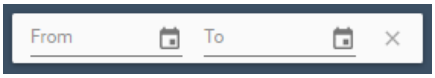
3.2.8 Ear(s) tested

Patients displayed in this list meet this criterion:

- Have at least 1 test saved in the database that were transferred via the HearSIM application.

3.2.9 Modified date range filter

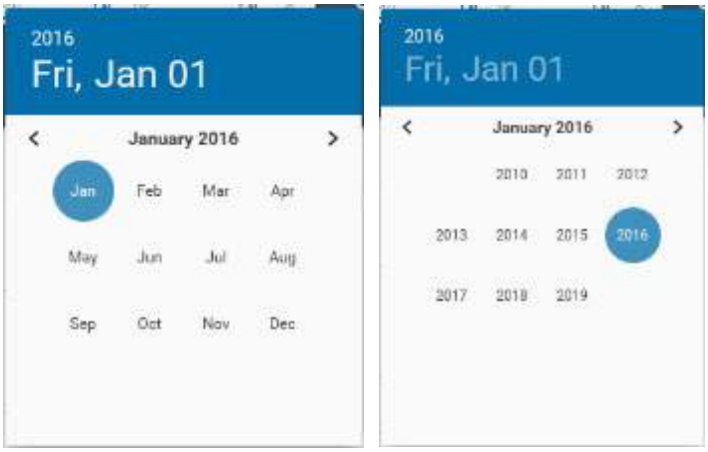
The **Calendar** icon in the upper right corner opens controls to set a last update date range filter. As you enter dates into the **From** and **To** fields the patient list will shorten to include only patients whose record was created or last modified within the specified range.



Set the **From** and **To** dates by typing in a date in each field or by selecting a date on the pop-up calendars that can be opened by clicking on the calendar controls inside the field. Today's date is circled for your reference.

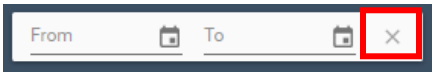
Controls (**<** and **>**) within the calendar page allow you to change the month.

Clicking in the top area of the calendar page changes the page view to allow selection of the month. Clicking again changes to a view of years.



Close the calendar by selecting a date or by clicking outside of the calendar.

Clicking the **X** at the right side of the field, closes the field and cancels the filtering, returning the full list of patients.



3.3 Selecting patients

Patients in the list can be selected in order to include this patient's record as you perform actions such as:

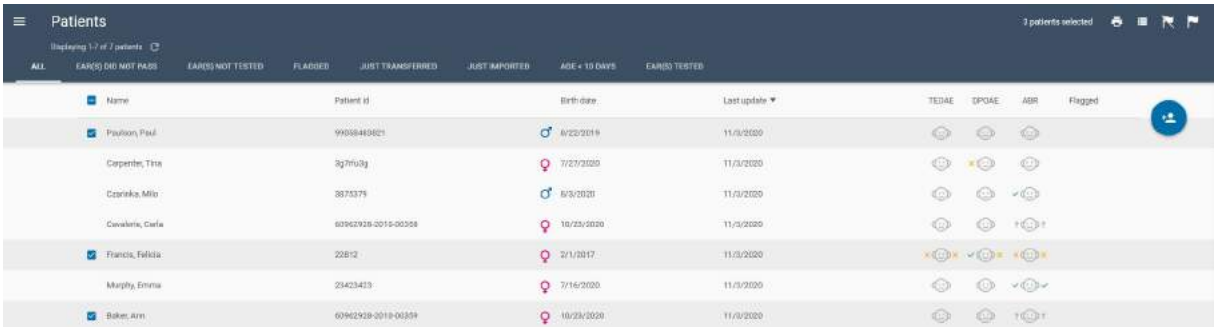
- Printing a list of patients
- Printing test reports for the selected patients
- Flagging a group of patients
- Transferring the patient's information to the hearing screening device

3.3.1 Selecting individuals

The **Select** box appears on the left side of the patient record as you hover the mouse over the patient's row.

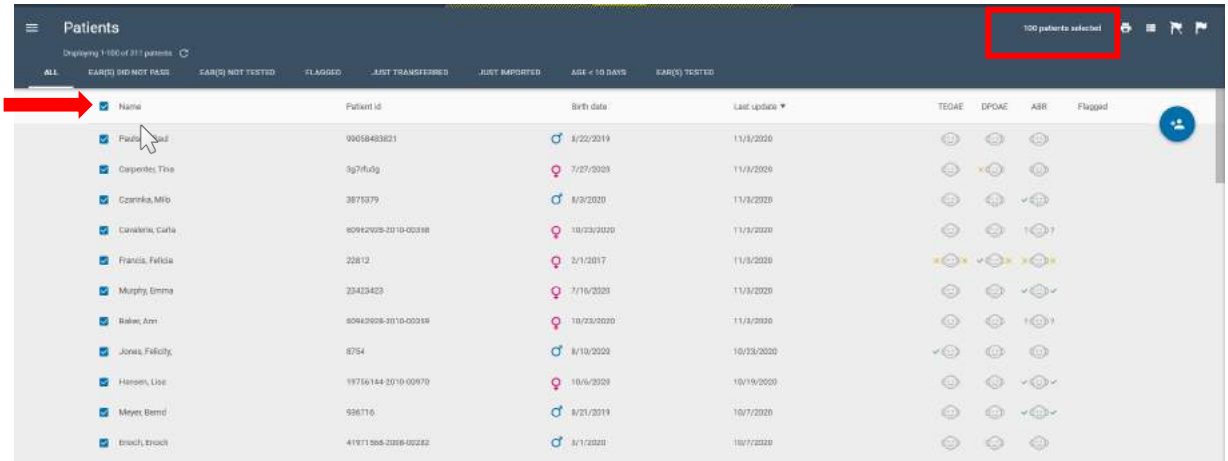
Clicking with the mouse in the box **Selects** the patient causing the selection box to remain visible when you move your mouse off of the patient's row.

Multiple patients can be selected by clicking the **Select** box in each patient's row.



3.3.2 Selecting all (displayed patients)

All patients displayed in the list can be selected by clicking with the mouse in the **Select All** box in the column header.



By default only 100 patients are displayed in the list at a time unless you have specifically chosen to display more patients by scrolling to the bottom of the patient list and repeating this action until all patients are displayed. Therefore you will note that when all displayed patients have been selected, information is shown in the top of the screen indicating the number of patients that are selected for the action that you will perform.

3.3.3 Deselect all (displayed patients)

All selected patients displayed in the list can be deselected by clicking again on the **Select All** box in the column header.

Selected patients remain selected until

- You deselect an individual using the **Deselect** control in the patient's row

OR

- You deselect them all using the **Deselect all** control
- You change the view to a different filtered list
- You **Exit** the application

Performing any of these 3 functions clears the selection boxes for all displayed patients and also returns the patient list to the default of 100 displayed patients.

3.4 Printing a patient list

After you have selected the patients you wish to print out in a list, select the Print List icon in the upper right corner. As an example, this might be a list of patients that you need to rescreen today or new patients that are ready for screening.

3.4.1 Print preview

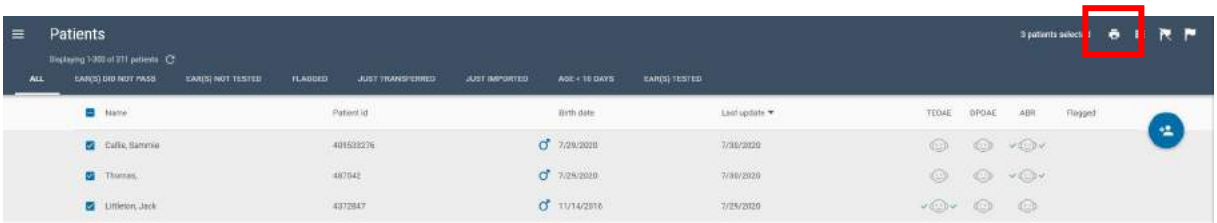
A print preview displays the following information as shown in the figure below.

Controls allow you to:

- Select the desired printer
- Set the page size
- Set the orientation
- Select the color mode
- Print
- Cancel

3.5 Printing patient test reports

After you have selected the patients for whom you wish to print a test report, select the Quick Print Report icon in the upper right corner.



A Quick print test report will automatically include the most recent test result for each ear and for each test method.

For each patient you have selected a separate report will be created and displayed in a print preview.

To choose and print specific tests for a patient see section 4. 14.

A Quick print report for a single patient can also be performed by selecting the Quick Print Report icon that appears on the far right when you hover the mouse over a specific patient's row.

3.5.1 Test report print preview

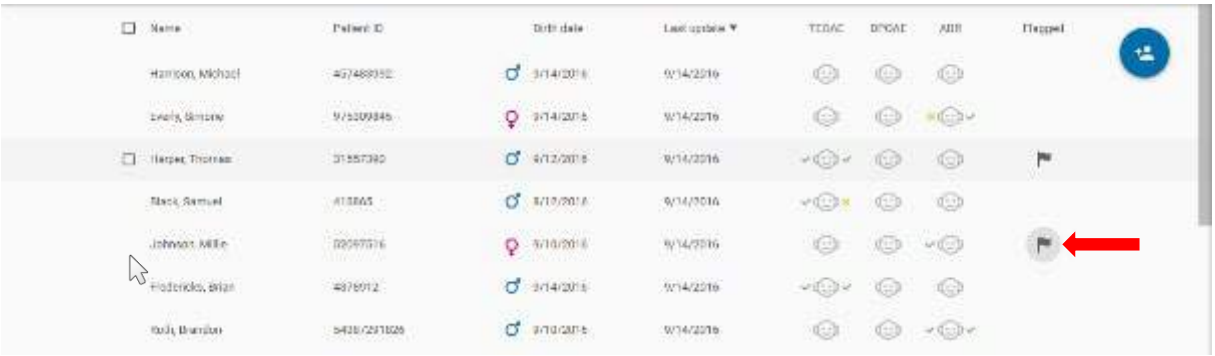
Set the desired printer settings. Select Print to proceed with printing the reports. The report header and logo file must be pre-defined in the Administration/Print section of HearSIM™.

3.6 Flagging patients

Patients in the list can be flagged as a reminder that some action is needed for this patient or to create a list of patients that need attention. The flag status remains persistent for the patient records when you move between filtered lists and even when the application is closed and relaunched.

3.6.1 Flagging individual patients

The **Flag** control appears on the right side of the patient record as you hover the mouse over the patient's row.



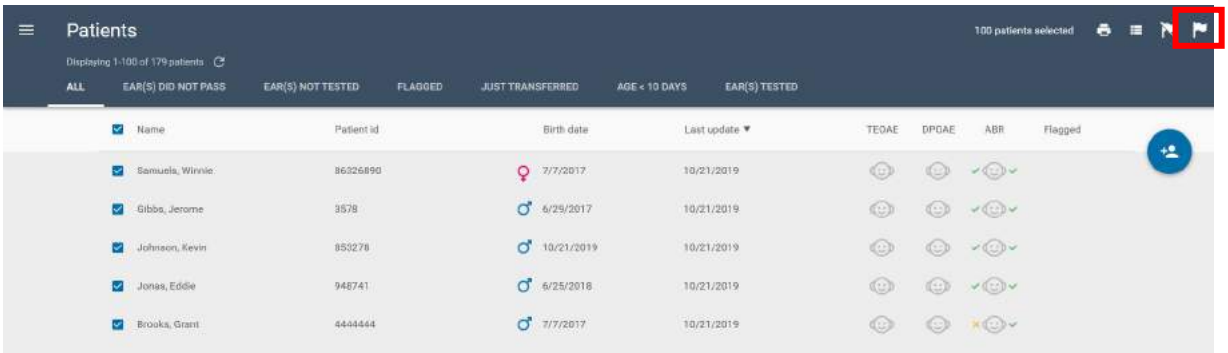
Clicking the mouse on the **Flag** causes the flag to remain visible when you move your mouse off of the patient's row. It appears in a grey circle.

Multiple patients (can be flagged by clicking the **Flag** in each patient's row.

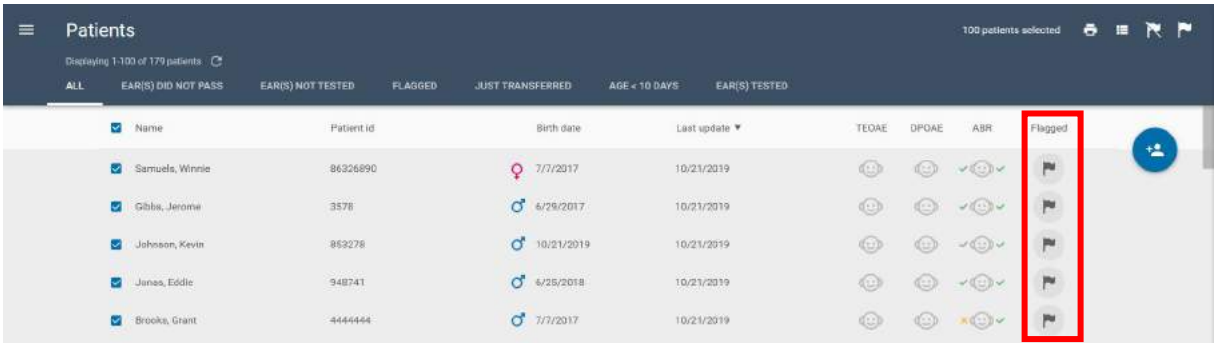
3.6.2 Flagging many or all displayed patients in a list

All patients displayed in the list can be flagged by:

- Clicking the mouse in the **Select All** box in the column header so that all patients displayed in the list are selected
- Selecting the **Flag** icon in the upper right corner of the screen



All selected patients are then flagged as seen below.



3.6.3 Unflagging selected patients

Flagged patients in the list can be unflagged by selecting them and then selecting the **Unflag** icon

3.6.4 Flagged patient filtered list

Flagged patients can be reviewed by selecting the **Flagged** filtered list.

3.7 Transferring patients to a device

To transfer patients to the device you first need to connect the device to the PC using the USB interface cable supplied with your device.

When the device is detected by the HearSIM™ software, a device graphic will appear in the bottom left corner of the PC screen indicating the status of the device.

The device screen will display “PC Controlled” or “Ready” when it is detected by HearSIM™.

NOTE: The device will not be detected if it is displaying any stage of a test from the patient preparation screen through the test “Done!” screen. Return to the Home screen if necessary.

NOTE: The device will not be detected when certain screens are displayed. Turn the device OFF and back ON if the “Ready” screen does not display immediately upon connection to HearSIM™.

3.7.1 Device status and transfer controls

The symbol displayed inside of the device graphic provides information about the device database and readiness for transfer of data. If you hover the mouse over the graphic, tooltips will also describe the status.

Device connected; patient and test data present in the device

Click on the device graphic to begin the import of device data to HearSIM™.

Note: Before other functions such as transferring patients to the device can be performed, test data on the device data must be transferred to HearSIM™ at which time the data is automatically deleted from the device.

Device connected; no data detected

The device is ready to accept patients but no patients are selected.

Device connected; ready to transfer selected patients to device

Click on the device graphic to begin the transfer of selected patients to the device.

Device connected; ready to transfer new device settings

Device connected; transfer of device settings not supported

Device connected; unable to communicate

See Troubleshooting section.

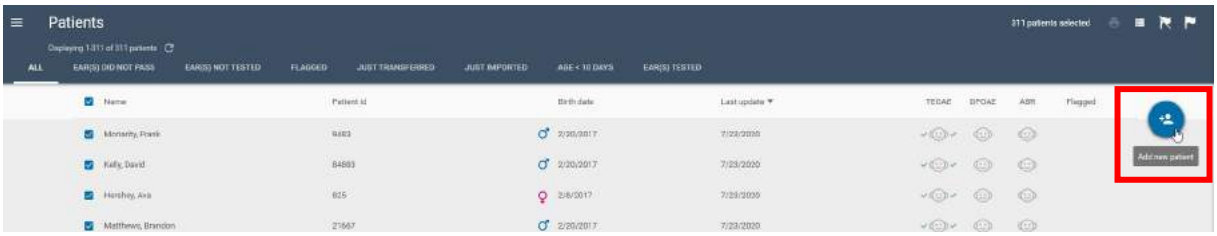
3.7.2 Patient transfer

Once you have selected the graphic to initiate the transfer of selected patients to the device a pop up screen will appear showing you the number of patients that are selected.

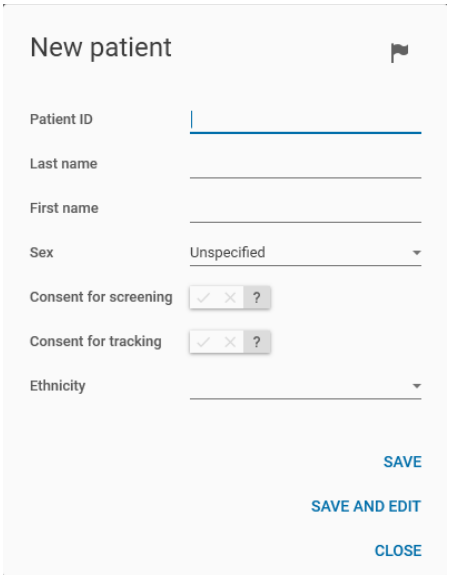
Select **Transfer** to proceed with the process. The screen will display progress and inform you when the process is complete.

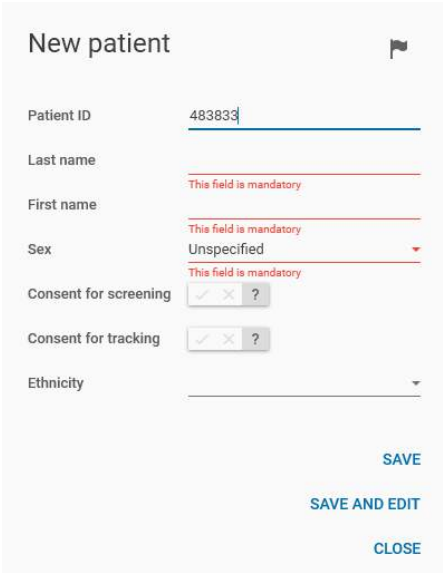
3.8 Adding new patients

New patients can be added to the database by selecting the **Add New Patient** icon. .



The New Patient screen will appear in which you can enter the basic patient demographics. Mandatory fields can be customized in the **Administration/Patient Details** page. Attempting to save the new patient when mandatory fields are not completed will not be allowed.



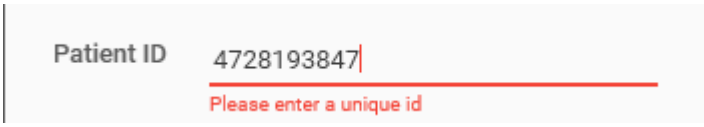


3.8.1 Patient ID

The Patient ID field is required for saving a new patient into the data manager. The value entered into this field must be unique in the database.

3.8.1.1 Patient ID conflict

An attempt to enter in a duplicate Patient ID will not be allowed. Notification of an ID conflict will be displayed below the ID field when you have entered a value that matches an ID already saved in the data manager. This means that a patient with this ID is already saved. You can find it by searching for this ID using the Search field in the Patient list.



You must enter a unique ID to save a new patient.

3.8.2 Last name & First name

The name fields allow entry of the patient's last and first names. These are optional fields.

3.8.3 Birth date

The birth date field defaults to display the today's date.

The patient's birth date can be typed into the field or entered using the **Calendar** control.

3.8.4 Biological sex

The patient's sex can be entered using the drop down control which opens a list including, Male, Female and Unspecified (default).

3.8.5 Consent for Screening

For programs that require tracking of parent consent for screening this check can be selected for Yes or the X can be selected if consent is not granted.

3.8.6 Consent for Tracking

For programs that require tracking of parent consent for sending data to a tracking center this check can be selected for Yes or the X can be selected if consent is not granted.

3.8.7 Ethnicity

For programs that require tracking of patient ethnicity, this can be input here using the drop down list that is populated based on the entries in the Configuration page.

3.8.8 Tracking ID

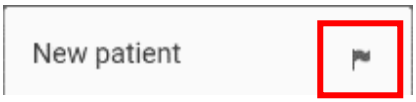
For programs that use a Tracking ID that is different from the Patient ID assigned at the hospital, a Tracking ID field can be enabled on the New Patient screen.

3.8.8.1 Tracking ID & HiTrack export file

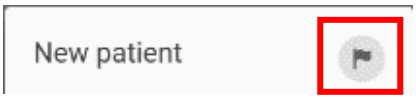
When a Tracking ID is entered for a patient and tests for that patietn are output to a HiTrack formatted export file, the Tracking ID will be substituted for the Patient ID field in the HiTrack file.

3.8.9 Flag

The patient can be flagged within the New Patient screen by selecting the **Flag** control.



Flag off



Flag on

Flagging the patient within the New Patient screen will cause the Flag to be set to ON in the patient list view once the patient has been saved to the data manager.

3.8.10 Save

After entry of the patient's information, select **Save** to:

- Save the patient to the data manager
- Clear the New Patient screen making it ready to enter another patient's information

3.8.11 Save and Edit

After entry of the patient's information, select **Save and Edit** to:

- Save the patient to the database
- Open the Edit Patient screen in order to add more details and/or risk factor information for this patient

NOTE: See section 3. 11 for more information about the Edit Patient screen.

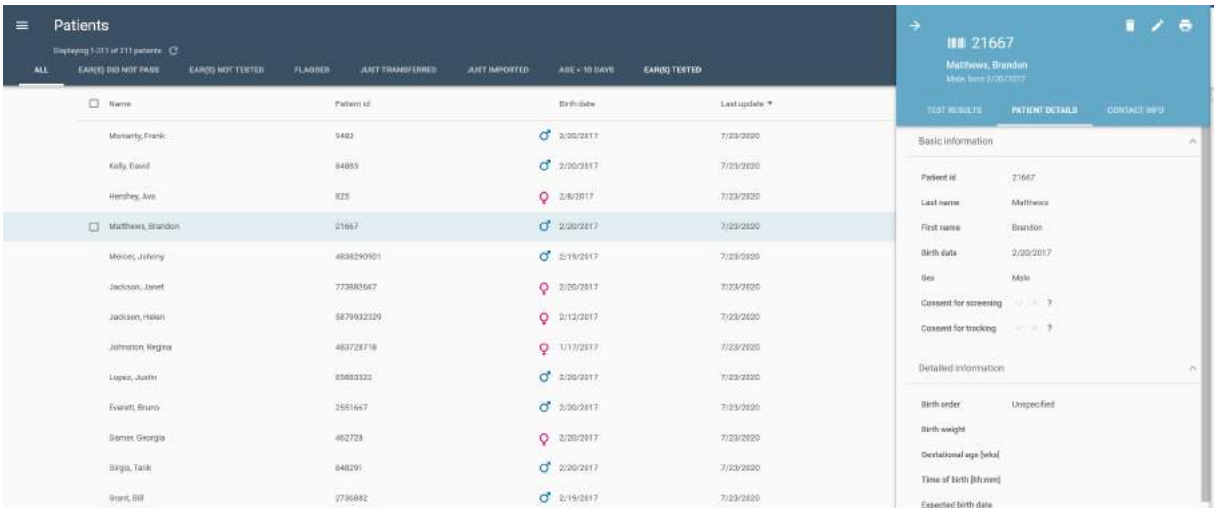
3.8.12 Close

Select **Close** to close the New Patient screen. If data is present in any of the fields when the **Close** control is selected, it will be discarded.

3.9 Patient details

To review all of the patient information fields, click on the patient's name or ID number in their row in the Patient List view. The Patient Details view is divided into 3 sections, Basic Information, Detailed Information and Risk Factors.

The fields displayed in these sections can be customized in the **Administration/Patient Details** page.



3.9.1 Basic information

The Basic information section supports display of the following demographics:

- Patient ID
- Last name
- First name
- Birth date
- Sex
- Consent for screening
- Consent for tracking
- Tracking ID (if enabled)

3.9.2 Detailed information

The Detailed Information section can display the following fields:

- Birth order
- Birth weight [g]
- Gestational age [wks]
- Time of birth [hh:mm]
- Expected birth date
- Race
- Ethnicity
- Birth facility
- Nursery type
- Insurance
- Physician
- Regional unique id
- Tracking variable 1
- Reason not screened
- Notes

3.9.3 Risk factors

Information about Risk factors is displayed in this section.

3.10 Contact info

To review the contact information for a patient, click on a patient's name in the patient list and select the Contact info tab. The Contact information is divided into 2 sections, Mother's information and Alternate contact's information.

The fields displayed in these sections can be customized in the **Administration/Patient Details** page.

3.10.1 Mother's information

The Mother's information section supports display of the following fields:

- Mother's ID
- Mother's last name
- Mother's first name
- Maiden name
- Mother's birth date
- Address Line 1
- Address Line 2
- City
- State/Province/Region
- Zip/Postal code
- Country/Area
- Phone number
- Email address

- Language
- Education level
- WIC participation
- ADA communication required
- Visual oral language

3.10.2 Alternate contact's information

The Alternate contact's information section includes fields for:

- Last name
- First name
- Address Line 1
- Address Line 2
- City
- Zip/Postal code
- State/Province/Region
- Phone number
- Language
- Relationship to patient

3.11 Editing patient and contact information

Patient and contact information can be edited or completed by selecting the Edit icon in the upper right corner of the Patient Details or Contact Info screens. The fields will become editable.

3.11.1 Editing basic information fields

The fields and controls in this section are identical to those in the Add New Patient screen. See Section 3. 8.

3.11.2 Editing detailed information fields

The fields and controls in this section are as follows.

3.11.2.1 Birth order

The drop down list control allows you to select the birth order for the infant. The default value is "Unspecified".

3.11.2.2 Birth weight [g]

This is a text entry field in which you can enter the infant's birth weight in grams.

3.11.2.3 Gestational age [wks}

The Gestational age field allows entry of the infant's gestational age at birth in weeks.

3.11.2.4 Time of birth [hh:mm]

The Time of birth field is formatted to accept entries in hh:mm format only and will only accept valid entries based on a 24 hour clock. Invalid entries will be deleted or reverted back to the most recently entered valid entry.

3.11.2.5 Expected birth date

This field allows entry of the infant's expected birthday either through direct entry or by use of the calendar control.

3.11.2.6 Race

This field allows selection of the infant's race by selection from a drop down list control. The items in the list are configured in Configuration page, Races tab.

3.11.2.7 Birth facility

The Birth facility field is a a drop down list that displays a facilities list that is defined in the Configuration area of the HearSIM™ software in the Facilities tab.

3.11.2.8 Nursery type

The Nursery type field is a a drop down list that displays a list that is defined in the Configuration page, Nursery types tab.

3.11.2.9 Insurance

The Insurance field is a a drop down list that displays a list that is defined in the Configuration page, Insurances tab.

3.11.2.10 Physician

The Physician field is a a drop down list that displays a list that is defined in the Configuration page, Physicians tab.

3.11.2.11 Regional unique ID

This is a text entry field in which you can enter a secondary ID for the patient such as a tracking ID, for example.

3.11.2.12 Tracking variable 1

This field is available to use as needed for your program.

3.11.2.13 Reason not screened

The Reason not screened field is a drop down list of possible reasons that an infant would not be screened. The list is fixed and cannot be edited.

When a 'Reason not screened" is selected from the list additional fields will open for entry of a "screener" name (for example the person making the entry) and the screening facility name so that these data fields are also present in the record.

For HiTrack database users who have enabled "automatic export" in HearSIM™, selection of an entry into this field automatically adds a record into the HiTrack export file so that merging the file into HiTrack will document the patient and reason they were not screened.

Additionally if you execute a HiTrack format or an XML format manual export including records created for patients with a Reason not screened, the patient and reason will be included in the export file.

Note: automatic or manual export of a tracking file in another format (CSV or OZ) will ignore any Reason not screened records and they will not be included in the export file.

3.11.2.14 Notes

This is a text entry field in which you can enter notes regarding the patient.

3.11.3 Editing risk factors

The default Risk Factors found in HearSIM™ include the recommended risk factors included in the 2007 Position Statement published by the Joint Committee on Infant Hearing[1] as well as legacy risk factors. These risk factors can be customized in the Configuration area of the HearSIM™ software.

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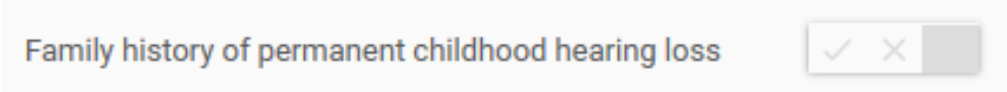
[1] Joint Committee on Infant Hearing, Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs, Pediatrics, 2007:Volume 120, Issue 4

3.11.3.1 Risk factor controls

The risk factor controls allow you to set values of Yes or No or to leave the value unspecified. Only the "Yes" risk factors display in the Patient Details view when the edit mode is closed.



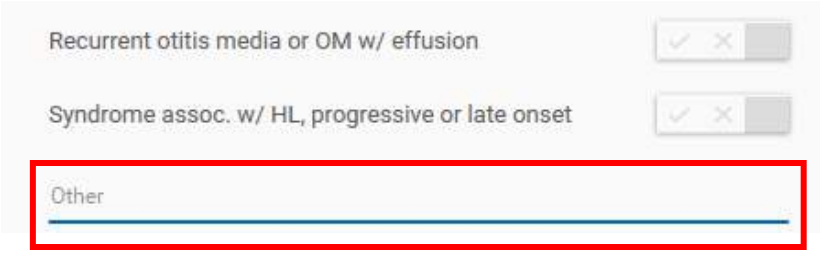
Yes, risk factor present

No, risk factor not present

Risk factor unspecified

Other risk factor

The **Other** Risk Factor field allows entry of text for a special risk factor.



3.11.4 Editing Mother's info

When you are viewing the Contact Info tab of the patient's screen you can add/edit the Mother's contact information. The following fields are available.

3.11.4.1 Mother's Id

This is a text entry fields in which you can enter an Identificaion number for the Mother.

3.11.4.2 Mother's last, first and maiden names

These are text entry fields in which you can enter the Mother's name and Maiden last name.

3.11.4.3 Mother's birth date

This field is for entry of the Mother's birth date either by typing it in or using the calendar control.

3.11.4.4 Mother's address

Text entry for Address Line 1, Address Line 2, City, Zip/Postal code and State/Province/Region can be made in these fields. A drop down list allows entry of Country/Area of residence.

3.11.4.5 Mother's phone number

This is a text entry field in which you can enter the Mother's telephone number.

3.11.4.6 Mother's Email address

This is a text entry field in which you can enter the Mother's email address.

3.11.4.7 Mother's language, education level

These fields present a drop down list from which you can choose the language relevant for the Mother. These lists are configurable in specified tabs of the same names within the Configuration page.

3.11.4.8 Mother's WIC participation

This field allows entry of Yes, No or unknown regarding the mother's participation in a special supplemental nutrition program for women, infants and children (WIC).

3.11.4.9 ADA communication required

This field allows entry of Yes, No or unknown regarding the need for a specialized communication.

3.11.4.10 Visual oral language

This field presents a fixed drop down list from which you can choose the Mother's preferred visual/oral communication mode.

3.11.5 Editing Alternate contact's info

3.11.5.1 Last, first names

These are text entry fields in which you can enter the Alternate Contact's name.

3.11.5.2 Address

Text entry fields for Address Line 1, Address Line 2, City, Zip/Postal code and State/Province/Region can be made here for the alternate contact.

3.11.5.3 Phone number

This is a text entry fields in which you can enter the telephone number.

3.11.5.4 Language

This is a drop down list from which you can choose the language relevant for the Alternate Contact.

3.11.5.5 Relationship to patient (child)

In this field you can select from a configured list describing the relationsip of the Alternate Contact to the child. The list can be customized in the Configuration/Relationships tab.

3.11.6 Saving or cancelling changes

Edits must be saved or cancelled to exit from the Edit Patient Information view using the controls at the bottom of the view.

3.11.6.1 Save changes

Selecting **Save Changes** will save the edits you made and close the edit view of the Patient Information screen.

3.11.6.2 Cancel

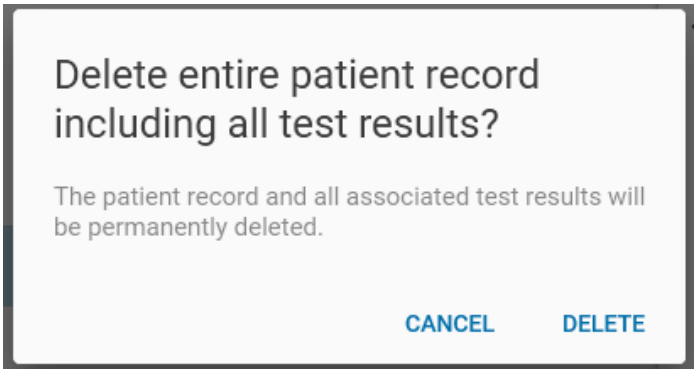
Selecting **Cancel** will discard all edits you have made without warning, returning all fields to their previous values, and close the edit view of the Patient Information screen.

3.12 Deleting a patient

A patient can be deleted from HearSIM™ by selecting the **Delete** icon in the upper right corner of the Patient Details view.

3.12.1 Delete confirmation

A pop-up message requires confirmation by selection of the **Delete** control. Deleting a patient also deletes all associated tests from HearSIM™.

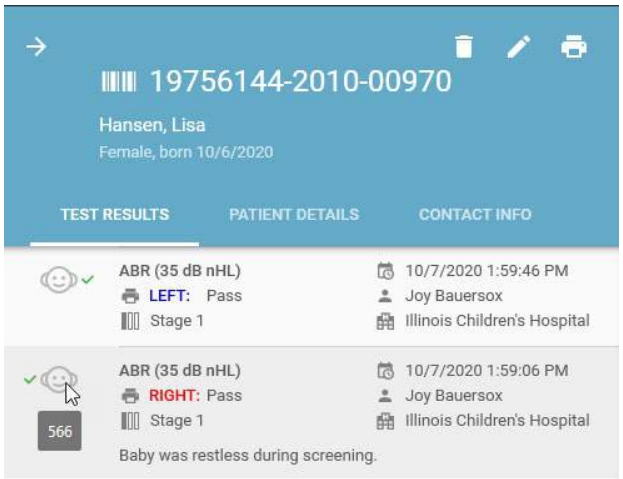


Seletion of **Cancel** cancels the operation and close the pop-up message.

3.13 Test results list

Select the **Test Results** tab in the patient's information screen to review a list of all tests that have been transferred into HearSIM™ from the device.

The tests list is sorted in reverse chronological order.



The information displayed includes the following (screening stage, screener, facility and comment are optional).

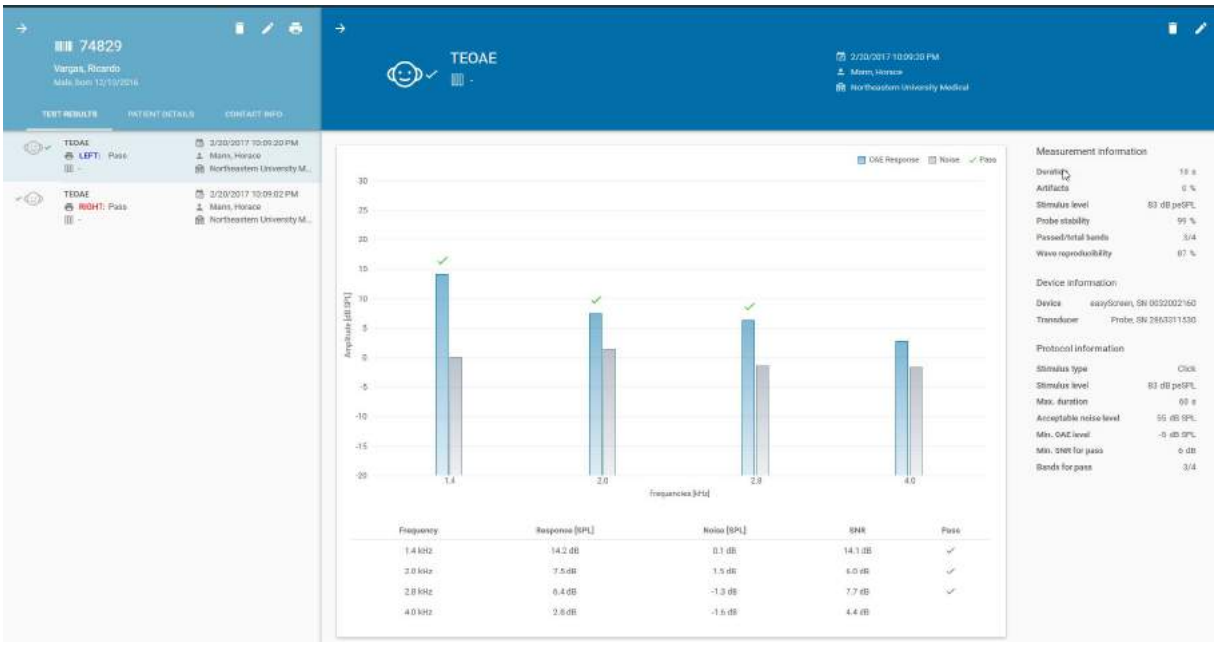
- Test ear
- Test type
- Result
- Screening stage
- Test date & time
- Screener
- Screening facility
- Test comment
- Test ID (tool tip pop-up displayed when hovering the mouse over the baby head graphic)

In the list, binaural ABR tests display with both ear's results reflected as seen below.

For incomplete tests, hover the mouse over the question mark symbol to view a reason for stopping the test (if one was entered).

3.14 Test details view

Select one of the tests in the list to open a detailed view with this test as the focus.



3.14.1 Graph view

A graph reflecting the test data for the selected test is displayed for review.

For DPOAE and TEOAE tests, a bar graph displays the OAE response and noise amplitude values for each of the test frequencies. A table of numeric values displays below the bar graph.

For ABR tests, a time graph displays showing the progress of the test toward achieving a passing test value over time.

3.14.2 Measurement information

Measured test values display in this section and will vary with the test type and with the device used for testing.

3.14.3 Device information

This section displays information about the device and transducer used to perform the test.

3.14.4 Protocol information

Protocol parameters that were in effect for the tests are displayed in this section as well as the protocol name.

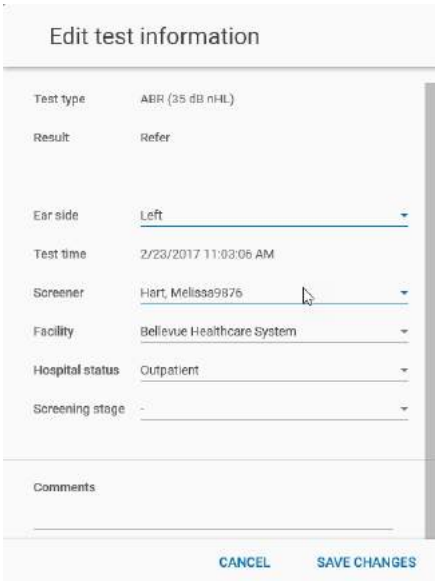
3.15 Editing test fields

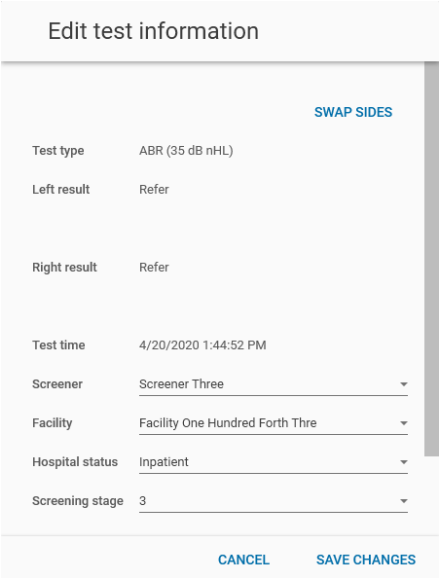
Some fields related to the test can be edited or added by selecting the **Edit** icon that displays when the test details view is open.

3.15.1 Edit test information window

In the Edit Test Information screen only certain fields can be edited in order to add information that was not available at the time of the test or to correct input errors.

As seen on the right, the editing screen for a binaural ABR test contains information for both ears.





3.15.1.1 Uneditable fields

Test type, result, test date and time cannot be changed but are displayed for review.

3.15.1.2 Stop reason

For an Incomplete test result a stop reason field will be available with options of:

- Could not test
- Invalid

3.15.1.3 Ear side

The ear can be changed in the event that the screener made an error while documenting the ear at the time of the screening.

For a binaural ABR test the **Swap Sides** button is available. When selected the results and test progress data for the ears will be exchanged. This feature is available to use in the event that the screener has placed the insert earphones incorrectly on the patient's ears for the test and only discovers it after the test is completed.

3.15.1.4 Screener

The screener name can be added or changed using the drop down list that displays the screener list as it is defined in the Configuration section of HearSIM™.

3.15.1.5 Facility

The screening facility can be added or changed using the drop down list that displays the facility list as it is defined in the Configuration section of HearSIM™.

3.15.1.6 Hospital status

The patient's hospital status at the time of the screening can be added or changed using the drop down list that includes the options of:

- Inpatient
- Outpatient
- Home visit

3.15.1.7 Screening stage

The screening stage can be selected from a drop down list.

3.15.1.8 Test comment

A comment about the screening can be added or edited in this memo field.

3.15.2 Saving or cancelling changes

Edits must be saved or cancelled to exit from the Edit Test Info view using the controls at the bottom of the view.

3.15.2.1 Save changes

Selecting **Save Changes** will save the edits you made and close the Edit Test Information screen.

3.15.2.2 Cancel

Selecting **Cancel** will discard all edits you have made without warning, returning all fields to their previous values, and close the Edit Test Information screen.

3.16 Printing a patient report

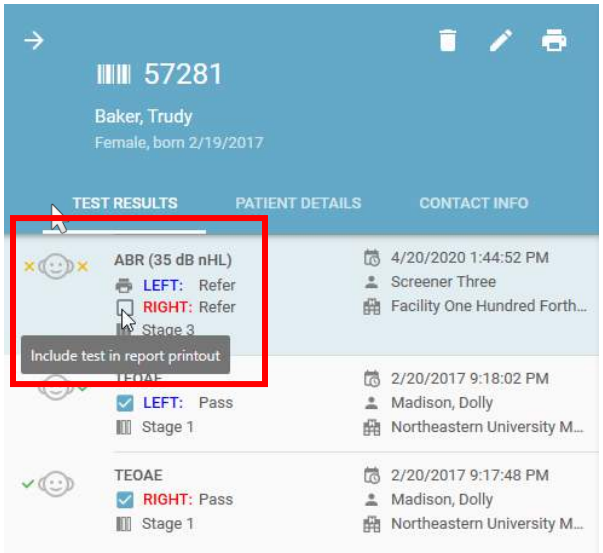
A test report for a patient can be printed while you are viewing the Test Results list for that patient.

3.16.1 Printing default

With the list open, select the **Print patient report** icon at the top of the window. This will automatically open a print preview of a report containing the last test for each ear for each technology that was performed.

3.16.2 Selecting tests

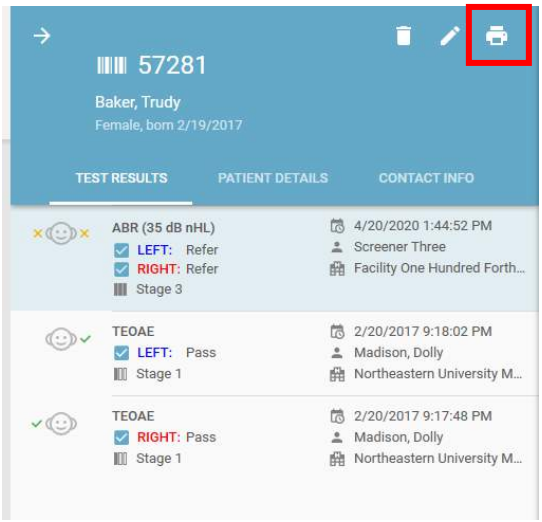
If you prefer to select specific tests for printing rather than having the default tests included, hover the mouse over the printer icon in the row for the test(s) you wish to print. The printer icon will change to a check box. Select the checkbox to choose the test for printing. Repeat that for all of the tests you want to include in the report.



Selected tests will display the checkbox which remains visible as you move from test to test.

3.16.3 Executing the report printing

After choosing the desired tests, select the **Print** icon in the upper right corner of the screen to display the Print Preview screen.



3.16.4 Print Preview

The test report print preview displays as follows:

Controls allow you to:

- Select the desired printer
- Set the page size
- Set margins
- Set the orientation
- Select the color mode
- Print
- Cancel

3.16.5 Report format

The test report is a fixed format report that displays the following information.

- Facility name and logo (if configured in Administration/Print screen)
- Title
- Patient information
- Screening results

3.17 Transfer data to HearSIM™ from device

To transfer patient and screening test information from the device to HearSIM™ connect the device to the PC using the USB interface cable supplied with your device.

When the device is detected by the HearSIM™ software, a device graphic will appear in the bottom left corner of the PC screen indicating the status of the device. The device screen will display "PC Controlled" or "Ready" when it is detected by HearSIM™.

NOTE: The device will not be detected if it is displaying any stage of a test from the patient preparation screen through the test "Done!" screen. Return to the Home screen if necessary for the connection to be made.

3.17.1 Device data import

See Section 3. 7. 1 for a review of all of the possible device graphics that can appear when HearSIM™ has detected that the device is connected.

If patient and/or test data is present on the device you will see the following graphic:

Device connected; patient and test data present in the device

Click on the device graphic to begin the import of device data to HearSIM™.

After you have clicked on the graphic to initiate the import, a screen will open in which you will select **Import** to perform the transfer.

After the transfer is complete, the data will automatically be cleared from the device.

The device will then be ready for transfer of selected patient names from HearSIM™ or for direct entry and testing of new patients.

Select the **Cancel** button to cancel the operation.

3.17.1.1 Screening vs Diagnostic device models

Screening models of certain OAE devices supported by HearSIM™ use test protocols with the following names:

- DP 4s
- DP 2s
- TE 32s
- TE 64s

Tests performed using these protocols are supported by HearSIM™ and will be transferred into HearSIM™/OtoAccess®.

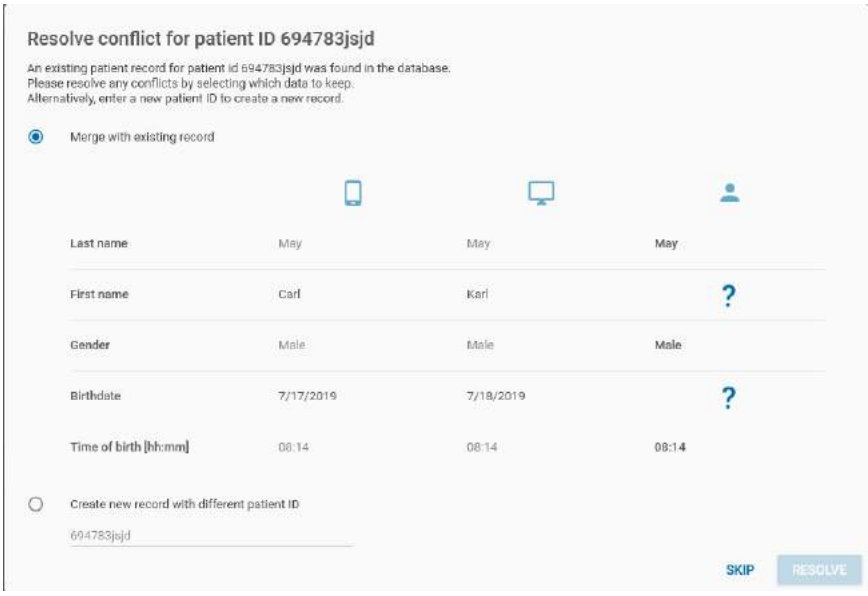
Some models of these devices allow testing usnig screening or diagnostic protocols with names other than those in the list above. When such data are encountered during data transfer to HearSIM™, these tests **will not be imported into HearSIM™ and will be deleted from the device**.

IMPORTANT NOTE: Tests performed with unsupported protocols **will NOT transfer** into the database and will be immediately deleted from the device after a transfer has occurred. Be sure to print out or otherwise save test results from unsupported protocols before transferring data to HearSIM™.

3.17.2 Merge conflict resolution

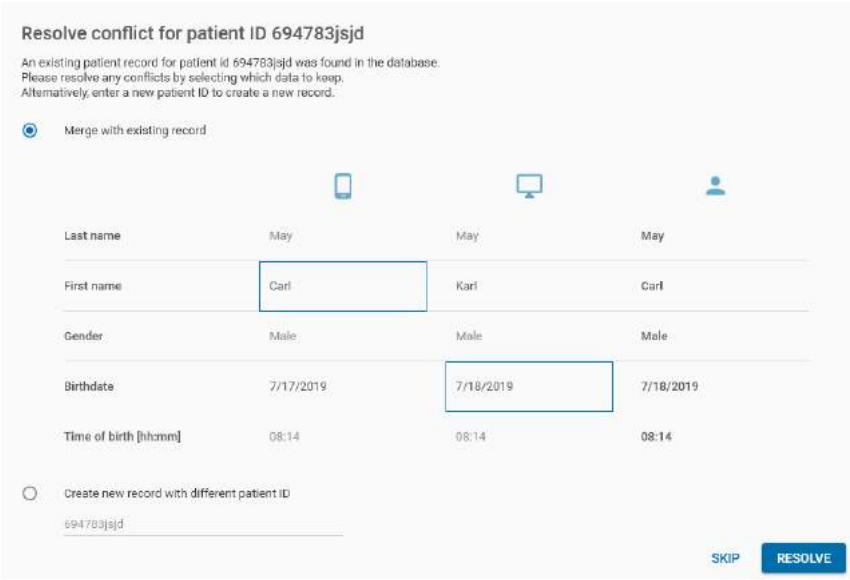
As data from the device is transferred to HearSIM™ the data will be merged in the case where the Patient ID transferred from the device matches an ID existing in the HearSIM™ database.

If the Patient IDs match but other basic patient fields have conflicting entries, then a screen will appear so that you can review the conflict and resolve it before the transfer is completed.



The table shows the basic patient fields in rows. The field entries for the device versus HearSIM™ are shown in the columns. The last column reflects the entries that will be saved in HearSIM once you have selected the correct entry, resolving any conflicts that are present.

To resolve the conflict, note the rows that have the question mark symbol ? in the last column. Then select the correct field entry for that field by clicking on either the device value or the HearSIM™ value.



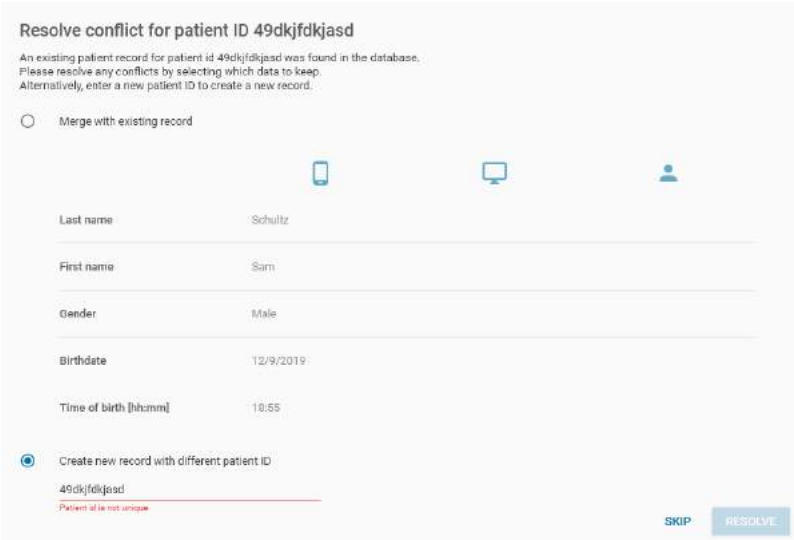
Once you have selected the accurate field entry, you can select the **RESOLVE** button to save this patient and associated tests to HearSIM. The data as observed in the last column will be saved to the HearSIM database for this patient.

If you choose to **SKIP** this patient, then it will not be transferred to HearSIM and will not be deleted from the device.

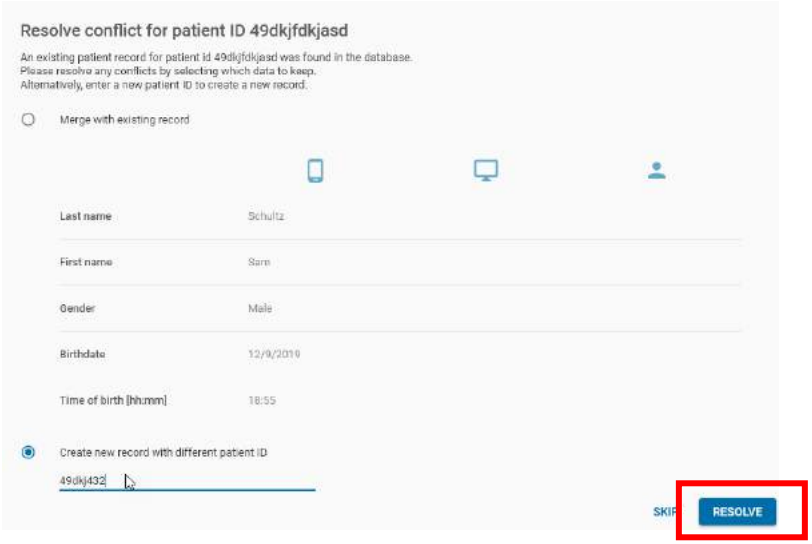
3.17.2.1 Changing the patient ID

As you review the conflicting data you may find that the device and the HearSIM™ software have the same patient ID (by some mistaken entry), but that these are actually two different patients. In this case you do not want to merge the test results together.

To resolve this situation you can choose the **Create new record with different patient ID** option and enter a new ID for the patient being transferred from the device.



As you edit the patient ID in the field, information will be displayed if the entered ID still matches a patient already saved in HearSIM™. If there are no matches, then you can create this new patient in HearSIM™ when you **RESOLVE** the conflict. The patient fields from the device will be saved with any associated tests under this new Patient ID number.



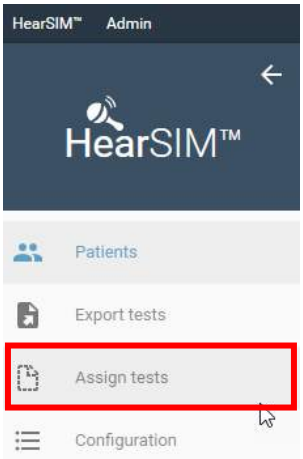
3.17.3 Import of unassigned tests

One supported device type allows tests to be performed on the device that are not associated with a specific patient. When this device is connected to HearSIM™ and unassigned tests are present then these tests will be temporarily stored in an “Unassigned Tests” page in HearSIM™.

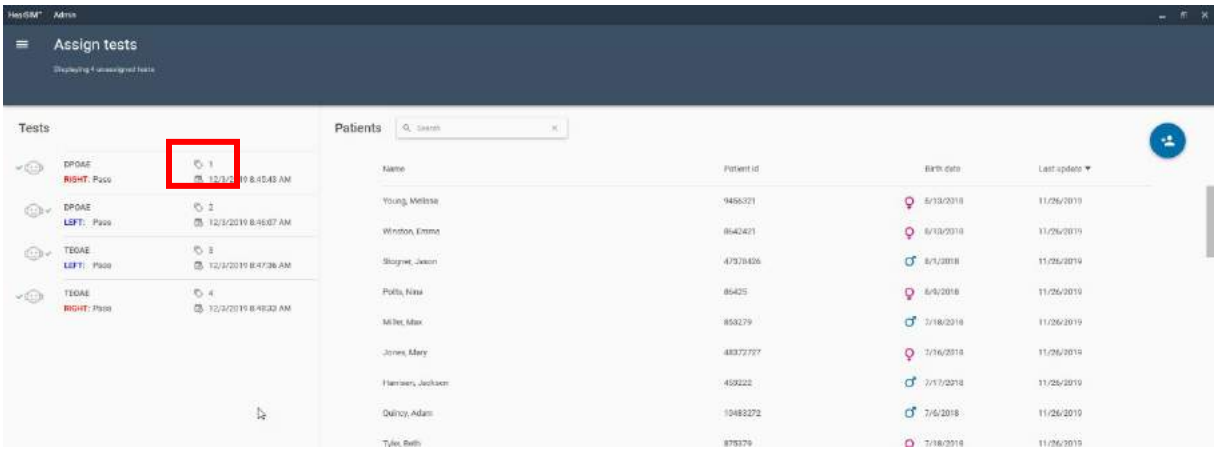
4 Unassigned tests

One device supported by HearSIM™ saves screening tests with a Test ID as the only identifier. These tests can be transferred into HearSIM™ and are saved in a temporary location waiting to be assigned to a patient that is already in the database or to a new patient.

After the tests have been transferred into HearSIM™, select the Assign tests menu item in the Main Menu.



A list of unassigned tests displays on the left showing the test number assigned by the device as well as other test information.

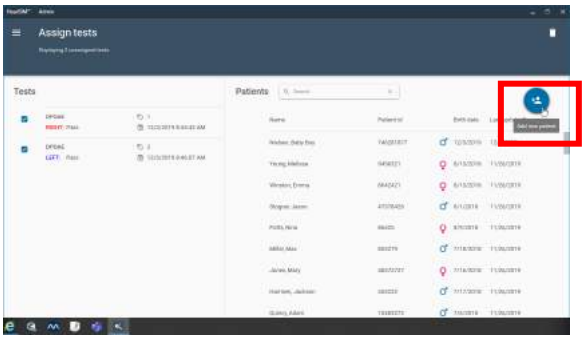


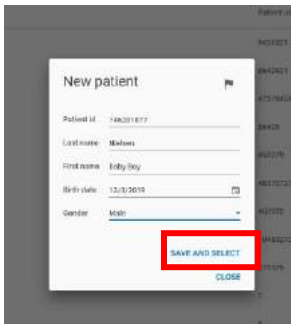
4.1 Assigning a test to a new patient

Select the tests you wish to assign to a patient by entering a checkmark in the checkbox that appears when you hover the mouse over a test in the list.

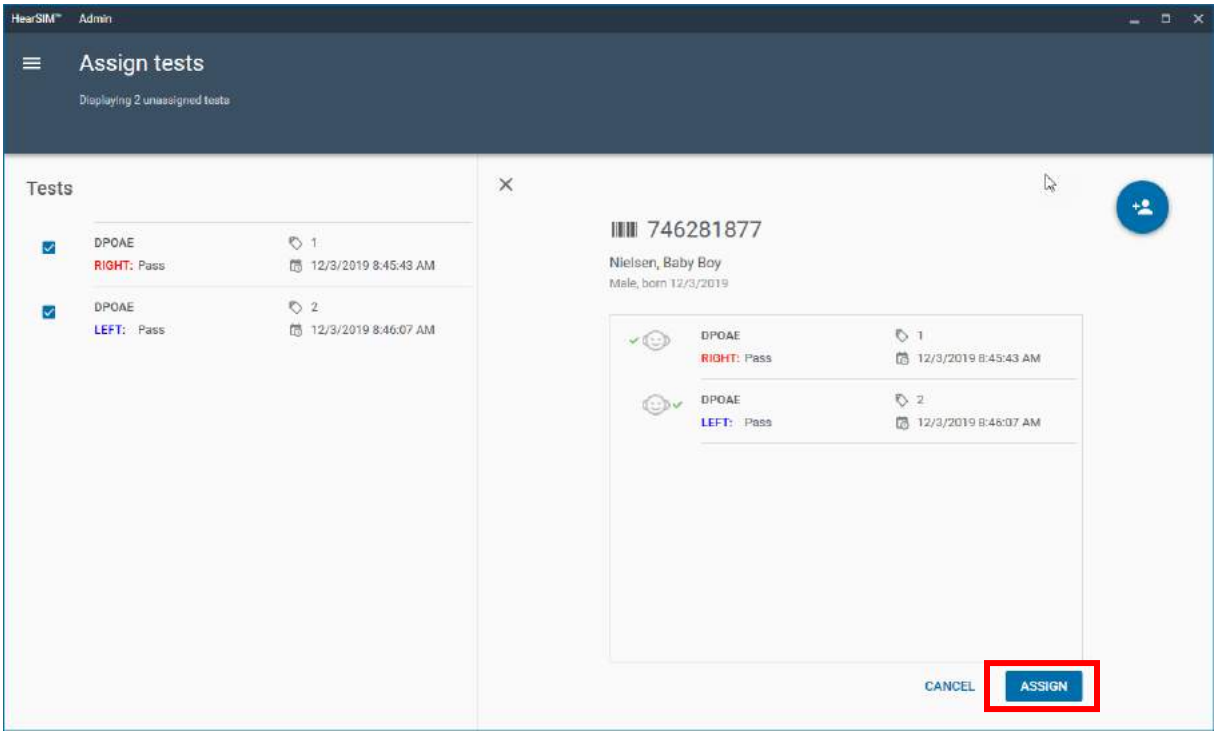
Select all tests you want to assign to the patient. Then select the **Add new patient** icon to open the New Patient entry screen. Enter the patient's information. At a minimum you must enter a patient ID to assign the test to a patient.

Select **Save and Select** when the data is complete.





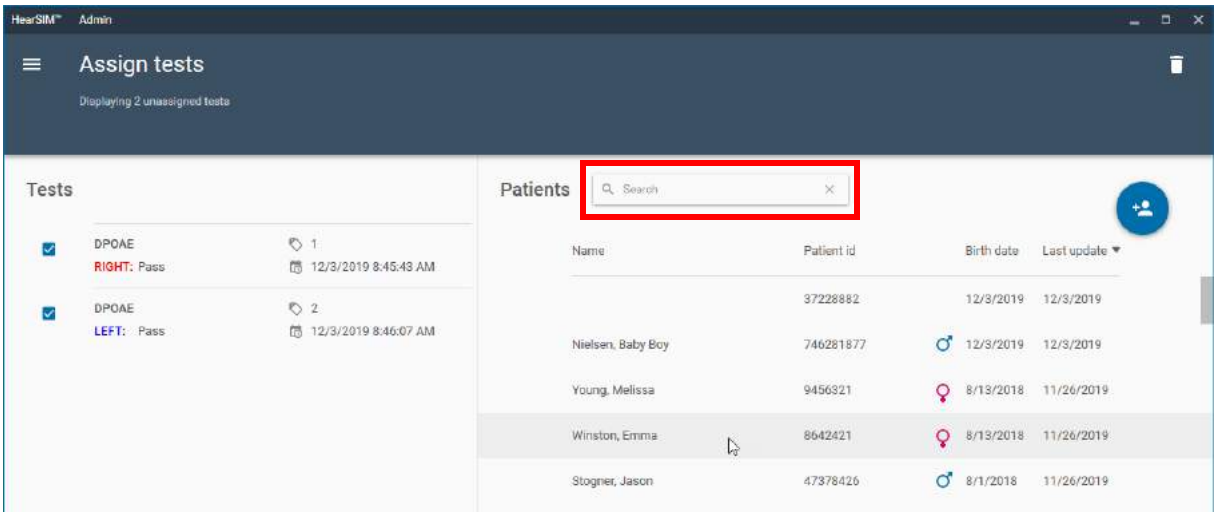
Review your selection in the next screen to verify that all information is correct. Select **ASSIGN** to complete the process. The tests will disappear from the list once they are assigned.



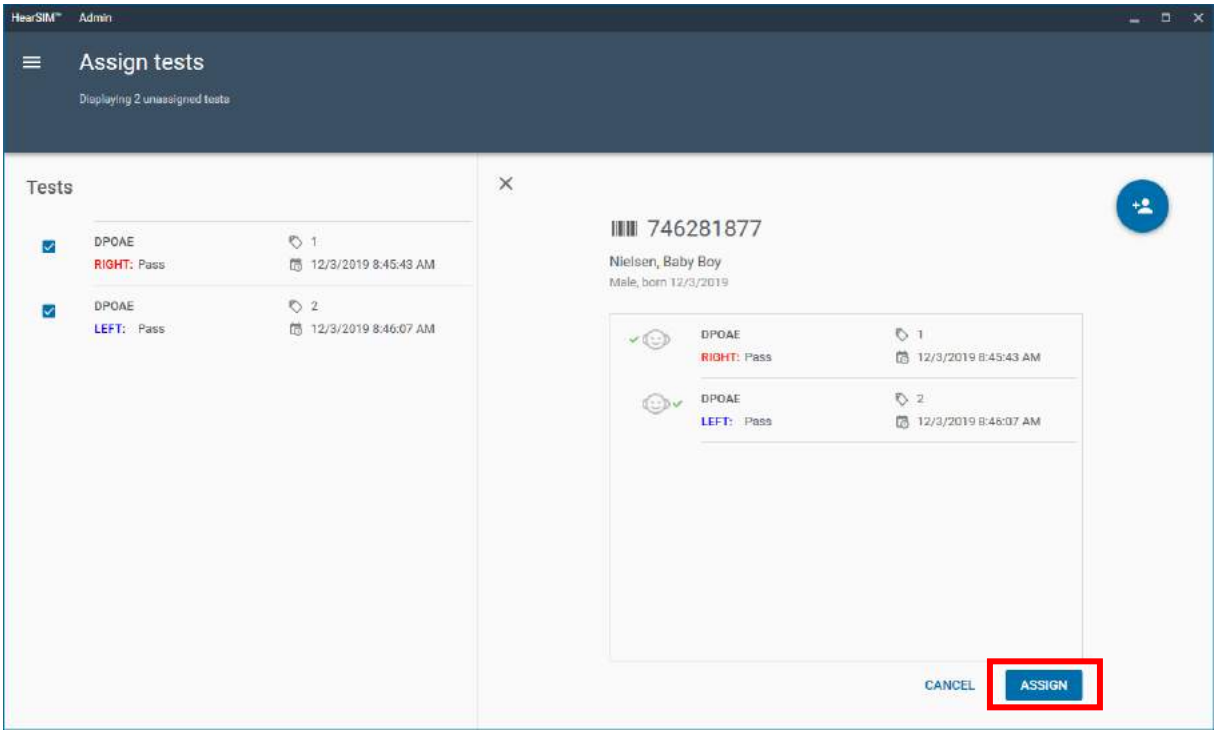
4.2 Assigning a test to an existing patient

Select the tests you wish to assign to a patient by entering a checkmark in the checkbox that appears when you hover the mouse over a test in the list.

Select a patient from the list of patients on the right side of the screen. Use the Search feature to find the desired patient by entering in Patient ID or Last name to begin to shorten the list to matching entries.

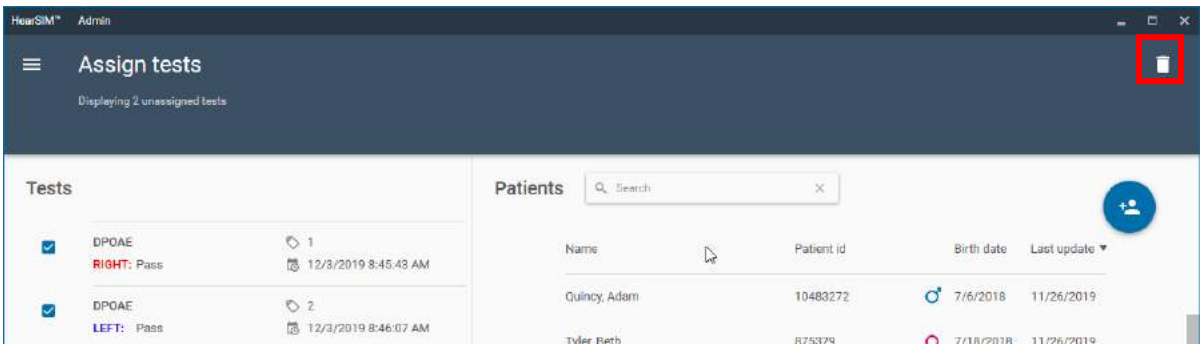


When you select a patient, the confirmation screen appears. Verify the accuracy of the information and select **ASSIGN**. The tests will be removed from the list.

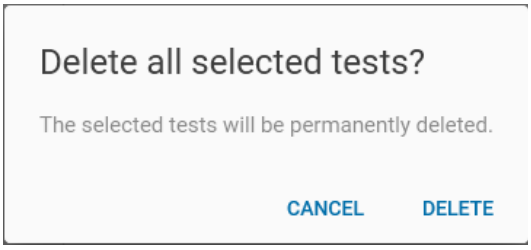


4.3 Deleting unassigned tests

Select the test you wish to delete by clicking on its checkbox. Select the trash can icon to delete it from the list.



Confirm that you really want to permanently delete the test from the list by selecting **DELETE**. Or, **CANCEL** the operation.


Delete all selected tests?
The selected tests will be permanently deleted.
CANCEL
DELETE

5 Import patients

The Import patients function allows you to import a list of patients into HearSIM from a file that you have exported from a different database. For example, you can export patient information from your hospital information system or from another third-party database such as HiTrack and then import the patient data into HearSIM. This avoids manual data entry errors.

5.1 Import fields

The import is compatible with an export file containing these data fields:

- Patient ID
- Last name
- First name
- Gender
- Birth date
- Time of birth

5.2 Import file format

The following file formats are supported.

5.2.1 HiTrack file format

Example of a “HiTrack” import file format:

```
"123456","Mueller","Anna","F",20190821,"03:00"
"123455","Meyer","Bernd","M",20190821,"02:00"
"a67123iojq","Cooper","Chad","M",20190821,"01:00"
"973441123","PAULSON","Paul","M",20190821,"04:16"
```

5.2.2 HearSIM XML

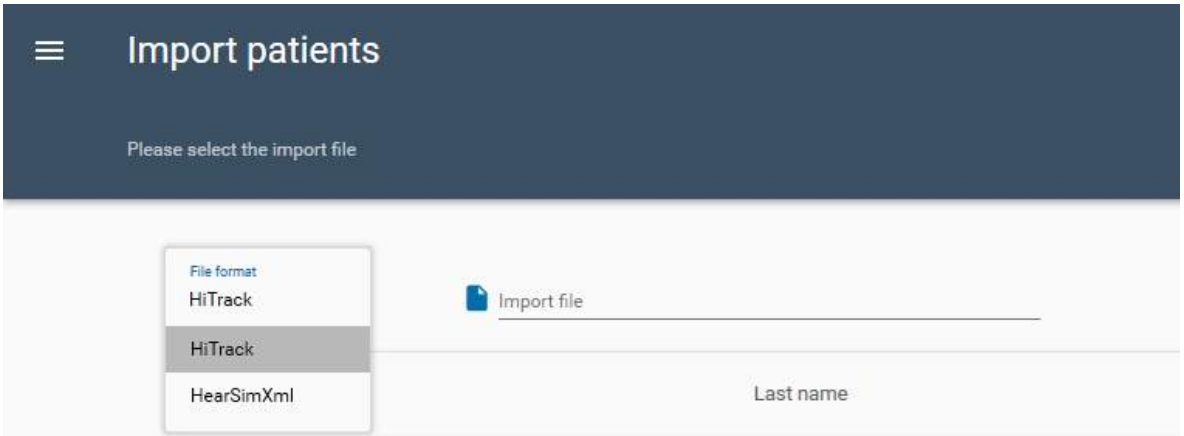
Example of a HearSIM XML file:

```
<?xml version="1.0" encoding="utf-8"?>
<HearSimXml xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance" xmlns:xsd="http://www.w3.org/2001/XMLSchema"
Version="0.3" ExportTime="2020-07-28T14:43:00.3559418+02:00">
  <Patients>
    <Patient>
      <Guid>2e392835-af98-4e44-8fab-a9777caccba0</Guid>
      <PatientId>948727</PatientId>
      <FirstName>Anna</FirstName>
      <LastName>Mueller</LastName>
      <Birthdate>2020-07-27T00:00:00</Birthdate>
        <TimeOfBirth>03:00</TimeOfBirth>
      <Gender>Unspecified</Gender>
    </Patient>
  </Patients>
</HearSimXml>
```

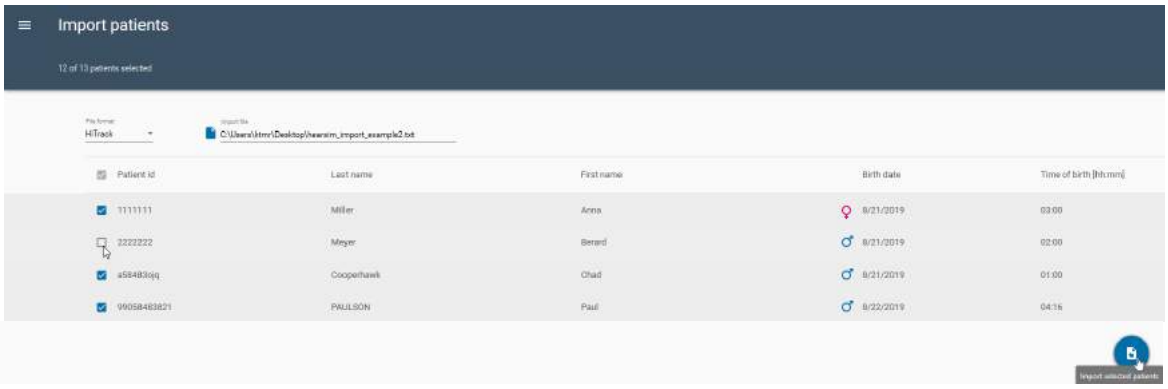
5.3 Settings

To import patients into HearSIM™, select the File Format of the file you will import.

Browse to the path containing the import file by clicking on the document icon. Find the path on which the file is saved. Select and **Open** it.



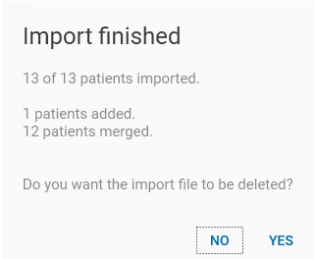
5.4 Executing the import



A list of the patients in the file will display. By default all will be selected for import. However, if you wish to exclude certain patients from importing, you can deselect the checkbox near the name.

To finalize the import, select the **Import selected patients** button in the bottom right corner of the screen.

A confirmation message will show the number of patients added to the HearSIM™ database.



Select **No** to close the message and keep the import file in its path. Select **Yes** to close the message and delete the file.

6 Export tests

HiTrack and OZ eSP™ are 3rd party data managers specifically designed to handle newborn hearing screening data. HearSIM™ allows screening data to be exported into formats that are compatible with either HiTrack or OZ eSP™ .

There are two methods for exporting HearSIM™ data to the HiTrack or OZ eSP™ file format.

6.1 Automatic export

HearSIM™ can be configured to automatically export screening data to either a HiTrack-compatible file or an OZ eSP™-compatible file during the data transfer.

When this feature is enabled, then each time that data is transferred into HearSIM™ the test data will be appended to the specified file.

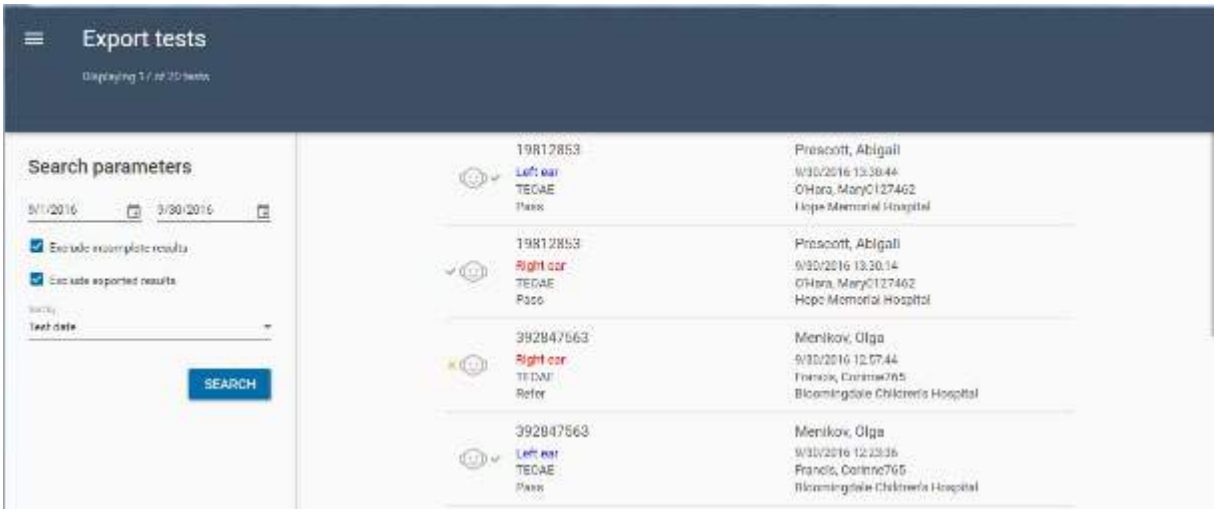
See section 8. 1 for more information about setting up the automatic export feature.

6.2 Manual export

You can perform a manual export of screening data to either a HiTrack-compatible (hearsim. txt) file, an OZ eSP™-compatible file (hearsim. oz), a Comma-Separated Value (hearsim. csv) file format or an XML (hearsim. xml) file format at any time.

6.2.1 Export tests dialog

Select the Export tests item in the HearSIM™ menu. Several settings allow you to define the criteria for the export.



6.2.1.1 Date range

These two fields allow you to set the starting and ending test date for tests you want to export. Type in the desired date or use the calendar control to select a date.

6.2.1.2 Exclude incomplete results

Enable this setting if you wish to export only screening results with Pass or Refer results and not the Incomplete tests.

6.2.1.3 Exclude exported results

Enable this setting to exclude from the export any tests that have previously been exported to an export file.

NOTE: Reason Not Screened records will not be excluded using this function.

6.2.1.4 Search

After you have set the criteria for the export, select the **Search** button in order to execute the search of the database for tests that meet the criteria.

6.2.1.5 Export test list

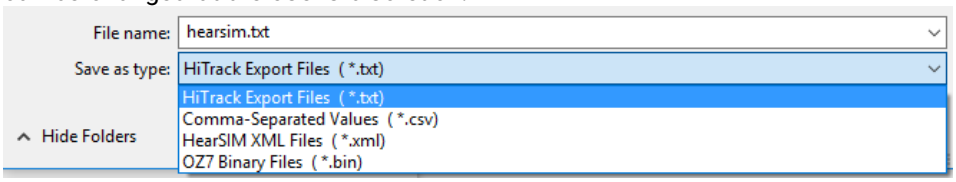
Upon executing the search the list will update to display a list of tests that will be exported. This gives you the opportunity to review the list and refine the export criteria if needed.

6.2.1.6 Export test list sort method

The test list can be sorted either by Test date, Patient ID or Patient name.

6.2.2 Export

Select the Export button to proceed with performing the export. A Save As dialog will appear allowing you to set the destination, the filename and the type of file (HiTrack, Comma-Separated Values, HearSIM™ XML or OZ eSP™ Binary). The default name of "hearsim. xxx" is recommended, but can be changed at the user's discretion.



After making these settings, select Save to execute the export and save it to the destination path.

7 Configuration

The Configuration section of HearSIM™ allows setup of the various lists including:

- Screeners (*)
- Facilities (*)
- Physicians
- Risk Factors (*)
- Ethnicities (*)
- Languages
- Nursery Types
- Races
- Insurances
- Education level
- Relationships (to child)

These lists are used in HearSIM™ and some can be transferred into the device (*).

Only the touch screen device supports transfer of some configured lists into the device.

The functions of adding and deleting values in the lists is the same for all lists. It will be described in detail only for the Screener, Facilities and Risk Factors lists. Follow these same instructions to configure the other lists.

7.1 Screeners

Screener names and passwords that will be transferred to the device are managed here.

7.1.1 Adding screeners

Select the **ADD** icon to open fields for entry of a new screener name and password. After entering the information select the **ADD** control to save it or **CANCEL** to cancel this operation without saving.

7.1.2 Deleting screeners

Select a name by clicking on it and then select the **More** icon to open a pop-up menu with a **Remove** control. Select it to delete a screener name from the list.

7.1.3 Editing passwords

After entry of screeners, passwords display in the list with *****. However the password can be viewed and edited by selecting the screener name and clicking the mouse in the password field.

7.2 Facilities

Facility names are managed here. This list is used as the drop down list in the fields of Birth Facility and Screening Facility.

7.2.1 Adding facilities

Select the **ADD** icon to open a field for entry of a new facility name. After entering the information select the **ADD** control to save it or **CANCEL** to cancel this operation without saving.

7.2.2 Deleting facilities

Select a facility by clicking on it and then select the **More** icon to open a pop-up menu with a **Remove** control. Select it to delete a facility name from the list.

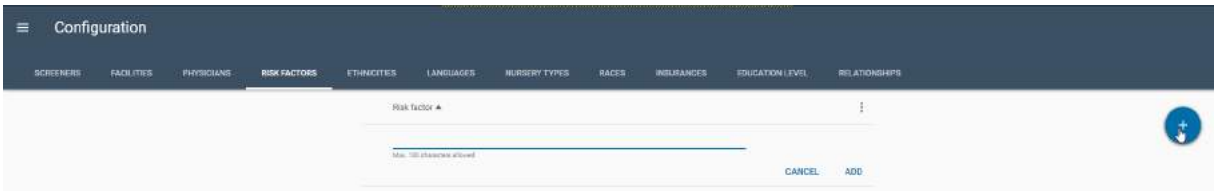
7.3 Risk factors

The list of Risk Factors is managed here.

7.3.1 Adding risk factors

The Risk Factors list is pre-populated with risk factors as recommended by the Joint Committee for Infant Hearing as well as some legacy risk factors.

Select the **ADD** icon to open fields for entry of a new risk factor. After entering the information select the **ADD** control to save it or **CANCEL** to cancel this operation without saving.



7.3.2 Deleting risk factors

Select a risk factor by clicking on it and then select the **More** icon near it to open a pop-up menu with a **Remove** control. Select it to delete a risk factor from the list.

7.3.3 Restoring manufacturer defaults

The following lists are pre-configured with values. Some are based on HiTrack, a third party newborn hearing screening database.

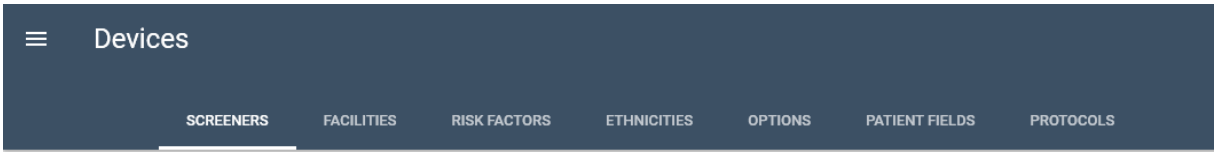
- Risk Factors (*)
- Ethnicities (*)
- Languages
- Nursery Types
- Race
- Insurance
- Education level
- Relationships

You can choose to edit the pre-configured lists to enter your own values. However, if you are a HiTrack user, this may invalidate the entries such that they cannot be exported into HiTrack. Edit the pre-configured lists only if you will not be using them for HiTrack export purposes.

To restore the values in the list to the manufacturer defaults, select the **More Options** icon next to the list header row to open a pop-up menu with a **Restore defaults** command. Select it to return to the manufacturer defaults.

8 Devices

The Device page in HearSIM™ allows configuring the options that can be set on the touchscreen type of device. This is the only device type that supports the functions described in this section.



It is in the Device page that you can choose the screener names you wish to transfer to the device. You can also view the various screening protocols that are available for use and select those that you want to transfer into your device.

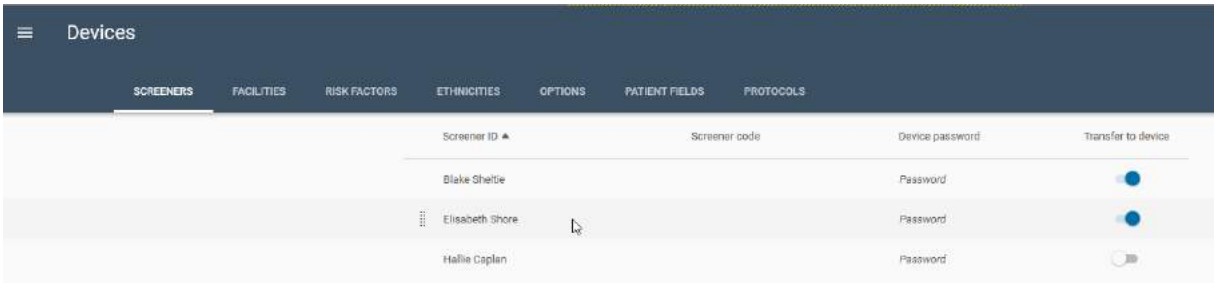
Additionally you can review the lists that are set up in the Configuration section and opt to transfer these and other settings, including making some fields mandatory, to the device.

8.1 Screeners

The Screener names that were added in the Configuration section are automatically displayed here.

8.1.1 Active or Inactive for transfer to device

An **Active** (or Inactive) control can be set. Only active screeners in this list will be transferred into the device.



8.1.2 Order

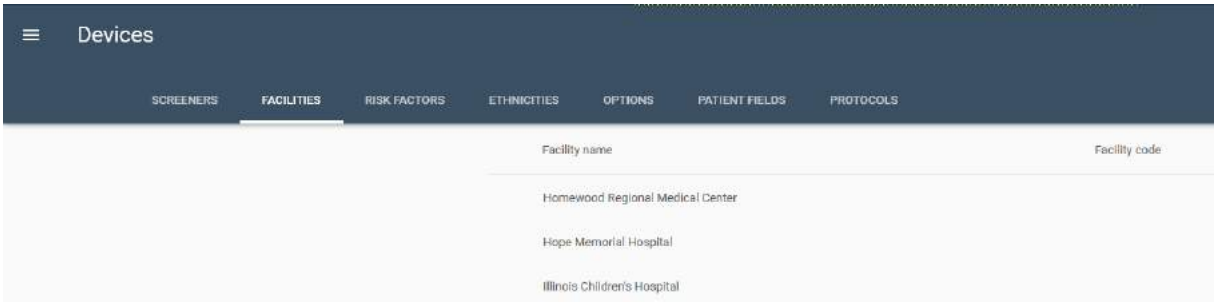
The order of the list can be modified here before it is transferred to the device. For example, you may want to place the names of screeners who perform most of the screenings at the top of the list to avoid scrolling on the device to find their names.

The **Screener ID** column header can be selected to set the list in A-Z alphabetical order. Additionally a **Drag** control appears in front of the name when you hover the mouse over a screener row. You can click and hold the Drag control and move and drop the screener name to a different position in the list.

8.2 Facilities

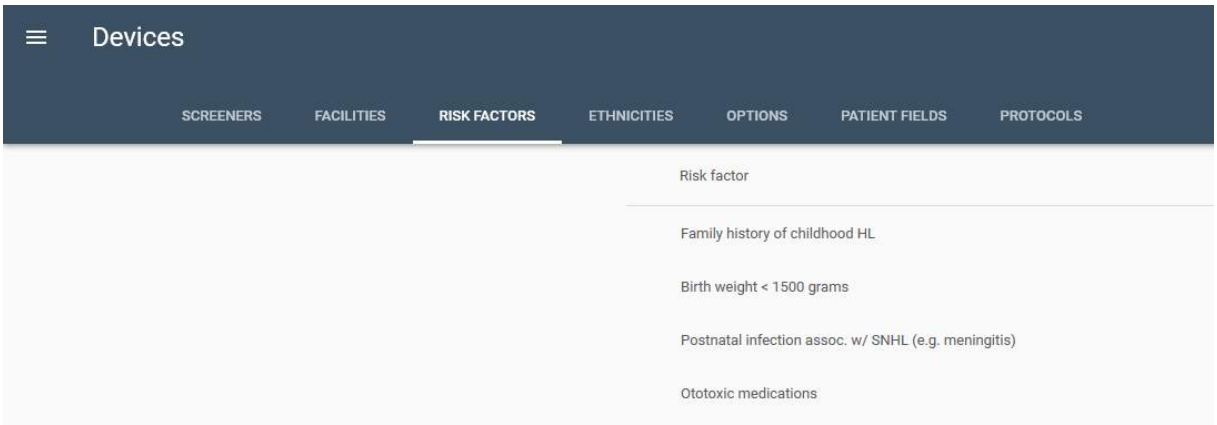
The Facility names that were added in the Configuration section are automatically displayed here. All facility names in the list will be sent to the device if you choose to transfer them.

In the device, it is possible to set the Screening Facility where the test is performed, but you must also enable the setting of Options/Test fields. See section 7. 4.



8.3 Risk factors

The Risk Factors that were setup in the Configuration section are automatically displayed here. All risk factors in the list will be sent to the device if you choose to transfer them.

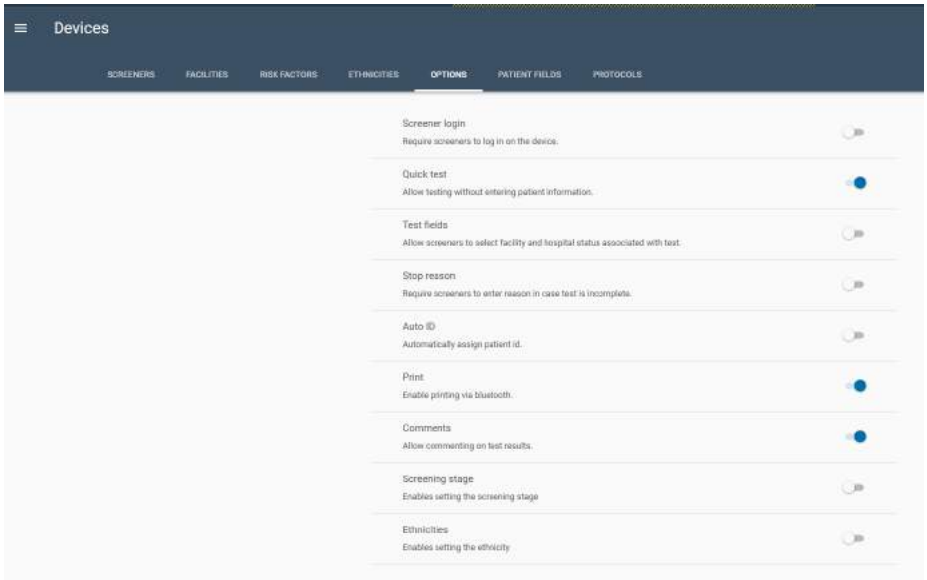


8.4 Ethnicities

The Ethnicities that were setup in the Configuration section are automatically displayed here. All ethnicitiesi n the list will be sent to the device if you choose to transfer them.

8.5 Options

The device Options are set here in preparation for transfer to a device. Each can be made Active or Inactive.



8.5.1 Screener login

Enable this control if you want a screener to select his/her name and enter the associated password in order to use the device. This way the screener name is automatically associated with any screenings that are performed.

Be sure that there are screener names setup in the Configuration section of HearSIM™ if you enable this setting on your device and that Screener names are activated to send to the device. If you enable this feature on your device but do not configure or transfer screener names you will not be able to login and this will have to be resolved before you can use the instrument.

8.5.2 Quick test

Enable this control if you want to allow screening tests to be performed without requiring entry of a patient ID.

8.5.3 Test fields

Enable this control if you want to save information about the screening facility and hospital status (inpatient, outpatient or home visit) with the screening data. If Screener login is disabled this setting also allows you to select a screener name from a list which will then be saved with the screening test.

Be sure that there are facility names setup in the Configuration section of HearSIM™ if you enable this setting on your device. If you enable this feature on your device but do not configure or transfer facility names you will not be able to perform a test and this will have to be resolved.

8.5.4 Stop reason

Enable this control if you want screeners to enter a reason of “could not test” or “invalid” for incomplete tests.

8.5.5 Auto ID

Entry of a patient ID is required in order to save tests on the device and later transfer them to HearSIM™. Typically this ID is one that is assigned to the patient by the hospital. Enable this control if your patients do not have IDs and you want the device to assign an ID automatically.

8.5.6 Print

Enable this control if you have purchased the wireless label printer which is an option offered with your device.

8.5.7 Comments

Enable this control if you want to have the opportunity to enter a comment on the device that is associated with a screening test.

8.5.8 Screening stage

Enable this control if you want to have the opportunity to enter a value (1,2 or 3) for the screening stage on the device that becomes associated with a screening test.

8.5.9 Ethnicities

Enable this control if you want to select a value from the Ethnicities list when you enter the patient information into the device.

8.6 Patient fields

Enable or disable the following fields to display and to set them as mandatory for completion before a patient can be saved both on the device and when a new patient is added in HearSIM™.

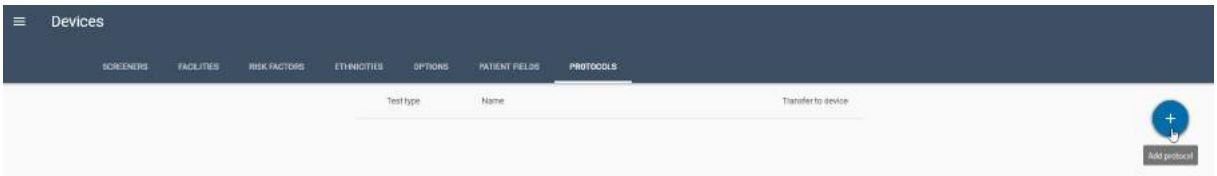
- Patient ID (mandatory by default)
- Last name
- First name
- Sex
- Consent for screenng
- Consent for tracking
- Ethnicity

8.7 Protocols

Each device is delivered ready to perform one manufacturer default screening protocol for each test method that you purchased with your instrument (ABR, TEOAE, DPOAE). If you wish to review the parameters of other alternative protocols or transfer more than one protocol per test method to your device, you can add more protocols into this page and then review and select the desired protocols for transfer to the device.

8.7.1 Adding protocols to the list

The Protocol page is empty by default. To access a list of available protocols saved to the hard drive of your PC during HearSIM installation, select the Add protocol button



A Windows browser window will open directly to the location of the available protocols files saved to your PC. The filename will indicate whether the file is an ABR (ABRIS), DPOAE, or TEOAE protocol. Additionally the filename will give you some information about the protocols parameters that will help you choose which protocols you want to add to the page.

Name	Date modified	Type	Size
IEC	11/3/2020 12:05 PM	File folder	
ABRIS A00 CE-Chirp 35 dB nHL.hpd	9/8/2020 3:34 PM	HPD File	1 KB
ABRIS A01 CE-Chirp 30 dB nHL.hpd	9/8/2020 3:34 PM	HPD File	1 KB
ABRIS A02 CE-Chirp 40 dB nHL.hpd	9/8/2020 3:34 PM	HPD File	1 KB
ABRIS A03 CE-Chirp 45 dB nHL.hpd	9/8/2020 3:34 PM	HPD File	1 KB
ABRIS A04 Click 35 dB nHL.hpd	9/8/2020 3:34 PM	HPD File	1 KB
ABRIS A05 Click 30 dB nHL.hpd	9/8/2020 3:34 PM	HPD File	1 KB
ABRIS A06 Click 40dB nHL.hpd	9/8/2020 3:34 PM	HPD File	1 KB
ABRIS A07 Click 45dB nHL.hpd	9/8/2020 3:34 PM	HPD File	1 KB
ABRIS A08 CE-Chirp 25 dB nHL.hpd	10/20/2020 3:50 PM	HPD File	1 KB
ABRIS A09 Click 25dB nHL.hpd	10/20/2020 3:50 PM	HPD File	1 KB
DPOAE D00 2-5 kHz, 3-4, SNR 6 dB.hpd	9/8/2020 3:34 PM	HPD File	1 KB
DPOAE D01 1.5-4 kHz, 3-4, SNR 6 dB.hpd	9/8/2020 3:34 PM	HPD File	1 KB
DPOAE D02 1.5-6 kHz, 3-5, SNR 6 dB.hpd	9/8/2020 3:34 PM	HPD File	1 KB
DPOAE D05 1.5-6 kHz, 3-6, SNR 7 dB.hpd	9/8/2020 3:34 PM	HPD File	1 KB
TEOAE T00 1.5-4 kHz, 3_4, SNR 4 dB.hpd	9/8/2020 3:34 PM	HPD File	1 KB
TEOAE T01 1.5-4 kHz, 2_4, SNR 6 dB.hpd	9/8/2020 3:34 PM	HPD File	1 KB
TEOAE T02 1.5-4 kHz, 3_4, 80 dB SPL.hpd	9/8/2020 3:34 PM	HPD File	1 KB

For example, the ABR protocol names will include information about the stimulus, that is, whether the stimulus is a CE-Chirp (our default) or a Click and the stimlus intensity.

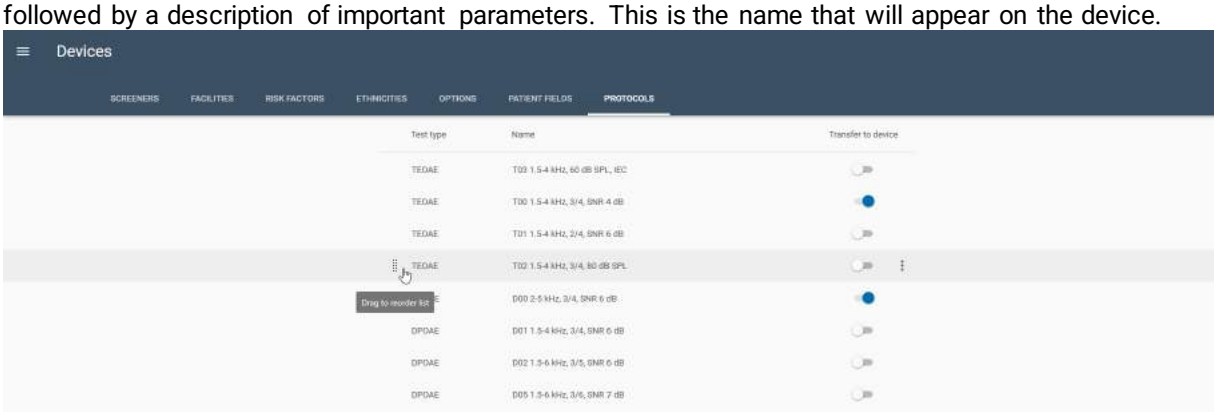
For DPOAE or TEOAE protocols, the filename will include information about the frequency range tested, the number of frequencies required to pass compared to the total number of frequencies testes, and the required signal to noise ratio for a passing result.

The protocols contained in the IEC folder are intended to be used for type testing. They are not recommended for general screening purposes.

Select each protocols that you want to add to the page and select the **Open** button at the bottom of the browser window.

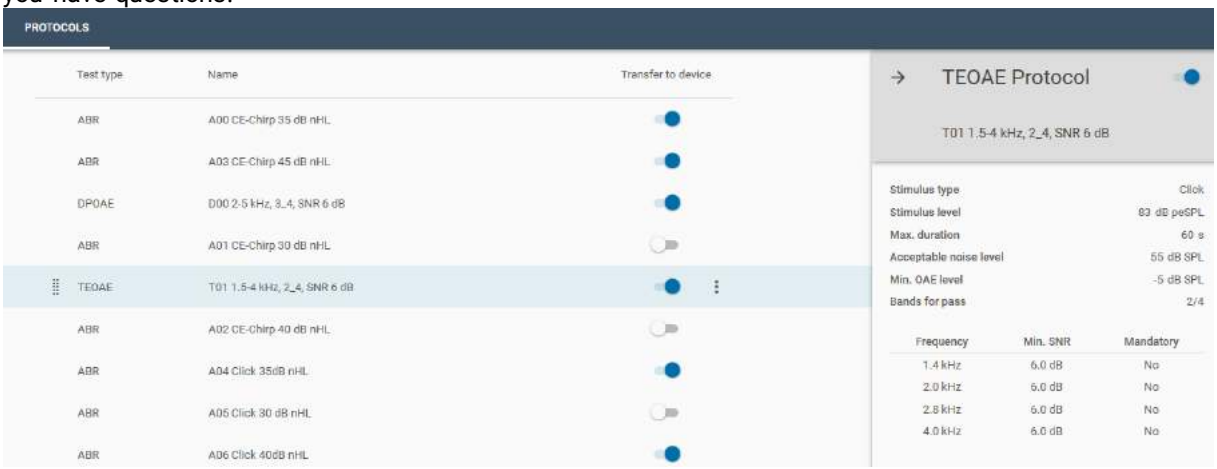
8.7.2 Test type and Name

Once added to the Protocols page, the protocols are displayed in the list described by their test type (ABR, DPOAE or TEOAE) and then a name that contains a unique identifier (A00 or D01, for example) followed by a description of important parameters. This is the name that will appear on the device.



Protocols identified as A00, T00 and D00 are the manufacturer default protocols for ABR, TEOAE and DPOAE, respectively.

Select a protocol by clicking on it to open a more detailed description of the parameters defined in this protocol. More information about the protocols provided with HearSIM™ can be found in separate documentation associated with your device. Contact your representative or the device manufacturer if you have questions.



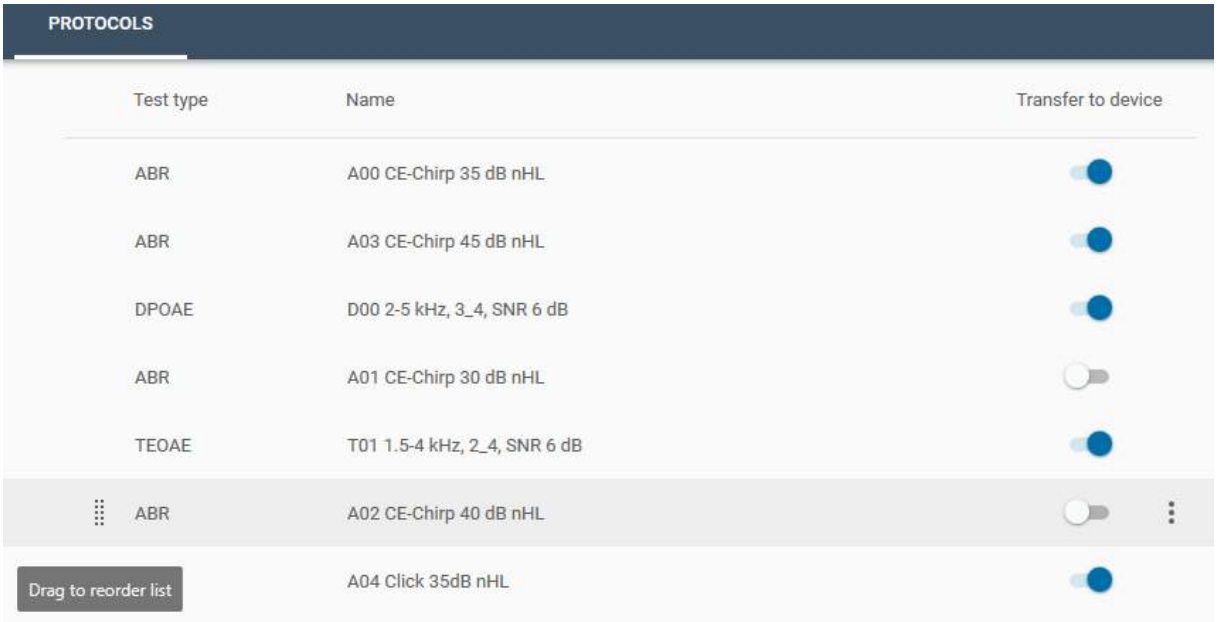
8.7.3 Active or Inactive for transfer to device

An **Active** (or Inactive) control can be set for each protocol. Only active protocols in this list will be transferred into the device. Protocols sent to the device which are not supported by the licenses purchased with your system will not display on the device.

8.7.4 Order

The order of the list can be modified here before it is transferred to the device. For example, you may want to place the names of protocols you perform most commonly at the top of the list.

The **Drag** control appears in front of the test type/name when you hover the mouse over a protocol row. You can click and hold the Drag control and move and drop the protocol to a different position in the list.



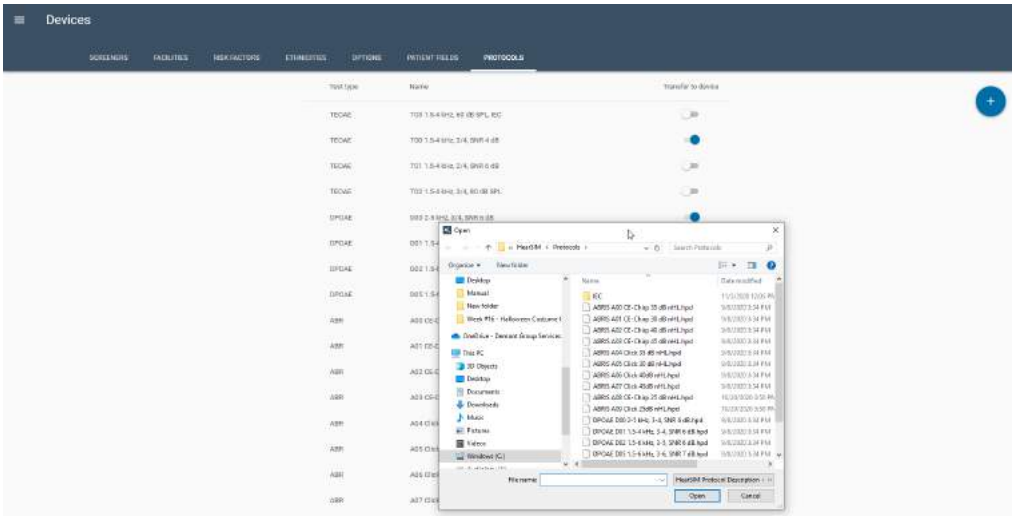
8.7.5 Deleting protocols from list

If you wish to eliminate a protocol from the HearSIM™ list, select it by clicking on it and then select the **More options** icon to open a pop-up menu with a **Remove** control. Select it to delete the protocol from the list.

8.7.6 Custom protocols

The Protocols saved on your PC during installation are commonly used/requested protocols for each test type. It is possible for a newborn hearing screening program to request a custom protocol and the device manufacturer will attempt to comply with your request by providing a custom protocol file which you can add to this list.

To add a custom protocol that has been provided on request, select the **ADD** icon to open a browser screen in which you can define the path to which the custom file has been saved. After locating the file (with extension . hpd) and selecting it, select the Open button to add it to the list.



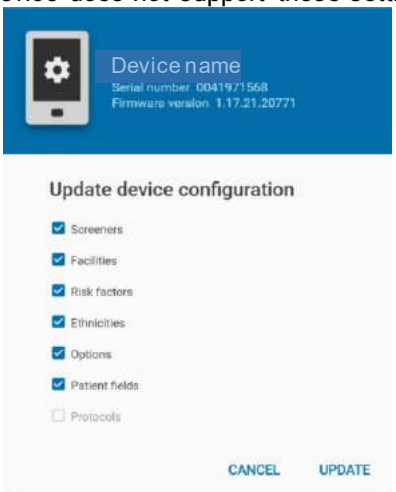
8.8 Transferring custom settings to device

After you have customized your device settings, including the desired protocols, you can transfer them to your supported instrument. Connect the device to the HearSIM™ PC with the provided USB cable. Enter the Device settings menu in HearSIM™ .

If patient data is present on the device you must first transfer the data to HearSIM™ before you will be able to transfer your new settings.

When the device graphic with a gear symbol in the center ap , then the device is ready to receive the new settings. Click on the icon to open the "update device configuration" window.

If the device graphic with the gear symbol has a bar drawn through the gear , then the connected device does not support these settings.



Select the checkboxes next to the settings you wish to transfer. Select the Update control to proceed with the transfer. Reboot your device after the transfer for the new settings to take effect.

All previous settings on the device will be overwritten with the new settings.

8.8.1 Incompatible device settings

During transfer of settings to the device, checks are performed to insure that related settings are set appropriately so the device will run smoothly.

For example, the option of Screener Login requires that there is a list of screeners defined and at least one is enabled in the Screeners page.

The Test Fields option requires that there are Screeners enabled and that there is at least one Facility in the configuration list.

At transfer of settings to the device, if there are inconsistencies found, then some Options will be automatically disabled and will not transfer to the device. A message will appear informing you that the option was disabled.

9 Administration

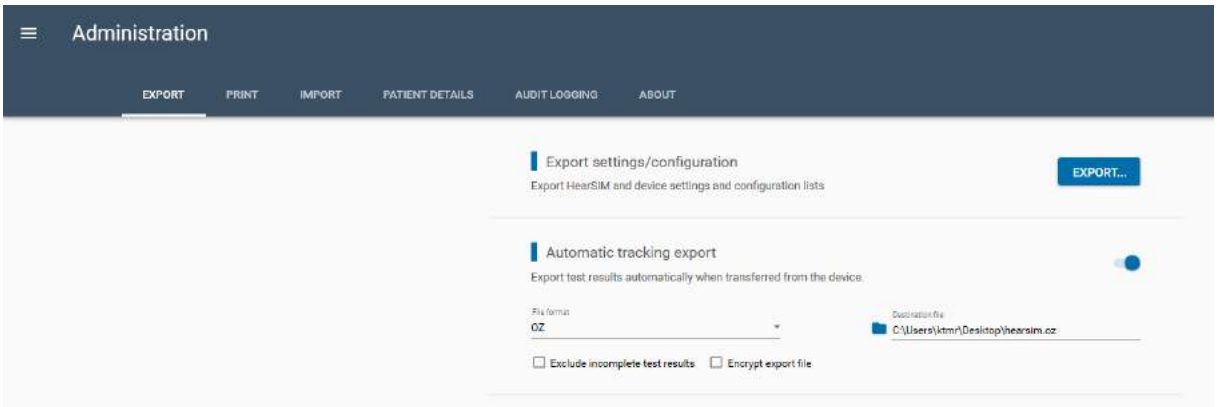
Tabs in the Administration section allow setup of preferences related to:

- Export of test data or HearSIM settings
- Report print details
- Import of HearSIM settings
- HiTrack pick list import
- Patient fields that will display and be mandatory

A tab is also available to view audit logging information regarding changes that have been made to patient or test data.

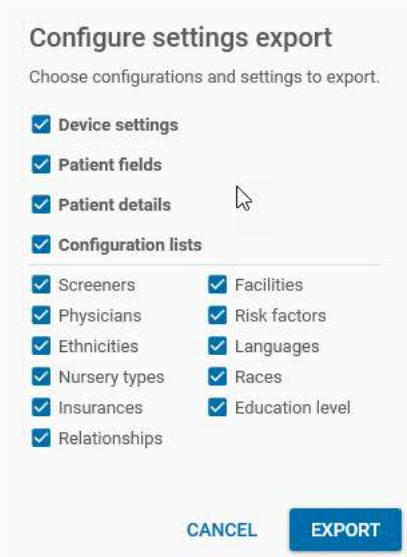
The About tab displays information about software versions.

9.1 Export



9.1.1 Export settings/configurations

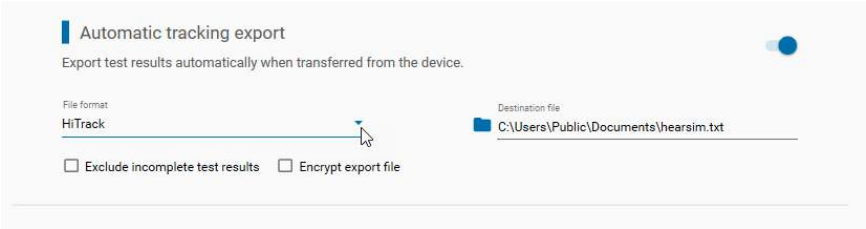
If you would like to share the configuration and device settings to another PC, select the Export button in the Export settings/configurations area. Then select the settings and configuration lists you would like to share.



After making your selections, choose the Export control that will open a Windows Save As window so that you can choose the destination path to which you want to save the file. The filename is provided automatically as “Configuration. hsim”. You can take this file to another PC and import it to avoid manual entry of lists and settings.

9.1.2 Automatic tracking export

This function can be enabled if you want to automatically save the data transferred from your device in a tracking file.



9.1.2.1 Automatic tracking export – on/off setting

If you want to export newly transferred screening data to a tracking file immediately and automatically after the transfer, enable this setting. When the setting is enabled then additional settings become available. These settings are recalled when the program is closed and relaunched so the setup is required only one time.

9.1.2.2 File format

Use the drop down to select the format for the file that is created. The choices are:

- HiTrack
- Oz
- HearSIM XML
- CSV

9.1.2.3 Destination file

Select the Folder icon preceding the field to open a browser tool. Set the destination path for the file. Default filenames will be present for all formats.

This field must contain not only the destination path but also must contain the filename. Default filenames are entered automatically. You can modify the path and filename but be sure that the full information is entered. Transfer of data into an tracking file will not be successful if the full path statement and filename are not present in this field.

9.1.2.4 Exclude incomplete results

Select this checkbox if you prefer that tests with Incomplete results are not exported into the tracking file. This means that only screening tests with either a Pass or a Refer result will be exported.

9.1.2.5 Encrypt (decrypt) export file

Select this checkbox if you prefer that the tracking file will be encrypted so that personal health information is not saved in readable form in the file.

A decryption tool (DecryptionTool. exe) is provided in this path during HearSIM installation: C:\Program Files (x86)\HearSIM. This tool must be used to decrypt an encrypted tracking file before it can be open and read in its intended application.

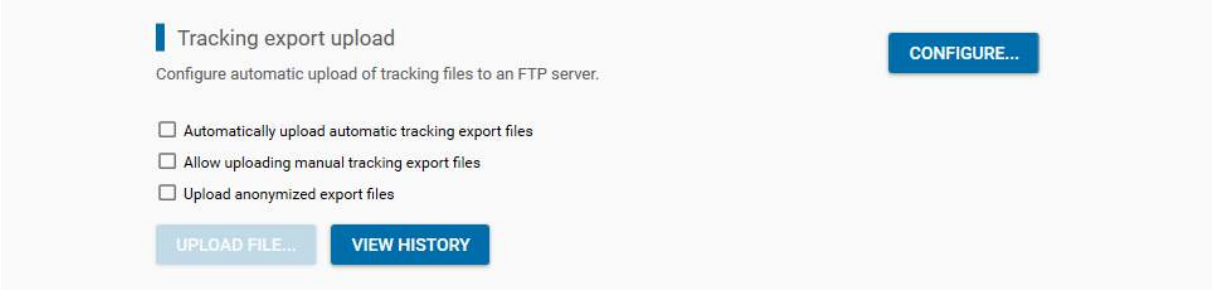
The decryption tool requires selection of the encrypted file and setting of the path for the decrypted file in order to decrypt it.

If you routinely use HiTrack Merge Companion or OZ Telepathy installed on the same PC as HearSIM™ to automatically merge your Hitrack or OZ tracking file into those 3rd party databases upon successful logon, you should not enable encryption of the tracking file. If you do enable encryption you must first use the tool to decrypt the file before you run HiTrack Merge Companion or OZ Telepathy.

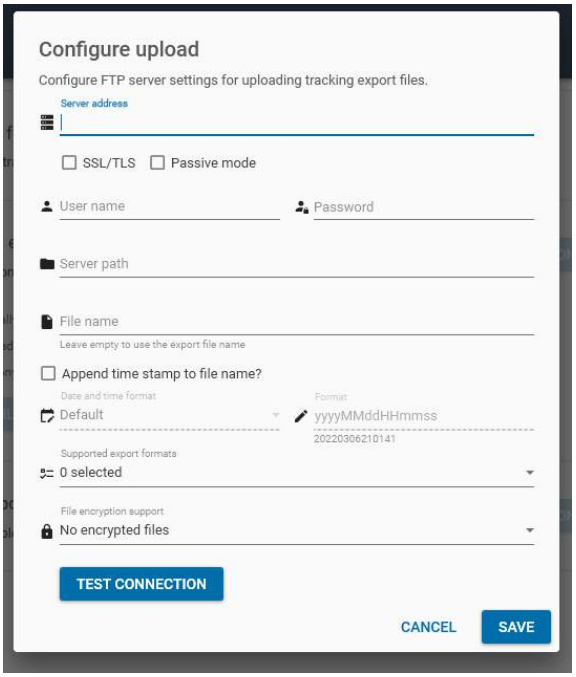
9.1.3 Consent for Tracking

Enable this setting to automatically anonymize patient data in tracking export files in case the patient did not agree to the tracking of the hearing screening.

9.1.4 Tracking export upload



With this feature you're able to set up a FTP-server connection directly out of the HearSIM™ application to transfer tracking export files to a dedicated FTP server.



You can configure the server address and enter your credentials for connecting to the FTP server. Enter the path on the server where the tracking files should be written to. Specify the name that your upload file should have for the FTP server. You can chose if a time stamp should be appended to the specified file name and configure that time stamp in more detail.

Select which tracking file formats you want to support and if encrypted files should be used.

You can test the connection to the FTP server.

9.1.4.1 Automatically upload automatic tracking export files

Select this option if you want the automatic tracking export files to be uploaded to the FTP-server immediately after they were created.

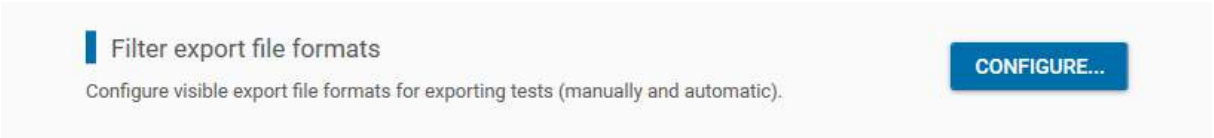
9.1.4.2 Allow uploading manual tracking export files

Select this option if you want to allow the upload of manually created tracking export files.

9.1.4.3 Upload anonymized export files

Select this option if you want to upload export files anonymized.

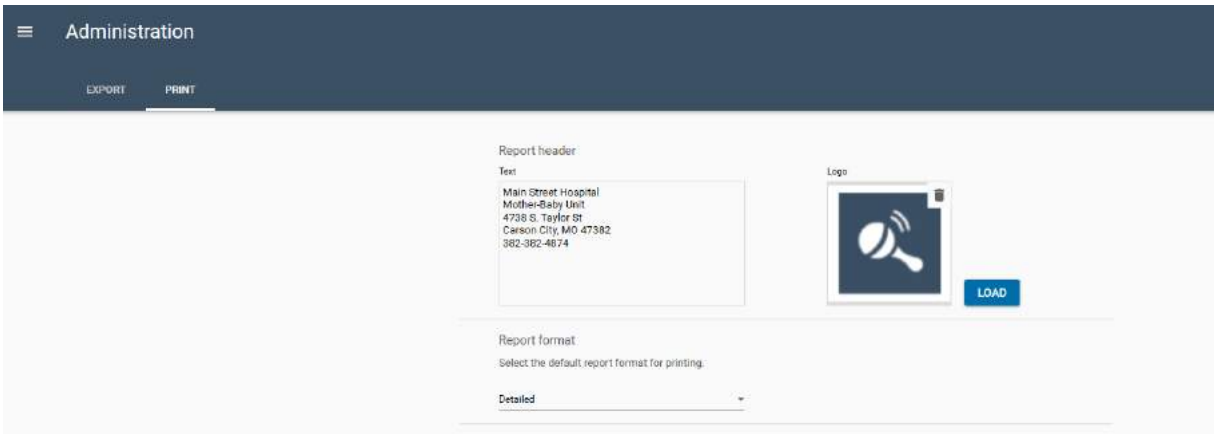
9.1.5 Filter export file formats



Here you can chose which tracking export file formats should be available for the users of this HearSIM system.

9.2 Print settings

Select the Print tab to define a report header and load a logo file that will print out on patient list and test reports and to select the type of report format you prefer.



9.2.1 Text

The text area permits input of multiple rows of text each with a maximum of 50 characters. It will be fixed in place on the top left side of the reports.

9.2.2 Logo

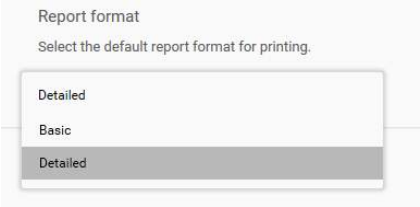
A logo file can be selected in a browser opened by selecting the **Load** button. The logo will display on the upper right corner of the print-outs.

9.2.2.1 Delete logo

If you want to remove the logo from the reports select the **Delete** icon in the corner of the logo display area. Additionally, you can select the **Load** button and choose a different logo file.

9.2.3 Report format

The Report format control allows you to select your preference for the report template you want to print for patient reports. You can select from the choices of Basic or Detailed.



A basic report prints some of the patient demographics plus the following information for each test you select:

- Test ear
- Result
- Test date & time
- Test type
- Screener name
- Facility

A Detailed report includes these fields but also prints out additional information that may include some of these fields:

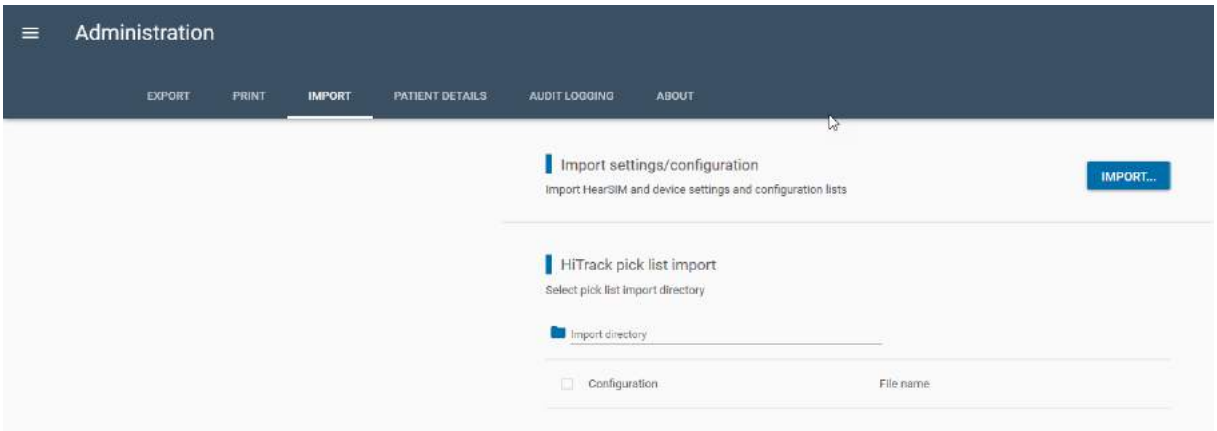
- Test duration
- Artifact %
- Additional measured values or test conditions (varies by test type)
- Device name and serial number
- Transducer type & serial number
- Test protocol name
- For OAE tests, bar graph showing OAE and Noise amplitude values
- For ABR tests, a graph showing progress of the test toward passing over time

9.2.4 OtoAccess® Preview/report creation

Enable this setting if you want to see previews and reports in the OtoAccess® Database interface. By default this setting is disabled to save memory in the database.

9.3 Import

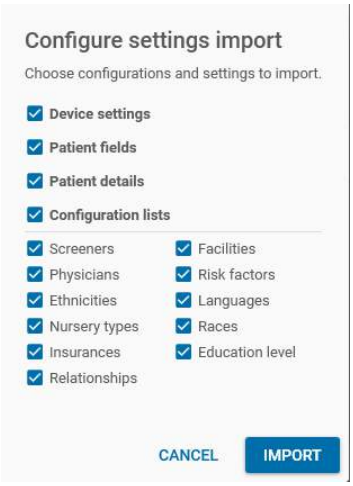
See the About tab to review information about the software manufacturer and version.



9.3.1 Import settings/configurations

If you would like to copy the configuration and device settings from another PC from which the settings have been exported (see section 9. 1. 1), select the Import button in the Import

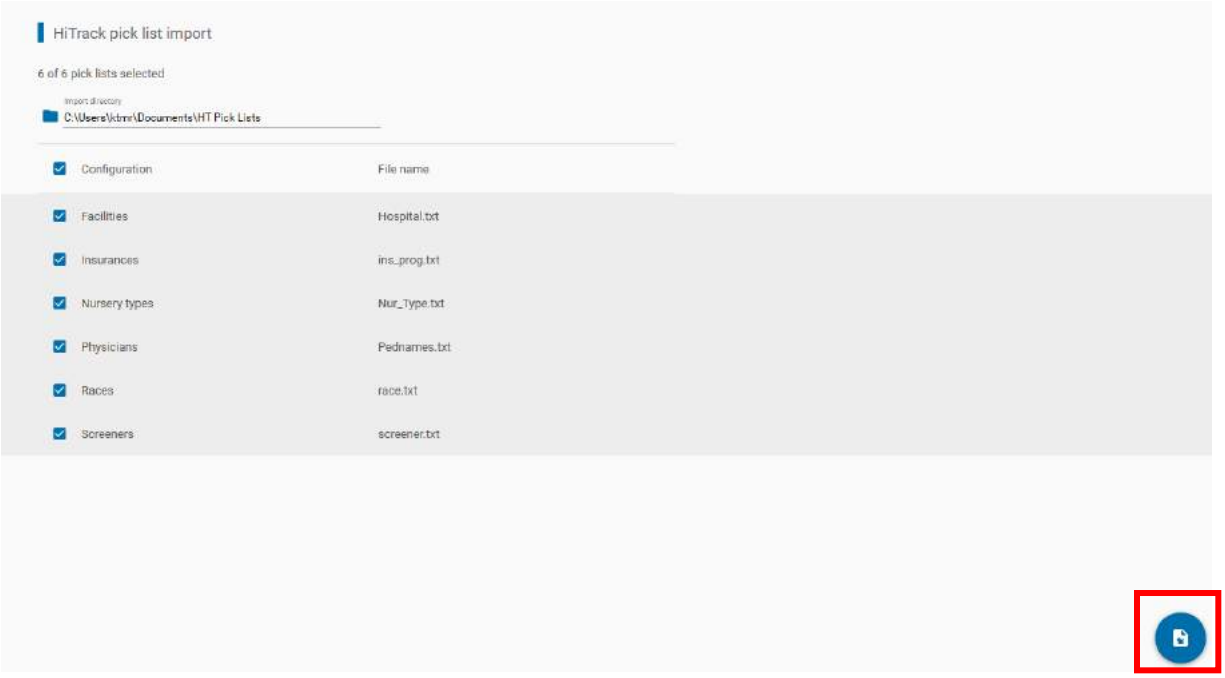
settings/configurations area. Then select the file that was created from the original PC. The filename will have the extension "*. hsim".



Select the categories you want to import using the checkboxes and select **Import** when your preferences are set.

9.3.2 HiTrack pick list import

Browse to the Import directory in which the HiTrack Pick List flat files reside. The program will detect which pick lists are present in the path and display a list of the available lists.



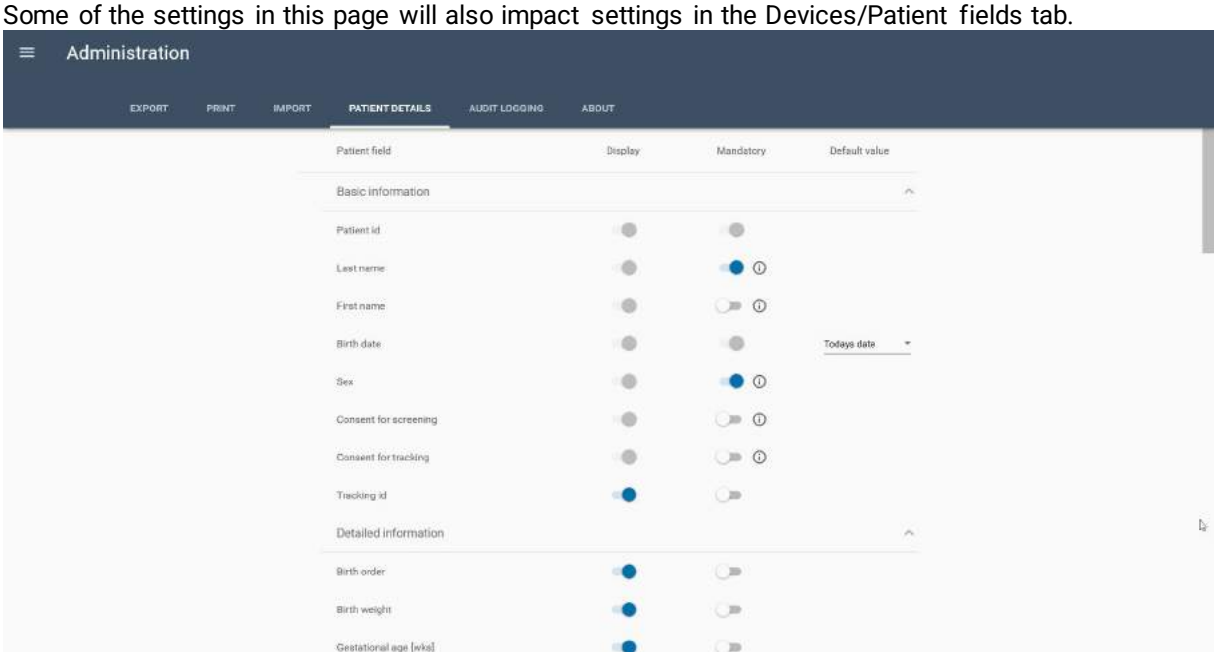
Use the checkboxes to choose the desired pick lists for import. Click on the Import control in the bottom right corner to execute the import.

9.4 Patient details

The Administration/Patient Details tab allows customization of the patient fields that will display in the Detailed information section and the Contact Info section in the Patient lists. These settings will also apply to the patient fields displayed on your device.

Additionally, fields can be set to mandatory for completion before saving of the patient is permitted.

Some of the settings in this page will also impact settings in the Devices/Patient fields tab.



Basic information fields are enabled by default and cannot be disabled for display, but can be set to mandatory based on your preferences.
Detailed patient information as well as Mother's Information and Alternate Contact's information can be completely customized to your preferences.

9.4.1 Default value fields

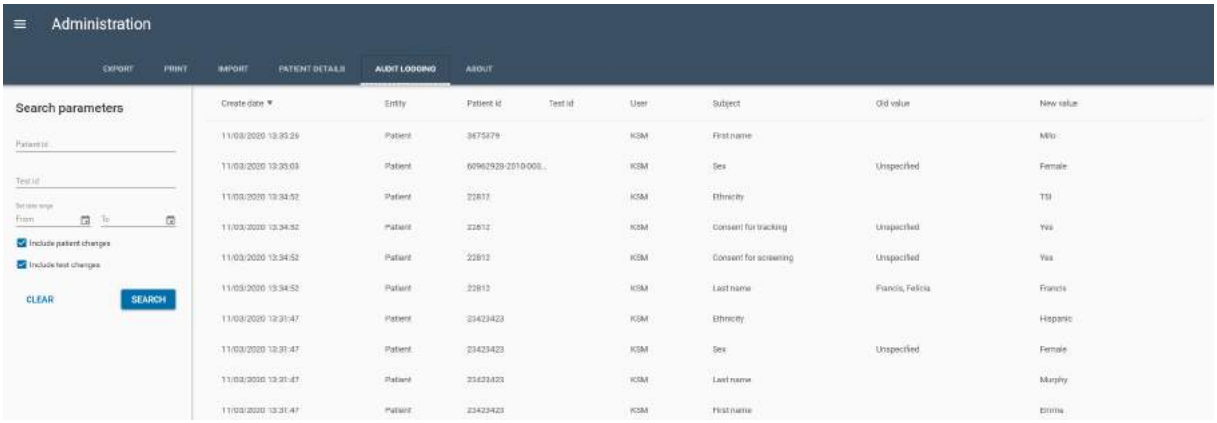
The Birth date field has an additional setting that can be customized to your preference. The default value can be set to "Today's date" so that the value of the current date will be present in the field by default when a new patient is created. The date can be changed by selection of the calendar control to choose a different date.

The default value of "Empty" will ensure that no date is pre-entered into the field and the user must select the birthdate.

9.5 Audit logging

Choose this page to audit changes to the database including information about:

- Time & date
- Entity (patient or test)
- Patient ID
- Test ID
- User
- Subject
- Old value (when an edit was made)
- New value (when an edit was made)



9.5.1 Search parameters

Search parameters can be defined to focus on locating specific information for audit purposes. Once you have defined the search parameters, execute the search by selecting the **SEARCH** button.

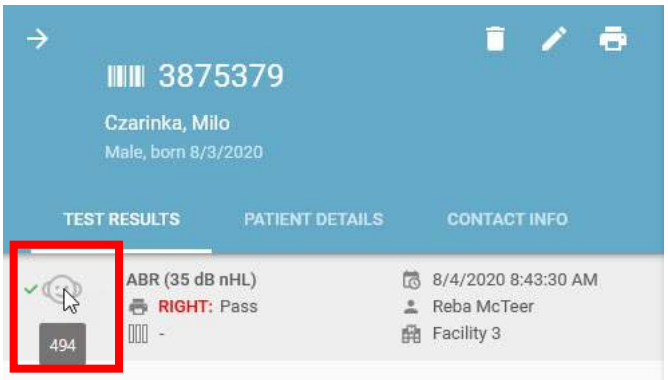
Use the **CLEAR** button to remove the search parameters.

9.5.1.1 Patient ID

Enter in the Patient ID to find information regarding a specific patient.

9.5.1.2 Test ID

Enter in the Test ID to find information regarding a specific test. The Test ID can be found in the Test Results tab by hovering the mouse over the graphic of the baby's head for the desired test.



9.5.1.3 Date range

Enter in a From and To date range to find information for a specific time period.

9.5.1.4 Include patient changes

Select or deselect the checkbox to reflect your preference for finding changes to patient information.

9.5.1.5 Include test changes

Select or deselect the checkbox to reflect your preference for finding changes to test information.

9.5.1.6 Export audit log

Export the audit log for archiving and reviewing later.

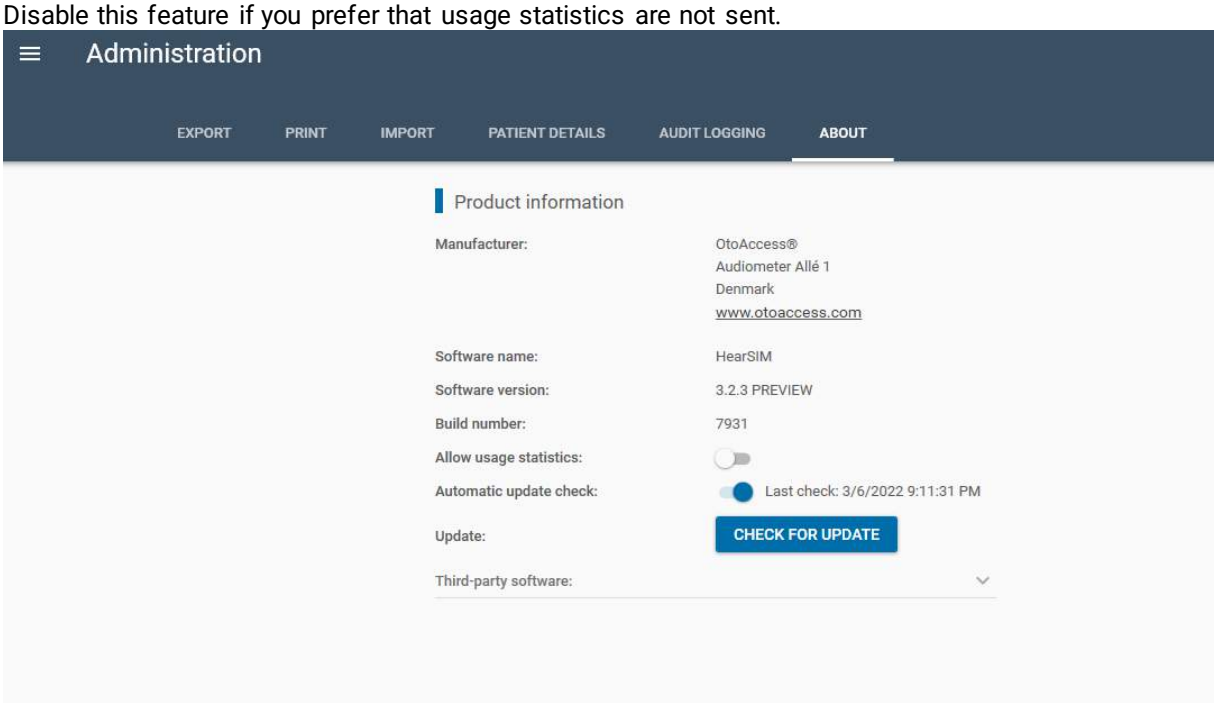
9.6 About

See the About tab to review information about the software manufacturer and version.

9.6.1 Allow usage statistics

Anonymous usage statistics are sent to the HearSIM manufacturer to assist with future development plans when this feature is enabled and the PC is connected to the internet.

Disable this feature if you prefer that usage statistics are not sent.



9.6.2 Update

When a new update for either the HearSIM™ application or the firmware of your device is available it will be displayed here. If you disabled the update function in the installation setup you will not see this function here.

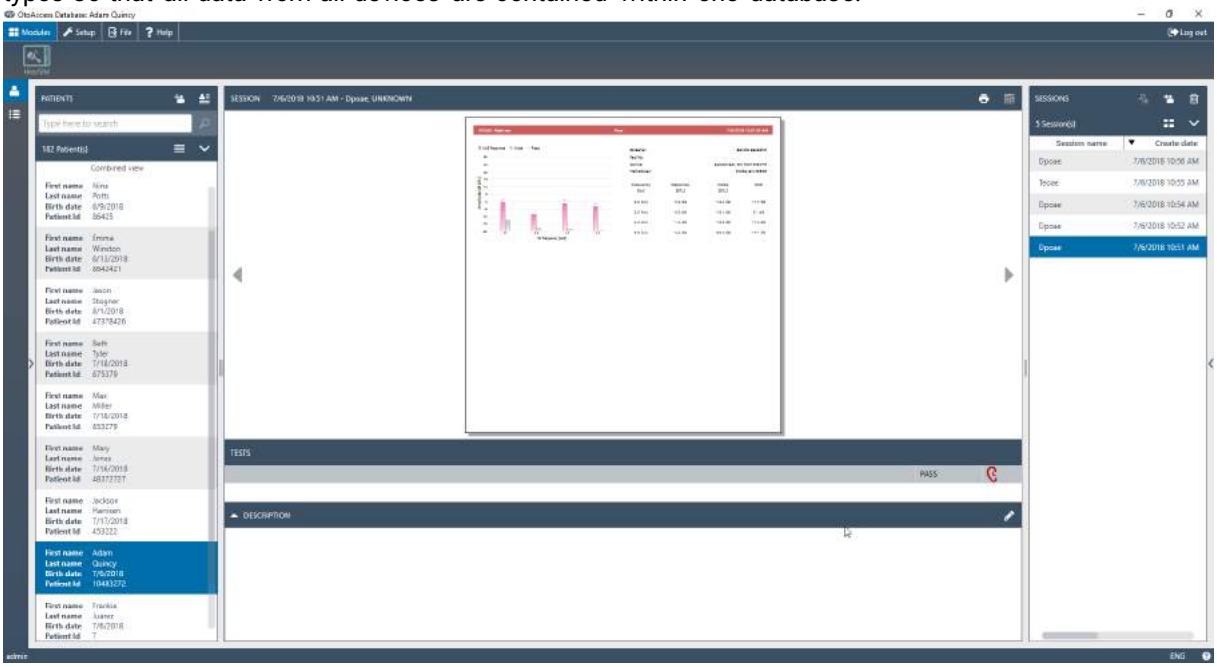
10 OtoAccess® functions

Installation of OtoAccess® places two short-cut icons on the PC desktop. One is named OtoAccess® Database and the other is named OtoAccess® Database Administration.

This section of the HearSIM™ manual intends only to briefly mention a few functions within OtoAccess® that may be most interesting to HearSIM™ users. A user manual is available that describes OtoAccess® functions in detail and the reader is referred to that manual for more information.

10.1 OtoAccess® Database

HearSIM™ patients and tests can be viewed in summary form within OtoAccess®. This function is generally only interesting to customers who use the OtoAccess® Database for other products and test types so that all data from all devices are contained within one database.



HearSIM™ only users are unlikely to view their newborn hearing screening data within OtoAccess®. The information displayed is limited to the most basic data. More detail is contained within the HearSIM™ module.

10.2 OtoAccess® Database administration

The OtoAccess® Database Adminstration utility program installed on your PC has functions that may be interesting to HearSIM™ users. The functions available are:

- Setting up User Accounts and authentication rules
- Setting up automatic database backup rules
- Restoring a previous version of the database
- Viewing a security log
- Setting up security log retention rules

Refer to the OtoAccess® Instructions for Use for more information regarding these functions.

10.2.1 User accounts

When HearSIM™ and OtoAccess® are installed HearSIM™-specific user profiles are available in the Users Accounts profile selection list.

The HearSIM™-specific account profiles are: Administrator, Supervisor, Editor and Viewer.

A HearSIM™ Administrator can perform all functions in HearSIM. At least one Administrator account is required.

See the table below for the restrictions imposed for the Supervisor, Editor and Viewer profiles.

	Supervisor	Editor	Screener	Viewer
Editing test info			No	No
Deleting tests	No	No	No	No
Editing patient info for existing patient				No
Resolving transfer conflicts of patient info				No
Delete patients	No	No	No	No
Viewing/editing Device settings	[2]	No	No	No
Viewing/editing Configuration settings		No	No	No
Perform manual export				No
Viewing/editing Administrator settings	No	No	No	No

[2] Supervisors can access, edit and transfer all device settings with one exception.

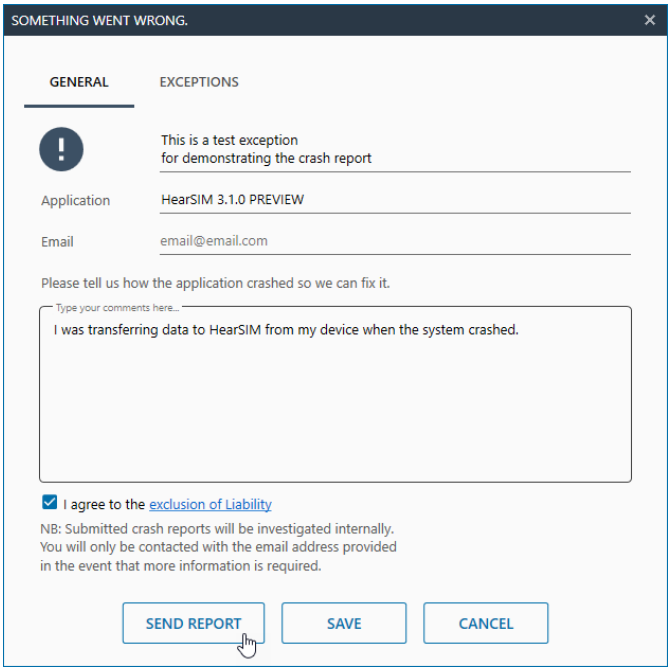
11 Troubleshooting problems & sharing feedback

Symptom	Cause	Suggestion
 Device detected but communication is not possible	• Incompatibility of device database with HearSIM™ application	• Contact device manufacturer customer support to ask about the "ERIS Repair Tool"
Device attached to PC but is not detected by HearSIM™	• Device display is showing one of the test screens • Device might have been in use and therefore not detected	• Press Home key on device to move away from a test screen • Switch device off and on again • Reconnect device with the USB cable
Some data did not transfer into HearSIM™ 	• HearSIM only supports transfer of data performed with these protocol names from this device type: ○ DP 4s ○ DP 2s ○ TE 32S ○ TE 64S	• Use only these protocols for data you want to transfer into HearSIM • Print out or otherwise save data that was acquired using protocols with a different name before transfer to HearSIM as all data is deleted from the device after transfer.

Contact your local manufacturer's representative for assistance when an issue is not resolved using these troubleshooting suggestions.

11.1 System crash

If a system crash occurs you will be prompted with a "Something went wrong" screen. Saving a file with information about the crash can potentially leading to improved software for a future release.

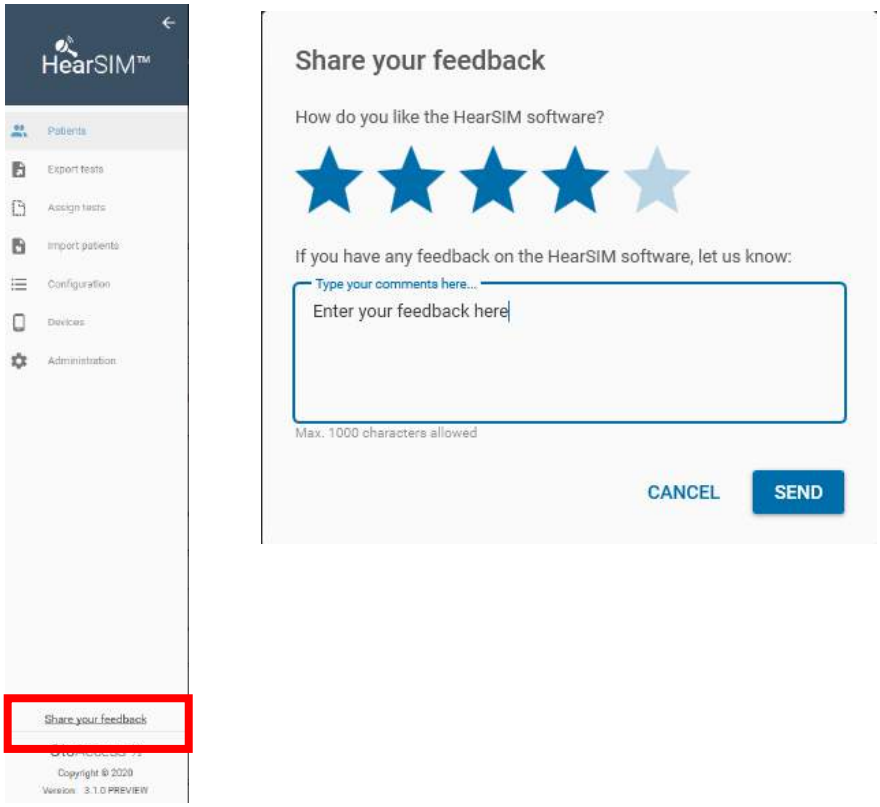


After saving the crash information and agreeing to the exclusion of liability, please **Send Report** or **Save** a crash file and send it later by contacting Technical Support so you can forward the file for review.

Information saved and transmitted in this crash report contains only information about the processes occurring around the time of the crash. No personal health information is saved or transmitted.

11.2 Sharing feedback

To provide feedback about the HearSIM™ application select the **Share your feedback** control at the bottom of the main menu when you are connected to the internet. Select **Send** to forward your feedback to the HearSIM™ manufacturer.


HearSIM™
Patients
Export tests
Assign tests
Import patients
Configuration
Devices
Administration
Share your feedback
Copyright © 2020
Version: 3.1.0 PREVIEW
Share your feedback
How do you like the HearSIM software?
If you have any feedback on the HearSIM software, let us know:
Type your comments here...
Enter your feedback here
Max. 1000 characters allowed
CANCEL
SEND

12 Ownership, warranty and disclaimer

12.1 Ownership

The HearSIM™ (hereinafter the "SOFTWARE") is solely owned by OtoAccess A/S. By purchasing the SOFTWARE the buyer is entitled the right of usage, but not ownership of the SOFTWARE. The SOFTWARE is to be used in accordance to the agreed terms of usage provisioned by OtoAccess®.

12.2 Copyrights

OtoAccess A/S ownership of the SOFTWARE is worldwide and is therefore, protected against any unauthorized copying of the SOFTWARE. Nonconformity of use of the SOFTWARE is strictly prohibited.

12.3 Restrictions

You may not:

- Reverse engineer or attempt in any manner to discover the source code of the SOFTWARE
- Attempt to defeat any mechanisms in the SOFTWARE, including those mechanisms responsible for password protection of data and limiting the number of concurrent users
- Rent, lease, sublicense or in any manner, copy or transfer (except as permitted above) the SOFTWARE
- Obscure or obliterate any OtoAccess A/S copyright or trademark notices which appear on the SOFTWARE, the documentation, the screen-display, or otherwise in connection with the SOFTWARE
- OtoAccess A/S specifically calls your attention to the fact that any violation or infringement of above restrictions will result in legal action
- The SOFTWARE can be used by any number of users, on any number of computers, and in any place, provided but not on more than one display screen at the same time

12.4 Limited warranty

OtoAccess A/S warrants that any physical media and physical documentation provided by OtoAccess A/S are free of defects in materials and workmanship. This limited warranty is effective for a period of ninety (90) days from the original purchase date.

If OtoAccess A/S receives notification within the warranty period of defects in materials or workmanship and determines that such notifications are correct, OtoAccess A/S will replace defective media or documentation.

Do not return any product until you have obtained authorization to do so from your supplier. The entire and exclusive liability and remedy for breach of this limited warranty shall be limited to replacement of defective media or documentation supplied by OtoAccess A/S and shall not include or extend to any claim for or right to recover any other damages, including but not limited to, loss of profit, data, or use of the SOFTWARE, or special, incidental, or consequential damages, or other similar claims, even if OtoAccess A/S has been specifically advised of possibility of such damages. In no event will OtoAccess A/S's liability for any damages to you or any other person ever exceed the lowest list price, or the actual price paid for the license to use the SOFTWARE, regardless of the form of the claim.

12.5 Disclaimer

OtoAccess A/S covers including but not limited to; all warranties, representations and terms and conditions, either expressed or implied; under specified terms of use and application of the SOFTWARE for its specific purpose. All other terms and conditions shall not apply.

Furthermore, OtoAccess A/S does not guarantee that the SOFTWARE or Documentation is free of bugs, or fulfill the relevant standards, requirement or needs of a user. In this case, all the warranties, guarantees and terms and conditions on all OtoAccess A/S-delivered physical disks and documentation shall be limited to the 90 days warranty period.

OtoAccess A/S is not liable for any third party's product, disks, SOFTWARE or documentation that is used in conjunction with OtoAccess A/S SOFTWARE or programs but is not directly manufactured or supplied by OtoAccess A/S.

12.6 General terms and conditions

Any change made to this Agreement shall be notified in writing, agreed, and signed between both parties, namely the purchaser of the SOFTWARE and a representative of OtoAccess A/S.

If the essential purpose of the above remedy (limited warranty) is not fulfilled, all other limited liability including the liability limits and exclusions of damage claims shall continue to apply

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