

Otobase

User Guide

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Technical service and support
Please contact your supplier.

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1 Introduction

Otobase is a simple and user-friendly database module for management of audiological data and patient information.

The functionality available depends on how Otobase is configured.

Available functions include:

- GDT integration and printing of Muster 15 reports
- EMR integration through HL7
- archiving in the native Otobase database.

Descriptions of screens and functions may differ from your configuration.

2 Intended use

Otobase is intended to be used by ENT doctors to link between PMS (Patient Management System)/EMR (Electronic Medical Record System) systems and measurement modules, such as Otosuite. Patient data is stored in the SQL database. In addition, Otobase can present the stored data in a report format.

3 Safety

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

When Otobase is used in conjunction with a medical device, make sure that all information and warnings in the manual for the medical device are followed. For safety specifics concerning test modules and medical devices, see the specific manuals.

4 Symbols used

Symbol	Standards Reference	Standard Title of Symbol	Symbol Title as per Referenced Standard	Explanation
	ISO 15223-1:2016 Reference no. 5.1.1 (ISO 7000-3082)	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Reference no. 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1, Clause 5.4.4 ISO 60601-1 Table D.1 symbol 10	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	IEC 60601-1, Table D.2 symbol 2	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	General warning sign	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

	N/A	N/A	N/A	Used in error message dialogs if software program fails. See the detailed information in the dialog box.
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5 Installing and configuring Otobase

For detailed instructions on installing Otobase, see the Otobase Reference Manual (English only).

Otobase cannot be installed, if Mirage GDT or Noah is installed on the PC.

- Uninstall Mirage GDT and Noah first.

5.1 Installing Otobase on a PC without Mirage or Noah

Starting the Otobase installation from installation media

1. Launch the installation media that contains the Otobase installation software.
2. If the content does not display automatically, navigate to the relevant drive or website.

Launching the installation

1. Close all Windows programs to avoid conflict with the installer software.
2. Double-click the file **setup.exe** to launch the installer software.
3. Follow the instructions in the installer software. The installer software installs Otobase and the Noah engine.



5.2 Launching Otobase the first time

The first time you launch Otobase, you will be prompted to enter the factory default user name and password

User name: ABC

Password: 123

After you log in the first time, change the factory default user name and password.

To add more users, see [User management](#) ► 7.

5.3 Configuration

The **Otobase Administration & Configuration Wizard** helps you to configure the database and its connection to the relevant database (i.e. Default or SQL Server database). It also manages the application localization settings, checks the database version, upgrades to the latest version, and updates Noah configuration.

You configure each Otobase installation as one of the following:

- Otobase Standalone Workstation
- Otobase Server
- Otobase Client

An EMR system can communicate with only one instance of Otobase. This instance is the Otobase Server and all other instances are configured as Otobase Clients or Otobase Standalone Workstations.

Start-up

The **Otobase Administration & Configuration Wizard** starts automatically the first time you run Otobase.

- Follow the on-screen instructions.

5.4 Language selection

Otobase supports a number of languages.

1. Navigate to **File > Change Language**. A list of supported languages is displayed.
2. Select a language from the list.
3. Restart Otobase for the change to take effect.

5.5 Licensing

Otobase and its features are license protected. For detailed information, see the Reference Manual.

- To register a license key, navigate to **Help > Register** and enter your license key.

5.6 Module management

The **Module Manager** displays a button for each installed Noah-compatible module.

- Click the relevant button to launch a module and conduct a measurement.

5.7 User management

Setting up users

1. Click **File > User Management > Users** to open the **User Manager** window.
2. In the **User Manager** window, click as needed to add, edit or delete users from the user list.

Note • If a role is not assigned to a user, then the functionality related to that role is not visible to that user.

5.8 User role management

Setting up user roles and user types

1. Click **File > User Management > Roles** to open the **Role Manager** window.
2. In the **Role Manager** window, click as needed to assign user roles to a particular user type.
Each user role has a predefined set of user rights. For example, the user management role can add, edit or delete users, and assign roles to user types.

Note • *If a role is not assigned to a user, then the functionality related to that role is not visible to that user.*

5.9 Changing the password

Otobase provides functionality for the user to change their own login password.

1. To change the password, click **File > User Management > Change Password**.
2. Follow the on-screen instructions.

5.10 Logging on/logging off

Automatic log-in using Windows session can be enabled/disabled by an administrator user using the Add/Edit User window for a particular user.

Automatic log on

This allows the user to setup Otobase for automatic log-on, so that they do not have to type a user name and password to log into Otobase. There are the following options:

- Use the user for the current Windows session for automatic log-on.
- Configure the Otobase native user for automatic log-on.

Logging off

1. Click **File > User Management > LogOff**.
If a user clicks the **LogOff** menu item, Otobase displays the log-in window, so that other users can log into Otobase.

5.11 HL7 Configuration

Interface Configuration

The Otobase EMR Connector for HL7 Interface must be configured in order to communicate with other EMR systems.

1. Click **Setup > EMR Connector > HL7 Configuration** to open the **HL7 Interface Configuration** window.

Work List Configuration

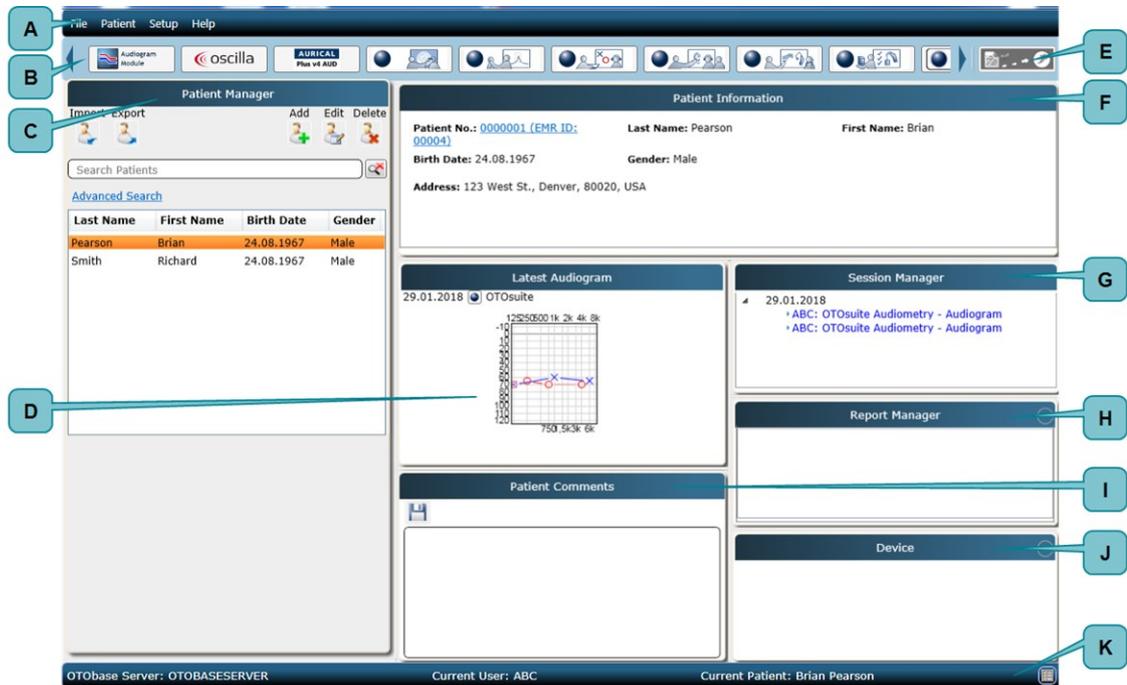
You can select which fields to include in the **Work List** window.

1. Click **Setup > EMR Connector > Work List Configuration** to open the window.

See the Otobase Reference Manual for more information.

6 Using Otobase

6.1 The Otobase main window



- | | |
|---|--|
| A. Menu bar | F. Patient Information |
| B. Module Manager | G. Session Manager |
| C. Patient Manager | H. Report Manager |
| D. Latest Audiogram | I. Patient Comments |
| E. Muster 15/Sign Off Patient/Print Preview button | J. Device Information - Fitting |
| | K. Status bar |

6.2 Patient management

The **Patient Manager** pane shows a list of patients available in Otobase. It allows you to add a new patient, edit existing patient details or delete a patient. When you select a patient in the list, the basic patient information is displayed in the **Patient Information** pane.

To edit patient details, click the **Edit Patient** icon in the **Patient Manager** pane.

Field Configuration

You can use the **Field Configuration** window to configure patient fields. You can:

- Activate/deactivate fields
- Mark fields as mandatory

- Assign fields to Main view or Advanced view
- Select fields for display in the **Patient Manager**

7 Muster 15

1. To generate a Muster 15 report, click on the **Muster 15** icon to the right of the **Module Manager** icons.
The report is generated based on the latest measurement. The **Reports** pane lists all of the saved Muster 15 reports for the selected patient.
2. You can configure the settings for the Muster 15 report in the **Settings** window. To open the window, click **Setup > Settings**.

8 Reports

Redesigning report templates

Report templates can be edited in Otosuite® Reports. Use the features provided by Otosuite® Reports to edit or create the template. See the Otosuite® Reports User Guide.

1. Open the template in Otosuite® Reports.
2. Edit the template or save the template as a new template.

Changing settings for report templates

1. From the Otobase main screen, select **Setup > Report Settings**.
2. The **Report Settings** dialog opens.
3. Select the folder with the report templates you wish to use: click **Template Folder** to browse.
4. Select the report template you wish to generate: click the **Select Template** drop-down list.
5. If needed, click to enable **Show report selector when signing off the patient**.
6. If you wish to apply view settings defined in Otobase to the selected report template, click to enable **Print using Otobase settings**.
7. Click **OK** to save the report settings.



Previewing reports

- To view a report, select **File > Preview Report/Preview Sign-off**.

Printing reports

- To print a report, select **File > Print report**.

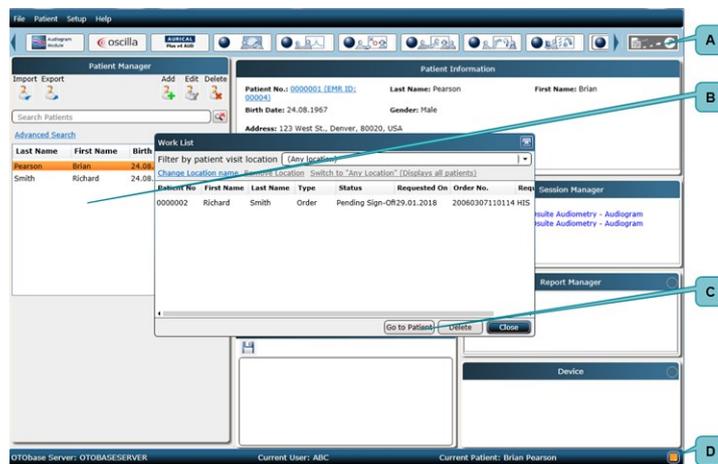
9 HL7 message handling

Descriptions of screens and functions may differ from your configuration.

Sending data from Otobase to an EMR system

EMR Connector functionality uses the HL7 protocol to communicate with an EMR system.

Handling work orders from an EMR



- A. Sign Off Patient button
- B. Patient list in Patient Manager
- C. Go to Patient button
- D. Pending Order Request icon

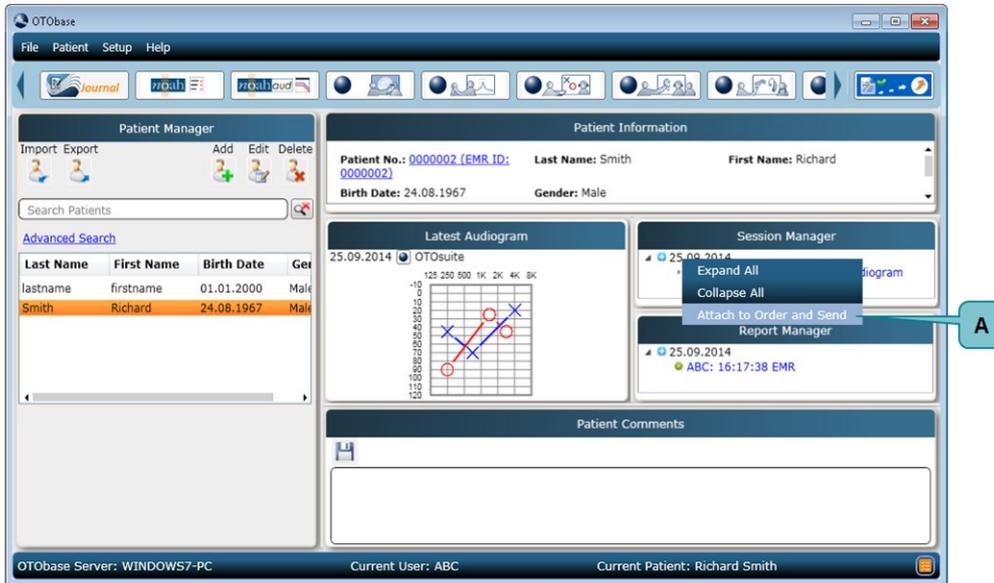
- After logging in, the **Work List** window appears. Click the **Pending Order Request** icon.
- Select the relevant patient in the **Work List**.
- You can limit the search to include patients who have visited a specific location: Select location from **Filter by patient visit location** drop-down list.
 - If needed, you can add or change location names: Click **Change Location Name**.
 - If needed, you can delete location names: Click **Remove Location**.
- If needed, show all patients: Click **Any Location (Displays all patients)**.
- Click the **Go to Patient** button. The patient appears selected in the list in the **Patient Manager**.
- Open the relevant test module by clicking it in the **Module Manager**.
- After conducting the required measurements, send the observation result to the EMR system by clicking the **Sign Off Patient** button.

9.1 Attaching an existing session to an order

If the order for a given test is not received – e.g. in case of no connection to the EMR system – the test can still be performed and then later sent to the EMR system.

When the order is received the session containing the measurements can be attached to it and sent to the EMR system.

In the Session manager, right click on a session row and then click **Attach to Order and Send**.



Caution • Steps should be taken to prevent data of a confidential nature to be accessible by others when patient data is stored outside the Ootabase system.

9.1.1 Session management

The **Session Manager** shows all the sessions for the patient that is selected in the **Patient Manager** pane. One session contains all of the measurements for the patient on one date.

10 HIPAA Logs

Important • Ensure that network share is accessible only to authorized personnel.

In Ootabase, the HIPAA Log is a time-stamped record of significant activities on the system. Recorded events can include users logging into and out of the system, as well as the commands that were issued by the user to the system while logged in such as creation/edit/deletion of a patient or measurement record.

In Otobase two types of Auditing are done:

1. Otobase Auditing
2. SQL Server Auditing

Configuration

To modify configuration settings such as enabling or disabling Otobase Auditing and SQL Server Auditing, navigate to **Setup > HIPAA Logs > Configuration**.

Report

To display the **Otobase Audit Log** or the **SQL Server Audit Log**, navigate to **Setup > HIPAA Logs > Report**.

11 Manufacturer

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11.1 Responsibility of the manufacturer

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

- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by the equipment manufacturer or personnel authorized by the manufacturer. ^{if:}
- The software is used in accordance with the instructions for use.

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