

Auditbase

Instructions FOR USE



Auditdata

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All information, illustrations, and specifications in this manual are based on the latest product information available at the time of publication.

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Trade name/Product name

AUDITBASE

Technical support

Please contact your supplier.

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1 INTRODUCTION	5
2 ABBREVIATIONS AND TERMS	6
3 SYMBOLS USED	7
4 COMPLIANCE WITH STANDARDS	8
5 INTENDED USE	9
5.1 Intended medical population and purpose	9
5.2 Intended user profile	10
5.3 Auditbase modules	11
5.4 Single current client	14
5.5 Limitations and constraints for using Auditbase	14
6 PRECAUTIONS AND SAFETY	15
6.1 Warnings, precautions and contraindications	15
6.2 Be aware	16
7 INSTALLATION, SETUP AND OPERATION	17
7.1 Installation and uninstallation	17
7.2 Setup	17
7.3 Logging on	18
7.4 Logging out	20
7.5 Password	20
7.5.1 Change password	21
7.6 Auto-log out (Screen saver)	22
7.7 Changing the User Interface theme	24
7.8 Modules	24
7.9 Noah4Auditbase subsystem	25
7.10 Sorting and saving listing screens	26
7.11 Column sort, word wheel search and scrolling	28
7.12 Toolbar and initial screen	28
7.13 Panes	30
7.14 User Favourites	31
7.15 Open, Close and Auto hide the Navigation Area	32
7.16 Pane Configuration	33
7.17 Printing and output redirection	34
7.18 Help	35
7.18.1 Contents	35
7.18.2 Documentation	36
7.18.3 Support	36
7.18.4 Profiling	38
7.18.5 About Noah	40
7.18.6 About Auditbase System	40
7.19 Accessibility options	41
7.20 Full operations guidance	42

8 TROUBLESHOOTING GUIDE	43
9 OPERATOR ROLES AND ACTIVITIES	48
9.1 Operator roles	48
9.2 Operator activities and recommended frequency	48
APPENDIX A	A-1
A.1 Server specifications	A-1
A.1.1 Hardware requirements	A-1
A.1.2 Software requirements	A-2
A.2 Client specifications (including Noah installation)	A-3
A.2.1 Hardware requirements	A-3
A.2.2 Software requirements	A-3
A.3 Client specifications (without Noah installation)	A-4
A.3.1 Hardware requirements	A-4
A.3.2 Software requirements	A-5
A.4 Security specifications	A-5
A.4.1 Encryption	A-5
A.4.2 Anti-virus and anti-malware	A-5
A.4.3 Windows authentications and passwords	A-6
A.4.4 Security of printouts	A-6
A.4.5 Port scanning	A-6
A.5 Network specifications	A-6
A.5.1 Network requirements	A-6
A.5.2 Naming Client workstations	A-6
A.6 Equipment and Network hazards and configuration changes	A-7
A.7 Information flow	A-8
A.7.1 Information flow – Diagram	A-8
A.7.2 Information flow – Assets	A-8
A.7.3 Information flow – Description	A-10
APPENDIX B	B-1
B.1 Manufacturer and System Data	B-1
B.2 Label signs interpretation	B-2
B.2.1 Label sample	B-2
B.2.2 Label interpretation for MDR	B-2

1 Introduction

This document's aim is to provide instructions on setting up, installing, and configuring the Auditbase software. It also includes essential information on safety measures and troubleshooting.

Auditbase consists of a number of modules reflecting working operations at a hearing Audiology clinic.

Depending on your purchased licenses, some of the modules described in this document might not be available in your version of the Auditbase software. Please contact your distributor to get more information on the licenses.

The Auditbase system modules are provided with online help. To activate this function, press F1, Shift+F1, or select Help in the menu.

Disclaimer:

This document is not intended to be a complete reference. For detailed information, please refer to the User and Admin Guides after installing the Auditbase software.

2 Abbreviations and terms

Term	Definition
AB	Auditbase
ABR	Auditory Brainstem Response (<i>a hearing test to determine how the inner ear (cochlea) and the brain hearing pathways are working</i>).
BSA	British Society of Audiology
OAE	Otoacoustic Emissions (<i>a hearing test to determine how the inner ear (cochlea) is working</i>).
QRP	Technology for building reports using Team Developer
RPT	Technology for building reports using Crystal Reports
IFU	Instructions for Use

3 Symbols used

Symbols are used in the system and in the documentation in places where this is required by regulations or where it is simply more convenient due to space restrictions.



General Warnings



Manufacturer address



CE

4 Compliance with standards

Auditbase application complies with the following standards:

No	Nomenclature	Standard name
1	ISO/IEC 27001:2013 +C1:2014 +C2:2015 (Edition 2)	Information technology - Security techniques - Information security management systems - Requirements
2	ISO/IEC 27002:2013 +C1:2014 +C2:2015 (Edition 2).	Information technology - Security techniques - Code of practice for information security controls.
3	EN 60601-1-6:2010 +AMD1:2013 CSV (Ed 3.1)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
4	IEC 62304:2006 + AMD1:2015 CSV (Edition 1.1),	Medical device software – Software life cycle processes
5	IEC 62366-1:2015 (Edition 1.0)	Medical devices - Application of usability engineering to medical devices
6	EN ISO 14971:2019 (Edition 3.0)	Medical devices - Application of risk management to medical devices
7	EN ISO 13485:2016 (Edition 3.0)	Medical devices - Quality management systems - Requirements for regulatory purposes
8	MDD - 93/42/EEC (M5/2007)	The Medical Device Directive (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices)
9	MDR (EU) 2017/745	Medical Devices Regulation (MDR)
10	IEC 82304-1:2016	Health software – Part 1: General requirements for product safety
11	DCB 0129 Amd 24/2018 Clinical Risk Management	Clinical Risk Management: its Application in the Manufacture of Health IT Systems

5 Intended use

Auditbase is a “Hospital Information System”

- For storage and transfer of electronic patient records, archiving of documents and data related to a specific patient.
- Various modules for recording, viewing and altering of clinical patient data.
- The stored information is partly intended for aiding in decision making for correct treatment.
- At the same time, Auditbase is not indicated as a sole means of diagnostics.

Product name	Trade Name	MDR Class	MDR Rule	GMDN	Basic UDI-DI
2003 Auditbase	Auditbase	Class IIb	11	61087	05711781DHF2003-12Z

5.1 Intended medical population and purpose

Auditbase Audiogram module (Type 2003 Auditbase)

The Audiogram Module is used by Audiology teams in public and private Hospitals. Audiology clinics provide services to patients with hearing loss.

The Auditbase Audiogram module is not indicated as a sole means of diagnostics.

The Auditbase Audiogram module is a software device intended for recording the measurements of hearing loss for aiding in decision making of the correct treatment for that hearing loss and suitability of the patient for a specific type of hearing instrument.

Auditbase Implant module (Type 2003 Auditbase)

The Implant Module is used by Implant teams in public and private Hospitals. Implant clinics provide services to patients with profound hearing loss.

The Auditbase Implant module is not indicated as a sole means of diagnostics.

The Auditbase Implant module is a software device intended for recording the measurements of hearing loss and speech and language discrimination for aiding in decision making of the correct treatment for a hearing loss in the determination of suitability of the patient for a specific type of (cochlear) implant.

Auditbase Surgery module (Type 2003 Auditbase)

The Surgery Module is used by ear surgeons in public and private Hospitals. Ear surgery clinics provide services to patients with profound hearing loss.

The Auditbase Surgery module is not indicated as a sole means of diagnostics.

The Auditbase Surgery module is used for recording what has been done at each stage of the patient pathway. The Auditbase Surgery module is not used in the process of making a diagnosis on the preferred treatment of the client's hearing condition, it is used for manually recording and monitoring the decisions and actions taken.

Auditbase ABR/OAE module (Type 2003 Auditbase)

The product is indicated for use by audiology teams in public and private Hospitals.

The Auditbase ABR/OAE module is not indicated as a sole means of diagnostics.

The Auditbase ABR/OAE module is used for manually recording the results of diagnostic or screening ABR and OAE measurements. Results of the measurements may be used in the process of making a diagnosis on the preferred treatment of the client's hearing condition.

Auditbase Questionnaire module (Type 2003 Auditbase)

The product is indicated for use by audiology teams in public and private Hospitals.

The Auditbase Questionnaire module is not indicated as a sole means of diagnostics.

The Auditbase Questionnaire module is used for manually recording the results of audiological questionnaires before and after treatment. Results of the questionnaires may be used in the process of making a diagnosis on the preferred treatment of the client's hearing condition.

5.2 Intended user profile

Auditbase audiogram module (Type 2003 Auditbase)

The Auditbase Audiogram module is typically used by the audiologist personnel in an audiological clinic. Typical user roles are the following:

- Audiologists;
- Users in the read-only (limited view) mode, typically in not audiology departments.

Auditbase Implant module (Type 2003 Auditbase)

The Implant Module is used by Implant teams in public Hospitals. Typical user roles are the following:

- Speech and Language therapists;
- Teachers of the Deaf;
- Audiologists;
- Implant surgeons.

Auditbase Surgery module (Type 2003 Auditbase)

The Surgery Module is used by ear surgeons in public Hospitals. Typical user roles are the following:

- Ear surgeons.

Auditbase ABR/OAE module (Type 2003 Auditbase)

The ABR/OAE Module is used by Implant teams in public Hospitals. Typical user roles are the following:

- Audiologists.

Auditbase questionnaire module (Type 2003 Auditbase)

The questionnaire Module is used by Implant teams in public Hospitals. Typical user roles are the following:

- Speech and Language therapists;
- Teachers of the Deaf;
- Audiologists;
- Hearing therapists.

Other modules in Auditbase are typically used by the personnel in an audiological clinic. Typical user roles are the following:

- Clerical staff;
- Audiologists;
- Hearing therapists;
- Repair specialists;
- Trainees;
- System administrators.

Users in the read-only (limited view) mode, typically in not audiology departments.

5.3 Auditbase modules

Patient Information

Includes advanced search function, option to store an assessment overview for a patient, merge of patient data, patient group definitions, GP and patient demographics, automated notices and more.

Visit screens, history and outcome recording for Implant teams

Information recording for Implant teams

Patient tests and questionnaires

Tests and questionnaires used by audiologists, Speech and Language Therapists and Teachers of the Deaf.

Professional contacts including GPs

Professional contacts including GPs, Health Visitors, schools etc.

Booking module, patient communication and resource planning

Comprehensive appointment administration including advanced search function, task related time allocation, waiting lists and appointment letters, group appointments, resource use and link to referrals.

Referral and Waiting list

Comprehensive, configurable and intuitive Waiting list and Referral modules with start, stop and suspend clock options to help comply with government pathway regulations.

Professional audiometry

There is the full ability to perform hearing tests using direct interfaces to manufacturer specific measuring equipment and to equipment with Noah compatible modules. Store and retrieve detailed measuring results including audiogram comparison using trend graphs. The audiometry module has multiple print options. Additional features include extended measurements, reports including audiogram and tympanometry data, detailed assessment plan for tinnitus patients or other issues (e.g. aural rehabilitation), protocols for vestibular testing and paediatrics

Other measurements

OAE and ABR measurements

Graphical speech

Outcome measurements for speech recognition applied in detailed graphical form with normative curves.

Journal module

Handling of patient journals including signed and non-signed journal texts, the option to set up auto generated journal actions, the use of journal templates, extensive formatting and text editing based on user rights.

Task list

Define prioritised patient related or general tasks and add reminders and other notes with reference to an individual member of staff or in general. Alerting can be set for on screen and/or at log in.

Treatment summary

Configurable patient overviews (e.g. selected Journal notes, audiogram picture, assessment or paediatrics).

Paediatric module

Selection of specific paediatric features such as automatic calculation of age based on date of birth, management of family and contact information, referrals, audiogram data and free text consultation.

Stock module

Handling of serial number and quantity controlled items including advanced search function and automated device issuing from Stock after fitting in Noah. Hearing instruments can be fitted using Noah compatible modules. Use a barcode reader for fast registration of stock. Other features include user secure editing of stock status, order and stock transaction overview as well as purchase orders, loan and returned instruments history and ear moulds.

Barcode stock verification

Verify stock with a barcode reader for a fast and easy way of doing inventory.

Auditbase Check-in

Patients can self-register on arrival via a touch screen.

Day view

An overview of patient and other appointments per location.

Location and Department Filtering

Handling of individual locations or departments with user or workstation related waiting lists, appointment/booking symbols, letters, stock types and documents specific to each location.

Import/export module

Electronic exchange of data for instance in connection with patient transfer to another Trust or exchange of data with other systems for further adaptation.

Repair module

Handling of repairs to/from external parties (standard version) and handling of internal as well as external repairs, invoicing, expedition and more (full version).

Documents and attachments module

Handling of documents and file attachments for clients as well as those not related to clients e.g. document templates; with the possibility of making client related documents based on templates.

Statistical module

In depth statistics for appointments, referrals and stock.

5.4 Single current client

Global client is always maintained regardless of which module is open. This is performed using an internal numerical patient identifier Patient ID independent of the external identifiers used by customers and users.

5.5 Limitations and constraints for using Auditbase

- Auditbase must be used by users who meet the Intended user profile described above.
- Auditbase must be used by trained users who have read and understood this Instruction for use.
- Auditbase is intended to be used in Audiological clinics.
- User full names registered in the system must be unique because Noah does not work for users with duplicated names.

6 Precautions and safety

6.1 Warnings, precautions and contraindications



Be sure to observe the safety requirements stated in this instruction, both during installation and use of this system.

- Be warned that Auditbase is intended to be used as part of an overall diagnosis and treatment process. Decisions should not be taken which could affect the safety of patients without reference to other ways and methods of assessment. Any findings should be confirmed with the patient before taking action and users should be alert to confirm any data with the patient which they suspect of being incorrect.
- The system the user is using has to fulfill the minimum system requirements in order to mitigate the risk that patient data cannot be read for the database where network latency is too high or the screen does not fit all the data where screen resolution is too low.
- PAS update: please ensure the client is the same as requested before saving.
- To avoid unauthorized persons accessing the system, make sure your password is secure enough in terms of length, complexity, and unpredictability and do NOT disclose it to anyone.
- For security, the System Administrator password must be changed at first use and must only be shared with persons nominated to make configuration changes. This password must be changed on a regular basis.
- If you have forgotten your password, you must contact your System Administrator immediately to change it. If you think you may have lost a record of it and someone else could have found it, then you must inform your System Administrator immediately.
- Double check you are assigning/associating correct rights/role, otherwise users can make inappropriate actions in the system.
- To prevent unauthorised access to patient data users must not leave their PC unattended.
- General search for a Client: be careful when exporting to CSV the results of client search as you might be running the risk of a PID (patient identifiable data) leak.
- When using Noah Fast data view, do not forget to close the Fast Data View document manually since Auditbase cannot close it automatically. Be careful with patient content, Auditbase cannot warn users that a Fast Data View document is still opened for a client when users select a second client.
- On the Client information screen, please ensure the e-mail address is correct; entering an incorrect e-mail can cause sending the client's data to a wrong addressee.
- Auditbase is intended as a system for all patients from young children to elderly adults. There are no contraindications indicating any groups of patients that it should not be used with.
- Users exporting the Onward referrals list to CSV must proceed with care when processing the file to avoid the loss/leak of patient data.

- Patient medical notifications must not be used as a single diagnostic tool. When onward referring a patient for further treatment, such notifications must be reviewed by qualified personnel alongside other patient data before any action is taken on the patient.
- Auditbase functioning cannot be impaired when the software is used with other medical devices such as cardio stimulators, high-frequency electro-surgery units, defibrillators, shortwave therapy equipment etc., and does not endanger the patient. Additional equipment that can be used with Auditbase must comply with the requirements of IEC 60601-1.
- Auditbase can work in combination with printers and barcode scanners. Auditbase will work safely with them and will not impair the specified performance of the devices where standard Windows drivers and software are used. There is a restriction that barcode scanners must be able to simulate typing on the keyboard and must be able to produce prefix and suffix additions to the information string.
- It is essential that the Business Process ensures that training is in place to all users before starting to use Auditbase.
- It is essential that the Business Process ensures that adequate resources are provided for client PCs according to the minimum system requirements. The Auditbase pre-install or pre-upgrade checklist must be accurately completed.
- Electronic instructions are provided instead of paper instructions. All users have access to the electronic version of the IFU available from the application itself. Users with access to a printer can therefore print a paper copy of the IFU themselves from the application.
- If the customer requires a paper copy of the IFU, it can be provided within 7 days of the user's request to the support@auditdata.com

6.2 Be aware


- BSA shadow masking symbols are not included in the Noah standard: therefore, they will not be transferred to Auditbase on saving the audiogram in Noah.
- When working in any module, before proceeding with reporting or treatment decisions, please make sure the correct client is selected to avoid making an incorrect report or treatment.

7 Installation, Setup and Operation


7.1 Installation and uninstallation

- For full step-by-step guidelines on how to install the Auditbase System, refer to the Auditbase Complete Installation Guide.
- Installation must be done by or with Auditdata support personnel assistance. Installation instructions can be found in the Complete Auditbase installation guide and Quick Auditbase installation guide available on the release CD.
- There are no specific interface system requirements to be considered at the installation time. Optional interface requirements are available and can be discussed with your Auditdata representative.
- Uninstalling Auditbase: See *Auditbase Complete installation guide*.
- Minimum and recommended client and server specifications are outlined in [Appendix A](#) of this document.

7.2 Setup

- The System Administrator referred to in this document uses the login SYSADM and a given password.
-  For security, this password must be changed at first use and must only be shared with persons nominated to make configuration changes. The password must be changed on a regular basis.
- Customers are recommended to employ Active Directory integration for login to Auditbase so that passwords are not in use, and they can employ multi-factor authentication to secure the Active Directory login.
- Immediately after the initial Auditbase installation, options for secure password configurations and auto-logout must be considered. See the corresponding sections below.
- Dependencies on other applications: Auditbase works with MS Word for processing documents, therefore, if processing documents is planned on the workstation, MS Word must be installed on that workstation,
- For details on how to configure Auditbase, see *Auditbase Admin Guide*.

7.3 Logging on

 It is essential that the Business Process ensures that training is in place to all users before starting to use Auditbase.

There are two ways to log into Auditbase:


- With an Auditbase account
- With a Microsoft Windows (Active Directory) account

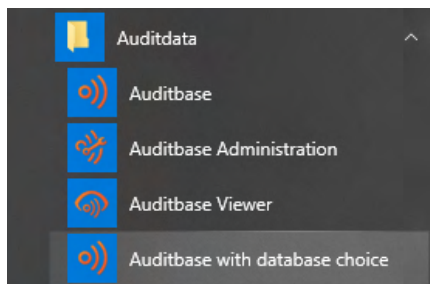
You can use only one type of account to log into Auditbase.

To be able to log in with a Microsoft Windows account, your System Administrator should have configured your Auditbase account to use your Windows credentials and enabled the Auto login for Windows authentication.

1. Log in using a Microsoft Windows account

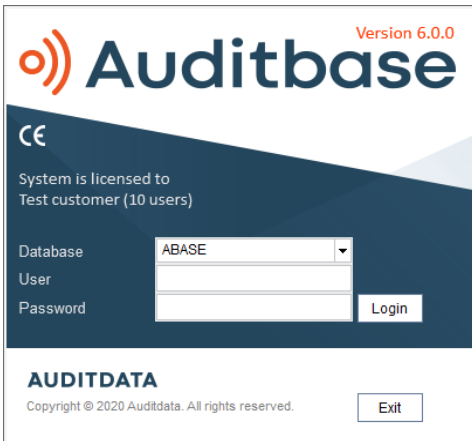
- Double-click on the Auditbase icon on your desktop
- Auditbase will log you in using your Windows credentials to the default database

If you want to log into a different database than the default database, you need to click the Windows icon () and go to **Auditdata > Auditbase with database choice**.



2. Log in using an Auditbase account

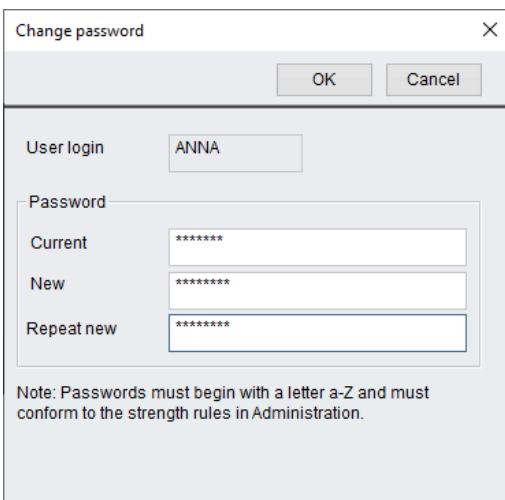
- Double-click on the Auditbase icon on your desktop
- Choose your **Database** name (usually ABASE)
- Enter your **Username** and **Password**
- Click **Login**



Security: The system locks out a user after some number of attempts to enter the wrong password (configured, typically 3). A record of this event is included in the log. Unlocking the user account must then be done by the System administrator.

2.1. Logging in for the first time

When logging in for the first time or the first time after the System Administrator has changed your password, a message will be generated requiring you to change your password before logging in.



If a quicker log in is required, your System Administrator can choose to load only the default module at start up. This will mean that opening subsequent modules will be slightly longer.

Symbols can be saved to the local PC which will mean that log in will again be slightly quicker. Your System Administrator can set up for the whole site, but this can be overwritten for a particular PC in Workstation Settings in the System Administration tool.

After logging on, if Noah does not initialize properly due to poor performing PC, when the Noah Modules navigation shortcut tries to populate or when going to open Noah, a message bar will appear stating the problem. A retry of the Noah initialization can be attempted from here by selecting the **Reinitialise** button.

If Auditbase or Viewer is opened directly from another system which passes the account and the password has been updated in that system and not in Auditbase, the login will fail and the new **Login** dialog will appear.

You may receive a message if a licence is already being consumed by this PC. One message where it is under your user name and you can clear it and another where it is under another user name and you should contact the System Administrator.

Login details are linked to the signatures which are used to identify what has been done with a patient, and by whom, throughout the database. If the **Username** and **Title history** is changed due to a name change or job change then the signature will be changed from the date forward of the change. This information relates to all journal, document, stock and client related information held within the database. The historical information is maintained the signature for the items.

If Single Sign On is being used and has been set up for your account, double clicking the icon will automatically log you on to Auditbase.

7.4 Logging out

From anywhere in Auditbase, not Noah, you can logout quickly by pressing F2 and the login window appears for another user to login. The system will prompt you to save any entered or edited data.

Pressing the F2 button also allows you to change user. This is useful if you work on a computer where someone else is logged in.

NOTE: If you have a dialogue box opened and/or data unsaved and have logged off, it will not be possible to change the user to another one except for Administrator.

As a System Administrator, you can log in as the previous user after the user has logged out. When a user has logged out of Auditbase, click on **Unlock**. This enables you to choose the Administrator option, where you enter your System Administrator password and then click **Unlock** again. You are now logged into Auditbase with the previous user's credentials.

When exiting Auditbase a confirmation appears **Are you sure you want to exit the application?** This can be disabled in Auditbase Administration.

7.5 Password

If you mistype your user name and password more than three times, the Auditbase system will shut down.

There is also now the option to Lock the user out of Auditbase should an incorrect password be entered more than a certain number of times consecutively. The number of incorrect passwords allowed is determined by the System Administrator. If a correct password is entered

then this resets the incorrect password count to 0. Should this happen the User account will need to be unlocked by the System Administrator.

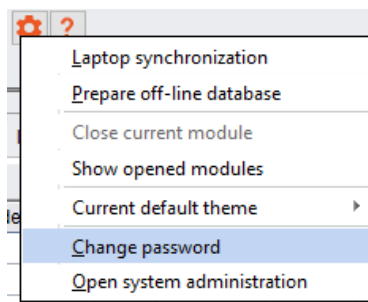
Moreover, the System Administrator may choose to lock out accounts which have not been logged into for a period e.g. 3 months. Should this be the case then contact the System Administrator to unlock the account.

If you press **Cancel**, the login window closes and the system returns to Windows.

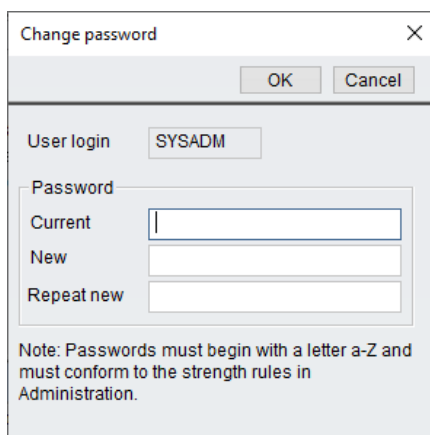
The system administrator manages the user name, password and expiration of password.

7.5.1 Change password

A user can change their password in Auditbase using the System settings -> Change password menu item:



In the opened dialog, the user needs to enter the current password, the new password, and repeat the new password:



Expiry of password

When a password will expire in less than 5 days (counted from the latest change of password), the user will be notified and asked whether to change the password now or login without changing the password.

If a password has expired, the user must change the password in order to access Auditbase. It will not be possible in any way to access Auditbase without changing the password. Please contact the system administrator to change your password.

Format of new passwords

- A password cannot be empty and is limited to 8 characters
- Old password must be entered in order to change it to a new one
- Passwords can only contain characters between A to Z and 0 to 9
- The first character in a password must be a letter from A to Z
- You might not be able to reuse old passwords – how far back the history goes depends on the site setup
- In the **Change password** window three mistakes in a row causes the window to close



WARNING: *To avoid unauthorized persons accessing the system, make sure your password is strong enough in terms of length, complexity, and unpredictability and do NOT disclose it to anyone.*

Lost or forgotten passwords

If you have forgotten your password, you must contact your System Administrator immediately to change it. If you think you may have lost a record of it and someone else could have found it, then you must inform your System Administrator immediately.

Strong Authentication

Strong authentication can now be employed in addition to the use of an Auditbase password. When activated in Auditbase administration, the user will be required to be logged into Windows using the strong authentication method set by the administrator, otherwise they will be refused access to Auditbase. Strong authentication could mean the use of a Windows smart card, biometric device or other method of logging into Windows.

Logging into Windows correctly will then allow a User to login to Auditbase.

7.6 Auto-log out (Screen saver)

Auditbase can be logged out temporarily manually or will logout automatically after a selected time if auto-logout is enabled to ensure that unauthorized persons cannot access the sensitive data in the system. Screen saver settings can be fixed as a site wide rule or per work station. Site wide settings are set by the System Administrator and workstation specific settings can be adjusted by assigned users with an Extended user right. For security reasons, the Screen saver should be used every time the work station is left unattended. When the screen saver is activated the Auditbase system is locked by the latest logged on user.

- Activate the screen saver manually by pressing **F2**.
- For automatic activation, settings should be defined in the System Administration tool.

- In the System Administration tool, you can decide if the screen saver automation should be **Disabled** or **Enabled**, and if so after how many minutes the screen saver should be activated.
- At activation, if no changes have been made, the **Login** window is presented with following options for proceeding:
 1. Unlock
 2. Login
 3. Exit

Unlock

- By pressing **Unlock**, the locked connection to the database is re-established (unlocked) and one of the options from the **Application locked** window should be selected to proceed:
- **Change user**
Another user can log on to the Auditbase system. A warning that the present user's unsaved data will be discarded will appear.

NOTE: If you have a dialogue box opened and/or data unsaved and have logged off, it will not be possible to change the user to another one except for Administrator.

Login

1. **Log in using a Microsoft Windows account**
 - Double-click on the Auditbase icon on your desktop
 - Auditbase will log you in using your Windows credentials to the default database
2. **Log in using an Auditbase account**
 - Enter user name and password of the user who was logged in at the time for the screen saver activation. The Auditbase system opens with the same status as before the screen saver activation.
If you enter the user name and password of a user other than the user who was logged in at the time of the screen saver activation, Auditbase system opens as a new instance without any data on the screen from the previous user

Exit

- A warning that the user's unsaved data will be discarded appears and the Auditbase system closes.
- After performing a correct login, the user returns to the Auditbase system and thus to the window/screen, as it was when the screen saver was activated.

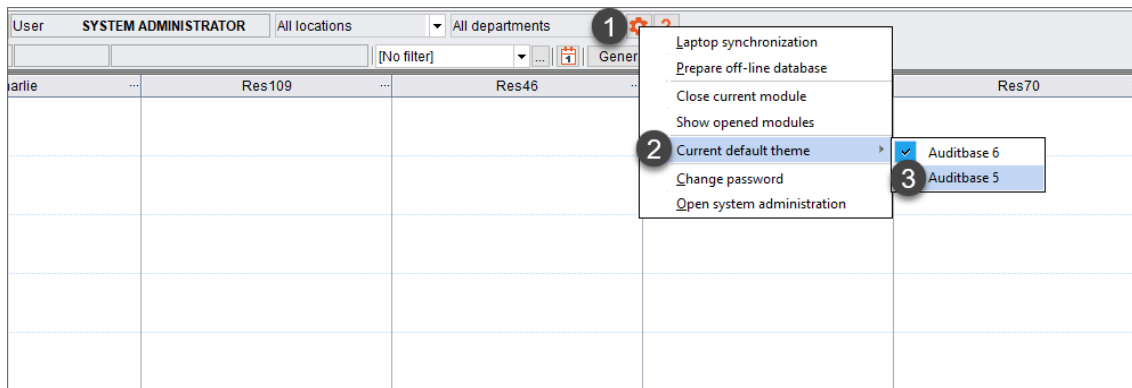
NOTE: The screen saver cannot be activated when Noah is running.

7.7 Changing the User Interface theme

When starting Auditbase in the new theme, you can always revert to the old theme as needed.

To change the theme:

1. In the **System toolbar**, click the Edit (Gear) icon
2. Go to **Current default theme**
3. Select **Auditbase 5**



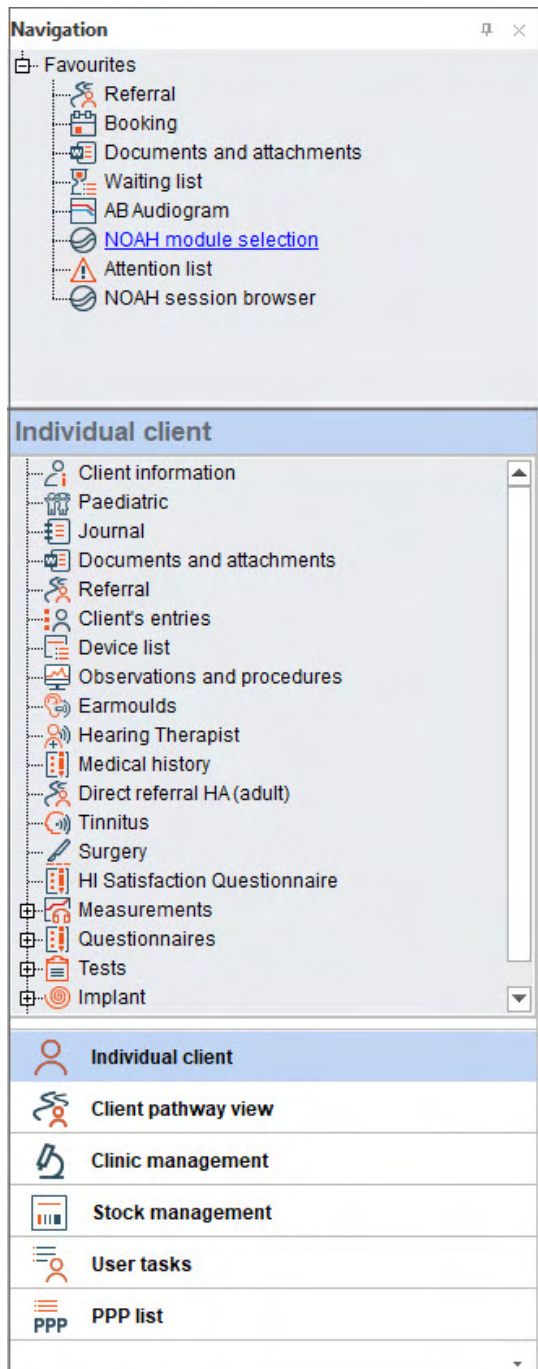
However, when applying the *Auditbase 5 theme*, note that after changing the theme:

- Only the UI color palette will change, the icons will not be reverted
- Until Auditbase is *restarted*, some screens will have inconsistent color palette

7.8 Modules

Auditbase consists of several modules that cover various areas of clinic and staff operations, for instance **Booking**, **Stock**, and **Journal**.

Licensed modules are accessible via the Navigation Pane to the left of the screen.



7.9 Noah4Auditbase subsystem

Noah is implanted in Auditbase using Noah4Auditbase, a wrapper to the functionality of Noah 4, a unified system for performing client-related tasks.

Note: After upgrading to Noah 4, installation of Noah modules directly from the Auditbase system has been discontinued. Noah modules can be installed from either the Auditbase Installation menu or individually with the module installers. Please refer to the Auditbase

System Quick Installation Guide and Auditbase System Installation Guide documents respectively for detailed instructions.

With the Noah4Auditbase subsystem, you can:

- Browse for Noah sessions to open them with the corresponding Noah module.
- Select a Noah module from the list to open it.
- Look through the client information.
- After logging on, if Noah does not initialize properly due to poor performing PC, when the Noah Modules navigation shortcut tries to populate or when going to open Noah, a message bar will appear stating the problem. A retry of the Noah initialization can be attempted from here by selecting the Repair button.

7.10 Sorting and saving listing screens

In any screen with a table listing, you can sort the list by a column by clicking on the column which you wish to sort by.

- Hovering over the column title will display a message saying **Click to sort column.**

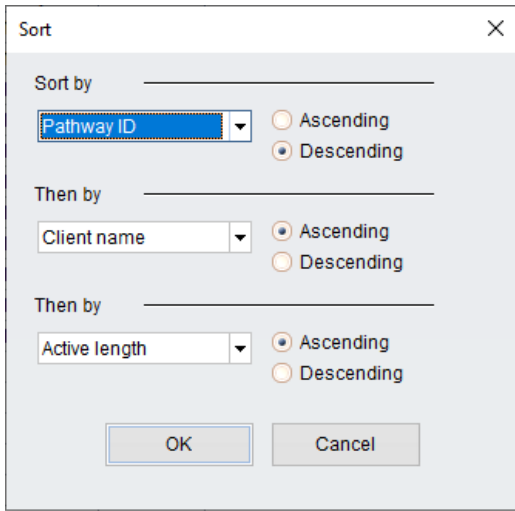
Pathway ID	RTT start	Assessment
0002-1700-3544	11/01/2011	21/02/2011, Has been breached, status not 'completion'
0002-1647-2247	12/01/2011	22/02/2011, Has been breached, status not 'completion'
0002 1721 6948	20/01/2011	02/03/2011, Has been breached, status not 'completion'
0002 1719 3022	19/01/2011	01/03/2011, Has been breached, status not 'completion'
0002 1716 1519	18/01/2011	28/02/2011, Has been breached, status not 'completion'
0002 1710 1024	21/01/2011	03/03/2011, Has been breached, status not 'completion'
0002 1645 9745	11/01/2011	21/02/2011, Has been breached, status not 'completion'

- The first click will sort the column ascending, while the second click will sort the column descending.
- You can also right-click on the column to **Select sort order**

Pathway ID	RTT start	Client name
0002-1700-3544	11/01/2011	M
0002-1647-2247	12/01/2011	M
0002 1736 8567	25/01/2011	M
0002 1730 4618	26/01/2011	M
0002 1730 2111	24/01/2011	M
0002 1729 4479	21/01/2011	M
0002 1721 6948	20/01/2011	M

- User view
- Site default view
- Application default view
- Select sort order
- Save user view
- Save site default view

In this window, you can change the default sort order with up to three columns.



Back in the table listing, you can move around with the columns if you want a different view.

- Hover the cursor over the bottom line of the column title box and a symbol appears.

Client name	Hospital no.	NHS no.	Active length	Assessment
MR FIRSTNAME23026 LASTNAME23026	T123026		479 w, 6 d	14/12/2010, Has been breached. No appt
MR FIRSTNAME1941 LASTNAME1941	T11941		479 w, 0 d	20/12/2010, Has been breached. No appt
MRS FIRSTNAME19079 LASTNAME19079	T119079		477 w, 0 d	03/01/2011, Has been breached, status not 'completion'
MRS FIRSTNAME3281 LASTNAME3281	T13281		476 w, 1 d	09/01/2011, Has been breached, status not 'completion'
MR FIRSTNAME21335 LASTNAME21335	T121335		478 w, 1 d	26/12/2010, Has been breached, status not 'completion'
MR FIRSTNAME6746 LASTNAME6746	T16746		471 w, 4 d	10/02/2011, Has been breached, status not 'completion'

- Once the symbol is displayed, you can click and drag the column to a different location in the table.

Client name	Hospital no.	NHS no.	Active length	Assessment
MR FIRSTNAME23026 LASTNAME23026	T123026		479 w, 6 d	14/12/2010, Has been breached. No appt
MR FIRSTNAME1941 LASTNAME1941	T11941		479 w, 0 d	20/12/2010, Has been breached. No appt
MRS FIRSTNAME19079 LASTNAME19079	T119079		477 w, 0 d	03/01/2011, Has been breached, status not 'completion'
MRS FIRSTNAME3281 LASTNAME3281	T13281		476 w, 1 d	09/01/2011, Has been breached, status not 'completion'
MR FIRSTNAME21335 LASTNAME21335	T121335		478 w, 1 d	26/12/2010, Has been breached, status not 'completion'
MR FIRSTNAME6746 LASTNAME6746	T16746		471 w, 4 d	10/02/2011, Has been breached, status not 'completion'

You can also change the width of the columns by hovering over the separation line between two column title boxes, then click and drag to make the box either wider or smaller – the box to the left of the cursor will be affected.

Once you have set up the table listing to your preference, you can save that view as the default view.

- Right-click on the table and choose **Save user view**.

Pathway ID	RTT start	Assessment
0002-1700-3544	11/01/2011	04/09/2011 - Has been booked, status not 'completion'
0002-1647-2247	12/01/2011	04/09/2011 - Has been booked, status not 'completion'
0002 1721 6948	20/01/2011	04/09/2011 - Has been booked, status not 'completion'
0002 1719 3022	19/01/2011	04/09/2011 - Has been booked, status not 'completion'
0002 1716 1519	18/01/2011	04/09/2011 - Has been booked, status not 'completion'
0002 1710 1024	21/01/2011	04/09/2011 - Has been booked, status not 'completion'
0002 1645 9745	11/01/2011	04/09/2011 - Has been booked, status not 'completion'
	03/11/2010	appt

- If signed in as an administrator, the site default view can also be saved here.

*Note: Certain modules in the application, like **Journal**, **Client information** and **Booking**, have customisable view options, which are saved by selecting **Save window setup** under the **View** menu. See descriptions of those modules for more information.*

7.11 Column sort, word wheel search and scrolling

In most of the windows you can sort the tables based on a column and make word wheel search within the sorted column. When you point to the column header, you will see a tooltip if the table supports column sort and word wheel search.

To sort the table, click on the column header.

When you select any row in the table, a search for a matching row is done for each key you press. In most cases the search string is shown in the status bar of the main Auditbase System window. To jump to the next row meeting the search string criteria press **Ctrl+Return** key. To clear the search string press **Backspace**.




Mouse scrolling


It is possible to scroll up and down through all tables using the mouse wheel.

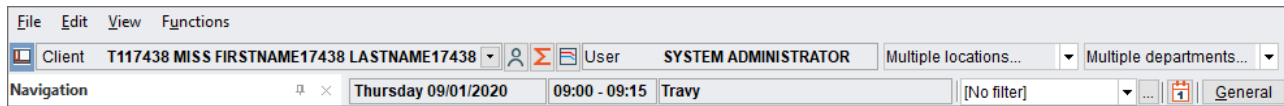
7.12 Toolbar and initial screen

All of the icons on the menus have a text label or a tooltip to make it clear what the icon represents.

The system toolbar contains the following:

- A button to open and close the **Navigation** Pane. Orange surround if open, grey when closed.
- The selected client’s Date of Birth or Code no. as selected by the System Administrator.
- The selected client’s name.
- A drop-down list  to select from recent clients.
- A button to switch to **Client information** .
- A button to create a client’s treatment summary and show it .

- A button to show client's latest audiogram .
- The name of the logged in **User**.
- The current **Location** which can also be selected from the drop-down list.



- Below this line, the active date, time and resource are shown.
- The **Clinic filters** and **Clinic filters set up** are also shown.

The default module that will appear when you log into Auditbase can be defined by the user. Contact your System Administrator to learn how to do this.

The ribbon at the top of the page will display icons within the module you are currently using. The available icons and functionality will differ depending on the module you have selected. The ribbons all have icons grouped into tabs of File, Edit, Functions, and View.

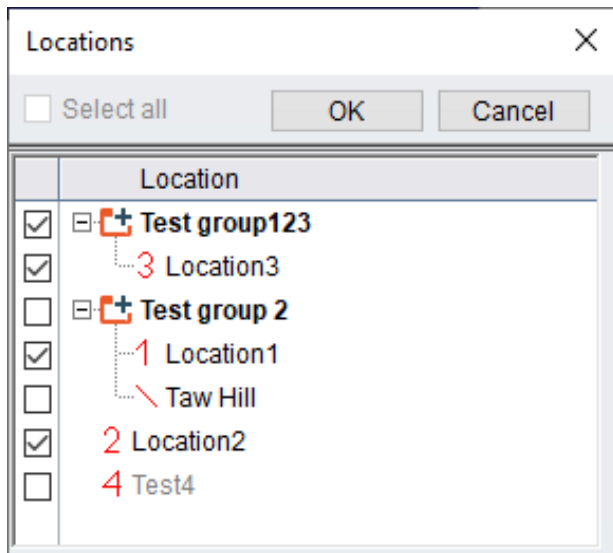
The ribbon can be displayed or closed. Double click the selected ribbon tab to close the ribbon. Double click again to open it.

The ribbon can also be auto closed or opened. First double click the selected ribbon tab in order to close the ribbon. A single click of the ribbon tab will then open the ribbon temporarily, clicking one of the icons or clicking elsewhere on the screen will cause the ribbon to close again. This allows for maxim screen space whilst still allowing ribbon access.

The ribbon groups icons according to their functionality and gives them a title. For instance, icons relating to search will be grouped and titled as such. They will then be separated from the next icon group by a divider.

Location and Department can be used for filtering with the Location Filtering licence; this is an optional extra for Auditbase.

You can make a single selection, select a Location group created by the System Administrator or make your own multiple selections. A multiple selection is made by selecting the appropriate option from the Location or Department drop down list. A window will open where selections can be made by checking the box next to the name of the Location or Department.



Once you have made your selection, OK will close the window or Cancel will close the window without any changes.

If multiple selections have been made, the Location or Department filter will display **Multiple locations**. These choices can be seen by placing the mouse cursor over the filter and viewing the tool tip. These selections are not saved, so if they are used regularly it is recommended to make Location groups as these are listed for ease of use.

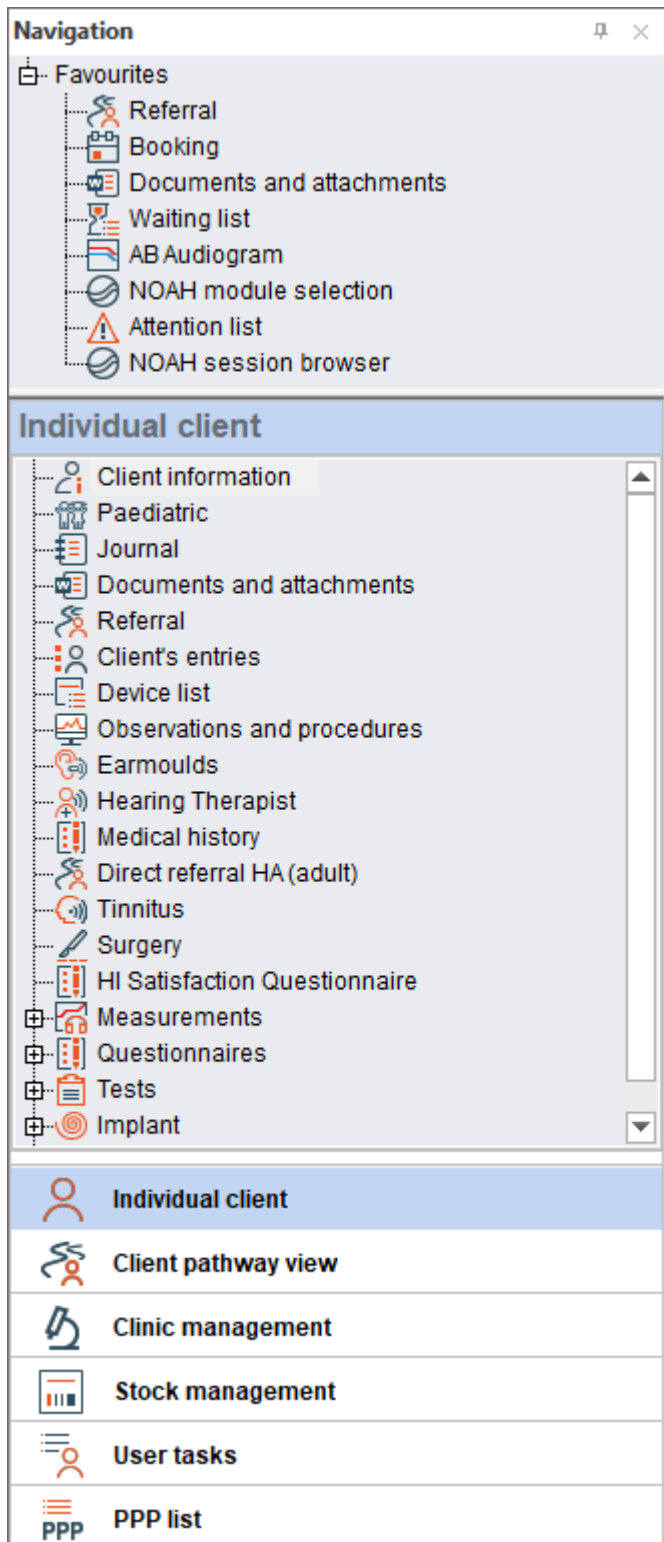
7.13 Panes

Navigation to the left of the screen holds shortcuts to all Modules, Measurements, Questionnaires and Tests. These are grouped into panes appropriate to their functionality. The available panes are shown at the bottom of the **Navigation** area. These panes will differ depending on the default view chosen by your System Administrator. Those displayed below are the default Auditbase 5 grouping.

- Individual client
- Client pathway view
- Clinic management
- Stock management
- User tasks
- PPP lists

The size of the **Navigation** area can be changed. Drag the **Navigation** area divider left or right from its right border edge. Click and drag the border using the mouse to re-size the viewing panes.

Select a pane appropriate to your needs and it will open showing its shortcuts above. Selecting a shortcut from this list will cause it to open to the right of the **Navigation** area.



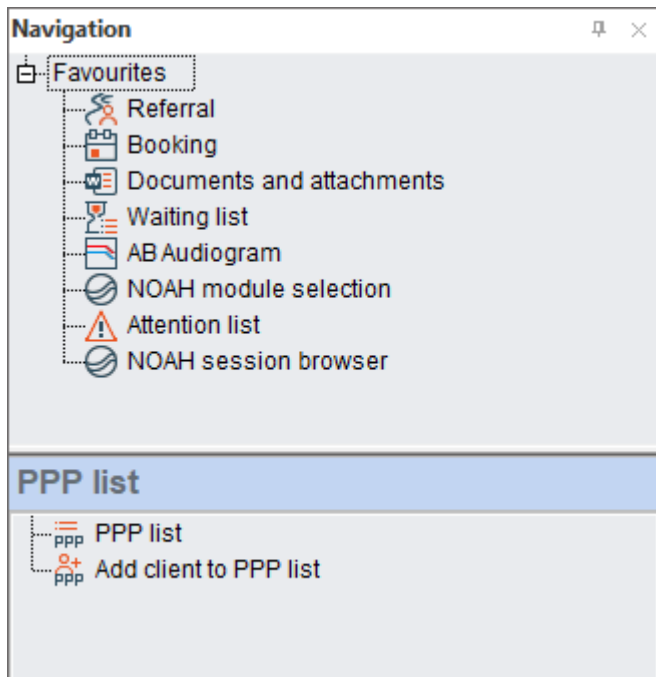
7.14 User Favourites

From the available Modules, Measurements, Questionnaires and Tests, select shortcuts from any Pane that are of most use to you and create a Favourites list.

Go to the **Navigation** area; select the navigation pane -> right click a shortcut -> click **Show in Favourites**.

The selected shortcut will then be copied into your favourites list at the top of the **Navigation** area.

Your favourites list will always display at the top of the **Navigation** area.



Move your mouse to the divider at the bottom of the Favourites area until it changes to the cursor in the picture above to expand the pane allowing you to view its entire contents. Both your favourites list and pane size will be remembered upon logging out of Auditbase.

Right click a shortcut and select **Remove from favourites** to remove from your favourites list.

To adjust the order the favourites list is displayed in, right click a shortcut and use the **Move up** or **Move down** options to give it a new placing.

7.15 Open, Close and Auto hide the Navigation Area




Click the icon to the left of the client name and the **Navigation** area will close. Click the same icon again to re-open the navigation area. When open, the icon will be outlined in orange.



When closed, the icon will have a grey surround. Closing the **Navigation** area allows maximization screen use.


The **Navigation** area can be put into hidden mode, allowing screen maximization whilst still giving easy access to the **Navigation** area.

 Click the small pin icon at the top right of the Navigation pane, the pin now displays horizontal. Hidden mode is switched on. Move away from the Navigation Pane and it will hide itself.


Take your cursor back to the Navigation area, hover over the words **Navigation**. The **Navigation** area displays again.

When unhidden, you can select shortcuts from the **Navigation** area by moving your cursor into it and making your selection.


When using the auto hide function, the navigation open and close icon will be inactive. You will need to use the pin icon to permanently open the navigation pane before the icon will become active again.

 Cause the Navigation pane to remain open by again clicking on the pin at the very top of the **Navigation** area. The pin now displays vertically.

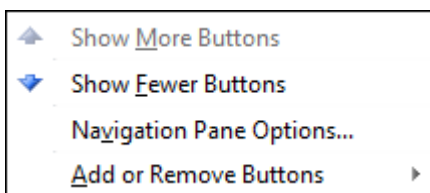
When the **Navigation** area open/close symbol is clicked and **Navigation** auto hide is in use, a warning message will appear. To prevent the message appearing on future occasions, check the **Don't show this message again** box. You can reset all messages to show again from within **System Administration -> User settings -> User specific options -> Reset all checkboxes 'Do not show this message again' to show again.**

Permanently close the **Navigation** area by clicking on the  at the top right of it. Open the pane again by clicking the icon to the left of the client name.

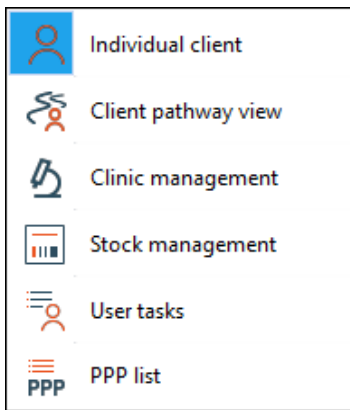
7.16 Pane Configuration

The panes in the Navigation area can be configured to suit individual user preference. At the bottom of the Navigation area and to the right of the last pane, is a small downward pointing arrow . Click this to open options for configuring the panes.

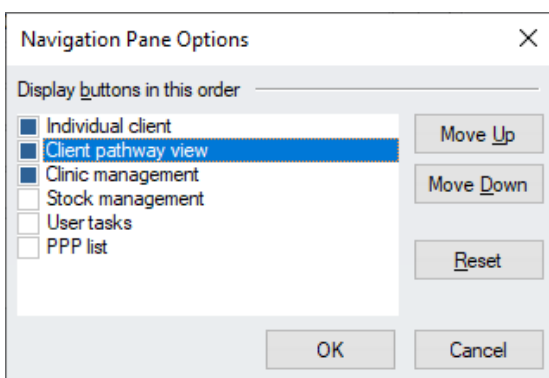
Selecting **Show Fewer Buttons** will minimize the last pane title to just an icon at the bottom. Select **Show Fewer Buttons** again to minimize the next, last pane title. Clicking, **Show More Buttons** will cause them to be replaced as full headings.



Hover over **Add or Remove Buttons** and a secondary menu will open. From the secondary menu, you can remove headings from the list completely. Replace the removed headings at any time by selecting them again in the same menu location.



Selecting **Navigation Pane Options** from the menu allows you to adjust the order the headings are displayed in, as well as removing and adding headings to the list.



Selections made here are user unique and will be remembered by Auditbase upon logging out.

Navigation panes and their contents can be decided upon by the System Administrator, therefore allowing limitation of what users may see and access. The System Administrator can decide who accesses what by individual user, role or system wide access.

Keyboard shortcuts are shown on mouse-over in the **Navigation** pane.

7.17 Printing and output redirection

Auditbase System can set up a selection of default configurations including all printouts. Users can select one of these configurations as their workstation default, thus controlling how printing works.

For all system printouts in Auditbase, your System Administrator can configure their output redirection. The redirection option can be defined for each report separately, which means that the options may vary for different reports. The following options are available:

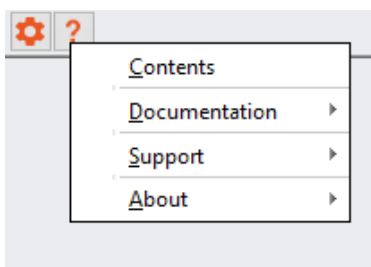
- Send the printout to the application default printer (no redirection).
- Send the printout to the Windows default printer.
- Show Windows **Print** dialogue before printing. In the dialogue, you can select printer and number of copies.

- Send the printout to a file.
- Send the printout to a file and attach the file to a new e-mail message. Additionally, for some reports processed with this option, the system copies the recipient e-mail address, if a relevant address exists in the system.

*Note: To send a printout to a file and to send a printout to an email, the Printing/Output extension module needs to be licensed. Microsoft Office must be installed on the user's PC, and the "Microsoft Office Document Image Writer" printer must be available.
User reports cannot be redirected.*

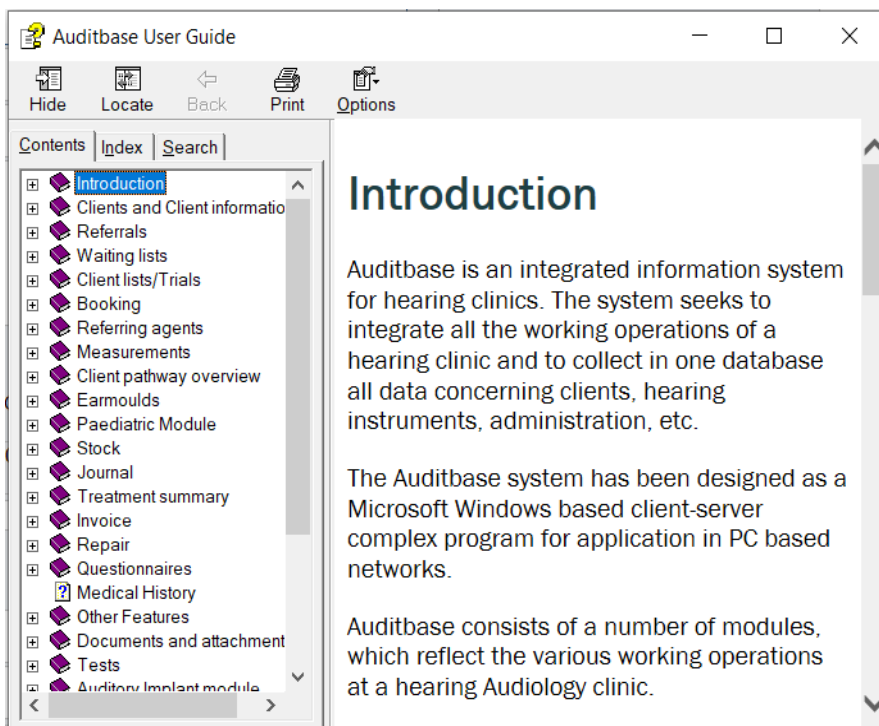
The configuration described above is performed by the system administrator.

7.18 Help



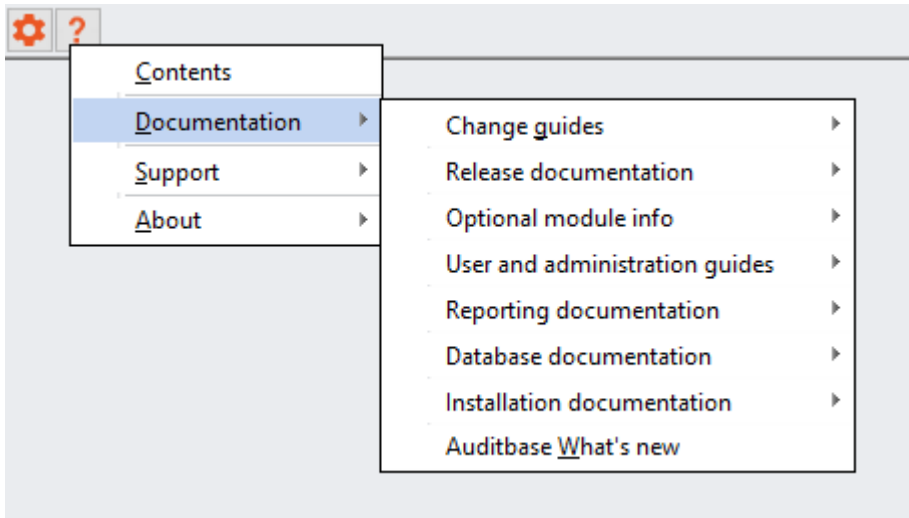
The Help menu item has separate options for help file Contents, user guides or other Documentation, and how best to access **Support**.

7.18.1 Contents



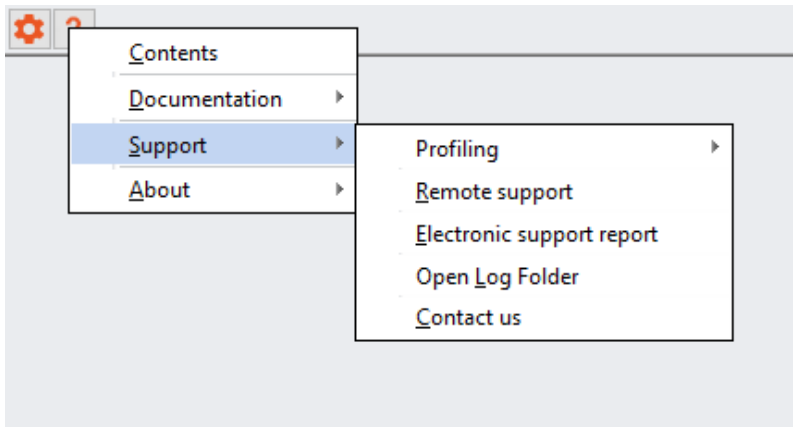
The entire help contents are displayed. Items can be searched for or individual items can be expanded to show subjects. The content mirrors the User Guide.

7.18.2 Documentation



A number of documents can be viewed by selecting Documentation and then further selecting from the selection of documents. Double-clicking will open any of the individual documents if a PDF reader is installed.

7.18.3 Support

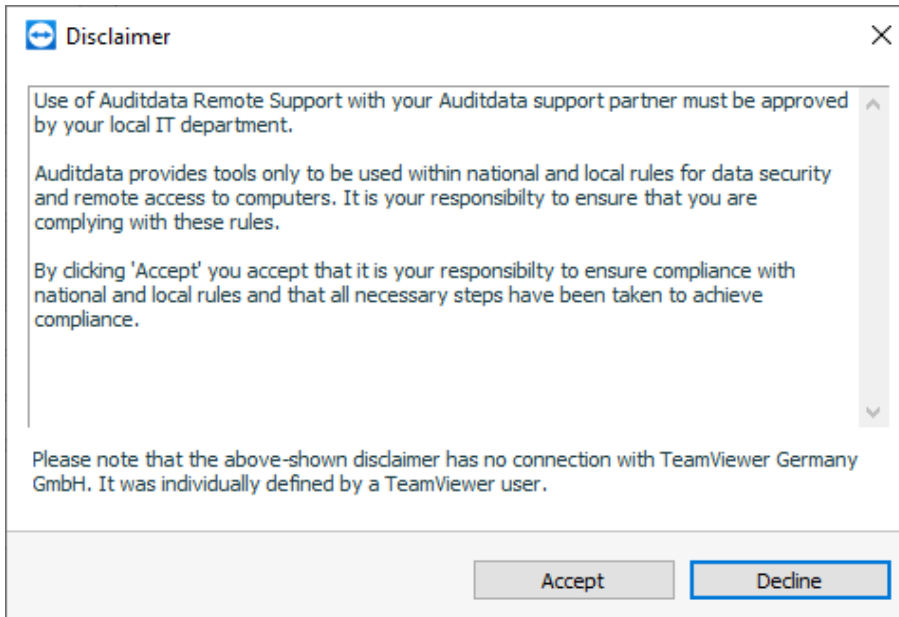


Profiling

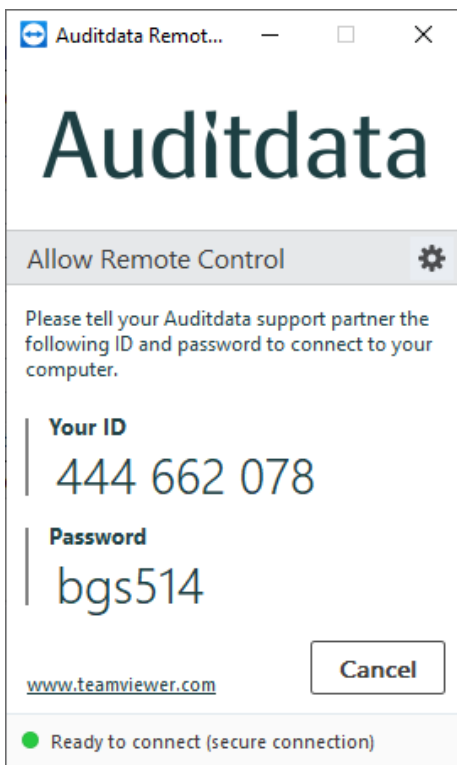
For details, see the section on [Profiling](#).

Remote support

- Selecting this option will launch the TeamViewer electronic support application.



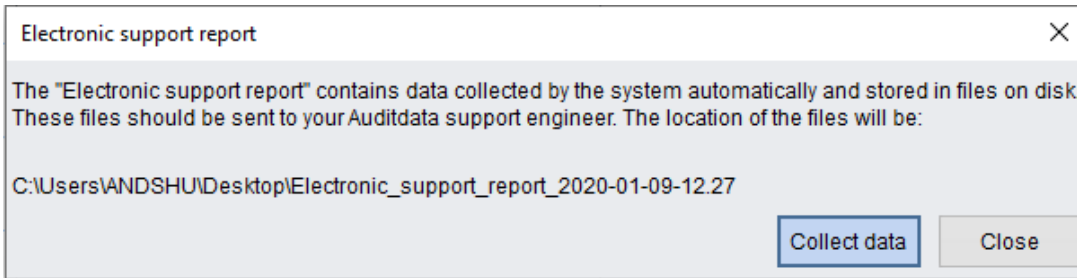
Accept the disclaimer if your IT department will allow you to use the TeamViewer.



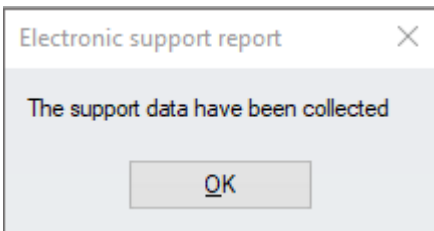
Your Auditdata supporter will require the ID number and Password that are displayed.

Electronic support report

- Selecting this option will produce an electronic report that can be sent to Auditdata.



Make a note of where the file is stored to, it should be your desktop, and then press **Collect data**. Once the information is collected, a confirmation message will be displayed.



A folder will be created on your desk top, containing two files. These files may be emailed to Auditdata to help resolve issues.

Open Log Folder

Open Log Folder in the Help menu will open a window where certain log files are stored. You may be asked by Auditdata support to send these files if you have reported an issue. No client data is contained in these logs.

Contact us

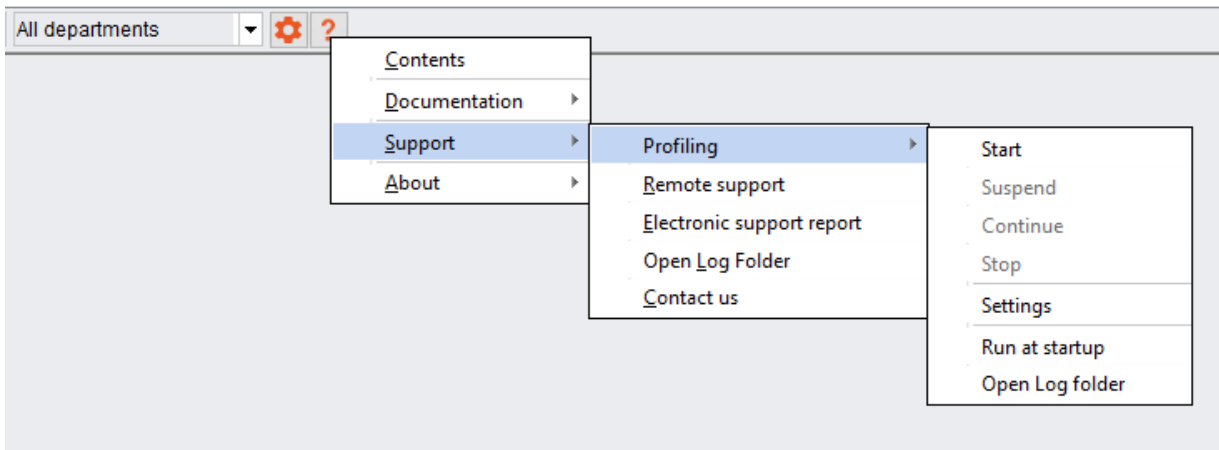
Contact us will open the contact page on the Auditdata website.

7.18.4 Profiling

Profiling is a support option in Auditbase, allowing users to collect information for developers about how the application is running.

It is practical when troubleshooting problems as profiling logs all system activity that can later be reviewed by the support team or developers. **IMPORTANT:** No client information is recorded.

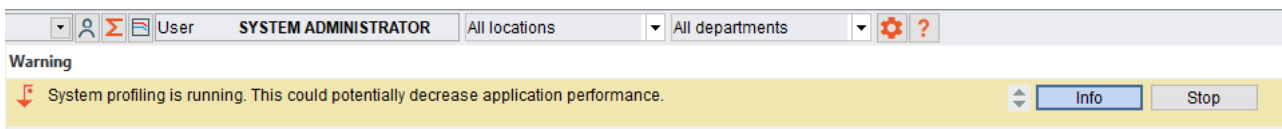
Users can access Profiling from the **Help menu** in the System toolbar:



The following controls allow management of the Profiling functionality:

1. *Start*: launches Profiling, which may potentially slow down the application
2. *Suspend*: temporarily stops Profiling if performing other tasks requires full system capacity
3. *Continue*: restarts profiling that has been suspended
4. *Stop*: quits the Profiling mode
5. *Settings*: contains additional Profiling settings
6. *Run at startup*: launches Profiling at the next Auditbase startup
7. *Open Log folder*: opens the folder with Profiling logs

Whenever Profiling is enabled, the corresponding banner will be shown. Users can obtain more information by clicking the **Info button**, or alternatively disable application logging by clicking **Stop**.



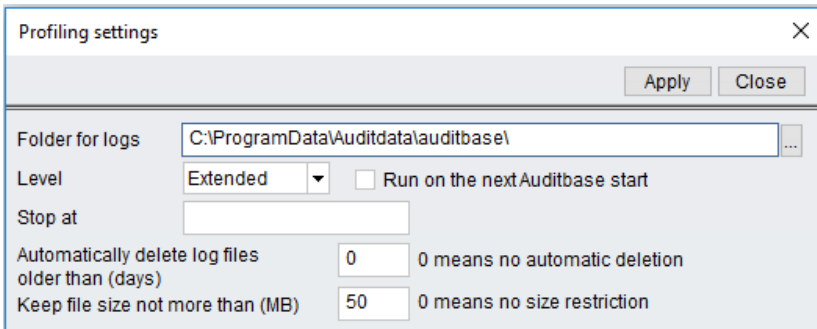
Since turning on **Profiling** may affect the performance of the application, it is recommended that users go into the Profiling mode only when instructed to do so by Auditdata support specialists.

Settings

More advanced configuration options are accessible from the Settings window. Here you can configure the following:

1. *Folder for logs*: use the default or specify your own folder
2. *Level*: define the level of profiling. Extended level is recommended
3. *Run on the next Auditbase start*: enable the launch of Profiling as soon as you start Auditbase
4. *Stop at*: define the date when Profiling will be turned off. Double-clicking inside the box inserts the current date that can be modified as needed

- 5. Automatically delete log files older than a specified count of days
- 6. Keep file size not more than a predefined size in MB



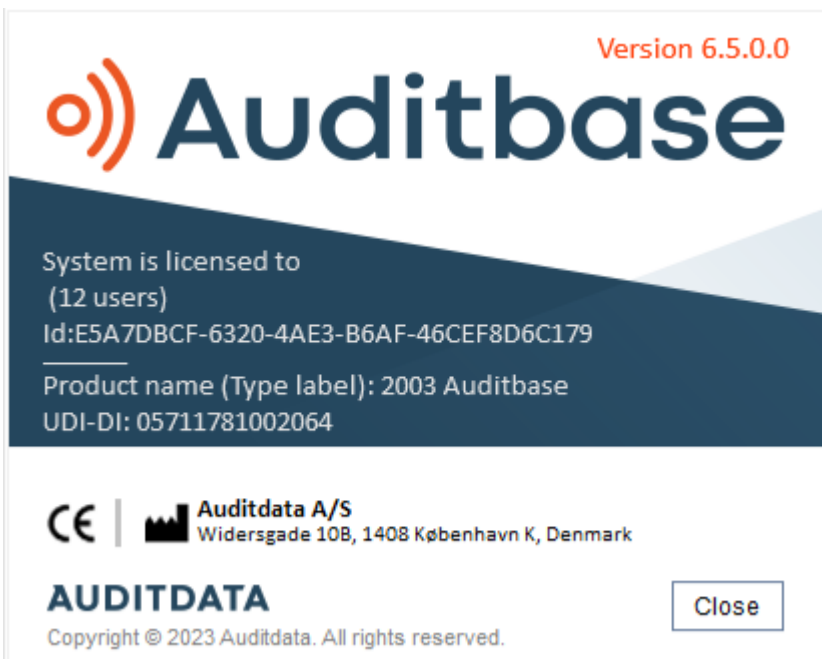
7.18.5 About Noah

Use this menu item to view license information on the installed version of Noah. The information includes customer name, Noah serial number, license type, days left before license expiration, and number of users licensed to access the system.

7.18.6 About Auditbase System

Use this menu item or press **F1** to see specific information on running the Auditbase System version.

You can see the revision number, build number, customer name, license ID, and the number of users licensed to access the system.



For more information, see [Appendix B.2 Label signs interpretation](#).

7.19 Accessibility options

Waiting list

(Accessibility option) With the **User** option in Admin **Waiting list type affected by refresh rule** checked and **Refresh Waiting list immediately after changing filter criteria?** set to **No**, the user can step through the waiting lists and have them read by a screen reader without selecting them. To select it, press **Enter**. To open the drop-down list, press **Alt + ArrowDn**.

Booking – Timeplan

Enable the **User** option in Admin **Show hours and minutes in every timeslot** to have a screen reader read the time for each row.

With the **Do not refresh Timeplan upper screen until selection confirmed in lower screen** option enabled, the Resource is not changed in the upper screen until **Enter** on the Resource row names in the lower section is selected. This must be done before the user selects the Resource they want to view.

To ensure a screen reader can read the correct Resource name in the lower table, take care to allow enough time between selecting each resource.

(Accessibility option) Press **Alt+C** to move focus to the calendar and here you can move between dates with arrows and **PgUp/Dn** keys.

Client search

With the user option in Admin **"Search clients: Display message with search results after filling the table (Accessibility option)"** checked, a message box displays the number of found clients upon completed search for a screen reader to read.

Use the space key to toggle the selection check mark.

Everywhere

(Accessibility option) Press **F6** to call up a small dialogue with the selected patient's ID and name that a screen reader can read.

Client's entries

(Accessibility option) The column with **Appt. Symbol** can be read by a screen reader if moved to the leftmost position in the saved user view.

7.20 Full operations guidance

Full operational guidance is available in *Auditbase User Guide*. This document is available from the Help menu described above.

8 Troubleshooting guide

If you have any problems with installing or running the software, please go through this guide first before contacting a Support/HOT-line.

Please verify that installation prerequisites are satisfied. For details, see [Appendix A](#).

If all installation prerequisites have been met and you still have issues with your software, please refer to the tables below for the solution of your problem.

SQL errors

Issue	Solution
9268 – Cannot connect	Contact Local IT to check the network, server and Gupta SQLBase service on the server.*
9024 – Session ended abnormally	Contact Local IT to check the network, server and Gupta SQLBase service on the server. *
9028 – Session ended abnormally	Contact Local IT to check network, server and Gupta SQLBase service on the server. *
1102 – Security violation attempting to access	Select the Error to show which table is affected. Assign appropriate table rights in the <i>System administration tool</i> -> <i>Users, security and views</i> -> <i>User administration and security</i> -> <i>User rights and setup</i> -> <i>Roles</i> .
803 - Fatal SQLBase System Failure	Stop all Auditbase activity. Contact Auditbase support.
805 – Insert/update of unique constrained columns with duplicate data	Contact Auditbase support.

* If no issues are found, contact Auditbase support at support@auditdata.com

Noah issues

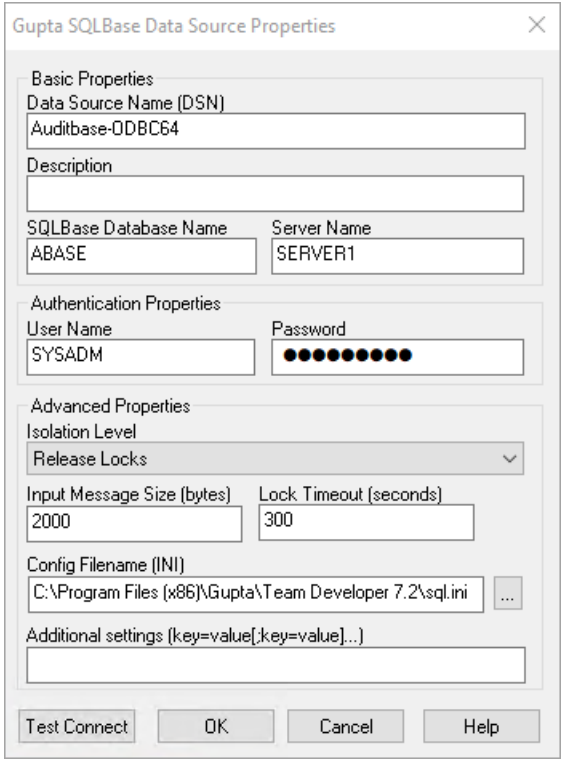
Issue	Solution
<p>For versions below 5.4.2 only.</p> <ul style="list-style-type: none"> Using Phonak Target 7.1, Hearing Aid serial numbers cannot be read. 	<p>Apply for upgrade to support@auditdata.com</p>
<p>Noah token error when logging into Auditbase.</p>	<p>Change your password from <i>Booking</i> -> <i>System setting</i> -> <i>Change password</i>. Repeat if the message appears again.</p> <ul style="list-style-type: none"> The password cannot be changed by the system administrator.
<p>For Noah versions below 4.13 (<i>Auditbase version 6.1.0</i>).</p> <ul style="list-style-type: none"> Noah validation fail (500) 	<p>See Noah's Data Validation Errors</p>
<p>Noah problems after Windows 10 Upgrade.</p> <ul style="list-style-type: none"> A problem with Noah initialization after an upgrade of Windows 10 (e.g., from 1809 version to 1903), irrespective of the version of Windows 10. An upgrade removes “Full control” permission from “Authenticated Users” in the HKEY_USERS\DEFAULT\Software\AuditData\NoahDBInterface registry folder used for connection to Noah. 	<p>There are 4 ways to fix the problem:</p> <ol style="list-style-type: none"> Add “Full control” permission for “Authenticated Users” in the registry folder HKEY_USERS\DEFAULT\Software\AuditData\NoahDBInterface. <ol style="list-style-type: none"> Open the registry editor. Go to HKEY_USERS\DEFAULT\Software\AuditData\NoahDBInterface. Right-click on the folder NoahDBInterface and select “Permission”. Click “Add” to add “Authenticated Users”. Add “Full Control” for “Authenticated Users” and click “OK”. Run AddNoahPermissionToRegistry.exe as Administrator from the folder AuditBase CD image\Auditbase\NOAH\RestoreRegistryPermission.

Issue	Solution
	<ol style="list-style-type: none"> 3. Copy all files from AuditBase CD image\Auditbase\NOAH\RestoreRegistryPermission, read the file readme.txt from the attached archive and run AddNoahPermissionToRegistry.bat as Administrator. 4. Reinstall Auditbase.

Miscellaneous

Issue	Action
<p>Auditbase is compatible with Windows 10 from version 6.x.x only</p>	<p>To upgrade, apply by email to support@auditdata.com</p>
<p>More users logged in than allowed by licence</p>	<p>Check connections in the <i>System administration tool</i> -> <i>Tools menu item</i> -> <i>Monitor connections</i>.</p> <p>Disconnect selected users.</p>
<p>Letters for keyboard shortcuts on buttons and tabs missing underlines</p>	<p>This is now controlled by the settings in Windows. If letters are not underlined, then:</p> <ul style="list-style-type: none"> • On Windows 10, go to <i>Settings</i> -> <i>Ease of Access</i> -> <i>Keyboard</i>, then switch on the "Underline access keys when available" option. • On Windows 7, go to <i>Control panel</i> -> <i>Ease of Access</i> -> <i>Change how your keyboard works</i>, then switch on the "Underline keyboard shortcuts and access keys" option.
<p>Incorrect version of gswag32.dll</p>	<ul style="list-style-type: none"> • Copy the files gswag32.dll, gswdll32.dll, from: C:\Program Files (x86)\Gupta\Runtime62\ • Paste to the folder: C:\Windows\SysWOW64\ <p>Repeat on each PC where the error appears.</p>

Issue	Action
Installing 64-bit ODBC drivers	<p>For each PC where you need to use the 64-bit ODBC connection:</p> <ol style="list-style-type: none"> 1. Make sure 'Enable Driver' is NOT ticked in the Auditbase Administration (<i>as this is just for the 32-bit ODBC connection</i>). It will not be ticked by default. 2. Install the C++ 64-bit runtime libraries by running the file <code>vcredist_x64.exe</code> <p>Also available from:</p> <ul style="list-style-type: none"> • Download Microsoft Visual C++ 2008 Service Pack 1 Redistributable Package MFC Security Update from Official Microsoft Download Center (<i>choose the x64 version</i>) • Right-click and select 'Run as Administrator' to install 3. Run 'Gupta SqlBase 64-bit drivers.msi' to install the Auditbase 64-bit ODBC drivers. <p>These drivers are in the Auditbase installation, which can be found on your sever at:</p> <ul style="list-style-type: none"> • <code>\\twhaudio01\AB Install\Auditbase 6.0.3.2.12346\Database\SqlBase drivers x64 setup</code> 4. Manually create the 64-bit ODBC connection: <ul style="list-style-type: none"> • Open the 64-bit ODBC Administrator from <code>C:\Windows\System32\odbcad32.exe</code> • Select the 'User DSN' tab and select 'Add' • Select the 'Gupta SQLBase 11.7 (64-bit) driver, then click 'Finish' • 'Configure' the data source as shown below • Press 'Test Connect' to check if it is working

Issue	Action
	 <p>Once the connection is working, you should be able to connect to the Auditbase ODBC from 64-bit applications (e.g., MS Access).</p>
<p>Problem printing RPT reports from AB with Crystal 11 installed. QRP reports are printed without any issues.</p>	<p>The problem is caused by an incorrect <i>Crystal XI runtime</i> which might be installed together with some MS products.</p> <p>To resolve:</p> <ol style="list-style-type: none"> 1. Uninstall Crystal Reports XI runtime 2. Install Crystal Reports XI from Auditbase install media \Auditbase\CRXIRuntime.msi

9 Operator roles and activities

9.1 Operator roles

The following are the operator roles generally expected to be involved in distribution, service and other activities with Auditbase.

- Application distribution – responsible for the distribution of desktop applications (including through MSI packaging if required).
- Auditbase administrator – responsible for configuration and setup of Auditbase including user creation, administration and authorisation.
- IT security – responsible for maintaining IT security.
- Database administrator – responsible for database backups.
- Clinical Safety Officer – responsible for clinical safety.

9.2 Operator activities and recommended frequency

Operator role	Activity	Recommended frequency
Application distribution	Client application installation	On installation
Auditbase administrator	Configuring user permissions; updating their permissions through modifying the relevant user roles	During user onboarding and after feature updates
Auditbase administrator	Revoking users	Users leaving
Auditbase administrator	Evaluation of audit logs	As required
Auditbase administrator	User training on account security and password handling	During user onboarding and after feature updates
IT security	Keeping anti-virus and malware protection up-to-date	Daily
IT security	Ensuring operating system security patches are up-to-date	Weekly
Database administrator	Monitoring backup	Daily

Operator role	Activity	Recommended frequency
Database administrator	Backup verification	As required
Database administrator	Preparation for backup restoration	As required
IT security/ Auditbase administrator	Informing Auditdata regarding relevant security incidents	As required
Auditbase administrator/ Clinical Safety Officer	Informing Auditdata regarding relevant clinical safety incidents	As required
IT security	Exchange of keys or certificates	As required

Appendix A



It is essential that the Business Process ensures that adequate resources are provided for client PCs according to the minimum system requirements below.

The Auditbase pre-install or pre-upgrade checklist must be accurately completed.

A.1 Server specifications

A.1.1 Hardware requirements

Virtualised servers and SAN storage are fully supported by Auditbase.

The minimum specification is aimed at existing installations being upgraded and should be discussed with Auditdata support. New installations should always use the recommended specification or above depending on the number of users.

Hardware Component	Minimum	Recommended	Comment
1 - 10 concurrent users			
Processor	Xeon Dual Core 1.5 GHz e.g., E3 v31 family	Xeon Dual Core 2.0 GHz e.g., E3 v31 family or above	Virtualised is supported
RAM	6 GB	12 GB	
10 - 200 concurrent users			
Processor	2 Xeon Quad Core 2.0 GHz e.g., E7 v21 family	2 x Xeon Quad Core 2.0 GHz e.g., E7 v21 family or above	Virtualised is supported
RAM	8 GB	12 GB	
All users			
HDD Type	SSD	Fast SSD	Fast SSD significantly improves performance
HDD Space	DB(s) size x 3 + 5	DB(s) size x 5 + 10 GB	Combined active DB size.

Hardware Component	Minimum	Recommended	Comment
	GB		
USB	2.0	3.0	

A.1.2 Software requirements

Software Component	Description	Comment
Operating System	Windows 2019 Server Windows 2016 Server Windows 2012 Server Windows 2022 Server	For 64-bit Server 32-bit application support must be enabled in order to run essential tools. All Microsoft Updates should be installed. Windows 2022 Server is only supported for SQLBase 12.3.0
Configuration	Configure as 'Application Server' not 'File sharing' where available.	'File sharing' will reserve 41% of system memory.
Database engine	Gupta SQLBase 12.2.1 Gupta SQLBase 12.1.3 Gupta SQLBase 11.7 SP4 (not supported on Windows Server 2016 and 2019)	Supplied by Auditdata. Minimum one port must be available for connecting to SQLBase, typically 2155.
Active Directory	Optional.	Auditbase integration with Active Directory was tested on Windows server 2016, Active Directory Schema 87.
Back-up facilities	A document detailing recommended backup procedures can be requested through the normal Auditdata contact or via e-mail request to support@auditdata.com .	Auditdata can provide recommendations on how to perform backup but cannot implement or service these routines.*

* Please be aware that Auditbase server backup is entirely the responsibility of the local IT department and that Auditdata cannot be held liable for any loss of data resulting from inadequate or inaccurate backup routines.

A.2 Client specifications (including Noah installation)

A.2.1 Hardware requirements

Hardware Component	Minimum	Recommended	Comment
Processor	Core i5	Core i7	
RAM	32 bit: 3.5 GB 64 bit: 4 GB	32 bit: 3.5 GB 64 bit: 8 GB	A high level of memory is additionally needed by Noah fitting modules. If other applications or services are running simultaneously more will be required.
HDD	SSD 2 GB free plus @1 Gb per Noah module.		Recommended by HIMSA.
Network Adapter	100 Mb/s	1 Gb/s	Network requirements, see below.
Graphics Adapter	Widescreen 16:9 1366 x 768	Widescreen 16:9 1920 x 1080	The minimum resolution for Auditbase is due to be increased to 1920 x 1080 in the near future, so please bear this in mind when planning hardware upgrades.

A.2.2 Software requirements

Software Component	Minimum	Recommended	Comment
Operating System	Windows 10 (64 bit)* Windows 11*	Windows 10 (64 bit)* Windows 11*	All Microsoft Updates should be installed *1) Contact the manufacturer for module or audiometer panel support; 2) Auditbase was tested on versions Win10 (22H2), Win10 (21H2), Win11 (21H2), Win11 (22H2).

Software Component	Minimum	Recommended	Comment
Ghosting	Ghosting images of Windows are not supported due to SID issues.		
Document editor	Microsoft Word 2007 - 2019, 365 Pro Plus (tested with version 1910).		
Noah modules	Must be Noah4 certified.		
Web Browser	Not required.		
Java	Not required.		
.Net	4.6.2 (installed with Windows 10).		

A.3 Client specifications (without Noah installation)

A.3.1 Hardware requirements

Hardware Component	Minimum	Recommended	Comment
Processor	Core i3	Core i5	
RAM	32 bit: 3.5 GB 64 bit: 4 GB	32 bit: 3.5 GB 64 bit: 8 GB	If other applications or services are running simultaneously more RAM will be required.
HDD	1 GB free	SSD 3 GB free	
Network Adapter	100 Mb/s	1 Gb/s	Network requirements, see below.
Graphics Adapter	Widescreen 16:9 1366 x 768 or above	Widescreen 16:9 1920 x 1080	The minimum resolution for Auditbase is due to be increased to 1920 x 1080 in the near future so please bear this in mind when planning hardware upgrades.

A.3.2 Software requirements

Software Component	Minimum	Recommended	Comment
Operating System	Windows 10 (64 bit) * Windows 11*	Windows 10 (64 bit) * Windows 11*	All Microsoft Updates should be installed *Auditbase was tested on versions Win10 (22H2), Win10 (21H2), Win11 (21H2), Win11 (22H2).
Ghosting	Ghosting images of Windows are not supported due to SID issues.		
Document editor	Microsoft Word 2007 – 2019, 365 Pro Plus (tested with version 1910).		
Web Browser	Not required.		
Java	Not required.		
.Net	4.6.2 (installed with Windows 10).		

A.4 Security specifications

A.4.1 Encryption

- Network traffic between the Auditbase database and client PCs can be encrypted using TLS1.2. It is recommended for security that this is requested.
- The Auditbase SQLBase database can be encrypted. It is recommended for security that this is requested. *Note that this may have a detrimental impact on performance.*
- HL7 Interfaces between Auditbase and hospital systems are required to be secured by the customers own traffic encryption and protection within their private network domain.

A.4.2 Anti-virus and anti-malware

- It is essential for security that anti-virus and anti-malware protection is installed on every PC where Auditbase is used. This protection must be updated on a regular basis.
- It is essential for security that in order to mitigate risks if a PC is infected by a virus or malware that users do not have any Administrator level rights in Windows which could be taken advantage of by the virus or malware.

A.4.3 Windows authentications and passwords

- It is essential for security that a method of strong authentication for Windows login is employed when Active Directory Windows login is enabled for Auditbase.
- It is essential for security that a policy for keeping Windows passwords secure is enforced.

A.4.4 Security of printouts

- For security, it is advised that a cover page that could include "PATIENT CONFIDENTIAL INFORMATION" is configured on printers where printouts from Auditbase are made.

A.4.5 Port scanning

- Auditdata suggests which ports to use for Auditdata applications. These may be changed by the customer after discussion with Auditdata support staff on how to reconfigure the application. The customer is responsible for ensuring that port scanning is performed on all relevant network interfaces.

A.5 Network specifications

A.5.1 Network requirements

Bandwidth: Approximately 10Mbit is required per user for the best working experience.

Latency: Performance decreases as latency increases. A latency of 0-20ms is preferred; a latency over 35ms will result in real delays noticeable by users. Latency over certain high levels (100ms/200ms depending on the network type and application area) will result in connection loss and the application will need to be restarted.

Loss of connection: Network connection must be maintained at all times otherwise the application will need to be restarted. Auditbase connection licensing does not support connection loss and licence number violation may occur in this circumstance.

Loss of packets: TCP handling will cope with a limited loss of packets. A 5% loss will result in a noticeable slowdown and around 50% will result in a loss of connection.

A.5.2 Naming Client workstations

Recommendation: Names of workstations should have unique last 8 characters. This is needed for efficient tracking of the Auditbase licences in use and, potentially, freeing hanging connections of the same user from the same workstation.

A.6 Equipment and Network hazards and configuration changes

On any equipment and network configuration change, or any patching to, for instance, Windows, anti-virus, or firewall software, the customers are strongly advised to carry out changes in a way, so that the minimum requirements described above are still met. Consideration must also be taken that any changes or patches to the above will still support the security goals and security capabilities of the system.

If Auditbase is run on equipment or network not satisfying minimum requirements, that can cause the following consequences:

- Low system performance, which can cause delays in patients' treatment and information disclosure;
- System crash, which can cause loss of unsaved data.

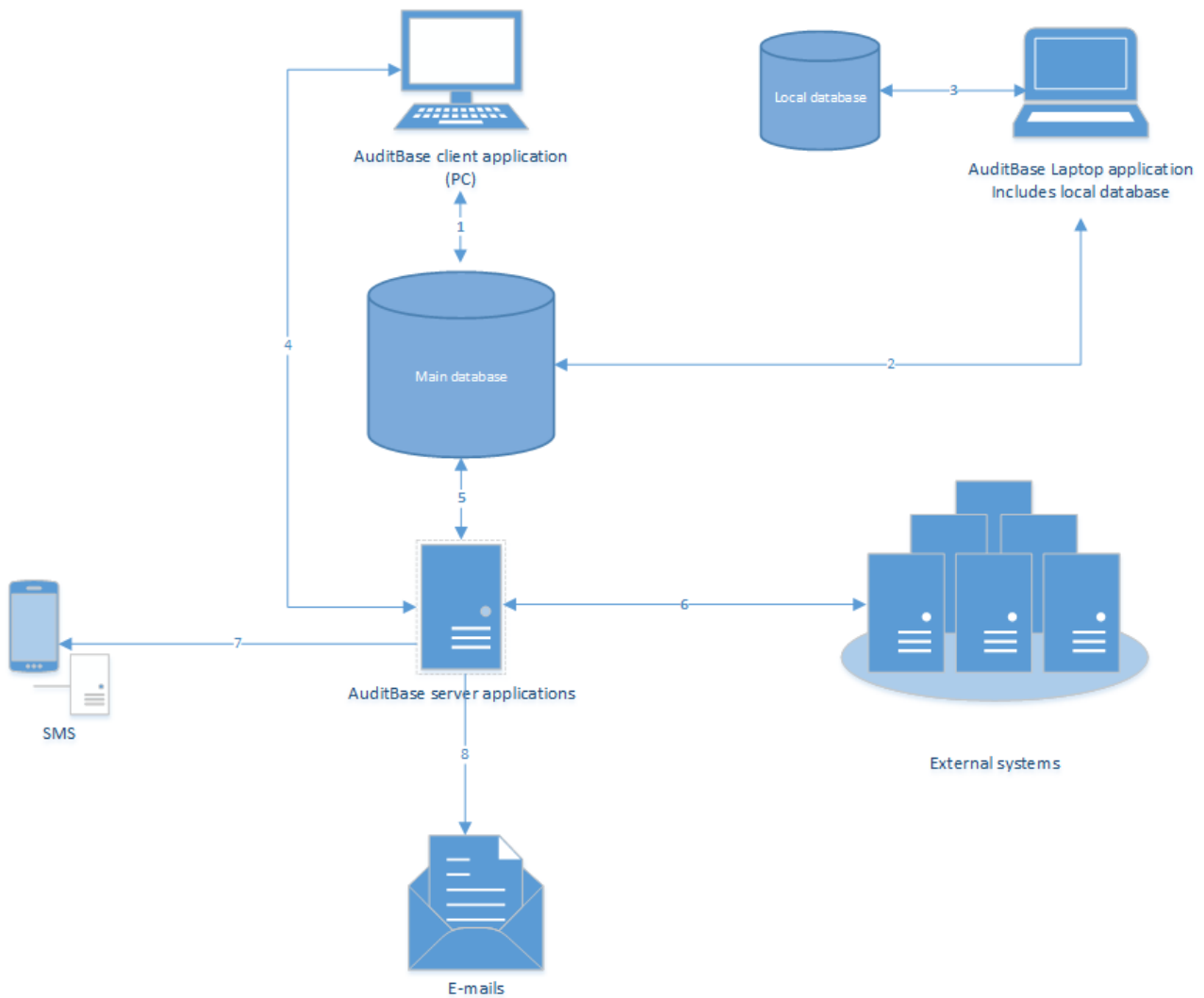
In general, customers are suggested, that using the system in an environment not satisfying minimum requirements can cause previously unidentified risks to patients, users, and third parties. Customers are responsible for analyzing and evaluating risks related to providing or changing their IT infrastructure.

Changes to the IT-Network include:

1. Changes in IT-Network configuration;
2. Addition of items (hardware and/or software platforms or software applications) to the IT-Network;
3. Removal of items from the IT-Network;
4. Update of hardware and/or software platforms or software applications on the IT-Network;
5. Upgrade of hardware and/or software platforms or software applications on the IT-Network.

A.7 Information flow

A.7.1 Information flow – Diagram



A.7.2 Information flow – Assets

Name	Description	Personal data	Storage
Auditbase client application (PC)	Auditbase client Windows GUI application. Operates in the local area network, connects to the Main database.	Yes. Users read and enter personal data using this application.	No

Name	Description	Personal data	Storage
Auditbase Laptop application, including Local database	<p>Auditbase client application configured for operation outside the local area network.</p> <p>Includes Local database engine for storing data.</p>	Yes	Yes
Main database	<p>The database where all data are stored.</p> <p>The owner of the database is the Customer; keeping the data is the Customer's responsibility.</p>	Yes	Yes
Local database	<p>The database is used as a part of the Auditbase Laptop application.</p> <p>Contains data about a very limited number of patients.</p> <p>The owner of the database is the Customer; keeping the data is the Customer's responsibility.</p>	Yes	Yes
Auditbase Server applications	Various standalone applications used for interfacing purposes.	Yes	Depends on the used interfaces
External systems	<p>Auditbase has interfaces to external Information systems. That can include:</p> <ul style="list-style-type: none"> ◦ Hospital Patient Administration System (PAS) for exchanging demographics and appointment information. ◦ Document storage system. ◦ Etc. 	Yes	Yes
SMS	SMS sent to patients for appointment reminders.	Configurable	On the patient's mobile phone according to their configuration

Name	Description	Personal data	Storage
E-mail	Documents e-mailed to patients and other parties.	Yes	Receiver responsibility.

A.7.3 Information flow – Description

Number	Description	Personal data processed
1	Auditbase client Windows GUI application reads and writes data to the main database; operations are done in the local area network.	Yes
2	The Auditbase Laptop application (configured for operation outside the local area network) reads data from the main database for further copying it to the Laptop database; it also synchronizes modified data to the main database. These operations are done in the local area network.	Yes
3	Auditbase Laptop application (configured for operation outside the local area network) reads and writes data to the Laptop database; operations are done inside a laptop PC.	Yes
4	Auditbase client Windows GUI application requests data from the Server standalone applications and receives a response.	Yes
5	Auditbase server applications read and write data to the Main database for interfacing needs.	Yes
6	Auditbase server applications exchange data with external systems.	Yes
7	Auditbase server application sends SMS to patients using E-mail or Web services provided by the Customer.	Configurable
8	Auditbase server application sends E-mail to patients and other parties using the e-mail service provided by the Customer.	Yes

Appendix B

B.1 Manufacturer and System Data

The SaMD Auditbase System is manufactured and sold in the EU by:

Head office:

Auditdata A/S

Wildersgade 10B 1408 København K Denmark

Phone: +45 70203124

www.auditdata.com

R&D site:

Auditdata Ukraine TOV, Ukraine

04053, Kyiv, str. Sihovykh Striltsiv, 23a

Phone: +38 044 284 18 65

www.auditdata.com



2003 Auditbase

Documentation version:

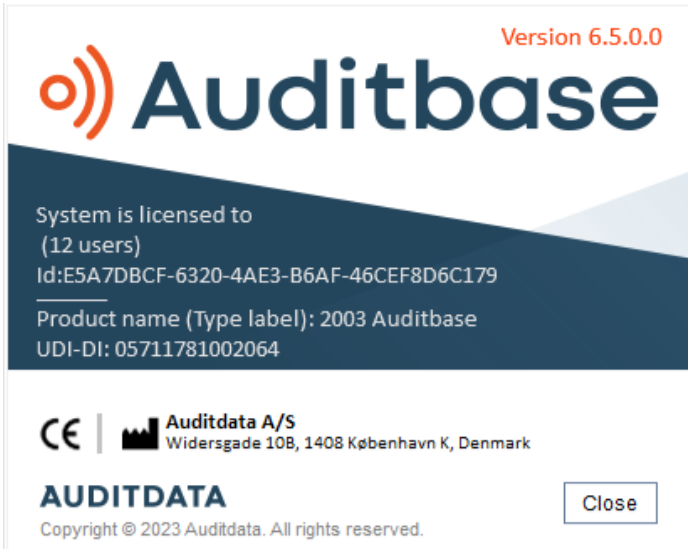
Auditbase Help System version (IFU) DN02187/06

Symbols used on the system, its packaging, and in documentation:

See the section "[Symbols used](#)" for an overview of symbols used.


B.2 Label signs interpretation

B.2.1 Label sample



B.2.2 Label interpretation for MDR

NOTE: The licences list is dynamic and varies according to the licence content for each customer.

Auditbase	Type of the device
Version 6.5.0.0	Device version
	Manufacturer's address
CE	CE marking
2003 Auditbase	Product name (type label)