FeNO by NIOX®

NIOX® Patient

User Manual

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1 Important information

1.1 Before using NIOX® Patient

NIOX® Patient should only be operated as directed in this manual by trained healthcare professionals. Trained status is achieved only after careful reading of this manual. Read the entire instructions for use and make certain that you fully understand the safety information.
Refer to the NIOX VERO ®User Manual for operation of the NIOX VERO® device.

Symbol	Description
WARNING!	Indicates a potentially hazardous situation that, if not avoided, can result in bodily harm or injury.
CAUTION!	Indicates a potentially hazardous situation that, if not avoided, can damage a product or system, cause loss of data or harm to business.
Note	Alerts the reader to important information on the proper use of the product, user expectations, error situations, and actions related to these.

1.2 About this manual

NIOX® Patient User Manual - English 000209, version 12, October 2025. Information in this document is subject to change. Amendments will be made by NIOX® as they occur.

The User Manual provides instructions on how to operate NIOX® Patient. It contains numbered step-by-step instructions with screens and illustrations. Buttons are illustrated in bold or as icons. Choices within steps are displayed with bullet points.

1.3 Responsible manufacturer and contacts

NIOX AB
Hansellisgatan 13, SE-754 50 Uppsala, Sweden
Phone: +46 (18) 32 88 37
e-mail: techsupport@niox.com
www.niox.com

1.4 Warnings

- NIOX® Patient should only be operated by healthcare professionals.
- Operate NIOX® Patient as stated in this manual. NIOX® accepts no responsibility for damaged application or faulty results, if the application is not handled according to this manual.
- Modification of NIOX® Patient application is not allowed.
- Do not use a damaged application.
- All warnings in the NIOX VERO® User Manual are also applicable when NIOX VERO® is used together with NIOX® Patient.

1.5 Intended use

NIOX® Patient is a PC application designed to store, display and report a patient's FeNO measurements obtained from NIOX VERO®.

As NIOX® Patient is preferably used in conjunction with NIOX® Panel and NIOX VERO®, it is recommended to read the user manual in conjunction with the use of NIOX® Patient.

NIOX® Patient can store data either locally or in a network database.

2 Product description

2.1 NIOX® Patient

NIOX® Patient is designed to manage patient records, measurements, users, reports and database administration. The software contains an administrative mode to manage user information, customize patient records and reports. The database allows measurements pertaining to a specific patient to be centrally collected even if they are performed on several different instruments.

2.2 NIOX® Panel

NIOX® Panel is described in the NIOX VERO® User Manual. NIOX® Panel is a visual aid that allows the user to operate the instrument from a PC and store measurements in the database.

3 Installation and setup

3.1 PC requirements

Operating systems

- Windows® 7, Windows® 8 (RT versions excluded), Windows 10 or Windows 11

Supported screen resolutions

- 1024x768
- 1366x768
- 1280x800
- 1920x1080

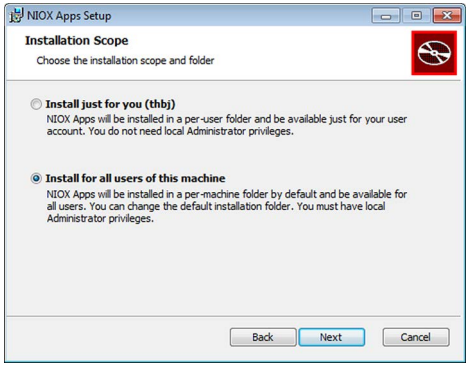
3.2 Installation

1. Select the file named setup.exe

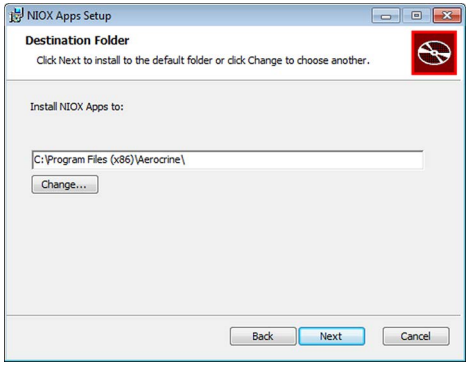
2. An installation wizard opens, accept license agreement.

3. To create a standard installation select “install” and continue with step 7. To change installation path or add more features than predefined select “advanced”.

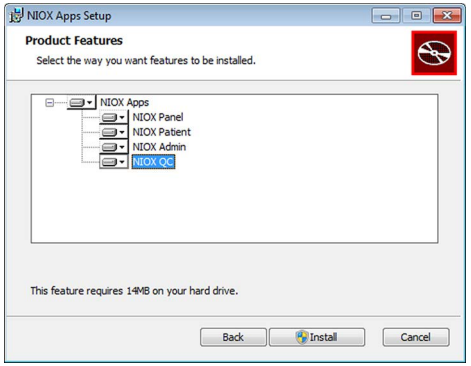
4. Recommended is to install for “all users of this machine”



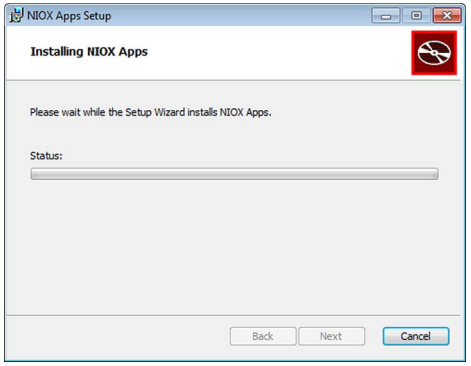
5. To edit installation path select “Change”.



6. Select what features to be installed, and then click “install”.



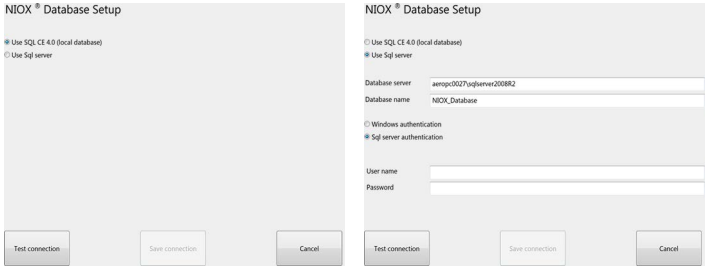
7. Wait for the programs to be installed.



8. The programs are now available in the selected location or in the start menu.

3.3 Database setup

NIOX® Patient is connected to a SQL CE database by default.



3.3.1 SQL CE Single user database setup

1. Start the Database (Db) program from the start menu.
2. Select SQL CE (local database)
3. Select **Test connection.**
4. Select **Save connection**.
5. NIOX® Patient is now connected to the local database installed on the computer.

3.3.2 SQL Multiuser Database setup

Note: Before NIOX® Patient can be connected to a multiuser Database, the database has to be created. For instructions “Installation of NIOX® Database on SQL server” on page 7

1. Start the Database (Db) program from the start menu.
2. Select Use SQL Server.
3. Enter the address of the SQL Server (computer name/database instance name).
4. Enter the name of the database.

5. Select Authentication Method: Windows Authentication (continue with step 7) or SQL Server Authentication.
6. Enter SQL Server user name and password.

Note: Print and save the credentials in a secure place.

7. Select **Test connection**.
8. If the test is successful, select **Save connection**.

3.4 Server requirements

Server requirements
- Microsoft® SQL Server 2008r2 to Microsoft® SQL Server 2022

3.4.1 Server installation and configuration

3.4.2 Network requirements

To be able to connect to the multiuser database, a network connection between the computer and the network database is needed. Contact your network administrator.

3.4.3 Import database

Start Admin, select Database & Setup. Select “Restore Database”. Select the backup-file to import.

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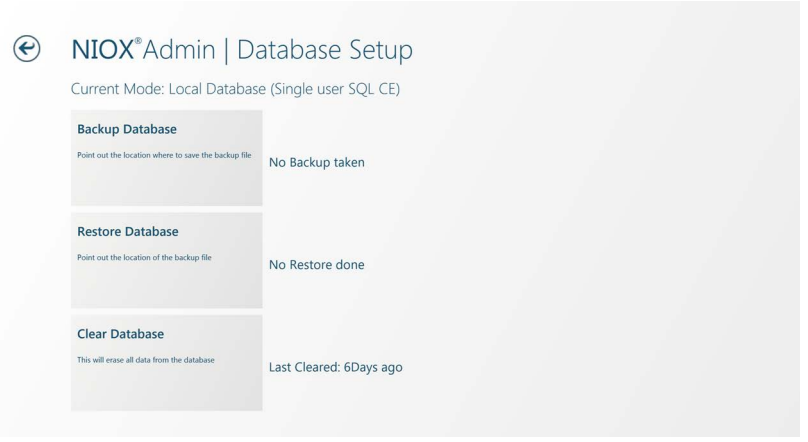


For network databases, contact your network administrator. NIOX® recommends creating a new single user database, importing as described above, exporting SQL CE definitions and data to a SQL script, running the script on the SQL Server. Start NIOX® Database and connecting to the SQL Server.

3.5 Set NIOX® administrator privileges the first time

The system comes with a default administrator account in NIOX® Admin.

1. Select the “Ad”-icon on the start menu. This opens the NIOX® Admin application.
2. Select NIOX® User. This opens the NIOX® User view.
3. Log in as:
   User name: **a**
   Password: **p**

4. Select the user from list and set a new user name (optional) and a new password (recommended). Refer to “Edit user” on page 17.
5. Print and save the new administrator credentials in a secure place.

Note: Make sure that the password is saved in a secure way.

3.6 Installation of NIOX® Database on SQL server

Before NIOX® Patient can be connected to a multiuser Database, the database has to be created. The database should be created by a network administrator.

1. Start Microsoft SQL Server Management Studio, log on to the SQL server.
2. Select Create new Database.
3. Name the database i.e NIOX®.
4. Open “New Query” in Management Studio. Copy the T-sql script (available in the SqlServerScript-folder) to the query window. Change “use database name” to “use NIOX®”.
5. Run the T-sql script. This creates all necessary tables to store NIOX® information and also initializes the user table with the built-in administrator account.
6. Connect to the database with NIOX® Database and then start NIOX® Admin to change the user name and password for the built-in administrator account.

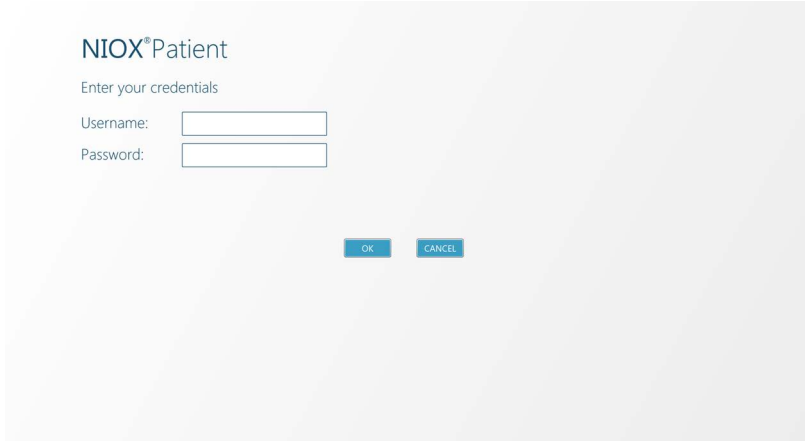
4 NIOX® Patient

NIOX® Patient is used to administrate information regarding a specific patient, create new patient records, search for specific patient records, view records, add or delete notes, manually add measurements or import measurements ®. It is also possible to print the records in various formats.
NIOX® Panel is used to automatically store measurements in the database or directly into a patient record.

Note: To avoid having to import measurements from instruments, NIOX® recommends selecting the patient in NIOX® Panel before performing a new measurement. If the patient does not exist, use NIOX® Patient to create the patient.

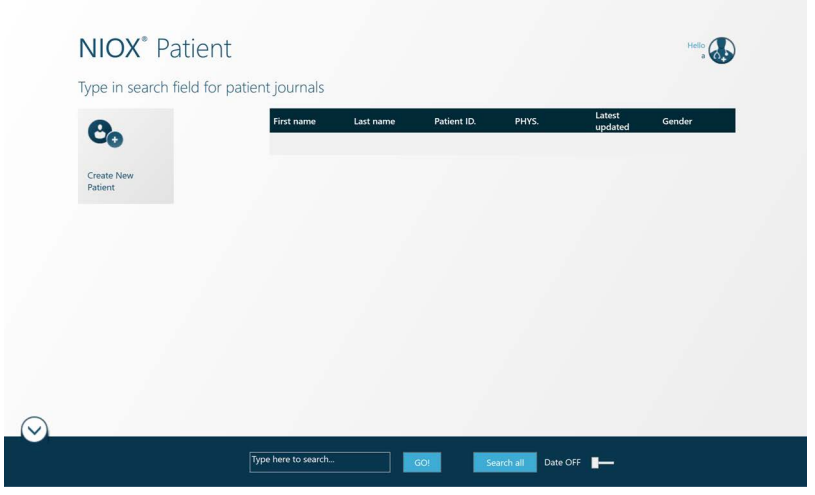
4.1 Start NIOX® Patient

1. Select **NIOX® Patient**. This opens the login view.

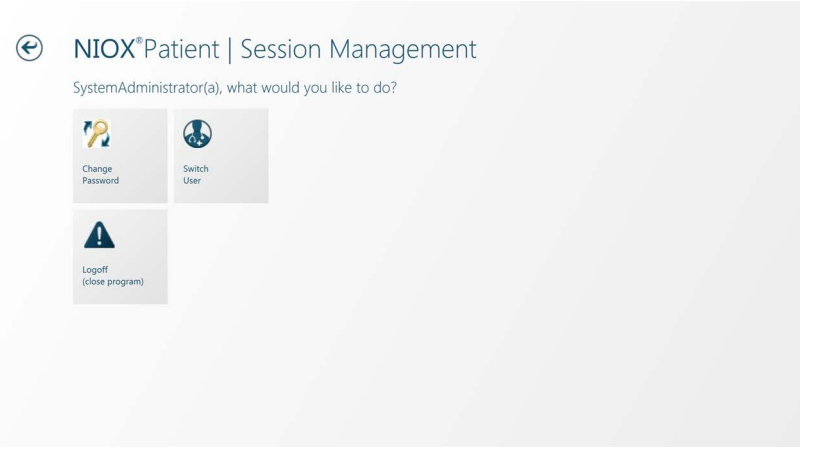


2. Enter user name in the User name text field.

3. Enter password and select **OK**. This opens the NIOX® Patient view.



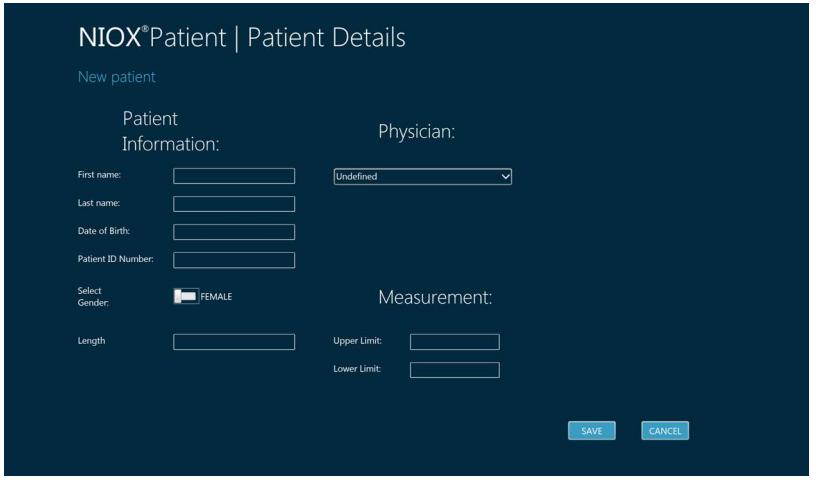
4. The name of the current user will be displayed in the top right hand corner. Select the name and the Session Management view will open.



5. In the Session Management there are three options:
   - Select **Change password** to change password.
   - Select **Switch user** to log in as a different user**.**
   - Select **Log off** to close NIOX® Patient.

4.2 Create new patient

1. In the NIOX® Patient view, select **Create new patient**. The Patient Details view opens.

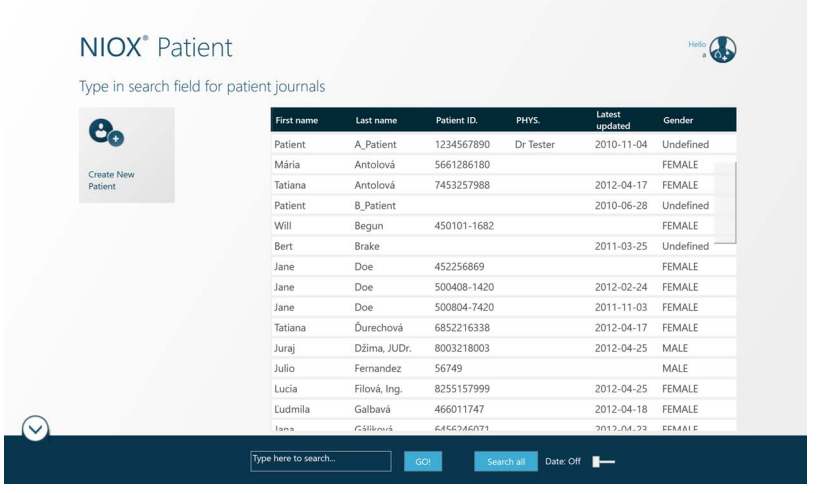


2. Select the relevant text fields and enter information.

Note: Mandatory information: Patient ID (must be unique).

3. Select **physician** from the drop down list.
4. Optional: Set upper and lower limits for the patient's FeNO value by entering the limits in the text fields.
   It is also possible to change the limits in the graph.
5. Select **Save** to return to the NIOX® Patient view.
   Cancel leaves the view without saving changes.

4.3 Search for a patient



1.If not already open, open the search text field at the bottom of the screen by the **up arrow** button.

2.Enter the patient details and select **Go**.

- To search enter a first name, last name, a patient ID or enter a date range to find the relevant patient.
- The search results search will be presented in a list.
- Leaving the search field empty and selecting go will show the patient records with the most recently performed FeNO measurements in a list.
- To view all patients in the database press **Search All.**
- To hide the search text field select the **arrow down** button.

Note: Scroll using the vertical bar to view all information in the search result list.

4.4 Open a patient Journal

1. In the search results list, select a row to open the corresponding record. The Journal for the selected patient is opened.

2. The Journal view displays an overview and several additional options for viewing patient data. The fields (tiles) to the left:
   - **Patient ID**, displays the latest measurement result, date and physician. Selecting this button opens the Edit Patient Details view. Refer to “Edit patient details” on page 11 for details.
   - **Journal Notes**, displays the number of available Journal notes and the latest note and date in full. Selecting this button opens the Journal Notes view. Refer to “View Journal note” on page 12 for details.
   - **Import Measurement from Database** - Selecting this button allows connecting measurements to the patient Journal. Refer to “Import measurements to a Journal” on page 13 for details.
   - **Manually Create Measurement**- Select this button to manually enter measurement details. Refer to page 13 for details
   - **Perform New Measurement**- Selecting this button starts NIOX® Panel and populates Patient ID with the opened patient. Only available when NIOX® Panel is installed on the same computer and in the same folder as NIOX® Patient. Refer to page 12 for details.
3. In the bottom search bar there are also options:
   - **Show measurement mode** - Select any option to display of the available measurement modes by clicking on it.
   - Select the date/time range displayed in the Journal by entering time intervals in the search field, select the **arrow down** button and set year/month/day. The interval starting time is entered in the top row, and ending time in the bottom row.
   - Select how to display the measurements. To show the graph, slide the **Graph** slide button to the right. The text beside the button will display **Graph ON**. To display the view without showing the graph, slide the **Graph** slide button to the left. The text beside the button will display **Graph OFF**.

4. To show the limits, slide the **Limits** slide button to the right. The text beside the button will display **Limits ON**. To display the view without showing the limits, slide the **Limits** slide button to the left. The text beside the button will display **Limits OFF**.

Note: To change limits just drag the numbers on the left side of the graph to the correct value.

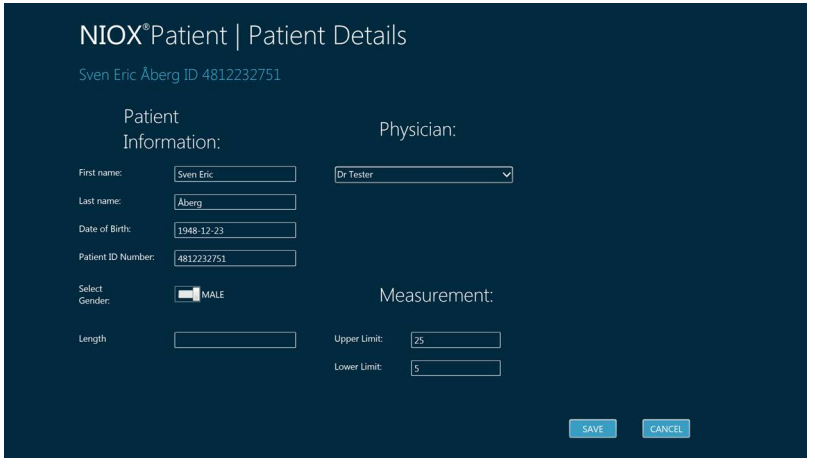
5. To print a report, select **Create Report.** See details in the section “Create a report of a Journal” on page 14.

4.5 Make changes to an opened patient record

When a patient Journal is opened, it is possible to edit patient details, enter a new Journal note, delete Journal notes, manually add measurements or import from an earlier connected instrument. If several instruments have been connected to the database, measurements can be imported from any of the instruments in the network.

4.5.1 Edit patient details

1. To edit patient details select the button displaying the patient ID. This opens the Edit Patient Details view.



2. Select the relevant text box/es and enter changes with the keyboard.
   - To change physician select and choose a physician from the appearing drop down list.

Note: To add a physician use NIOX® Admin, new physician.

3. Select **Save** to save the changes and return to the open patient Journal view. **Cancel** leaves the view without saving changes.

4.6 Start a measurement from an opened patient record

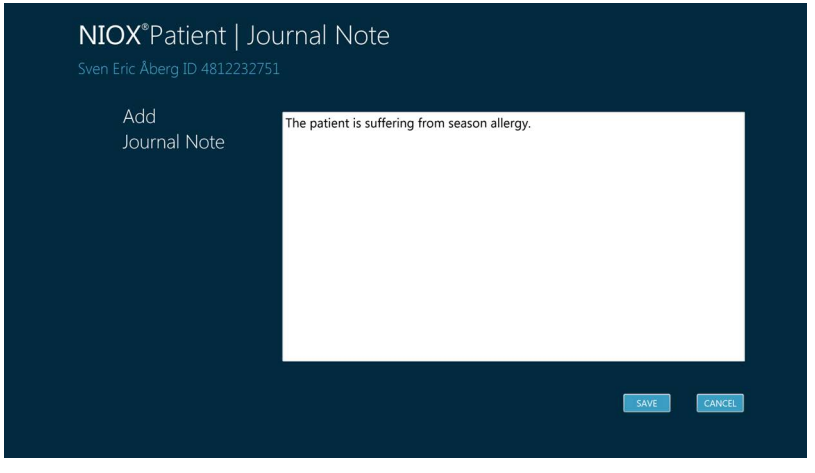
To start NIOX® Panel and automatically populate patient ID, select the **Perform New Measurement** button.

Note: Only available when NIOX® Panel is installed on the same computer and in the same folder as NIOX® Patient.

4.7 Patient Notes

4.7.1 Enter Journal note

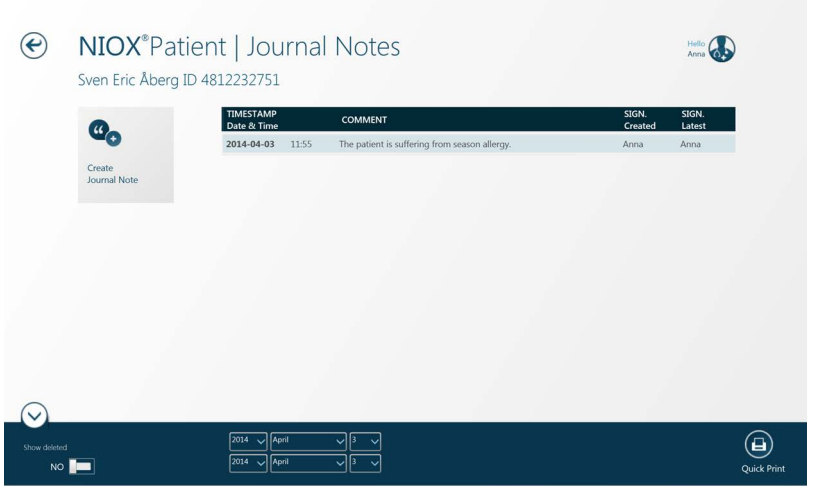
1. To enter a new Journal note, select **Create Journal Notes**. The Journal Notes view opens.



2. Enter the new Journal note in the text field. Select **Save** to save the changes and return to the open patient Journal view. **Cancel** leaves the view without saving changes.

4.7.2 View Journal note

1. Select Journal Notes in the patient Journal view. This opens the Journal Notes view.



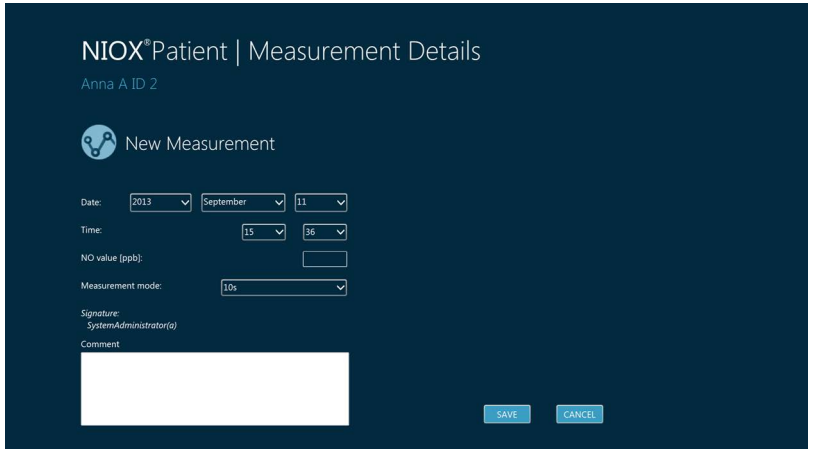
4.7.3 Delete a Journal note

1. To delete a Journal note, select the row with the relevant Journal note. The Edit Journal Notes view opens.
2. Slide the button **Deleted** to display **Yes.**
3. Select **Save** to save the changes and return to the Open Patient Journal view.

4.8 Manage measurements

4.8.1 Manually add measurement to a Journal

1. To add a measurement to an open patient Journal, select **Manually Create Measurement**. The Measurement Details view opens.



2. Select the relevant text box/es and enter changes with the keyboard, or select the arrow down button and then mark a value in the appearing drop down list.

Note: Mandatory information must be entered: FeNO value.

3. Select **Save** to save the changes and return to the Open Patient Journal view. **Cancel** leaves the view without saving changes.

4.8.2 Add comments to a measurement

To add comments to a measurement select the measurement in the list, add the comment and click **Save**.

The signature of the current user will be added automatically.

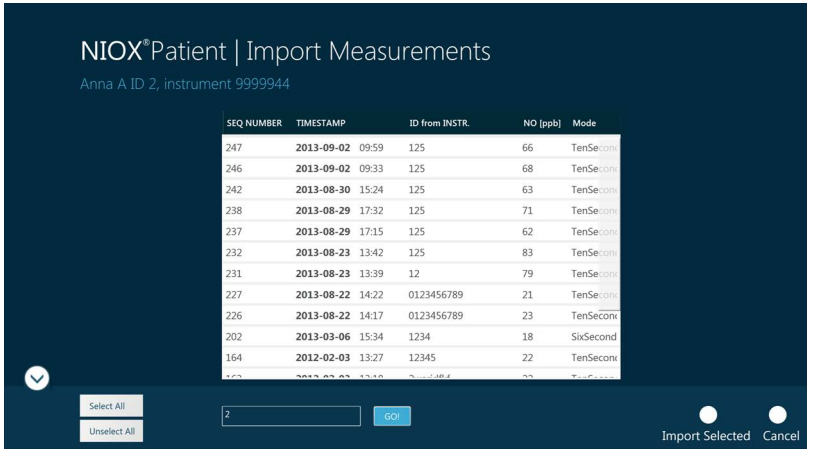
4.8.3 Import measurements to a Journal

1. To import measurement to an open patient Journal, select **Import Measurement from Database.** The Import Measurements view opens illustrating which instruments are connected to the database via NIOX® Panel.
2. Select which instrument to import measurements from. This opens the Select Measurements to Import view.

Note: The measurements displayed are performed on an instrument when connected to NIOX® Panel and not matched to a patient ID. For more details see page 15.

Note: If only one instrument has been connected to the database, step 2 is not available. Proceed to step 3.

Note: The search field is automatically populated with the open patient journal ID.



3. Scroll the list for the measurements to import.
4. Select the row/s with the measurement/s to include in the import. The selected row/s will be highlighted.
5. Select **Import Selected** to start importing and return to the opened patient Journal view.
   Cancel returns to the opened patient Journal view without importing any measurements.

Note: In case a measurement is imported to the wrong patient Journal, it is possible to delete the measurement from the patient Journal and make it available for reimporting to the correct patient Journal.

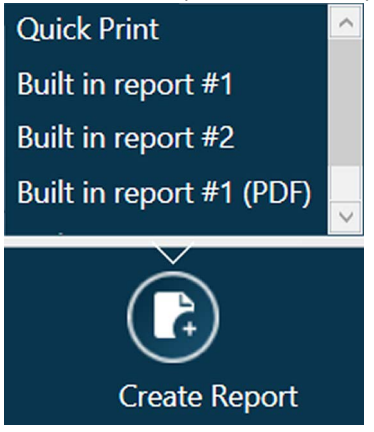
- Select the faulty imported measurement from the Patient journal measurement list or select it in the graph.Then slide the **Delete** button to display **Yes.** To save changes select **Save**.

4.9 Create a report of a Journal

In the opened patient Journal view there are several print options.

Note: The report will contain the content shown on the screen. Select whether to include or exclude graphs, limits and time intervals according to the descriptions on page 10.

1. Select Create Report. A view with print options will open:



- **Quick print**. Prints the content shown on the screen.
- **Built in report 1 or Custom report 1.** Creates a Word-file which allows for further editing.
- **Built in report 2 or Custom report 2**. Creates a Word-file which allows for further editing.
- **Built in report 1 (PDF) Creates a PDF** file with the same appearance as Built in report 1 or Custom report 1.
- **Built in report 2 (PDF)** Creates a PDF file with the same appearance as Built in report 2 or Custom report 2.

2. After saving/printing you will return to the opened patient Journal view.

- To build a customized report start with either PatientReport1.doc or

PatientReport2.doc and save the document with a new name.

- To load the customized report use NIOX® Admin Customize reports on page 18.
- To create a completely customized report refer to BuiltinReportVariables.docx. BuiltinReportVariables.docx contains all possible variables to use in a customized report.

4.10 Automatic import of measurements from NIOX® Panel

NIOX® Panel is an optional visual aid and software allowing the user to operate the NIOX VERO® from a PC.

Provided that the patient ID is entered, a patient measurement performed using NIOX® Panel will automatically be saved to the correct patient in the NIOX® database.

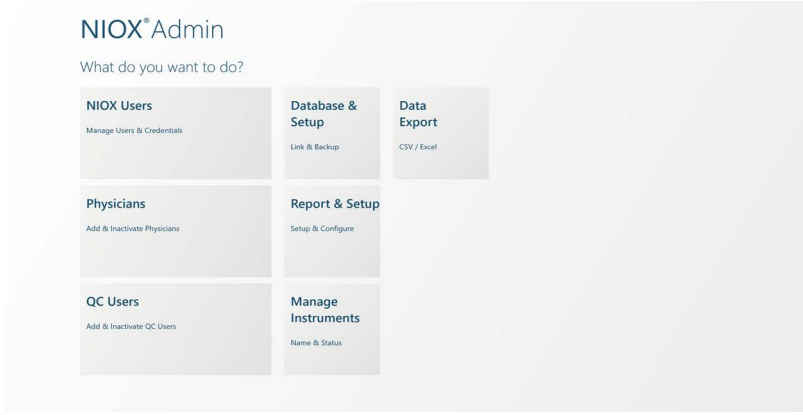
Note: A measurement performed with NIOX® Panel without entering the patient ID is stored in the NIOX® database but must be matched manually to the correct patient in the database.

Note: If a patient Journal is already opened the patient will be selected in NIOX® Panel patient ID search field.

5 NIOX® Admin

The application NIOX® Admin is used to manage user information and user privileges. It contains several options:

- **NIOX® Users** is used to manage users, edit user information, add new user and manage account credentials.
- **Physician** is used to add or edit a physician.
- **Database & Setup** is used to perform backup, restore or clear the database (for standalone usage).
- **Report & Setup** is used to customize the information shown in Journals and reports.
- **Manage Instruments** is used to name the instruments in the database and to inactivate instruments that are no longer in use.
- **Data Export** is used to select and export data from the database to .csv- or .xls-format



If the multiuser network database setup is implemented, the system can access data from all connected instruments.

One or several users may be appointed administrators of the system. Administrators can add and delete NIOX® users and set privileges and status.

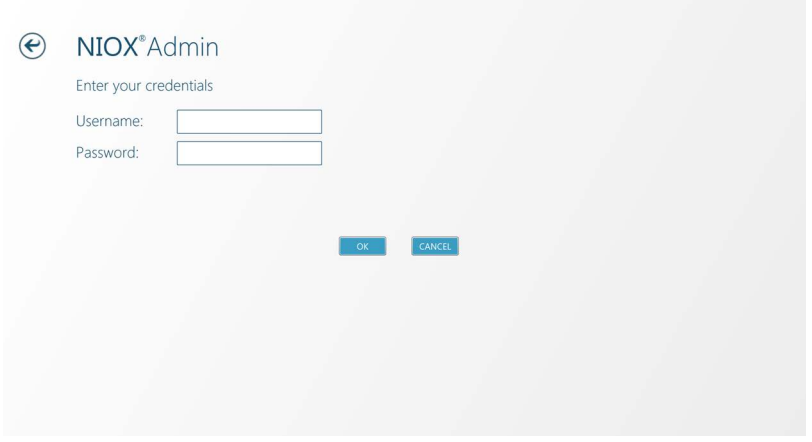
5.1 Start NIOX® Admin

1. Select NIOX® Admin. This opens the NIOX® Admin view where further choices can be made.
2. To return to the NIOX® Admin view from any other view, select the **arrow icon** next to the view title in the top left hand corner of the screen.
3. To close NIOX® Admin, select the **X** in the top right corner.

5.2 NIOX® Users

NIOX® Users allows administrators to add or inactivate users and set relevant privileges to the users.

1. Select **NIOX® Users**. This opens the NIOX® Admin login view.



2. Enter User name and password.
3. This opens the Users & Settings view displaying users and applications access.
   - Applications marked with a check mark are accessible
   - Applications without a mark are not accessible.
4. Select which category of users to display by setting the slide button **Show users that are** to show **Active** or **Inactive** in the bottom left corner.

5.3 Create new user

1. Select **Create New user**. This opens the New User view.
2. Select the relevant text boxes and enter the user account information and user details including ID with the keyboard.
   - User name and Identity must be unique.
   - User name, identity and password is mandatory to enter.
   - Enter notes by selecting the Notes text box.

Note: Remember to note the user name and password to give to the new user.

3. Check the relevant privileges check box/es to give the user access to: NIOX® Admin and/or NIOX® Patient applications.

Note: To inactivate a user in the database slide the User status button to show Inactive.

4. Select **Save** to save the changes and return to the NIOX® Admin Users & Settings view. **Cancel** leaves the view without saving changes.
5. Remember to inform the new user of their user name and password.

5.3.1 Search user

1. Select the search text field at the bottom of the screen, enter the user details and select **Go**.
   - Type a name or user name or an ID in the search field.
   - Search among inactive users by setting the **Show users that are** slide button to **Inactive**.
2. The results matching the search will be presented in the list.

Note: Scroll using the vertical bar to view all information in the search result list.

5.3.2 Edit user

1. Select a user from the list. This opens the Edit User view.
2. Edit the relevant information by selecting the text box and enter the new information using the keyboard.

   •Set privileges by selecting the relevant check box. A check marked box gives the user access to the application.
   •To remove privileges, uncheck the check box.

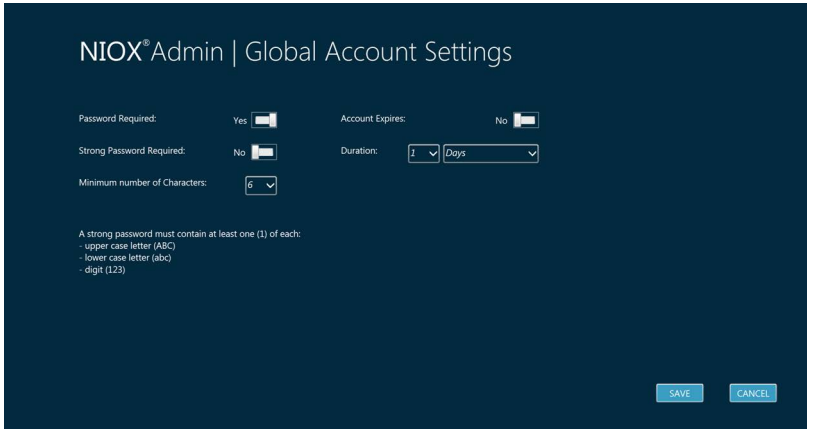
   - Set the user status by setting **User Status** button to display **Active** or **Inactive**.
3. Select **Save** to save the changes and return to the NIOX® Users view. **Cancel** leaves the view without saving changes.

5.3.3 Set global account rules

Global account setting regulate the general rules on password usage and account duration for all users included in the system. Setting or changing global account rules requires administrator privileges.

Note: Administrator accounts never expires.

1. Select **Account settings.** This opens the Global Account Settings view.



2. Slide the button **Password required** to show **Yes** or **No**. If password is not required, then go to step 6 below.

   3.Select the **arrow down** button and select a number for the minimum numbers of characters for the required password.

   4.Slide the button **Strong password** to show **Yes** or **No**.
5. Slide the button **Account expires** to show **Yes** or **No**.
6. Select the arrow down button and select values for the account duration.
7. Select **Save** to save the changes and return to the NIOX® Admin Users & Settings view. **Cancel** leaves the view without saving changes.

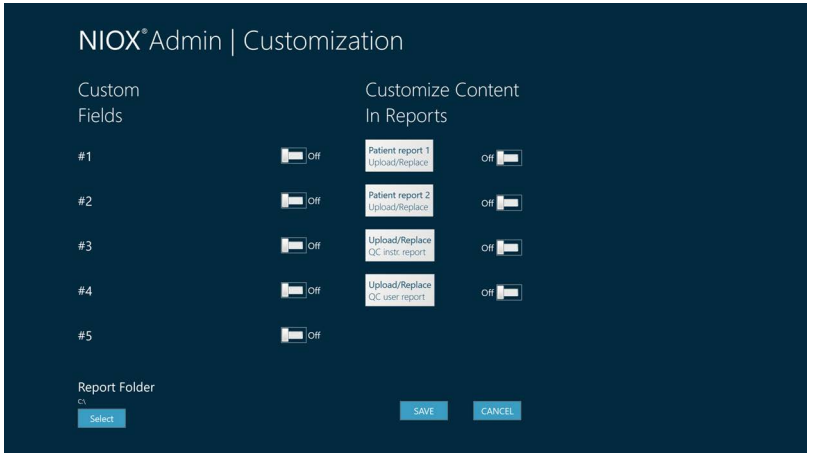
5.4 Customize patient Journals

This options enables NIOX® users to customize patient Journals and Reports.

5.4.1 Custom fields

To add custom fields to patient Journals.

1. Select **Report & Setup** in the NIOX® Admin view. This opens the Customization view.



2. Select a custom field and enter the title of the custom field to appear on the patient Journal. Repeat to add more fields.
3. Slide the button next to the relevant custom field to show **On** for it to be displayed.

5.4.2 Customize content in reports

Built in reports are installed during the installation and saved in the folder C:\Program Files (x86)\NIOX\NIOX Apps\Built-in-reports.

The report is created and available in word-format. The content in the patient journal view that can be customized in the report is shown in the word-file "ReportingVariables" as unique identifiers.

Note: Patient report can be selected from NIOX® Patient Journal view.

To customize the appearance of a report:

1. Open the built in reports-folder C:\Program Files (x86)\NIOX\NIOX Apps\Built-in-reports.
2. Select one report to customize, open the "ReportingVariables" and find the id for the fields to add to the report. i.e "__ID 33" and "__ ID 38" for custom field 1, save.

Note: Make sure to use the exact correct unique identifiers otherwise the information will not be recognized and shown in the report.

3. To select where the graph is displayed just move the picture in the document and save.

Note: The tables will include all measurements for the specific patient. It is also possible to set date ranges by selecting the dates in the bottom bar in the patient journal view.

Note: To edit the appearance of the PDF reports, edit one of the word files to preferred look, upload it as custom report 1 or 2.

For a complete customization of a report open the Reporting-Variables file to identify all possible information to be shown in the report.

__ID01	Patient name
__ID02	Patient identification
__ID03	Patient date of birth
__ID04	Patient gender
__ID05	Patient's current physician
__ID06	Upper limit (-- when not set)
__ID07	Lower limit (-- when not set)
__ID08	Latest FeNO value for the patient
__ID09	Date and time for latest FeNO value
__ID10	Date only for latest FeNO value
__ID11	Latest ambient NO value
__ID12	Date and time for latest ambient NO value
__ID13	Date only for latest ambient value
__ID14	Latest note text for the selected patient
__ID15	Date and time for latest note
__ID16	Date only for latest note
__ID17	Instrument identification, when applicable for example QC-reports

5.4.3 Upload a customized report:

1. Upload the customized report by selecting **Upload/Replace** button.
2. Select a report to be uploaded.
3. Slide the button next to the uploaded report to **ON**.
4. Click **Save** and the uploaded report is available in NIOX® Patient for print.

5.4.4 Reports folder

To set a default folder for reports generated in NIOX® Patient.

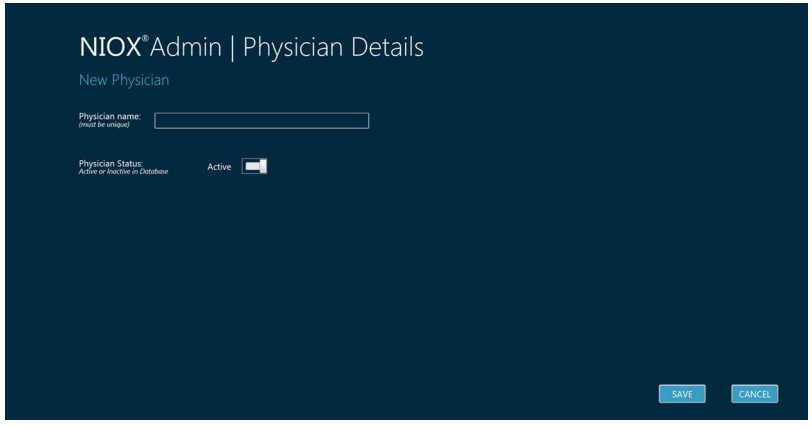
1. Select Report & Setup in the NIOX® Admin view.
2. Under Report folder click on "Select", this opens a browse window to select which folder to be set as default.
3. Select "Save" All reports generated in NIOX® Patient will now by default be saved in that folder.

5.5 Physicians

The option Physicians, available in NIOX® Admin, is used to create user profiles for the professionals working with the NIOX® instruments. Entering the physician is useful for a doctor when searching for a patient.

5.5.1 Add a physician

1. Select **Physicians** in the NIOX® Admin view. This opens the Physicians view.
2. Select **New Physician.** This opens the New Physicians view.



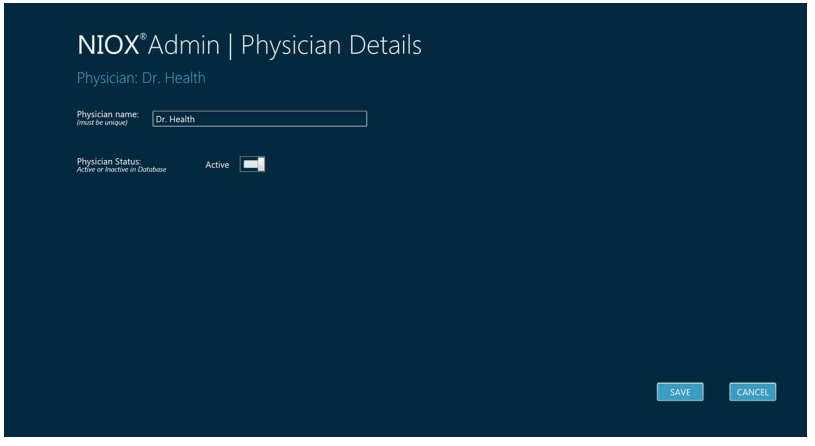
3. Enter the physicians name.

Note: Physicians name must be unique.

4. Set the **Physician status** by sliding the button to show Active or Inactive.
5. Select **Save** to save the changes and return to the Physicians view. **Cancel** leaves the view without saving changes.

5.5.2 Edit a physician entry

1. Select the physician in the in the appearing list. This opens the Edit Physicians view.



   - Select the text box and edit the physicians name.
   - Change the **Physician status** by sliding the button to show Active or Inactive.
2. Select **Save** to save the changes and return to the Physicians view. **Cancel** leaves the view without saving changes.

5.6 Database & Setup

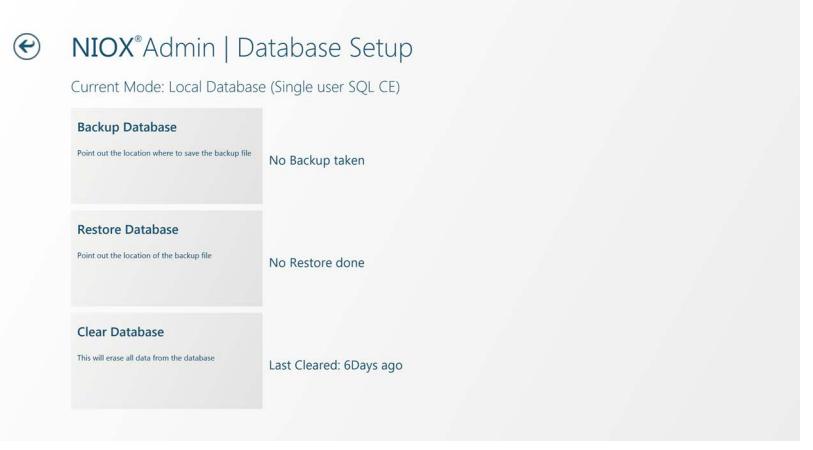
The option Database Setup, available in the NIOX® Admin view, is used to manage the database links and backup routines.

Note: In a Multi User setup, the backup is performed by the network administrator and there is no option to clear database.

Note: The setup can be changed later. Refer to the “Database setup” on page 5 for details.

5.6.1 Start Database & Setup

Select **Database & Setup** in the NIOX® Admin view. This opens the Database Management view displaying current setup and status. For the Multi User setup, go to section 5.6.5, Check connection to Network database.



5.6.2 Clear a Single User database

Clearing the database can be relevant if the system have been used for test purposes and to erase all test data permanently before clinical use. It can also be useful after archiving (backup of) a database, to start with a new empty database.

WARNING! Clearing the database will erase all stored data permanently.

1. Select **Clear Database**. A popup warning appears.
2. Complete the dialog. This will erase all data from the database.

5.6.3 Perform a backup of a Single User database

1. Select **Backup Database.** This opens a popup dialog.
2. Select a folder where to store the backup file.
3. Select Save. This creates a backup-file of the database.

5.6.4 Restore database to previous version

If the data stored in the database has been corrupted in any way, choose to restore the database from a previously saved backup-file.

1. Select **Restore Database**. This opens a popup dialog.
2. Select the backup-file.
3. Select Open. This restores the database to the selected version.

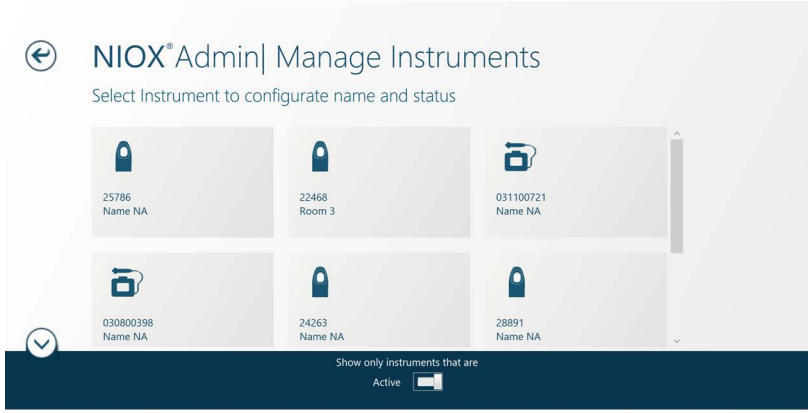
5.6.5 Check connection to Network database

1. Select **Check connection with Database.** This verifies the network connection.
   - A fully functioning connection is reported with “Connection successful”
   - A malfunctioning connection is reported with ”Connection not successful”. Contact the system administrator to address the problem.

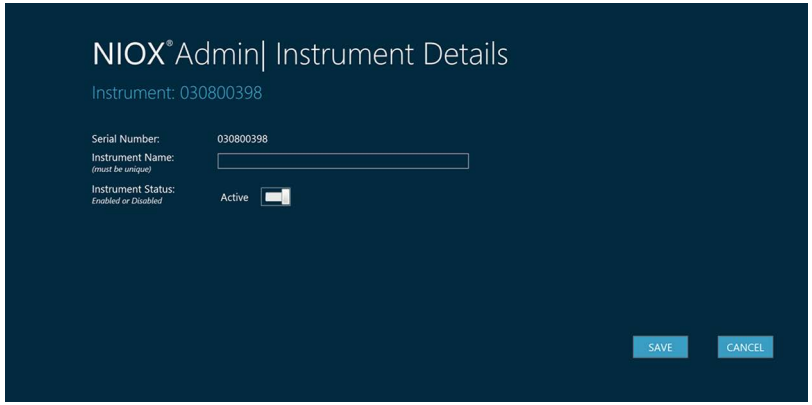
5.7 Manage Instruments

Add name to an instrument in the database or inactivate instruments that are no longer in use (expired).

1. Start NIOX® Admin
2. Select **Manage Instruments**. This opens the Management Instruments view.



3. Select the instrument to manage. This opens the Instrument Details dialog.



4. Enter name in the text box and click “Save” to name the instrument.

5. To inactivate the instrument slide the button to show “inactive” and click save.

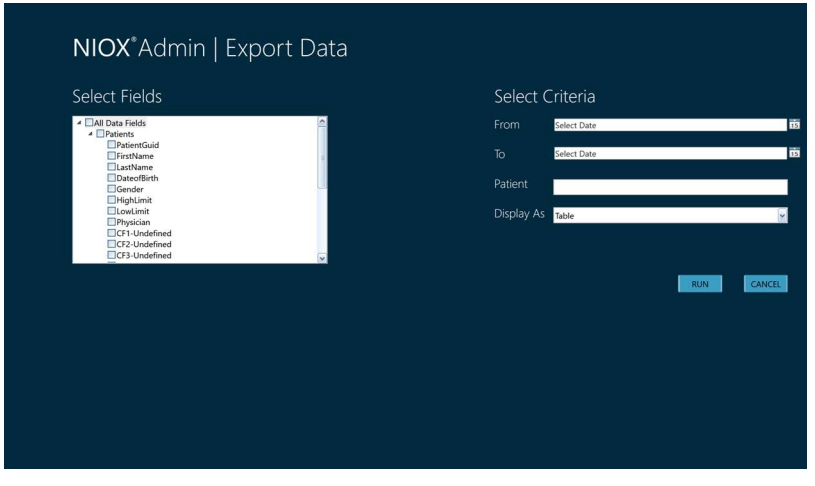
5.8 Data Export

Data export makes it possible to export patient journal data to an Excel-file (.xls- and .csv-format), it is also possible to view the data on the screen in a table.

1. Start NIOX® Admin
2. Select Data Export, this opens a login dialog.

Note: Exporting data from the database requires administrator rights.

3. Select which parameters to export, select date range, patient and format.



4. Select Run, this exports the selected parameters for the chosen patient.

Note: Leaving the patient field empty exports selected parameters for all patients in the database.

Information in this document is subject to change.

Amendments will be made available as they occur.

Based on the company's intellectual property, NIOX® Group plc develops and commercializes products for the monitoring of nitric oxide (NO) as a marker of inflammation, to improve the management and care of patients with inflammatory disease in the airways.

Patents:

NIOX® products are protected by a number of patents in the US, Europe and a range of other countries.

NIOX AB, an ISO 13485 certified company

NIOX AB, Hansellisgatan 13, SE-754 50 Uppsala, Sweden

Phone: +46 18 32 88 37, E-mail: techsupport@niox.com

www.niox.com

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