

Administration Tool Manual

UNEEG™ EpiSight Server

Version number 1.11



UNEEG™ EpiSight is released as part of the medical device encevis™



Manufacturer:

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Use-by date:

Windows 10: 10/2025



Notified Body:

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Caution: Please read paragraphs marked with this symbol carefully as they contain important safety information.

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Warnings and precautions



This version of UNEEG™ EpiSight is CE-certified as a medical device. If your country requires any other approval for medical devices you must not use this version of UNEEG™ EpiSight. Please contact your local distributor to receive a version of UNEEG™ EpiSight that is not certified as a medical device and can be used outside countries that accept the CE mark.



The modules from UNEEG™ EpiSight for the automatic analysis of EEG cannot replace the examination by the physician. As for any other automatic procedure there can be inaccuracies during the analysis with UNEEG™ EpiSight. The original EEG still needs to be used for the evaluation and the results of UNEEG™ EpiSight need to be confirmed based on the unaltered raw EEG trace.



UNEEG™ EpiSight does not provide any diagnosis or diagnostic recommendations or predictions of the patient's state. It remains the responsibility of the physician to decide over the diagnosis or to induce treatment.



The use of the software cannot replace the real-time surveillance by medical staff particularly of the vital functions. The patient's safety remains the responsibility of the medical professional.



The maximum length for one continuous EEG recording that can be analyzed with UNEEG™ EpiSight is one year. If a recording is longer than one year, UNEEG™ EpiSight will stop processing.



UNEEG™ EpiSight seizure detection cannot be used as an alarm system, since there may be a delay of several minutes between the clinical onset of a seizure and the display of the detected pattern. Some EEG-events with epileptic seizures that have an electrographic correlate might be missed. For this reason, UNEGG EpiSight seizure detection can only support but cannot replace the qualified expert in the real-time monitoring.



UNEEG™ EpiSight detection of rhythmic pattern, aEEG or background frequency must not be used as an alarm system, since the visualization of patterns could be delayed by up to several minutes.



Some events, where patterns defined in the Standardized Critical Care EEG Terminology of the American Clinical Neurophysiology Society are visible in the EEG, might be missed. All measures of the module UNEEG™ EpiSight pattern detection must be evaluated in combination with the original raw EEG and must not be the only basis for a diagnosis, treatment or change of treatment.



Contraindications

There are no known contraindications for the use of UNEEG™ EpiSight.

Possible adverse effects

There are no known possible adverse effects when using UNEEG™ EpiSight.



UNEEG™ EpiSight Server Administration Tool

UNEEG™ EpiSight Server Administration Tool is an application for an easy installation of the UNEEG™ EpiSight Server and its components. It is distributed with the UNEEG™ EpiSight Server installation package and is started with the executable "AdministrationTool.exe".

The UNEEG™ EpiSight server takes care of the connection between the UNEEG™ EpiSight viewer stations, the UNEEG™ EpiSight database and the UNEEG™ ProConnect.

The start and setup of the UNEEG™ EpiSight Server consist of 4 steps that must be followed in chronological order with the "*Next* >" buttons, as shown below.

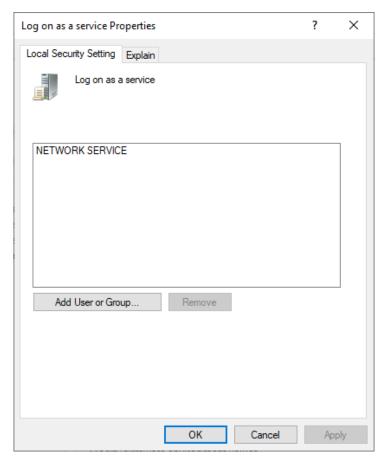


Step 0: User account

A user account should be defined beforehand that will run the server. This user needs to have administration rights and additional rights to "Log on as a service". Make sure these rights are defined before starting. Instructions on how to do it are described below. You will need to enter username and password in Step 3 of the setup, see section Run server.

Set rights to "Log on as a service"

Under the Administrative Tools, go to the following setting: *Administrative Tools > Local Security Policy > Local Policies > User Rights Assignment > Log on as a service*.



If the chosen user is not in the list as seen below, click on "Add User or Group" and enter the username.



Step 1: Database settings

Start the UNEEG™ EpiSight Server Admin tool, the executable is *AdministrationTool.exe*. The settings for the first step will open.

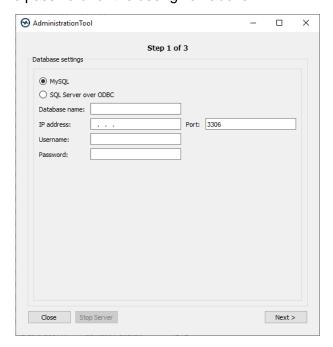
In the first step you will define the UNEEG™ EpiSight database that will be used with the UNEEG™ EpiSight server components. This is also the database that you use with the UNEEG™ EpiSight viewer. This database stores the patient information, information about the retrieved data and the results of the UNEEG™ EpiSight automated EEG analysis.

Two database technologies are supported for UNEEG™ EpiSight server: MySQL and MSSQL (SQL Server over ODBC). The settings are described in more detail below.

MySQL database

In the case of a MySQL database, you have to define:

- Database name: This is the name of the database scheme. This database scheme
 must exist at your MySQL database server before you can continue. The
 Administration tool will not create it for you. Usually it will be provided by your
 database administrator.
- IP address of your database server
- Port of the database
- **Username**: EpiSight Server will use this username to access the database. Make sure that the user has read and write permission for the database that you defined in "Database name"
- Password: The password for the user given above

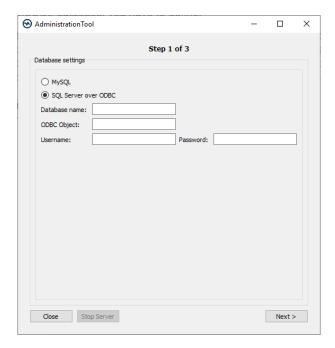




MSSQL database

In the case of a MSSQL database, you have to define:

- Database name: This is the name of the database scheme. This database scheme
 must exist at your MSSQL database server before you can continue. The
 Administration tool will not create it for you. Usually, it will be provided by your
 database administrator.
- ODBC object: This is the name of the ODBC data source, that connects to the MSSQL database. The ODBC data source needs to be set up before using this Administration tool. Please see section ODBC drivers for details.
- **Username:** EpiSight Server will use this username to access the database. Make sure that the user has read and write permission for the database that you defined in "Database name"
- Password: The password for the user given above



If unsure about any of the entries in the fields, please consult your database administrator.

Stop server

The button "**Stop server**" will only be enabled if the UNEEG™ EpiSight server is already running as explained in section <u>Server check and stop</u>.



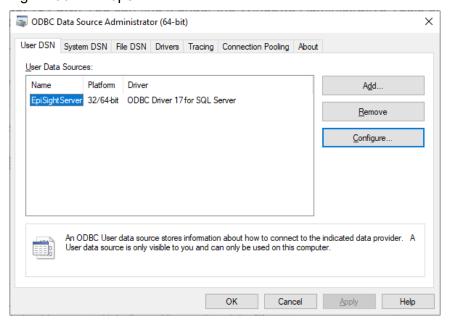
ODBC drivers

ODBC objects enable the communication with the MSSQL database. They need to be set up in the ODBC Data Source Administrator. In the following, the necessary steps are described.

Check ODBC objects

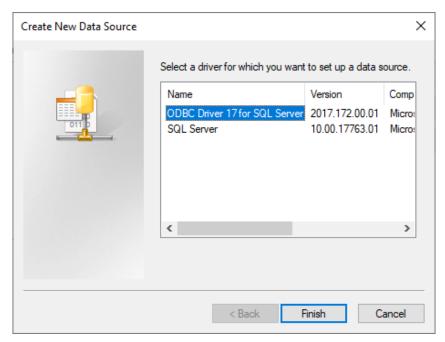
Make sure that you have the correct ODBC drivers installed. Please follow the steps described below:

1. Start the *ODBC Data Source Administrator (64 bit)*. You can find it under the Windows Administrative Tools or by looking for "ODBC" in the search menu. The following window will open:



- 2. Select the tab "System DSN". You will need administrator rights.
- 3. If an ODBC data source with the correct driver "ODBC Driver for SQL server" is listed, make sure it is connected to your MSSQL database. For more details, go to sections Add data source and Test connection.
- 4. If no data source with the "ODBC Driver for SQL server" driver is listed, click on the button "Add". This should open the following window:

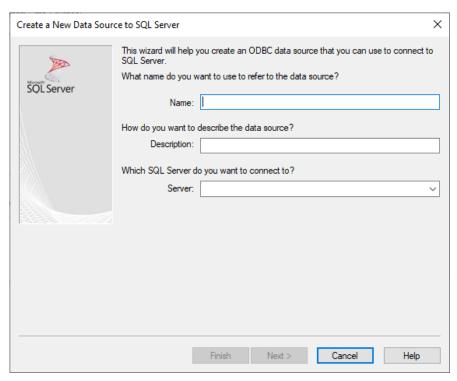




- 5. If an "ODBC Driver for SQL server" appears in the list, select it and press "Finish" Then, fill out the fields of the data source as explained in section Add data source.
- 6. If no "*ODBC Driver for SQL server*" appears in the list, you should install one. Go to section <u>Install ODBC drivers</u> for more details on this.

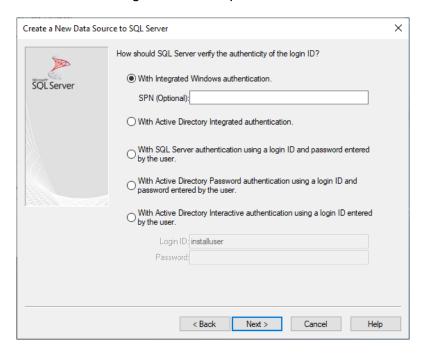
Add data source

Once you clicked "Finish" in the "Create New Data Source" window, the following dialog will open:



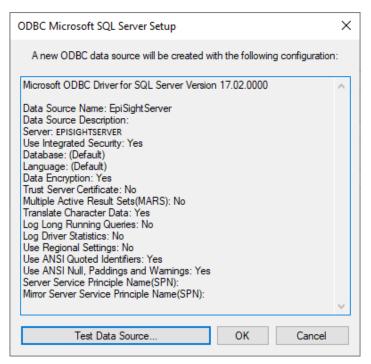


- 1. Fill out the fields:
 - Name: This is the name that will be used for your ODBC connection. You will use
 this name as the "ODBC object" later in the Administration Tool for UNEEG™
 EpiSight Server.
 - Description: Enter a description for the connection of leave it empty
 - Server: Use the drop-down menu to select your MSSQL server from the list of available servers in your network. If the correct server does not show up, type in the name or the IP address of the server. If this does not work, contact your database administrator.
- 2. Click on "Next". The following window will open:



- 3. Select the correct authentication. This will depend on the settings of your MSSQL database. We recommend to use the option "With SQL Server authentication using a login ID and password entered by the user". Please enter the user name and password provided by your administrator. It should be the same username/password that you will later use in the UNEEG™ Server Administration Tool. Alternatively, you can use the option "With integrated Windows authentication". For more details please contact your database administrator.
- 4. Click on "**Next**" until you get to the last window. No other settings need to be adjusted.
- 5. Click on "Finish". This will open the following window:





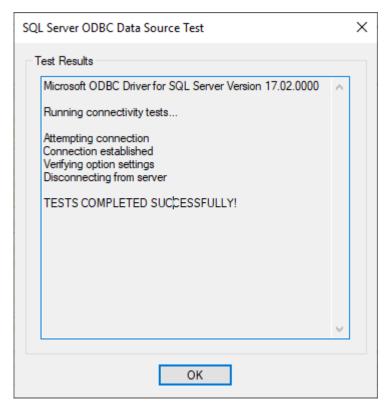
- You can now test the connection to the data source. Click on "Test data source". For more details on this, see section Test connection.
- You can now click on OK.

Test connection

If you want to test the connection of the data source, follow the steps below:

- 1. Start the *ODBC Data Source Administrator (64 bit)*. You can find it under the Windows Administrative Tools or by looking for "ODBC" in the search menu.
- Select the tab "System DSN".
- 3. Select the data source in the list and click on "Configure" or double click on it.
- 4. Check, if the fields are filled out correctly.
- 5. Click on "Finish".
- 6. Click on "Test data source".
- 7. If the connection is working the following window should appear:





8. If the test fails, check the configuration again as described in section Add data source or contact your database administrator.

Install ODBC drivers

If you don't have any ODBC drivers for SQL, you will need to install one. You can download it using the following link: https://docs.microsoft.com/en-us/sql/connect/odbc/download-odbc-driver-for-sql-server-ver15. The versions 11 to 17 will work.



Please always install the 64bit version of the ODBC driver. The 32bit version will not work.

Start the installer and follow the steps in order to install the ODBC driver.

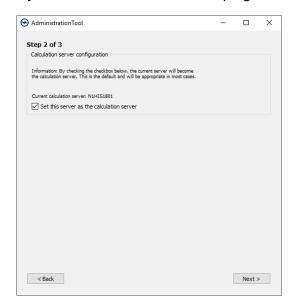


Step 2: Calculation Server settings

The calculation server will run all analysis of data on a centralized server. The analyzed data can then be retrieved and opened with the EpiSight viewers. Please make sure that all EpiSight viewers are connected to the same central EpiSight database that you configured in step 1.

In this step, you can make this EpiSight server the central calculation server. This means that all EpiSight viewers connected to the EpiSight database configured in Step 1 will use this central calculation server to analyze data. If you don't set this server as the calculation server, the analysis will run on the local machine where the EpiSight viewer is running.

The check box is checked by default. We recommend keeping the default configuration.



If a calculation server has already been configured for this database, it will be shown next to 'Current calculation server: <server name>'. If the name of this calculation server is not the local hostname of the computer you are installing this software and the checkbox is checked, the entry for the calculation server will be changed to the hostname of the local machine. All new calculations will then be performed on this new calculation server. This should be the default behavior.

If you want to keep the old calculation server please uncheck the check box. In this case make user that the old calculation server still runs the UNEEG™ EpiSight calculation manager.



Step 3: UNEEG™ EpiSight Server and File location configuration

In the final step the following information has to be provided:

EpiSight server

Fill out the fields related to the EpiSight server.

IP address of the EpiSight server

If the UNEEG™ ProConnect and the UNEEG™ EpiSight server run on the same PC you can keep the default value "http://localhost" as IP address. If UNEEG™ ProConnect and the UNEEG™ EpiSight server are running on different PCs please enter the IP of the computer you are currently installing this software on. This IP must be accessible from the computer running UNEEG™ ProConnect. You must provide this IP also during the installation of the UNEEG™ ProConnect.

Port of the EpiSight server

For the EpiSight server port please provide a port that is not taken by other services on the machine. If you have a setup where UNEEG™ ProConnect and the UNEEG™ EpiSight server run on different PCs you must provide the same port number during the installation of UNEEG™ ProConnect.

UNEEG™ ProConnect

UNEEG™ hostname and port

Enter the host name and port of the computer running UNEEG™ ProConnect to which the EpiSight server will connect. If both systems are running on the same PC you can keep the default values.



You need a running UNEEG™ ProConnect with a valid hostname and port in order to start the EpiSight server using the Administration tool. If you cannot connect to the UNEEG™ ProConnect installation will fail.

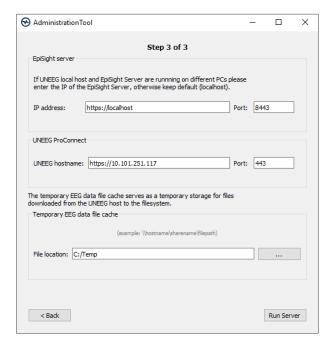
Temporary EEG data file cache

You must specify a path to the file cache where EEG-data will be downloaded using the EpiSight server. Make sure that you have enough disk space to store large amount of data. It is important that this path is also accessible from all EpiSight viewer stations. We therefore enforce the use of a network drive for this file cache.

File location

Enter the path of the file cache or select it using the explorer button. Please make sure you have read/write permission for the share. The file cache must be on a network drive.





Run Server

By clicking on "Run Server", the EpiSight server will be started.

In case the UNEEG™ EpiSight Server Admin tool is not already running with administrator rights, you will be prompted to provide admin credentials.

Make sure you are using the correct user that you defined beforehand and who has the rights to "Log on as a service" as described in section <u>Step 0: User account</u>.

For checking if everything is running as it should and for stopping the server, refer to section Server check and stop.

Error messages

Wrong user account

Make sure to always use the same user account defined in $\underline{\text{Step 0: User account}}$, otherwise you will get the following error message:



Missing rights for user account

Make sure that the user has the rights to "Log on as a service" as described in Section Step 0: User account, otherwise the following error message may arise:





Connection

If no connection between the EpiSight server and the UNEEG™ ProConnect server can be established, an error will be shown, as seen below. Please go back and check the information given in the previous steps.





Server check and stop

If all goes well the server has started. You can check the components using the task manager or the Administration Tool.

Check using the task manager

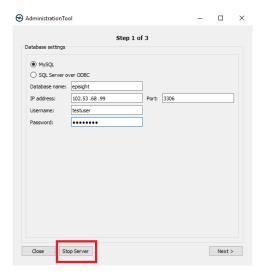
In the task manager check for the service "Watchdog service" and the background applications "CalculationManager.exe" and "HTTPFileManager.exe".



If any of these components is not running EpiSight server might not work properly.

Check using the Administration Tool

Another check can be done by starting the Administration Tool again. During the first step a button "*Stop Server*" indicates the status of the EpiSight Server. If this button is enabled, the EpiSight server is running.



You can stop the server by clicking this button. The Administration Tool will ask you if you also want to delete the database entries. By clicking yes, all database entries about the current server such as the UNEEG™ ProConnect IP or global calculation server name will be deleted.

Stopping the server will also stop any ongoing calculations on patient data.