

UNEEG™ PROCONNECT

USER MANUAL

UNEEG™ medical

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1. INTRODUCTION

1.1 INTENDED USE

The intended use of UNEEG™ ProConnect is to store, convert and save data received from UNEEG products and third-party computer-assisted review systems, and upload of data to UNEEG data stores.

1.2 INDICATION FOR USE

Not applicable for this product.

1.3 CONTRAINDICATIONS

There are no known contraindications with the use of UNEEG™ ProConnect.

1.4 WARNINGS AND PRECAUTIONS

No warnings or precautions have been identified.

1.5 SIDE EFFECTS

There are no known side effects related to the use of UNEEG™ ProConnect.

2. PRODUCT DESCRIPTION

UNEEG™ ProConnect is a local host service installed at the hospital that creates a binding between the UNEEG™ Cloud and UNEEG™ EpiSight Server (**FIGURE 1**). When the binding is established, UNEEG™ ProConnect will function as a persistent storage for telemetry data of all patients connected to the system via UNEEG™ Cloud. Moreover, UNEEG™ ProConnect will offer an interface to UNEEG™ EpiSight Server from which the healthcare professional can securely retrieve the data using UNEEG™ EpiSight or UNEEG™ EpiSight Analyzer.

The interface between UNEEG™ ProConnect and UNEEG™ EpiSight Server is not in scope for this manual. For information concerning UNEEG™ EpiSight Server, UNEEG™ EpiSight and UNEEG™ EpiSight Analyzer see the instructions from the manufacturer.

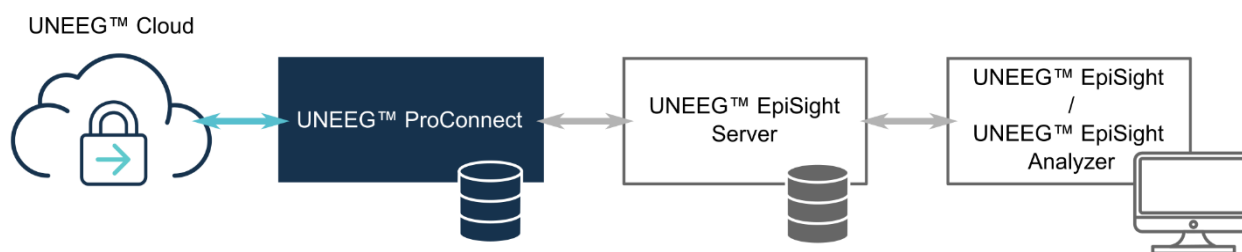


FIGURE 1. UNEEG™ ProConnect ensures a secure transfer and storage of data from UNEEG™ Cloud and UNEEG™ EpiSight Server.

2.1 USER PREREQUISITES TO INSTALL AND MAINTAIN UNEEG PROCONNECT

To install, configure and monitor UNEEG™ ProConnect, it is required that the user has IT knowledge and skills in computer hardware, operating systems, and SQL database management.

2.2 CONFIGURATION

UNEEG™ ProConnect consists of a service and a database instance, which are installed as a local database setup. This configuration supports the installation of the UNEEG™ EpiSight client¹ on one or more external client machines.

In this configuration, both the UNEEG™ ProConnect service and the UNEEG™ ProConnect database are installed in one machine (**FIGURE 2**).

¹ After version 2.0, the client software UNEEG™ EpiSight was renamed UNEEG™ EpiSight Analyzer. Henceforth, UNEEG™ EpiSight client refers to both UNEEG™ EpiSight (v1.11 or newer) and UNEEG™ EpiSight Analyzer (v2.0 or newer).

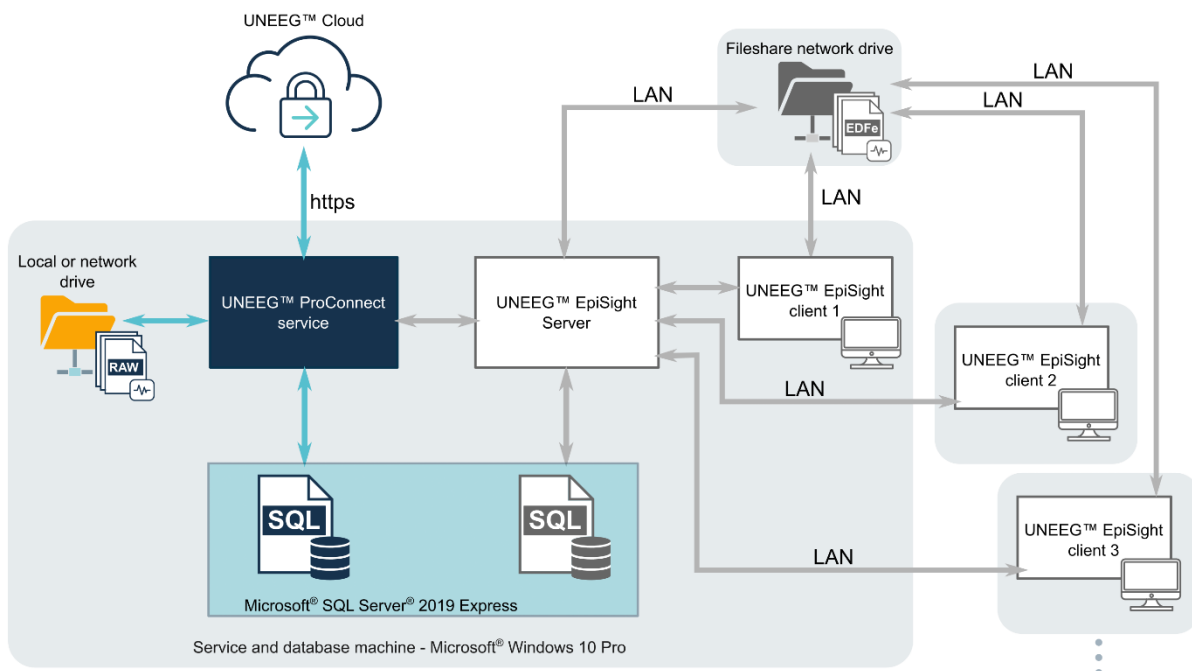

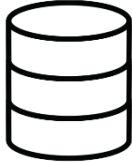


FIGURE 2. Schematic representation of the configuration of UNEEG™ ProConnect. Blue boxes and light blue arrows indicate the parts and connections described in this document. As indicated with the grey rounded boxes, the service machine also serves as client, and additional client machines (running UNEEG™ EpiSight client) are optional.

2.3 COMPATIBLE PRODUCTS

PRODUCT	PARTS	DESCRIPTION
	UNEEG™ Cloud	Transfers data from UNEEG products to UNEEG™ ProConnect.
	UNEEG™ EpiSight Server	Transfers data from UNEEG™ ProConnect to computer-assisted review system for EEG data. Available to healthcare professionals only.

3. BEFORE INSTALLING UNEEG™ PROCONNECT

UNEEG medical will provide a secure link via e-mail to download the installer package of UNEEG™ ProConnect. The e-mail will also include the unique identifier for your hospital and a corresponding provision key, which must be used to finalize the installation.

3.1 CYBERSECURITY MEASURES

The following cybersecurity measures were taken into consideration for UNEEG™ ProConnect:

- when a UNEEG™ EpiSight client instance fails to provide a valid certificate, the corresponding client connection is rejected.
- when UNEEG™ Cloud fails to provide a valid certificate, UNEEG™ ProConnect rejects all communication from UNEEG™ Cloud.
- data download is interrupted with lack of network connection. Nonetheless, data are safely stored in UNEEG™ Cloud and download can be resumed once network connection is reestablished.
- log files are generated to trace all activity to UNEEG™ ProConnect.

Moreover, to fulfill further cybersecurity measures, UNEEG medical recommends the following:

- it is required to have a running instance of Microsoft SQL Server 2019 or Microsoft SQL Server 2019 Express. It is recommended to have a basic/default installation (including instance name).
- keep your operating system, firewall and anti-virus software up to date.
- do not run UNEEG™ ProConnect on Windows operating systems for which the support has been discontinued by Microsoft. For details on compatible operating systems, see section 3.2.
- ensure that access to UNEEG™ ProConnect is limited to authorized personnel with administrator rights.
- ensure that only the Local System Account and user with administrator rights have write permission to the UNEEG™ ProConnect data folders.
- adopt best practices for setting usernames and passwords where UNEEG™ ProConnect is installed.

If suspicious activity occurs other than already described in this document, please shut down UNEEG™ ProConnect and contact UNEEG medical.

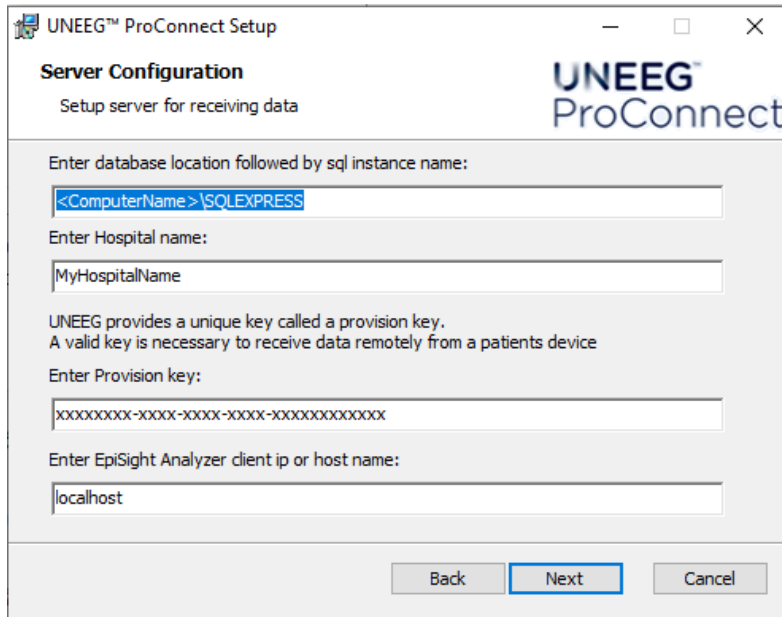
3.2 MINIMUM REQUIREMENTS

SPECIFICATIONS	
Operating system	Windows 10 Pro
Memory	32 GB RAM
Processor	Intel Core i9-9900 processor
Connectivity	Internet connection: 10 Mbps bandwidth
Free hard disk space	4 TB (1 TB per 10 patients per year)
Additional software	<ul style="list-style-type: none">- Microsoft SQL server 2019 or Microsoft SQL server 2019 Express- SQL Server Management Studio (SSMS)
Network port	443
UNEEG™ EpiSight Server version	1.11

If the above-mentioned requirements are not fulfilled, you might experience a reduced performance.

4. INSTALLATION

1. Run the UNEEG™ ProConnect installer package 'Setup ProConnect.exe'.
2. Set database location to <ComputerName>\<InstanceName>. By default, the installer will point to a local default installation of Microsoft SQL Server Express.
3. Enter the unique identifier (Hospital name) and provision key from the received e-mail.

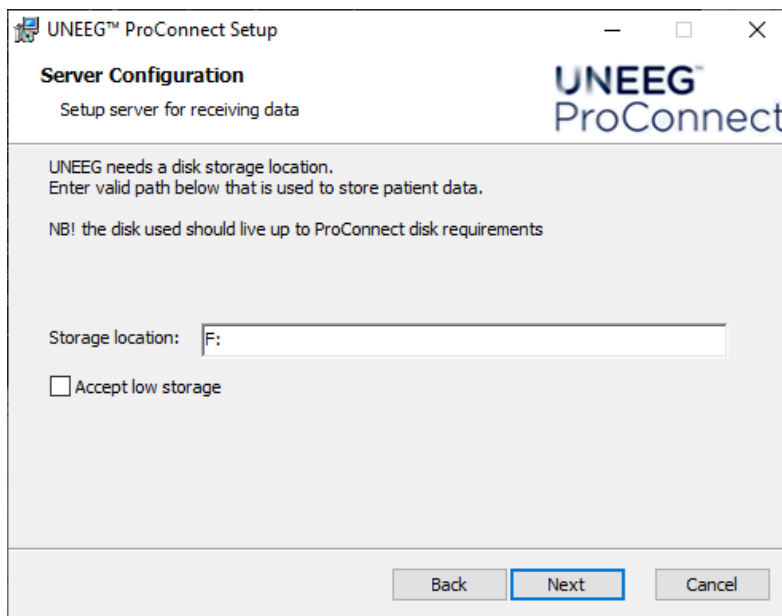


The screenshot shows the 'Server Configuration' window of the UNEEG™ ProConnect Setup. The window title is 'UNEEG™ ProConnect Setup'. The subtitle is 'Server Configuration' and the description is 'Setup server for receiving data'. The UNEEG™ ProConnect logo is in the top right corner. The window contains the following fields and text:

- Enter database location followed by sql instance name:
- Enter Hospital name:
- UNEEG provides a unique key called a provision key. A valid key is necessary to receive data remotely from a patients device
- Enter Provision key:
- Enter EpiSight Analyzer client ip or host name:

At the bottom, there are three buttons: 'Back', 'Next' (highlighted with a blue border), and 'Cancel'.

4. Enter the storage location used by UNEEG™ ProConnect to store patient data. The minimum recommended disk size is 4 TB.



The screenshot shows the 'Server Configuration' window of the UNEEG™ ProConnect Setup. The window title is 'UNEEG™ ProConnect Setup'. The subtitle is 'Server Configuration' and the description is 'Setup server for receiving data'. The UNEEG™ ProConnect logo is in the top right corner. The window contains the following fields and text:

- UNEEG needs a disk storage location. Enter valid path below that is used to store patient data.
- NB! the disk used should live up to ProConnect disk requirements
- Storage location:
- ☐ Accept low storage

At the bottom, there are three buttons: 'Back', 'Next' (highlighted with a blue border), and 'Cancel'.

5. Verify that the service machine has a static IP address. This is needed for the EpiSight client(s) to connect to.
6. Verify that the service machine is running in the local time zone.
7. If the running instance of the SQL Server is Microsoft SQL server 2019, set the server memory to the maximum available RAM minus 11 GB. The purpose is to reserve 11 GB free for the UNEEG™ ProConnect service and UNEEG™ EpiSight Server.

Example: If the service machine has 32 GB RAM installed, the SQL Server maximum server memory shall be limited to 21 GB (= 32-11 GB).

For more information on how to set a maximum limit on the size of the database, check the server memory configuration options of Microsoft SQL.

If the running instance of the SQL Server is Microsoft SQL Server Express, it is not necessary to limit the memory used by SQL Server.

8. If installation is successful, the UNEEG™ ProConnect status icon will turn green within five minutes.



5. MAINTENANCE AND DISPOSAL

5.1 MONITORING

When monitoring UNEEG™ ProConnect, it is advised to consider the following:

- it is recommended that the operator checks that the service is running after the first installation and installation of updates.
- UNEEG™ ProConnect should always be online, as UNEEG™ Cloud requires data to be downloaded by UNEEG™ ProConnect at least every 30 days. In rare situations should the UNEEG™ ProConnect be offline, a backup of patient data will be available within 30 days.
- it is recommended to service the computer hardware running the UNEEG™ ProConnect in regular intervals. It is recommended to monitor that the computer fulfils the requirements for free RAM and disk space that are listed in this document.
- start-up procedure: UNEEG™ ProConnect is a Windows service that is configured to start up automatically.
- shut-down procedure: the Windows computer where UNEEG™ ProConnect is installed should always be shut down according to Windows shut-down procedure.

5.1.1 BACKUP

It is recommended:

- that the hospital has a documented procedure on how to back up regularly and how to restore if this should be necessary.
- that regular backups include log files, installation folders (including the configuration file), data folders and the database.

5.2 UPDATES OF UNEEG™ PROCONNECT

Updates to UNEEG™ ProConnect will be distributed via a secure link to the registered e-mail.

Updates will be installed just like when installing for the first time (section 4).

The version number of the UNEEG™ ProConnect installed can be found using the Windows '*apps & features*' function under system settings.

5.3 UNINSTALLATION

It is recommended to uninstall UNEEG™ ProConnect by using the Windows '*add or remove programs*' function under system settings.

5.4 SERIOUS INCIDENT REPORTING

Per European Regulations: report any serious incident that has occurred in relation to this device to the manufacturer and the competent authority of the EU Member State where the device was used.

6. TROUBLESHOOTING

In TABLE 1 you will find information of how you should react in different situations.

TABLE 1. Troubleshooting

DURING INSTALLATION		
PROBLEM	POSSIBLE CAUSE	POSSIBLE SOLUTION
After completing all installation steps (section 4), UNEEG™ ProConnect status icon stays yellow after more than five minutes.	Either the hospital name and/or the provision key is incorrect.	Uninstall UNEEG™ ProConnect. Ensure that both the hospital name and provision key are inserted exactly as provided by UNEEG medical in section 4, step 3. Start installation again (section 4). If the problem persists, contact UNEEG medical.
	Internet connection is down.	Verify there is internet connection to the service machine.
DURING MANTEINANCE		
PROBLEM	POSSIBLE CAUSE	POSSIBLE SOLUTION
UNEEG™ EpiSight remote client(s) cannot access the data.	Local access network is down.	Verify there is connection between the clients and the service machine.
UNEEG™ EpiSight remote client(s) cannot access the data.	Internet connection is down.	Verify there is internet connection to the service machine.
	UNEEG™ ProConnect service is down on the service machine.	Restart the UNEEG™ ProConnect service under Windows services.
	Other error.	Contact UNEEG medical.

7. TECHNICAL DESCRIPTION

7.1 DATA PROTECTION

All data on UNEEG™ ProConnect are transferred and stored in an encrypted format to guard against tampering and information disclosure.

Please contact UNEEG medical if you discover any suspicious activities or suspect a data breach. If any breach related to data security is detected by UNEEG medical, you will be informed on how to act to ensure that data protection is restored.

7.2 CYBERSECURITY BILL OF MATERIALS (CBOM)

The main off-the-shelf software components that are used in UNEEG™ ProConnect can be found on the UNEEG website.



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