



syngo CT

Instructions for Use – *syngo* Expert-i client

Version 10.0

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Legend



Indicates a hint

Is used to provide information on how to avoid operating errors or information emphasizing important details



Indicates the solution of a problem

Is used to provide troubleshooting information or answers to frequently asked questions



Indicates a list item



Indicates a prerequisite

Is used for a condition that has to be fulfilled before starting a particular operation



Indicates a one-step operation



Indicates steps within operating sequences

Italic

Is used for references and for table or figure titles



Is used to identify a link to related information as well as previous or next steps

Bold

Is used to identify window titles, menu items, function names, buttons, and keys, for example, the Save button

Orange

Is used to emphasize **particularly** important sections of the text

Courier

Is used for on-screen output of the system including code-related elements or commands

Courier

Is used to identify inputs you need to provide

Menu > Menu Item

Is used for the navigation to a certain submenu entry

<variable>

Is used to identify variables or parameters, for example, within a string



CAUTION

Used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury or material damage.

CAUTION consists of the following elements:

- Information about the nature of a hazardous situation
- Consequences of not avoiding a hazardous situation
- Methods of avoiding a hazardous situation

WARNING

Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

WARNING consists of the following elements:

- Information about the nature of a hazardous situation
 - Consequences of not avoiding a hazardous situation
 - Methods of avoiding a hazardous situation
-





Legend

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1 Introduction

This *syngo* CT Instructions for Use document serves as a guide to find the information needed to work with the *syngo* Expert-i client software.

The *syngo* Expert-i software enables:

- Every user to access and use the *syngo* Acquisition Workplace and its full range of functionality from any Expert-i client in the network. (→ Page 21 *Direct Login*)
- Experts (for example, physicians) to support local users at any *syngo* Acquisition Workplace via a single-session password. (→ Page 33 *Single session*)

This remote access is handled via a suitable computer (remote computer) connected to the local network.

The software provides full-screen display and allows the remote user to use all *syngo* Acquisition Workplace functionalities like image viewing, filming, exporting data, 3D reconstruction, and data postprocessing.



To learn more about the security of your SOMATOM CT system and to obtain the Manufacturer Disclosure Statement for Medical Device Security (MDS), contact your Siemens Healthineers Representative and ask for the document entitled Product & Solution Security Whitepaper and MDS².

1.1 Scope

These Instructions for Use apply to all SOMATOM CT systems equipped with the following software versions:

- *syngo* CT VA30A

1 Introduction

1.2 Authorized users

The system must only be operated by persons with the certified specialist knowledge according to country-specific regulations, for example, physicians, trained radiologists or trained technologists, after an appropriate application training. This document is addressed to these persons. If more than the frequently used functions are required, the Siemens Healthineers Service must be consulted.

1.3 Trademarks

Product names, logos, brands, and other trademarks featured or referred to in the instructions for use are the property of their respective trademark holders.

Exemplary list of trademarks used in the instructions for use:

- SOMATOM®
- Microsoft® (for example, Windows 10, Windows 7, Windows Explorer)

1.4 Availability of functions

The following functions are available since the software versions *syngo* CT VA30:

- Direct Login at the *syngo* Acquisition Workplace
- Expert-i during **CARE Bolus**

2 Safety information

Follow the safety information in this document.



To ensure the safe use of your product and the safety of people, you must adhere to the safety information provided in the Instructions for use documents. In addition, also observe your country-specific regulations and guidelines.

Safety information is located in the safety section and repeated within context where a hazardous situation may occur. To make sure safety information is understood, always read it in context of the situation.

WARNING and CAUTION are highlighted in the text:

WARNING	Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

WARNING and CAUTION have the same structure. The following example CAUTION instructs you how to read a WARNING or a CAUTION:

CAUTION

This text describes the hazardous situation: Images with lossy compression are used for diagnosis!


This text describes the hazard: Wrong diagnosis.

- ◆ **This text describes how to avoid the hazardous situation:**
 - Always verify your evaluation results with the original DICOM images (first reader duty).
 - ◆ Never use lossy ...

2 Safety information

2.1 General safety information

For the secure operation of your medical device, it is the responsibility of the system owner to ensure that each person who operates the system reads and understands the provided Instructions for Use.

 WARNING
<p>Not observing the Instructions for Use and the safety information of the medical device and the equipment!</p> <p>Injury to the patient or personnel, and damage to the equipment.</p> <ul style="list-style-type: none">◆ Always observe the Instructions for Use of the particular units used. This includes the labels applied on the equipment as well as the Instructions for Use documents.◆ Always use this Instructions for Use document in conjunction with all Instructions for Use documents provided.◆ Follow the safety instructions and safety signs.◆ For references purposes, store the Instructions for Use near your workplace.

Electronic Instructions for Use are provided on your CT system and on the workplace.

2.2 Specific safety information

In this chapter, you find safety information concerning the *syngo* Expert-i software and its usage.

CAUTION

Misuse of data handling!

Wrong diagnosis

- ◆ Make sure that only a trained user gets remote access to the system.

CAUTION

Remote and uncontrolled patient movement!

Possible injury to the patient by moving parts.

- ◆ Do not leave the *syngo* Acquisition Workplace unattended if full access is enabled. Local user still has full responsibility for appropriate usage of system.

CAUTION

The display quality at the remote assistance workplace cannot be guaranteed!

Wrong basis for diagnosis.

- ◆ If the remote assistance workplace shall be used for diagnostic purposes, make sure that all necessary regulatory and legal requirements for the monitor are fulfilled.

2 Safety information

3 Installation

3.1 Hardware requirements

The remote computer, respectively the local network, have to meet the minimum requirements listed below.

Computer hardware

<i>Processor remote computer</i>	<i>850 MHz</i>
<i>Operating system</i>	<i>Windows 10, 7, XP, Vista</i>
<i>Primary storage</i>	<i>256 MB</i>
<i>Network card</i>	<i>100 Mbit/s</i>
<i>Graphics card, monitor</i>	<i>1280 × 1024</i>
<i>Color</i>	<i>32 bit</i>

Local network

<i>Local network</i>	<i>100 Mbit/s or higher</i>
<i>Min. transfer rate</i>	<i>> 6 Mbit/s</i>
<i>Response time</i>	<i>< 30 ms</i>

If the remote computer and the network meet the recommended requirements, it is possible to use the connection in high quality mode. #Installation_at_the_Remote_Computer#

If the requirements are not met, the performance and the display on the remote computer may be affected.

3 Installation



The data is not encoded during transfer. For this reason, use the *syngo* Expert-i software only in the local network. If you use the wide area network (WAN) connection, use router encryption.

You should use this feature in a secure network environment only, for example, from outside the secure hospital network by means of a virtual private network (VPN) connection.



Additionally to a remote connection within the local network, the service engineer can connect from outside to the *syngo* Workplace. The service engineer connects via Smart Remote Service by using the *syngo* Remote Assist.

You can only establish either a *syngo* Remote Assist connection or a *syngo* Expert-i connection on your *syngo* Workplace at the same time.

3.2 Installation at the *syngo* Acquisition Workplace

A license is required to activate the *syngo* Expert-i functionality at the *syngo* Acquisition Workplace. It provides the installation medium, IP-address, and computer name, which are necessary for setting up a connection between the remote computer and the *syngo* Acquisition Workplace. The **Direct Login** functionality can also be activated.



You can see this icon in the status bar of the *syngo* Acquisition Workplace if the *syngo* Expert-i license is available.

After installation, the **Direct Login** functionality of *syngo* Expert-i can be configured. The configuration can be configured by you or the administrator. (→ Page 22 *Configuration at the syngo Acquisition Workplace*)

3.3 Installation at the remote computer



Always install the newest client version on your remote computer, regardless of the version at the *syngo* Acquisition Workplace. You do not need to uninstall the previous version if you want to import old connections.

To install the software on the remote computer:

- 1 Insert the installation medium.
- 2 Double-click the installation file.
- 3 Follow the installation instructions and select the path where **Expert-i** is to be installed.

You will find additional information in the **Readme** file on the installation medium.



If you do not have write access to the directory on which Expert-i is installed, contact your local system administrator.

3.3.1 Setting up connections

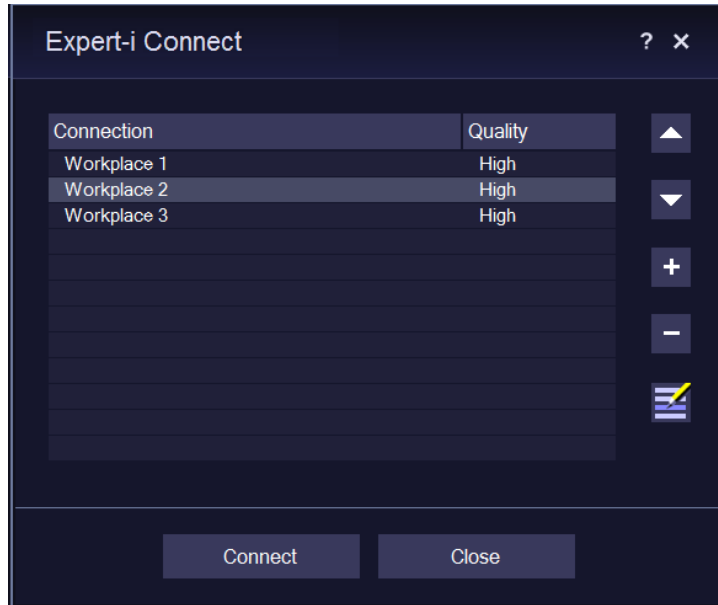
After you installed the Expert-i software, you must set up connections to the required workplaces.



- 1 Click the program icon to start the Expert-i software at the remote computer.

The **Expert-i Connect** dialog box opens.

3 Installation



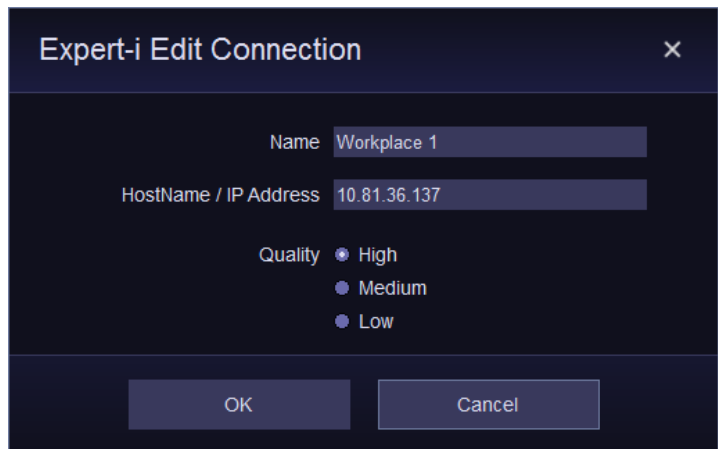
2 Click the **Add** icon to create a new connection.

– or –



Click the **Edit** icon to modify an existing connection.

The **Expert-i Edit Connection** dialog box opens.



- 3 In the **Name** field, enter a unique and meaningful name for the connection.
- 4 In the **HostName / IP Address** field, enter the host name or IP address of the workplace you want Expert-i to connect to.
- 5 In the **HostName / IP Address** field, additionally enter the prefix **directlogin://** if you wish to use the **Direct Login** remote access, and if it is configured on the *syngo* Acquisition Workplace.
- 6 To ensure a smooth image transmission, select the **Quality** of the Expert-i display according to your network bandwidth:
 - **High:** For diagnostic purposes, high quality mode is required. (→ Page 15 *Hardware requirements*)
 - **Medium or Low:** You can use low or medium quality to accelerate the data transfer. A message is displayed to warn you that the display quality is not suitable for primary reading. You can hide the message.
- 7 Click **OK**.



- 8 When configuring the first connection, click the **Settings** icon to use the default port number 5902 or the port number that is used in your network. You need administrator rights.



For VA30, it is not recommended to use the port 5902 as this port is unauthorized and will be blocked by the firewall.



The used port needs to be the same as used on the ICS (Image control system). You can only use ports that are included in the Whitelist.

3.4 Using more than one monitor



If you use the Expert-i client on a PACS system with more than one monitor, it is not recommended to switch to full-screen mode.

Otherwise, it may occur that the virtual network computing (VNC) dialog box disappears. This happens if you have moved the dialog box to another monitor other than the main monitor, and you have switched to full-screen mode. To display it again, use the control elements for the dialog box in the upper right corner of the main monitor.



By default, the primary display (right monitor) is visible when a dual monitor configuration is connected using *syngo* Expert-i, and you can use hot key combination **Alt + F5** to switch between primary monitor display and dual monitor display.



If you are using three monitors, the Expert-i client starts always on the primary display. When a remote connection is established, the remote dialog box will start on the primary display, too. If the remote dialog box is moved to another display and is maximized to full screen, it may disappear to the background. This depends on other software running on the system, for example, some PACS systems.

You can activate the remote dialog by moving the cursor to the upper right corner of the primary monitor. To display the remote dialog box, click the **Maximize** icon in the upper right corner.

4 Direct Login

4.1 Overview

With the **Direct Login** remote access, every individual remote user, having the appropriate privilege, can access and use the *syngo* Acquisition Workplace from any **Expert-i** client in the network. The remote user will be able to connect without confirmation of the local user by using his individual user credentials.

For working as a remote user on the *syngo* Acquisition Workplace, the following steps have to be performed:

- Each individual remote user, that shall be able to use **Direct Login**, must be created as a local user on the *syngo* Acquisition Workplace.
- The privilege of using **Direct Login** needs to be attached to a newly created role on the *syngo* Acquisition Workplace.
- This role needs to be attached to each individual remote user.



You can switch to a user account with fewer rights. Thus, you can ensure that your data is protected before you grant the remote user access to the *syngo* Acquisition Workplace.

View Only is not available for **Direct Login**.



Each time you work with the *syngo* Expert-i software, the protocol inputs are entered into the audit trail.

4.2 Configuration at the *syngo* Acquisition Workplace

To use **Direct login**, you need to create a specific user account with the necessary role operations in the Administration Portal at the *syngo* Acquisition Workplace. For the configuration at the *syngo* Acquisition Workplace, you must be logged on as the clinical administrator.

4.2.1 Role manager

Users are only allowed to perform a task if their user account was assigned to a role.

With **Role Manager**, you can assign users or groups to roles or remove assignments.

4.2.2 Creating a user role

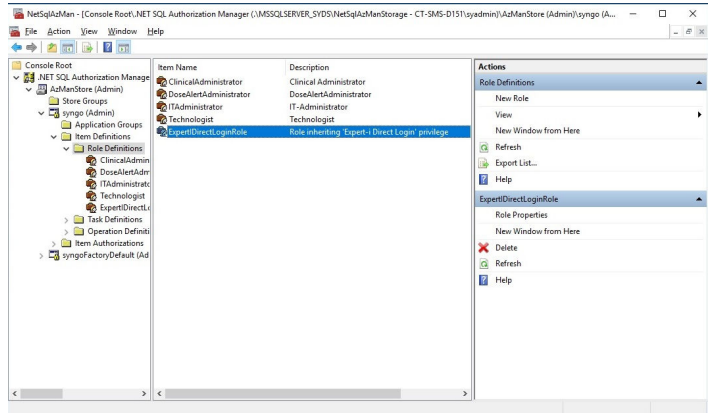


To use Expert-i, a new *syngo* role needs to be created and the operation **op_Expert_i_Direct_Login** needs to be assigned to the role.

To create a role:

- ✓ You are logged on to the Administration Portal as a clinical administrator.
- 1 In the **Clinical Configuration** workspace, from the navigation tree, choose **User and Role Administration**.
- 2 In the **User and Role Administration** area, click the **Role Manager** button.
- 3 Authenticate with a user account that has local administrator rights on the machine.

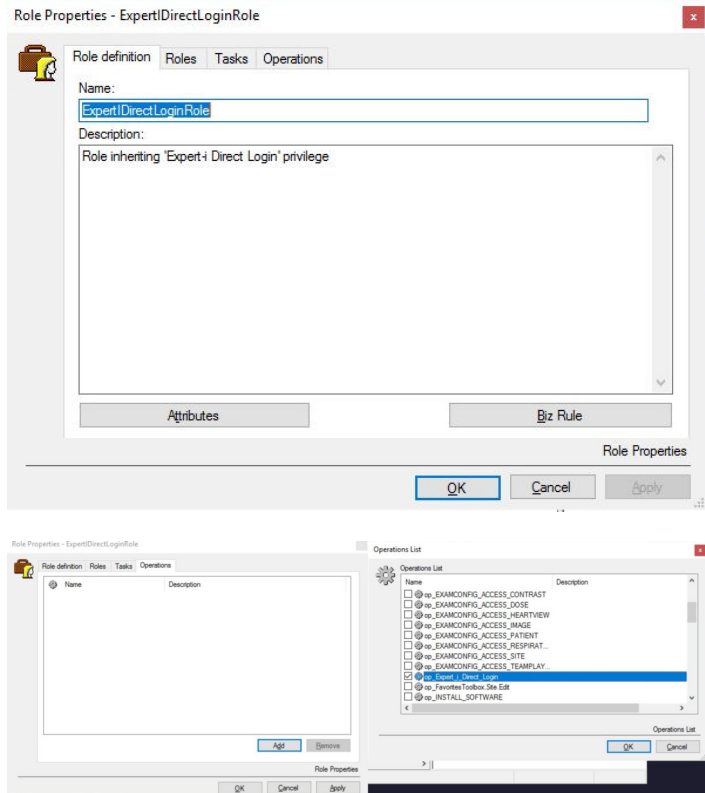
The **NetSqlAzMan** (NET SQL Authorization Manager) opens.



- 4 Expand the tree down through **NET SQL Authorization Manager** > **AzManStore** > **syngo** > **Item Definitions** > **Roles Definitions**.
- 5 Right-click **Roles Definitions** and select **Add Role**.
- 6 Name a role.
- 7 Change the **Description** to the name to be displayed in the user interface.
- 8 Right-click the name and select **Role Properties**.

A **Properties** dialog box opens, for example, **Role Properties - ExpertIDirectLoginRole**.

4 Direct Login



- 9 In the **Operations** tab, click the **Add** button.
- 10 From the **Operations List**, choose **op_Expert_i_Direct_Login**.
- 11 Click **OK**.

The role will be rendered in the UI as set in the **Description**.



Changes are only visible after closing the **Role Manager**.

4.2.3 Creating local user accounts for *syngo* Acquisition Workplace



To use Expert-i, a new *syngo* role has to be created and the operation **op_Expert_i_Direct_Login** has to be assigned to the role.

To create a role:

✓ The **Administration Portal** is open.

- 1 In **Clinical Configuration**, from the navigation tree, choose **User and Role Administration**.
- 2 In **User and Role Administration**, click the **Role Manager** button.
- 3 Enter a role with local administrator rights on the machine.
Local User Manager (Lusrmgr.msc) opens.
- 4 Right-click **Roles** and choose **New User...** from the context menu.
- 5 In the **New User** dialog box, fill in the new user information.



There are no *syngo* Acquisition Workplace-specific rules for user names or passwords. But the Windows password policy enforces complexity requirements by default. New passwords must meet the following minimum requirements:

- Passwords cannot contain the user's account name or parts of the user's full name which exceed two consecutive characters.
- Passwords must be at least six characters in length.
- Passwords must contain characters from three of the following four categories:
 - English uppercase characters (A through Z).
 - English lowercase characters (a through z).
 - Digits (0 through 9).
 - Non-alphabetic characters (for example, !, \$, #, %).

- 6 Select the **Password never expires** check box.

4 Direct Login



Selecting the **Password never expires** check box is optional. The system is prepared to handle the use cases related to expired or soon-to-expire user account passwords.

7 Click the **Create** button.

8 Fill in user information for an additional user.

– or –

Click the **Close** button.

Optionally, add users to user groups in the Local User Manager.

CAUTION

Limited system access because security measures, for example, licensing issues!

System access might be hindered or restricted in emergency cases.

- ◆ Set up an emergency access environment if necessary. This may include:
 - Creating an emergency user account with limited access rights and ensuring that this account is available to appropriate personnel only.
 - Disabling the screen saver at the designated emergency treatment clients.
 - Establishing a license strategy to ensure that sufficient licenses are always available at the designated emergency treatment clients.

CAUTION

User access may be prevented due to forgotten or unknown accounts or passwords, account lockout policy, or wrong setup, for example, in case of an emergency!

Inaccessible system

- ◆ Define a general user account for emergency access and assign it to a group and a role both called **Emergency Access**.
- ◆ Define a local user account for emergencies. The password for this account should never expire.
- ◆ Do not allow users to change the password for the emergency account.
- ◆ The users shall contact administrators immediately in case of problems.

4.2.4 Assigning users to roles in the Administration Portal

A user is only allowed to perform a task if his user account was assigned to a role.

In the **Administration Portal**, as a Clinical Administrator you can assign users/groups to *syngo* roles, or remove the assignment.

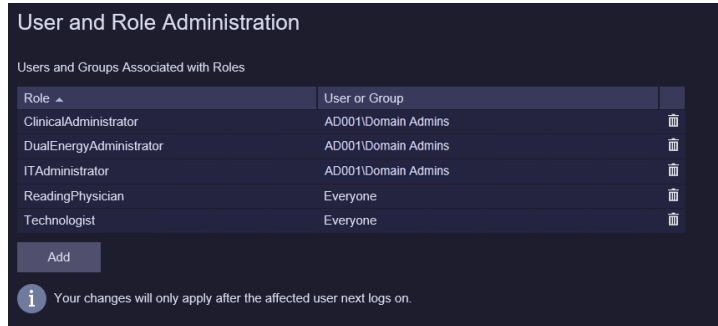
✓ You know the name of the Windows user or group to be authorized.

- 1 Log on to the **Administration Portal**.
- 2 First select the **Technical Configuration** workspace and then choose **User and Role Administration** from the navigation tree.

The **User and Role Administration** window opens.

A table with the current role assignments is displayed.

4 Direct Login



- 3 Click the **Add** button to add a new assignment.
- 4 From the **Role** list, select the role that you want to assign.
- 5 In the **Windows User or Group** field, type the name of the Windows user or group.



- 6 Click the **Add** icon.

The new role assignment is displayed in the table.



To delete a role assignment, click the **Delete** icon at the end of the corresponding table row.



The changes take effect when the user logs on again.

4.3 Connecting to the *syngo* Acquisition Workplace

Expert-i allows remote access to a customer workplace from a PC in the same local area network (LAN).

The following restrictions apply:

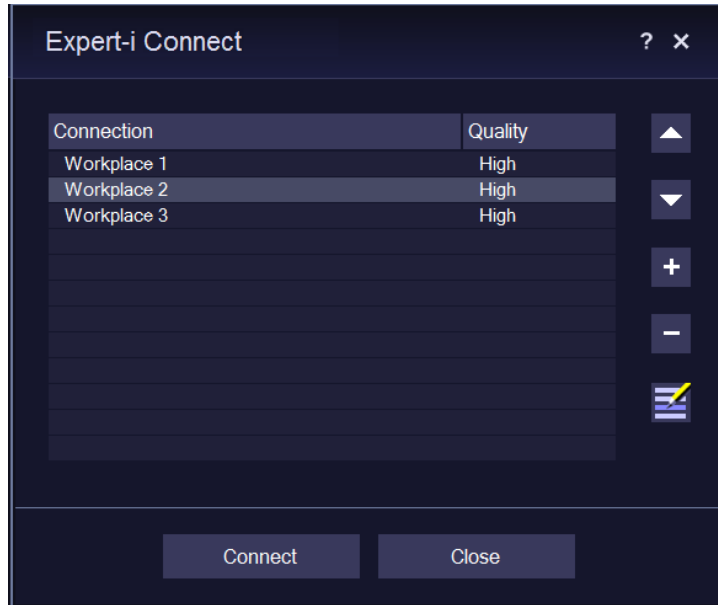
- Only one remote session can be activated at a time.
 - A connection to a *syngo* Acquisition Workplace cannot be established if an CT-guided intervention examination is being performed.
 - The remote connection is disconnected automatically, when CT-guided intervention examinations are started.
 - When the remote connection is established in **Full Access** mode, the **Feed** icons are dimmed for the remote user. The table movement is only possible by pressing the **MOVE** key on the control box (also during **Calibration**).
- 1 The first time you log on, you need to change the initial password at the *syngo* Acquisition Workplace to your individual password. This has to be done directly at the ICS. (→ Page 22 *Configuration at the syngo Acquisition Workplace*)



- 2 Click the **Program** icon to start the Expert-i software at the remote computer.

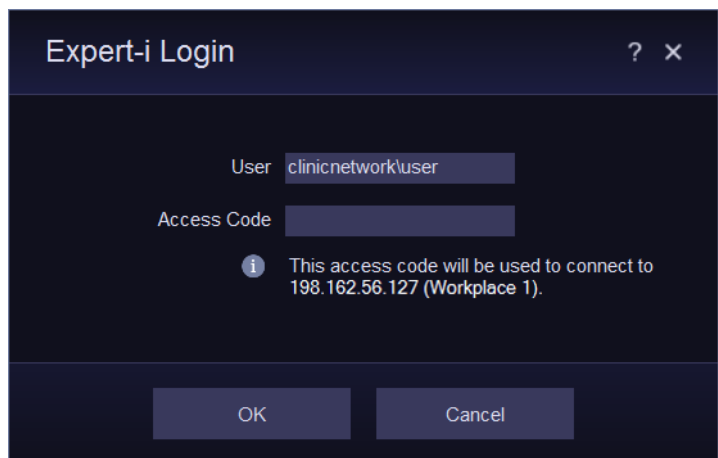
The **Expert-i Connect** dialog box opens.

4 Direct Login



- 3 Select one of the available connections you have already configured.
- 4 Click the **Connect** button.

The **Expert-i Login** dialog box opens on the remote computer.



- 5 The user role is assigned to the remote access. Enter your user credentials from the *syngo* Acquisition Workplace.
- 6 Enter the password generated at the *syngo* Acquisition Workplace as **Access Code**.
- 7 Click **OK**.

At the *syngo* Acquisition Workplace, a dialog box opens for the time configured in the **Expert-i Configuration** dialog box (default 10 s). The local user has the option of declining this remote session by clicking **Deny**.

If the local user clicks **Connect** or if the configured time is over, the Expert-i connection is established automatically in **Full Access** mode.



After the connection is established, the **Tray** icon in the status bar of the *syngo* Acquisition Workplace changes.



The connection will not be established if another remote user is already logged in.

A message box is displayed, informing you about login, IP address, and/or host name of the user already logged in, depending on the network configuration.

4 Direct Login

5 Single session

5.1 Overview

Experts (for example, physicians) can support local users at any *syngo* Acquisition Workplace, accessing the *syngo* Acquisition Workplace remotely via a single-session password.

It enables the simultaneous operation from the *syngo* Acquisition Workplace as well as from the remote computer.

For working as a remote user on the *syngo* Acquisition Workplace, the following steps have to be performed:

- The local user generates a password and establishes the Expert-i connection at the *syngo* Acquisition Workplace via Expert-i client.
- The remote user connects to the *syngo* Acquisition Workplace via Expert-i client.



You can switch to a user account with fewer rights. Thus, you can ensure that your data is protected before you grant the remote user access to the *syngo* Acquisition Workplace.



Each time you work with the *syngo* Expert-i software, the protocol inputs are entered into the audit trail.

5.2 Workflow on the *syngo* Acquisition Workplace



- 1 Click the **Tray** icon in the status bar of the *syngo* Acquisition Workplace.

The **Expert-i Connection Status** dialog box opens and a password is displayed.

- 2 Select the **Full Access** option to allow the remote user full access to the *syngo* Acquisition Workplace.

5 Single session

– or –

Select the **View Only** option to allow the remote user to view the user interface of the *syngo* Acquisition Workplace and to point to items on the screen with a separate red mouse cursor.

3 Inform the remote user about the password.

4 Click **OK**.

After clicking **OK** to confirm the **Expert-i Connection Status** dialog box with **OK**, the remote user has 120 s to establish the remote connection. When this time has passed, a new password must be generated and the software needs to be restarted.



If the password is entered incorrectly three times, the local user must open a new session and a new password will be generated.



The **Tray** icon changes to the wait mode.



After the connection is established, the icon changes again.

The local user must be present at the *syngo* Acquisition Workplace as long as the remote connection is established and must pay attention to actions performed remotely.

5.3 Connecting to the *syngo* Acquisition Workplace

Expert-i allows remote access to a customer workplace from a PC in the same local area network (LAN).

The following restrictions apply:

- Only one remote session can be activated at a time.
- A connection to a *syngo* Acquisition Workplace cannot be established if an CT-guided intervention examination is being performed.

- The remote connection is disconnected automatically, when interventional examinations are started.
- When the remote connection is established in **Full Access** mode, the **Feed** icons are dimmed for the remote user. The table movement is only possible by pressing the **MOVE** key on the control box (also during **Calibration**).
- ✓ You know the password that was generated at the *syngo* Acquisition Workplace. (→ Page 33 *Workflow on the syngo Acquisition Workplace*)



- 1 Click the **Program** icon to start the Expert-i software at the remote computer.

The **Expert-i – Connect** dialog box opens.

- 2 Select one of the available connections you have already configured.
- 3 Click the **Connect** button.

The **Expert-i Login** dialog box opens on the remote computer.

- 4 In the **Access Code** field, enter the password generated at the *syngo* Acquisition Workplace.
- 5 Click **OK**.

5 Single session

The screen of the remote computer displays the user interface of the *syngo* Acquisition Workplace. You have access to the *syngo* Acquisition Workplace.

6 Disconnecting

6.1 Disconnecting the active connection



You can terminate a currently established connection instantly by pressing **Alt+Q** on your keyboard.

At the client, you can terminate a currently established connection only if you have a **Full Access** connection.

6.1.1 Local user



1 Click the **Tray** icon in the *syngo* Expert-i software at the *syngo* Acquisition Workplace.

The **Expert-i** status dialog box opens.

2 Click **Terminate** to disconnect the remote connection.

The remote connection is disconnected and the **Tray** icon changes appearance to indicate the disconnected state.

6.1.2 Remote user



1 Move the cursor to the top of the window and click the **Expert-i** icon to open the menu.

2 Choose **Close**.

– or –

Click the **Tray** icon at the remote computer.

The **Expert-i Connection Status** dialog box opens.

3 Click **End connection** to disconnect the remote connection.

The remote connection is disconnected and the **Tray** icon changes appearance to indicate the disconnected state.

6 Disconnecting

7 License disclaimer

Among other components, the product contains Open Source Software that is licensed under an Open Source Software License and that was developed by third parties.



You can find further information about third-party software components in the **About syngo Expert-i** box.

7 License disclaimer

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Caution: Federal law restricts this device to sale by or on the order of a physician, dentist, or veterinarian (21 CFR 801.109(b) (1)).

The original language of this document is English.

.....
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