



# Instructions for Use

## MasterScope

- Spirometry
- ECG

782126-WSSU  
Version 03.00



## MOVING AHEAD REQUIRES A SURE PATH FORWARD

Trials are inherently risky, and every detail matters. We spot risks before they become problems to help you avoid costly delays through an array of solutions that provide confidence at every turn.



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Please note that this study specific MasterScope device may only be used if the user attended a detailed training covering the applicable technical aspects of the MasterScope and the associated peripherals.

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Subject to technical modifications.

## Indication for Use

MasterScope WSSU is a medical device to measure inspiratory and expiratory lung function parameters in adults and children aged 4 years and older.

With the option ECG a 12-channel surface electrocardiogram (ECG) can be measured and recorded. It is not intended for intracardial use.

MasterScope WSSU is a portable, mains power independent, active diagnostic medical device for transient application ( $\leq 60$  min). It can be used by physicians in the office or hospital.



FEDERAL U.S. LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. (Rx only)



Please refer to the Short Guide for additional study specific information.

# ERT Customer Care Contacts

### Available 24 hours a day, 7 days a week, year-round

ERT’s Global Customer Care team is always available to address any questions, concerns or equipment needs. You can request immediate assistance by calling the helpdesk team. Alternatively, send us an email or fax using the information below.

ERT’s Global Customer Care team is always available for technical support. A trained specialist is standing by for your call now. Please be sure to have your ERT study name, Portal account login or the ticket number for an existing case, if available.

### Call the ERT Helpdesk (not toll-free)

US Toll number: +1 908 595 2020

German Toll number: +49 9305 720 9891

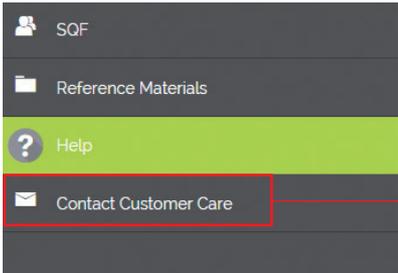


ERT Helpdesk Toll-Free (where available) numbers can be found on the ERT’s website: [www.ert.com/contact/contact-customer-care/](http://www.ert.com/contact/contact-customer-care/)



Please note that the ERT Customer Care phone system logs the caller ID (phone number) of incoming phone calls. The numbers are stored with a date and time, and separately from any other call, ticket, study, site, or subject information, in a separate password-protected database. If required, the data is used for troubleshooting purposes and the generation of call metrics only, and is only accessible by authorized ERT personnel who work in Customer Care. To avoid disclosing a private telephone number, it is recommended to use a site-owned phone to call in rather than a private phone. Alternatively, if needed, it is possible to block the caller ID before calling.

### Contact us via ERT Portal



Click in the ERT Portal on “**Contact Customer Care**” and follow the instructions on the screen to submit a helpdesk ticket.

### Contact Us by Email

You can email questions and comments to the Global Helpdesk at [customercare@ert.com](mailto:customercare@ert.com)



Our approximate turnaround time for incoming emails is 48 hours (during business days). If your request is urgent, please call the ERT Helpdesk for immediate assistance using the telephone number for your country above.



International Support is responsible for **all hardware and software** issues and should be contacted as soon as a problem occurs at a site.



Please have the following information available when you call:

- **Study name**
- **Site number**
- **System #**
- **Subject/CRF Number or SYS Number**
- **Whether this issue has been reported by the respective site to the hotline before**

The Technical Hotline Operator will ask you for this information in order to provide the most efficient service.



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[CustomerCare@ert.com](mailto:CustomerCare@ert.com)

## Notes on Safety in Instructions for Use

Following the **ANSI** recommendations (American National Standards Institute) for safety notes, specific passages of the Instructions for Use are clearly marked as safety notes.

Degree of Danger	Injury to Persons	Damage to Property	Use in case of:
	X		<b>DANGER</b> indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury. This signal word is to be limited to the most extreme situations.
	X		<b>WARNING</b> indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	X	(X)	<b>CAUTION</b> indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.

Additional icons shown in the Instructions for Use:

			Important and useful information. Information does not warn of dangerous or harmful situations.
			Hints for use.

## Declaration of Conformity



The original document of the Declaration of Conformity can be found in the Accompanying Documents.

## Introduction

The MasterScope is a customized system used to support clinical studies. This manual will guide you through setting up and operating the MasterScope.

### Training

All individual users of the MasterScope equipment must have had a training session by a certified trainer.

### Safety

Along with the practical information required to use the MasterScope, the MasterScope Instructions for Use contains important safety information. Please refer to the chapter "**General Safety Precautions**" before installing and using the equipment.

### Troubleshooting

If any of the MasterScope components are not functioning properly, please consult the MasterScope Instruction for Use, chapter "**Troubleshooting**".

## What is MasterScope?

MasterScope is your comprehensive solution for conducting clinical trials. Our customized software allows for protocol-driven workflows and can be tailored for use in multi-center studies.

MasterScope provides automated and secure data transmission for global data collection and analysis, including review of protocol compliance, test acceptability and overall quality monitoring.

MasterScope is the most advanced system on the market providing biometric fingerprint identification to comply with the 21 CFR Part 11 requirements. All actions are logged in an audit trail, which makes quality and compliance monitoring easy.

With the MasterScope, data can be transmitted via ethernet, wireless LAN, web upload or analog modem to the ERT Data Center. If a data transfer is not possible, data can be backed-up on a external media which is then sent to the ERT Data Center by mail.



Do not put excessive weight on the Equipment Bag.

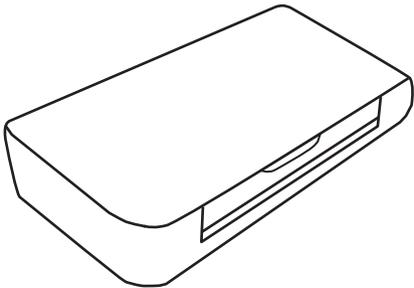
# Printer



Prior printing with the MasterScope, the delivered printer has to be prepared and connected to the MasterScope.

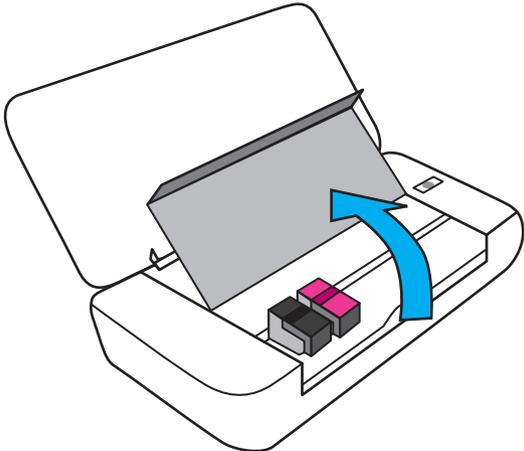
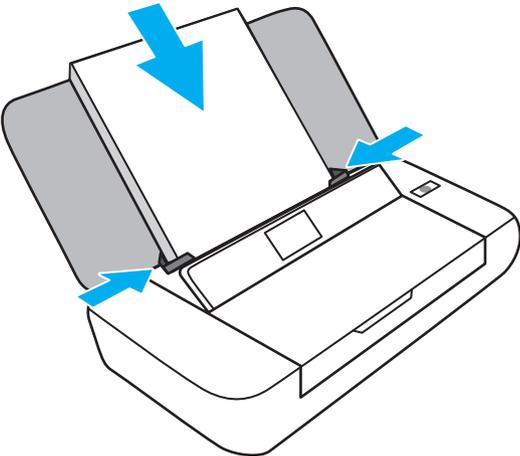


The following description applies to any printer model supported by the MasterScope. Only printer models provided by ERT can be used with the MasterScope system.



Remove the protection tapes from the printer and open the paper feed holder and the front panel. Remove the blue transport protection, if enclosed.

Insert the paper into the paper tray of the printer.



Insert the power cable from the external power supply into the back of the printer. Connect the other end of the external power supply to the wall socket. Insert the parallel printer cable into the back of the printer and connect the other end to the MasterScope. Press the power button to turn the printer on.

Remove the protection seal from the cartridges.



Do NOT touch or remove the copper strip underneath the tape.

Open the lid of the printer. The printer head will move to the cartridge loading position. Unlock the blue and grey handles and insert the ink cartridges.



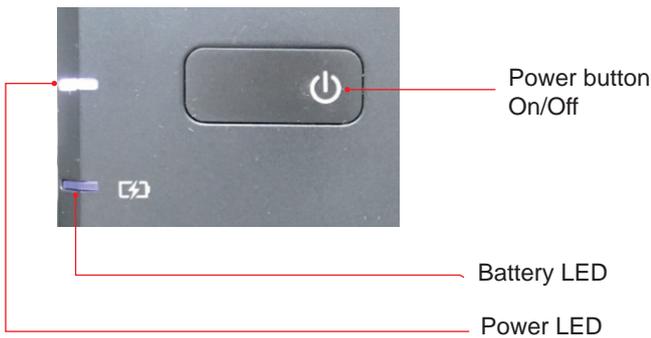
Lock the handles.



The cartridge number can vary by printer models! The pictures above are just examples in regards to the cartridge number.

## Printer HP 200

Lights and keys:



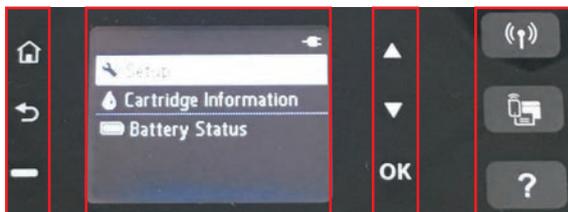
### On/Off

Power LED lightning: Printer is turned on  
Power LED dark: Printer is turned off

### Battery LED

Not used with ERT configuration!

Ensure that the printer power cable is always connected to use the printer (battery is not provided with the printer).



Not needed with ERT setup

Use the keys to navigate

Display with instructions, e.g. when printing

Use the keys to navigate



The printer is pre-configured by ERT. **There is no need to go into the Setup menu to configure the printer.** Please ensure to plug in the power cord, insert paper and cartridges, connect it to the MasterScope, switch it on and the printer is ready to use.



ERT is not providing the battery for the printer! It works only if the power cable is plugged in!



Power Adapter

Power Adapter connected to printer



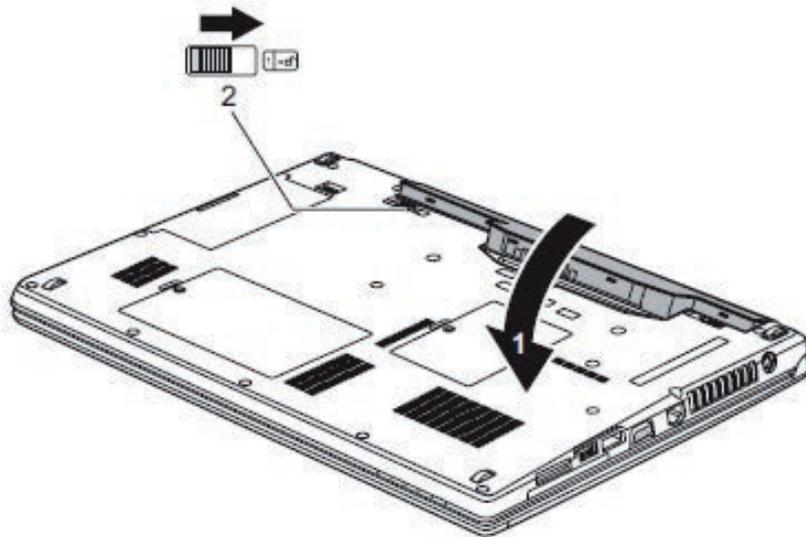
**Ensure first to plug the delivered "Power Adapter" into the printer and then plug in the power cable!**

# 1. The MasterScope Setup (Fujitsu E756)

## 1.1 Installing the Battery in the Notebook



Due to regulatory safety for Lithium Ion batteries transportation it is necessary to remove the battery from the notebook before shipping.



1. Remove the notebook battery from foil package.
2. Position the battery at the edge.
3. Insert the battery into the battery compartment until it engages positively (1).
4. Slide the release button in the direction of the arrow (2).
5. Keep the foil package for the return of the equipment.

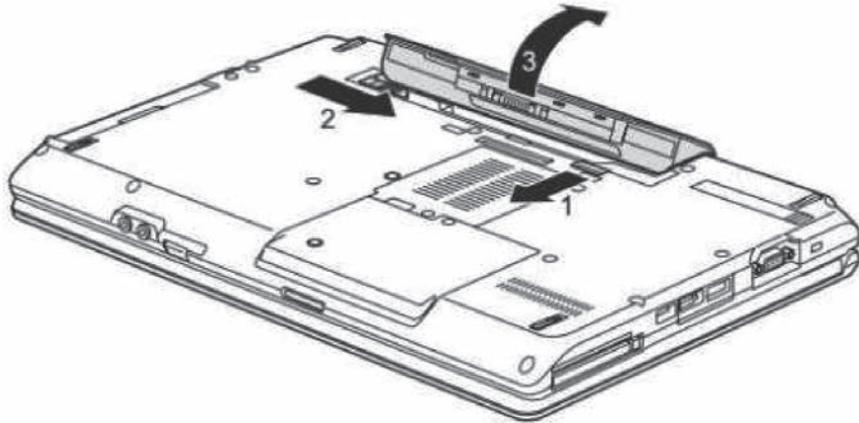


Battery **must be charged permanently** to avoid complete battery failure!

## 1.2 Removing the Battery from the Notebook



**Before shipping** the device the battery **must be removed** from the notebook!



1. Slide the release button in the direction of the arrow (1).
2. Slide the release button in direction of the arrow (2) and hold it in place.
3. Remove the battery from the battery compartment (3).
4. Place the battery in the foil package next to the notebook in the MasterScope shipping box.

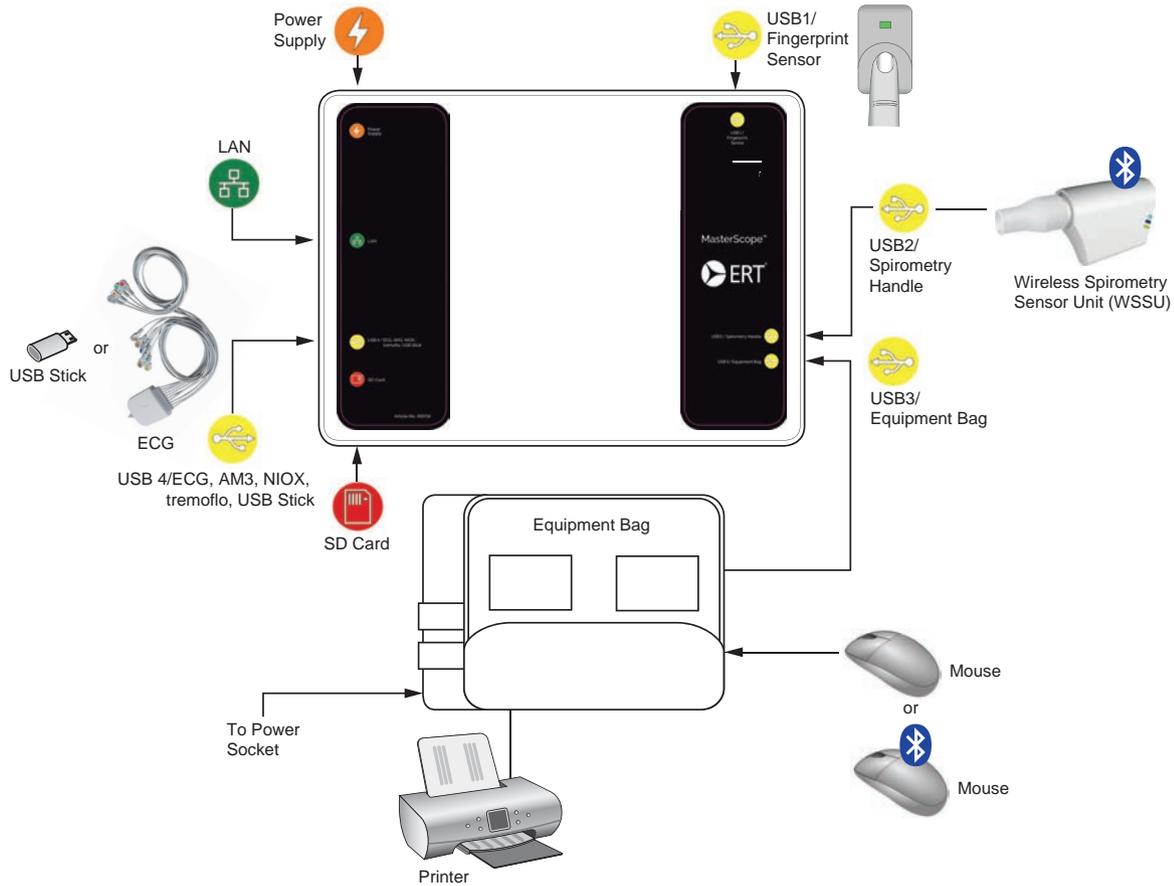
## 1.3 Faulty/Damaged Batteries



**It is prohibited to ship faulty/damaged Lithium Ion batteries. Please recycle those according to your local recycle rules.**

## 1.4 Connecting the MasterScope Accessories (Fujitsu E756)

All MasterScope accessories must be connected to the Equipment Bag and the MasterScope.



For USB ports with multiple device connections please always ensure to connect the right device properly before starting the workflow action, e.g. if the next workflow action is a backup on the USB stick, then unplug the currently connected device at the particular USB port and connect the USB stick properly before starting the workflow action.



**Please note that with Fujitsu E756 analog data transmission is not supported anymore. Please use WiFi/LAN or SD Card upload instead.**

## 2. Turning on the MasterScope

Connect your MasterScope to a power socket which corresponds to the local regulations (110/240V). Turn the MasterScope ON using the power switch on the keyboard.



**After turning on the MasterScope, please wait for about 5 minutes before starting the first measurement.**

The notebook is protected by a power-on password, which will be distributed by ERT during the training session.

### Running system on power supply

If the MasterScope is not connected to the power supply while in use, a warning message is displayed on top of the screen. Please make sure that the power cable is connected to the MasterScope.

The system is running on battery power. Remaining battery power is 90%.

Do not use the notebook without connecting it to the power supply since it could lead to loss of data. Never do a measurement without connection to the power supply. The MasterScope should be shut down at the end of each visit day, while keeping it connected to the power supply. The MasterScope must be connected to the power supply and turned on at least once a month for a minimum of 24 hours. This is to keep the battery charged and to save essential settings of the notebook, e.g. date and time.



**In case the MasterScope is not in use for longer than 12 hrs the system will shut down automatically. This is to avoid any damage on the hard disk.**

### 2.1 Login

The identification of the current user is necessary during startup and before each measurement.

For further information, see chapter “**Program Access**”.

## 2.2 MasterScope First Time Use

The MasterScope must be installed with the protocol-specific software prior to system use.

When the system is turned on for the first time, the MasterScope Configuration Wizard will start and will guide the user through the process. There are two options to install the MasterScope:

1. Online Setup: Install the software via internet download
2. Offline Setup: Install the software via setup medium, e.g. SD Card or USB stick.

### 2.2.1 MasterScope Online Setup

For installing the MasterScope software online, the following steps need to be completed:

- Step 1: Complete the Site Qualification Form (SQF) via any PC/laptop with internet access (not possible via MasterScope).
- Step 2: Connect all necessary peripherals to the MasterScope (see Chapter "Connecting the MasterScope Accessories" and Chapter "Device Management Wireless Spirometry Sensor Unit") and turn on MasterScope.
- Step 3: Establish an internet connection first (WiFi or LAN)
- Step 4: Download the study-specific software with your MyStudyPortal account and the SQF PIN.
- Step 5: Install software
- Step 6: Register all site users

Here is the detail description for each online setup step:

Step 1: Complete Site Qualification Form (SQF)



SQF needs to be completed on any internet PC/laptop (SQF is not possible via MasterScope) before the online setup can be performed on the MasterScope.

#### **What is SQF?**

Before any site can start working in a clinical trial with ERT systems it is necessary to register the site in ERT's My Study Portal (MSP). MSP is ERT's online system that provides access to reports, queries, supply ordering and reference materials. In addition it enables the capability for MasterScope to download and install the most current software versions.

#### **What do I need to complete SQF?**

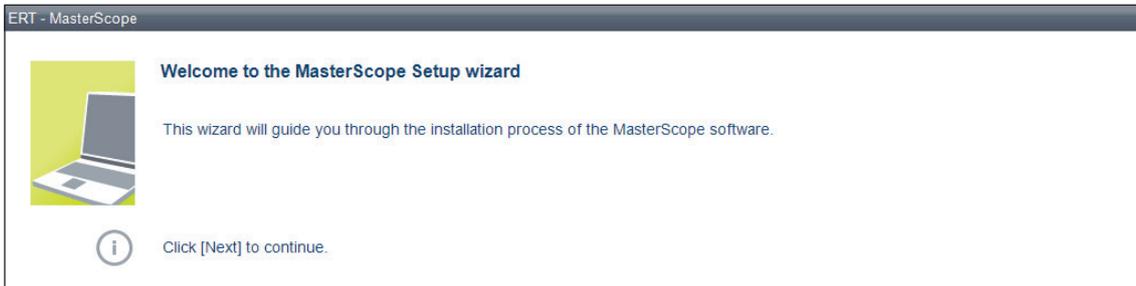
You will need the study specific SQF PIN (received via e-mail), your Site ID, full contact information for your Site's Principal Investigator, Shipping Contact, Report Receiver, and Query Receiver.

#### **How to complete SQF?**

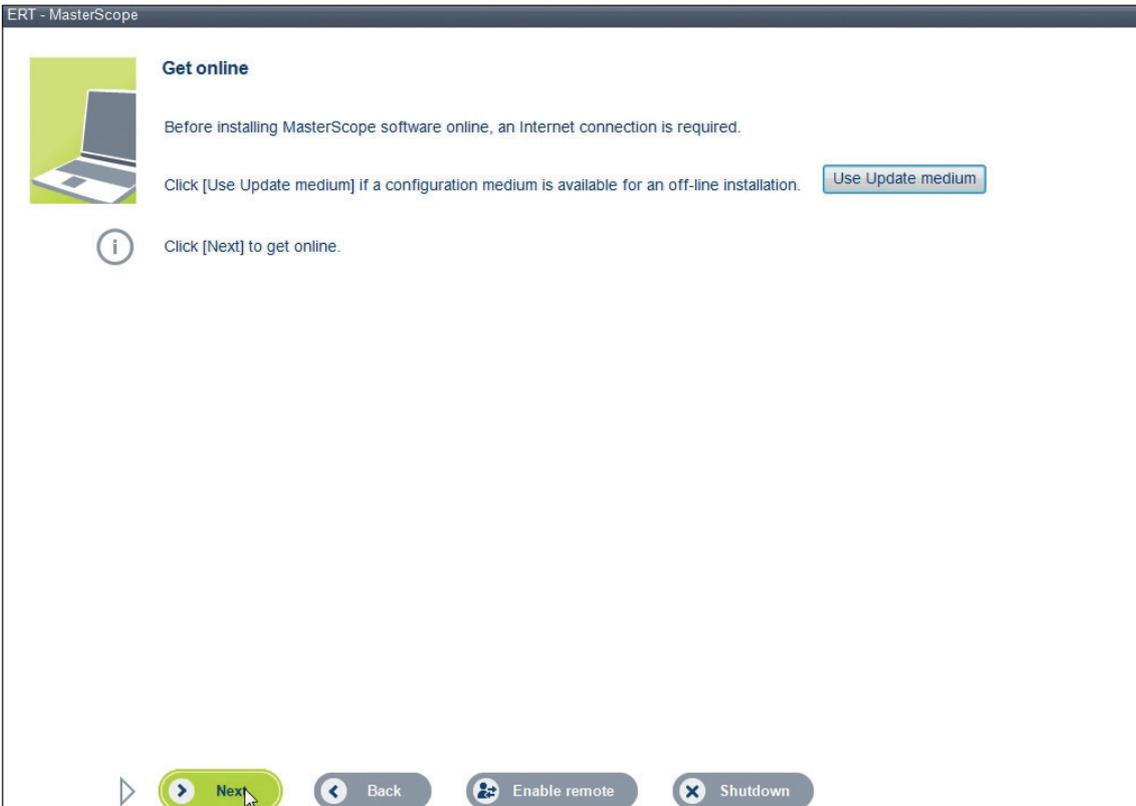
Please see the Site Qualification Form Quick Guide which explains the process for creating accounts and completing the Site Qualification Form (SQF).

Step 2: Connect peripherals and turn on MasterScope

Connect all peripherals as described in chapter 1.4 and turn on MasterScope. Enter the power on password (received during the training) and the configuration wizard will appear.



Click <**Next**> to start the setup wizard.



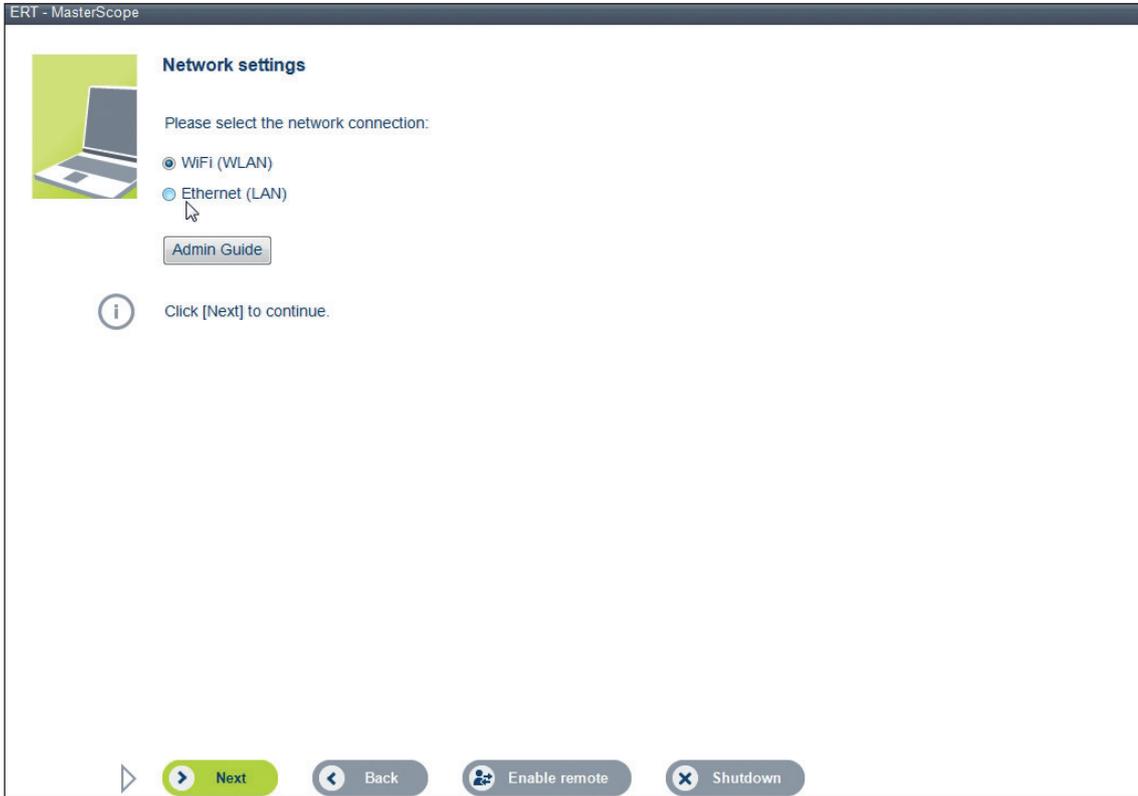
Click <**Use Update medium**> to continue with offline setup and go to the respective chapter.



Click <**Next**> for online-setup and continue with the next step.

Step 3: Establish an internet connection first (WiFi or Lan)

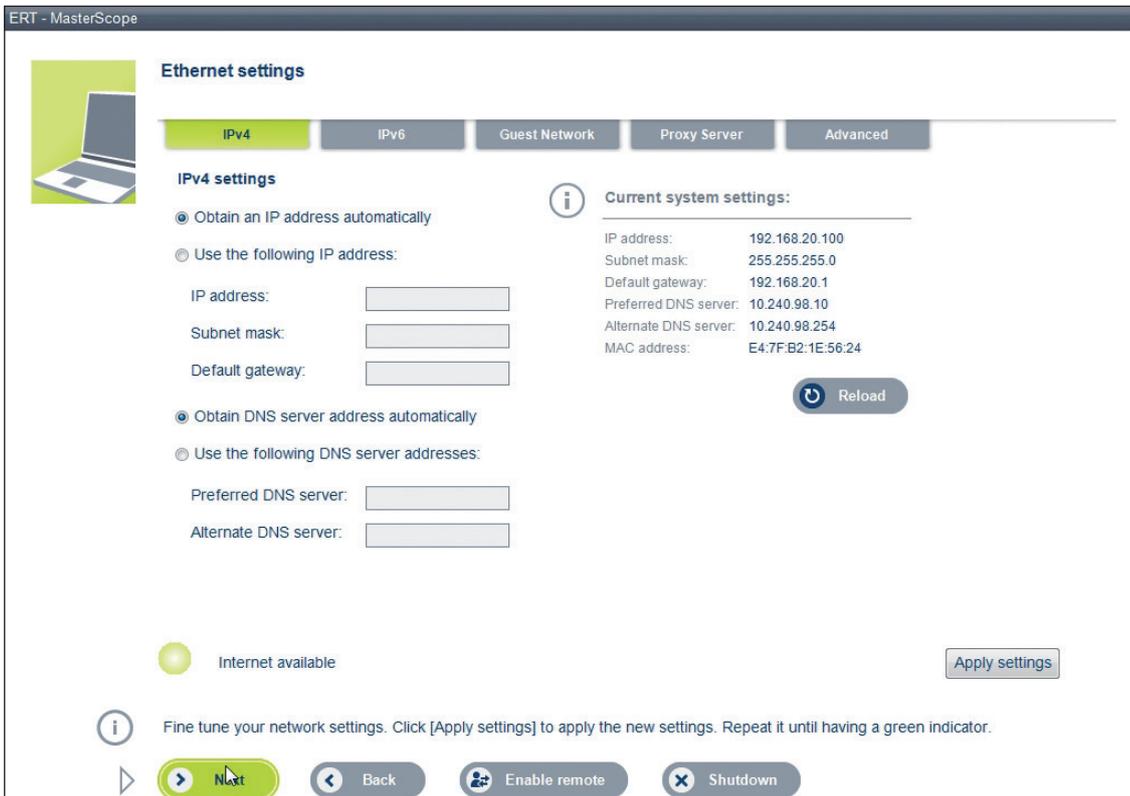
It is necessary to establish an internet connection before the protocol specific software can be downloaded and finished.



Select the preferred internet connection (WiFi or LAN) according to your local IT settings and click **<Next>** to continue.



For more detailed information about the MasterScope internet settings click on **<Admin Guide>**. This might be useful for your IT System Administrator in case of connectivity issues.

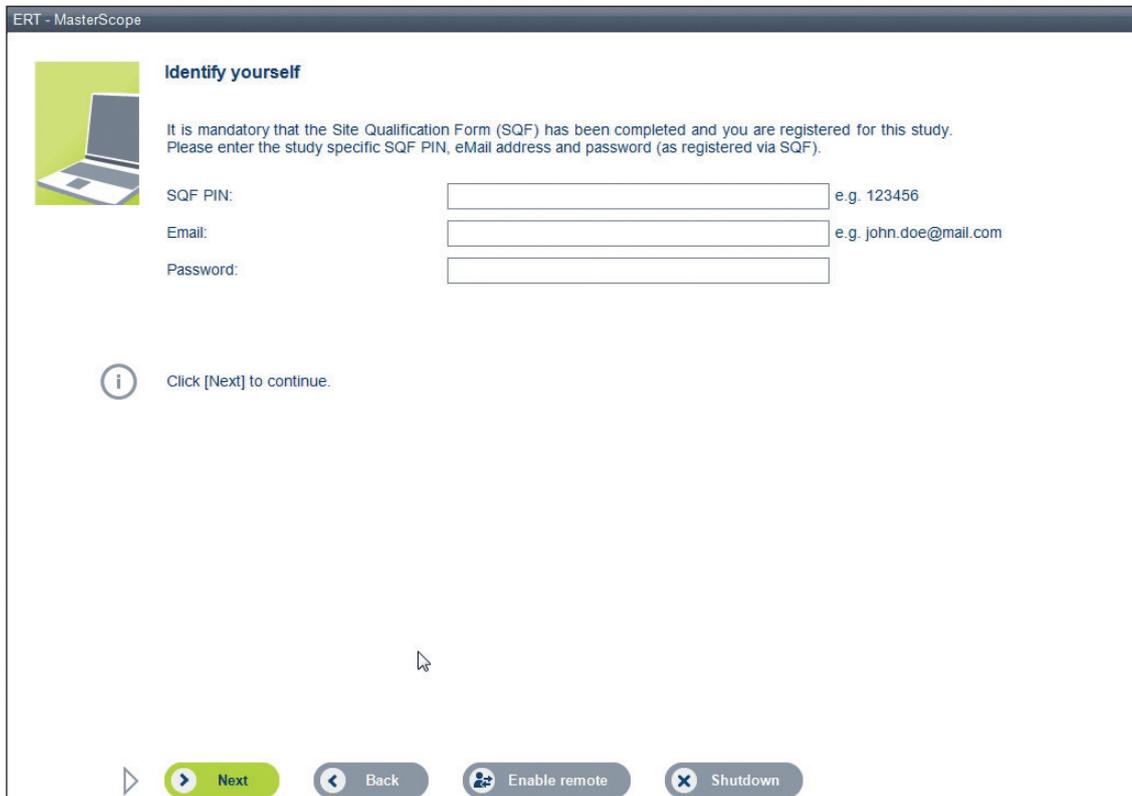


The example screen above shows LAN (Ethernet) internet settings. Please refer to the data transfer settings chapter for more detailed information.



The “green indicator - Internet available” indicates if an internet connection has been established. It will be red if there is no internet connection available. If so, ensure the settings are correct according to your local IT environment.

Step 4: Download the study-specific software with your MyStudyPortal account and the SQF PIN



Enter the following information to download the protocol-specific software:  
SQF PIN: Site Qualification PIN received from ERT. This PIN is protocol specific.  
Email: Enter your e-mail address as registered for ERT's My Study Portal  
Password: Enter your password as registered for ERT's My Study Portal.



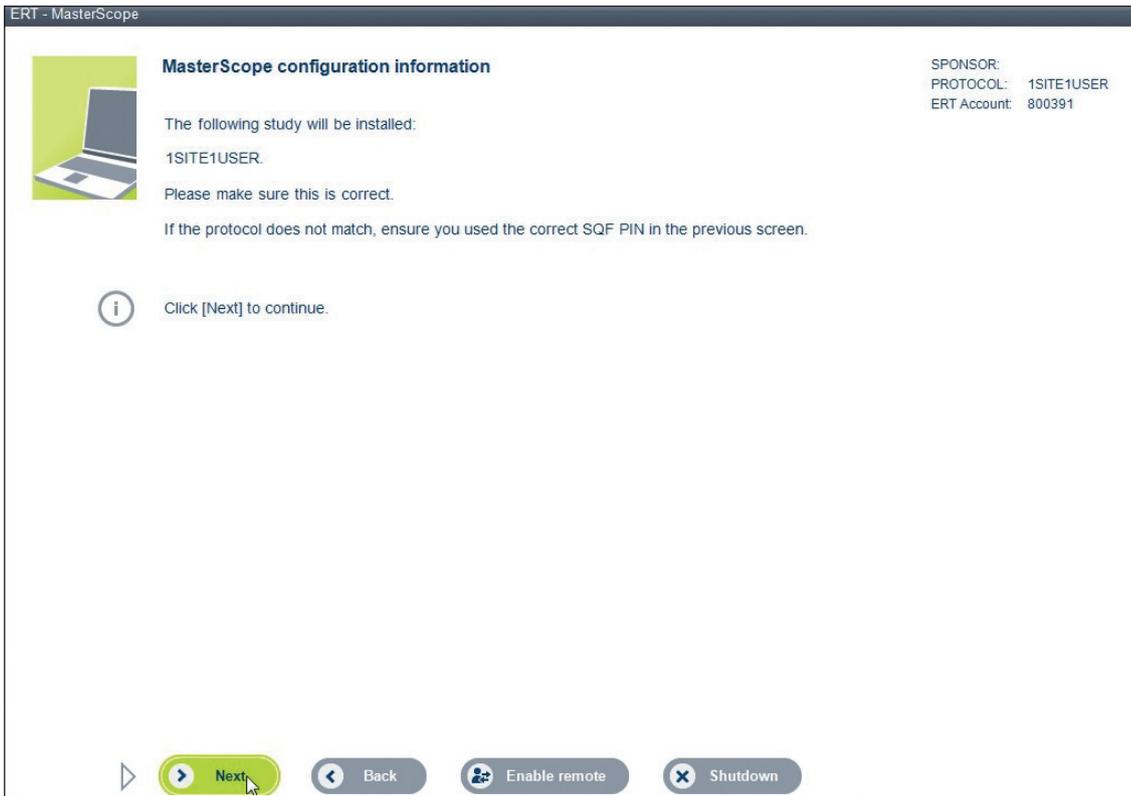
The SQF PIN is case sensitive! Ensure that it is entered correctly.  
If the login will not work, please ensure that

- SQF PIN is correct
- E-mail address correctly entered and it is the one used for My Study Portal registration
- The password is correct.

In case you forgot your password, please go to the My Study Portal website to reset your password.



Click **<Next>** to retrieve the MasterScope configuration information.



Ensure that according to the SQF PIN entered in the previous screen, the software which will be installed is correct. If not, please verify the SQF PIN used and correct it by clicking on the **<Back>** button.

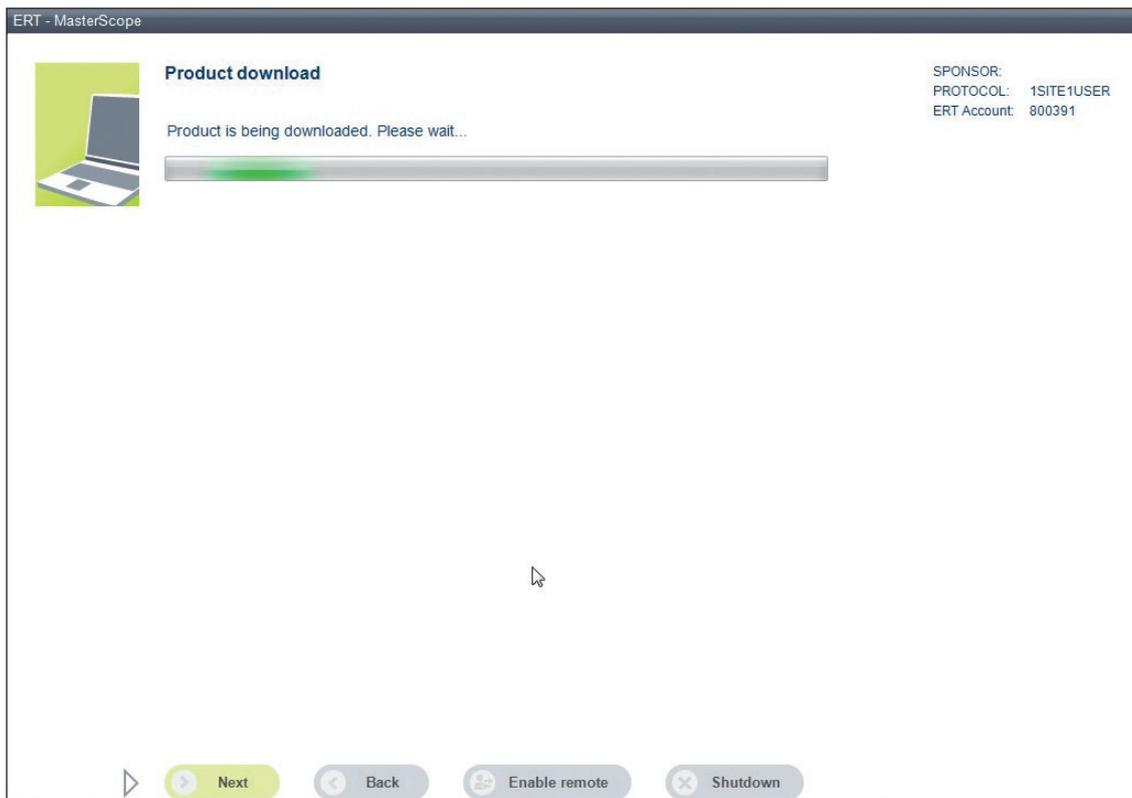


If the software matches the protocol which shall be installed, click **<Next>** to start the software download.

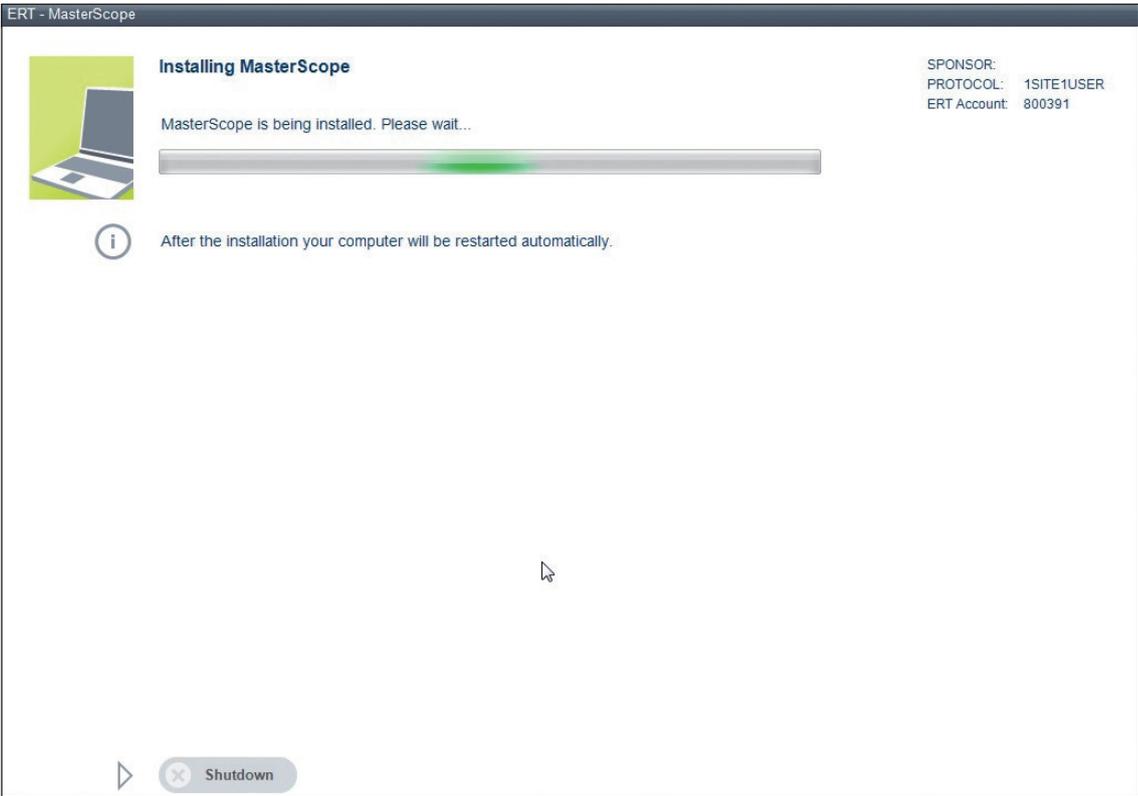


If the wrong protocol is setup on the system, it is necessary to ship the device back to ERT and receive a new system!

### Step 5: Download and Install Software



Please wait until the download is complete. Do not shut down/switch off the MasterScope or disconnect the internet connection during this process! This can take several minutes depending on your internet connection speed.



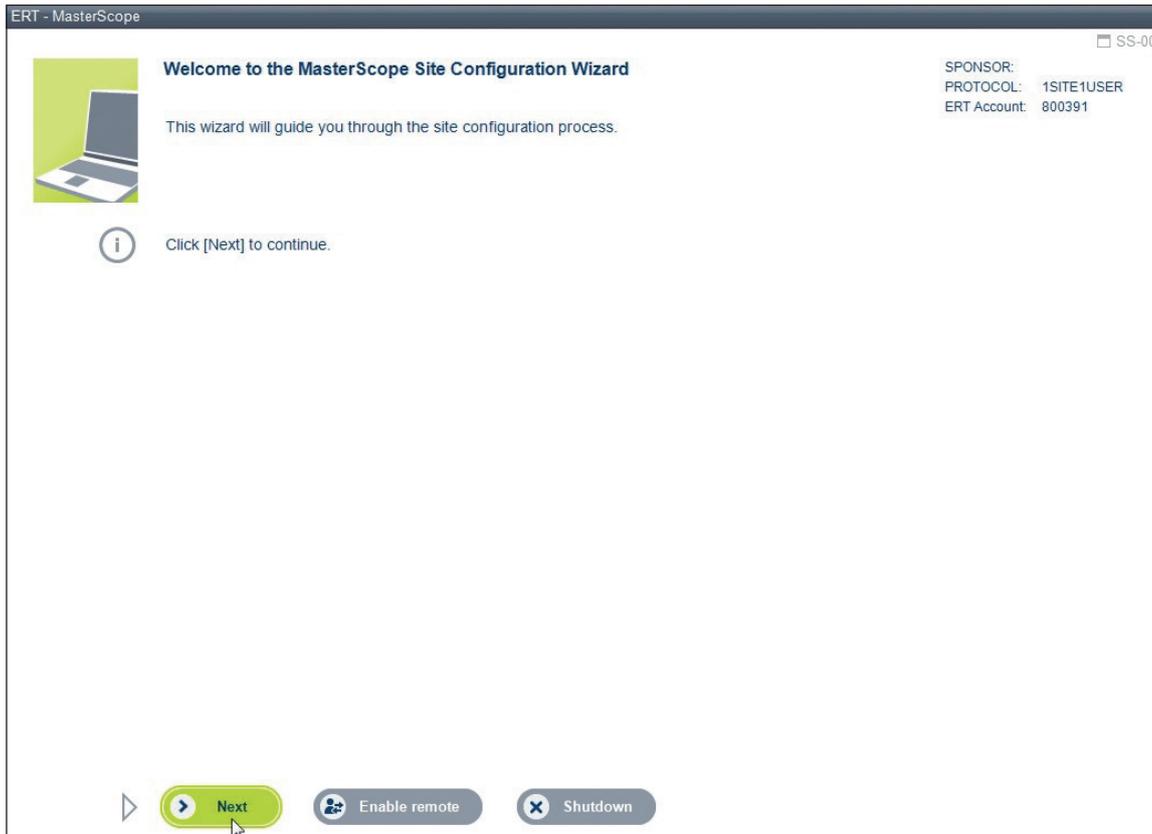
After the successful download the installation will start automatically. Once completed, the system will restart automatically.



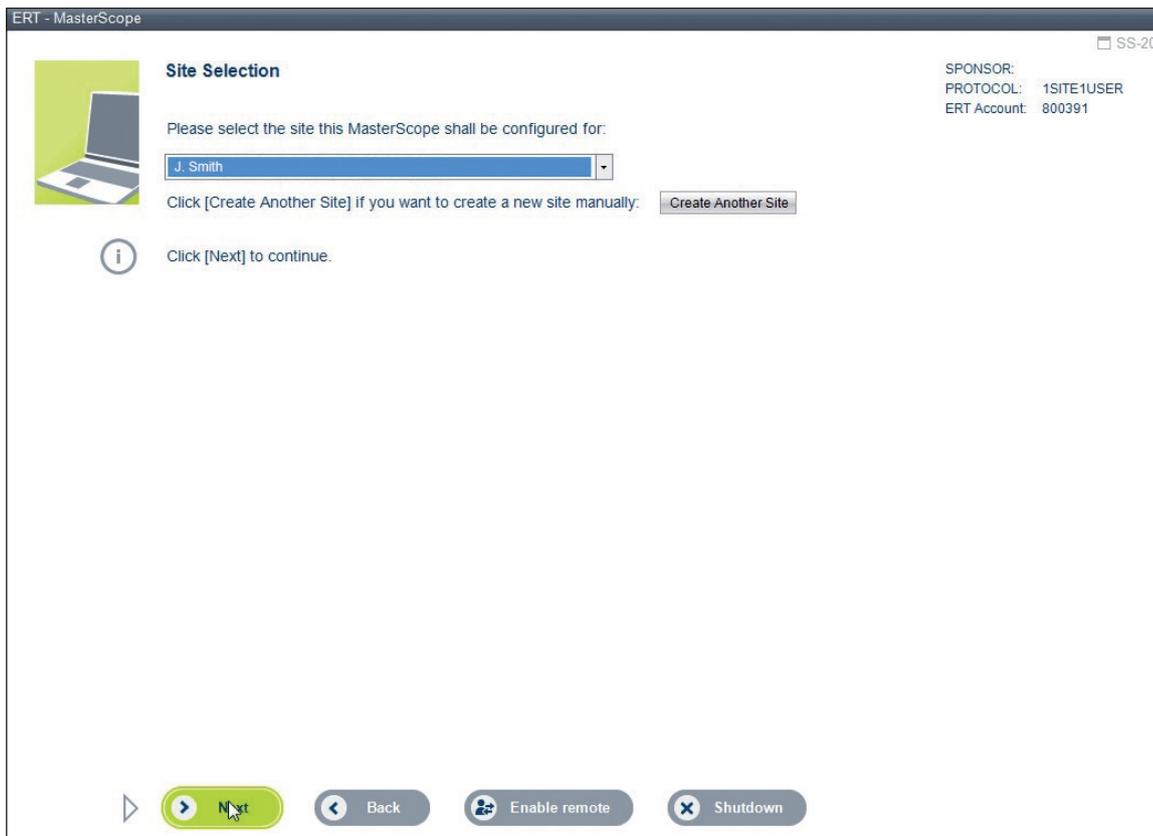
Please wait until the installation is complete. Do not shut down/switch off the MasterScope during this process! This can take several minutes.

### Step 6: Site Configuration

After the successful software installation and reboot of the system, the MasterScope configuration wizard will appear. Now, the site-specific information will be setup.



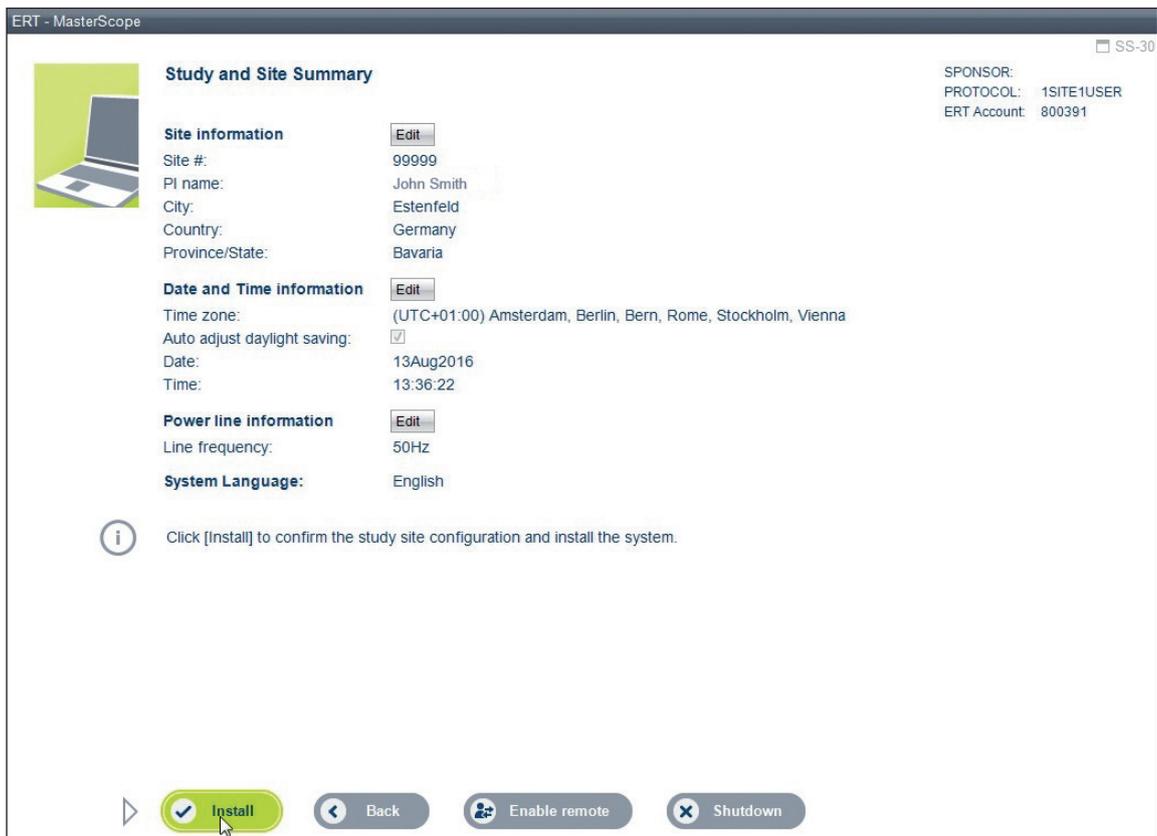
Click <Next> to start the site configuration process.



The site your My Study Portal account is registered for (which you used at step 4) is automatically displayed in the drop down. Select it and click **<Next>** to continue.



If the My Study Portal account has access to multiple sites, e.g. CRA then in the drop down all sites will be listed according to the user's access rights. Then select the site the system should be configured for.



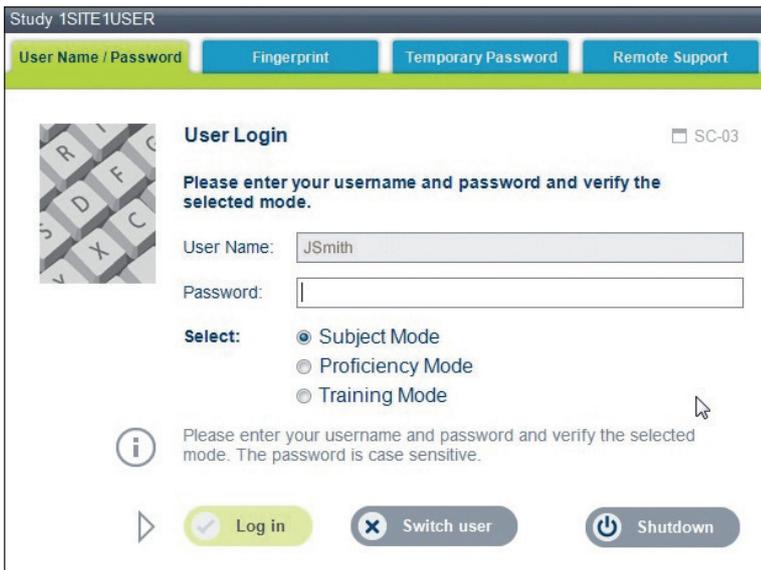
Review the site information and correct where necessary with clicking on **<Edit>**.



If all information is correct, click **<Install>** to continue.

**Step 7: User Fingerprint Registration**

During the download process all users which have already been registered via SQF for the particular site were downloaded to the MasterScope. For these it is necessary to register their fingerprints for the login. If a user was not created via SQF and downloaded, then it is still possible to add the user manually on the MasterScope.

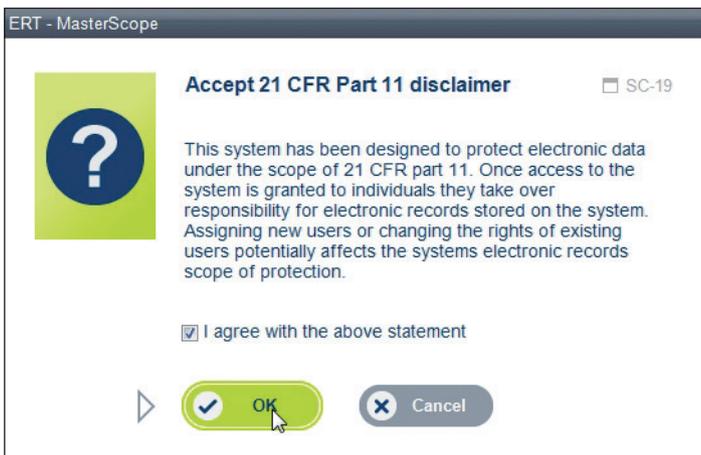


In case proficiency PIN is necessary to access the subject mode (if applicable for your trial), please use the proficiency or training mode to start the User Fingerprint Registration. After proficiency was passed the subject mode can be activated for the particular user.

After the installation was successful, the user login screen will appear. It will be prefilled with your username which was automatically created from your first and last name.



Password: You need to enter your My Study Portal password and click <Log In> to continue.



If you accept the 21 CFR part 11 disclaimer, click <OK>.



Then register your fingerprint by selecting a finger. Put the respective finger 4 times on the fingerprint sensor. It is recommended to register a second finger.



Click <Save> when the fingers have been registered successfully.

**User Information** SC-14

User Name: JSmith      Phone:

First Name: John      Fax:

Last Name: Smith      Training ID: Change

Title: Mr.

Email: lalit@xzz.com

User Role: Site Administrator

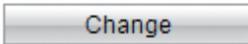
**User Status**

User is currently active. Change

**Fingerprints**

Add/change registered fingerprints Change

Next User    Done



A summary screen will show the User Information. Click on <Change> to amend any information.



All user information were downloaded from ERT's My Study Portal account. Any changes which will be done on the MasterScope to the User Information will not be synchronized with ERT's My Study Portal account.

**User Management** SC-15

First Name	Last Name	User Name	User Role	Active
John	Smith	JSmith	Site Administrator	True

Show deactivated users

Create new user    Show Details

Close



If you go to the User Management via the Tools menu and select “**Show deactivated users**”, the system will display all users who have been registered for this site via SQF already. These users were downloaded automatically. Just select the user who should also get access and click on <**Show Details**> to add the fingerprints. There is no need to add them as new users.



If a user is not listed at all, then click on <**Create new user**>.

Otherwise the system software installation and user registration is complete.

## 2.2.2 MasterScope Offline Setup

For installing the MasterScope software offline, the following steps need to be completed:

- Step 1: Ensure the setup medium with the most current protocol-specific software version has been received from ERT.
- Step 2: Connect all necessary peripherals to the MasterScope (see Chapter 1.4) and turn on the MasterScope.
- Step 3: Insert the setup medium into the MasterScope laptop computer and install the software.
- Step 4: Register all site users.

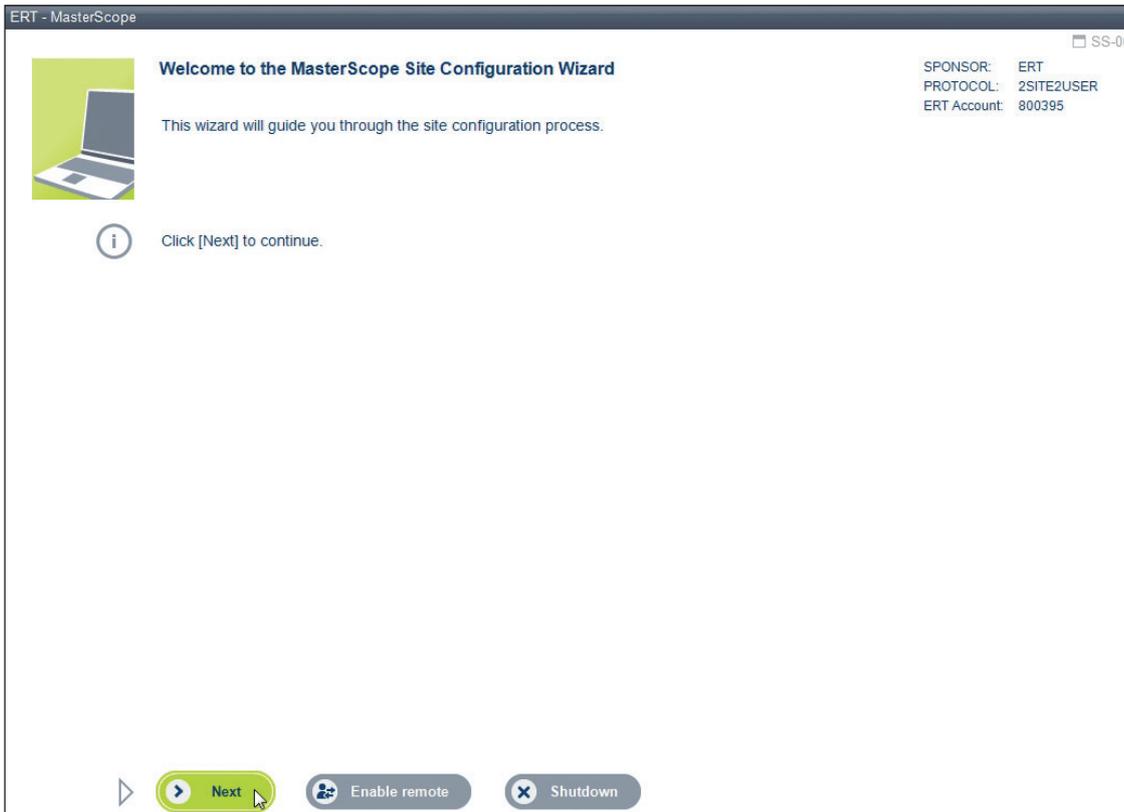
Here is the detail description for each offline setup step:

### Step 1: Update medium (SD Card or USB Stick)

Ensure the setup medium (SD Card or USB stick) with the most current protocol-specific software version has been received from ERT. Have it ready before continuing with the next steps.

## Step 2: Connect peripherals and turn on MasterScope

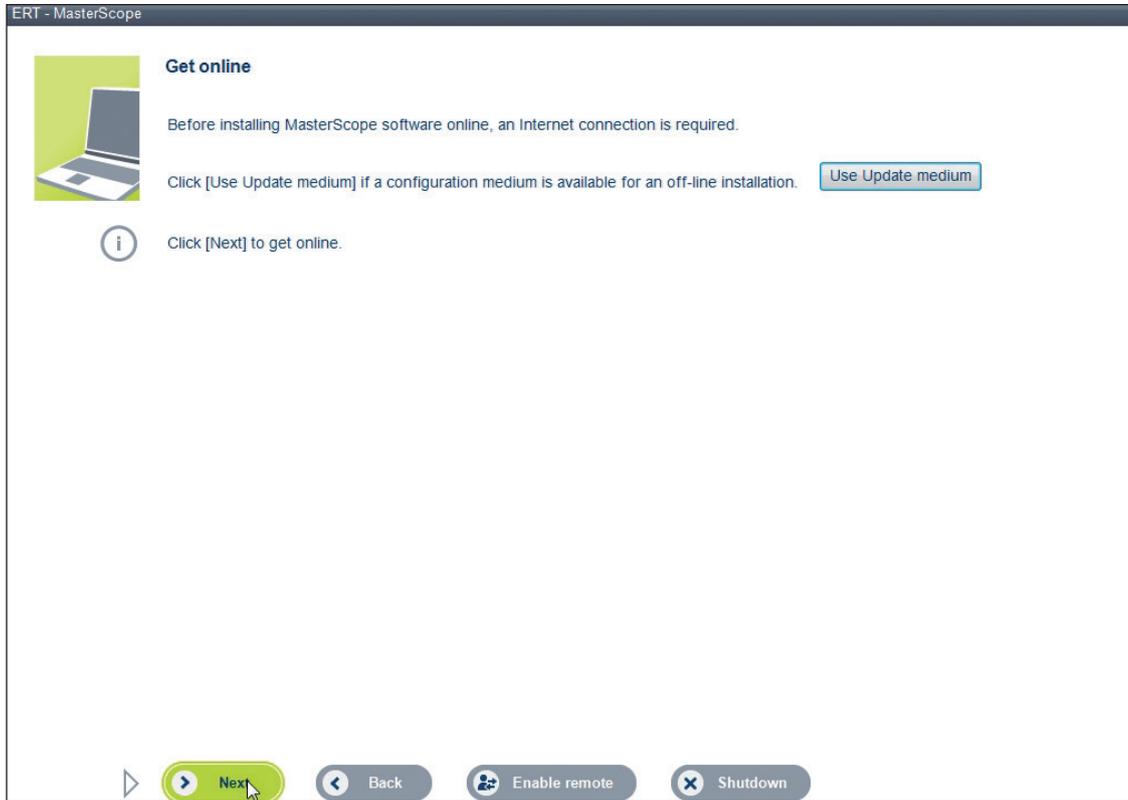
Connect all peripherals as described in Chapter 1.4 and turn on the MasterScope. Enter the power-on password (received during the training) and the configuration wizard will appear.



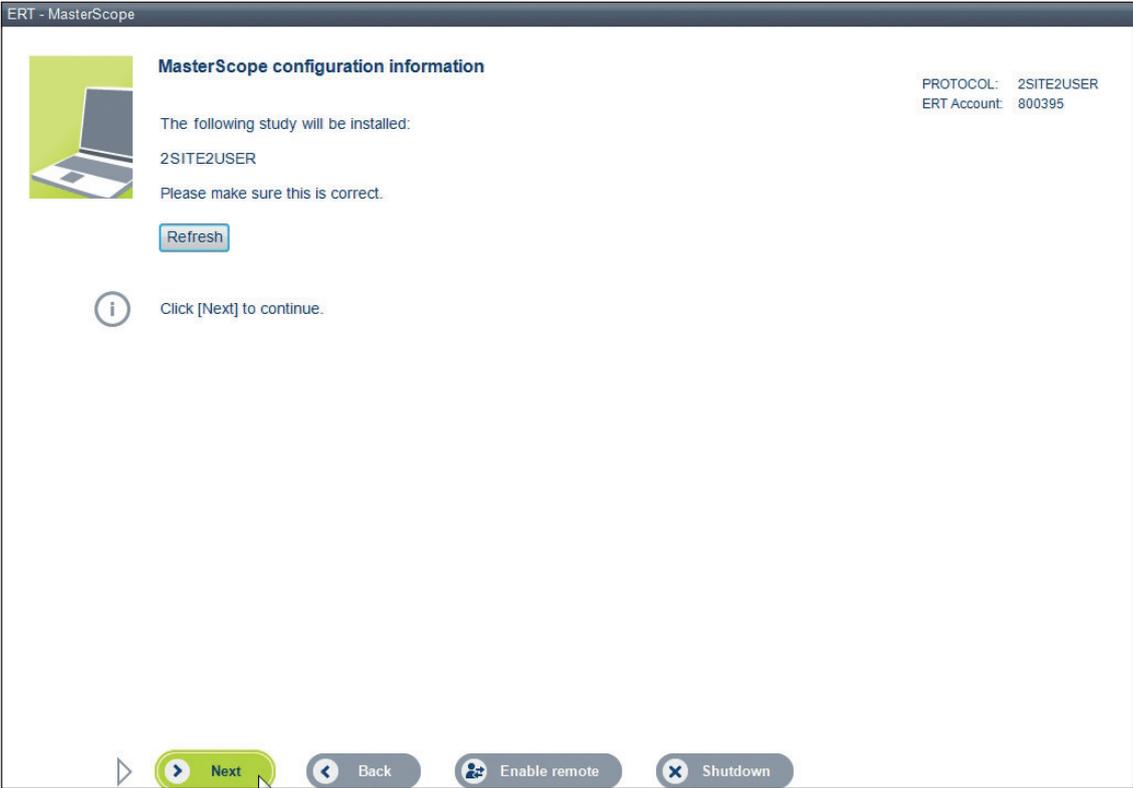
Click <Next> to start the site configuration process.

### Step 3: Install the software

Insert the setup medium into the MasterScope laptop computer and install the software.



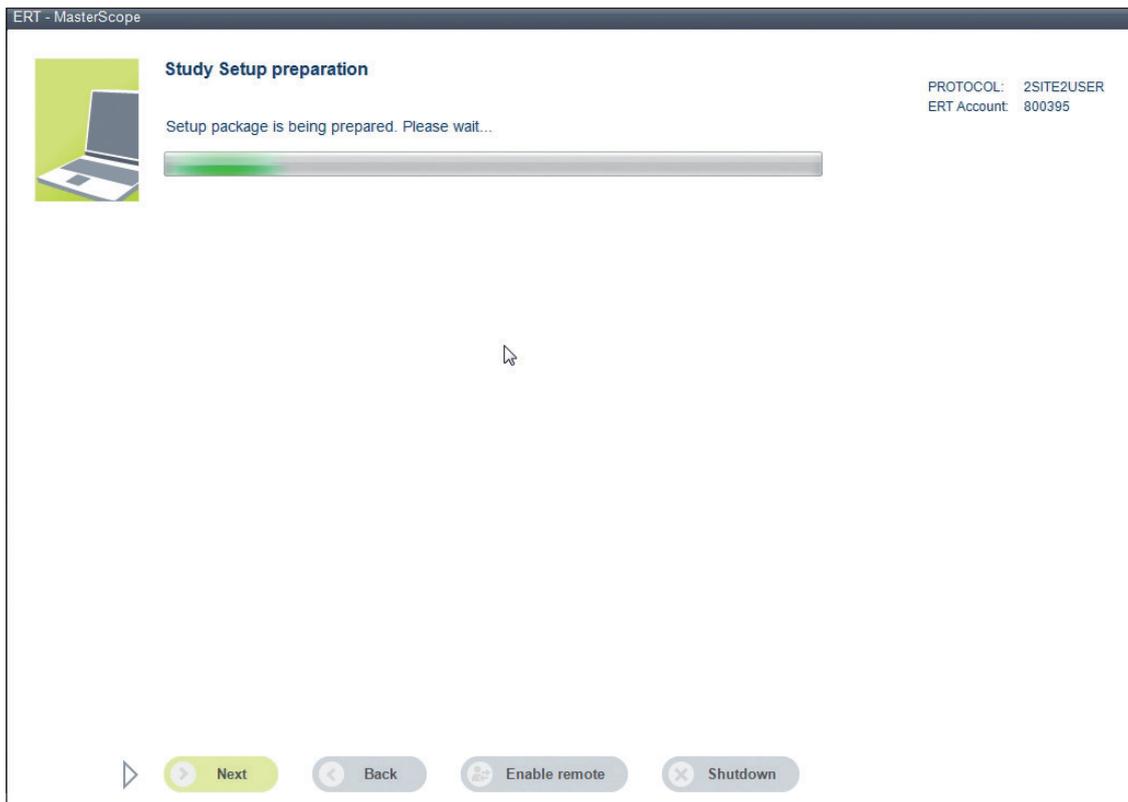
Ensure that the update medium is inserted in the MasterScope and click <**Use Update medium**> to continue with the offline setup.

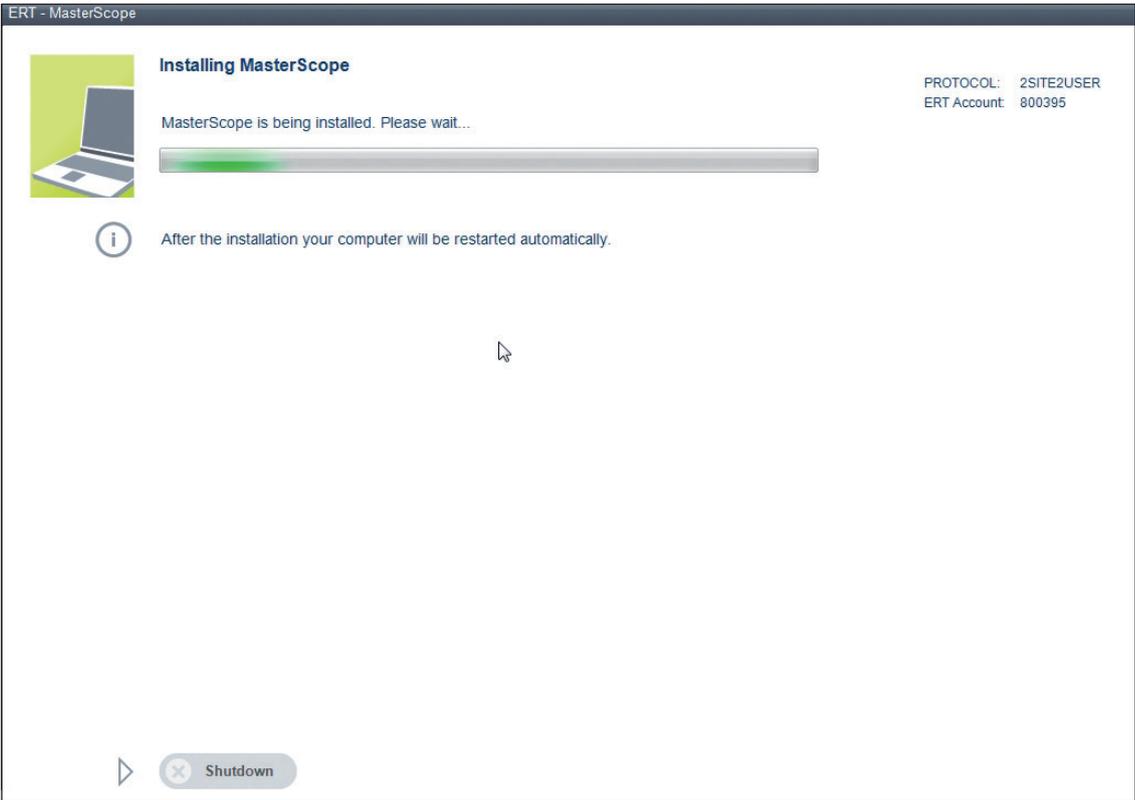


Make sure that the protocol information listed is the correct protocol which the system must be setup for and click on **<Next>**.



If the wrong protocol is setup on the system, it is necessary to ship the device back to ERT and receive a new system!





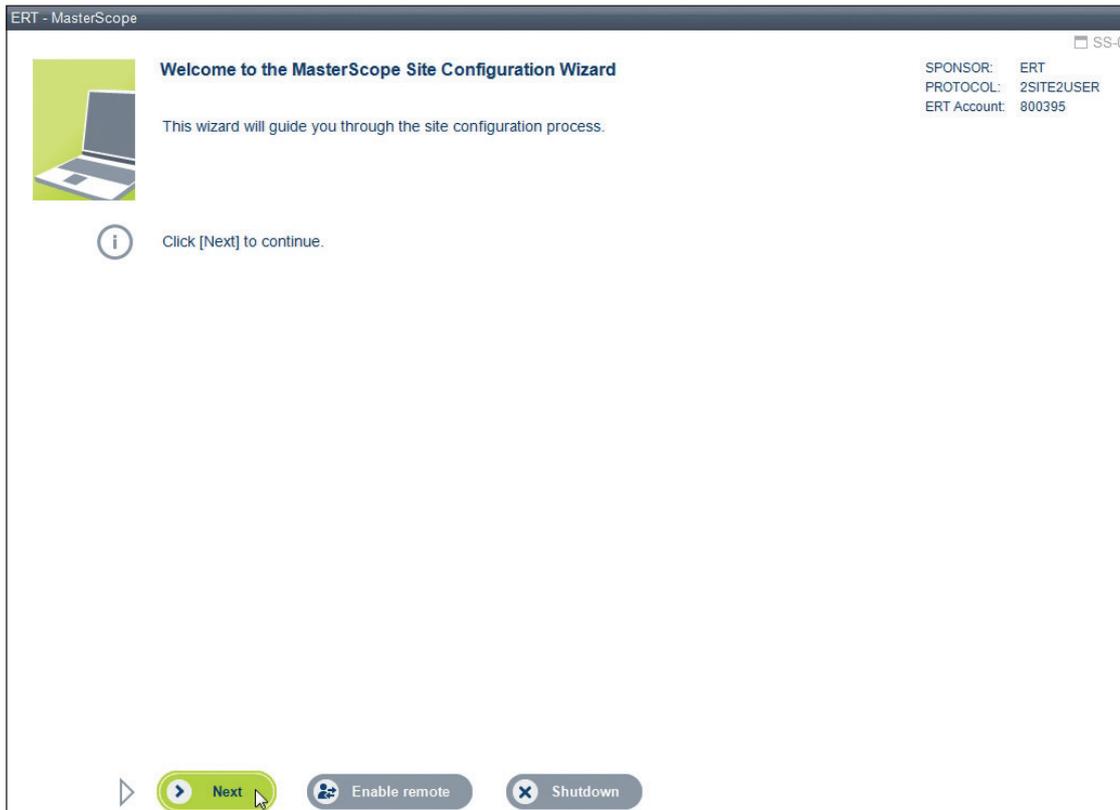
After the successful preparation the installation will start automatically. Once completed, the system will restart automatically.



Please wait until the installation is complete. Do not shut down/switch off the MasterScope during this process! This can take several minutes.

### Step 4: Site Configuration

After the successful software installation and reboot of the system, the MasterScope configuration wizard will appear. Now, the site-specific information will be setup.



Click <Next> to start the site configuration process.

ERT - MasterScope SS-10

SPONSOR: ERT  
 PROTOCOL: 2SITE2USER  
 ERT Account: 800395



### Site Information

**Site information**

Site #:  e.g. 00001

PI Name:  e.g. John Doe

**Country selection**

City:  e.g. Chicago

Country:  select from the list

Province/State:  select from the list (if available)

i Click [Next] to continue.

▶

▶ Next

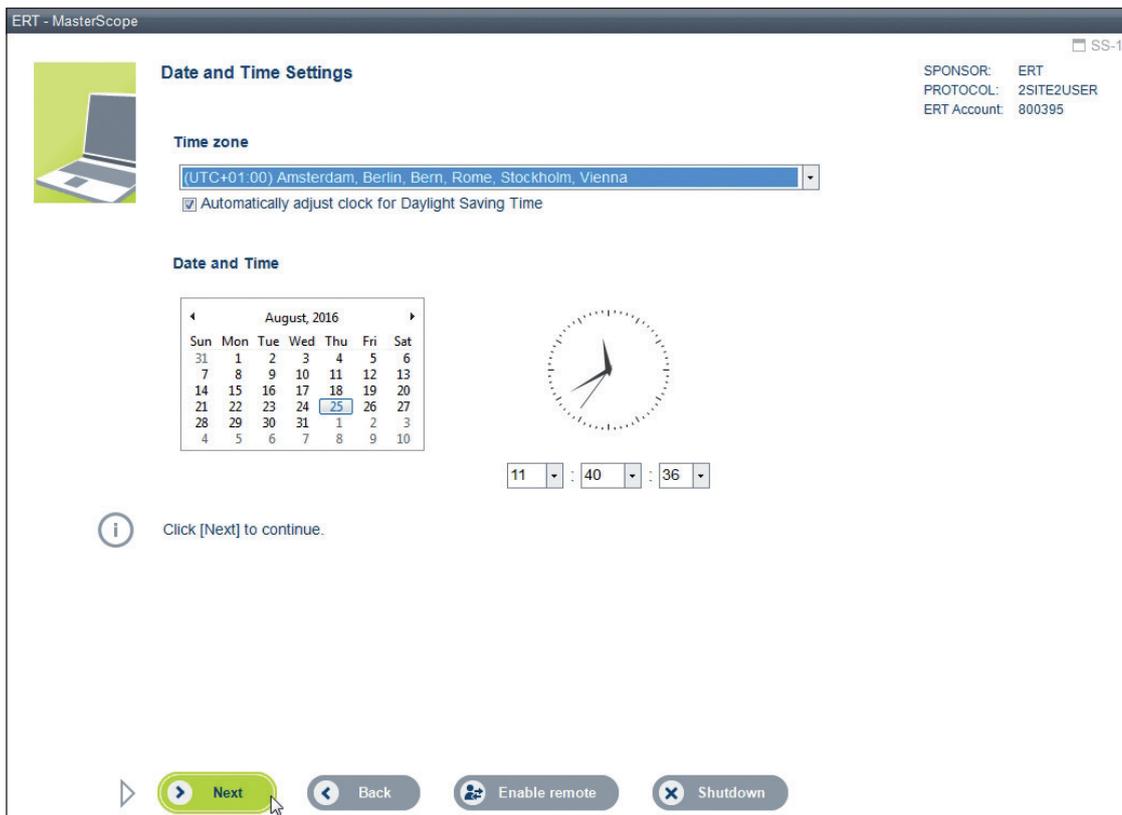
◀ Back

⚙️ Enable remote

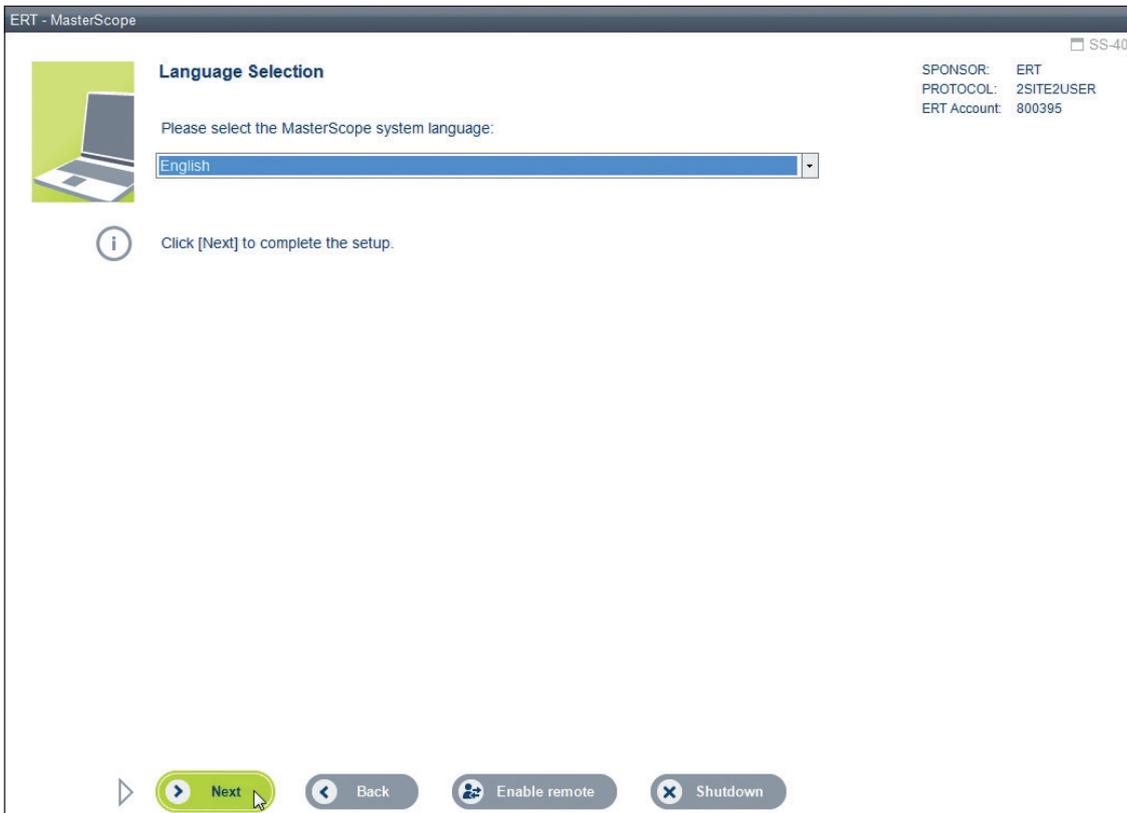
✖ Shutdown



Enter all site information and click <Next>.



Select the time zone, date and time of your site location. Please check if your country uses daylight saving time and click on **<Next>**.

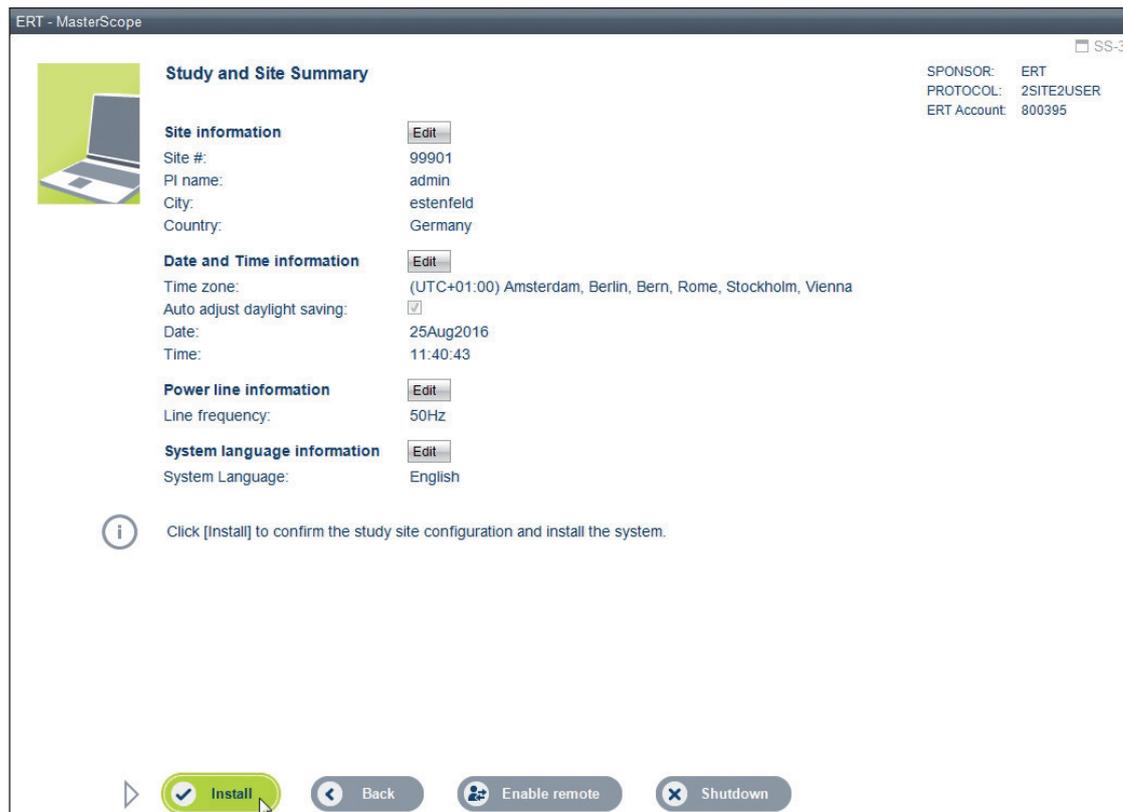


Select your preferred system language and click on **<Next>**.



There are only languages listed which are available for the particular protocol setup. If your preferred language is not available, please use English language.

A summary screen shows all of your settings done:

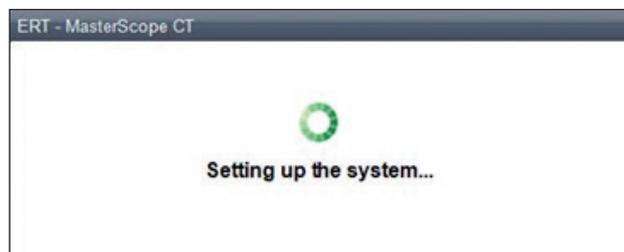


To accept these settings, click on <Install>.



In order to change some of the above data, click <Edit> and repeat data entry.

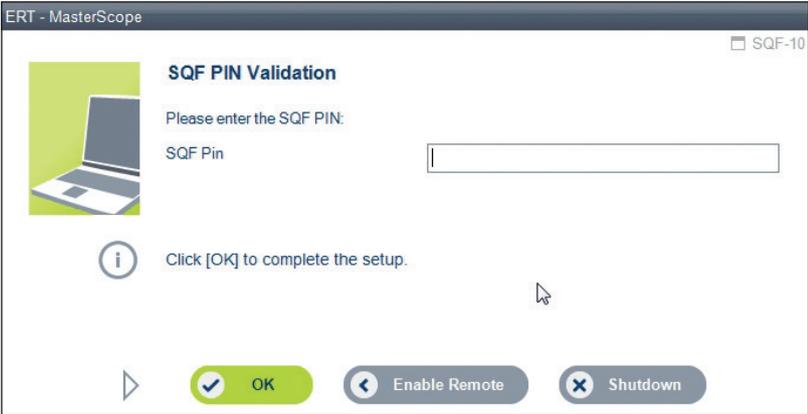
The MasterScope setup starts automatically. This procedure may take a few minutes.



During the setting up the system:

- **Make sure that the laptop computer is not running on battery power.**
- **Do not switch off the laptop computer.**
- **Do not remove the setup medium.**

When the setup of the system was successful, the SQF PIN Validation screen will appear:

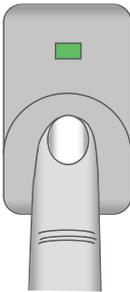


In order to start registering users for the system you need to enter the SQF PIN (Site Qualification Form PIN) which you have received by e-mail. Then, click <OK>.



The SQF PIN entry is case sensitive!

## 2.3 MasterScope User Registration



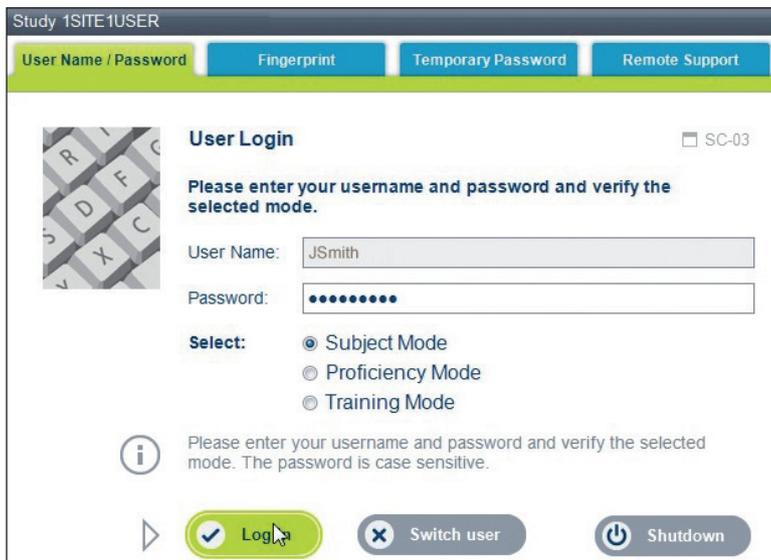
In order to register site personnel on the MasterScope, the user name must be entered and at least two different fingers must be registered using the fingerprint sensor.

The MasterScope User Registration can be started in three different ways:

**First**, by using the My Study Portal account as described under Online Setup chapter or by using the SQF PIN as described under the Offline Setup chapter. This is the procedure to create new users (also the CRA) on a new configured MasterScope system, i.e. if neither the CRA nor any users have been previously registered.

To login with My Study Portal account, follow the steps 1 to 4 below:

1. User Name: First letter of first name + last name (automatically filled in after the successful online setup)
2. Enter the password of your My Study Portal account (see online setup chapter).
3. Select either "**Subject Mode**", "**Proficiency Mode**" or "**Training Mode**".



4. Click <Log In> to continue.

**Second**, new users can be registered more easily in the CRA's or site user's (who has the respective role to create new users) presence. For doing this, follow the steps below:

1. Login with the fingerprint sensor. (User who can add new users to the MasterScope according to their role.)
2. Go to "**Tools**" on the right menu bar of the system.
3. Click the tab "**User Management**" in the "**Tools**" menu.
4. Follow the steps for registering new users as described in the respective chapter of the Instructions for Use manual.

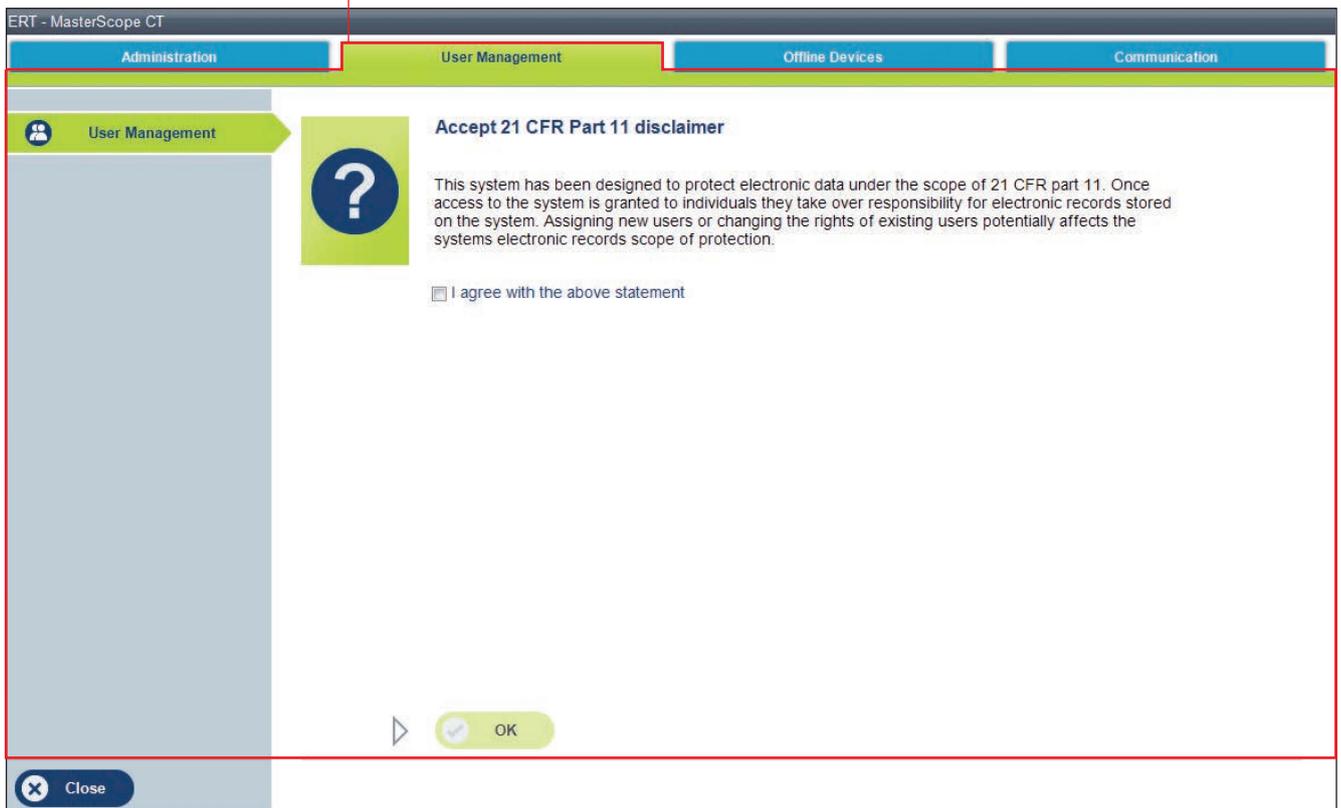
**Third**, new users can be registered if none of previous registered users are available. For doing this, follow the steps below:

1. Go to the login screen and click on the **"Temporary Password"** tab.
2. User Name: **"Enroll"**.
3. Call Customer Care and explain the situation why to receive a one-time password. Follow Customer Care instructions.
4. Enter the password provided by Customer Care.
5. Click **<Log In>** to continue.
6. Follow the steps for registering new users as described in the respective chapter of the Instructions for Use manual.



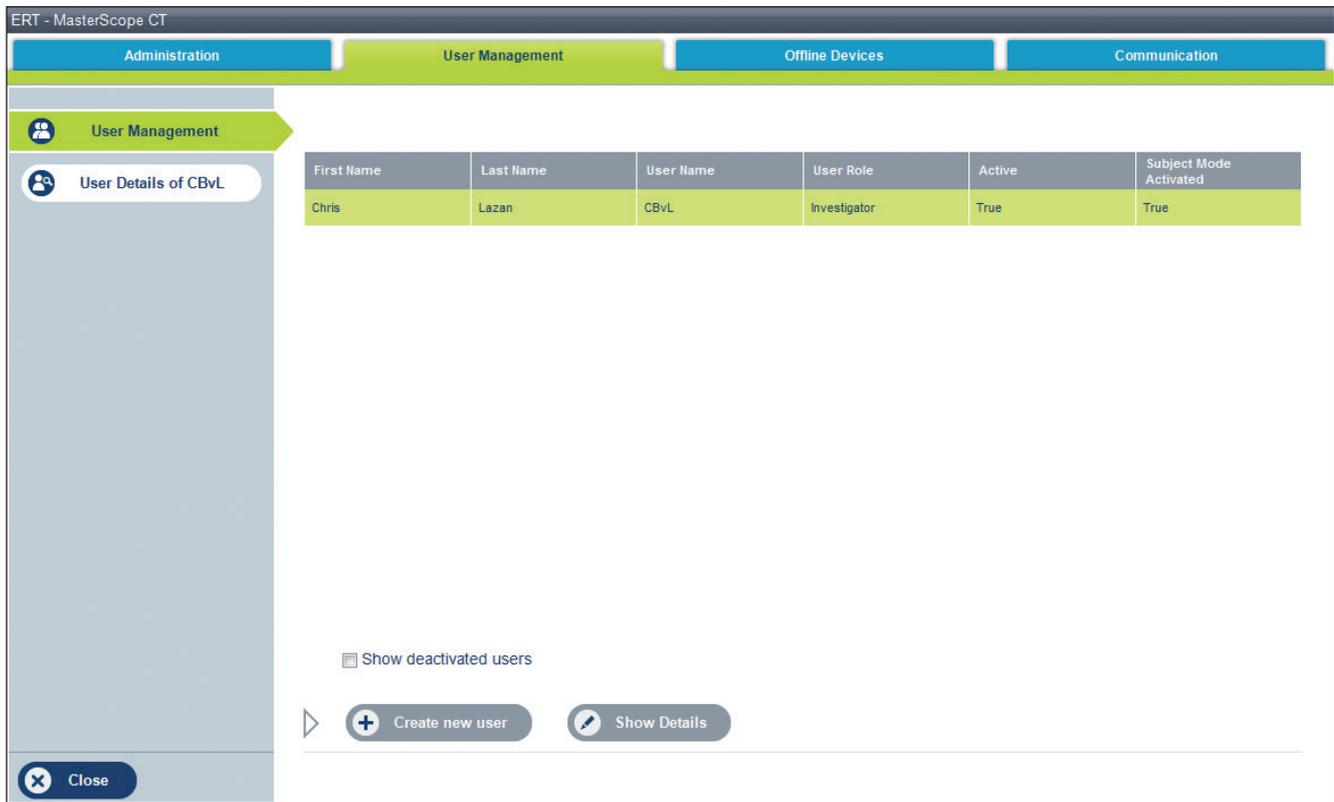
Follow the steps below to register a new site user on the system:

1. Select the **<Tools>** icon from the Utilities bar.
2. Select the **<User Management>** tab and the following screen will appear. Assigning new users or changing the rights of existing users potentially affects the system's electronic records scope of protection. Therefore it is necessary to confirm the statement shown on the screen.

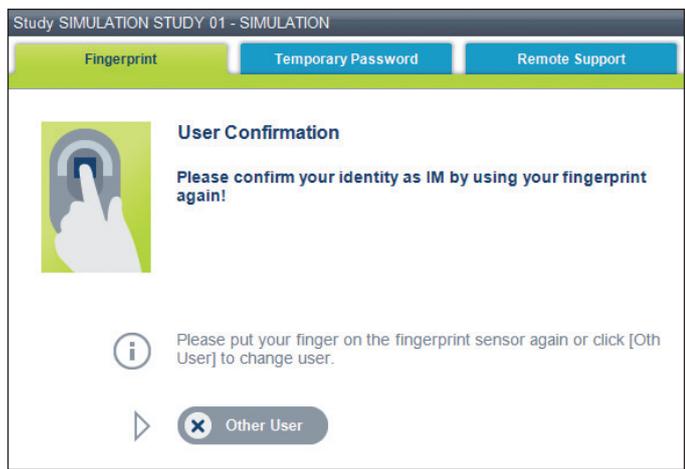


Check the box **<I agree with the above statement>** and confirm with **<OK>**. Otherwise it is not possible to create a new user.

2. The MasterScope User Registration main screen shows the previously enrolled users.



To create a new user, click the <Create new user> button. The following screen appears:



Prior to creating a new user, the enrolled user has to verify again.

3. Enter the new user name (maximum of 8 characters) and fill in the other fields. Fields marked with an asterisk ("\*") are mandatory.

ERT - MasterScope CT

Administration User Management Offline Devices Communication

User Management

User Details of CBvL

**Enter User Information** Step 1/2

**User Information**

**User Name:** \*  e.g. JSmith

**First Name:** \*  e.g. John

**Last Name:** \*  e.g. Smith

**Title:**  e.g. Dr.

**Email:**  e.g. JSmith@ert.com

**Phone:**  e.g. Country and Area Code + Number

**Fax:**  e.g. Country and Area Code + Number

**Training ID:**  e.g. ERT Training ID (if available)

**User Role:**

**Assigned Role:** \*

\* mandatory field

Next Back Cancel

Close

Check, if portal access is needed. For portal access it is necessary to enter the email address.



Monitor or Site Administrator rights are only to be granted to CRAs/Site Administrators involved in the study. This allows them to register new site users or perform specific functions.

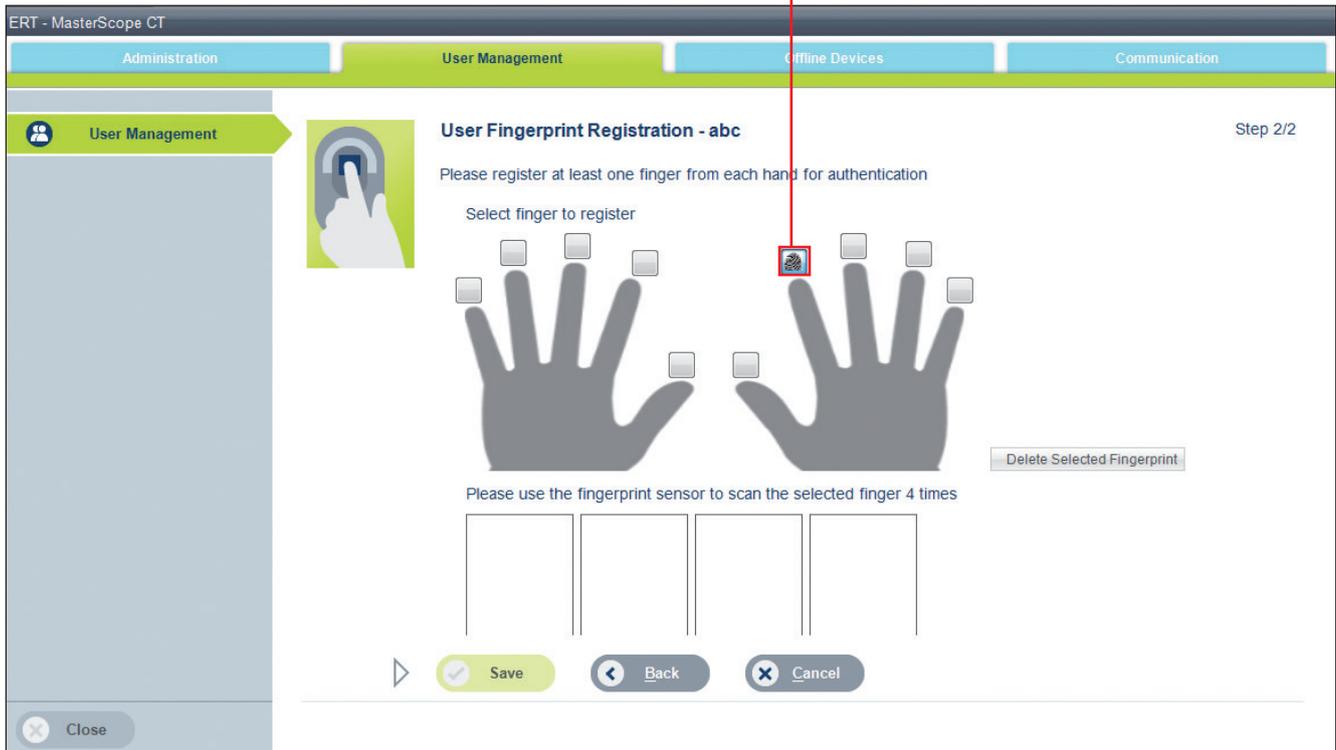


If another user registered on this system is already using the same initials, modify the new user name to ensure unique user identification. The MasterScope User Registration will not accept identical initials.



Continue with <Next>.

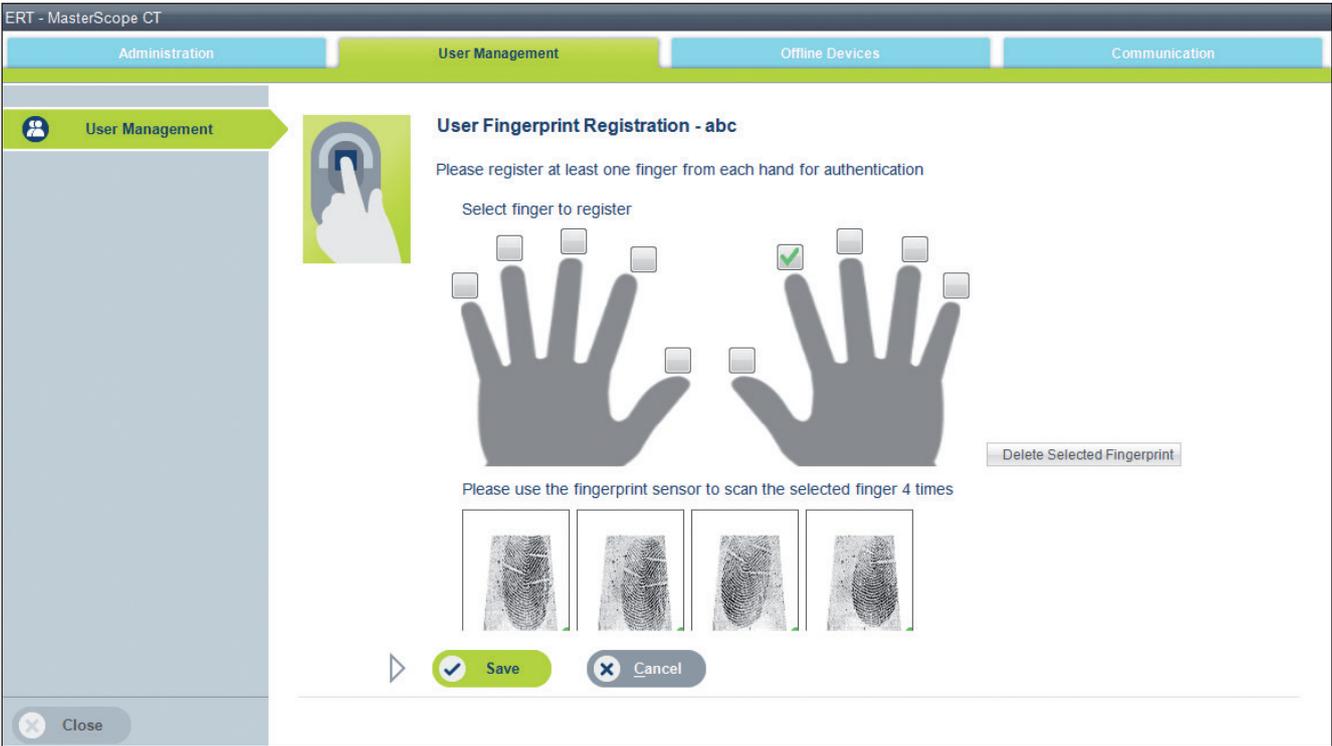
Select a finger by clicking on the respective box above.



Instruct the new user to press the selected finger onto the biometric fingerprint sensor flat to the surface with moderate pressure. This has to be repeated 3 times for capturing 3 more fingerprints of the same finger.



Please ensure that the user understands that his/her fingers must be dry prior to the fingerprint registration.



As soon as the fingerprint is successfully scanned four times, the **<Save>** button becomes available.

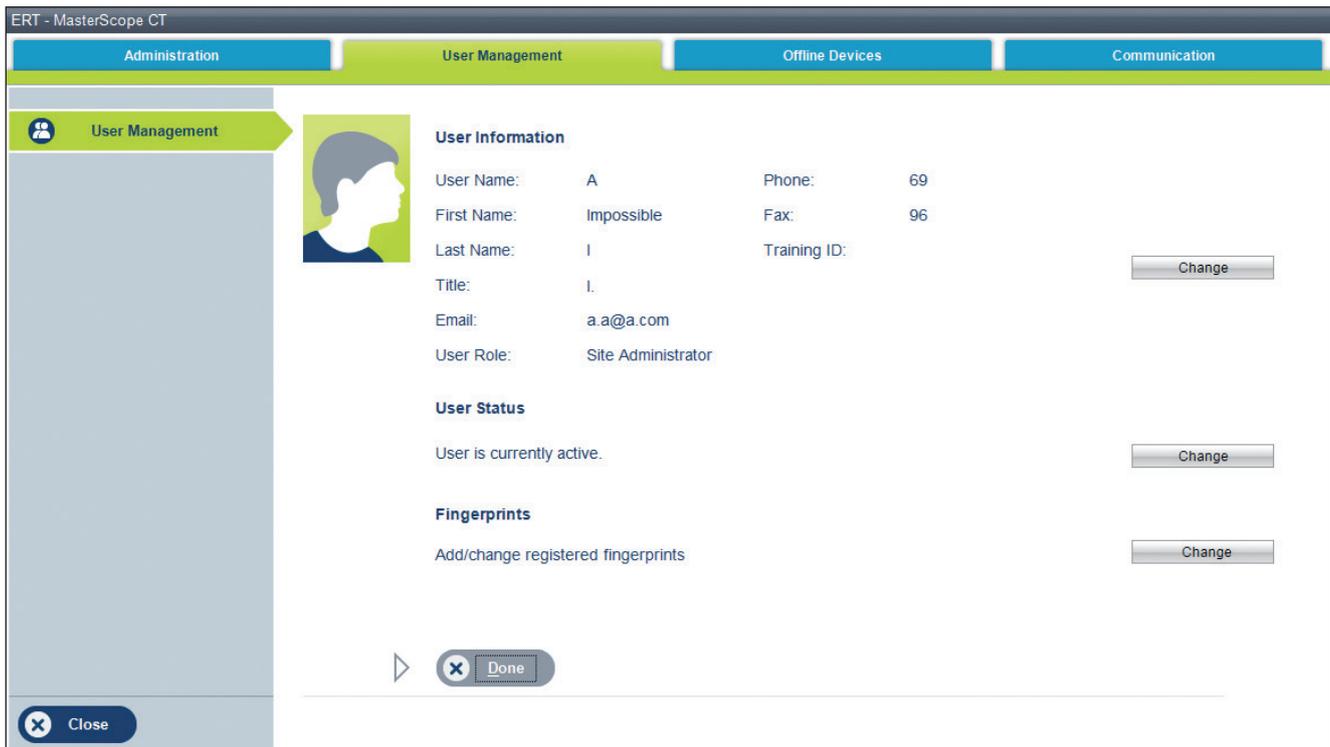
It is possible to register a second fingerprint. In order to do that, select another finger by clicking on the respective box above and continue as described on the previous page.



It is recommended to register two fingers, the same finger on both hands.

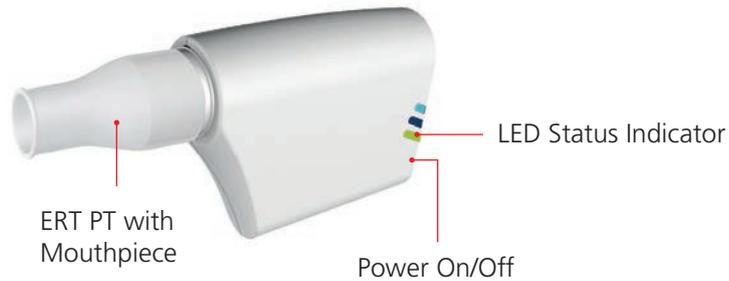


Click <**Save**>. Following screen appears:



Click <**Cancel**> to return to the MasterScope User Registration main screen.

### 3. The Wireless Spirometry Sensor Solution (WSSS)



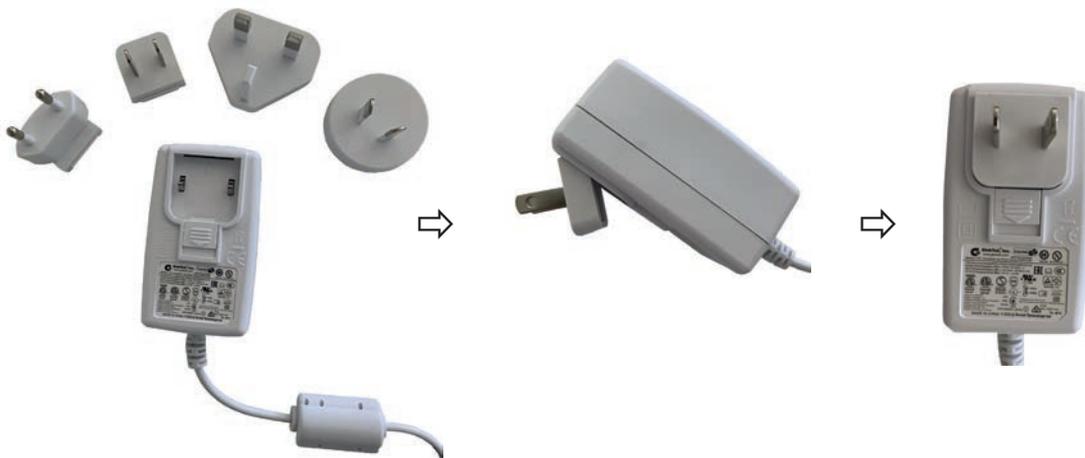
**The Wireless Spirometry Sensor Unit must not be exposed to direct sunlight nor positioned immediately near heating elements.**

#### 3.1 Wireless Spirometry Charging Station

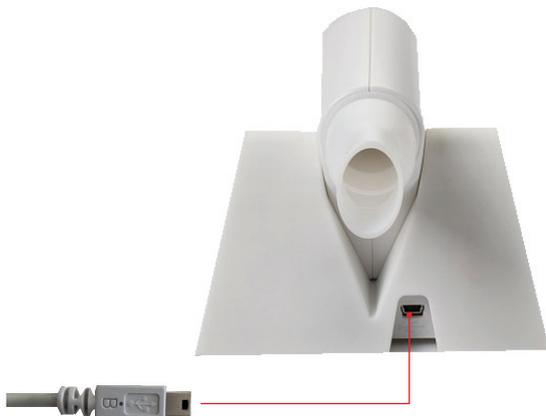
Ensure the Wireless Spirometry Sensor Unit is permanently charged if not in use. Insert the sensor into the charging station and plug in the power cord to the wall socket for charging.



The power plug includes various country specific adapters. Select the right one and click it into the plug. Now connect the charging station to a wall power socket.



Connect the other end of the power cable (mini USB connector) on the backside into the charging station.



### 3.2 Charging the Wireless Spirometry Sensor Unit

Put the wireless spirometry sensor unit into the slot of the charging station as shown below.



**LEDs indication wireless spirometry sensor unit:**

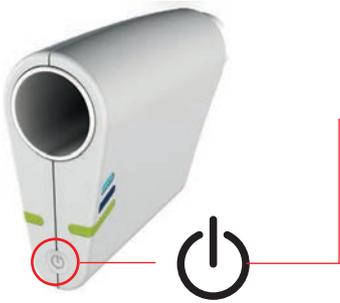
	<b>LED Indication</b>	<b>Description</b>	<b>Action</b>
	Orange LED on	Charging in cradle	
	Orange LED off	No charging/charging complete in cradle	
	Orange LED blinking slowly	Low battery	Put the wireless sensor unit into charging station.
	Orange LED blinking fast	Indicates an error of wireless spirometry sensor unit	Indicates an error in the Wireless Spirometry Sensor Unit. - Restart the wireless sensor unit by pressing the power button on the wireless sensor unit for > 8 seconds - If issue persists after restart, check in MasterScope "Device Management" if sensor is connected properly and reconnect if necessary.
	Blue LED on	Wireless Spirometry Sensor Unit is transferring data to MasterScope	
	Blue LED off	Wireless Spirometry Sensor Unit in sleep mode or turned off	Press the power on button on the Wireless Spirometry Sensor Unit to turn it on or in case the battery is discharged, put the sensor in the Charging Station
	Blue LED blinking slowly	Wireless Spirometry Sensor Unit turned on and connected to MasterScope	



The orange LED has priority before the blue LED!

**LEDs indication wireless spirometry sensor unit:**

	<b>LED Indication</b>	<b>Description</b>	<b>Action</b>
	Blue LED on	Charging station ready	
	Blue LED off	No power	Ensure that Power supply is plugged in and USB connector properly attached on the backside of the charging station.



### 3.3 Switch on the Wireless Spirometry Sensor Unit

Prior to usage, switch on the Wireless Spirometry Sensor Unit by pressing the "Power on" button for at least 3 seconds. Once switched on and connected to the MasterScope the blue LED is blinking slowly.

### 3.4 Prepare Wireless Spirometry Sensor Unit for a Measurement (Insert and Remove ERT PT)

Insert an ERT PT into the wireless spirometry sensor unit and attach a mouthpiece. Ensure that the rail with the sensor holes of the PT tube with the grooved edge of the wireless spirometry sensor unit (as below) when inserting the ERT PT.



**WARNING**

ERT PT is only for single use. Do not reuse the ERT PT due to risk of cross contamination.

Do not remove the mouthpiece from the ERT PT. Only use the ERT PT with connected mouthpiece.



Prior to the first use, make sure that the Wireless Spirometry Sensor Unit is fully charged.



**WARNING**

The maximum surface temperature of the Wireless Spirometry Sensor Unit can get up to 47°C during charging.



Spirometry should only be performed by patients who can cooperate in the performance.



**Remove the ERT PT** in the direction of the arrow.

## 3.5 Device Management Wireless Spirometry Sensor Unit

Navigate to the “**Tools Menu**” and click on <**Device Management**>. Details about the connected Wireless Spirometry Sensor Units can be found under the device entry “**Spirometry Sensor**” which are:

- ERT Sensor Unit #: ERT-SU-xxxxxxx (Default):  
In case multiple sensors are paired only one sensor will be defined as default.
- Default:  
Indicates if multiple wireless spirometry sensor units are paired which of the sensors is used as “Default” for patient measurements.
- Serial Number:  
Displays the Wireless Spirometry Sensor Unit serial number
- Firmware Version:  
Displays the FW version of the Wireless Spirometry Sensor Unit
- Flow Correction Table Version:  
Displays the version of the flow correction table
- Battery charge level:  
Status of Wireless Spirometry Sensor Unit (only available if sensor is currently turned on and connected)
- Last used:  
Date/time when Wireless Spirometry Sensor Unit was last used

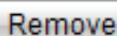
### Possible Functions:

#### Identify



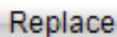
Click <**Identify**> to identify the sensor to be used in case multiple ones are available in your clinic. The Wireless Spirometry Sensor Unit to be identified will show a flashing green LED. Please note it will only work if sensor is turned on and connected.

#### Remove



Click <**Remove**> to unpair the sensor from the MasterScope. Follow the instructions on the screen.

#### Replace



Click <**Replace**> to exchange the sensor with a new one. Follow the instructions on the screen.

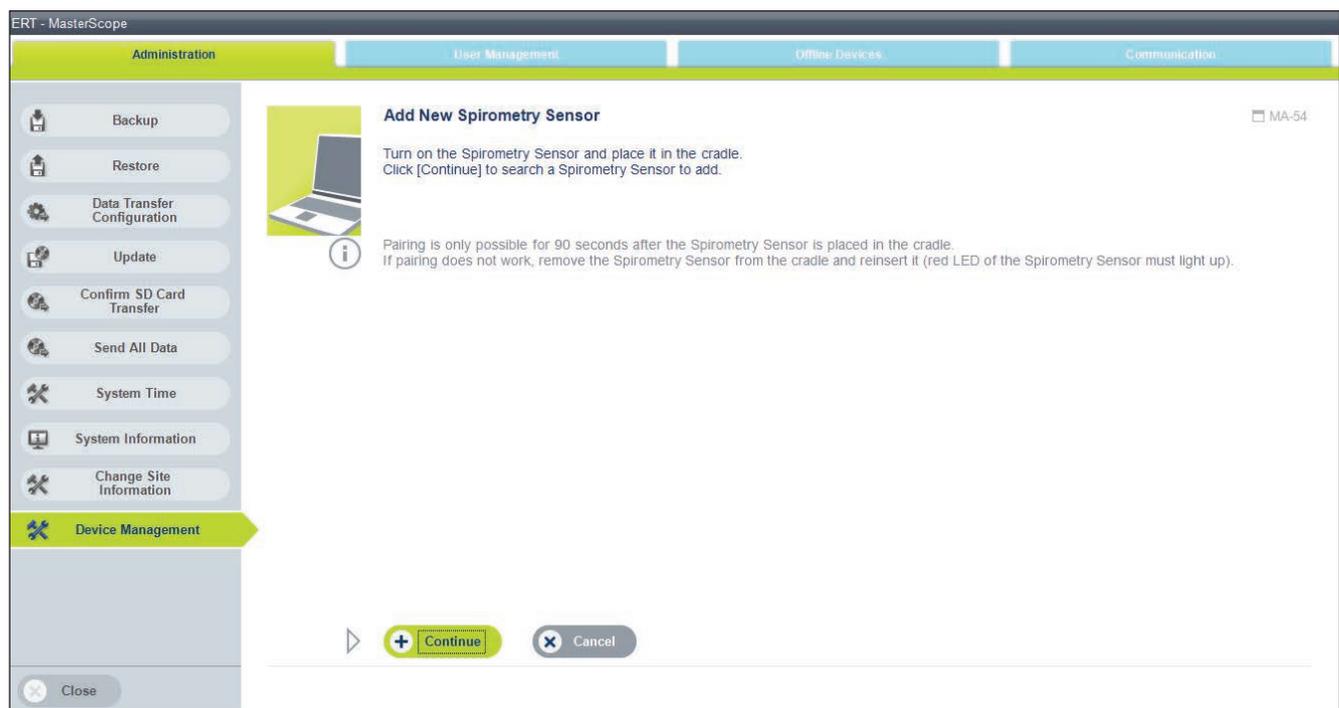
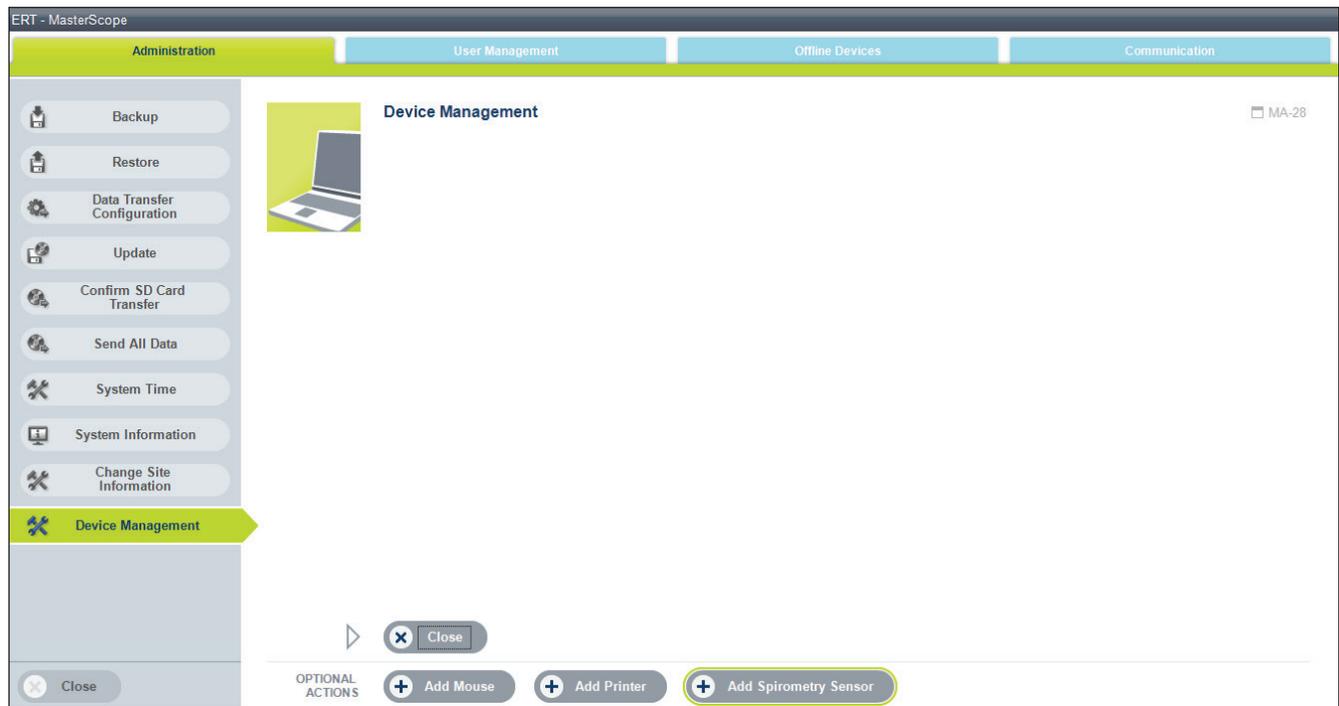
#### Add Spirometry Sensor



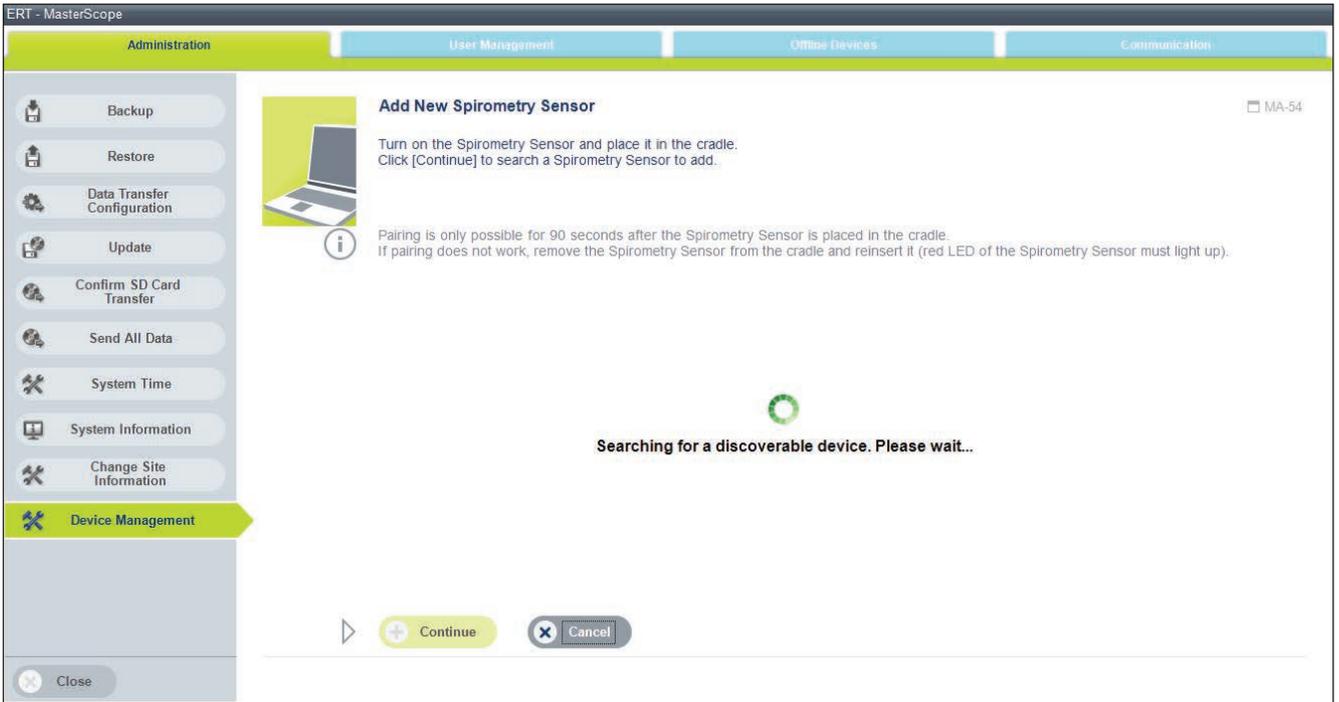
Click <**Add Spirometry Sensor**> to add additional sensors to the MasterScope.



The initial MasterScope delivery is coming with a paired Wireless Spirometry Sensor Unit. Use this function only to add additional sensors.



Ensure the charging station is power plugged in. Ensure to turn on the Wireless Spirometry Sensor Unit and place it into the charging station. Click <Continue> to start the pairing process.



Pairing is only possible for 90 seconds after the Wireless Spirometry Sensor Unit is placed into the charging station (Sensor visible via bluetooth). If the sensor cannot be discovered, remove the sensor from the charging station and reinsert it. Then repeat the steps.

