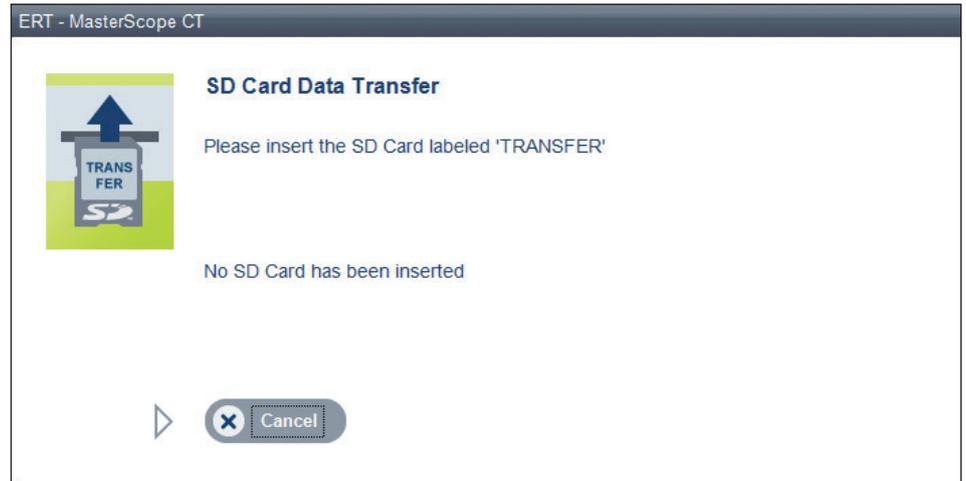How Web Upload Data Transfer Works

1. In the Utilities bar, click on the <**Send Data**> icon to initiate the data transfer process.

2. Select SD card as the method to transfer the clinical data and press the <**Start**> button.

Please do not change this setting until you are instructed from the ERT Customer Care Helpdesk.

3. Ensure that the "**Transfer**" SD card is not in the write protected status (not applicable if USB Transfer Kit was delivered).

Writing/Erasing possible   Writing/Erasing impossible
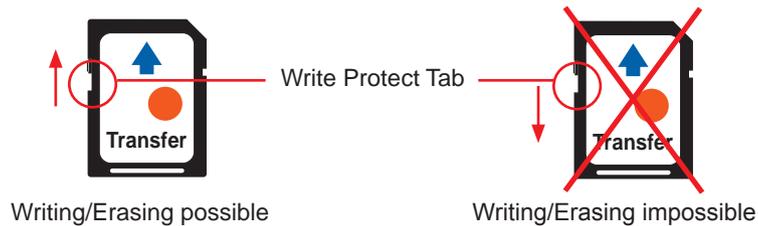
Please use only SD cards or USB sticks provided by ERT which are labeled "**Transfer**" for a specific system for transferring MasterScope data.

Do not use SD card or USB stick from another ERT device or any other SD card or USB stick.

4. Insert the SD card or USB stick to start transferring the data to the media.
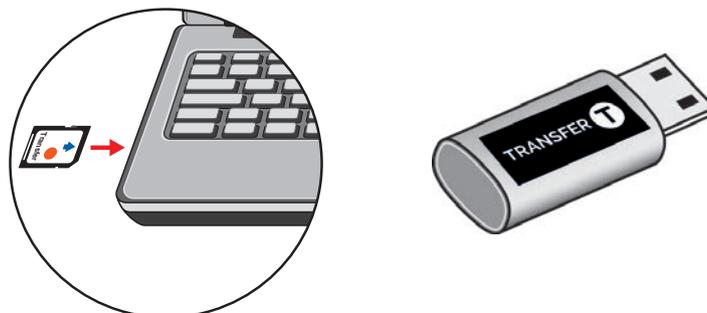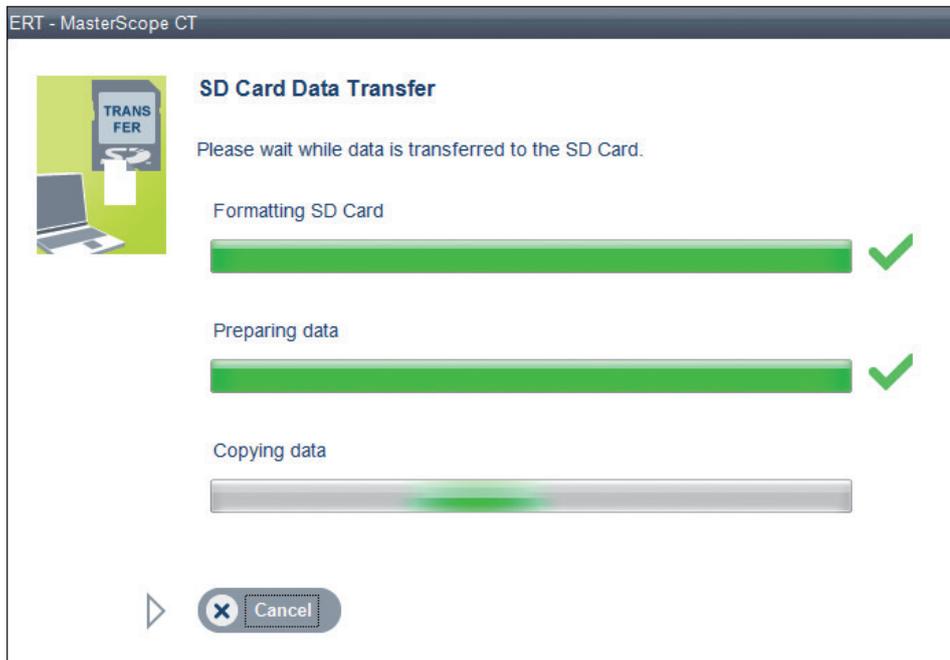
5. Confirm the formatting of the SD card or USB stick by pressing the <**Continue**> button.
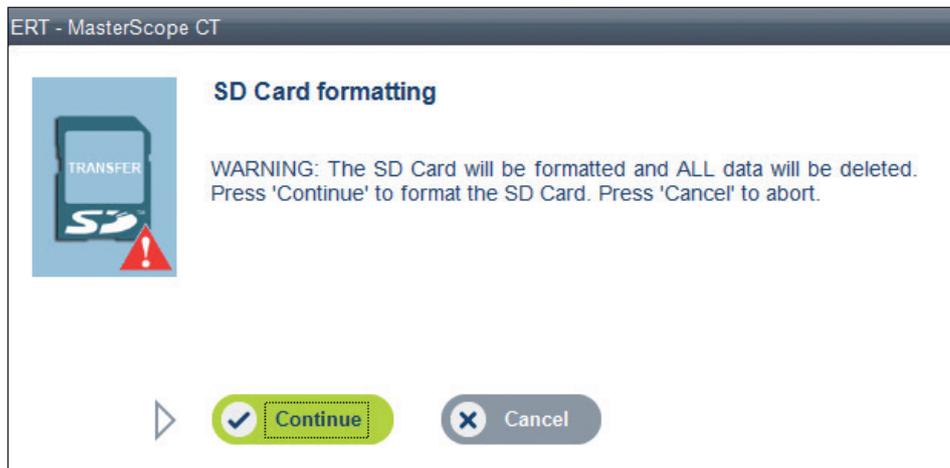

 Please do not store any data except the MasterScope data files on the medium.

6. The progress of the data transfer process will be indicated in the screen below:

 Please do not remove the SD card or USB stick until instructed to ensure a correct and complete data transfer!

7. Remove SD card or USB stick after the data is successfully copied to the external medium (indicated by the screen below).
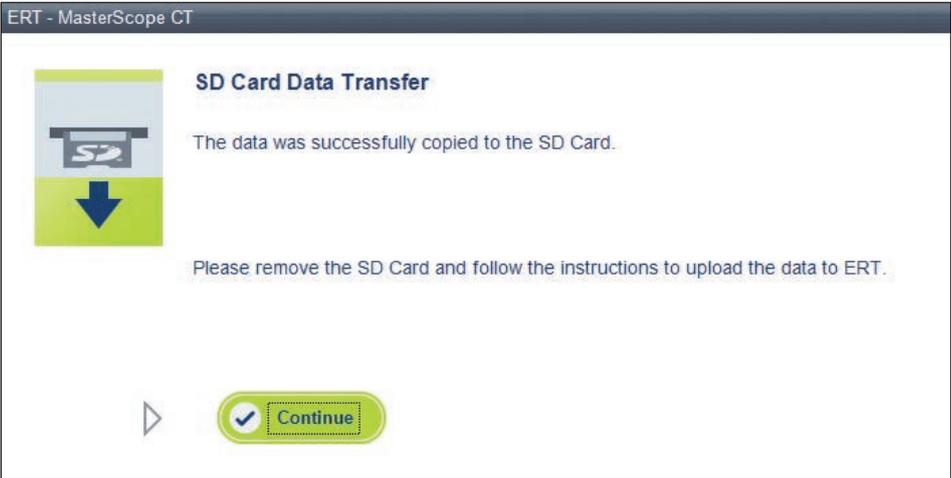
8. Click <**Continue**> to proceed with the upload of the data on the web-based PC.

How the Data Upload Works Using MyDataUploader™

1. Please insert the SD card or connect the USB stick which includes the transfer file from the MasterScope to the web-enabled PC.
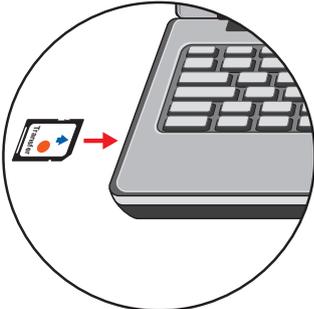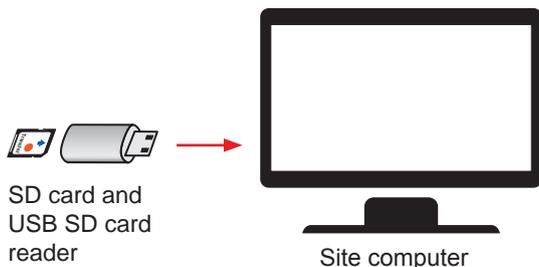

Web-enabled PC

USB stick

In the case that the computer has no SD card slot, please use the provided USB SD card reader as shown below:

SD card and
USB SD card
reader

Site computer

2. Open your internet browser and go to the MyDataUploader™ webpage by entering the following address:

https://mdu.ert.com

3. Clicking the <**Upload**> button will start the data transfer.

You will be guided step by step through the data upload process on the right side of the webpage with highlighted short instruction depending on the current step of the process.

Choose File

4. Please select the data transfer file for upload by selecting the <**Choose File**> button. In the following file, open the dialog of your browser, search and select the SD card or USB stick drive labeled "**Transfer**". Then search and select the single data transfer file. The file name starts with "**MScCT32_** "(see example below).
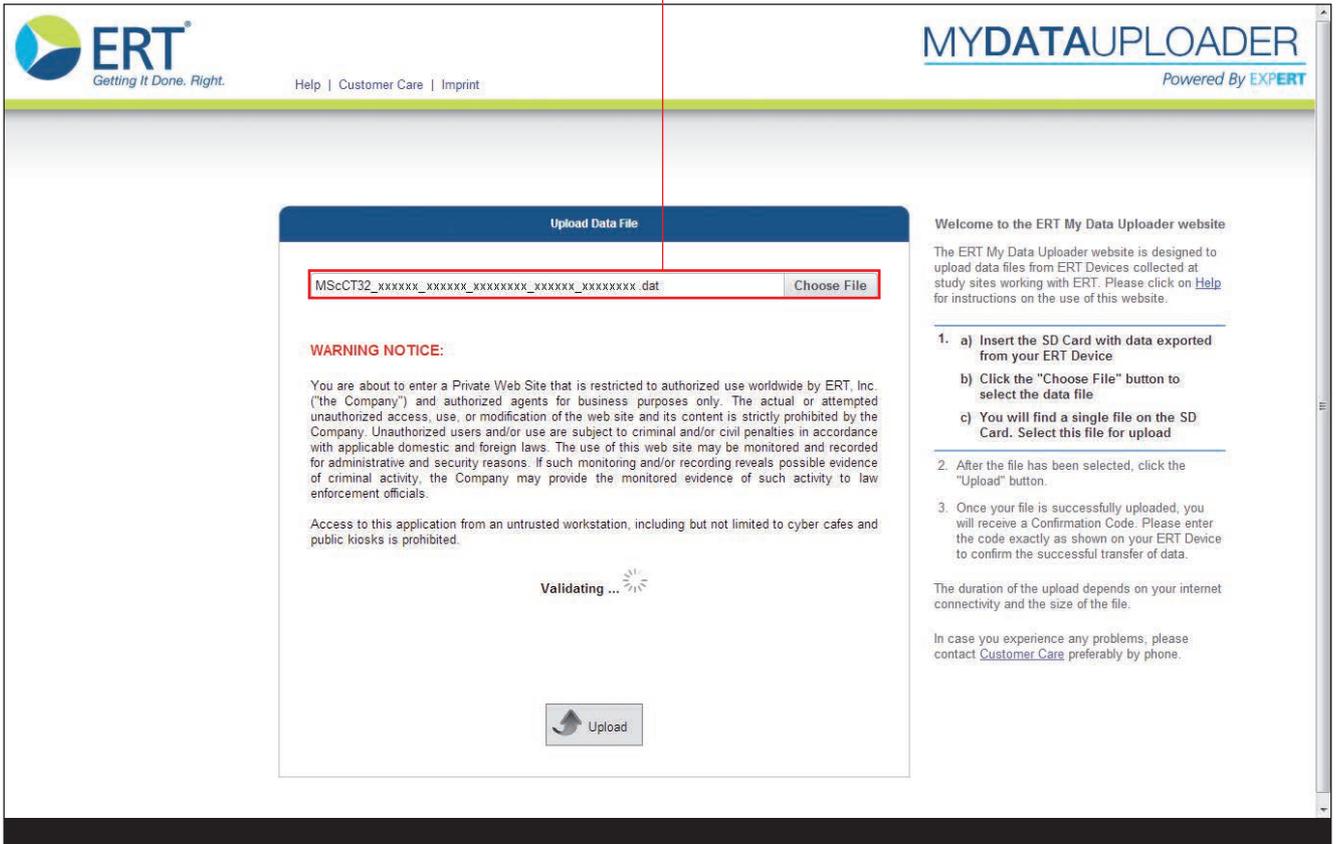
5. If the selected file is valid, the next screen will display your study information. See example below.

6. If you would like to receive the Confirmation Code additionally via email, please enter your email address in the corresponding entry field below the study information.

> If you would like to receive this information via email, please enter your email address and click "Send Email" button.
>
> **Email:** user@ert.com   Send Email

7. Clicking the <**Upload**> button will start the data transfer.

> The duration of the upload depends on your internet connection and the size of the data transfer file. In case you experience any problems, please contact the ERT Customer Care Helpdesk.

> **Please do not remove the SD card or USB stick to ensure a correct and complete data transfer!**

8. After you successfully uploaded the data file, a confirmation code will be displayed.

> The confirmation code is a 8-digit alphanumeric code which is displayed when the data was successfully uploaded to the ERT data center.
> Example: ABCD1234 (as shown above)

9. Please record the code exactly as displayed, print it or it will be sent to you via email.

- To print the confirmation code, please click the <**Print**> button. This will open your standard printer dialog and you can proceed as usual.

- If you have not already provided your email address you can enter it here to receive the confirmation code via email. Enter your valid email address into the field Email to get the confirmation code via email.
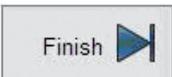
10. After you have received the confirmation code, finish the data upload by clicking the <**Finish**> button.

How to Confirm the Data Transfer on MasterScope

1. Please enter the confirmation code on the MasterScope (see screen on previous page).

   A detailed description on how to get the Confirmation Code can be found under "**How the data Upload works using MyDataUploader™**".

> ⚠️ To avoid large data transfer files with the next data transfer, it is recommended to confirm the data transfer with the confirmation code immediately after the upload. In case a data transfer is not confirmed, the next data transfer will contain all data which have not yet been confirmed as well as all new data.
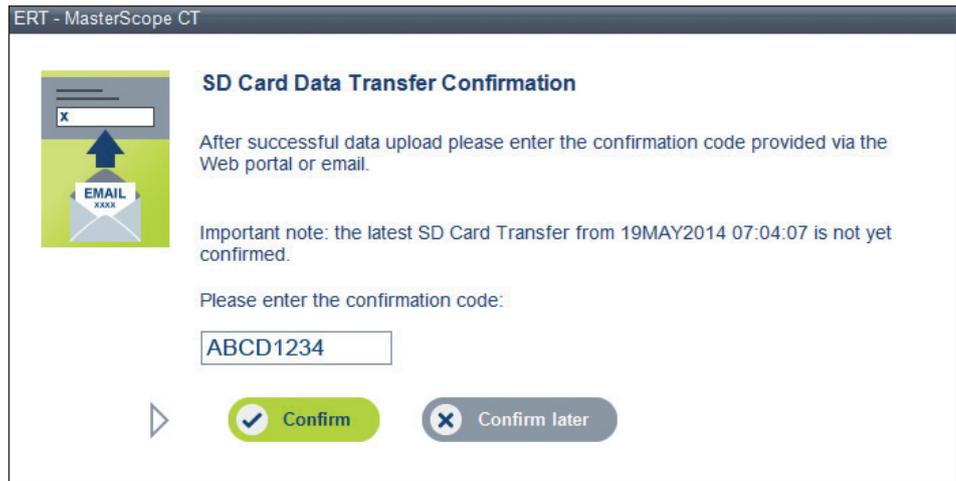
2. The following message will indicate the end of the successful data transfer via web upload.
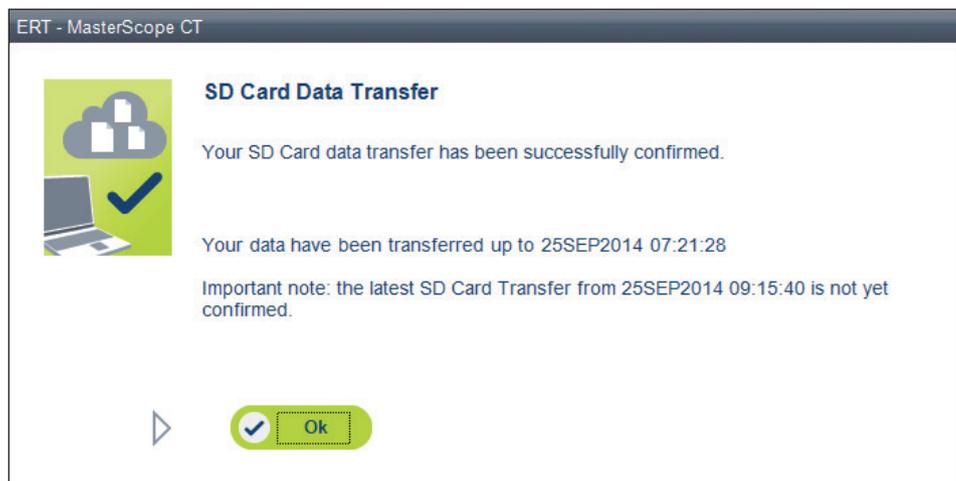
> ⚠️ If the data transfer is not confirmed, you will be notified about the date and time of the not yet confirmed data transfer. Please enter the latest displayed or received confirmation code in the "**Tools**" section.
>
> Confirm web upload transfer at the next system start up or before the next data transfer.
>
> To enter the confirmation code, start with step 10 of the chapter "**How the data Upload works using MyDataUploader™**".

Tools

In case you want to confirm the web upload transfer via the tools section, please
- Select <**Tools**> from the Utilities bar.
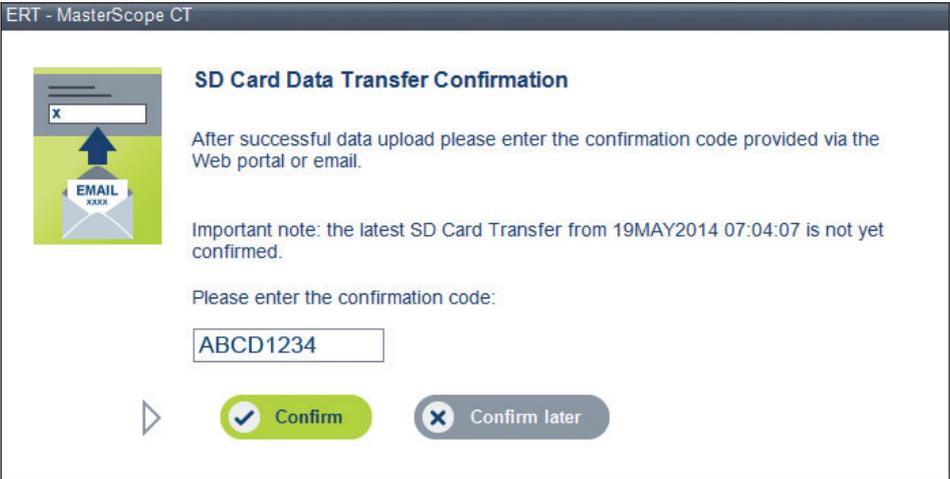
Confirm SD Card Transfer

- Choose <**Confirm SD Card Transfer**>.

- Enter and confirm the confirmation code in the following screen.

ERT - MasterScope CT

SD Card Data Transfer Confirmation

After successful data upload please enter the confirmation code provided via the Web portal or email.

Important note: the latest SD Card Transfer from 19MAY2014 07:04:07 is not yet confirmed.

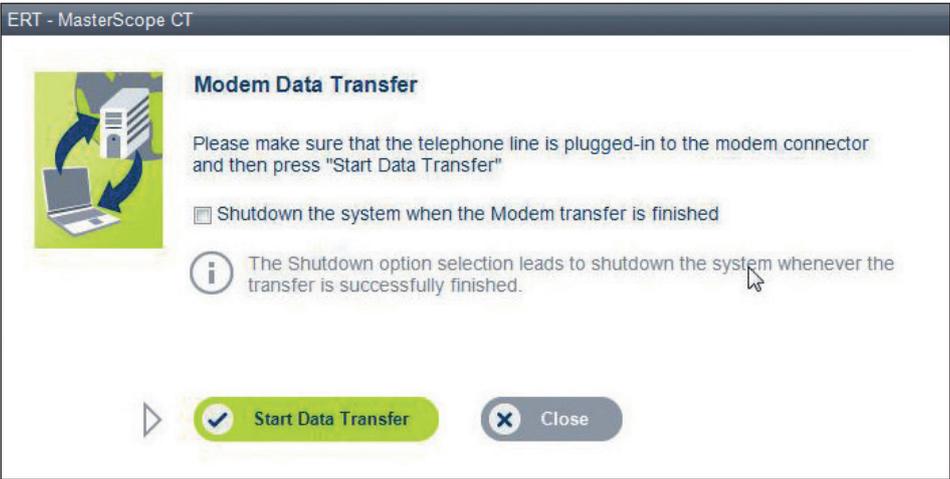Please enter the confirmation code:

ABCD1234

✓ Confirm   ✗ Confirm later

13.1.4   Analog Modem Data Transfer

Data is transferred via an analog line. If your phone line does not work, please try the fax line.

Send Data

In the Utilities bar, click on the <**Send Data**> icon. Select "Modem Data Transfer".

ERT - MasterScope CT

Modem Data Transfer

Please make sure that the telephone line is plugged-in to the modem connector and then press "Start Data Transfer"

☐ Shutdown the system when the Modem transfer is finished

ⓘ The Shutdown option selection leads to shutdown the system whenever the transfer is successfully finished.

✓ Start Data Transfer   ✗ Close
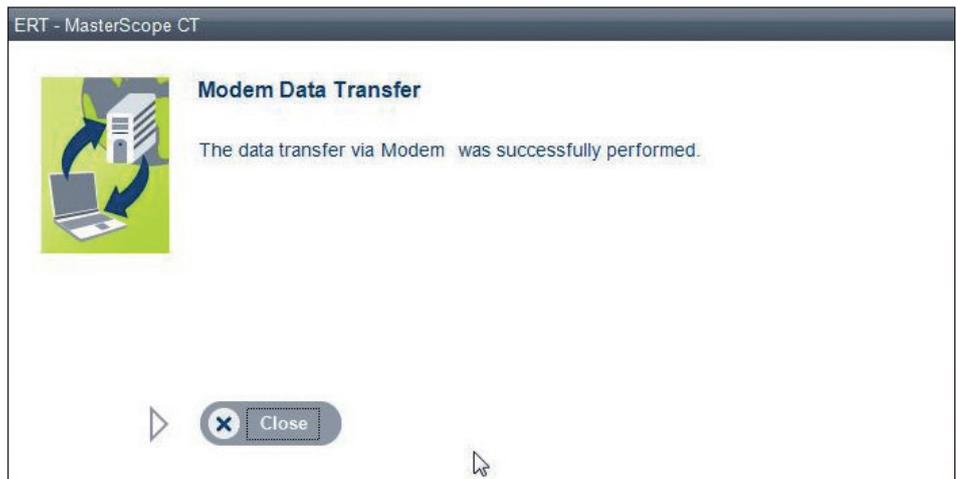
Start Data Transfer

Press the <**Start Data Transfer**> button.

The progress of the download process will be displayed by a bar indicator.
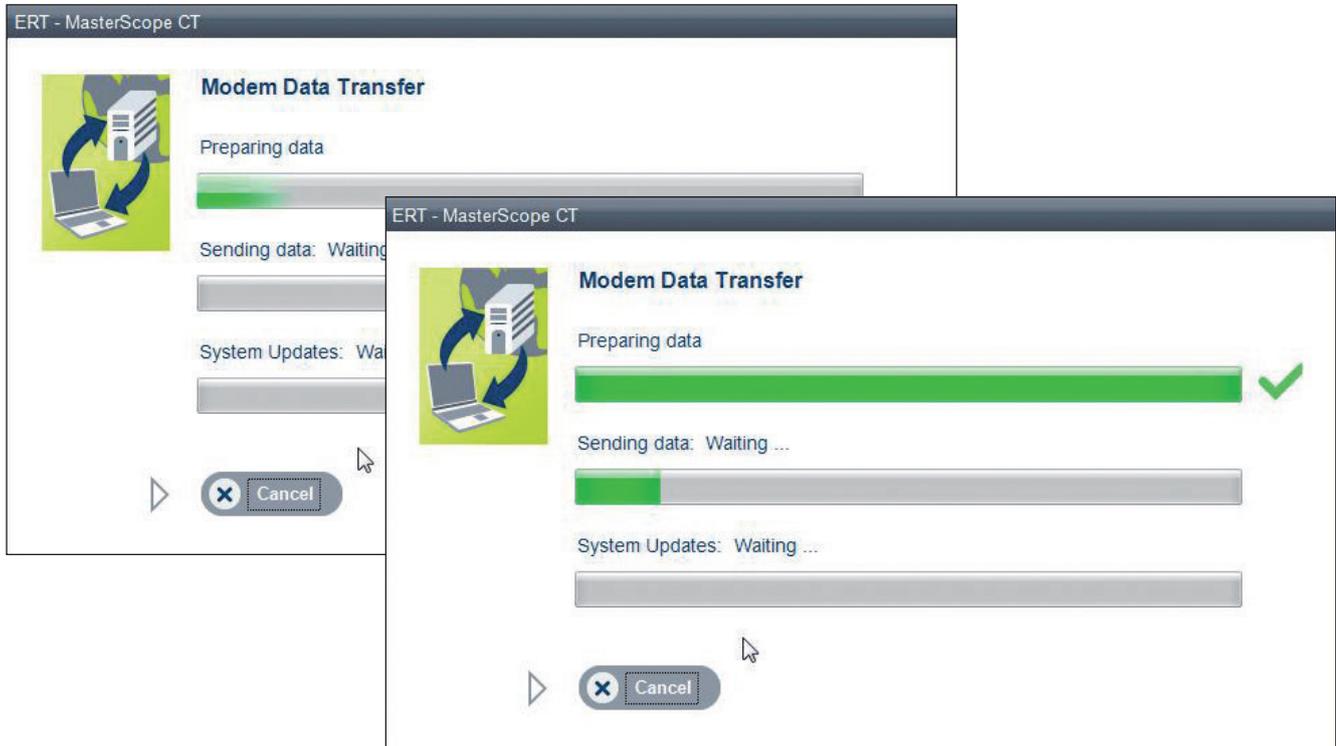
When the modem data transfer is complete, the following screen will appear:


Click <**Close**> to exit.

In case the analog modem transfer is not successful please verify your modem settings or try another transfer methodology.

If you are still unable to transmit the data, contact the CRA or ERT Customer Care.
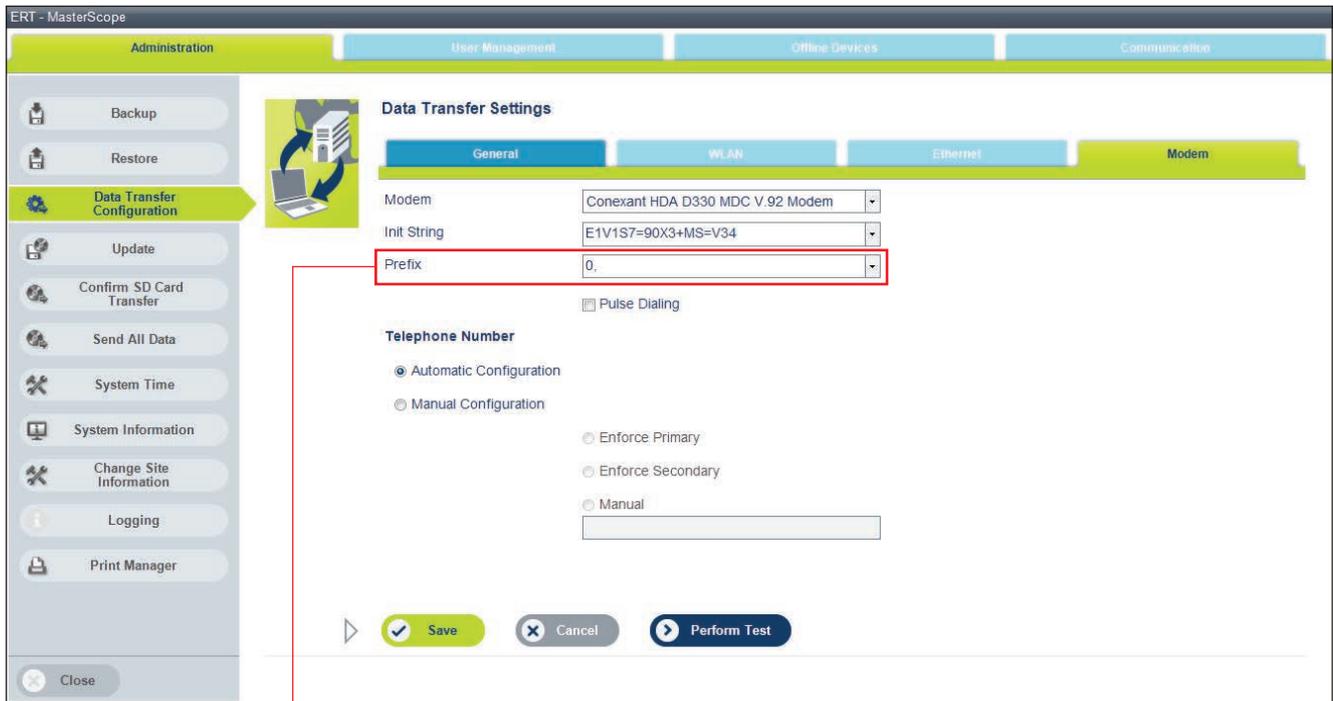
13.1.4.1 Data Transmission Settings

To enable the data communication with the data center via modem, the modem settings in the MasterScope must be set correctly.

> ⚠ **Please note that with Fujitsu E756 analog data transmission is not supported anymore. Please use WiFi/LAN or SD Card upload instead.**
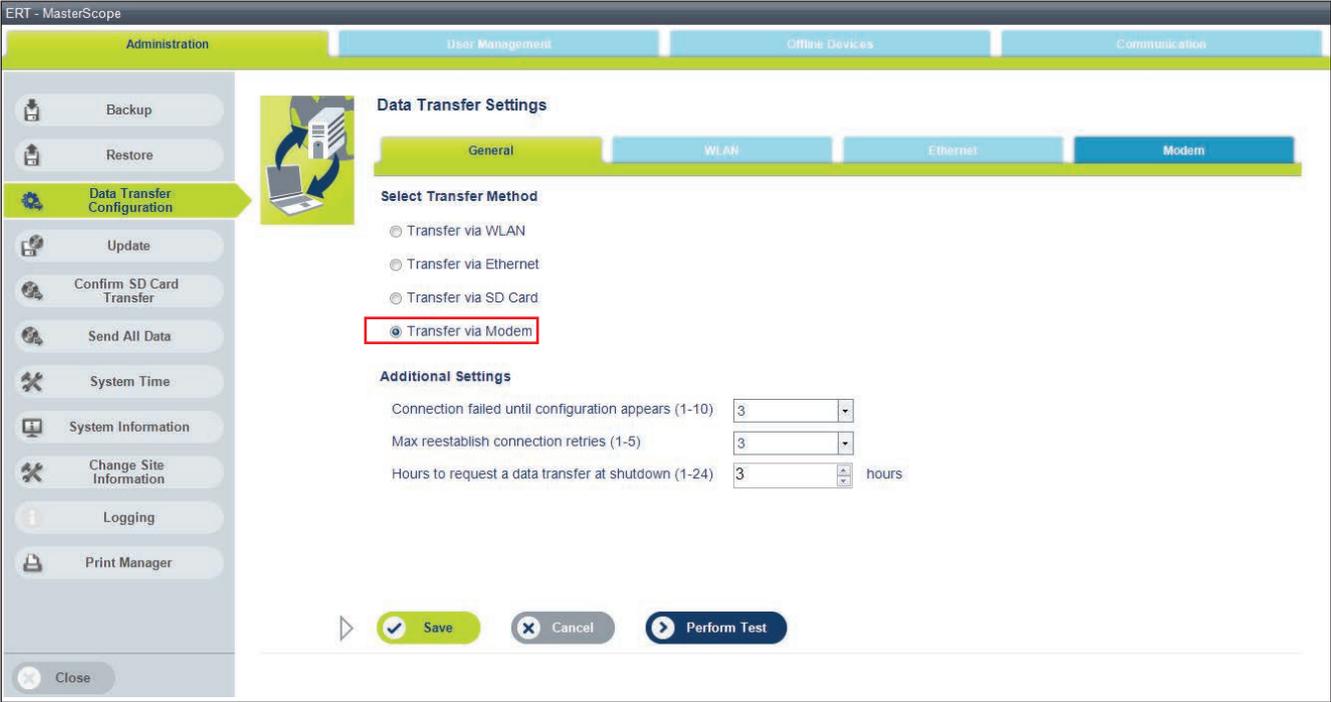
✓ **Save**   Confirm with <**Save**> and the following screen appears:

Enter in "Prefix" the number which needs to dialed for an outside line of your building followed by a "comma" for a pause.

If no prefix is necessary within your building to get an outside line then the field must be empty.

> **Do not change any other settings unless instructed by ERT Customer Care!**

For most of the countries, toll-free telephone numbers to the data center are established, i.e. the phone call to the data center is free of charge for the investigator.

If a country toll-free number is not available, the **Direct Access German Data Center Number** can be used or the data transfer has to be accomplished by downloading data to a removable disk. Before changing these settings during the study, ERT must be consulted.

If you are having difficulties getting a working connection, try to find a fax machine connected to the telephone network. Use this line for a test, adding the same prefix numbers that are required to send a fax.

> If the toll-free telephone number is not working, try the direct access number.
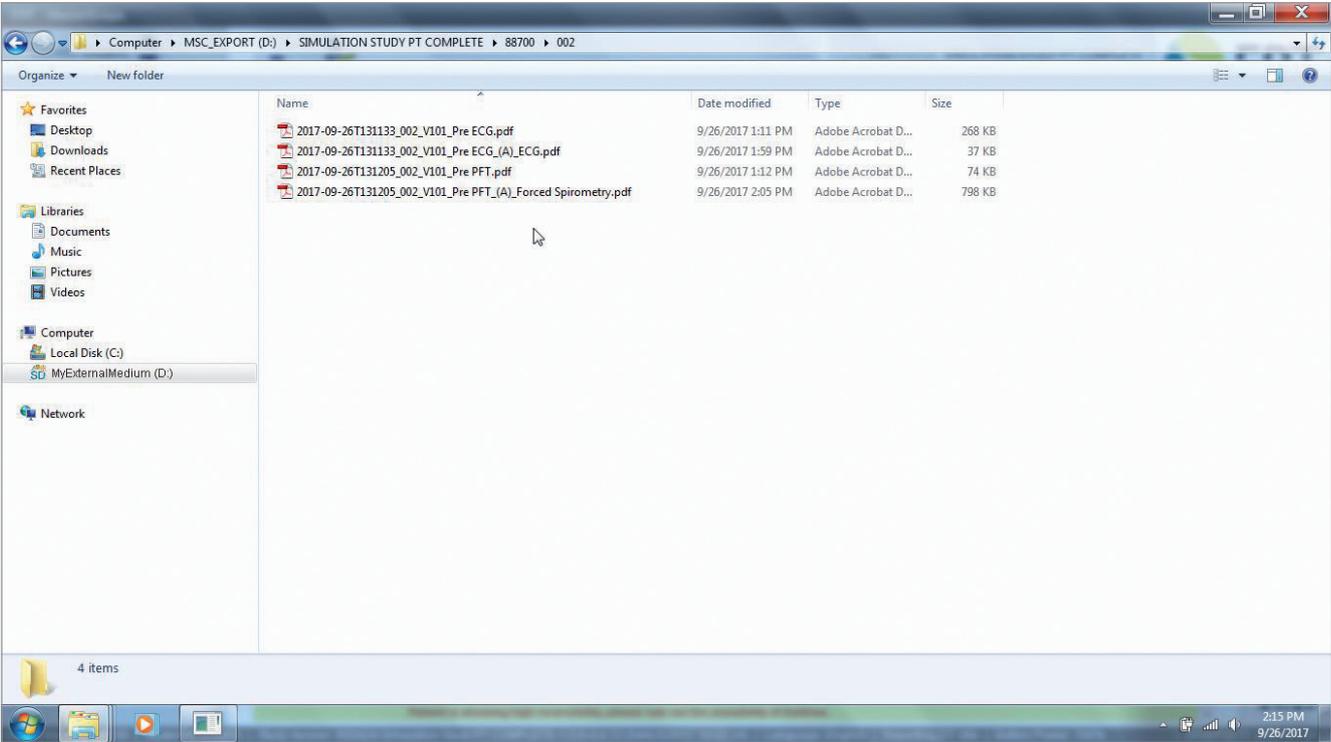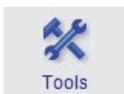
14. Backup

! At the end of each visit day, the data generated by the MasterScope **must** be backed up onto a removable storage medium (SD Memory Card or USB stick). When shutting down, the system reminds you to perform a backup.

The backup also includes all measurement reports created on the MasterScope and overread result reports (only supported if you use WiFi/LAN for data transmission). This will allow that the PDFs can be viewed and printed on any other computer as well.

! Please note that all reports must be printed, signed and filed with the source documentation! MasterScope offers two options to print which is either directly from the MasterScope or via export / backup function where it can be printed on any other computer!

 Tools

For performing a backup, select <**Tools**> from the Utilities bar. Click on <**Backup**> in the "**Administration**" tab.
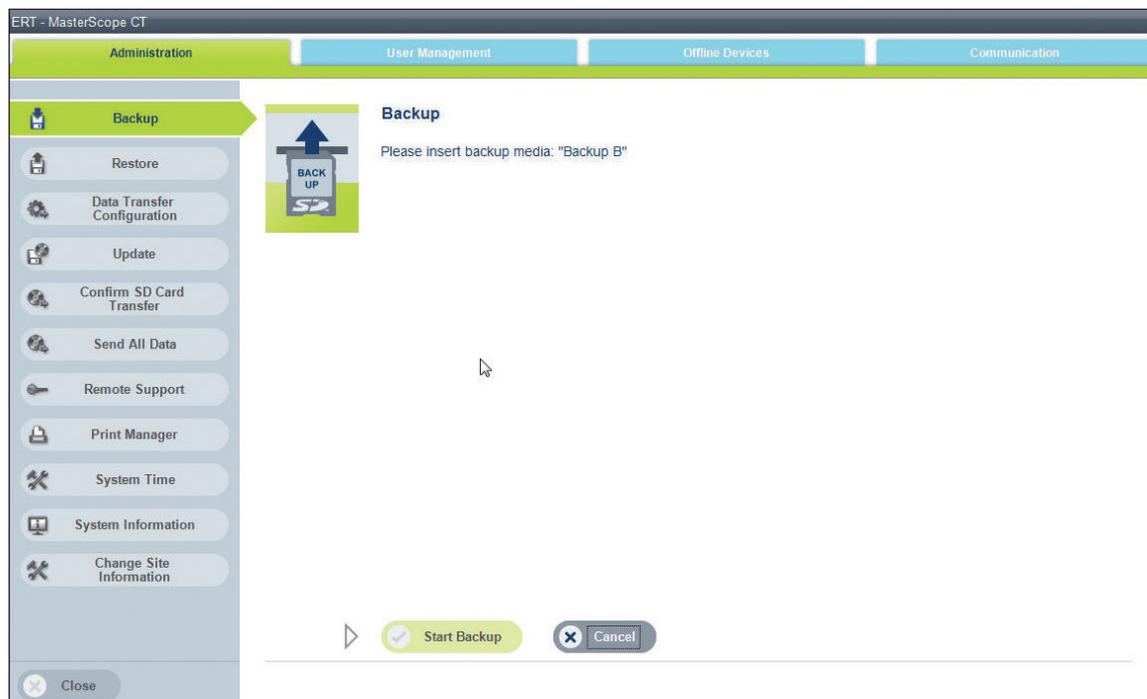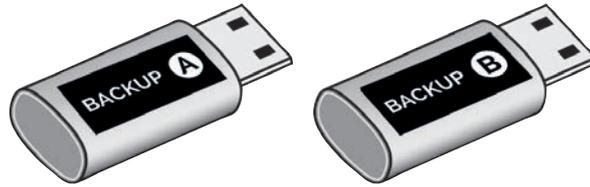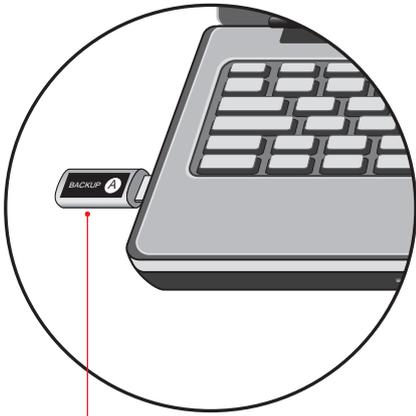

Depending on your study setup the system is delivered either with SD cards or USB sticks for performing the backup.

The system asks you to insert Backup media "A" or "B".

Insert the SD medium into the corresponding slot of the MasterScope.
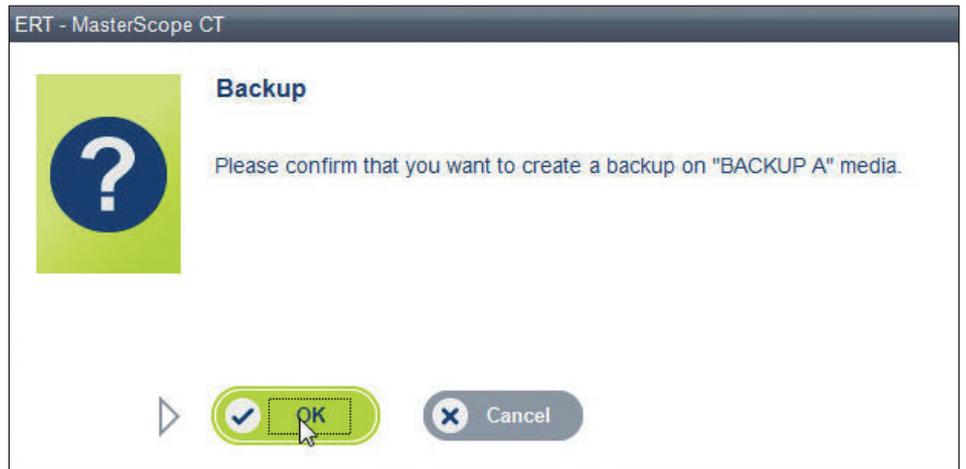
The system asks you to insert the USB stick.

Insert the USB stick into the corresponding slot of the MasterScope.
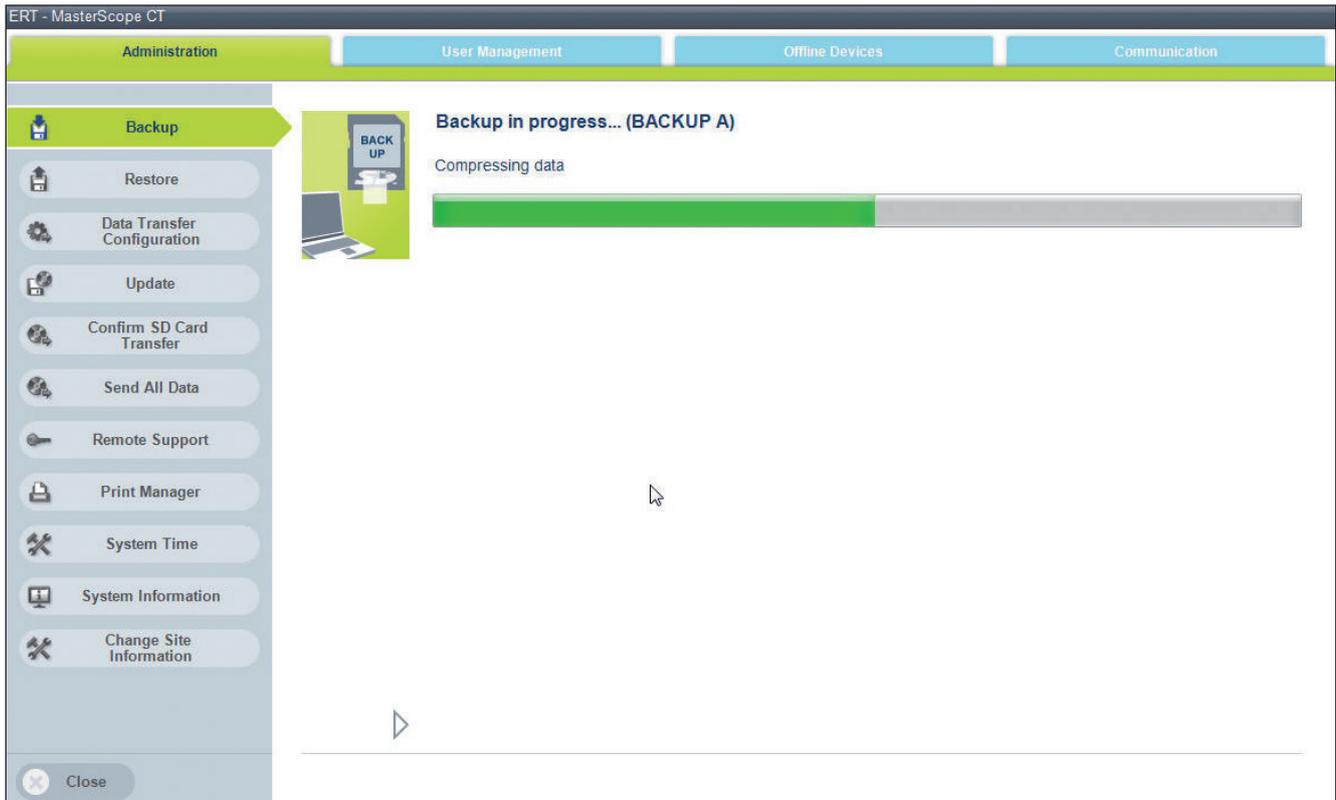
Start Backup

Click <**Start Backup**> to start the backup procedure. The following message screen appears:

OK
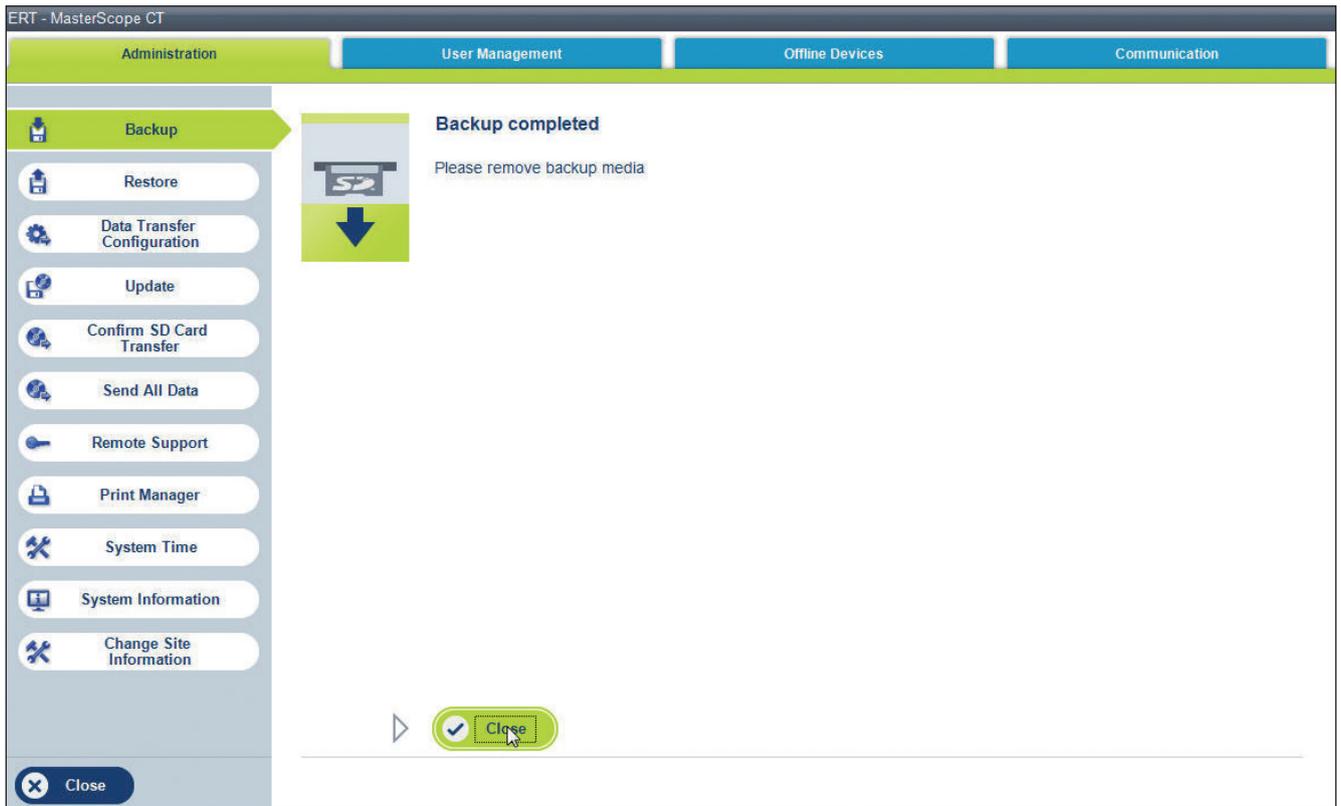
Confirm with <**OK**>.

The progress of the backup procedure is shown in the following screen:

If the backup is complete, you are asked to remove the backup medium:

Click <**Close**> to finish the backup process.

> ⚠️ Do not perform a backup if you have a severe system error or database error. Contact the CRA or ERT Customer Care person first.

> ⚠️ Please ensure that the backup media are stored separately from the notebook.

In case of an unexpected data loss, the backup serves as source to restore your MasterScope.

15. MasterScope Software Updates
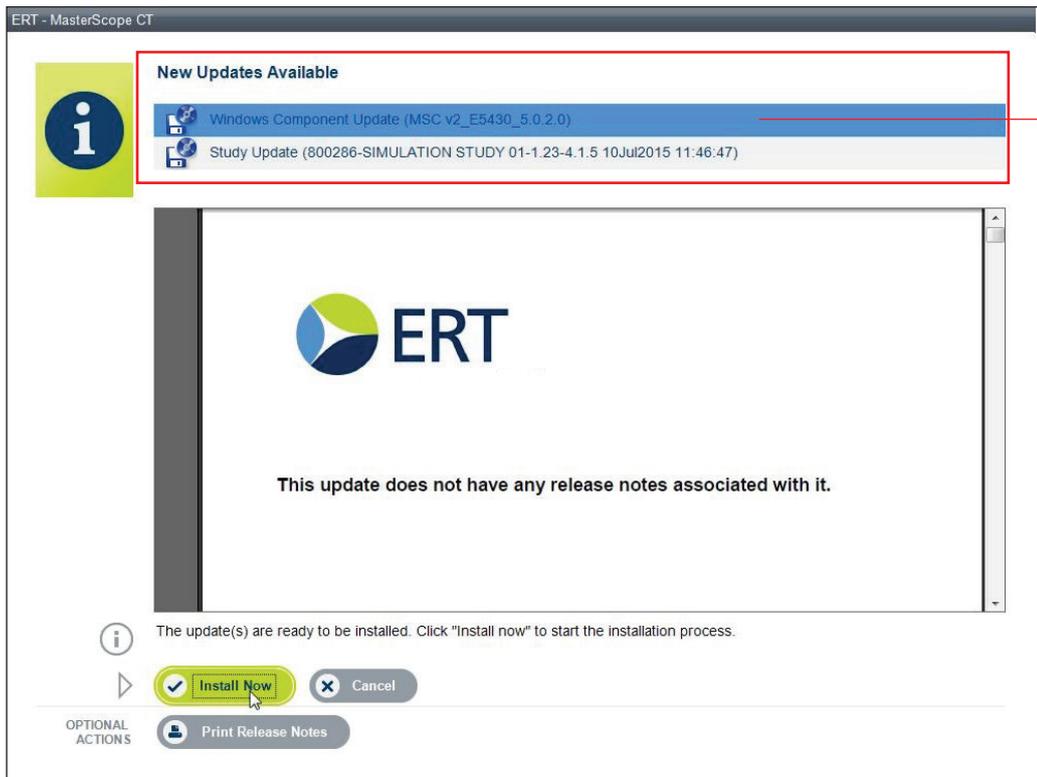
15.1 Online Update

Everytime when the MasterScope transmits the data to the data center, it will automatically check if there are any new software updates available. If so, the update(s) will be downloaded automatically after the data transfer. Once downloaded the new update(s) can be installed.

There are two different updates possible to receive:

- software update for protocol configuration, e.g. protocol amendment
- windows component update, e.g. daylight saving changes in a specific country

> Online Update will not be supported with the SD Card Upload transfer methodology. If you are using this methodology either switch to another methodology e.g. WLAN or contact ERT Customer Care to receive the new software update on a SD Media card via mail.

Available updates are listed here separated by protocol update or windows update. By selecting an update, a respective "Release Note" will be displayed with detailed information about the update.

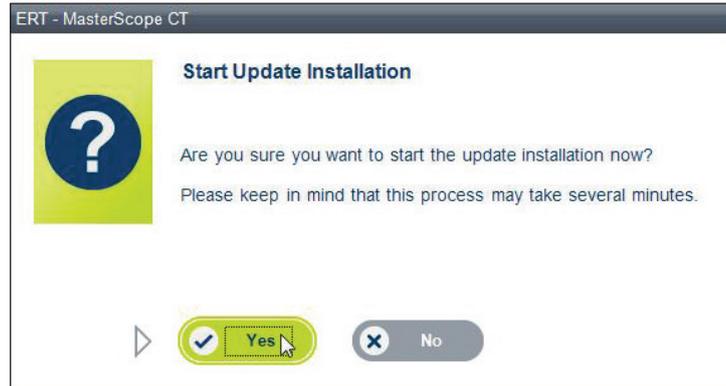Click <**Install Now**> to start the installation.

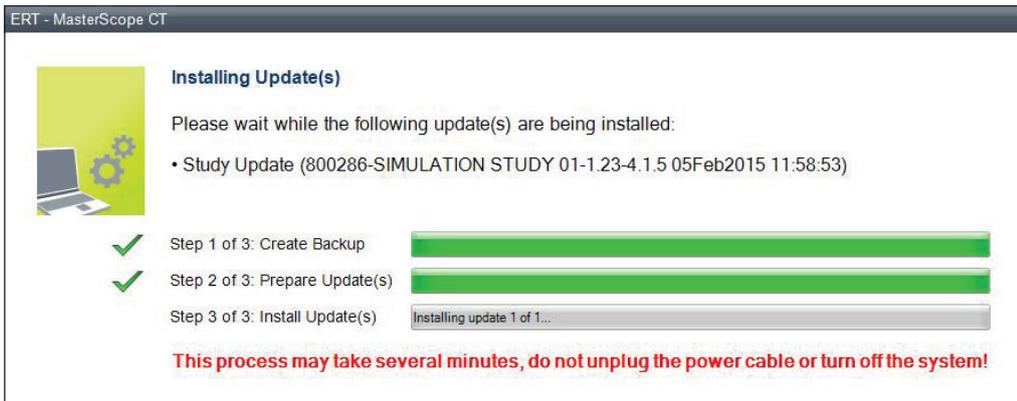Click <**Cancel**> to install the update later.

> Updates should be installed immediately after downloading. If you have ongoing subject visits, make sure to install the update(s) after the patient visits are completed for that particular day.

The following screen appears:

 Click <**Yes**> to to start the Update Installation.

After successful installation, the following will be displayed:

 Click <**OK**> to confirm.

Now, it is necessary to restart the system.

Click <**Restart Now**> to finish the procedure.

For starting the process manually, select <**Tools**> from the Utilities bar. Click on <**Update**> in the "**Administration**" tab.
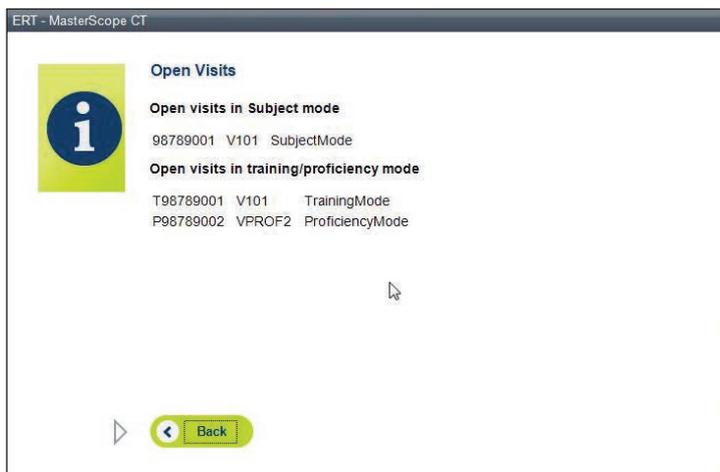
15.1.1 Optional Actions

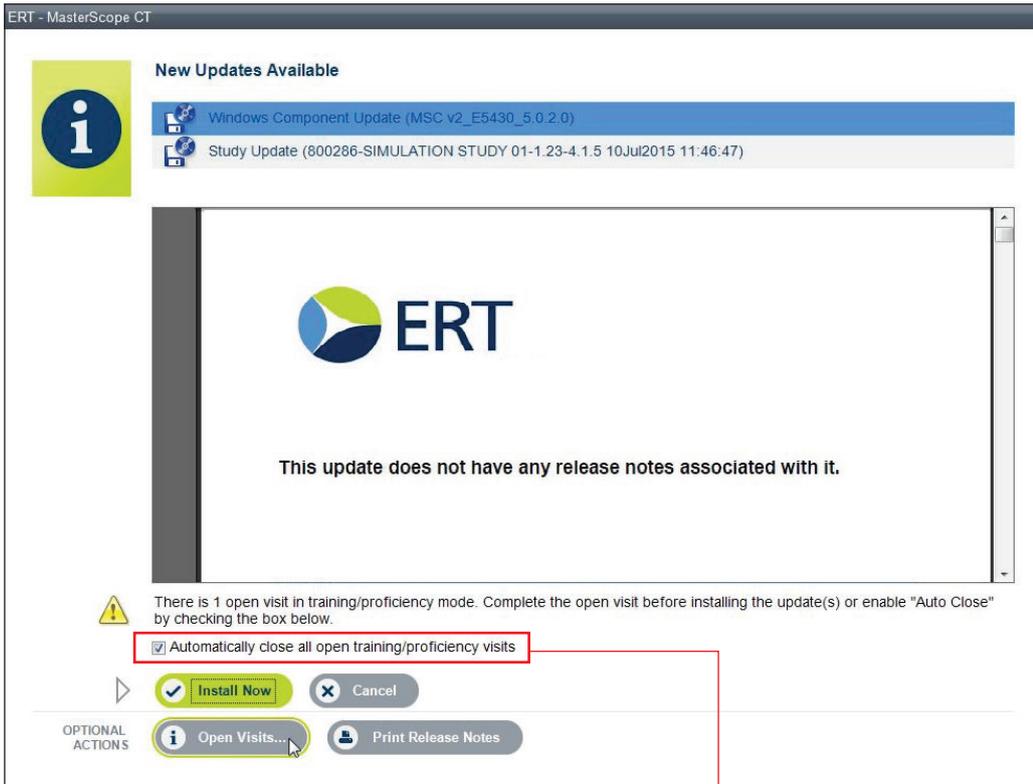<**Print Release Notes**> - prints the release notes.

If <**Install Now**> cannot be activated, click <**Open Visits...**>.

A list appears showing visits of subjects which were started today. If these visits are complete already, the system offers to finalize these visits. If these visits are still ongoing, install the update after completing the visits.
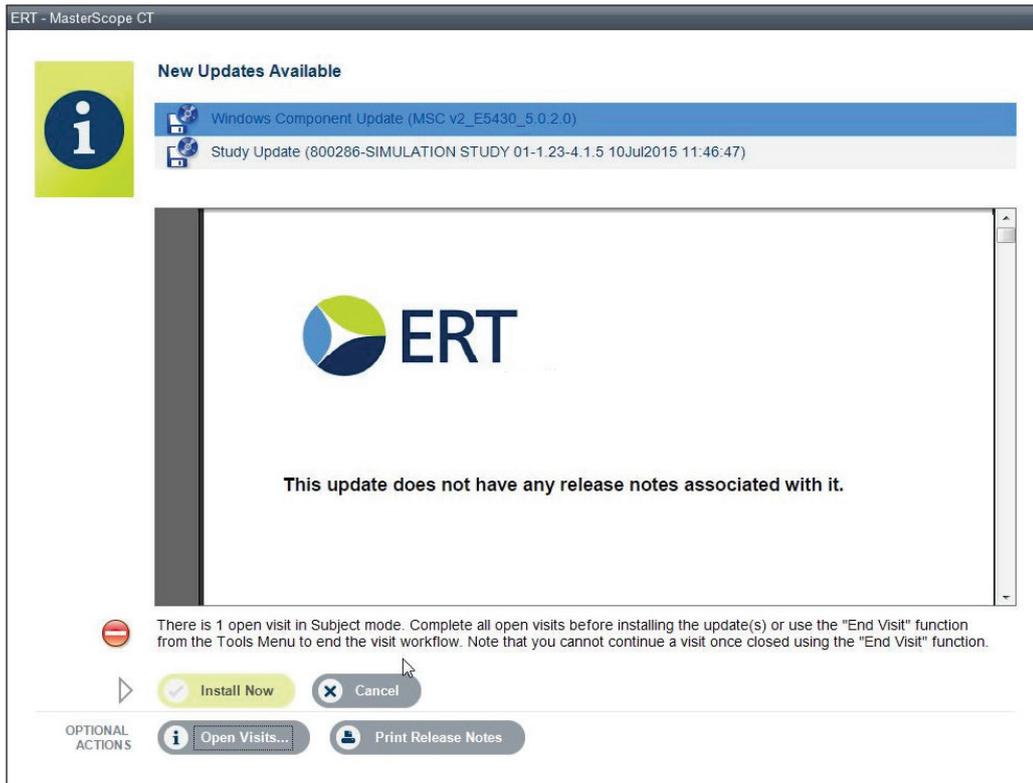
Open Visits in Training/Proficiency Mode:

As an alternative, checkmark "**Automatically close all open training/ proficiency visits**".

> If the warning sign is yellow ⚠, one or more visits are open in Training or Proficiency Mode. They can be closed automatically, if you set the flag "Automatically closed".

Open Visits in Subject Mode:

If the warning sign is red ⛔ , one or more visits are open in the Subject Mode and the subject visits must be completed first.

15.2 Installation of Software Update via SD Card or USB Stick

> ❗ All update(s) will be provided typically via online download (see chapter Online Update). Your site will only receive the update via SD Card/USB Stick if you are having issues with the online download. Please get in touch with our Customer Care if you need to receive the update via SD Card/USB Stick.

Due to changes in the study protocol or other software issues, it might become necessary to install a software update on MasterScope. The procedure is described in this chapter.

You will receive an SD Card/USB Stick containing the new software. The medium is labeled with the respective update version.

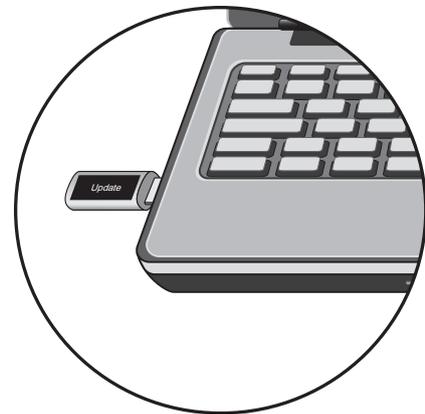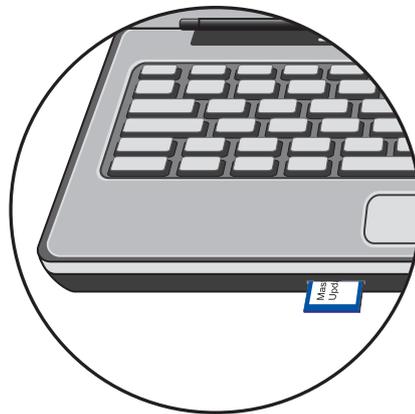> ❗ The update media is not site specific. Therefore it can be reused at other sites.
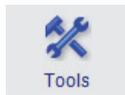
SD Card
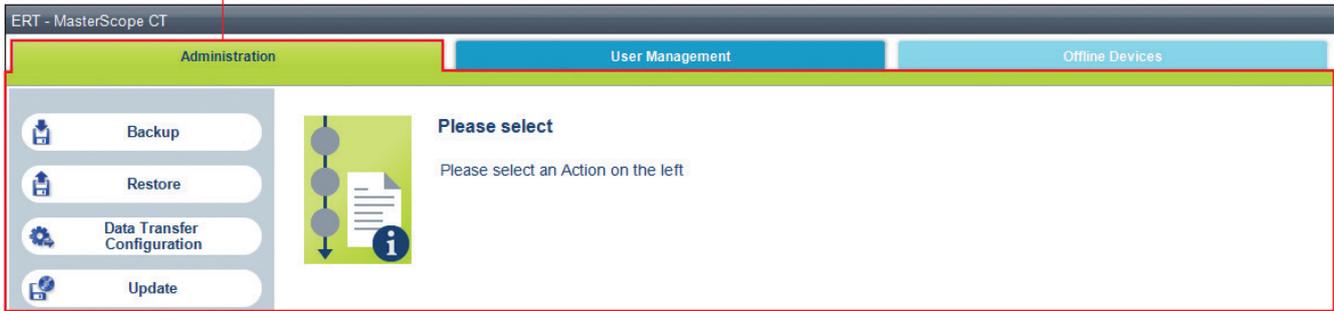
USB Stick

Proceed step by step:

1. Insert the SD Card/USB Stick with the updated software into the respective slot of the laptop. It is the same slot that the site uses for the daily backup routine.
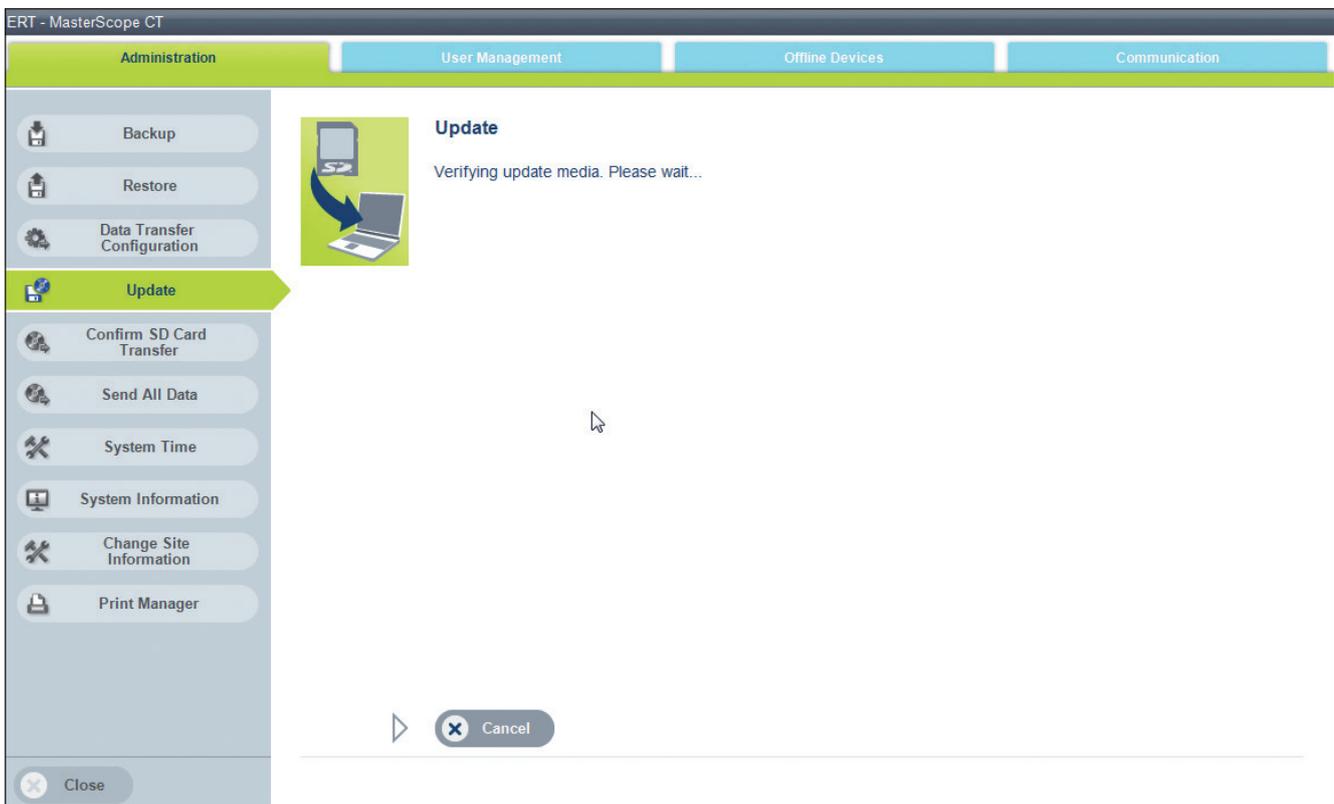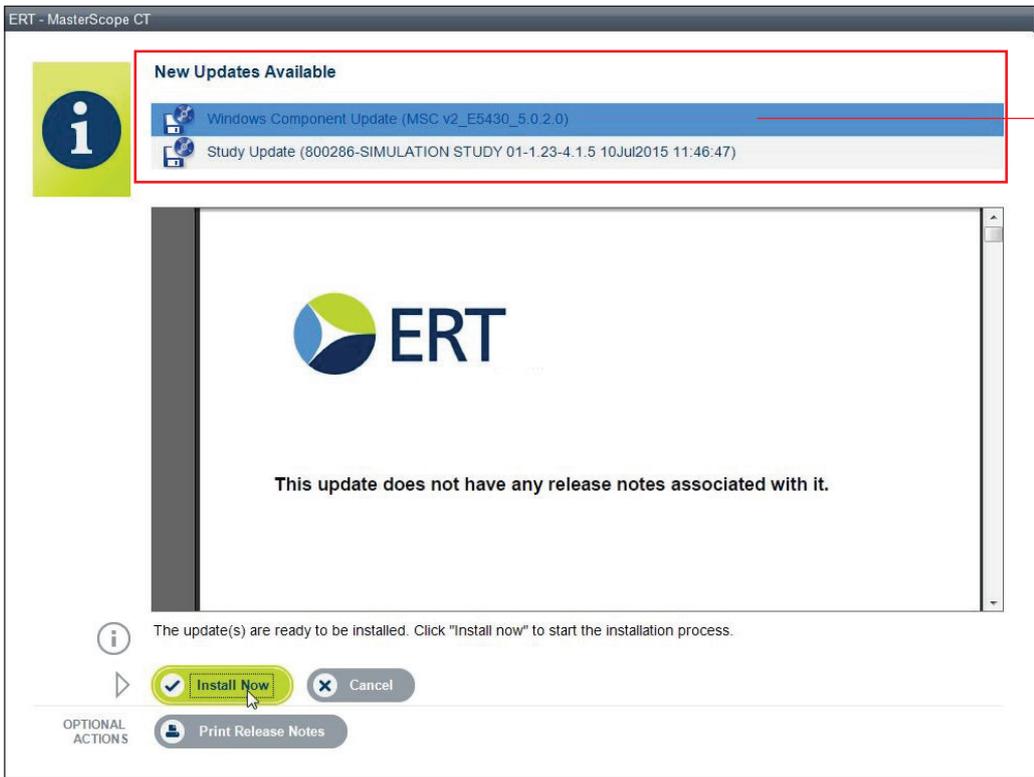
Tools

2. Select <**Tools**> in the menu bar on the right-hand side of the screen.

3. Select the <**Administration**> tab.

ERT - MasterScope CT

Administration	User Management	Offline Devices

Backup
Restore
Data Transfer Configuration
Update

Please select

Please select an Action on the left

Update

4. Click on <**Update**> and the following screen will appear:

ERT - MasterScope CT

Administration	User Management	Offline Devices	Communication

Backup
Restore
Data Transfer Configuration
Update
Confirm SD Card Transfer
Send All Data
System Time
System Information
Change Site Information
Print Manager

Update

Verifying update media. Please wait...

Cancel

Close

Available updates are listed here separated by protocol update or windows update. By selecting an update, a respective "Release Note" will be displayed with detailed information about the update.

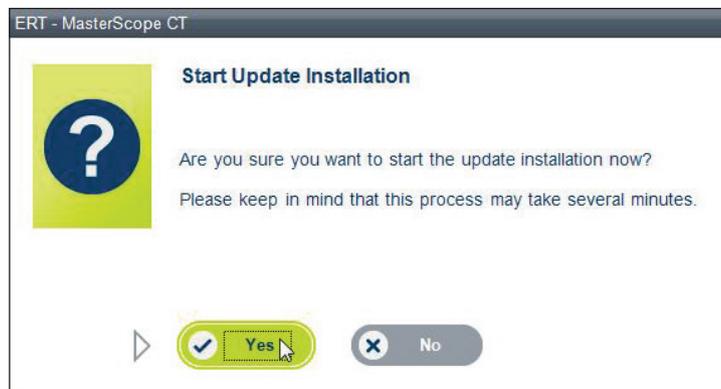 Click <**Install Now**> to start the installation.
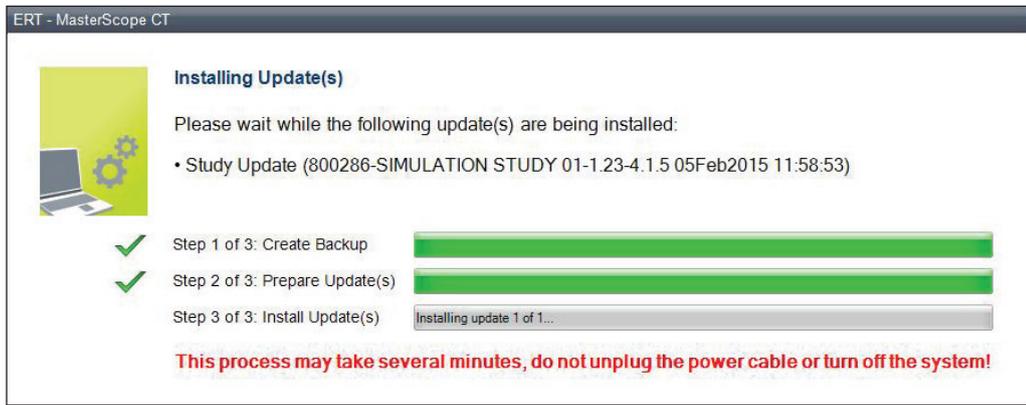
 Click <**Cancel**> to install the update later.

 Updates should be installed immediately after downloading. If you have ongoing subject visits, make sure to install the update(s) after the patient visits are completed for that particular day.

The following screen appears:

 Click <**Yes**> to to start the Update Installation.

After successful installation, the following will be displayed:

   Click <**OK**> to confirm.

Now, it is necessary to restart the system.

   Click <**Restart Now**> to finish the
procedure.

   For starting the process manually, select <**Tools**> from the Utilities bar. Click on
<**Update**> in the "**Administration**" tab.
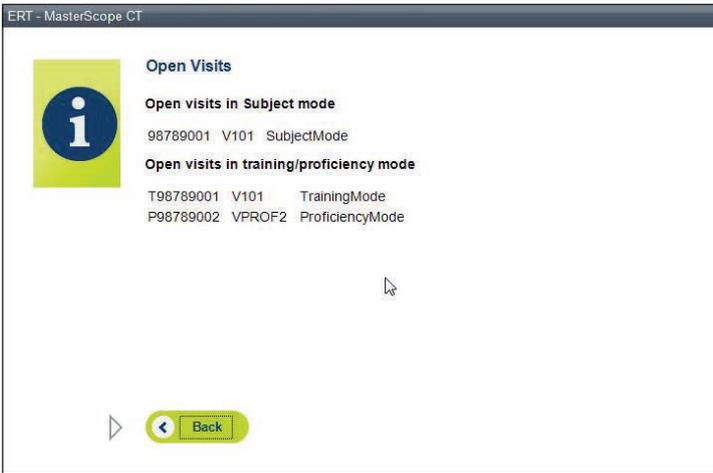
15.2.1   Optional Actions

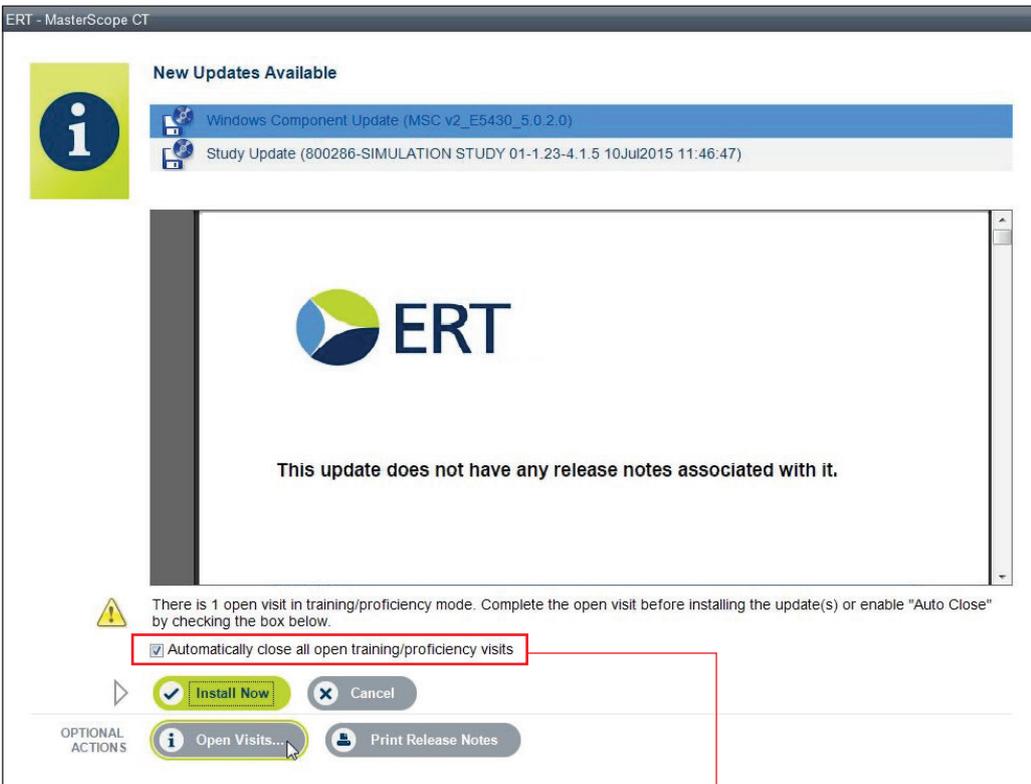<**Print Release Notes**> - prints the release notes.

If <**Install Now**> cannot be activated, click <**Open Visits...**>.

A list appears showing visits of subjects which were started today. If these visits are complete already, the system offers to finalize these visits. If these visits are still ongoing, install the update after completing the visits.

Open Visits in Training/Proficiency Mode:

As an alternative, checkmark "**Automatically close all open training/proficiency visits**".

> ! If the warning sign is yellow ⚠ , one or more visits are open in Training or Proficiency Mode. They can be closed automatically, if you set the flag "Automatically closed".

Open Visits in Subject Mode:

> ! If the warning sign is red ⛔ , one or more visits are open in the Subject Mode and the subject visits must be completed first.

15.3   Date/Time Check and Correction

It might be necessary to check the date and time (and also time zone) of the system.

Refer to the following steps:

1. Click on <**Tools**> in the menu bar on the right-hand side of the screen.

2. Select the <**Administration**> tab.

3. Click on <**System Time**> and the following screen will appear:

> ⚠️ The "**Automatically adjust clock for daylight saving changes**" check box **must be checked** and ticked, if daylight savings apply to the respective time zone. The field is grayed, if no daylight saving time exists in the respective time zone.
>
> Please be careful with all changes here. Settings have an effect on all future measurement results. The use of this function is recorded in the Audit Trail.

> Next   Continue with <**Next**>.

Adjust date and time of your location.

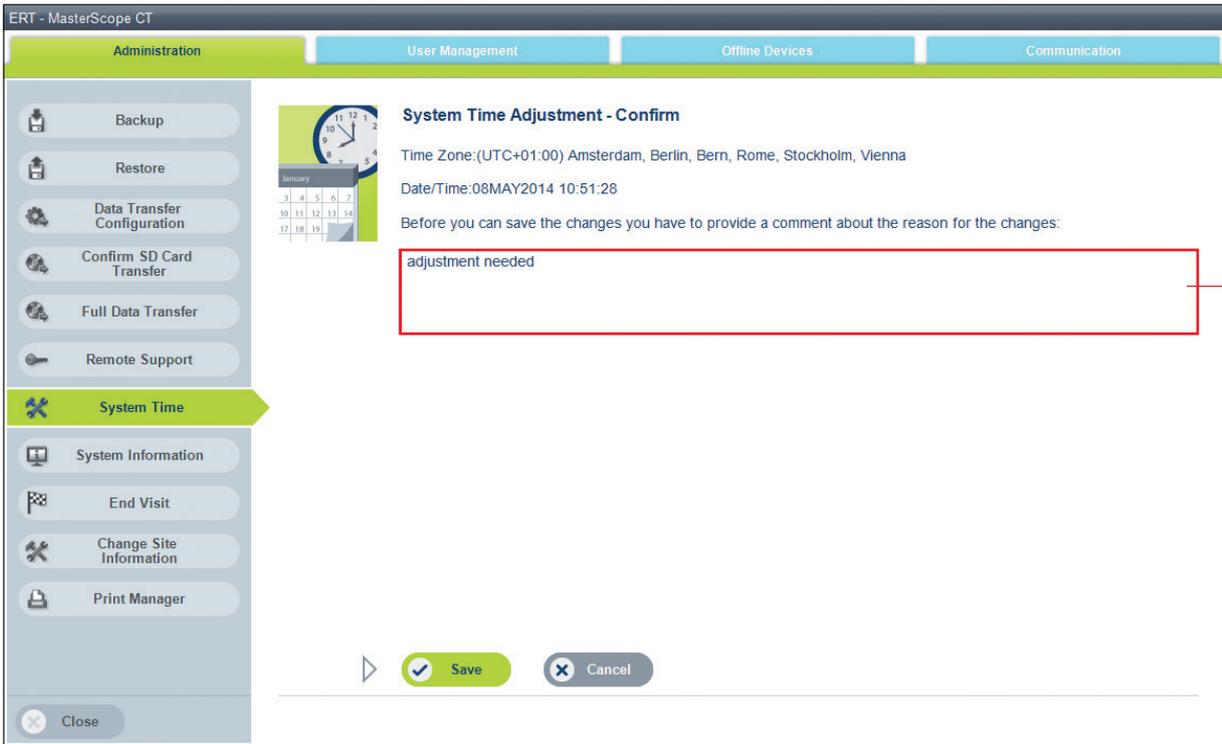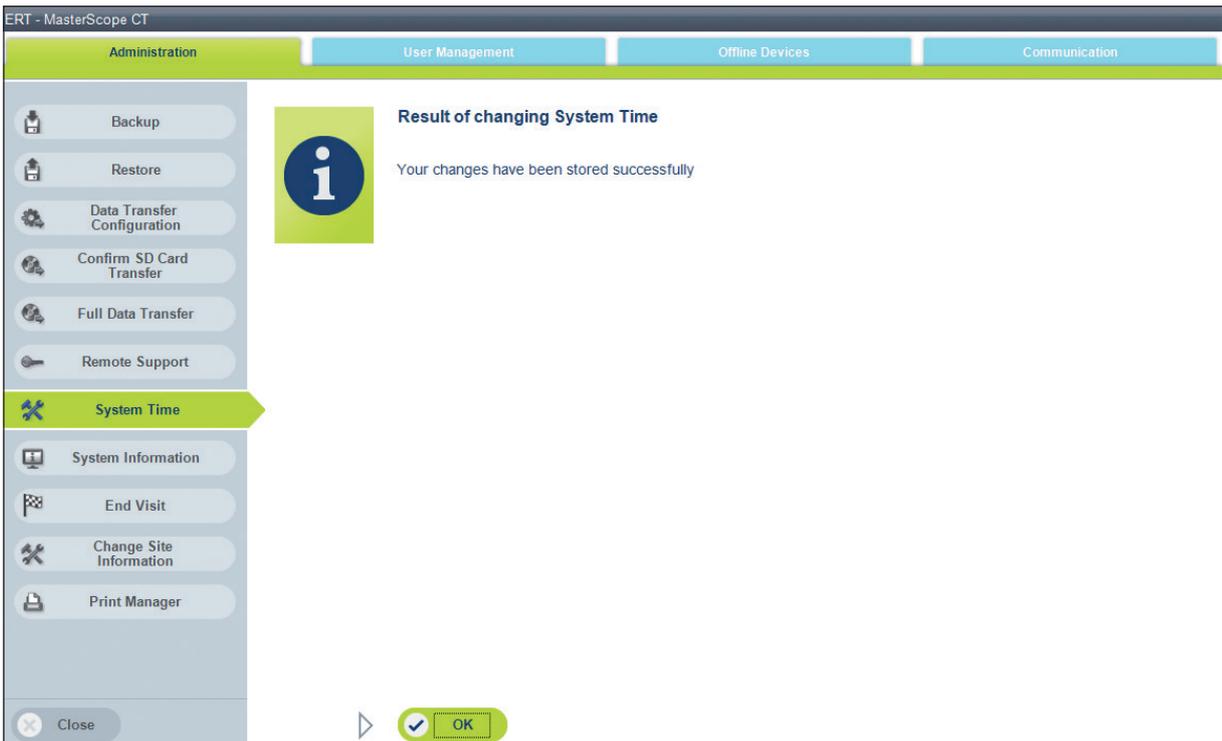**✓ Save**   Continue with <**Save**>.

Enter a reason for the system time adjustment.

Confirm with <**Save**>.

Confirm with <**OK**>.

16. Data Corrections and Communications

16.1 New DCR

Using the Data Clarification Request Form, data corrections can be initiated from the site. These relate to data inconsistencies discovered by the site/CRA. DCRs will be submitted electronically. Fill out the data correction on the MasterScope.
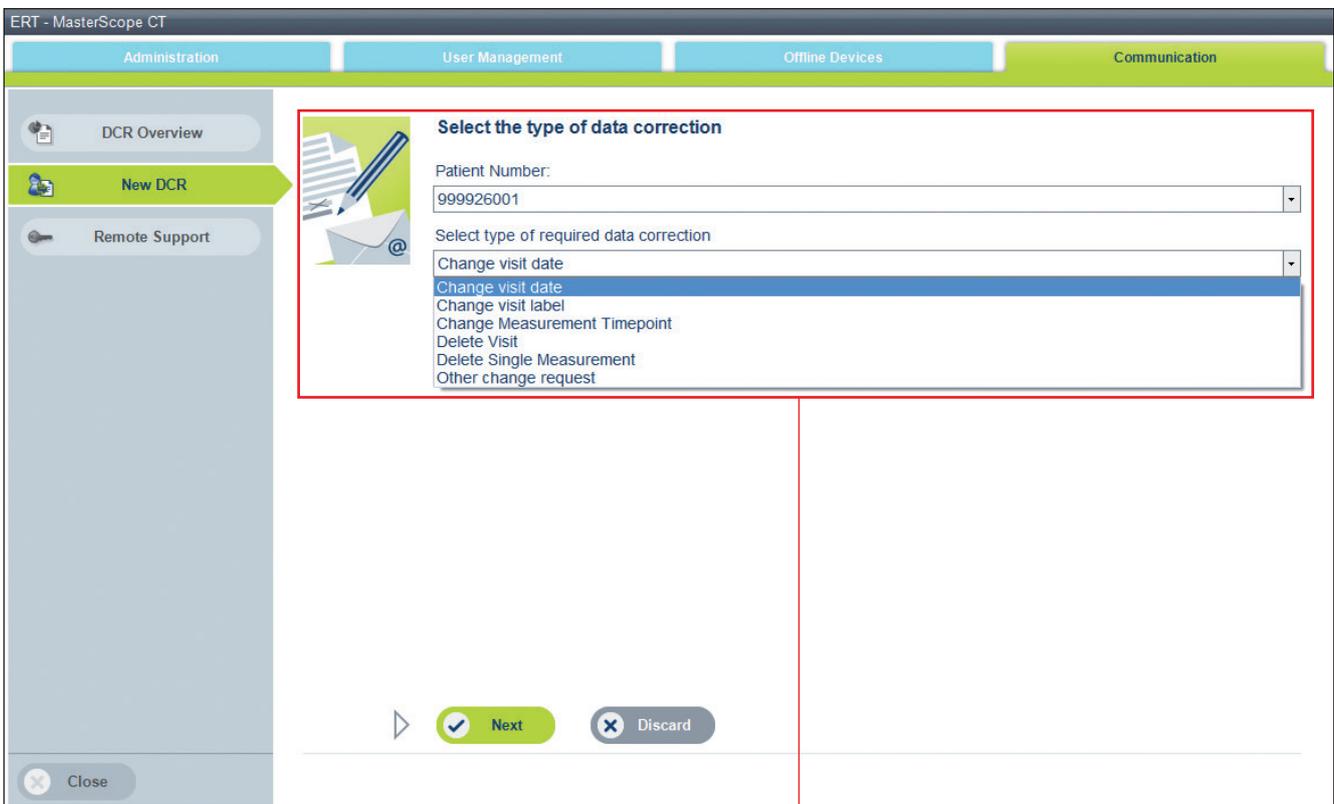
Refer to the following steps:

1. Click on <**New DCR**> in the menu bar on the right-hand side of the screen.

2. Select the <**Communication**> tab.

2. Click on <**New DCR**> and the following screen will appear:

Choose the appropriate subject number and the type of the required data correction. Confirm your selection with <**Next**>.

 Select the appropriate study visit, measurement and current value and enter the new date and time of the measurement. Please enter the reason for revision and confirm with <**Next**>.The following screen will appear:
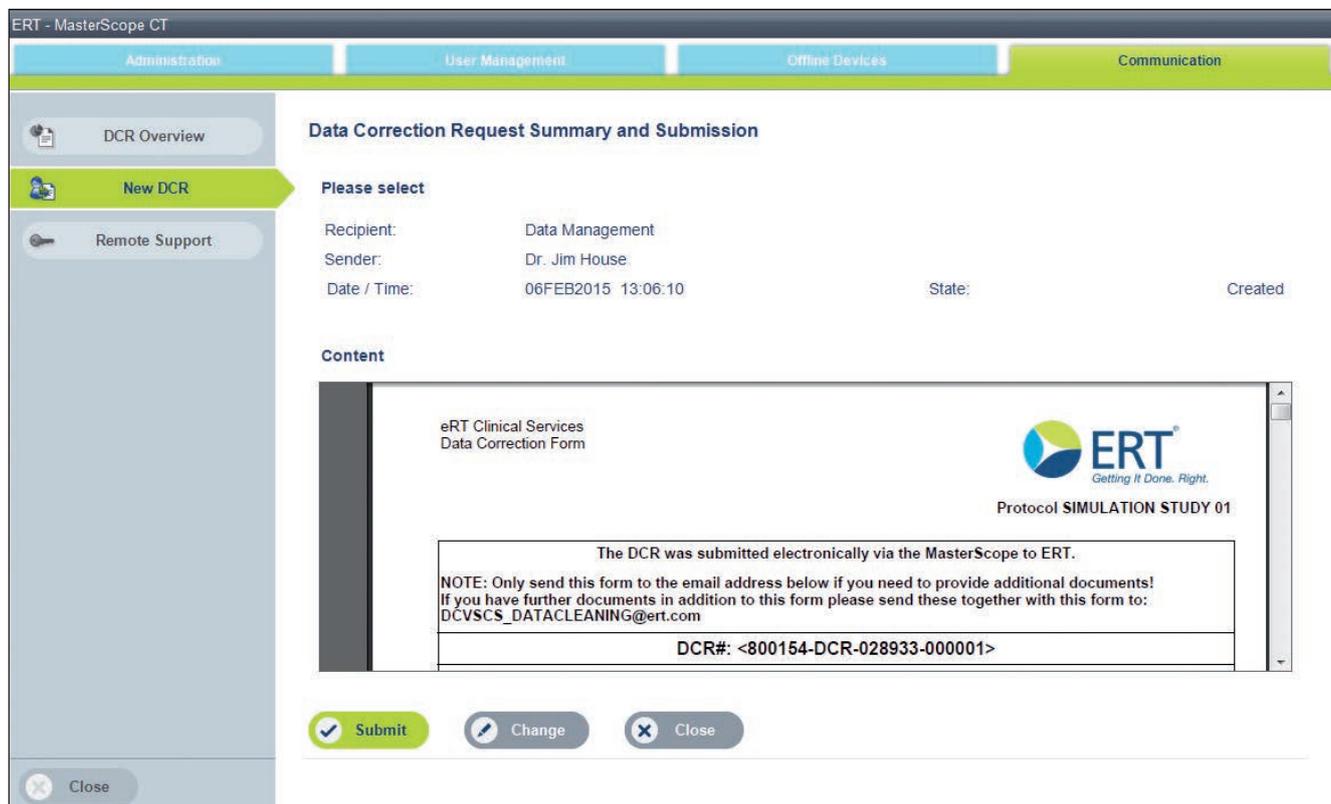
Once completed click on <**Submit**>. The system will now ask you for your fingerprint to confirm the correctness of the requested changes and to sign the DCR electronically.