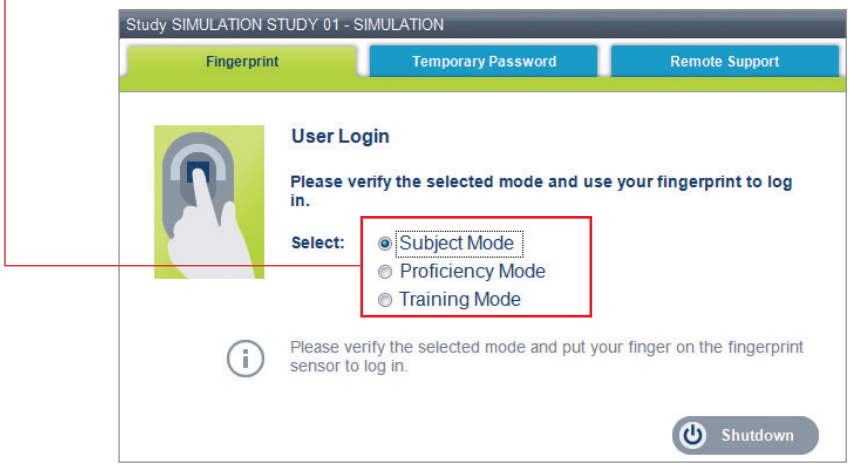
Identify the correct Wireless Spirometry Sensor Unit by the serial number (see label on the backside of sensor) and select it from the list. Click <**Continue**> to start the pairing process.

The bluetooth symbol indicates with dark blue that the sensor is currently connected. If the symbol is greyed out check if the sensor is turned on and connected.

4. Subject, Proficiency and Training Mode

Choose whether you would like to work in Subject Mode, Proficiency Mode or Training Mode.



4.1 Subject Mode

The data from subjects entered in Subject Mode will be used for the study and transferred to the study database. In Subject Mode you will have to follow the time periods and study phases as outlined in the study protocol when testing a subject. All tests performed in Subject Mode pass through the corresponding QA processes.

The Subject Mode is blocked for all users until successfully passed proficiency. See chapter "**Subject Mode Activation**" how to enable the Subject Mode per user.

4.2 Proficiency Mode

In Proficiency Mode, measurements are performed for the purpose of user certification. The goal of the Proficiency Test is for the user to show that he/she is capable of performing a designated number of acceptable spirometry measurements (tests). In Proficiency Mode, only Proficiency Test Subjects can be created or selected. All data entered or measured in Proficiency Mode will not be included in the study data.

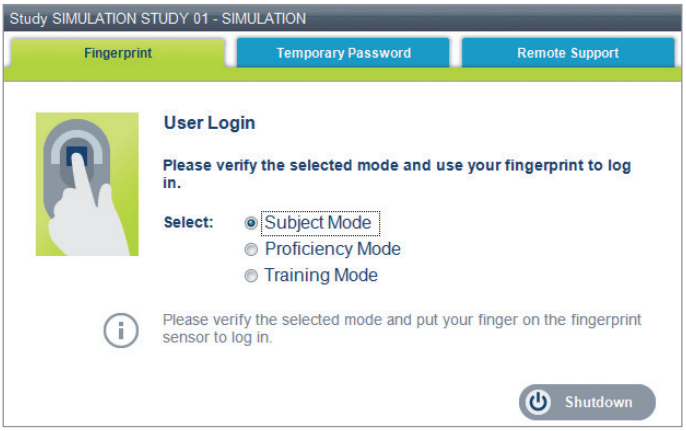
Proficiency tests should be performed on healthy, preferably PFT naïve volunteers. Please perform the requested number of proficiency tests and transfer the data. The quality of the tests will be reviewed and the results will be sent back to the site. Once you have passed the sufficient number of tests, you will receive a Proficiency Certificate.

4.3 Training Mode

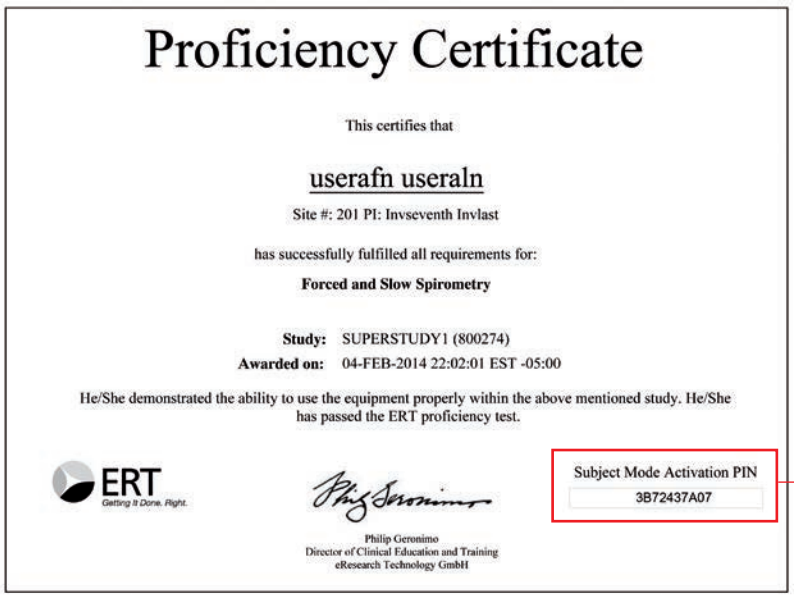
The Training Mode is for practice purposes only to get a major understanding of the look and feel of the MasterScope system with protocol specific customized visit workflows. Mainly the ideal workflow path can be worked through without considering criteria are met or not. However, if there are complex side workflow paths within the study specific visit configuration then these workflow paths are ONLY available if the criteria are fulfilled even in the Training Mode.

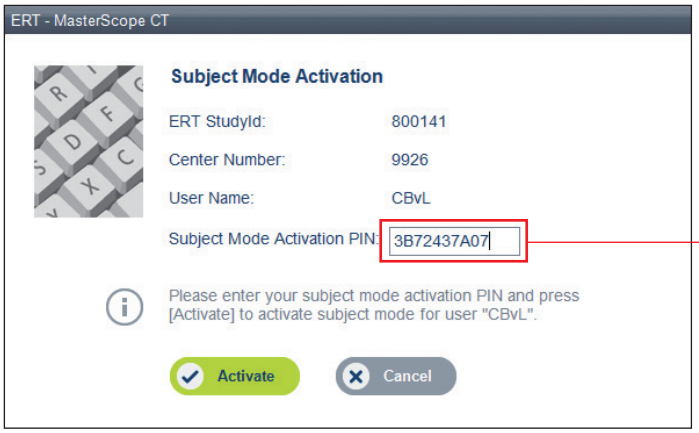
4.4 Subject Mode Activation

1. Select Subject Mode and put your finger on the sensor twice.



2. Enter the Activation PIN for this user from the certification report.

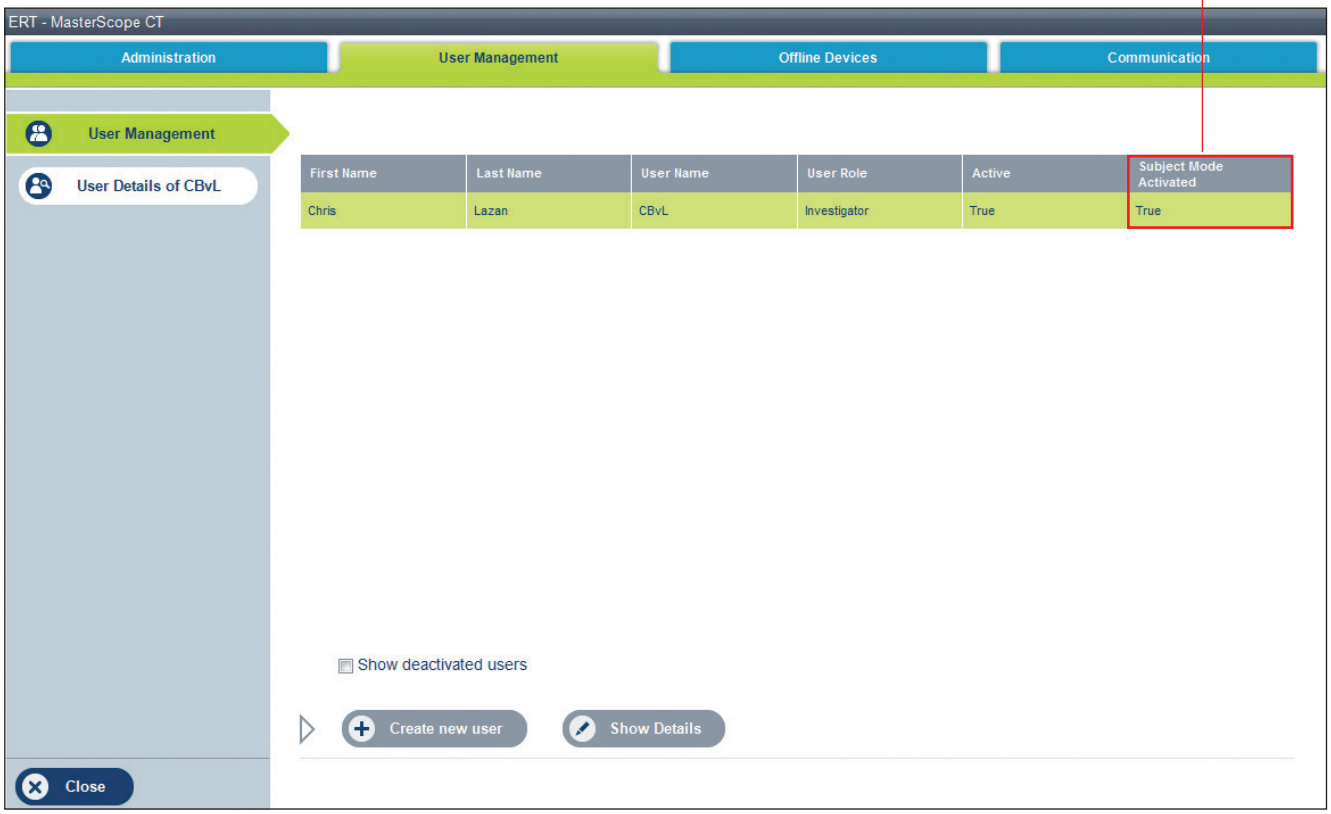




Click on <**Activate**>.

3. The User can now access the Subject Mode and is allowed to perform spirometry measurements.

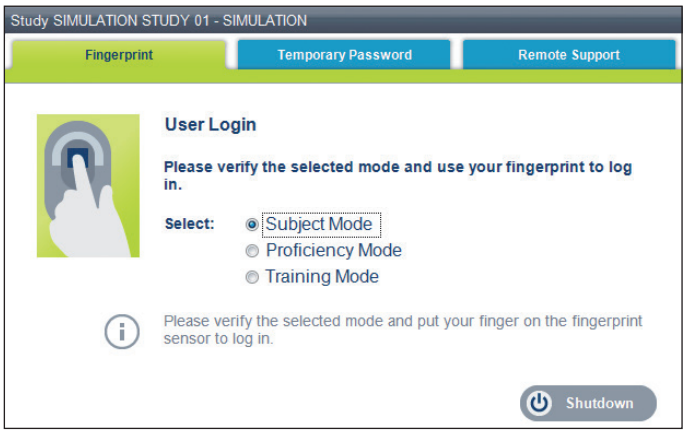
Select the User Management tab of the Tools menu to check if the Subject Mode for each registered user is activated or not.



5. Program Access

System access to the MasterScope requires fingerprint identification.
Your CRA and/or a representative of ERT will perform this registration at the training or during an onsite visit. The identification of the current user is necessary during start-up and before each measurement.

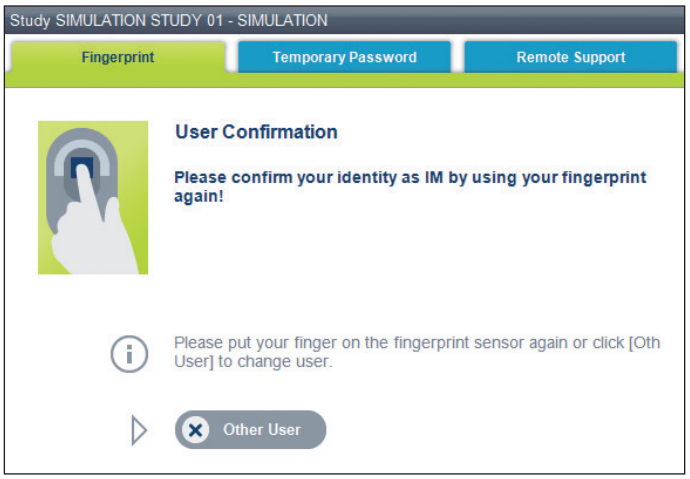
5.1 Fingerprint Identification



To log in using the fingerprinting sensor, follow these steps:

1. Choose whether you would like to work in Subject Mode, Proficiency Mode or Training Mode (details see chapter "**Subject, Proficiency and Training Mode**").
2. Place your registered finger flat and centered on the sensor, using moderate pressure.
3. The system will look for a match of your fingerprint against the one registered under your user name.

The following window appears:



4. Your user name is shown on the screen.
5. If the User Name is correct, place your finger a second time on the sensor.
6. The system will verify your fingerprint.
7. The dialog box disappears.

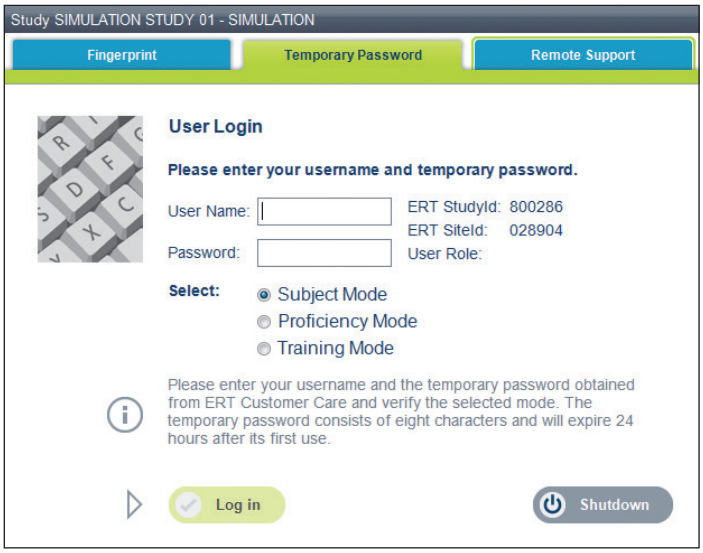
If the fingerprint identification device fails to recognize the fingerprint of a registered user, you may also use the "**Temporary Password**" tab to gain access (see chapter "**Temporary Password**").

5.2 Temporary Password

If the fingerprint identification failed, you may use the "**Temporary Password**" tab. This temporary password is a unique eight-digit code which can be obtained from ERT International Help Desk. A temporary password can only be used for the next 24 hours.

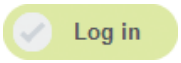
Please have the following information available when you call the Help Desk:

- User Name
- ERT StudyId
- ERT SiteId
- User Role

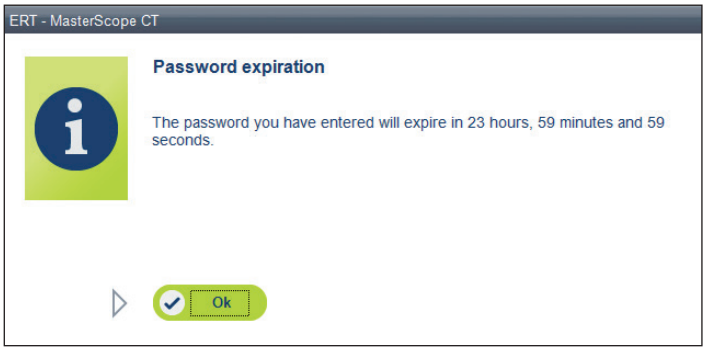


Example screen

In order to gain access to the system, the user has to enter his registered user name (e.g. the initials) and the provided temporary password.



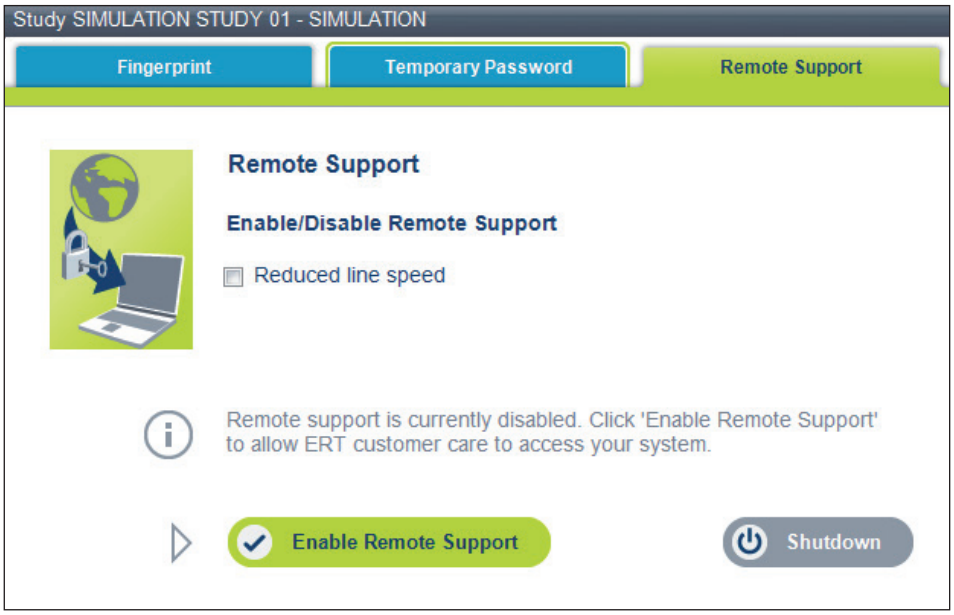
Click <**Log in**> to enter the system. Following window appears:

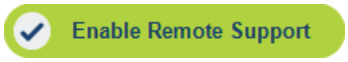


Click <**Ok**>.

5.3 Remote Support

This function enables the ERT support personnel to remotely access your system.



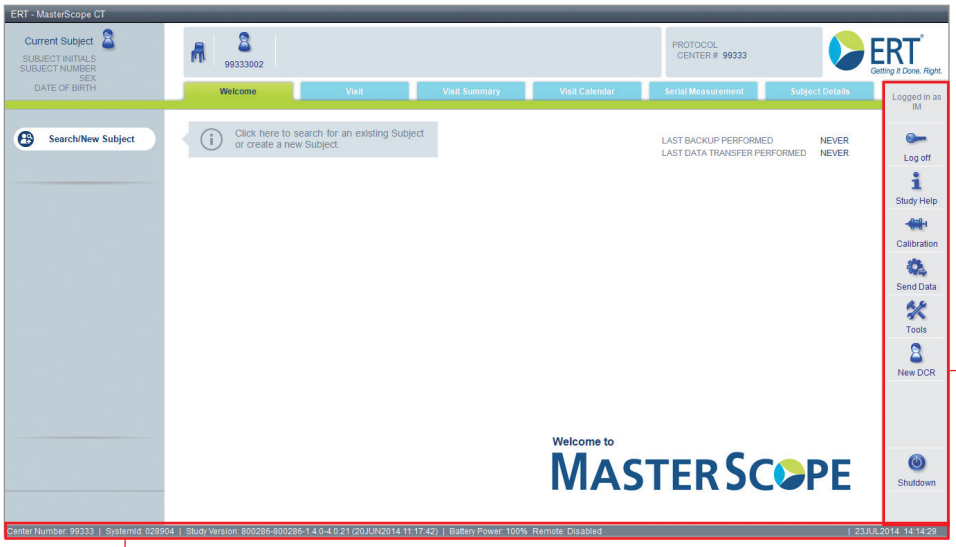


Click <**Enable Remote Support**>.

6. System Overview

6.1 Main Menu

The main menu guides you through the process of the clinical trial protocol and controls the access to all program functions.



Status bar

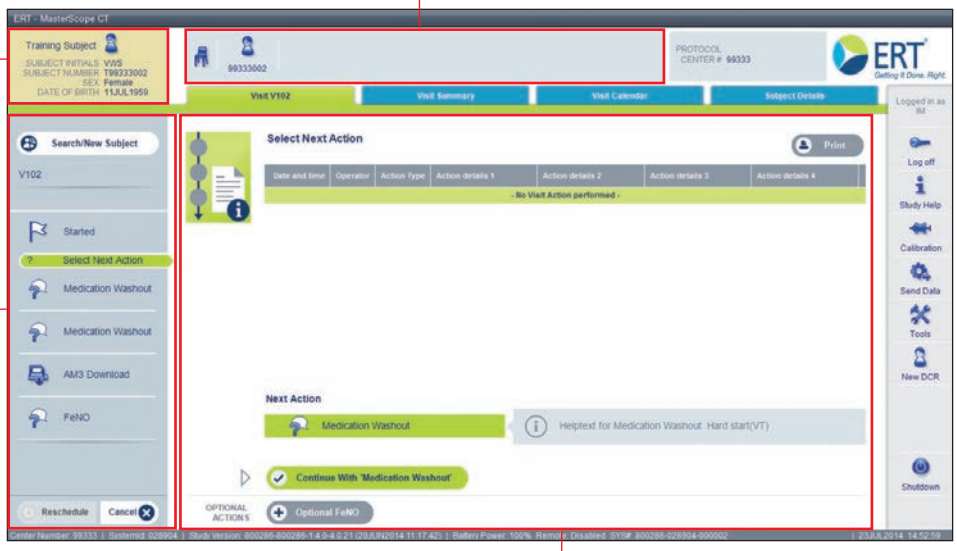
Utilities bar

Click <**Search/New Subject**> to select a subject to work with (also see "**Search/New Subject**").

In a visit workflow the screen content will change.

Waiting room

Current subject



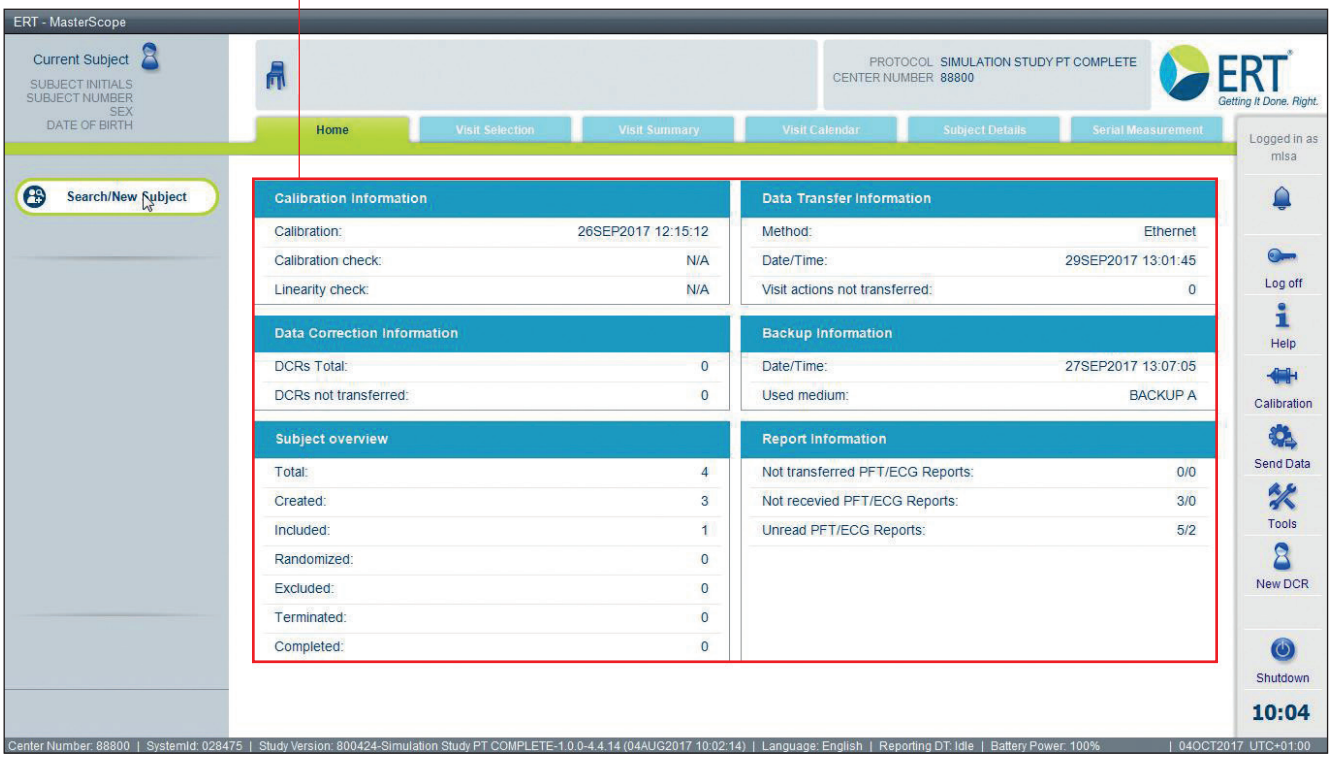
Workflow elements or submenus

Dialog/work area

6.2 Dashboard

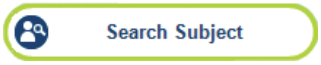
The MasterScope offers a dashboard via the "Home" tab. Various information of the system can be found here depending on your product mix and features selected for your study.

It will display e.g. Calibration, Data Transfer, Backup information or a Patient overview. More or other information might be displayed depending on the study setup.

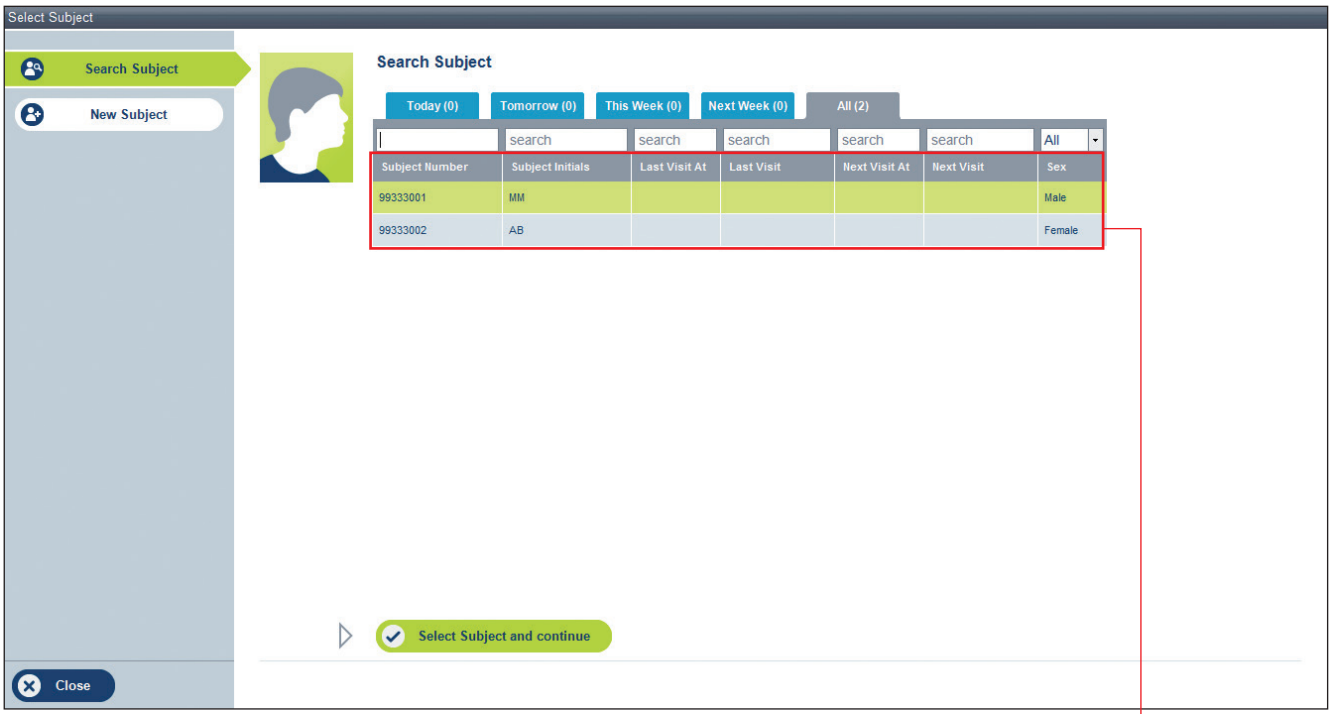


6.3 Search/New Subject

6.3.1 Search Subject

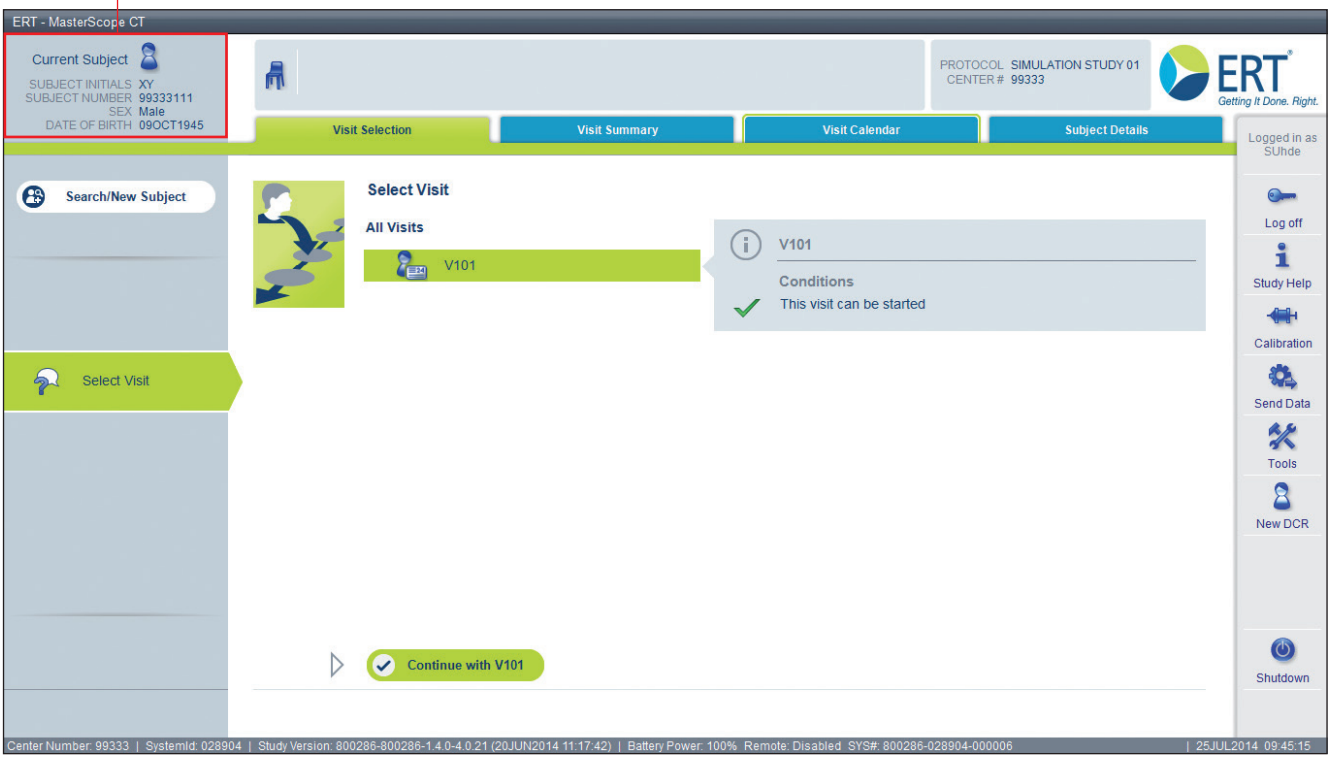


Click this icon and a list of **all available subjects** is shown, i.e. all subjects whose next visit date period contains the selected time point (e.g. today) are listed. As default, the subjects scheduled for "**Today**" with their "**Subject Number**", "**Subject Initials**" (if applicable), Date and Number of their "**Last Visit**", Date and Number of their "**Next Visit**" as well as their Sex are listed. The numbers in the brackets show the number of subjects in the respective group. As an alternative, the subjects scheduled for "**Tomorrow**", "**This Week**" and "**Next Week**" or "**All**" subjects can be displayed. It is also possible to search individually for Subject Number, Subject Initials (if applicable), Date and specific visits (Last Visit, Next Visit) and Sex.

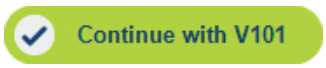


The subject is either selected by double-clicking or by highlighting the respective subject and then clicking on the <**Select Subject and continue**> button.

In this window, the currently selected subject is shown.

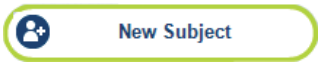


In addition, the currently possible visits are displayed.



Click <**Continue with V101**> to start the selected visit of the current subject.

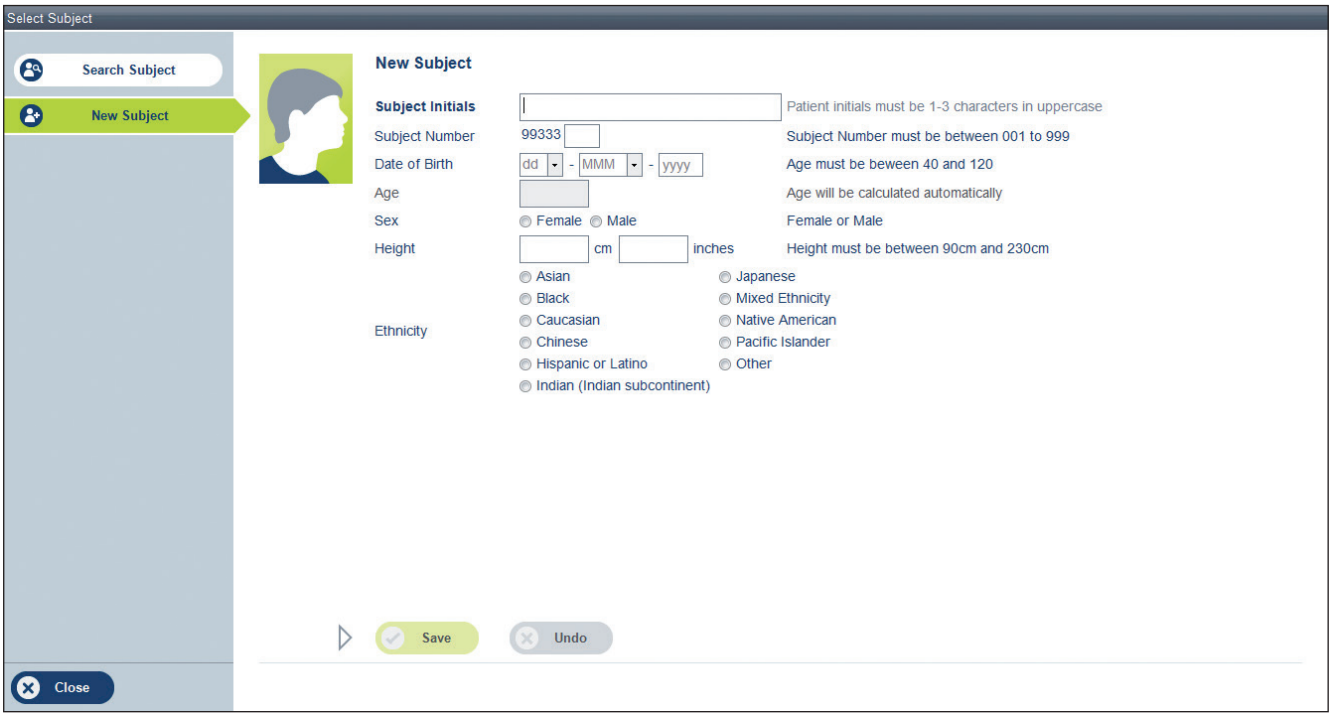
6.3.2 New Subject



Click this icon for adding new subjects.

Entry ranges:

Subject Initials: Subject initials must be 1-3 characters in uppercase.
Subject Number: 001 to 999
Date of Birth: Day - Month - Year
Age: will be calculated automatically (40 to 120 years)
Sex: Female or Male
Height: 90 to 230 cm
Ethnicity: Select appropriate ethnic group.



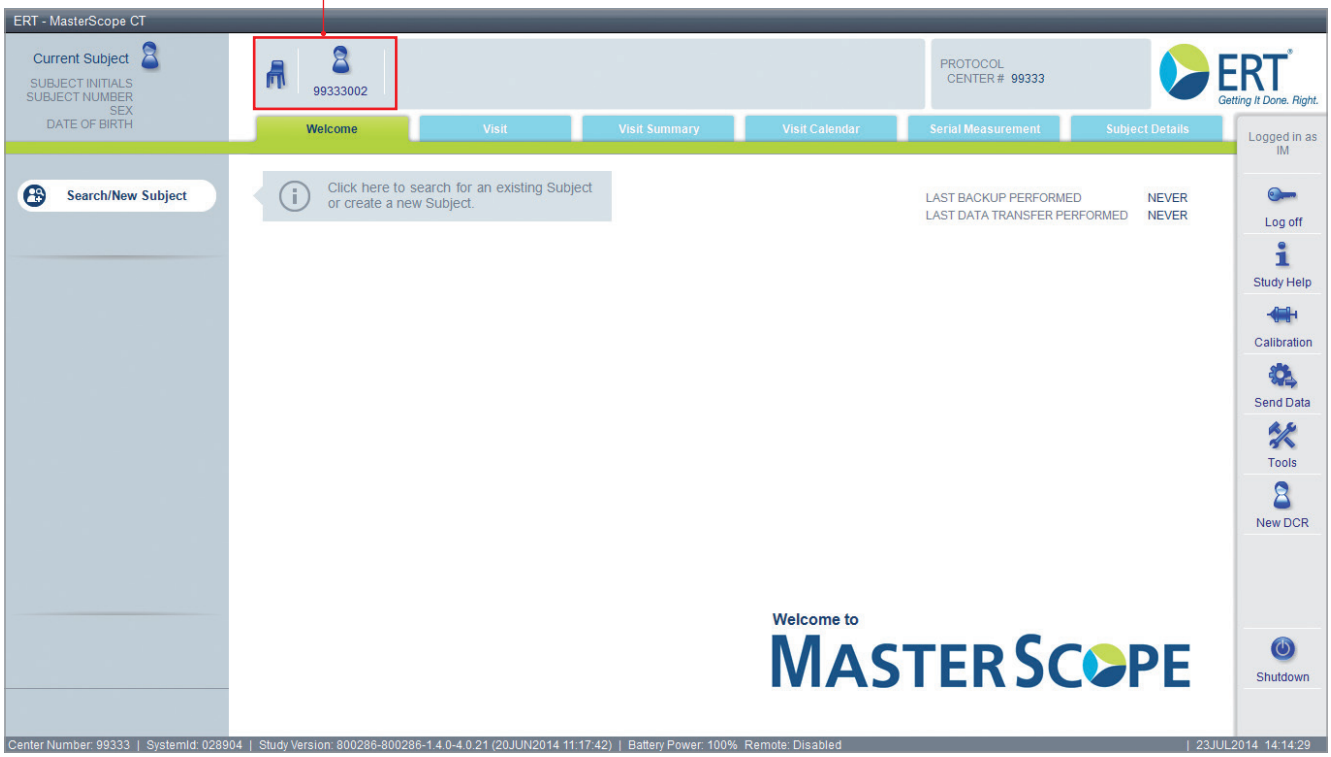
Confirm your entries with <**Save**>.

6.4 Waiting Room

"**Waiting Room**" provides the possibility of switching between subjects currently performing a visit.

If you have started a visit for your current subject and then select or enter a new subject, the previous one will be placed in the Waiting Room automatically.

The previous "**Current Subject**" now appears in the "**Waiting Room**".

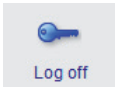


Click on a subject in the "**Waiting Room**" to activate this subject. The subject will become the current subject and the last position in the visit workflow will be displayed. The subject you were working with before will automatically be displayed in the waiting room window.

A subject is staying in the "**Waiting Room**" until his/her visit is complete or until midnight.

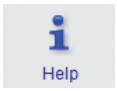
6.5 Utilities

Some Utilities functions are only available for specific user groups.



Log off:

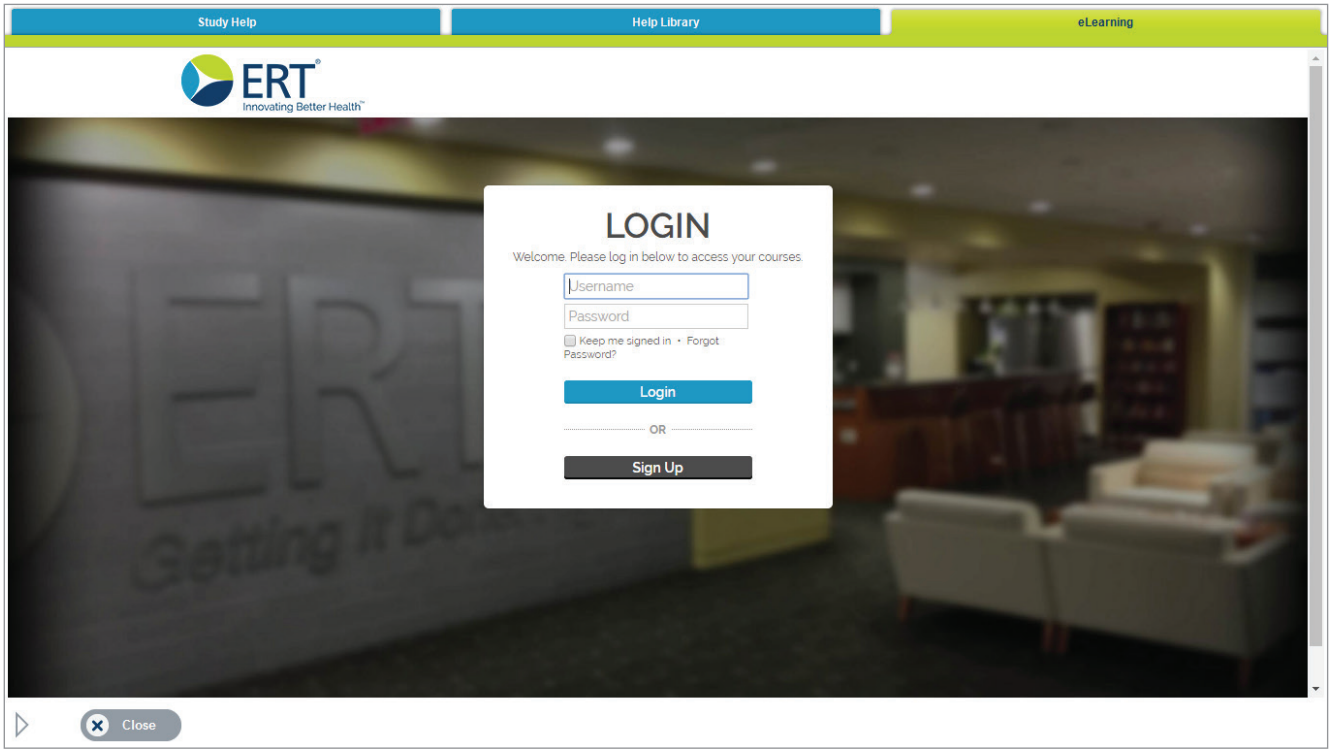
Click this icon to change the user of the system. Please use the shutdown if the system is not needed anymore.

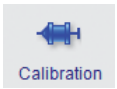


Help:

Click this icon to access material such as Short Guide, local videos (if available for the study) and direct login to ERT's online learning system (if available for the study).

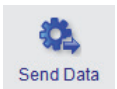
- Study Help tab: Here you will find study material in PDF formats such as the Short Guide.
- Help Library tab: Here you will find videos or additional study material (if available for your study) which are stored locally on the MasterScope.
- eLearning tab: When you are using WiFi or LAN as transfer methodology you can login to ERT's Learn online platform directly from the MasterScope and review all available courses for your account (if available for your study).





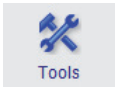
Calibration:

Click this icon to set Ambient Conditions and perform Calibration Check and Linearity Check.



Send Data:

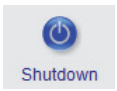
Click this icon to manually activate the transfer of the data to the central database. (= Data Transfer to ERT backend center via modem or via web upload)



Tools:
Click this icon and the following tabs can be selected:

- "**Administration**"**:** administrative functions such as Printer Manager, Logging, Change Site Information, System Information, Update, System Time, Data Transfer Configuration, Confirm SD Card Transfer, Send All Data, Backup, Restore, Device Management
- "**User Management**"**:** User Details can be modified, registered fingerprints can be edited, new users can be registered.
- "**Offline Devices**"**:** Special functions for AM device
- "**Communication**"**:** Remote Login, New DCR (= Data Clarification Request) can be filled in online messages to ERT.

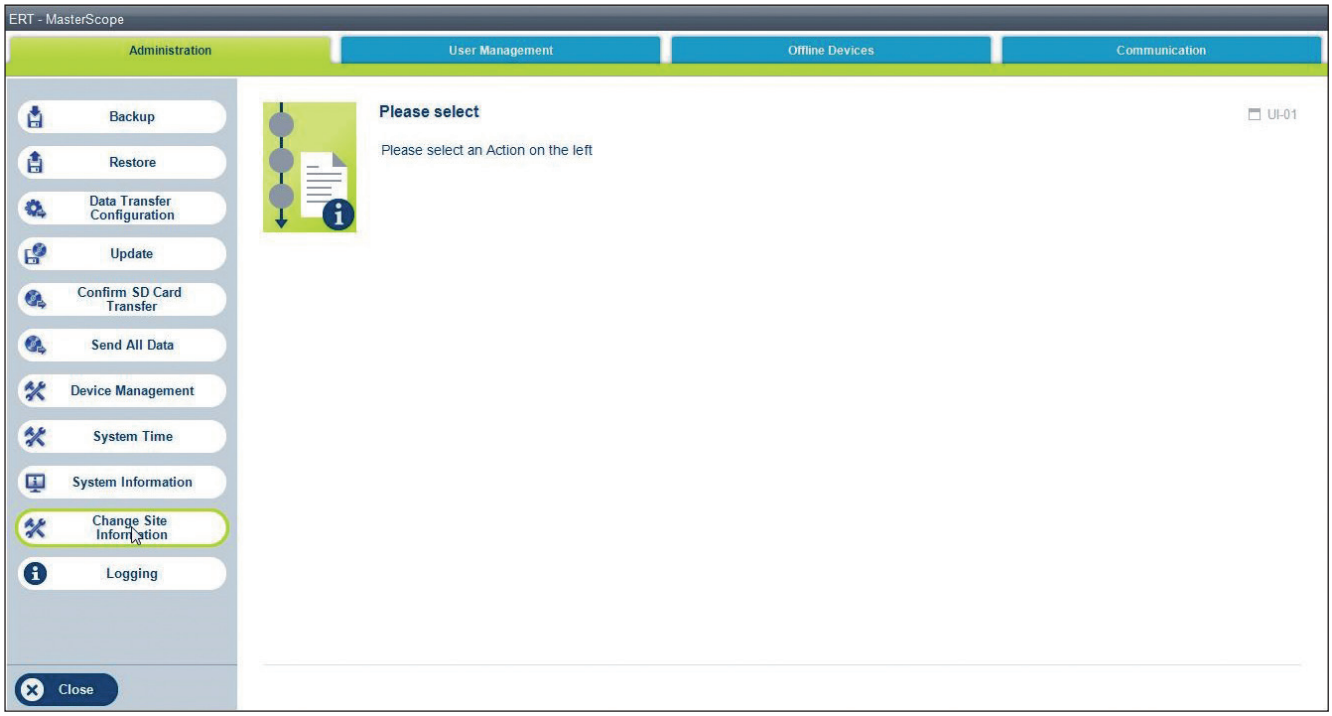
New DCR: Data corrections related to data inconsistencies can be initiated. For this, a new DCR can be filled in online.



Shutdown:
Click this icon to shut down the MasterScope. Backup and data transfer will be initiated automatically.

6.5.1 The Tools Menu

In the tools menu it is possible to adjust various settings.



Backup:
Click this icon to create a backup. See chapter "Backup" on how to perform a backup.

Restore:

Click this icon to restore your MasterScope in case of an unexpected data loss. The latest backup will serve as data source.

Data Transfer Configuration:

Click this icon to set a transfer method and make additional data transfer settings. For detailed information see chapter "Data Transfer".

Update:

Click this icon to install a software update on your MasterScope. See chapter "MasterScope Software Update" on how to install a software update.

Confirm SD Card Transfer:

Click this icon to confirm a web upload transfer. Detailed information can be found in the "Web Upload Data Transfer" chapter.

Send All Data:

Click this icon to send all data.

Device Management:

Click this icon to adjust the settings of the devices connected to your MasterScope. In this section it is possible to replace the device, to download data and to close the respective device.

System Time:

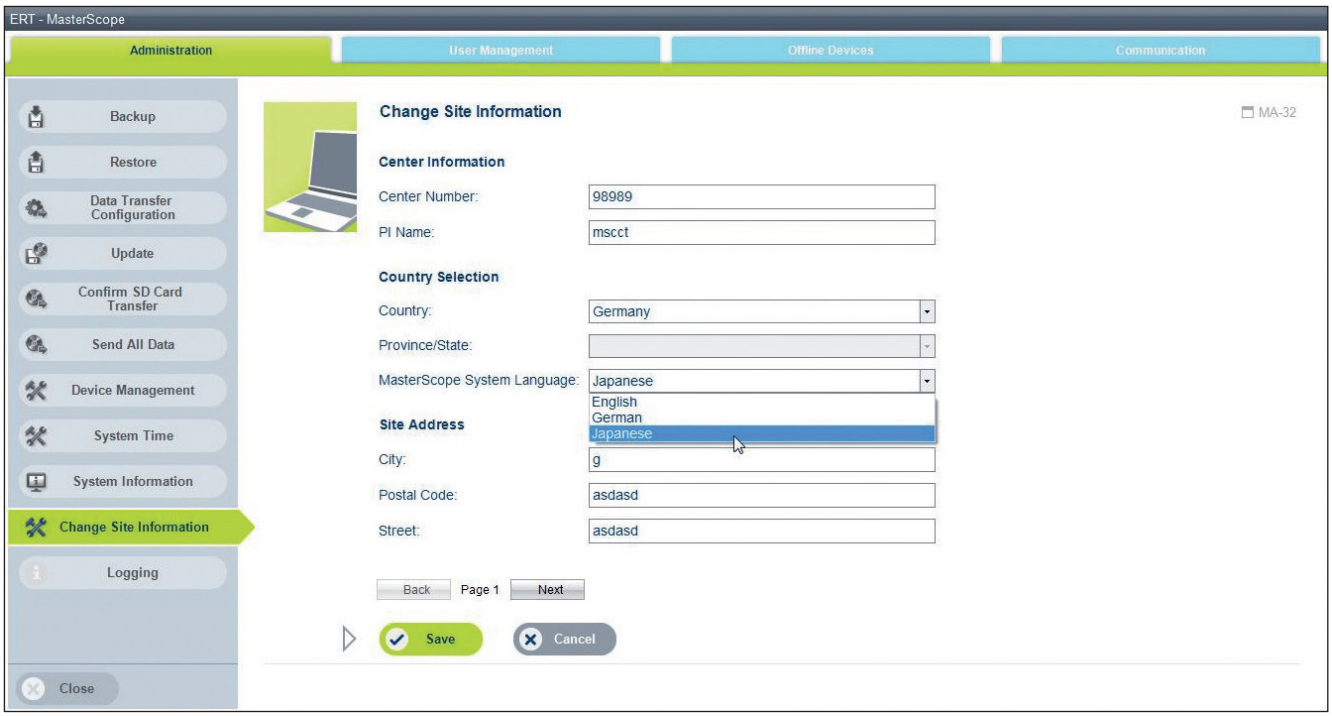
Click this icon to set the time zone your site belongs to and to adjust the date and time of your system. See chapter "Date/Time Check and Correction" for further information.

System Information:

Click this icon to display detailed information on your system.

Change Site Information:

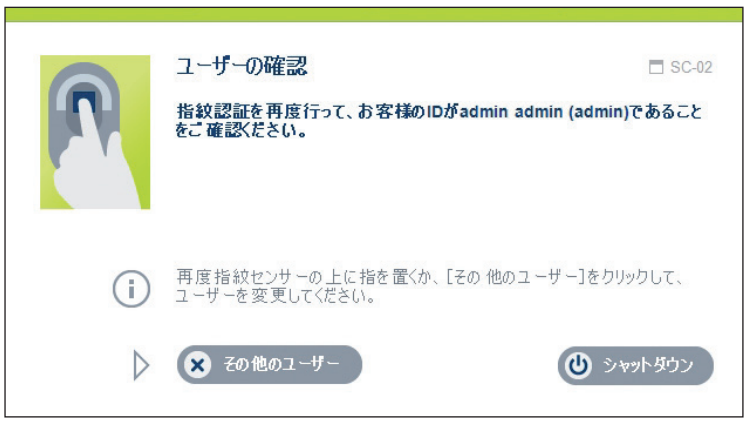
Click this icon to adjust or enter information on your site and to set the system language.



Select your preferred system language and confirm with <**Save**>.

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

Screen example (with "Japanese" set as the MasterScope system language):



Logging:
Review of audit trail information

6.6 Status Bar

Displays the Center number, SystemID, Study Version, Battery Power, Remote status, SYS# (if a subject is selected) as well as the current date/time.

7. Ambient Conditions and Calibration Check

7.1 Ambient Room Conditions

At least once a day it is necessary to check the ambient room conditions.

This can optionally be done by the Ambient Sensor (Automatic Ambient Condition Registration) or manually, if the system prompts the user to enter the ambient room conditions (dialog box displayed below) when attempting to perform a spirometry measurement on a subject.

Since important correction factors are calculated based on ambient conditions, they should be checked at regular intervals. Incorrect or imprecise ambient conditions result in measuring errors.

7.1.1 Ambient Sensor (Automatic Ambient Condition Registration)

The ambient sensor receives via bluetooth the following ambient conditions:

a) Temperature
b) Relative Humidity
c) Absolute pressure

The ambient sensor must not be exposed to direct sunlight nor positioned immediately near heating elements or aircondition elements.

Once the MasterScope received the ambient conditions confirm these to proceed.

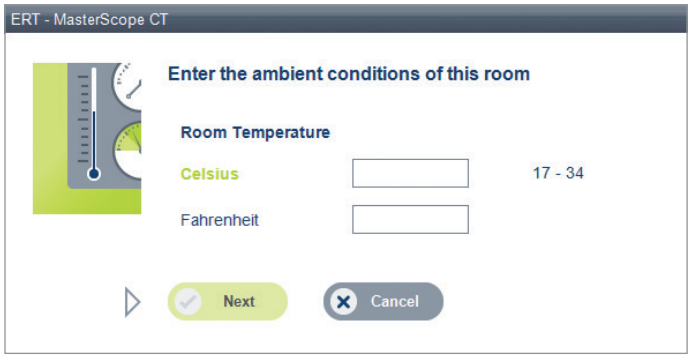
In case of connection issues with the ambient sensor the ambient conditions can be entered manually! Ensure to use ambient conditions from the room where the patient measurement takes place! Barometric pressure must be taken from the room where the measurement takes place! It is not allowed to take it from the internet since this could lead to measurement errors.

7.1.2 Manual Entry of Ambient Conditions

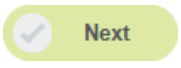
1. Enter the current room temperature in °C or °F in the appropriate field. The conversion of these units will be displayed as well.

   A warning will be displayed if a value outside the normal range (17 – 34 °C/ 63-93 °F) is entered. Please double-check to be sure this value is entered correctly.

Click the <**Ambient Conditions**> icon to enter the following current ambient conditions.

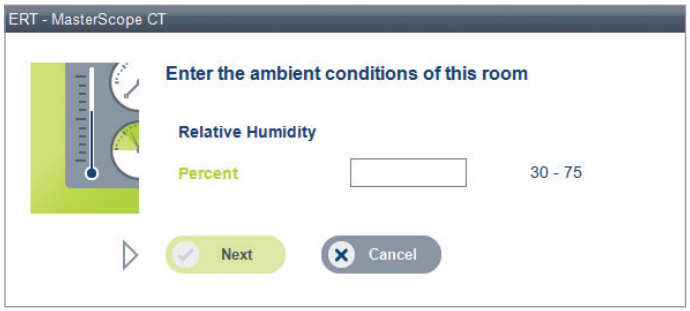


Entry ranges (°C or °F):
Room Temperature: 17 to 34 °C or 62 - 93 °F



Continue with <**Next**>.

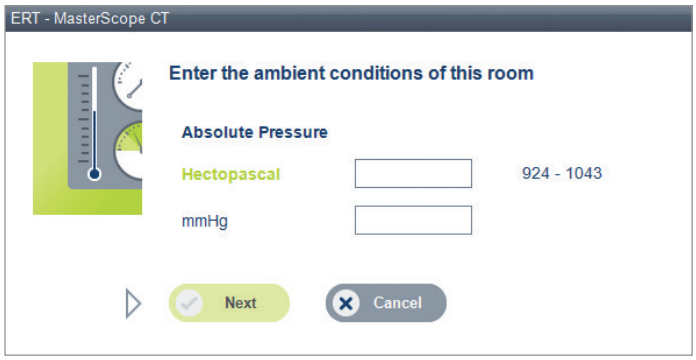
2. Enter the current relative humidity in the room.



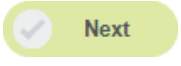
Entry ranges:
Relative Humidity: 30 to 75%

Confirm with <**Next**>.

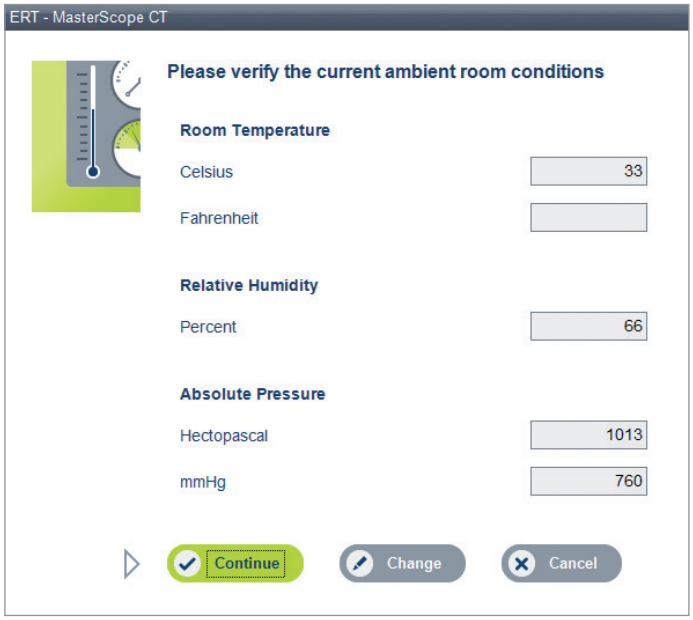
3. Enter the current relative ambient in the room.



Entry ranges (hPa or mmHg):
Absolute Pressure: 924 to 1043 hPa



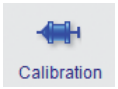
Confirm with <**Next**>.



Press the <**Continue**> button to verify and store the ambient room condition values.

Press <**Change**> to make corrections.

It is important that the correct units are used.



You can adjust the ambient conditions at any time by clicking the icon <**Calibration**> in the Utilities tool-bar.

Following that, select the <**Ambient Conditions**> icon shown on the left.

7.2 Wireless Spirometry Sensor Check

The ERT PTs included with the delivery are pre-calibrated as part of manufacture. A sensor check can be performed to confirm accurate measurement data.

7.2.1 Quality Control for Flow-Volume Measuring Devices in Compliance with ATS/ERS 2005

With regards to volume accuracy*[1], calibration checks should be performed every day at least three times to give a range of flows varying between 0.5 and 12 L·s-1 (with 3-L injection times of ~6 s and < 0.5 s.). The volume at each flow should meet the accuracy requirement of ± 3.5 %.
For checking the linearity of the flow-volume sensor, linearity check should be performed weekly. A 3-L syringe is used to deliver three relatively constant flows at a low flow, three at a mid-range flow and three at a high flow. The volumes achieved at each of these flows should each meet the accuracy range of ± 3.5 %.

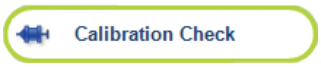
*[1] Literature:
MR Miller et al. Series "ATS/ERS Task Force: Standardisation of Lung Function Testing", Standardisation of Spirometry" Eur Respir J 2005; 319-338

7.2.2 Wireless Spirometry Sensor Calibration Check (ERT PT Check)

ERT PTs are pre-calibrated as part of their manufacture, as such MasterScope is a calibration-free device. It is possible to perform a calibration check to confirm that the device is measuring as expected. A 3L syringe used for such a check is not included as standard, but can be purchased on demand.

Ensure a new ERT PT (with mouthpiece removed) is connected to the 3 L calibration syringe via an adapter (as shown). In order to perform a calibration check, click on **<Calibration Check>**.

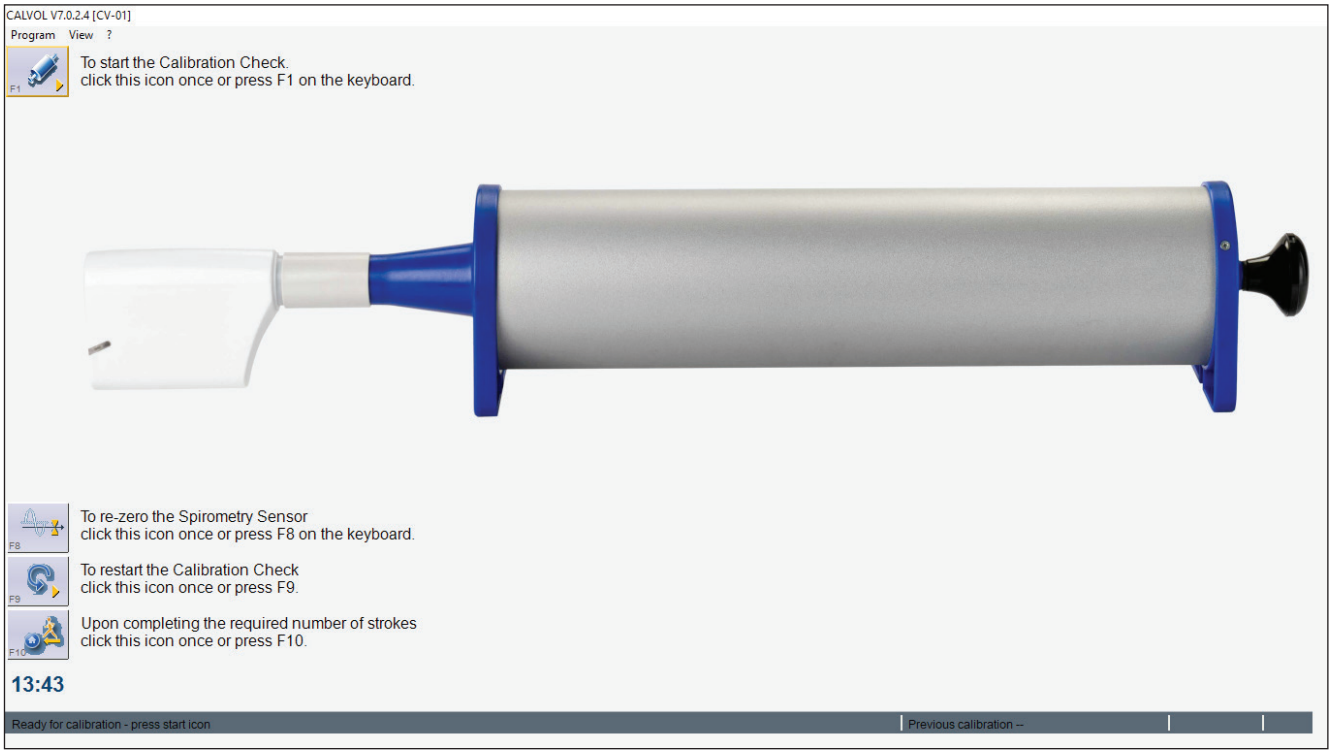
An automatic zero adjustment of the connected ERT PT is performed.



Proceed as follows:

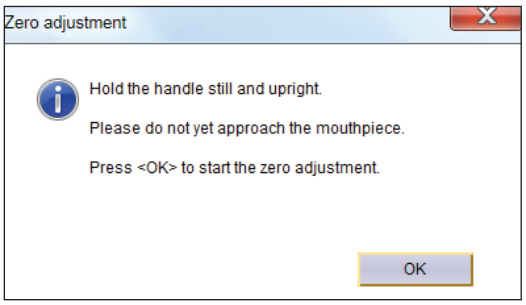
1. Press the <**Calibration Check**> icon. In the following screen you will be asked to verify the current ambient room conditions.

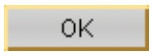
Confirm with the button <**Continue**>. Following window appears:



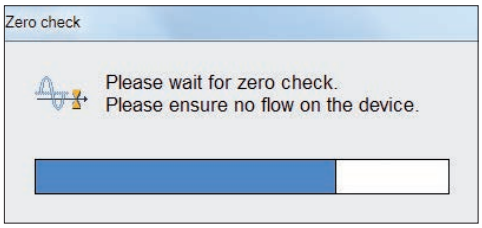
2. Use the 3-L calibration syringe for calibration. Connect the calibration syringe to the wireless spirometry sensor unit.

3. Press <**F1**>. An automatic zero adjustment of the connected pneumotach will be performed. The following window appears:

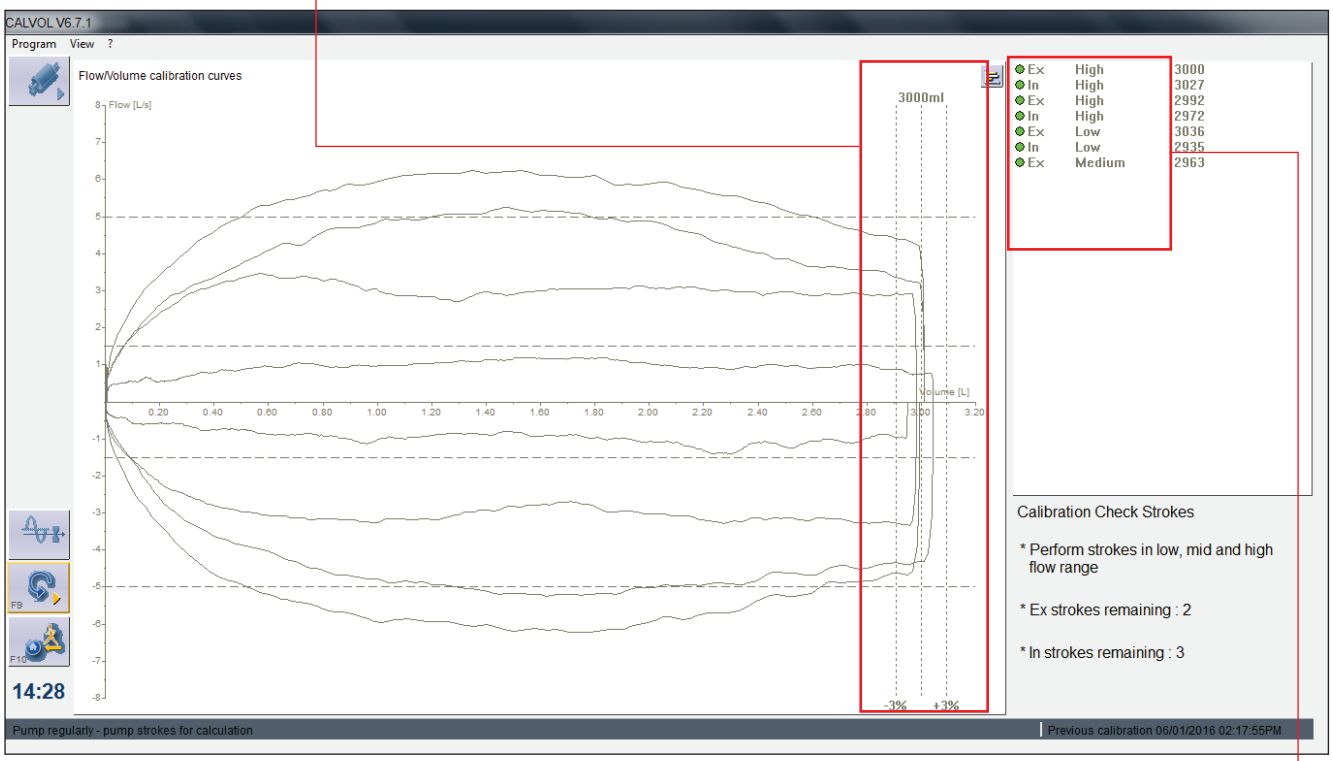




4. Press **<OK>** to start zero adjustment.

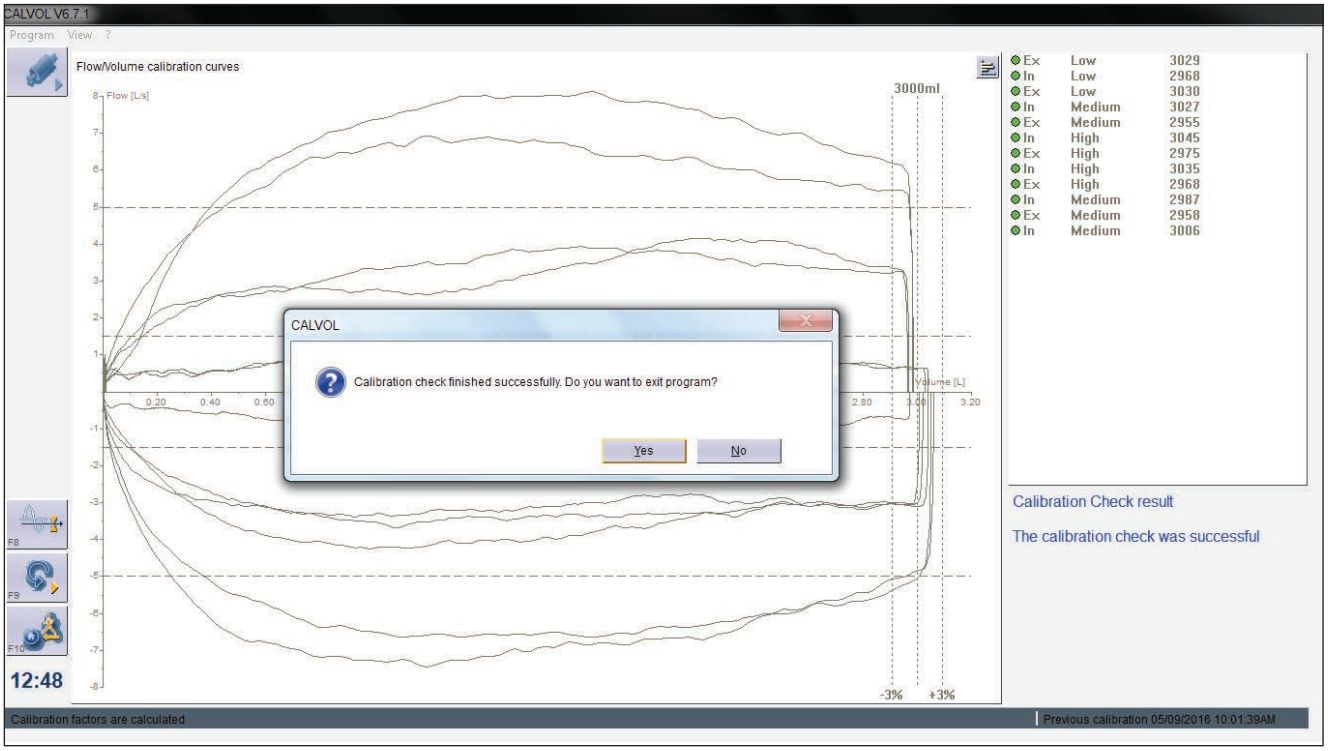


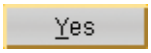
5. The screen now shows you the standard flow/volume calibration graph.
6. Start to pump the calibration syringe with complete strokes - incomplete strokes could lead to errors.
7. The first three strokes are discarded and can be performed at any flow rate. A counter in the bottom right window will count down the number of strokes performed. The inhaled and exhaled volume of each stroke is recorded in the upper right window.
8. The determined values "**EX**" and "**IN**" must be within a range of 2910 to 3090 mL (± 3%) and are displayed on the flow volume graph.



9. The result of each pump stroke is displayed in the upper right window. "**Green**" means better than +/- 3%.

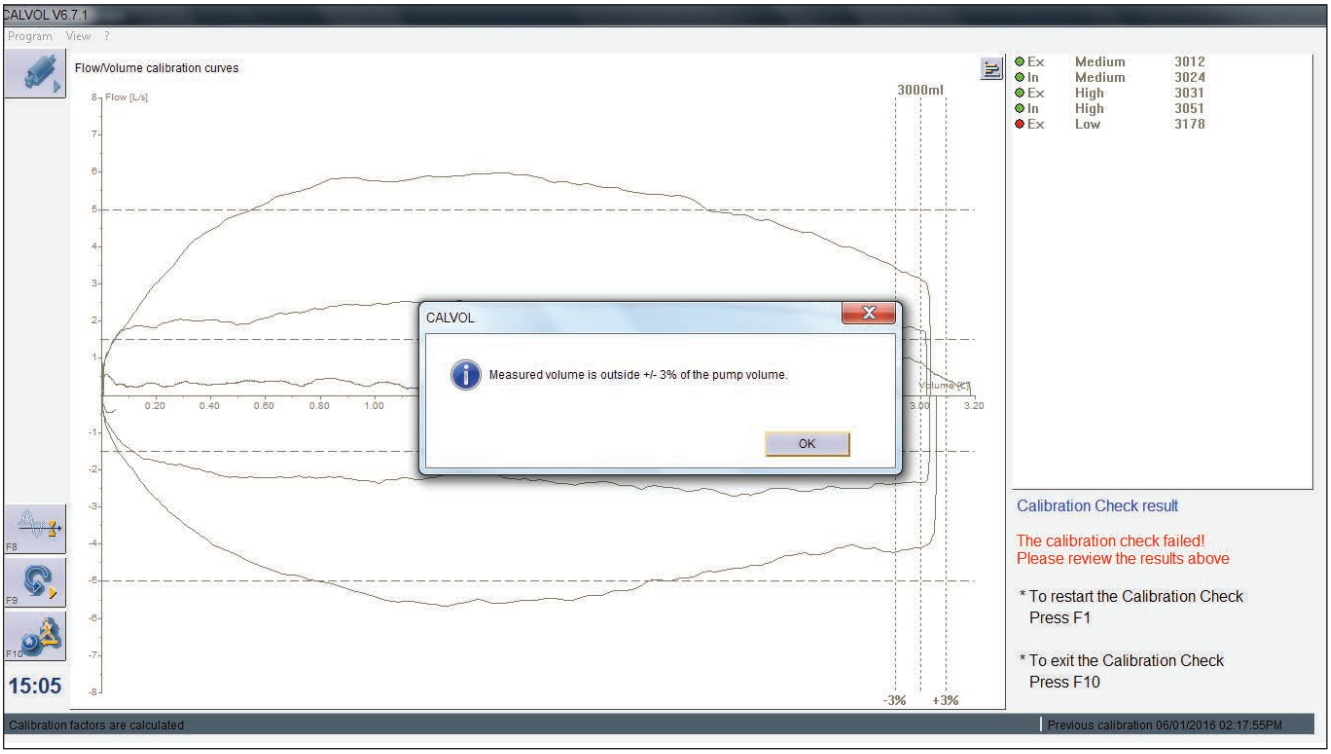
With the completion of the calibration check, following window appears:

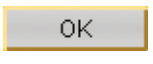




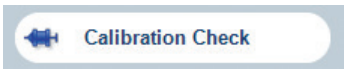
If the calibration check is successful, exit the calibration check program with <**Yes**>.

If any of the strokes are outside this limit, the calibration check will automatically stop, and the message "**Measured volume is outside +/- 3% of the pump volume.**" will be displayed.





Click <**OK**> and restart the calibration check with <**F1**>. If the check continues to fail, exchange the pneumotach and repeat this procedure. If it still fails, please contact ERT Customer Care.



To re-calibrate at any time, click <**Calibration Check>** on the icon bar on the left and select the respective icon. Follow the procedures described above.

The calibration check log report can be printed by selecting <**Calibration**> and the <**Calibration Check Log**> icon.

7.2.3 Wireless Spirometry Sensor Linearity Check

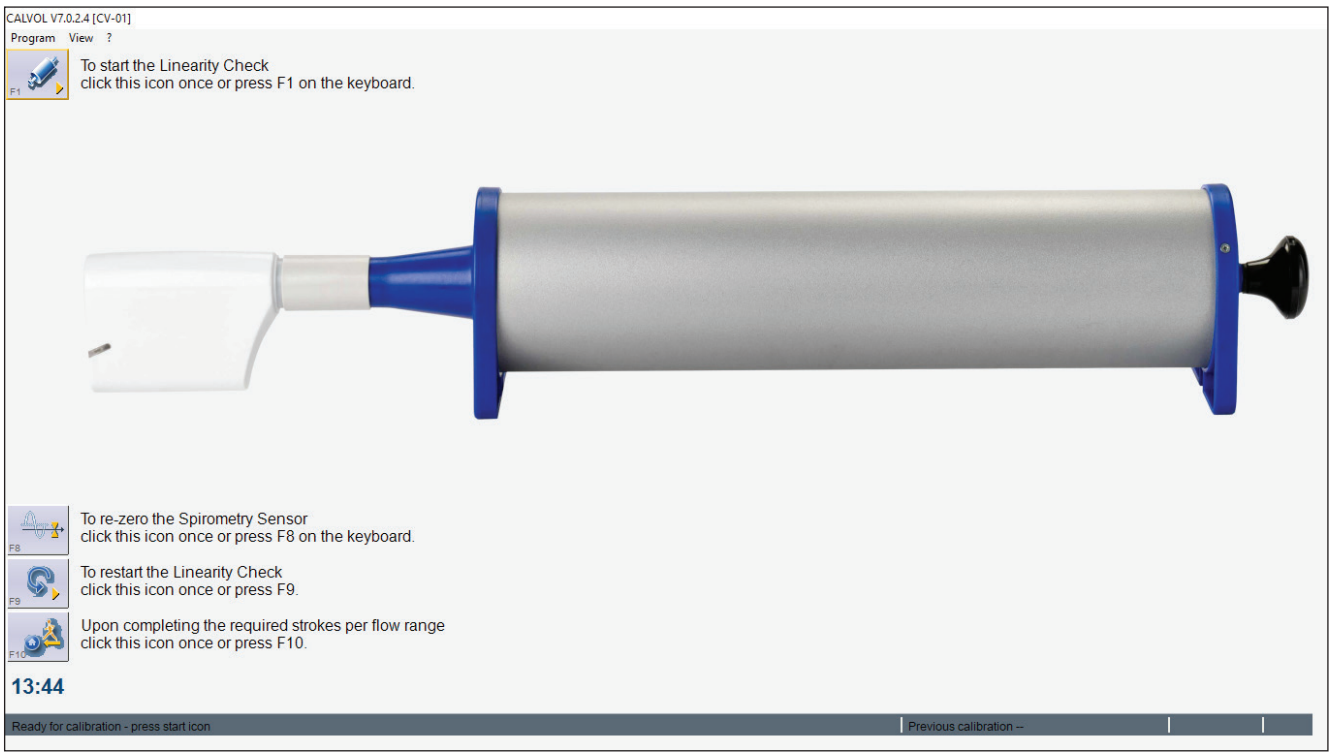
ERT PTs are pre-calibrated as part of their manufacture, as such MasterScope is a calibration-free device. It is possible to perform a linearity check to confirm that the device is measuring as expected. A 3L syringe used for such a check is not included as standard, but can be purchased on demand.

For a linearity check, a volume calibration should be performed weekly with a 3-L syringe to deliver three relatively constant flows at a low flow, then three at a mid-range flow and finally three at a high flow. The volumes achieved at each of these flows should each meet the accuracy requirement of ± 3.5%.

Proceed as follows:

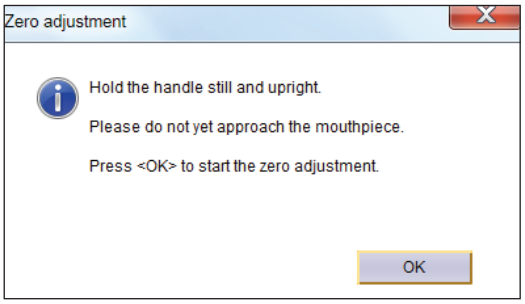
1. Press the <**Linearity Check**> icon. In the following screen you will be asked to verify the current ambient room conditions.

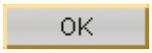
Confirm with the button <**Continue**>. Following window appears:



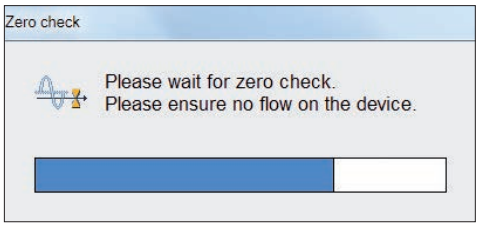
2. Use the 3-L calibration syringe for calibration. Connect the calibration syringe to the wireless spirometry sensor unit.

3. Press **<F1>** to start the procedure. An automatic zero adjustment of the connected pneumotach will be performed. The following window appears:



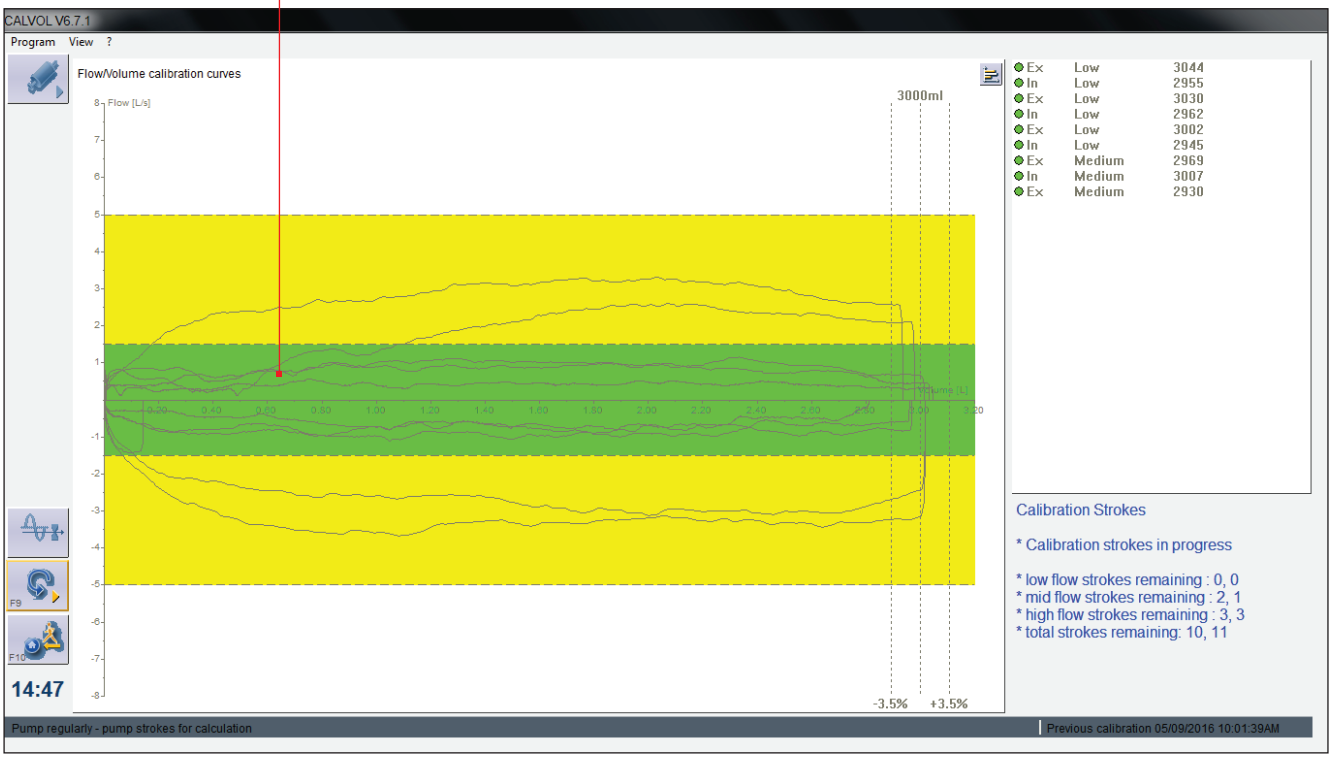


4. Press <**OK**> to start zero adjustment.



5. The screen now shows you the standard flow/volume calibration graph.
6. Start to pump the calibration syringe with complete strokes - incomplete strokes could lead to errors.
7. The first three strokes are discarded and can be performed at any flow. A counter in the bottom right window will count down the number of strokes performed. The inhaled (IN) and exhaled (EX) volume of each stroke is recorded in the top right window.

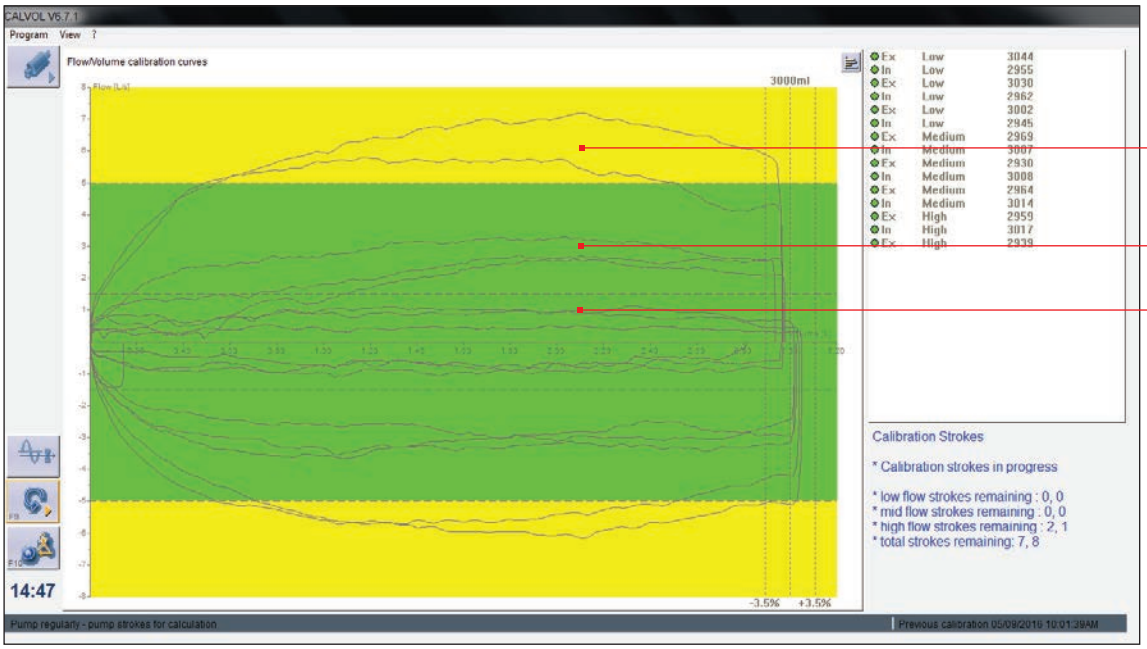
8. After completing the discard strokes, the lower right window changes and will instruct you to perform strokes in the low flow range. The screen will change to the standard flow/volume calibration graph with the low flow range highlighted in yellow. Perform the calibration maneuver with three complete strokes in the low flow range. The inspired (IN) and expired (EX) side on the graph will turn green when the correct number of strokes has been performed (minimum 3) at low flow range. If the flows are outside this range, it will not be counted.



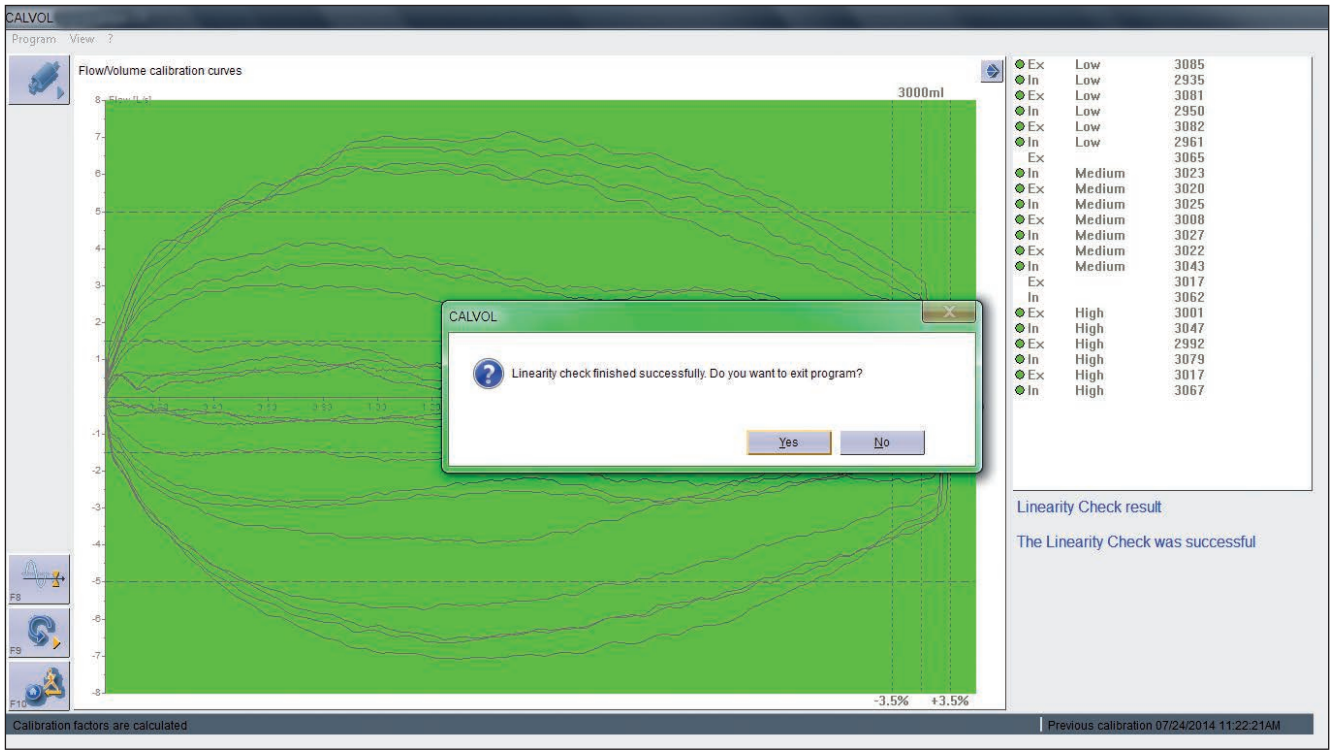
9. When both sides of the graph are green, the screen will then show the mid flow range highlighted in yellow. Perform the calibration maneuver with three complete strokes in the mid flow range.

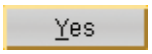
   When both sides of the graph are green, the screen will then show the high flow range highlighted in yellow. Perform the calibration maneuver with three complete strokes in the high flow range. The maximum number of strokes is 15.

For easier pumping in the flow range, turn the pump-knob while pumping to reduce the friction.



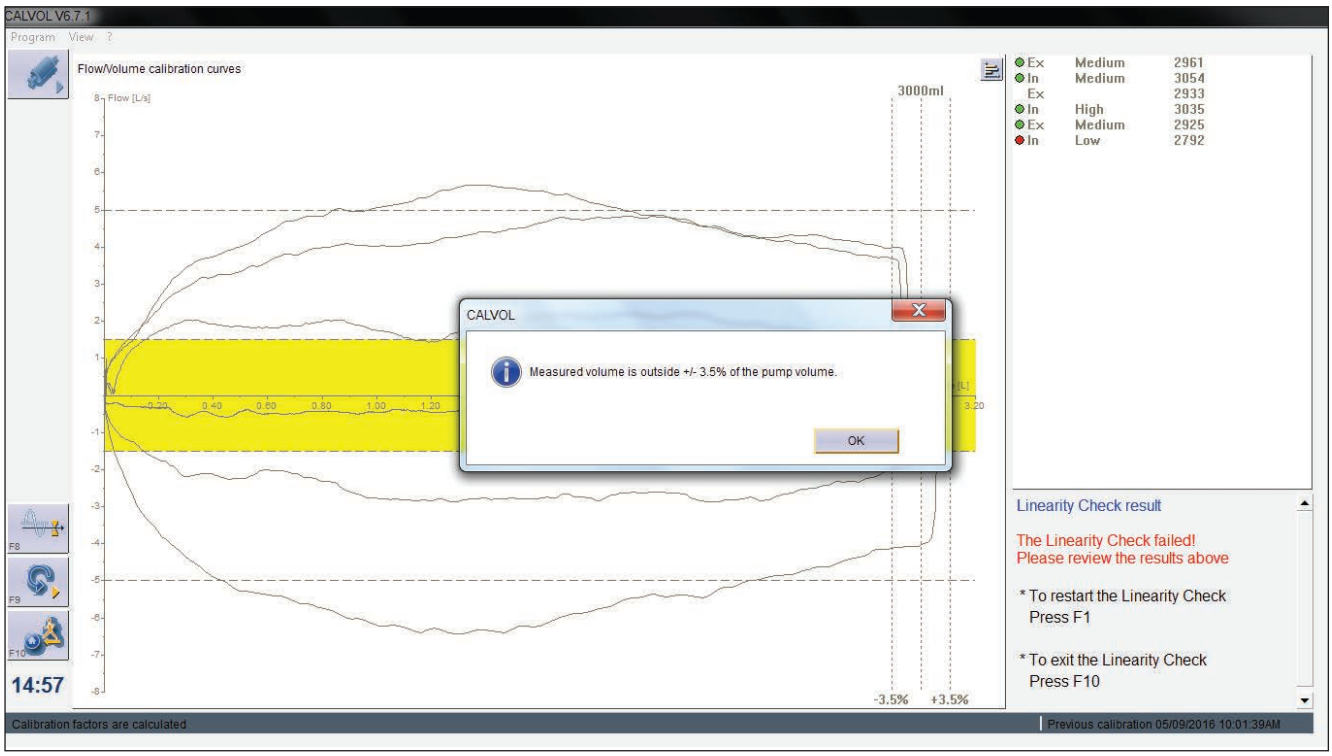
10. The result of each pump stroke is displayed in the upper right window. "**Green**" means better than +/- 3.5%.

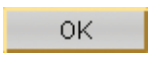




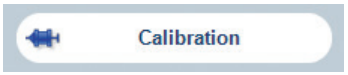
If the linearity check is successful (all areas are green), exit the linearity check program with <**Yes**>.

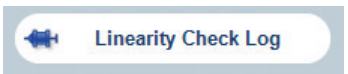
If any of the strokes are outside this limit, the calibration check will automatically stop, and the message "**Measured volume is outside +/- 3.5% of the pump volume.**"





Click <**OK**> and restart the linearity check with <**F1**>. If the check continues to fail, try changing the pneumotach head, and repeat the linearity check. If this also fails, please contact ERT Customer Care.





The linearity check log report can be printed by selecting <**Calibration**> and the <**Linearity Check Log**> icon.

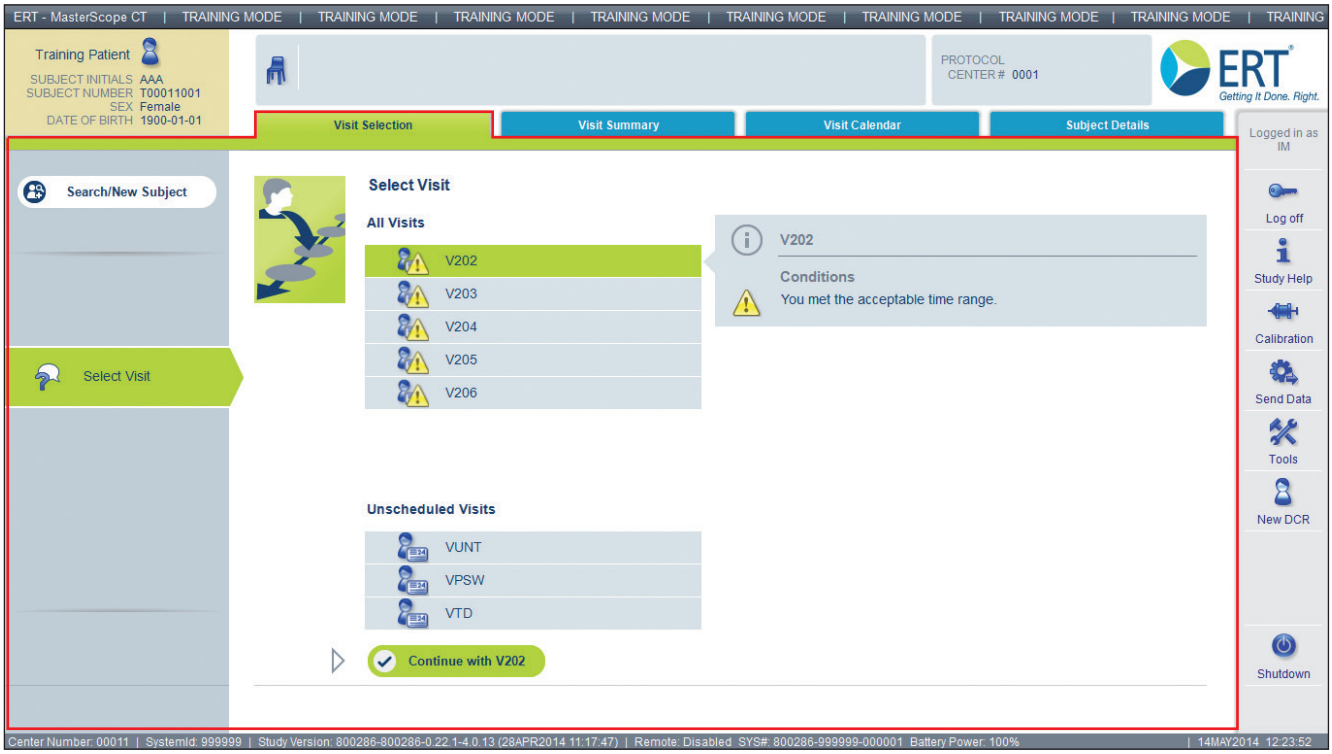
8. Visit

A visit is a summary of various measurement of different levels and activities for the currently active subject.

Visit Selection	shows	the next visit planned and available other visits
Visit Summary	shows	a summary of visits performed including key results performed
Visit Calendar	shows	planned visits (including ranges)
Subject Details	shows	the demographic data of the current subject

8.1 Visit Selection

Shows the next planned visit(s).

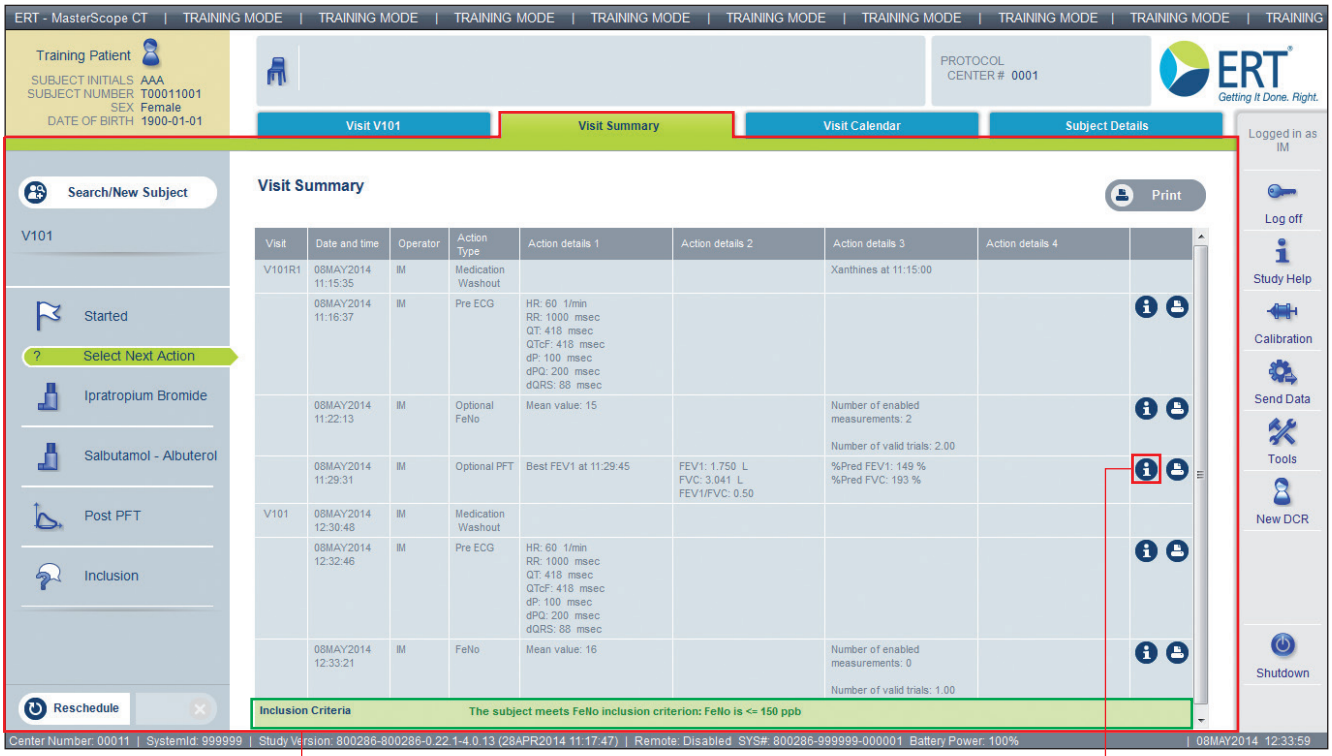


The visit selection screen shows all possible visits for the selected subject. Click the appropriate visit and additional information on the visit is displayed in the "**Conditions**" window.

8.2 Visit Summary

For the currently active subject, the visit summary shows

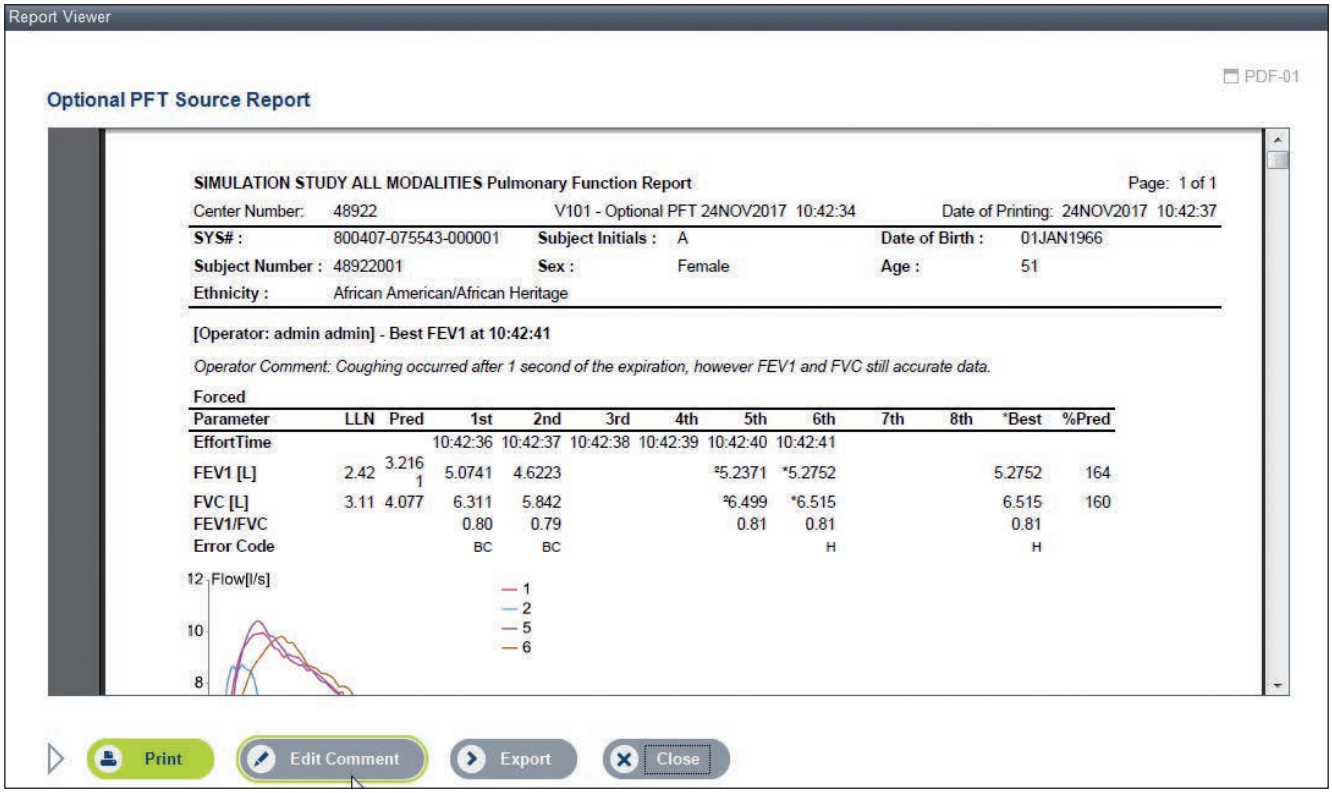
- Visits performed
- Date and time of performed actions
- Operator
- Action type
- Action details
- Detail (detailed report view - see next page)
- Edit
- Print

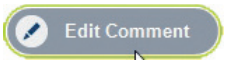


- Messages indicating criteria which were met or not.

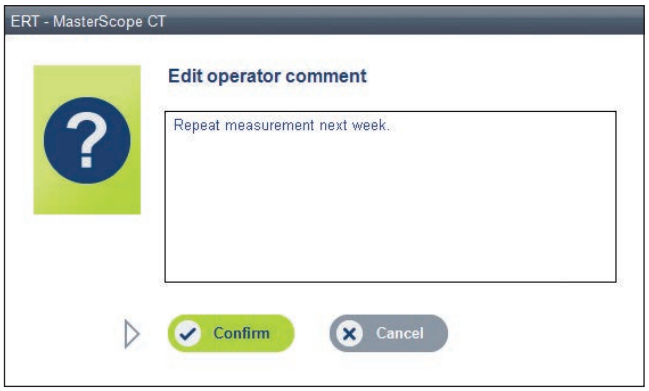
Click this icon to switch to the detailed report view of the respective visit.

Detailed report view:





Click <**Edit Comment**> and the entered operator comment can be overwritten.



The comment is saved with <**Confirm**>.

Change operator comment is only applicable until the measurement results have been transferred via Data Transfer to the ERT Data Center.

8.3 Visit Calendar

Shows all visits performed and planned for the current subject.