8.4 Subject Details

Shows all available subject details.

Update the values as described in Chapter "**System Overview**" - "**New Subject**".

Click on <**Save**> to store the data as entered.

9. Spirometry Measurement

Spirometry consists of the Slow Spirometry and /or Forced Spirometry measurement.

9.1 Basic Conditions prior to starting a Measurement

In order to perform high-quality measurements, the following conditions should be fulfilled:

- A waiting time of 10 to 15 minutes prior to the first examination ensures normal ventilation as a prerequisite for a high reproducibility of the examination results.
- To improve motivation, cooperation and coordination of the subject, the measurement procedure should be explained or, if necessary, demonstrated prior to starting the measurement.
- The subject is always measured in a straight sitting position.
- He/she should keep his/her head straight or slightly extended.
- The nose-clip is put on the lower half of the nose.
- The subject should slightly bite on the mouthpiece.
- Make sure that the subject carefully seals his/her lips around the mouthpiece.
- The subject's tongue should be below the mouthpiece.
- Dentures do not influence the measurement results.
- Tongue piercings should be removed prior to the measurement.

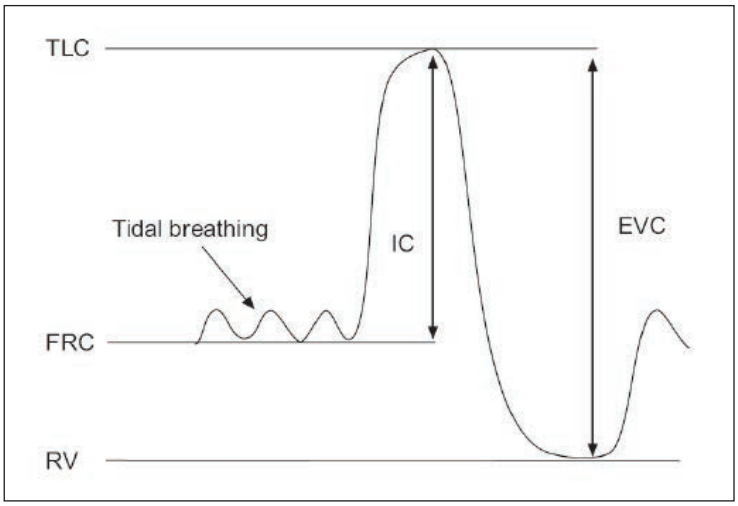
Activities that should be avoided prior to starting a measurement:

- Smoking within at least 1 h of testing
- Consuming alcohol within 4 h of testing
- Performing vigorous exercise within 30 min of testing
- Wearing clothing that substantially restricts full chest and abdominal expansion
- Eating a large meal within 2 h of testing.

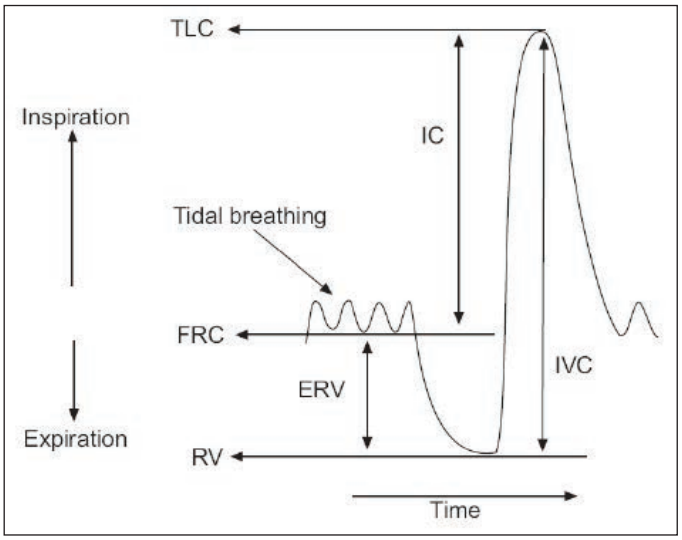
9.2 Slow Spirometry (VC and IC)

Definition of VC and IVC

The VC is the volume change at the mouth between the position of full inspiration and complete expiration, expressed in litres at BTPS. The slow VC can be derived in two ways. The expiratory vital capacity (EVC) is the maximal volume of air from the point of maximal inhalation. The IVC or VCin is the maximal volume of air inhaled from the point of maximal exhalation, achieved by an unforced exhalation from end-tidal inspiration. These maneuvers are unforced, except at the point of reaching RV or TLC, respectively, where extra effort is required.



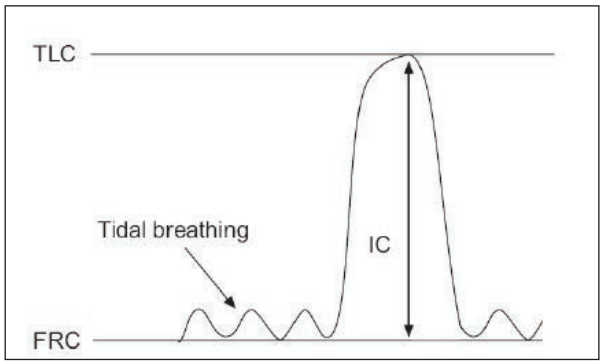
Tracing of tidal breathing followed by an inspiratory maneuver to total lung capacity (TLC) followed by a full but not forceful expiration to residual volume (RV) to record EVC or VCex; FRC: functional residual capacity.



Tracing of tidal breathing followed by an expiratory maneuver to residual volume (RV), followed by a full inspiration to total lung capacity (TLC) to record IVC or VCin. FRC: functional residual capacity; ERV: expiratory reserve volume.

Definition of IC

Inspiratory capacity (IC) is volume change recorded at the mouth when taking a full inspiration with no hesitation, from a position of passive end-tidal expiration, i.e. FRC, to a position of maximum inspiration, expressed in liters at BTPS. IC is an indirect estimate of the degree of lung hyperinflation at rest, and is useful to assess changes in FRC with pharmacological interventions and physical exercise.



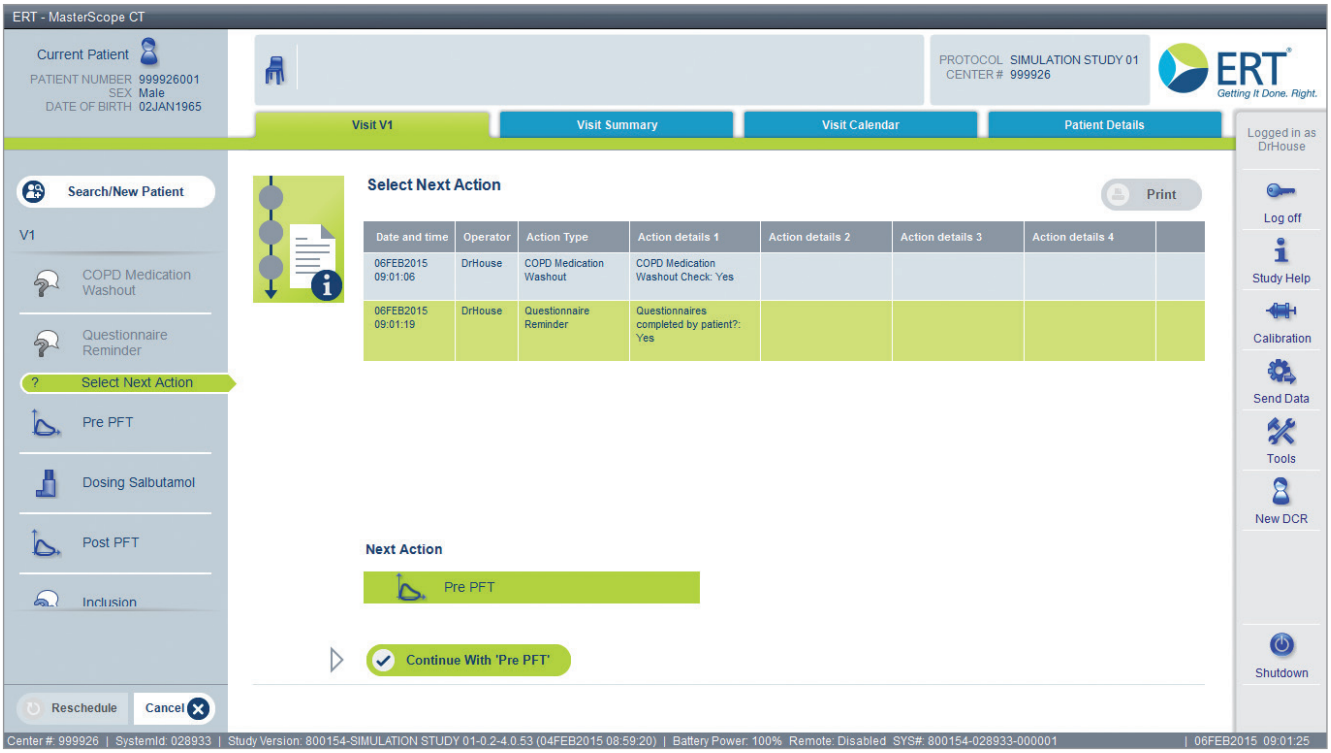
Tracing of tidal breathing followed by an inspiratory maneuver to total lung capacity (TLC) to record inspiratory capacity (IC).

9.3 Perform a Slow Spirometry Measurement

Please observe the instructions for hygiene of your system.

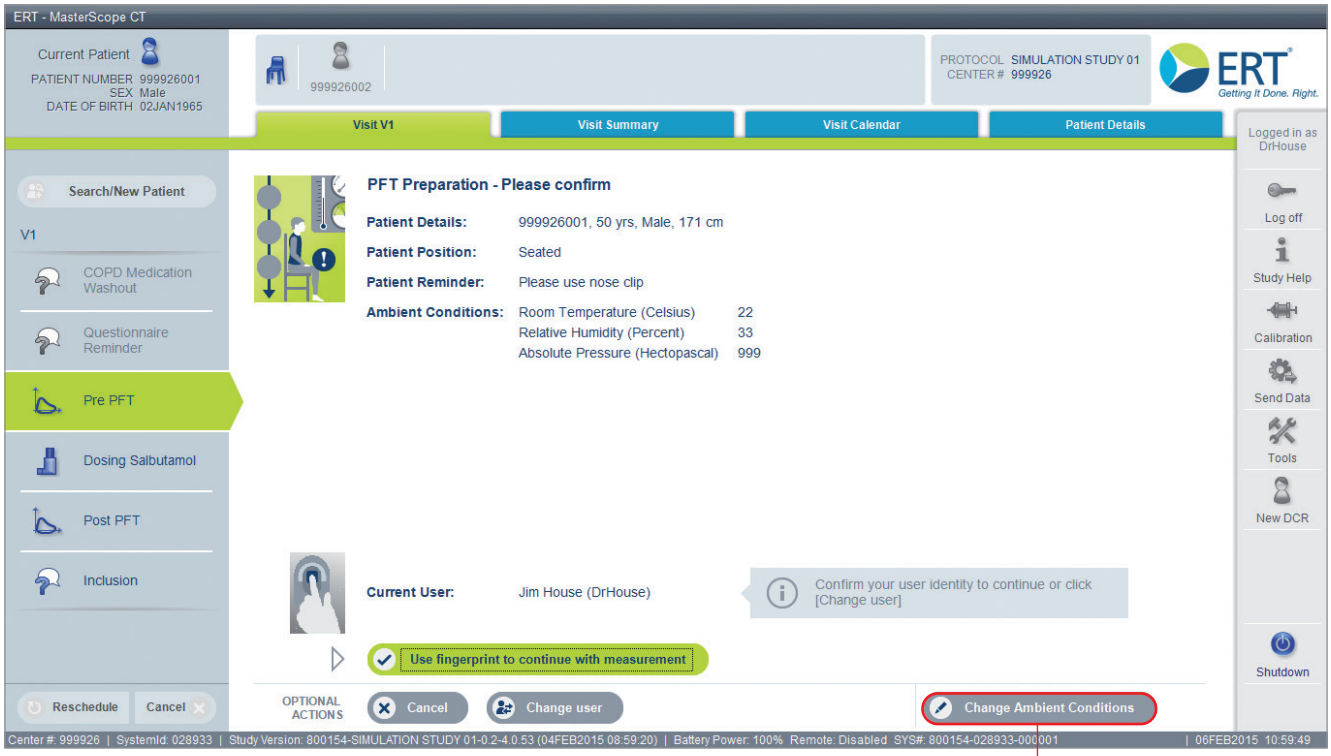
To ensure optimal subject safety, we recommend only the use of accessories which are distributed with the MasterScope.

Make the proper preparations.
(see "**Basic Conditions prior to starting a Measurement**")



Start Spirometry by pressing the <**Continue With 'Pre PFT'**> icon.

Please follow the notes on the screen.

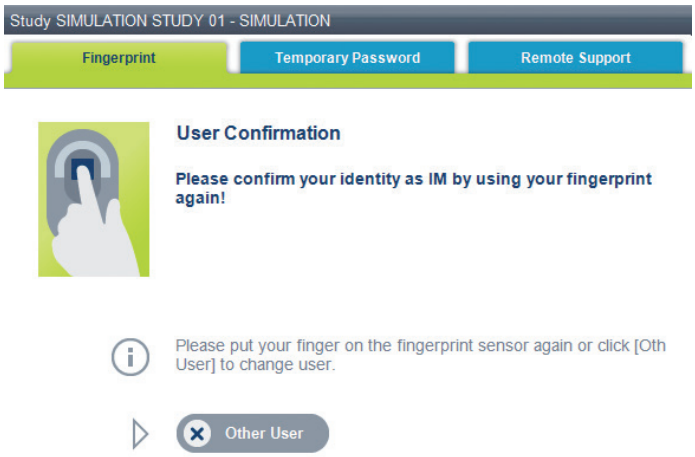


Please check and, if necessary, correct the ambient conditions shown on the screen by clicking <**Change Ambient Conditions**>.

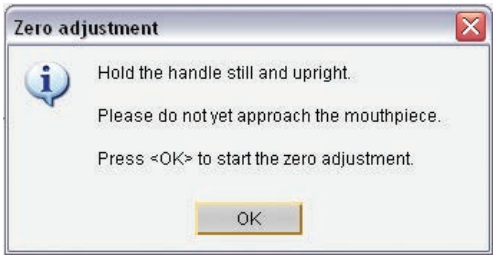
Put your finger on the fingerprint sensor to continue.

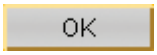
As an alternative, click the <**Use finger print to continue with measurement**> icon to continue.

Prior to starting the Spirometry measurement, the authorized investigator has to verify again.

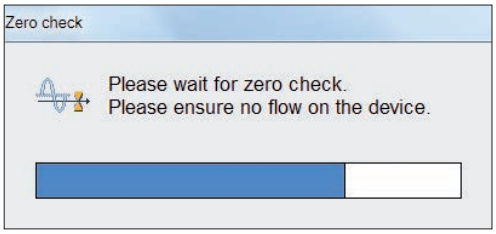


Any measurement starts with a zero adjustment of the pneumotach.





Continue with <**OK**>.



Do not breathe through the pneumotach and do not move the pneumotach during zero adjustment.

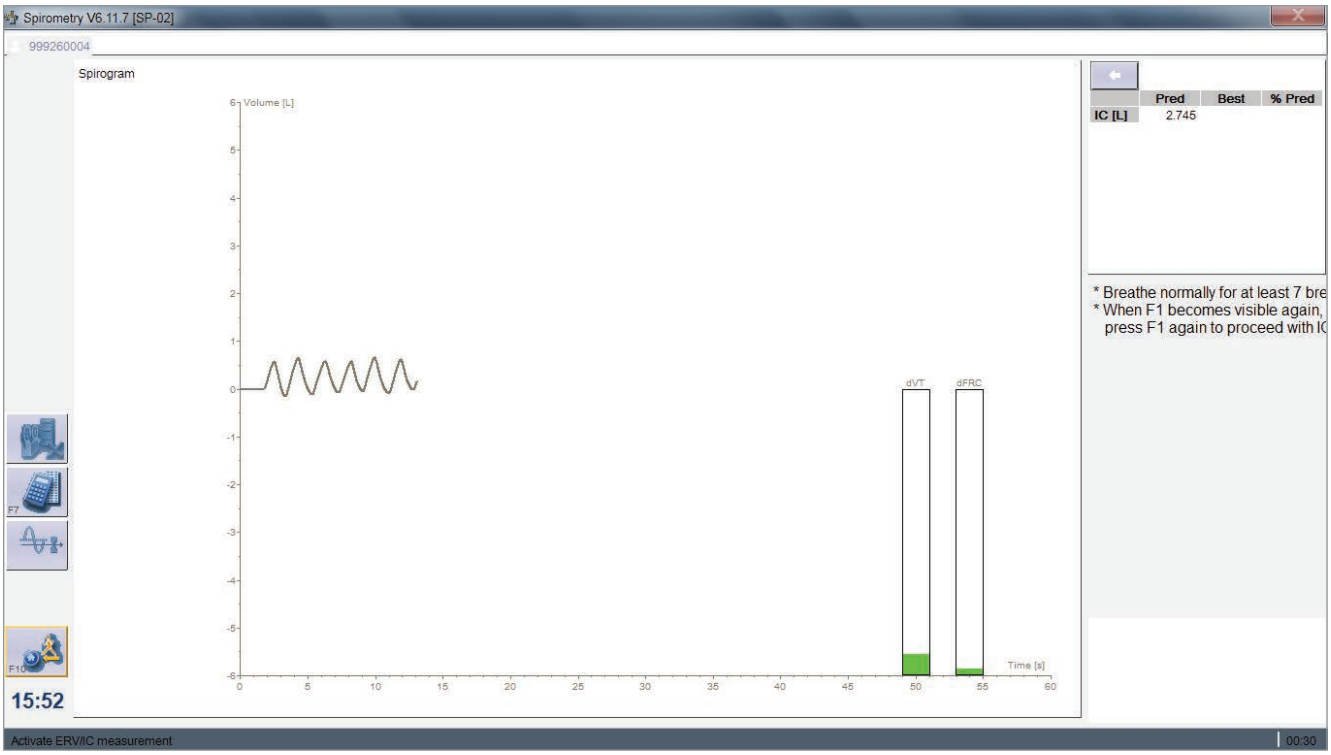
If the zeroing fails, a corresponding message will be displayed.

When the zero adjustment is complete, instruct the subject to close his/her nose with the nose-clip and to approach the mouthpiece. Make sure his/her lips seal around the mouthpiece.

Instruct the subject to hold the sensor in one hand.

The results of the Spirometry measurement depend on the subject's cooperation. Explain the breathing exercise to your subject thoroughly.

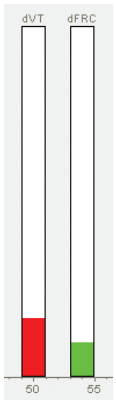
Start with <**F1**>.
The subject should breathe normally until stable tidal breathing is shown.



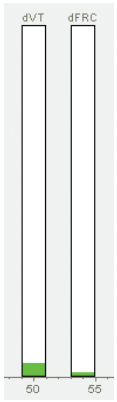
After some breaths, the <**F1**> icon will re-appear.

Wait until the baseline is stable (indicated by the dFRC and dVT bars). Stability is achieved when both bars are green.

Wait longer

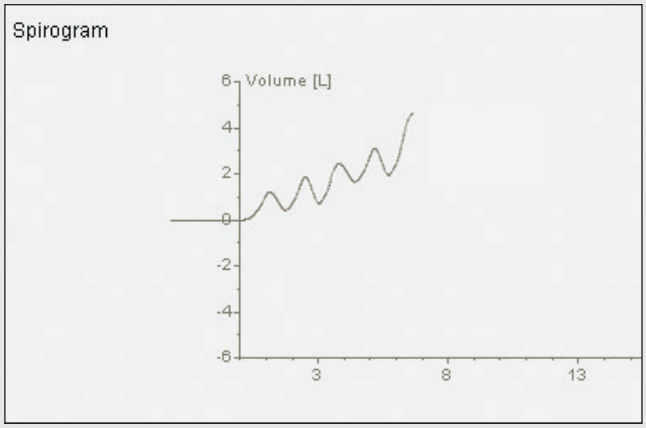


Cont.with <**F1>** (2^{nd} best)



Continue with <**F1**>

Note:



The volume signal must run horizontally after the measurement was started (subject not yet breathing into device). If you observe curves going up or down (see example) during a measurement, the pneumotach has not been properly zeroed.

In order to fix this, press <**F7**> "**Result**" to enter the Result phase and then press <**F8**> "**Zero**" to start zero adjustment again.

Make certain that the pneumotach is not moved and the subject is not breathing through the mouthpiece.

Hint: Close the opening of the pneumotach during zero adjustment with the palm of your hand.

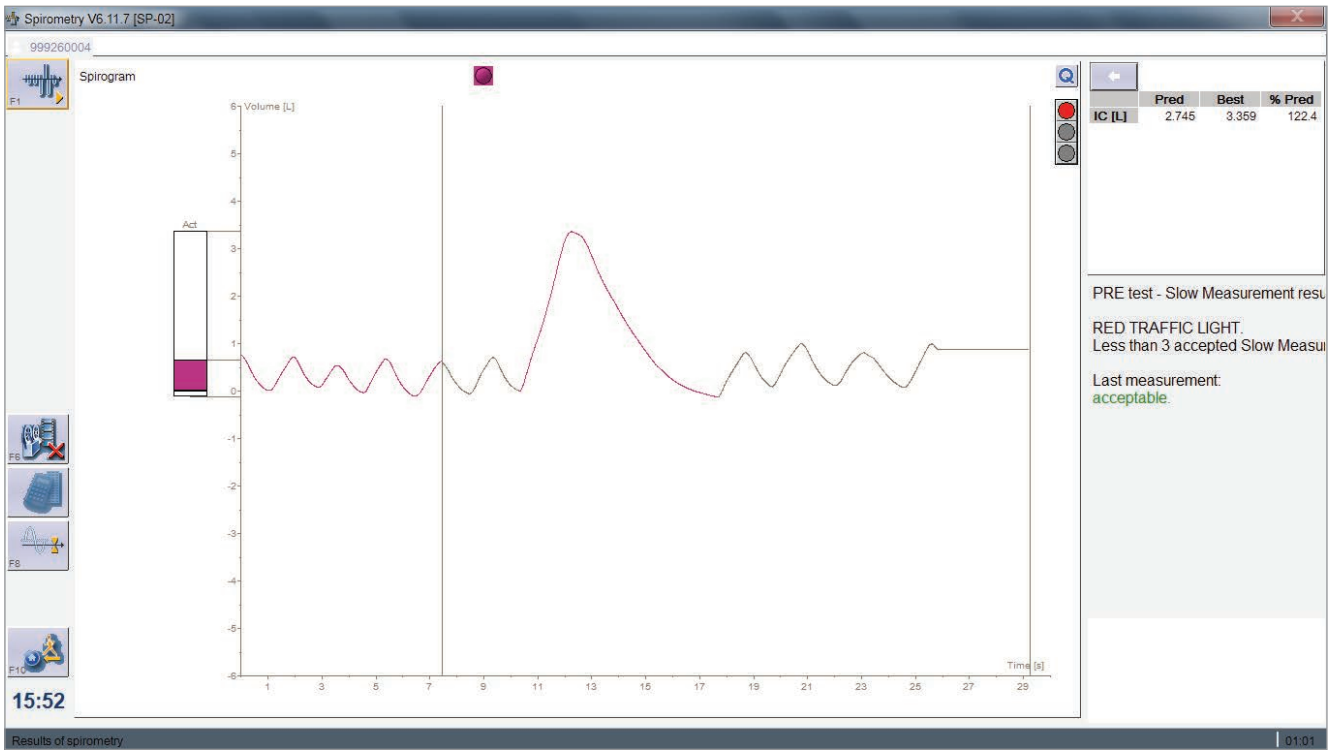
Two vertical lines will automatically be set in the spirogram window indicating the space to be filled by the breathing maneuver.

9.3.1 Recording of Different SVC Maneuvers on the MasterScope

Depending on the study protocol one of the following maneuver needs to be performed to record the parameters needed – please also see the protocol-specific Short Guide.

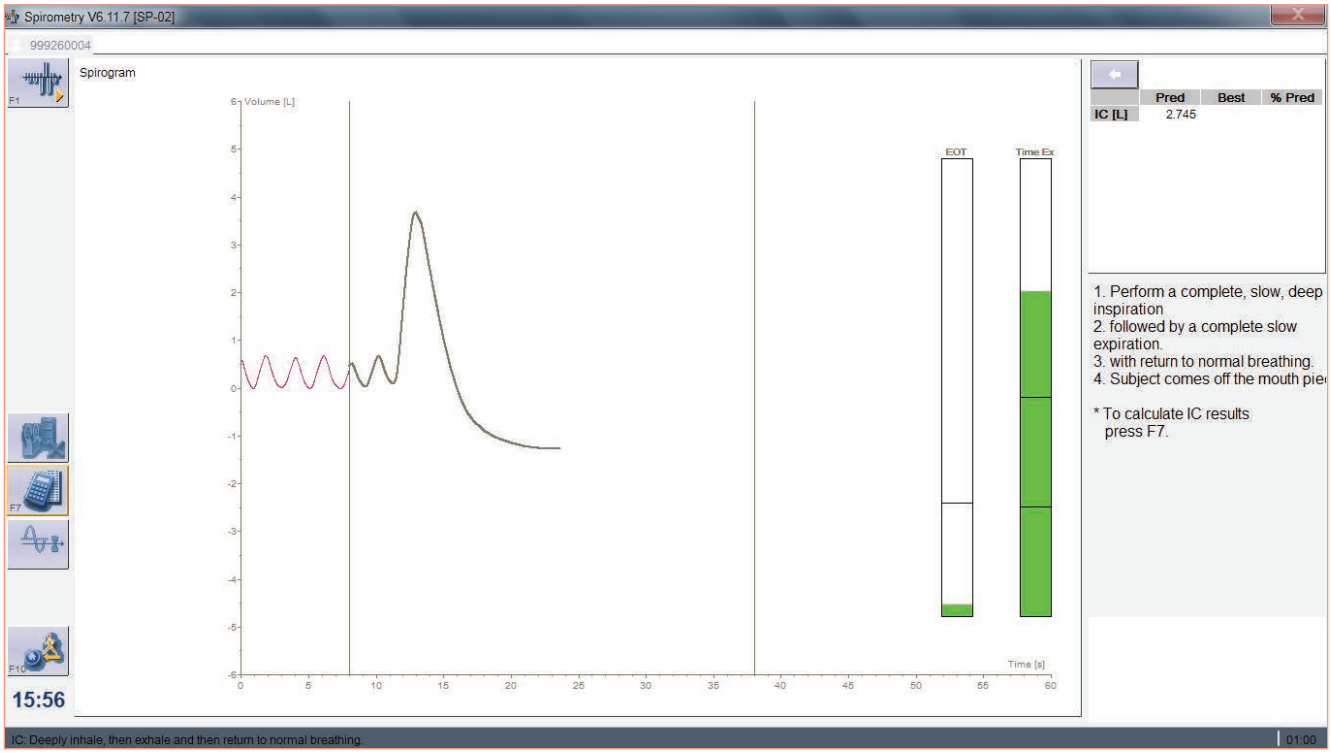
IC - Inspiratory Capacity

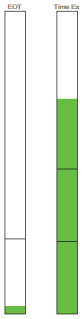
The measurement starts with tidal breathing (establishing a stable baseline may require more than 5 tidal breaths). From tidal breathing the subject takes in a maximum inspiration to total lung capacity (TLC). When TLC is achieved, the subject's exhalation should be relaxed and the subject should come back to tidal breathing (no maximal expiration to ERV).



VCEx or VEX - Expiratory Vital Capacity

The measurement starts with tidal breathing (establishing a stable baseline may require more than 5 tidal breaths). From tidal breathing the subject takes in a maximum inspiration to total lung capacity (TLC). When TLC is achieved, a full but relaxed exhalation to residual volume (RV) should occur, followed by an inspiration back to tidal breathing to record EVC or VCex.



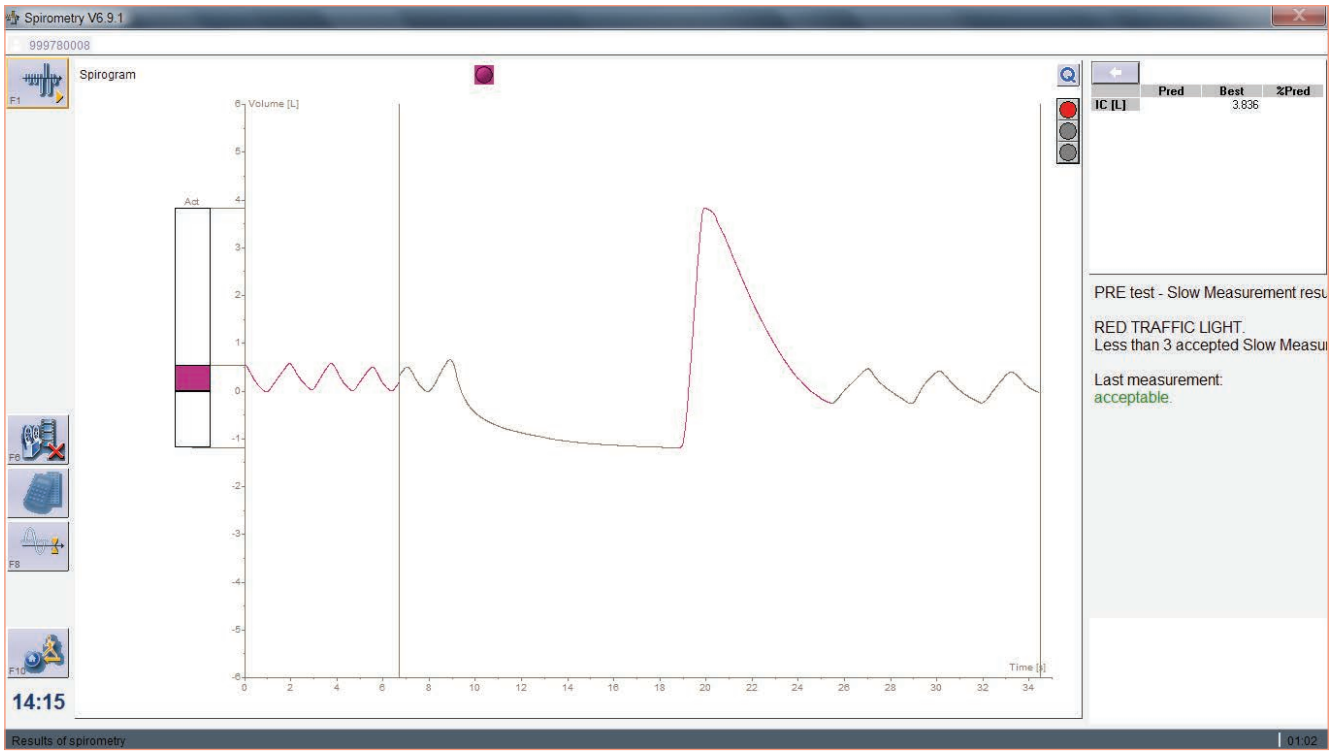


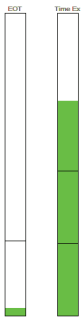
The **Time Ex (expiration time) of the maneuver** should last at least 6 seconds. For visualization, a bar appears which is slowly filled up in red color during expiration. After 3 or 6 seconds of expiration (children or adult), the filling color turns green and this test quality criterion is fulfilled.

The **EOT (End of Test)** bar shows the change in volume in the last second. As the bar shrinks and changes from red to green, the end of test quality criterion is fulfilled.

VCin or IVC - Inspiratory Vital Capacity

The measurement starts with tidal breathing (establishing a stable baseline mayrequire more than 5 tidal breaths). From tidal breathing the subject exhales fully to residual volume (RV), followed by a full inspiration to total lung capacity (TLC) and back to tidal breathing to record IVC or VCin.





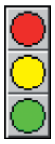
The Time Ex (expiration time) of the maneuver should last at least 6 seconds. For visualization, a bar appears which is slowly filled up in red color during expiration. After 3 or 6 seconds of expiration (children or adult), the filling color turns green and this test quality criterion is fulfilled.

The **EOT (End of Test)** bar shows the change in volume in the last second. As the bar shrinks and changes from red to green, the end of test quality criterion is fulfilled.

Press <**F7**> to end the test and see the results.

The quality of the slow spirometry measurement depends on the subject's cooperation. In order to assess reproducibility (repeatability) and thus the quality of cooperation, it is recommended to perform at least 3 trials.

Press <**F1**> to record another trial.



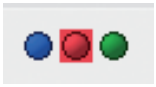
This traffic light indicates the repeatability of the trial:

Red: Less than 3 efforts were performed.

Yellow: 3 or more accepted efforts were performed and the repeatability criteria were not met.

Green: 3 or more accepted efforts were performed and the repeatability criteria were met.

A green traffic light does not imply that all ATS criteria for the test are met. The green light only signifies that repeatability has been established.



The best breathing maneuver (in our example the red one) will automatically be calculated and displayed on the screen.

Explanation of icons from left to right:

- Show previous trial
- Show all trials
- Show next trial

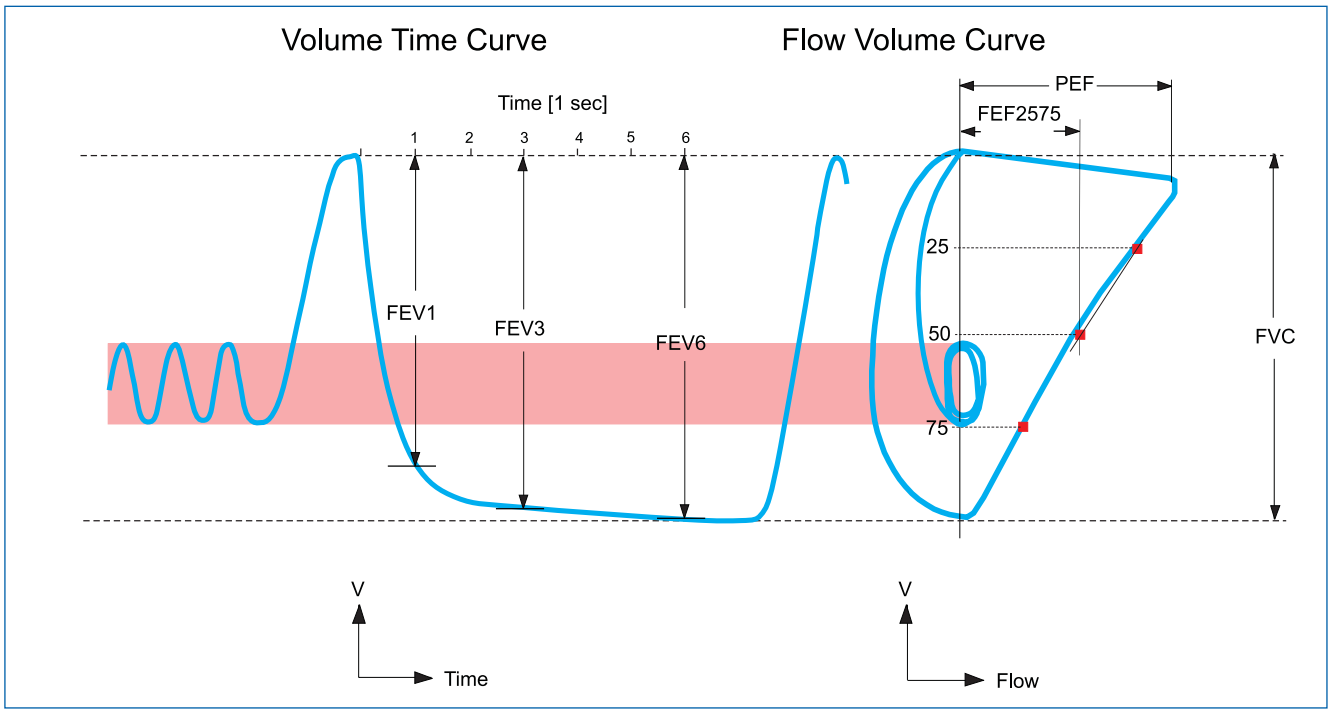
Up to 8 efforts can be performed.

You may now continue with the Forced Spirometry measurement by pressing <**F2**> (depends on study setup. In screenshot above <**F2**> is not shown but might be available in your trial.).

It is not possible to add Slow Spirometry efforts once you have started a Forced Spirometry effort.

9.4 Forced Spirometry Measurement

Parameter Definition



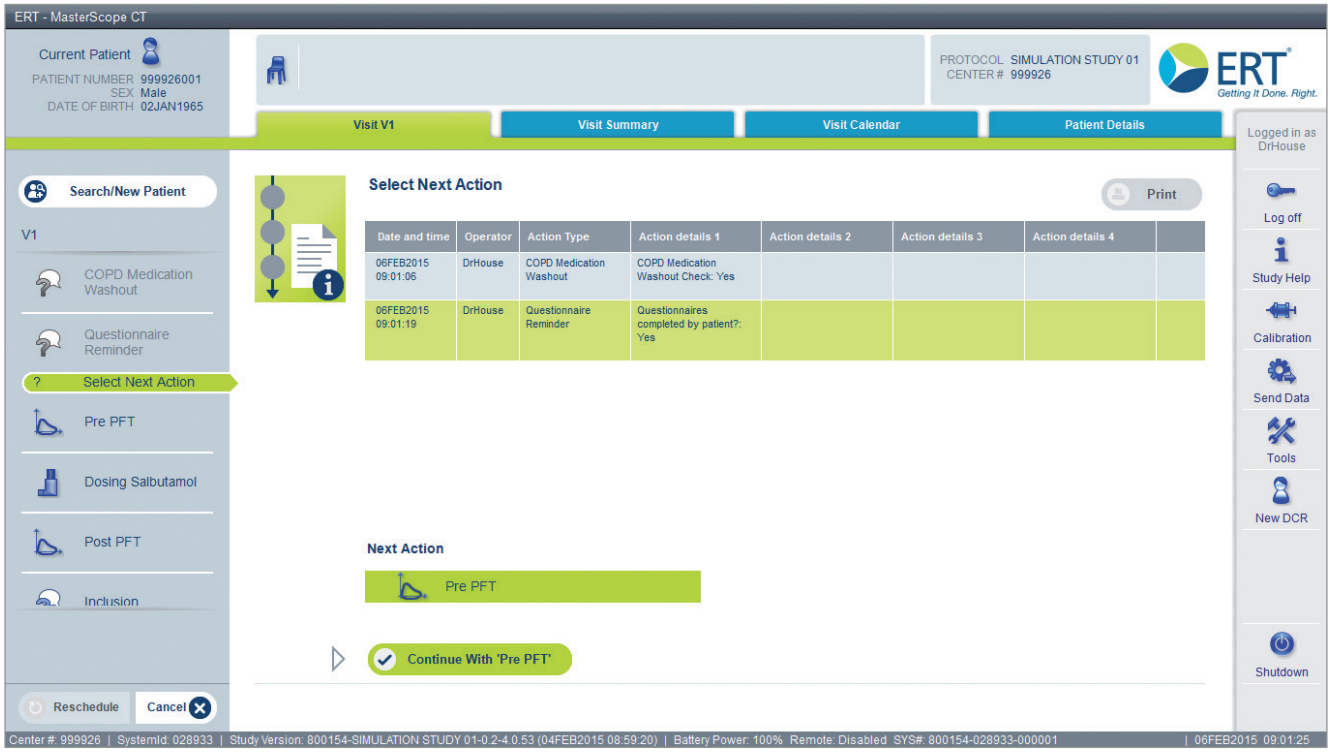
FEV1	Forced expiratory volume after 1 second
FVC	Forced expiratory vital capacity
PEF	Peak expiratory flow (peak flow)
FEF25-75	Mean maximal expiratory flow between 25 and 75% of FVC
FEV3	Forced expiratory volume after 3 seconds
FEV6	Forced expiratory volume after 6 seconds
FEV1/FVC	FEV1 in % of forced expiratory vital capacity
FEV1/FEV6	FEV1 in % FEV6

9.5 Perform a Forced Spirometry Measurement

Please observe the instructions for hygiene of your system.

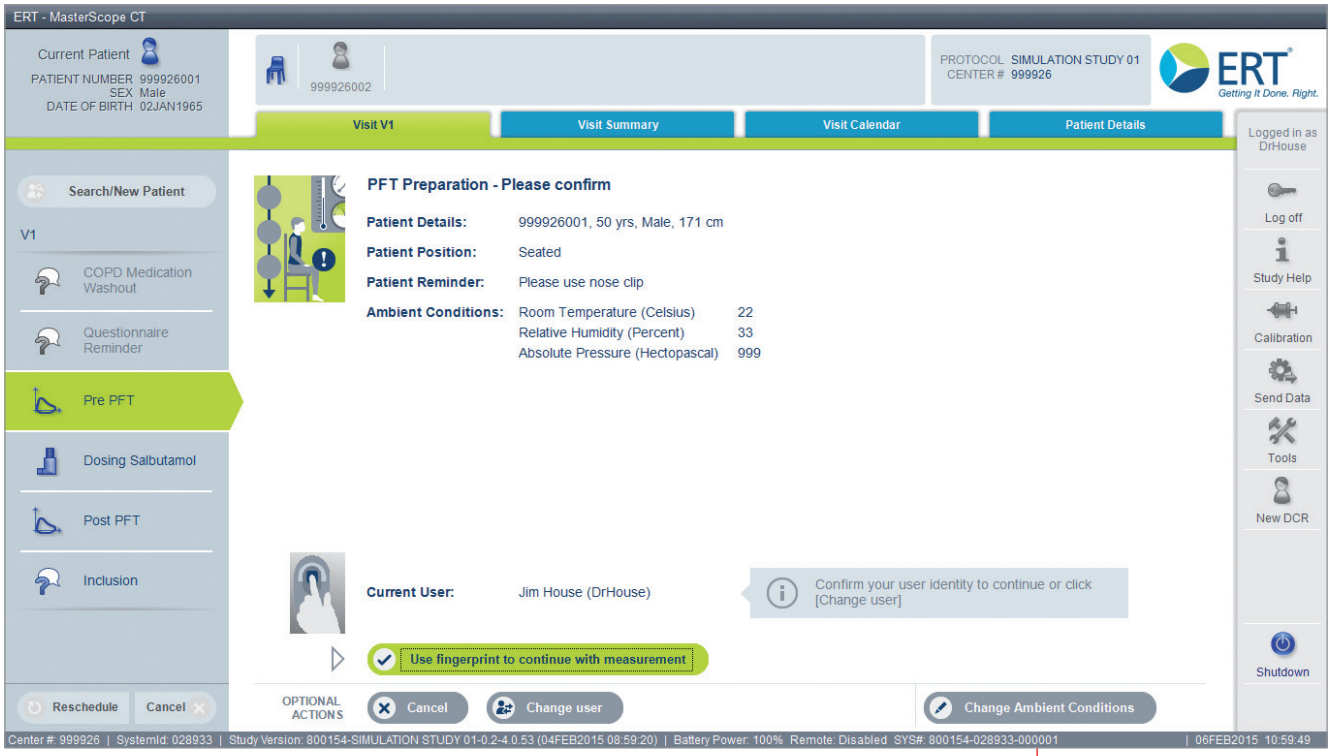
To ensure optimal subject safety, we recommend only the use of accessories which are distributed with the MasterScope.

Make the proper preparations.
(see "**Basic Conditions prior to starting a Measurement**")



Start Spirometry by pressing the <**Continue With 'Pre PFT'**> icon.

Please follow the notes on the screen.



Change Ambient Conditions

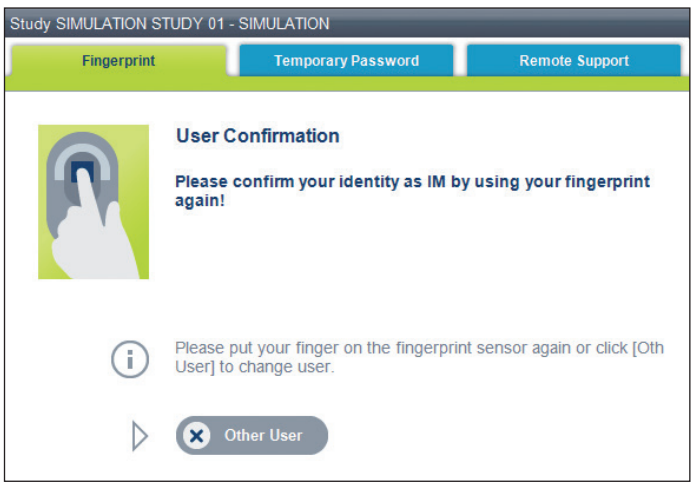
Please check and, if necessary, correct the ambient conditions shown on the screen.

Put your finger on the fingerprint sensor to continue.

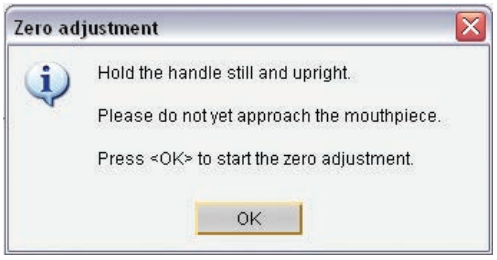
As an alternative, click the <**Use finger print to continue with measurement**> icon to continue.

Use finger print to continue with measurement

Prior to starting the Spirometry measurement, the authorized investigator has to verify again.

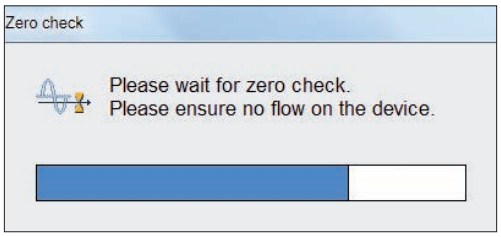


Any measurement starts with a zero adjustment of the pneumotach.



OK

Continue with <**OK**>.



Do not breathe through the pneumotach and do not move the pneumotach during zero adjustment.

If the zeroing fails, a corresponding message will be displayed.

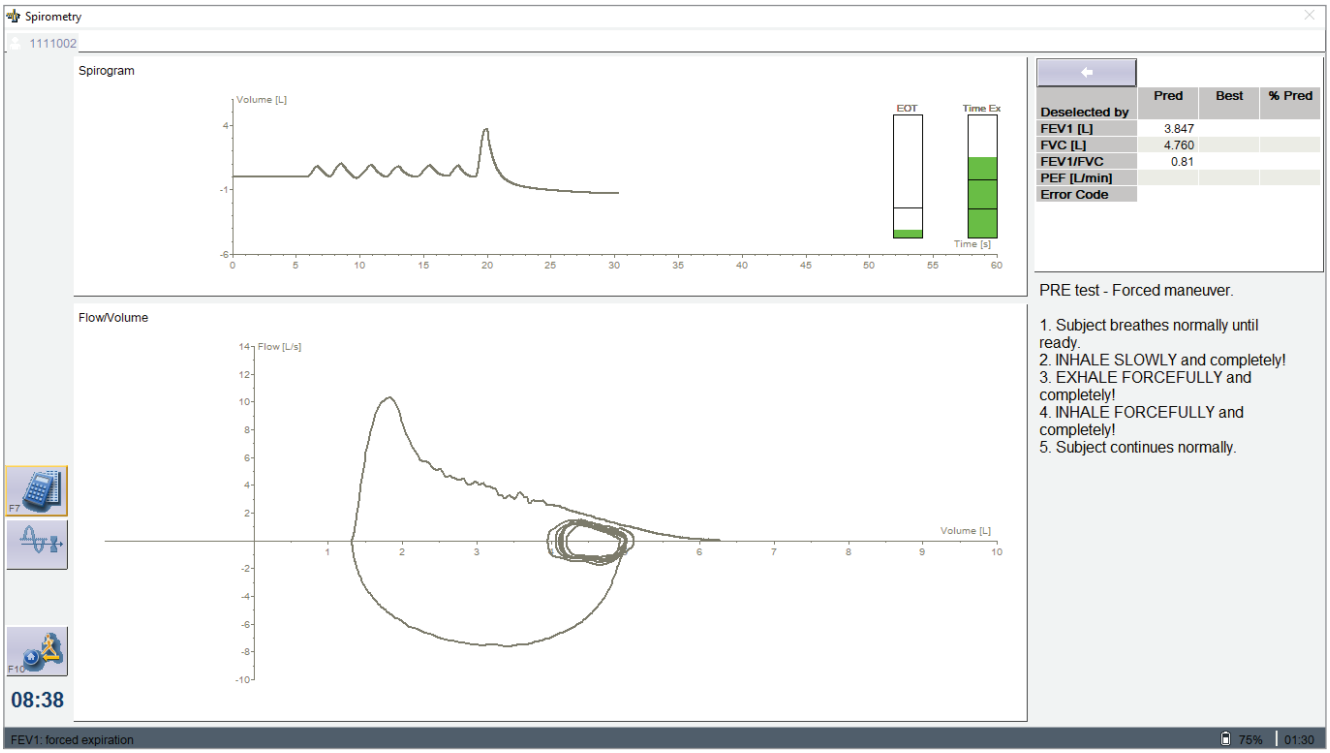
When the zero adjustment is complete, instruct the subject to close his/her nose with the nose-clip and to approach the mouthpiece. Make sure his/her lips seal around the mouthpiece.

Instruct the subject to hold the pneumotach in one hand.

The results of the Spirometry measurement depend on the subject's cooperation. Explain the breathing exercise to your subject thoroughly.

Start with <**F2**>.

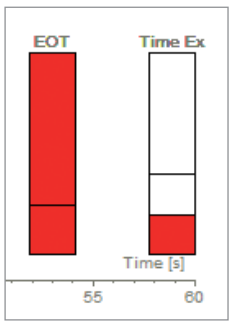
The subject should breathe normally until stable tidal breathing is shown.



From tidal breathing, the subject is instructed to inhale as deeply as possible. Without interruption, the subject should now immediately exhale as fast and as much (FEV1) and as long (FVC) as possible. The maneuver is usually completed by a maximal inhalation (VC IN) and continue to normal breathing.

Please note: During the whole examination, the subject must not leave the mouthpiece.

The upper window shows the spirogram in volume-time display.
The lower window shows the flow-volume curve.



The **Time Ex (expiration time)** of the forced expiratory maneuver should last at least:

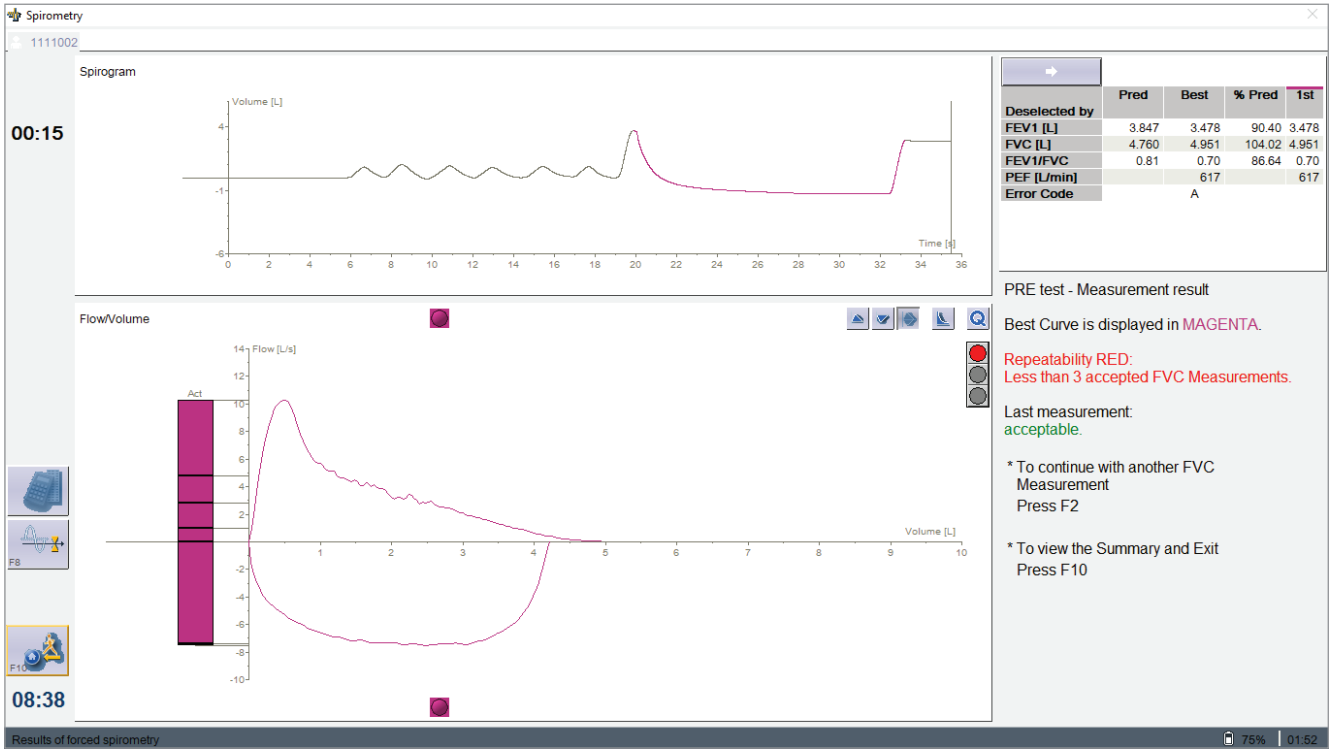
- 3 seconds for patients <10 years
- 6 seconds for patients >= 10 years.

For visualiziation, a bar appears:

After 3 seconds (first bar for patients < 10 years) or 6 seconds (second bar for patients >=10 years) of expiration, the filling color turns green and this test quality criterion is fulfilled.

The **EOT (End of Test)** bar shows the change in volume in the last second. As the bar shrinks and changes from red to green, the end of test quality criterion is fulfilled.

Screen display after pressing <**F7**> "**Result**".



Explanation of icons from left to right:

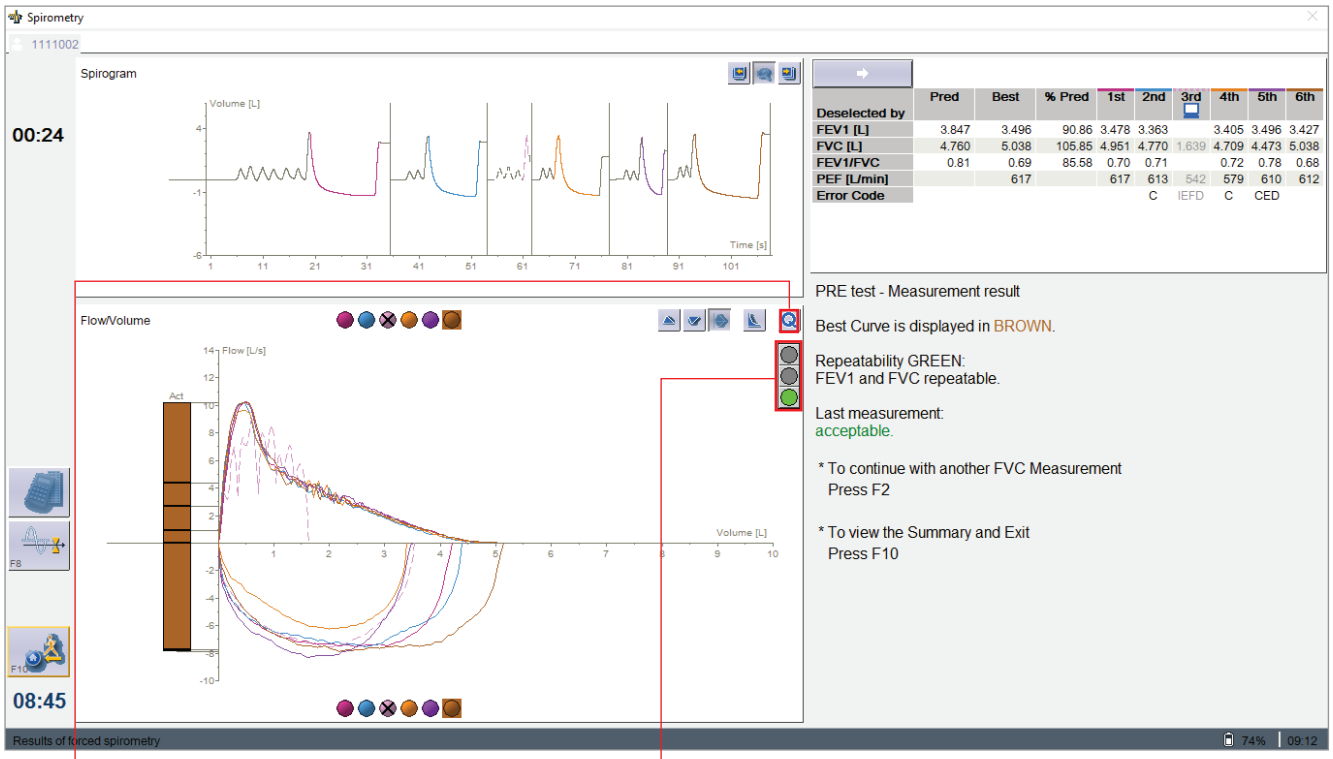
- Show expiration only
- Show inspiration only
- Show F/V loop
- Switch to Tiffeneau
- Show quality errors

The quality of the flow-volume curve depends on the subject's cooperation.In order to assess reproducibility (repeatability) and thus the quality of cooperation, it is recommended to perform at least 3 trials. The result of the best and the second best trial for FEV1 and FVC may differ by ≤ 150 mL or < 5%.
For FVC ≤ 1 L a difference of ≤ 100 mL is valid*.

* Literature:

- MR Miller et al. Series "ATS/ERS Task Force: Standardisation of Lung Function Testing", Standardisation of Spirometry, Eur Respir J 2005; 319-338 Copyright © ERS Journals Ltd. 2005

Screen display after three reproducible trials:



This traffic light indicates the repeatability of the trial:

Red: Less than 3 efforts were performed.

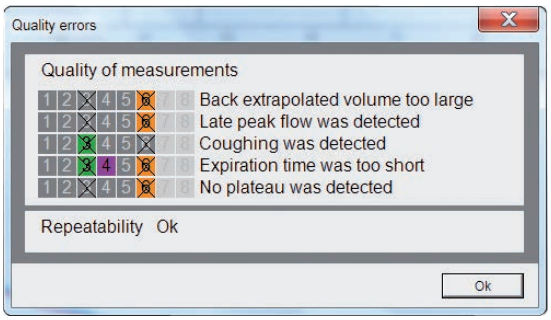
Yellow: 3 or more accepted efforts were performed and the repeatability criteria were not met.

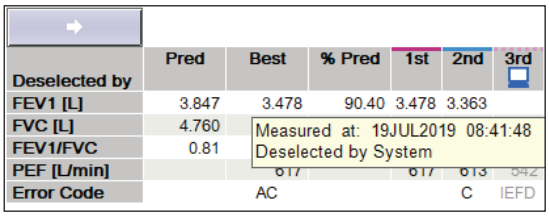
Green: 3 or more accepted efforts were performed and the repeatability criteria were met.

A green traffic light does not imply that all ATS criteria for the test are met. The green light only signifies that repeatability has been established.

Up to 8 efforts can be performed.

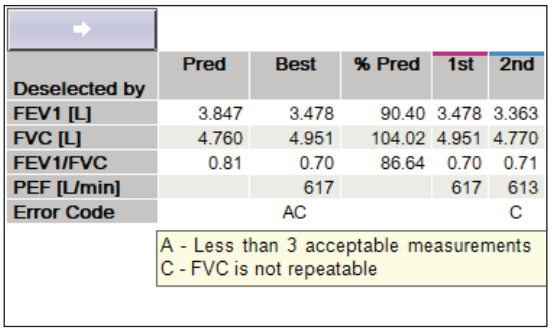
Clicking the Quality Errors Button opens the quality errors window shown below. Quality errors of each effort are highlighted and described in this window.





With mouse over on the effort number (here 3rd effort) the date/time of the measurement will be displayed and if the effort was deselected by the system or by the user (if applicable).

Colors above the effort number matching the color of the flow/volume loop for easy identifing the loop vs. the parameters. Dashed color indicates the effort was deselected while a solid colored line indicates the effort is valid.



With mouse over of the error codes (here in best column error code A and C) the description of the error code will be displayed.

9.6 ATS Criteria (ATS/ERS 2005)

Forced Spirometry: Acceptability of individual efforts

- **A plateau was detected at the end of the expiration**
  The volume change in the last second of expiration is less than 25 mL.
- **Expiration time is long enough (6 sec)**
  The duration of expiration is greater than 6 seconds.
- **Back-extrapolated volume is not excessive**
  The back extrapolated volume is less than 150 mL or less than 5% of FVC.
- **No late peak flow was detected**
  The peak flow is reached earlier than 120 ms after extrapolated start of the maneuver. Indicates a poor effort.
- **No coughing was detected in the first part of the expiration**
  Coughing during the first second of the maneuver affects the measured FEV1 value and other parameters.

Forced Spirometry: Repeatability of test set

- **No repeatability: Less than 3 acceptable measurements recorded**
- **FEV1 repeatability is unacceptable**
  Difference in FEV1 from best to second best is greater than 150 mL.
- **FVC repeatability is unacceptable**
  Difference in FVC from best to second best is greater than 150 mL.
- **PEF repeatability is unacceptable**
  Difference in PEF from best to second best is greater than 0.67 L/sec.

Slow Spirometry: Repeatability of test set

- **IC repeatability is unacceptable**
  Coefficient of Variation (CV) is greater than 6%.
- **VC repeatability is unacceptable**
  Difference in VC from highest to second highest is greater than 150 mL.

Messages for repeatability and/or acceptability are evaluated. This is also recalculated after every new measurement performed.

In the MasterScope, acceptability and repeatability errors are implemented as error codes. These error codes are shown on the screen and on the PFT reports:

Forced Spirometry:

E code	Description
A	No repeatability: Less than 3 acceptable forced measurements
B	FEV1 repeatability is unacceptable
C	FVC repeatability is unacceptable
D	Expiration time was too short
E	No plateau was detected at the end of the expiration
F	Back extrapolated volume was too large
G	PEF repeatability is unacceptable
H	Late peak flow detected
I	Coughing was detected in the first part of the expiration

Slow Spirometry:

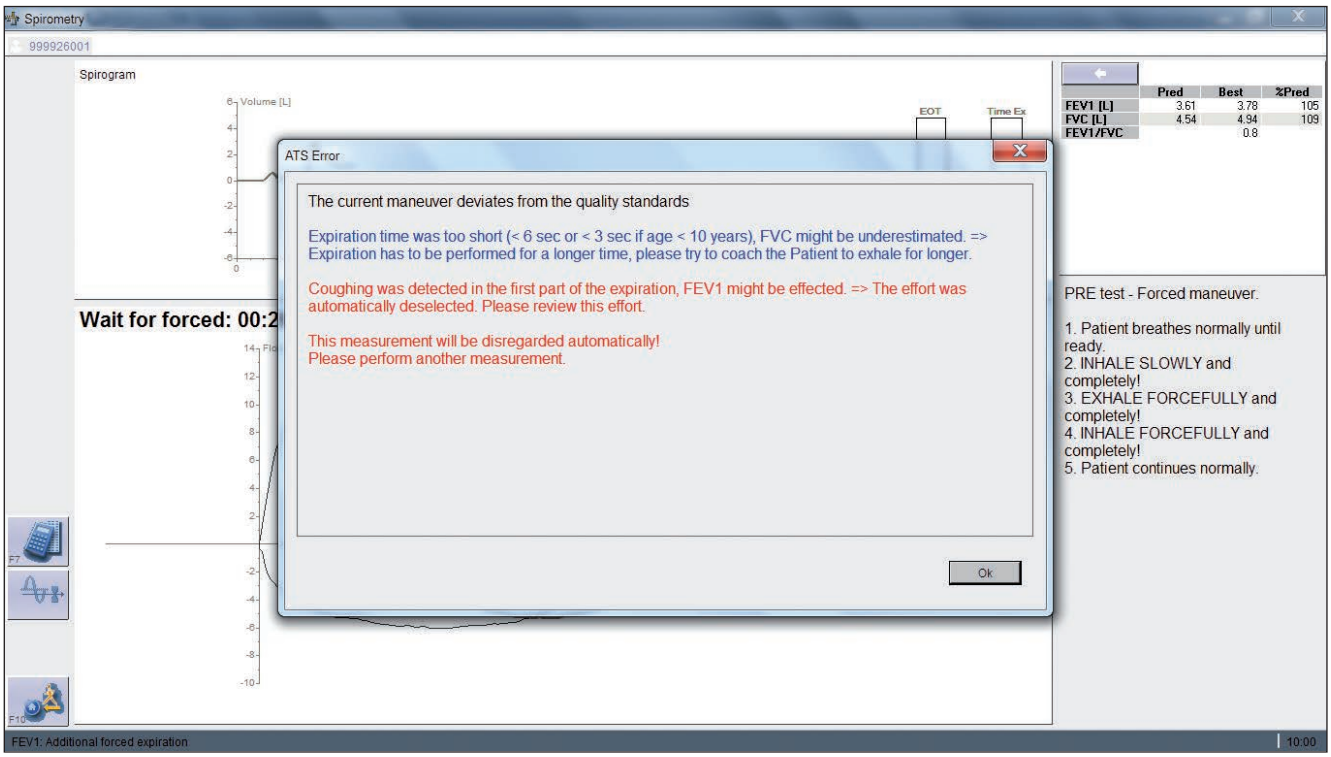
E code	Description
L	IC repeatability is unacceptable
M	VC repeatability is unacceptable
N	No repeatability: Less than 3 acceptable slow measurements
O	Expiration time was too short
P	No plateau was detected at the end of the expiration
Q	End-expiratory level of the tidal breathing was too variable

9.7 Unacceptable Efforts

Immediately after each effort, messages are displayed, which indicate whether the last effort should be disregarded (not accepted) by the operator and how to prevent such errors in the future. MasterScope automatically discards efforts which show the following issues:

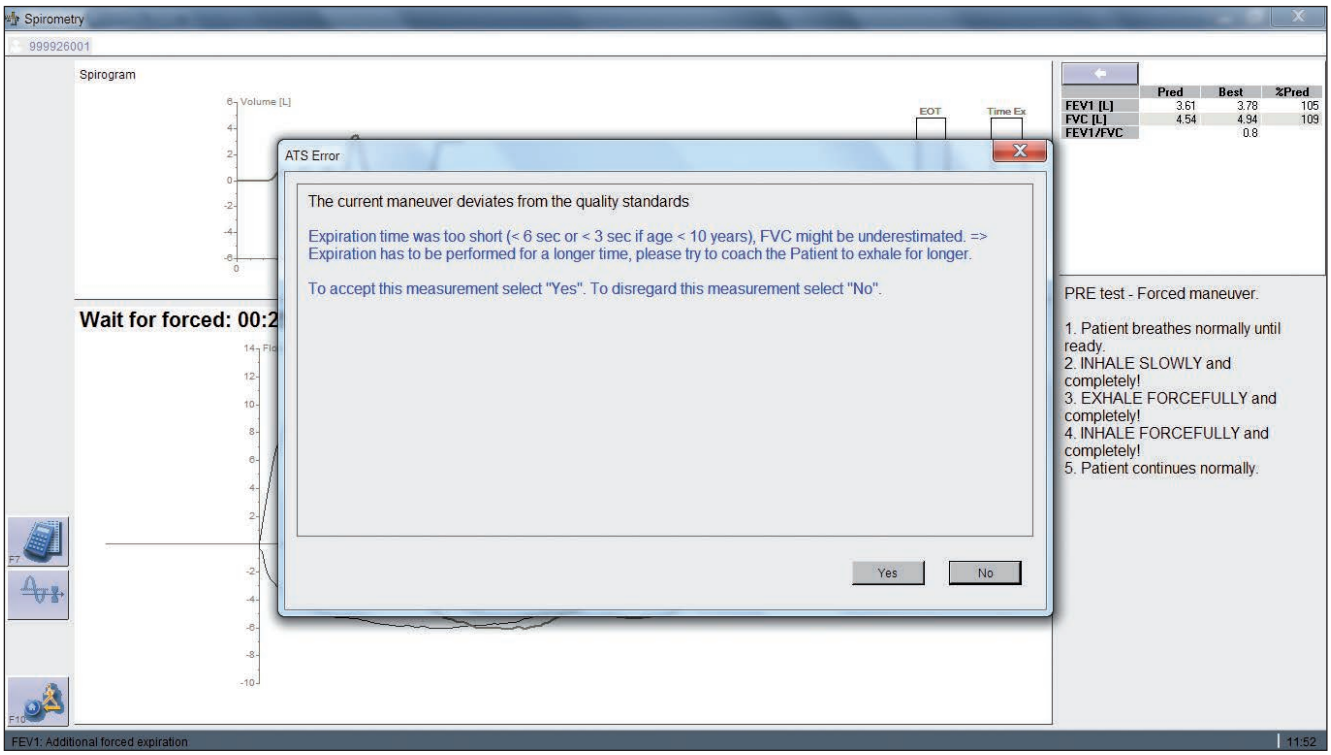
- **Back-extrapolated volume too large**
- **Coughing during first second of test**
- **Delayed PEF (possible poor effort)**

In such a scenario, a message like the following appears displaying all of the criteria that are not met:

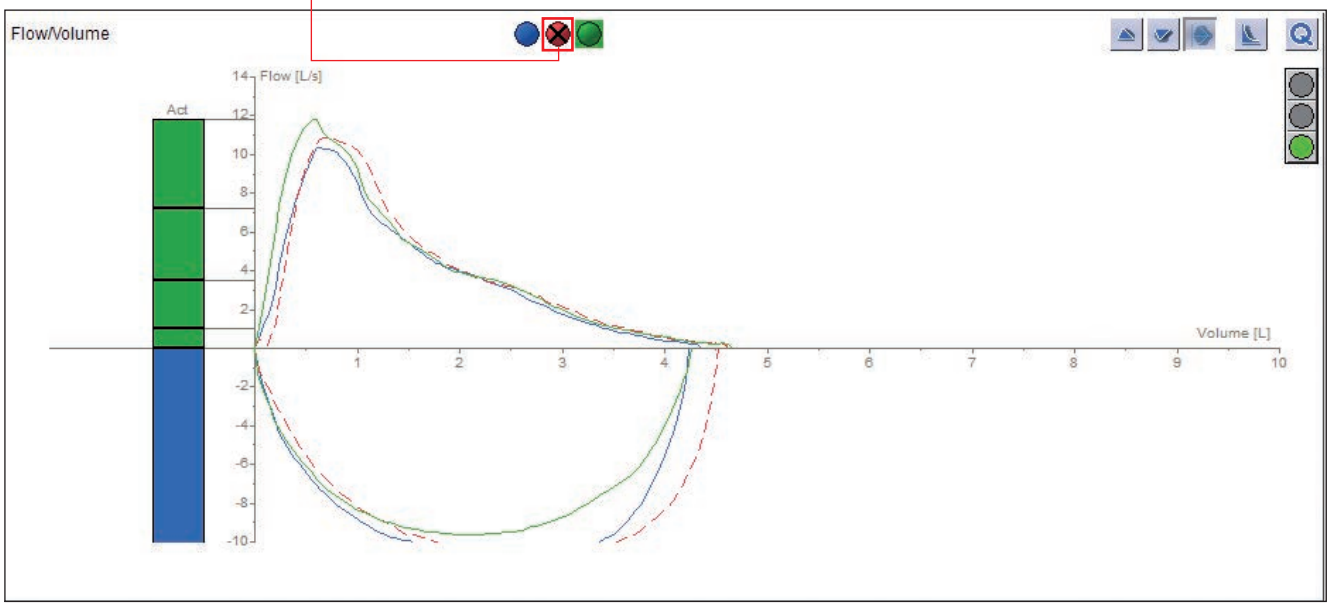


Depending on the study setup the system either allows the user to decide if the efforts should be kept or it will not allow to deselect the effort for the following errors:

- **Expiration time shorter than 6 sec.**
- **No plateau at end of expiration detected**



The automatic removal of unacceptable efforts is based on ATS/ERS guidelines. The investigator can accept an effort again if indicated by clicking on the deselected dot with the left mouse button. To disregard an effort, click on the colored dot with the left mouse button.



Discarded efforts are not counted for the minimum three efforts.

9.8 Selection of Best Parameters

The best Forced Spirometry parameters will be selected for reporting and displayed as follows:

- All parameters, except for FEV1 and FVC, are taken from the measurement with the highest sum of FEV1+FVC (best test).
- The best FEV1 is the maximum value of all accepted maneuvers.
- The best FVC is the maximum value of all accepted maneuvers.

The best FEV1 and FVC may come from different test curves.

9.9 Measurement Summary Result and Comments

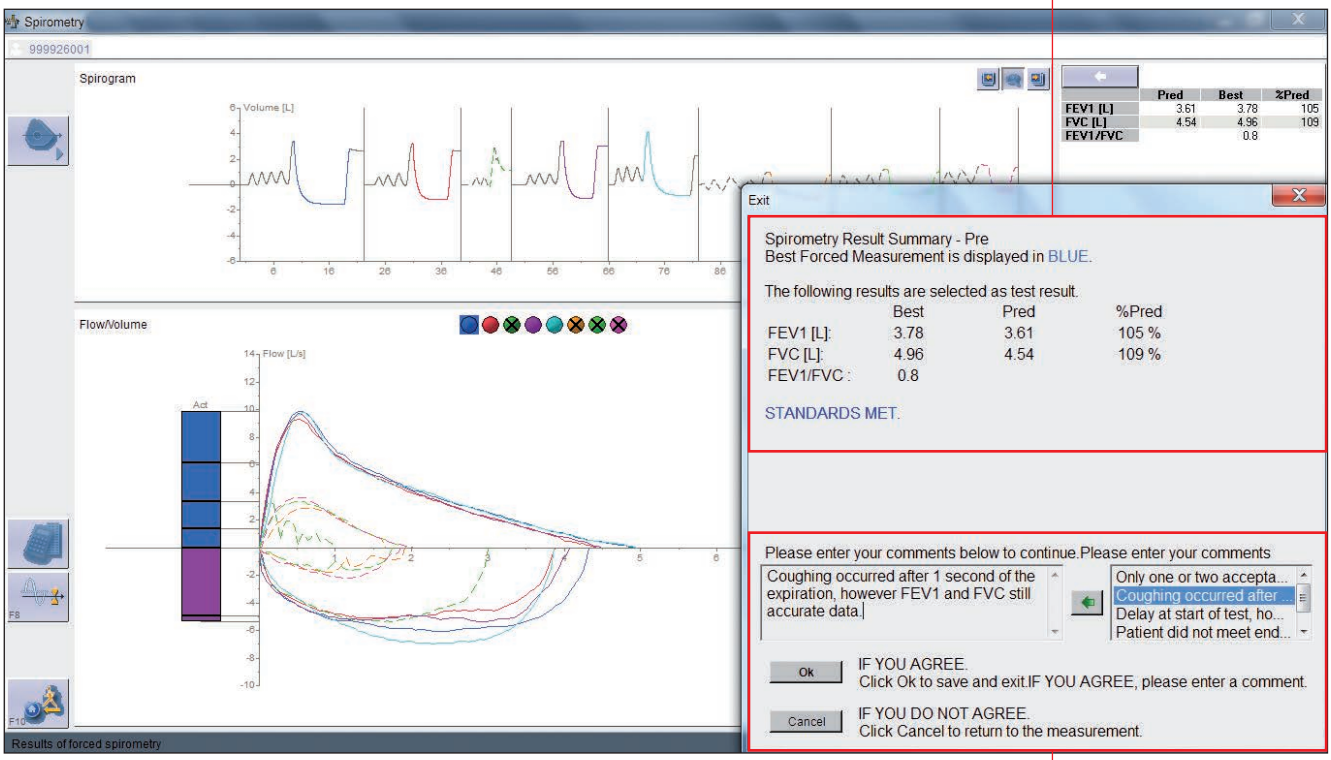
After acceptable efforts have been obtained and no additional efforts are indicated, proceed by pressing <**F10**>.

The Summary screen shows the best and predicted values of the parameters FEV1 and FVC.

Best = Best values from all trials

Pred = Predicted value

%Pred = Best value in % of predicted value



Operator comment

Enter an operator comment in the respective entry field or select a preset comment and move it to the entry field by clicking the arrow key.

It is recommended to enter comments in the text field when applicable.

A comment is expected if the subject, for instance, was not able to perform acceptable and/or repeatable efforts.
Comments should be meaningful and entered in English. This will help the Overread department to analyze the data.

If further flow volume measurements are required to achieve acceptable results, press <**Cancel**>. This returns you to the measurement screen.

When the measurement results satisfy the requirements, press <**Ok**> to save the test and exit.

9.10 Review Results and Edit Comments

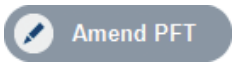
At any time, measurement details can be reviewed by clicking on the corresponding tab and Info icon in the Visit Summary screen.

Typical information provided with the measurement results are:

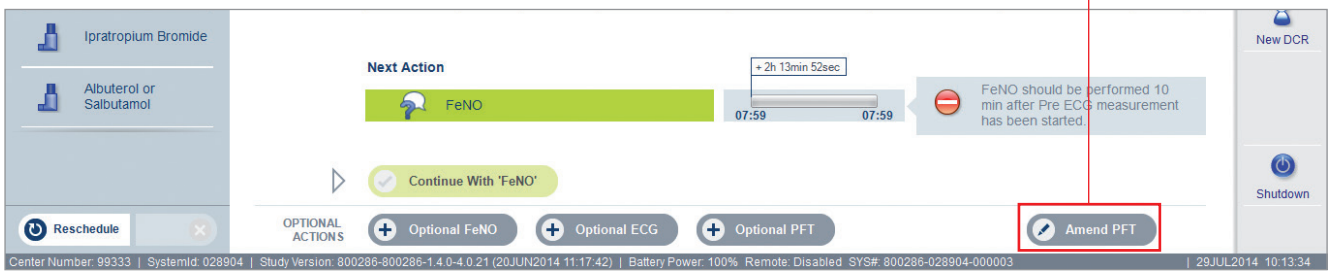
1. Parameter values from measurements
2. Flow Volume curves
3. ATS error codes for single measurements and best test.
4. Comments for this test, which can be amended.

9.11 Amending Spirometry Measurements

Once a spirometry test has been saved, it can be reopened and amended if no other workflow steps (inclusion, randomization, data transfer) have been completed.



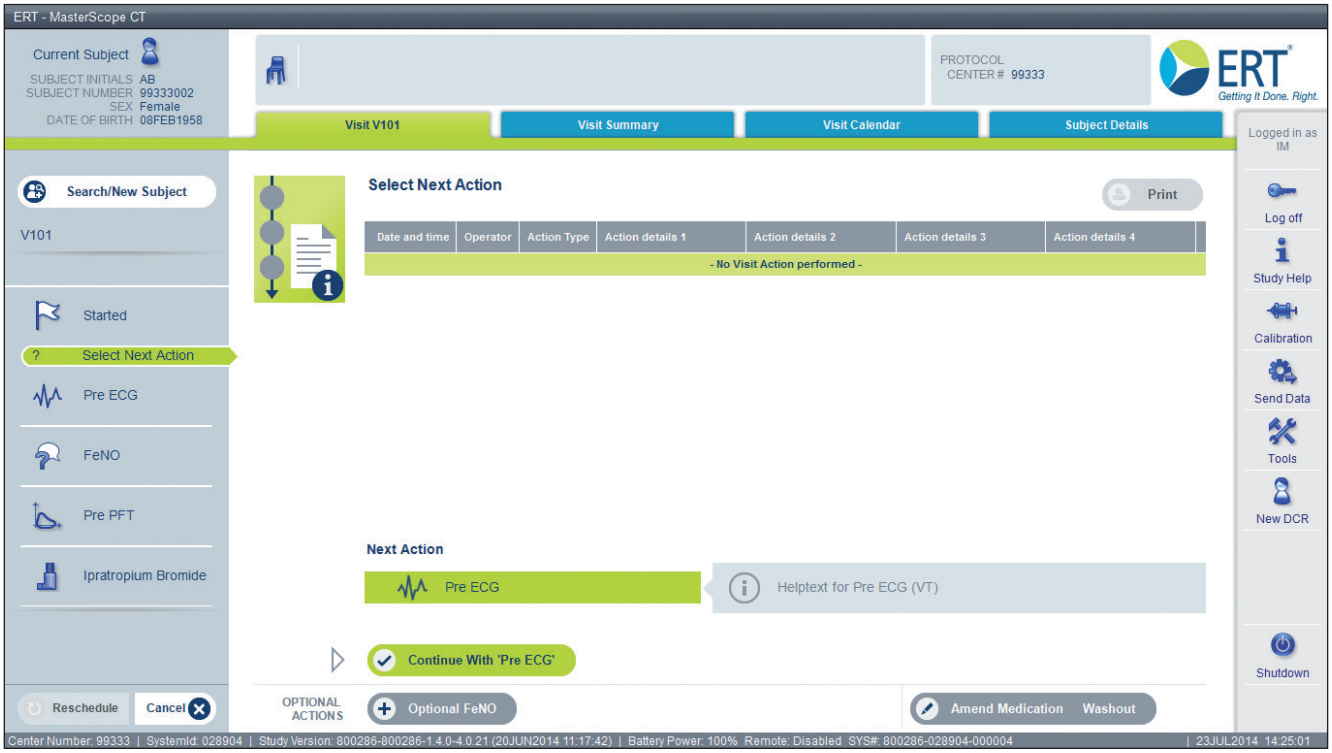
In order to amend the last test, click the icon <**Amend PFT**>. The spirometry module will allow performing additional measurements.



Amending PFT is only applicable until the measurement results have been transfered via Data Transfer to the ERT Backend Center.

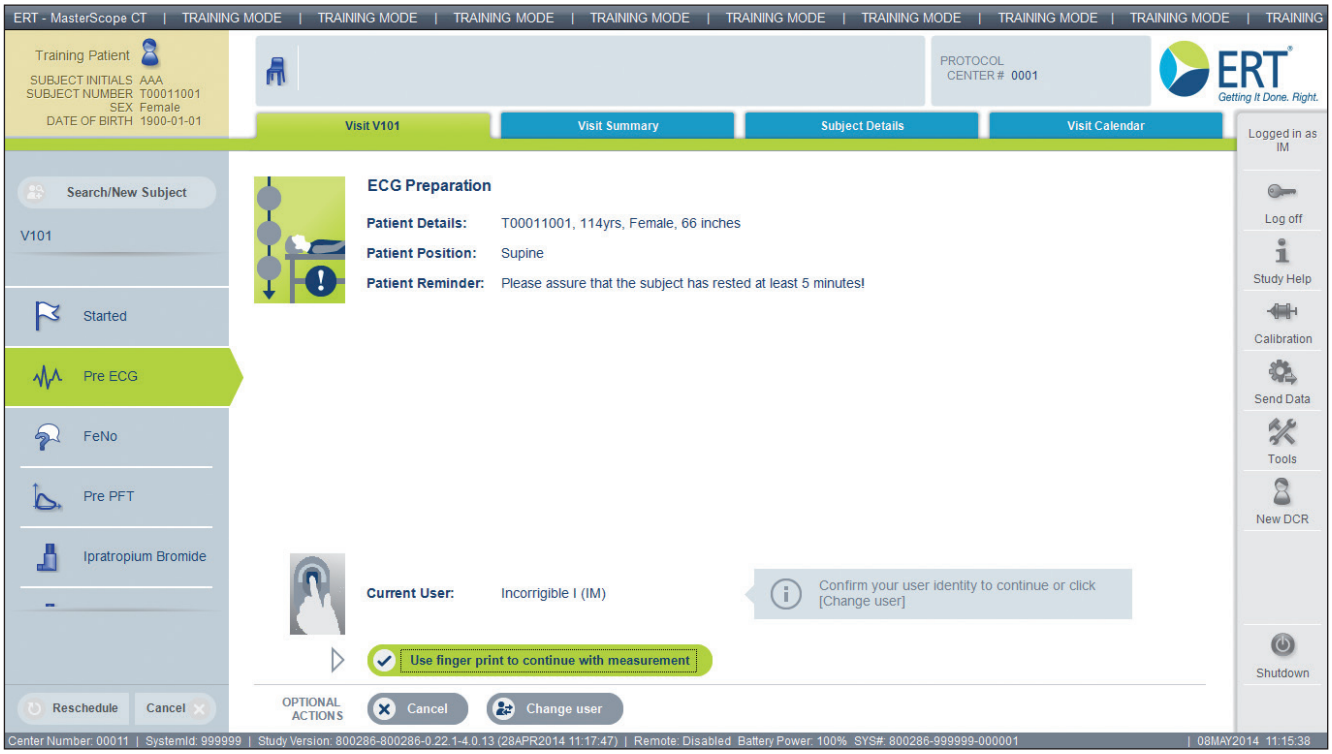
10. Resting ECG

MasterScope ECG allows to record a 12-lead resting ECG measurement.



Click the <**Continue With 'Pre ECG'**> icon.

Following screen appears:

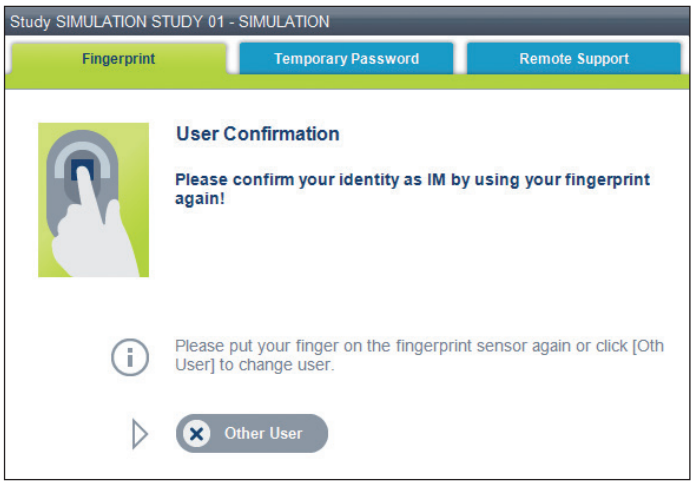


Please follow the notes on the screen.

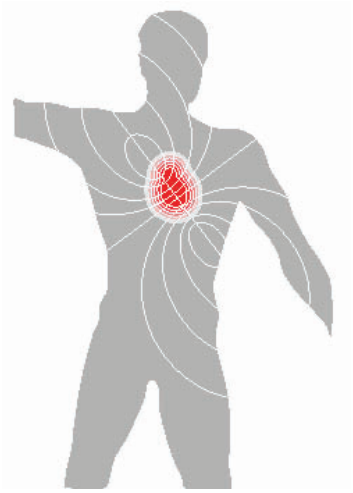
Put your finger on the fingerprint sensor to continue.

As an alternative, click the <**Use finger print to continue with measurement**> icon to continue.

Prior to starting the ECG measurement, the authorized investigator has to verify again.



After the user confirmation, please follow the instructions given in chapter "**Performing an ECG Recording**".



10.1 Information on ECG Recording

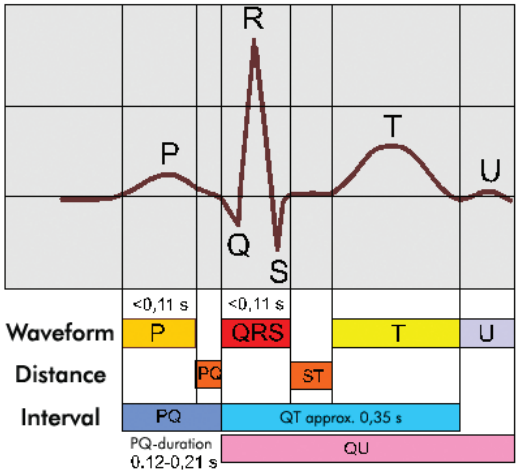
An electrocardiogram (ECG) is a graphic recording of the changes occurring in the electrical potentials (millivolt changes) at defined sites on the skin. The continuously changing electrical fields are the result of depolarization and polarization of the heart and are distributed in the body without any delay.

The electrical fields are caused by the cardiac cells, which are electrically polarized.

The ECG is a graphic recording of cardiac electrical activity but is not a measure for cardiac pumping capacity (muscle strength).

10.1.1 The Waveform

Willem Einthoven (1860-1927), Professor of Physiology and Winner of the 1924 Nobel Prize, developed the ECG Standard Leads I, II and III, which are named after their inventor.



Einthoven named the prominent waves alphabetically P, Q, R, S, T and U.

The flat amplitudes P, T and U are called waves, Q, R and S are called peaks.

The P-wave represents the wave of depolarization that spreads from the atrium. The Q, R and S peaks, also referred to as QRS-complex, represent the wave of depolarization from the ventricle.

The T-wave represents the repolarizations of the ventricle.

The U-wave is undefined.

10.1.2 ECG Leads

To minimize artifacts, the skin of the defined lead positions has to be prepared thoroughly.

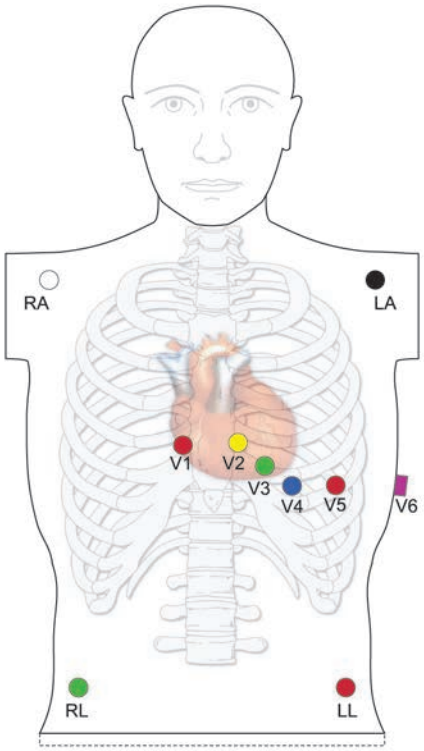
Preparing the subject's skin:

1. Identify the (10) electrode sites on the torso by referring to the picture and description below.
2. Remove any hair from the electrode site using a razor.
3. Wipe oils from the electrode sites with an alcohol prep pad.
4. Remove any dead skin from the electrode sites with an abrasive cleaner.
   Two to three moderate rubs at each site should be sufficient.

TIP: Electrodes should be stored in an air-tight container. Electrodes will dry out if not stored properly which will cause loss of adhesion and conductivity. Please note the storage conditions indicated on the electrode packaging.

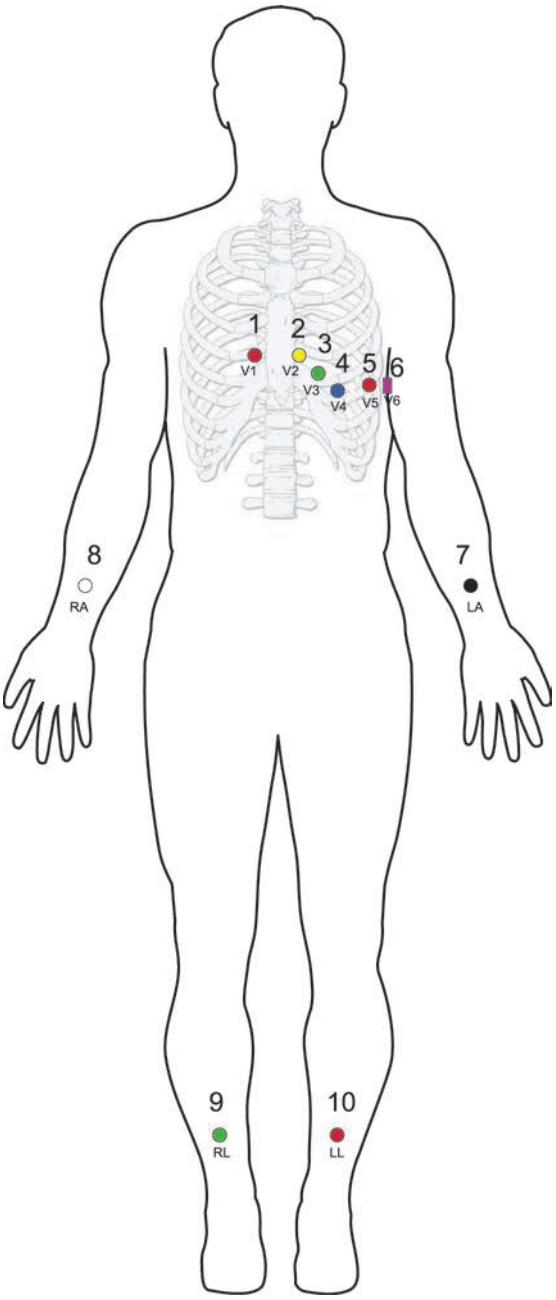
Correct electrode placement is important for acquiring a successful ECG recording.

10.1.3 Chest ECG



V1	Fourth intercostal space at the right sternal border
V2	Fourth intercostal space at the left sternal border
V3	Midway between V2 and V4
V4	Fifth intercostal space at the left of the midclavicular line
V5	Anterior axillary line at same horizontal level as V4
V6	Mid-axillary line on same horizontal level as V4 and V5
LA	Left deltoid
RA	Right deltoid
RL	Right thigh
LL	Left thigh

10.1.4 Limb ECG



- V1 Fourth intercostal space at the right sternal border
- V2 Fourth intercostal space at the left sternal border
- V3 Midway between V2 and V4
- V4 Fifth intercostal space at the left of the midclavicular line
- V5 Anterior axillary line at same horizontal level as V4
- V6 Mid-axillary line on same horizontal level as V4 and V5
- LA Left wrist
- RA Right wrist
- RL Right ankle
- LL Left ankle

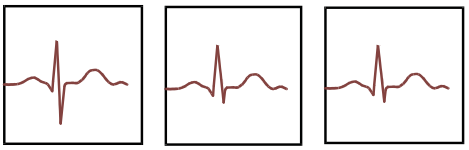
When connecting the electrodes to MasterScope ECG, the tiny and fast potential differences originating from the heart can be detected on the surface of the body between either two individual electrodes or between one individual electrode and a group of combined electrodes and recorded by MasterScope ECG.

The different measurement setups are commonly referred to as leads.

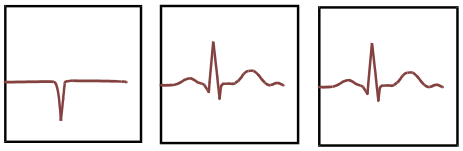
For a standard 12-lead ECG, four electrodes are placed at the limbs and six at the chest.

The 12 leads are:

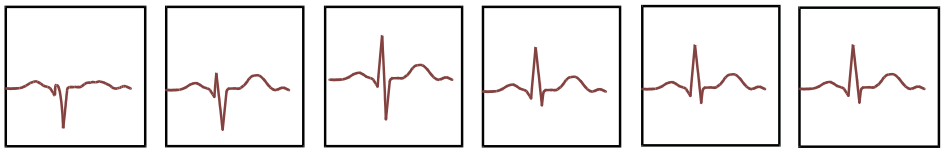
Three bipolar limb leads: I, II and III (according to **Einthoven**)



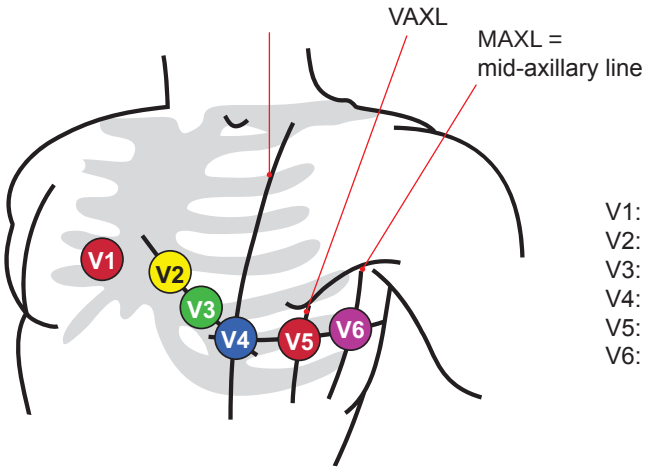
Three unipolar limb leads: aVR, aVL and aVF (according to **Goldberger**)



Six unipolar chest leads: V1, V2, V3, V4, V5, V6 (according to **Wilson**)



In contrast to the limb leads, the chest leads have to be positioned precisely. The lead positions are internationally standardized.



V1:	4th intercostal space, right sternal border
V2:	4th intercostal space, left sternal border
V3:	midway between V2 and V4
V4:	5th intercostal space, left mid-clavicular line
V5:	between V4 and V6, left anterior axillary line
V6:	level with V4, left mid-axillary line

10.1.5 Basic Conditions for ECG Recording

For high-quality ECG recording, certain criteria have to be met:

CAUTION

- Mentally prepare the subject for the examination in order to eliminate pain and consequently tachycardia and muscle tremor.
- Ambient temperature should be at least 23 °C to avoid shivering; make sure that the subject is lying comfortably on a suitable couch or bed and eliminate all sources of noise.
- Check the condition of your equipment to ensure proper signal sampling.
- Make sure that the chest electrodes are positioned according to international standards and pay attention to polarity of the limb and chest electrode cables.
- The subject should try to avoid movement during the measurement because this can lead to motion artifacts.

WARNING

Only use original electrode cables delivered by ERT. If the wrong cable is used the defibrillation energy delivered to the patient can decrease, the device can be damaged, or electric shock to the operator or other persons occur.

10.1.6 Preparing for the Measurement

1. Attach electrodes

Procedure:

- Clean the subject's skin with a skin-sensitive agent to remove probable fatty residues.
  Make sure that the skin is dry before applying the electrodes.
  Only the supplied disposable electrodes are to be used:
  Remove protecting foil and attach the electrode to the skin.

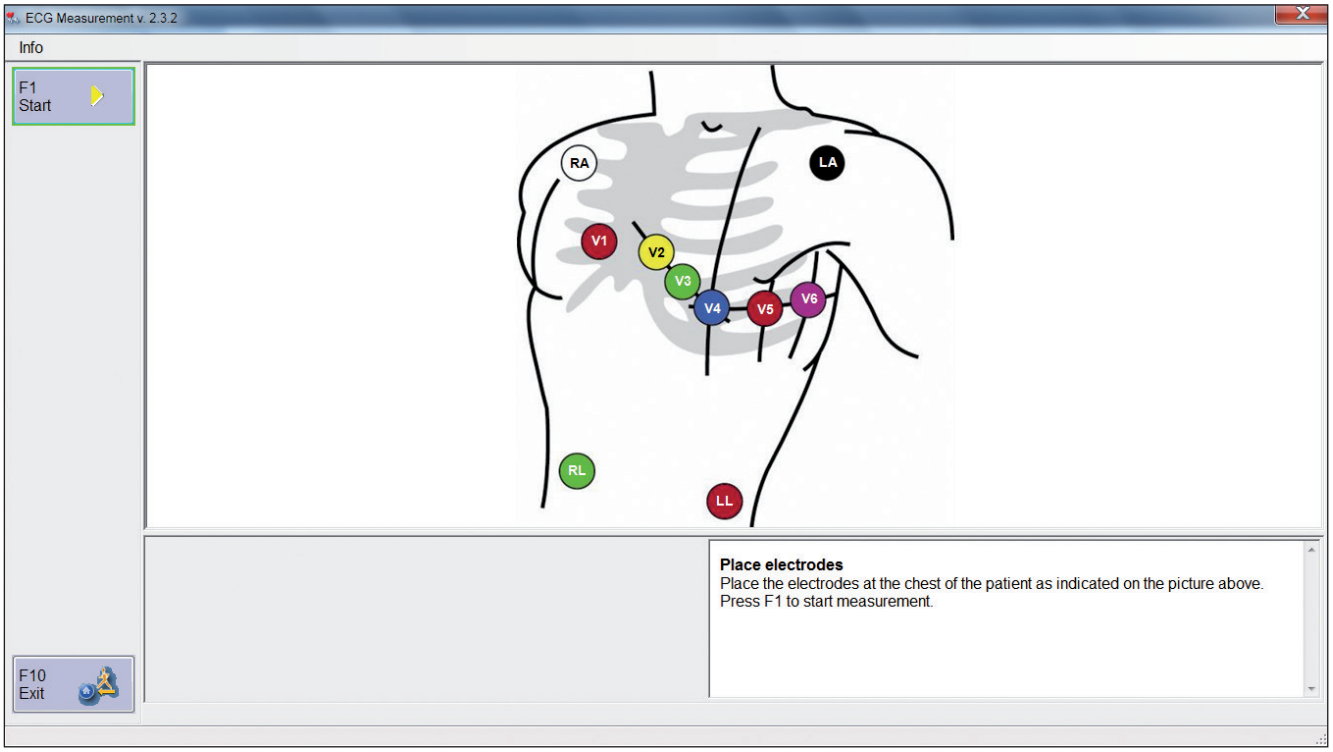
2. Connect the ECG amplifier electrode cables with the electrodes.

10.2 Performing an ECG Recording

A screen displaying the correct placement of the electrodes for the ECG recording will appear.

10.2.1 Electrode Test

Before an ECG recording is started, an automatic electrode contact measurement is performed. This measurement is started by pressing <**F1**>.



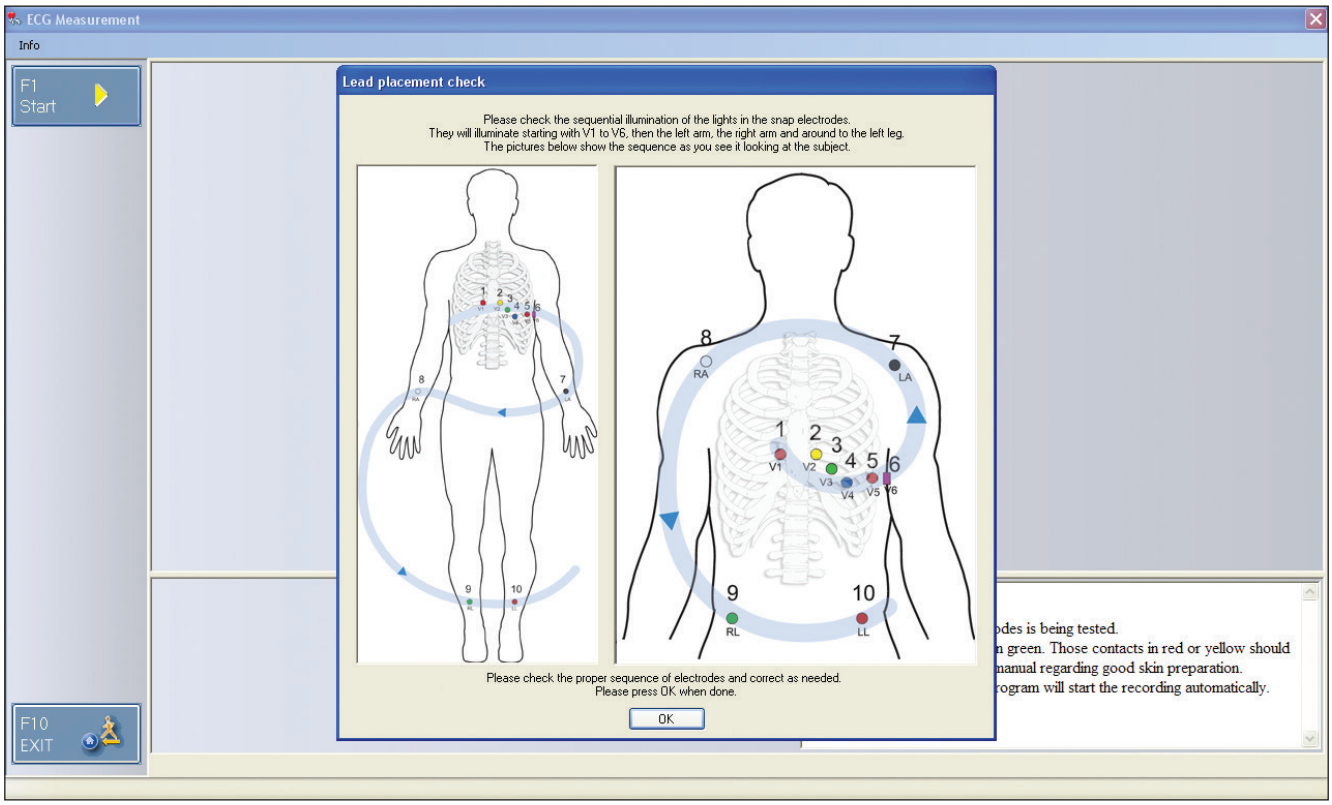
The electrode test program automatically checks whether the electrodes are in good contact with the skin. If a contact is poor, the respective electrode will immediately be indicated on the screen and directly at the electrode.

- good contact (only on the screen)
- bad contact (flashing)

If an electrode contact is indicated as poor, please check the respective contact.

The lead placement check will start automatically as soon as all electrodes are in good contact with the skin.

To enable an easy check of the electrode placement, the system will illuminate the electrodes in a fixed sequence.



Depending on the used ECG, the electrodes are visually checked ("**running lights**"), starting with "**V1**" and ending with "**LL**":

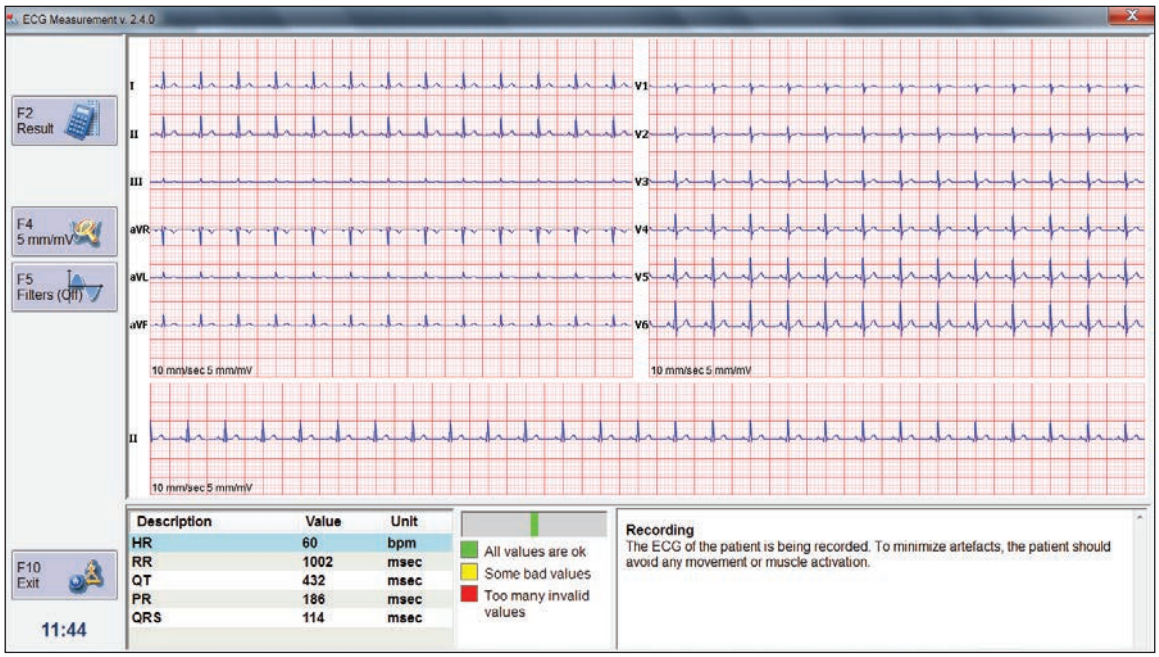
Chest ECG electrode sequence:	"**e**" shape
Limb ECG electrode sequence:	mirrored "**S**" shape

OK

Pressing <**OK**> will start the recording of the ECG signals.

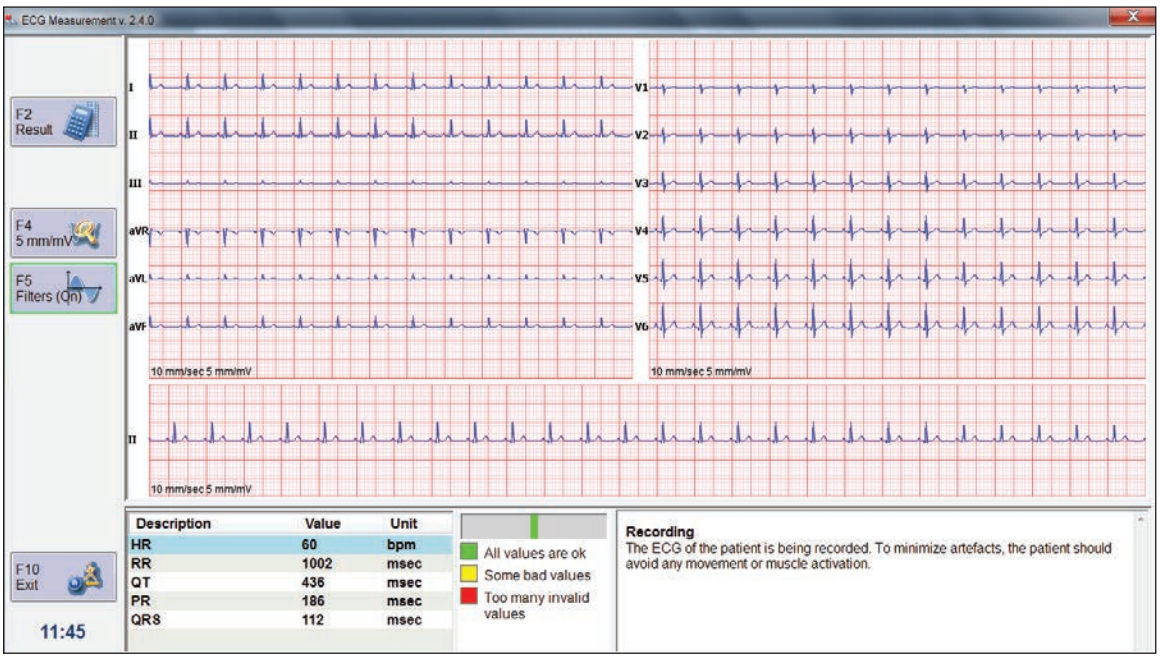
10.2.2 ECG Recording

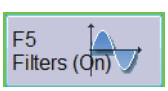
The recorded ECG waveforms are displayed on the screen.



Scaling and Filter

Press <**F4**> to change between the scalings 5 mm/mV and 10 mm/mV.



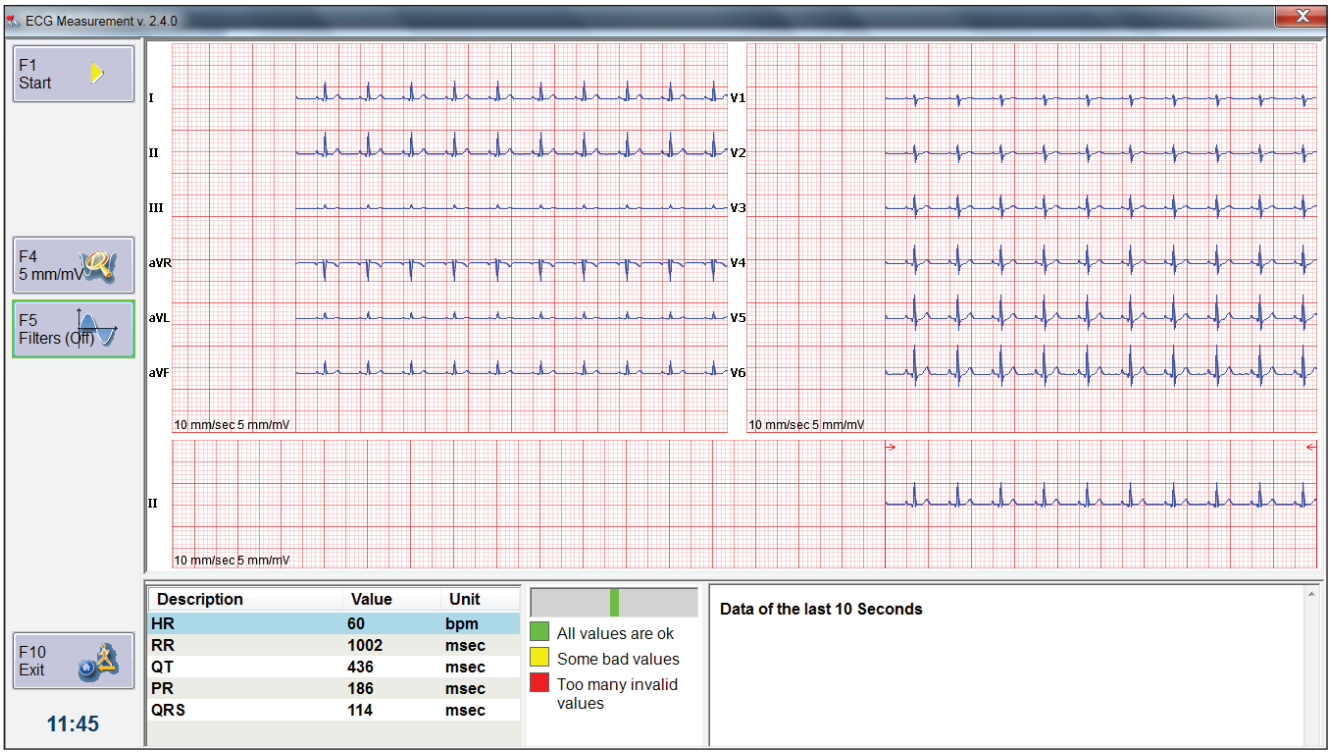


Press <**F5**> to turn on/off the notch filter. Turn this on if there is noise seen on the ECG signal.

Before using the notch filter ensure there is no other interference causing the noise, e.g. electric interference next to the ECG amplifier.

10.2.3 ECG Evaluation

Inspect the recording quality of the signals. If the signals are free of drift and noise, press <**F2**> to analyse the last 10 seconds of the recording and halt the aquisition. HES® Interpretation will be performed and the results will be displayed on the screen.



Interpretation according to HES®

MasterScope ECG provides the Hannover ECG System HES®, which has been developed together with leading cardiologists all over the world.

Today, the HES® algorithm is considered as quasi standard for ECG recording and interpretation.

WARNING

Automatic interpretation of the ECG is not possible for pediatric subjects with an age below 16 years and for pacemaker subjects.

WARNING

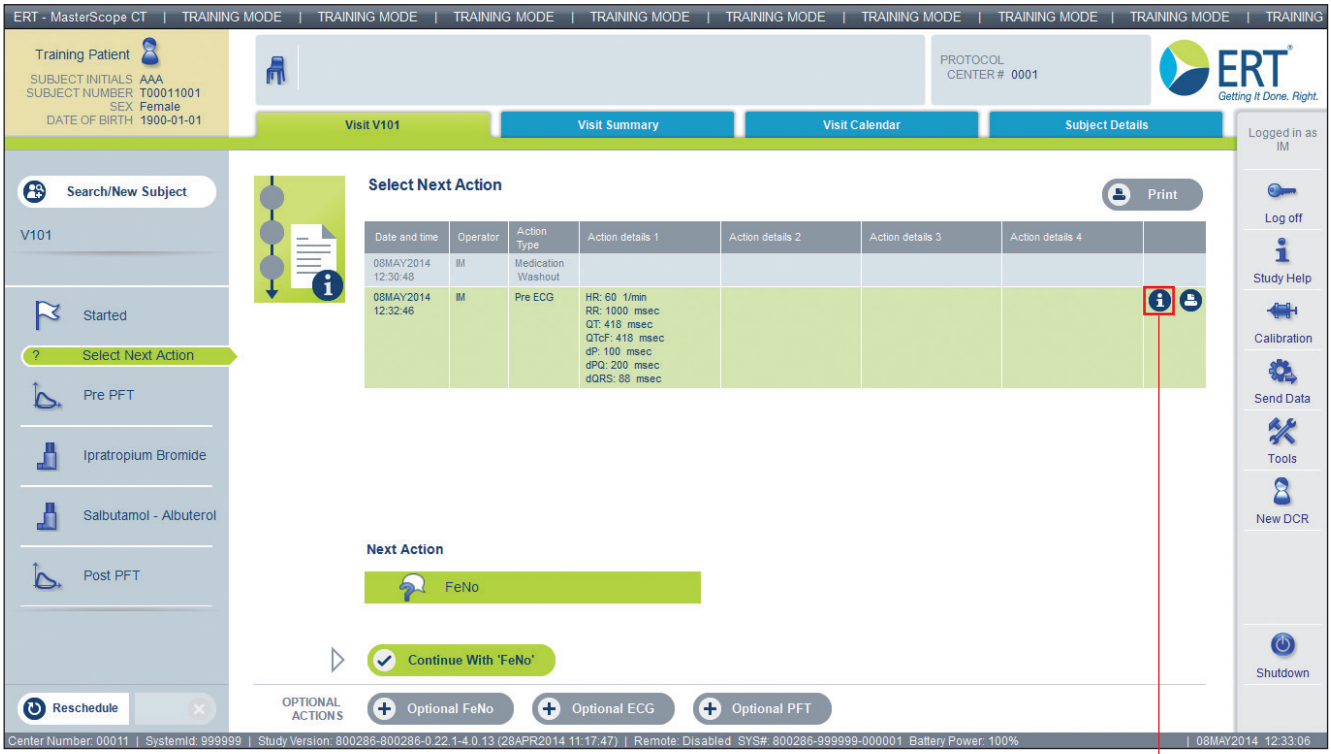
A qualified physician has to reassess all MasterScope ECG measurements. An interpretation by MasterScope ECG is only significant when considered together with other clinical findings. ECG interpretation statements made by MasterScope ECG represent partial qualitative and quantitative information on the subject's cardiovascular condition and no therapy or drugs can be administered solely on the interpretation statements.

It is extremely important that the ECGs submitted have clean baselines and are free of any drifts. See "Recording Quality ECGs" on the next page.

If the quality of the recorded data is not sufficient, a new ECG recording should be started prior to pressing <**F10**> (= save and exit ECG recording).
For this, press <**F1**> to delete the recorded data and restart ECG recording.

Press <**F10**> to save the current ECG recording and exit the program.

Enter a comment and click <**Save**>.
Following screen appears:



Click this icon to display the detailed ECG report.