Instructions for Use

SpiroSphere® ECG

781239

Version 02.02

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Indications for Use

The SpiroSphere is a compact device to measure inspiratory and expiratory lung function parameters in adults and children aged 4 years and older.

With the option ECG electrocardiographic diagnoses can be made. For this purpose a 12-channel surface electrocardiogram can be measured and recorded. Automatic interpretation of the ECG is not possible for pediatric subjects with an age below 16 years and for pacemaker subjects. It is not intended for intra-cardial use.

The minimum age for ECG application is 4 years.

It can be used by physicians in the office or hospital.

Contraindications

⚠ WARNING

According to "STANDARDIZATION OF SPIROMETRY 2019 UPDATE" (American Journal of Respiratory and Critical Care Medicine, October 2019) performing lung function tests can be physically demand for a minority of patients. The forced expiratory maneuver used in spirometry increases intrathoracic, intraabdominal, and intracranial pressures. Potential risks of spirometry are primarily related to maximal pressures generated in the thorax and their impact on abdominal and thoracic organs, venous return and systemic blood pressure, and expansion of the chest wall and lung. The physical effort required can increase myocardial demand. Caution must be used for patients with medical conditions that could be adversely affected by these physiological consequences:

Due to increases in myocardial demand or changes in blood pressure

- Acute myocardial infarction within 1 week
- Systemic hypotension or severe hypertension
- Significant atrial/ventricular arrhythmia
- Noncompensated heart failure
- Uncontrolled pulmonary hypertension
- Acute cor pulmonale
- Clinically unstable pulmonary embolism
- History of syncope related to forced expiration/cough

Due to increases in intracranial/intraocular pressure

- Cerebral aneurysm
- Brain surgery within 4 weeks
- Recent concussion with continuing symptoms
- Eye surgery within 1 week

Due to increases in sinus and middle ear pressures

- Sinus surgery or middle ear surgery or infection within 1 week

Due to increases in intrathoracic and intraabdominal pressure

- Presence of pneumothorax
- Thoracic surgery within 4 weeks
- Abdominal surgery within 4 weeks
- Late-term pregnancy

Infection control issues

- Active or suspected transmissible respiratory or systemic infection, including tuberculosis
- Physical conditions predisposing to transmission of infections, such as hemoptysis, significant secretions, or oral lesions or oral bleeding

Spirometry should be discontinued if the patient experiences pain during the maneuver. Relative contraindications do not preclude spirometry but should be considered when ordering spirometry. The decision to conduct spirometry is to be determined by the ordering healthcare professional on the basis of their evaluation of the risks and benefits of spirometry for the particular patient. Potential contraindications should be included in the request form for spirometry.

LIMITATION:

- The ECG unit is not suitable to be used with HF surgery devices.
- The ECG unit is not intended for intracranial use.
- The ECG unit is not intended for use in an EMS environment (Emergency Medical Services Environment).
- The ECG unit is not intended for use in home healthcare environments.
- The ECG unit is intended for indoor use only.

⚠ CAUTION

Any non-observance of the procedure described in this Instructions for Use (such as preparation for the measurement, operation, desinfection, accessories and replacement of parts etc.) results in a deviation from the intended use.

Table of Contents

Notes on Safety in this Instruction Manual

Following the ANSI (American National Standards Institute) recommendations for safety notes, specific passages of this instruction manual are clearly marked as safety notes.

Degree of Danger	Injury to persons	Damages to property	Meaning of Indicator
DANGER	X		**DANGER** indicates an immediate hazardous situation, which, if not avoided, may result in serious injury or death. Limited to extremely dangerous situations.
WARNING	X		**WARNING** indicates a potential hazardous situation, which, if not avoided, may result in serious injury or death.
CAUTION	X	(X)	**Caution** indicates a potential hazardous situation, which, if not avoided, may result in minor or slight injury. Also used to indicate precarious procedures.

Additional icons used in this manual:

			Important information on operation and other useful information. Does not warn of dangerous or harmful situations.
			Tips, general information and information on operation.

Declaration of Conformity

The original Declaration of Conformity document can be obtained from ERT.

Graphical Symbols on the ECG amplifier

Symbol	Description
	Applied Part of type CF, Defibrillation-proof (ECG unit cable variant)
	Disposal of electronic devices in compliance with WEEE
IP20	IP classification according to IEC60529
	Radio symbol, non-ionizing radiation
	Manufacturer
	Date of manufacturing
CE 0482	CE conformity symbol (Medical Device Directive) with code number of Notified Body.
	Follow the Instructions for Use
Rx only	Federal U.S. Law restricts this device to sale by or on the order of a physician.
	Attention! General warning sign acc. to ISO 7010-W001
	On button

Device Description

The SpiroSphere is a compact spirometry device. Its Sensor Unit is battery-powered. The Main Unit can be powered by battery or power supply. The SpiroSphere is used to measure inspiratory and expiratory lung function parameters in adults and children aged 4 years and older. The measured data is saved into the device and can be read out at any time.

The disposable easy-to-exchange, high-quality pneumotach guarantees a high degree of patient safety and provides precise recording results.

The Main Unit is equipped with a graphical LCD touch display, providing a state of the art solution for selection of menu functions and the navigation throughout the menu.

The SpiroSphere Sensor is paired via Bluetooth with the Main Unit.

A printer can be connected with the SpiroSphere and all needed data can be printed. Moreover, it is possible to transfer data via USB, WiFi, optional 3G module and Ethernet.

With the option ECG electrocardiographic diagnoses can be made. For this purpose a 12-channel surface electrocardiogram can be measured and recorded. Automatic interpretation of the ECG is not possible for pediatric subjects with an age below 16 years and for pacemaker ubjects. It is not intended for intra-cardial use.

The minimum age for ECG application is 4 years. The SpiroSphere is intended to be used in a professional healthcare facility environment.

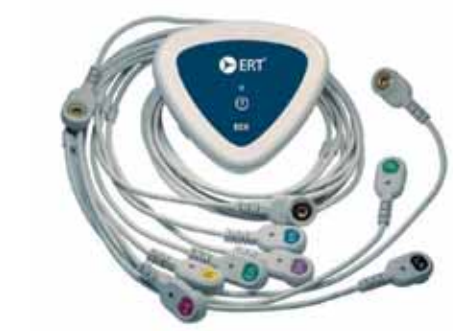
Unpacking and Starting Operation

SpiroSphere is delivered with the following accessories*:

1 Main Unit
1 SpiroSphere Sensor
1 Power Supply with country adapters
4 ERT PT with Mouthpiece
2 Nose clips and Pads
1 Instruction manual

Optional:

1 ECG Unit



WARNING

Death due to suffocation may occur if packing material is swallowed.

Store packing material out of reach of children and dispose of properly!

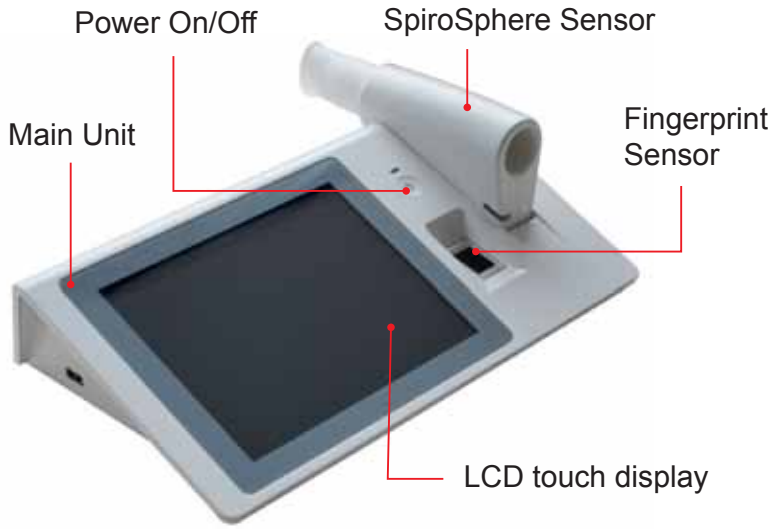
Use only **ERT** approved accessories and spare parts for this medical device.

* *Depending on the type of equipment either included in the delivery or available as an option*.

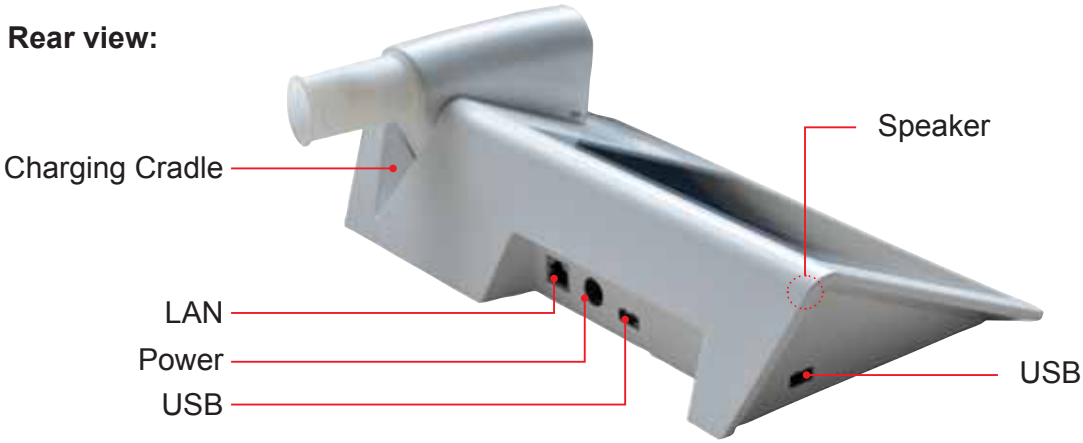
The SpiroSphere

Main Unit:

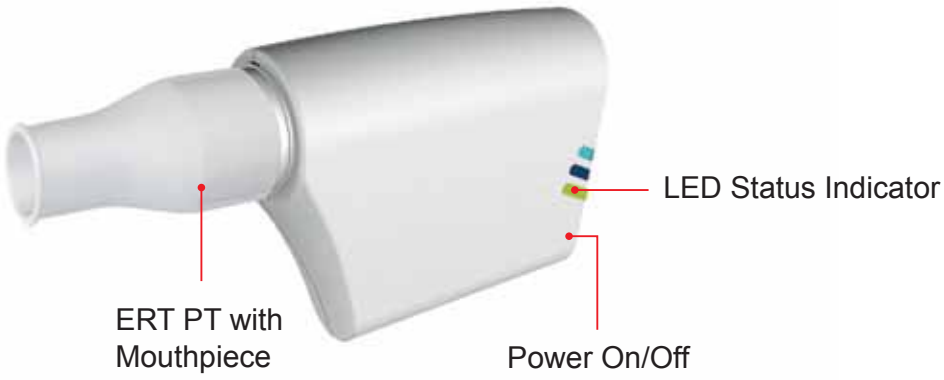
Front view:



Rear view:



SpiroSphere Sensor:

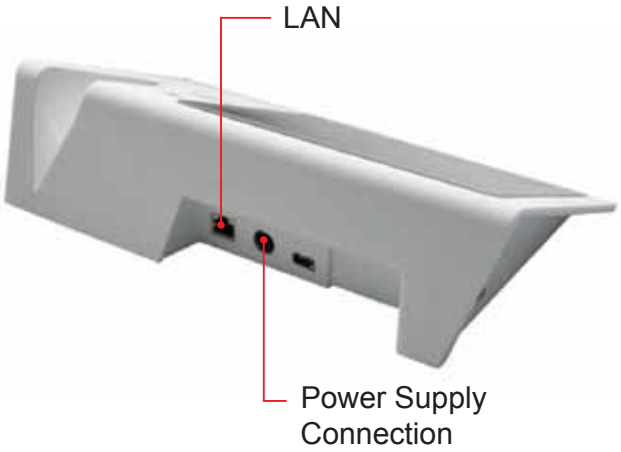


The **SpiroSphere** must not be exposed to direct sunlight nor positioned immediately near heating elements.

Power supply:

Start-Up

1. Connect the **SpiroSphere** to a power source complying with local regulations.



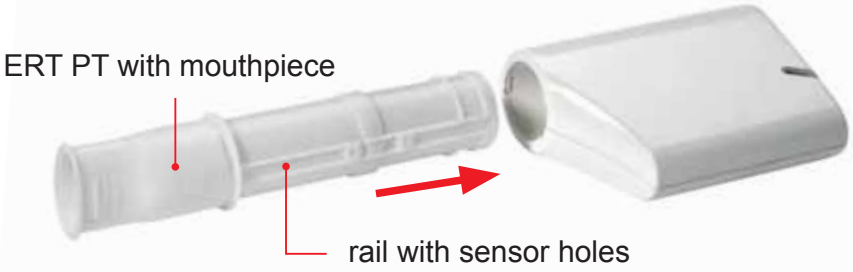
2. Put the **SpiroSphere Sensor** into the slot of the main unit as shown below.

3. Use the Power On switch located at the front of the main unit to switch on the **SpiroSphere Main Unit**.

The operating status of the device is indicated via an LED on the main unit and on the SpiroSphere Sensor. Please refer "LED Status SpiroSphere and "LED Status SpiroSphere Sensor" on page 9.

4. Prior to the first usage, switch on the SpiroSphere Sensor by pressing the "**Power On**" switch located at the back side of the SpiroSphere Sensor for at least 3 seconds.

5. Ensure an ERT PT is inserted correctly into the **SpiroSphere Sensor** (refer to Chapter "Sensor Insert"). Take care that you have aligned the rail with the sensor holes of the PT tube with the grooved edge of the SpiroSphere Sensor (as below) when inserting the ERT PT into the SpiroSphere Sensor.



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

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

Prior to the first use, make sure that the SpiroSphere Sensor is fully charged.

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

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

Shut down

1. To power off the **SpiroSphere Main Unit**, press the "**Power**" button located at the front of the main unit. Disconnect the main unit from the power source (please note that this will prevent the battery from charging).
2. Power off the SpiroSphere Sensor by pressing the "**Power**" button located near the LEDs of the SpiroSphere Sensor.

WARNING Do not position the Power Supply and the SpiroSphere so that it is difficult to operate the disconnection of the device from the mains supply.

LED Status SpiroSphere

		To do:
Blue LED On	Main Unit powered on	N/A
Blue LED Off	Main Unit powered off	N/A
Blue LED Pulse	Main Unit Standby	N/A

Orange LED On	Charging	
Orange LED Off	Not charging/ charging complete	
Orange LED blinking	Low battery	Connect Main Unit to a mains supply

LED Status SpiroSphere Sensor

Orange LED On	Charging in cradle	
Orange LED Off	No charging/ charging complete in cradle	
Orange LED blinking slowly	Low battery	Put the SpiroSphere Sensor into the cradle of the Main Unit
Orange LED blinking fast		Indicates an error in the SpiroSphere Sensor. The user has the following options: - restart the SpiroSphere Sensor by pressing the power button on the SpiroSphere Sensor for more than 8 seconds - go to "Spirometry Settings" > "Sensor" and try connecting to the SpiroSphere Sensor

Blue LED On	SpiroSphere Sensor is actively transferring data to the Main Unit	
Blue LED Off	Device in sleep mode	Device may be off or battery might be discharged. Put the device into the charging dock or press the Power On switch
Blue LED blinking slowly	Device powered on and paired with Main Unit	

Only the highest priority LED at a time is turned on (LED priority: Orange - Blue).

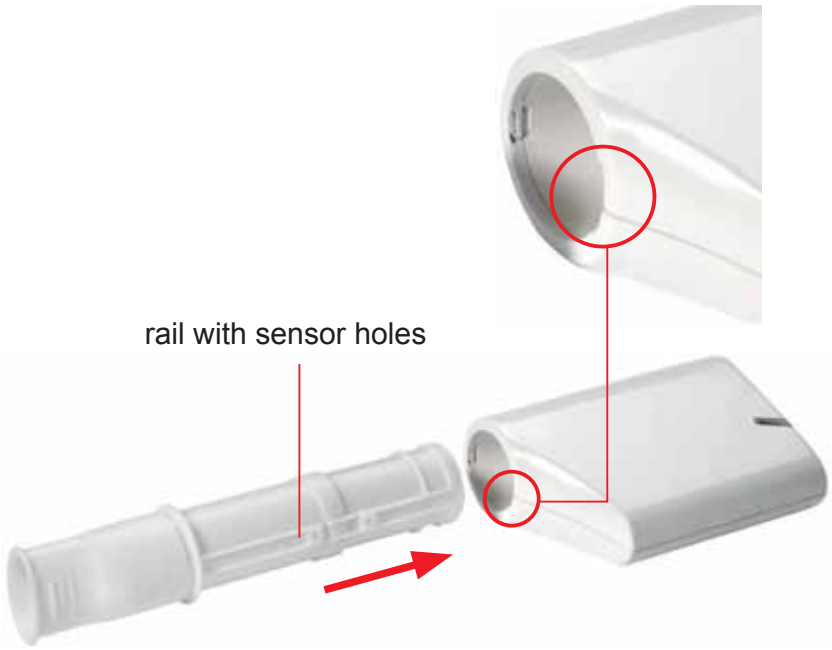
Troubleshooting

Problem	Troubleshooting
SpiroSphere Main Unit does not start	SpiroSphere Main Unit is not switched on. Try to switch on with the power button (press the button for at least 3 seconds).
	Power supply is not connected and the battery discharged. Connect the power supply and let the SpiroSphere Main Unit charge for a few minutes.
	SpiroSphere Main Unit is in standby mode. Use the touch screen or power button to wake up.
SpiroSphere Sensor does not start	SpiroSphere Sensor is not switched on. Press the power button for at least 3 seconds to switch the SpiroSphere Sensor on.
	Battery is discharged. Place the SpiroSphere Sensor in the charging cradle for at least 10 minutes, then try again.
SpiroSphere Main Unit LED is blinking orange	Battery is discharged. Connect power supply immediately.
SpiroSphere Sensor orange LED is blinking slowly	Battery is discharged. Place SpiroSphere Sensor in charging cradle of the SpiroSphere Main Unit.
SpiroSphere Sensor LED is off while in the charging cradle	SpiroSphere Sensor is in sleep mode. Remove from the cradle and insert again.
	SpiroSphere Sensor might be fully charged or off.Try to identify the SpiroSphere Sensor in the Spirometry Settings. Place the SpiroSphere Sensor again in the charging cradle.
SpiroSphere Sensor can't be paired	SpiroSphere Sensor is powered off. Switch on SpiroSphere Sensor (see above)
	SpiroSphere Sensor is not in the pairing mode. Remove the SpiroSphere Sensor from the charging cradle if already inserted and then insert the SpiroSphere Sensor in the charging cradle. SpiroSphere Sensor is now in pairing mode for 90 seconds.
Connection to the SpiroSphere Sensor is not possible	SpiroSphere Sensor is off. Power on SpiroSphere Sensor (see above).
	SpiroSphere Sensor is out of range. Check that the SpiroSphere Sensor is in the range (10m in the line of sight).
Calibration Check or Linearity Check not successful	Check if the calibration pump has the correct volume setting.
	Check if ERT PT is inserted correctly.
	ERT PT has been used – replace by a new ERT PT
SpiroSphere Main Unit is not responding	Touch the Home icon (top left).
	Restart the SpiroSphere Main Unit by pressing the Power button for 3 seconds – Shutdown Menu – use restart.
	Press the power button for more than 8 seconds to switch off the SpiroSphere Main Unit. Then restart by pressing the power button for min 3 seconds.

Problem	Troubleshooting
SpiroSphere Sensor orange LED is blinking fast (error in SpiroSphere Sensor)	Press the power button of the SpiroSphere Sensor for more than 8 seconds to switch off the SpiroSphere Sensor. Then restart by pressing the power button for min. 3 seconds.
	Try to identify the SpiroSphere Sensor in the Spirometry Settings.
Finger prints not recognized	Clean and dry the fingerprint sensor
	Restart the SpiroSphere Main Unit
Touch Screen not reacting on touch	Press the power button for more than 8 seconds to power off the SpiroSphere Main Unit. Then restart by pressing the power button for min 3 seconds.
No Flow detect	Check if ERT PT is inserted correctly.
	Press the power button of the SpiroSphere Sensor for more than 8 seconds to power off. Then restart by pressing the power button for more than 3 seconds.
SpiroSphere Sensor is not charging	Check if the power supply is connected to the SpiroSphere Main Unit. The SpiroSphere Sensor will only be charged if the power supply is connected.
	Check if the SpiroSphere sensor is inserted correctly in the cradle.
	SpiroSphere Sensor might be fully discharged; place it in the cradle and wait a few minutes then try to power on the SpiroSphere Sensor by pressing the power button for more than 3 seconds.
SpiroSphere Main Unit is not charging	Check if the power supply is connected to mains supply.
	Check if power supply is connected to the SpiroSphere Main Unit.

Sensor Insert and Remove

Take care that you have aligned the rail with the sensor holes of the PT tube with the grooved edge of the SpiroSphere Sensor (as below) when inserting the ERT PT into the SpiroSphere Sensor:



The ERT PT should be inserted fully without force.

Remove the ERT PT in the direction of the arrow.

Setup

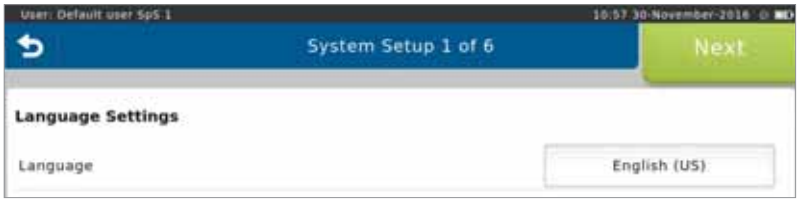
Prior to the first use, a system setup needs to be performed.

After switching on the SpiroSphere for the first time, following screen appears:

Enter the Global Password and press <**OK**>. (The preset global password is "691982".)

The System Setup wizard starts automatically.

Follow the system setup steps (step 1 - 6) and enter or select the appropriate settings. Tap on <**Next**> to confirm the respective settings and to continue with the next step.



1. Language Settings

Select the appropriate language and confirm with <**Next**>.

(Refer to chapter "Settings & Tools >Regional")

2. Date & Time Settings

Select the appropriate settings and confirm with <**Next**>.

(Refer to chapter "Settings & Tools >Timezone Date & Time")

3. Sensor Settings

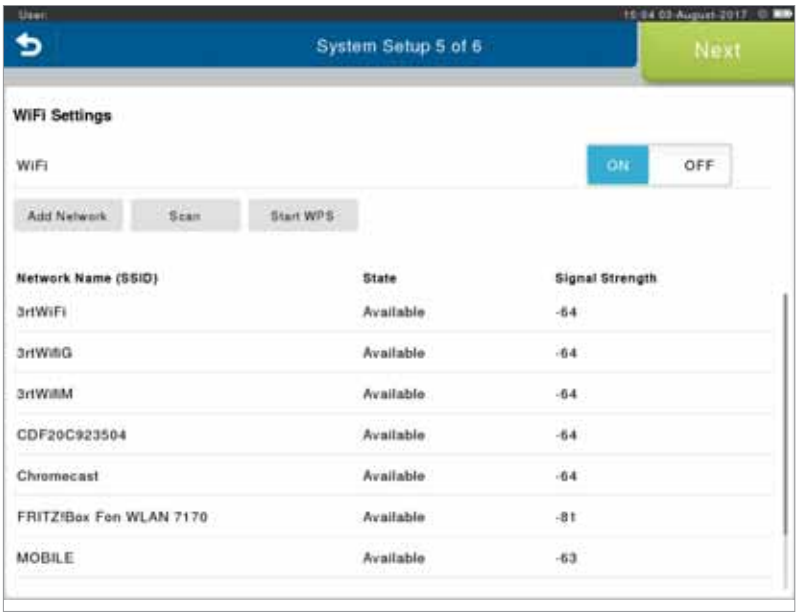
Place the SpiroSphere Sensor in the cradle, and tap on <**Scan**> to scan for available sensors. Tap on the sensor you want to pair the SpiroSphere with and select <**Pair**> from the dropdown menu. Confirm with <**Next**>.

(Refer to chapter "Settings & Tools >Spirometry Settings - Sensor")

Note that pairing is only possible for 90 seconds after the SpiroSphere Sensor is placed in the cradle.

4. Ethernet Settings

Choose the appropriate settings and confirm with <**Next**>. (Refer to chapter "Communication".)



5. WiFi Settings

Choose the appropriate settings and confirm with <**Next**>. (Refer to chapter "Communication".)

6. User Management Settings

This tool enables an authorized person to create an Administrator account. The newly created administrator will then be able to create additional accounts for individuals authorized to work with the **SpiroSphere**.

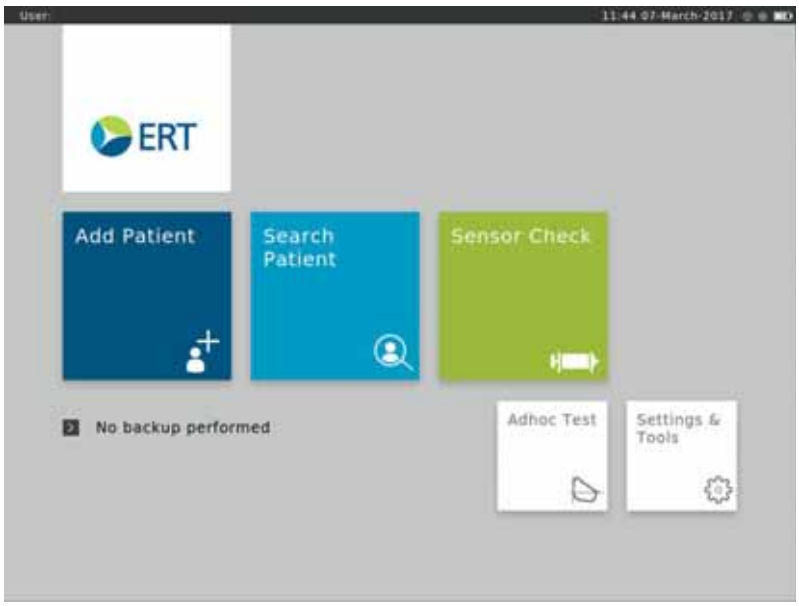
Choose the appropriate settings and confirm with <**Next**>. (Refer to chapter "User Management").

Complete the initial setup of the device by tapping on <**Yes**>.

All settings made in "SpiroSphere Setup" can be changed at any time should be changed. For detailed information please refer to chapter "**Settings & Tools**".

The Home Screen

After the SpiroSphere has been set up, upon powering on the device the following screen appears:



Here, you can select the submenus "**Add Patient**", "**Search Patient**", "**Sensor Check**", "**Adhoc Test**" as well as "**Settings and Tools**" by tapping on the respective button.

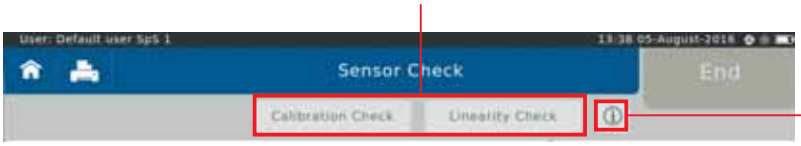
Add Patient	Enter patient data for a new patient into your patient directory and start a test.
Search Patient	Search for a specific patient in your patient directory. Select a specific patient from the list to perform a test or to edit his/her data.
Sensor Check	Perform a volume or linearity check.
Adhoc Test	Immediately perform a test without entering patient data or searching for a specific patient first.
Settings & Tools	Change settings.

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.

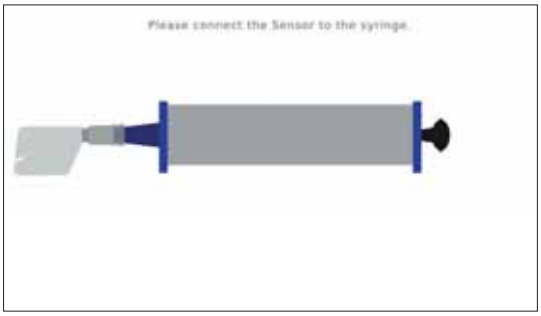
Tap <**Sensor Check**> to perform a sensor check.

The sensor check consists of a **calibration check** as well as a **linearity check**.



Tapping on the "**i**"- symbol will display information on the respectively selected check type.

Following screen appears:



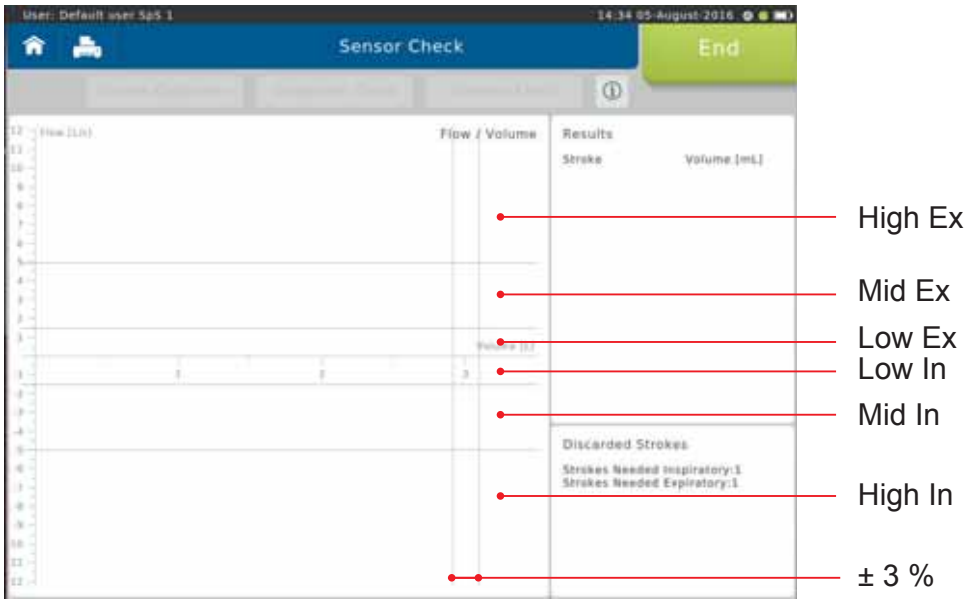
Calibration Check

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, tap on <**Calibration Check**>.

An automatic zero adjustment is performed.

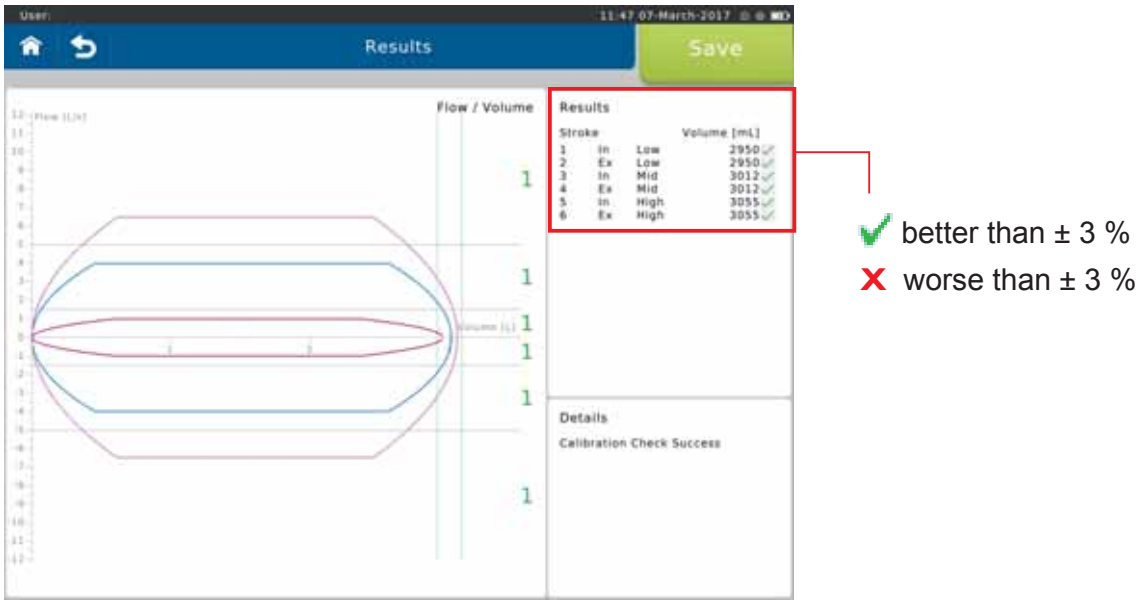
The **calibration check** is used to check the volume accuracy within 3 different flow ranges. With each syringe stroke, the volume accuracy should be within ± 3 %.



It is important to pump without interruption from impact to impact. The first pump stroke is not relevant and will be discarded. There should be one pump stroke in each of the following flow ranges; low, mid and high range.

1 syringe stroke = pump twice, i.e. from impact to impact.

Screen display after a total of three syringe strokes:



End the calibration check by tapping on <**Save**>.

Linearity Check

In order to perform a linearity check, tap on <**Linearity Check**>.
Proceed as described in the "**Calibration Check**" section.

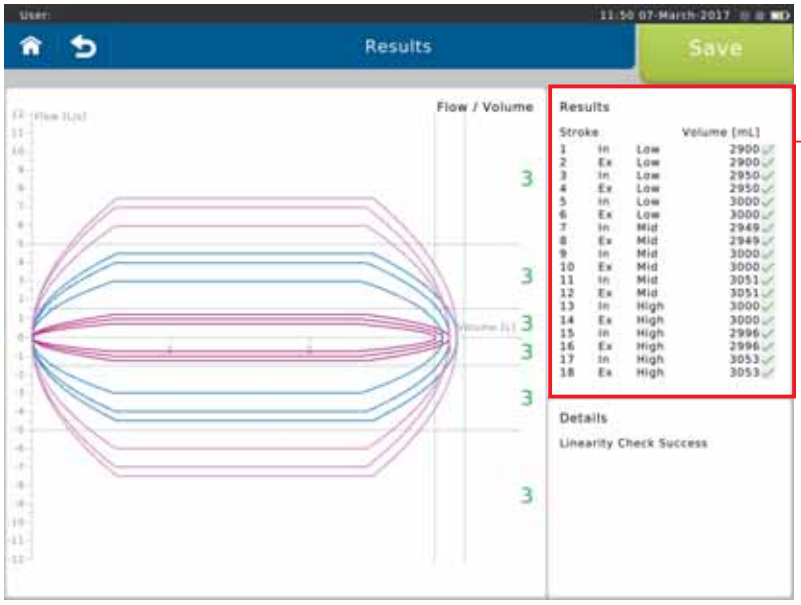
During a linearity check, volume accuracy at different flows is tested. Three syringe strokes at a low, three at a mid-range flow and three at a high flow are required.

With each syringe stroke, the volume accuracy should be within ± 3.5 %.

It is important to pump without interruption from impact to impact. The first pump stroke is not relevant and will be discarded. Three pump strokes are required in each of the following flow levels; low, mid and high range.

1 syringe stroke = pump twice, i.e. from impact to impact.

Screen display after a total of 9 syringe strokes:



✔ better than ± 3.5 %

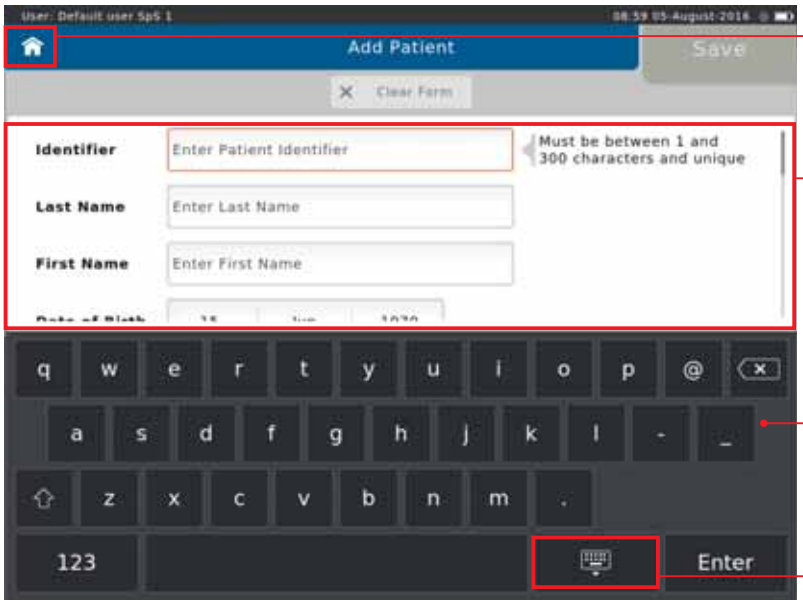
✘ worse than ± 3.5 %

End the linearity check by tapping on <**Save**>.

Add Patient

Before measuring a patient for the first time, the patient's personal data has to be entered. Predicted values are calculated from patient data, so verify that the entered data are correct. Incorrect patient data produces incorrect predicted values!

To add a new patient to your patient directory, tap on the "**Add Patient**" button on the Home Screen. The following screen appears:



Return to the Home Screen

Entry fields with instructions on entering

Touchscreen Keyboard

Hide Keyboard

Enter

Enter the appropriate patient data using the touchscreen keyboard and confirm with <**Enter**>. The cursor automatically jumps to the next entry field.

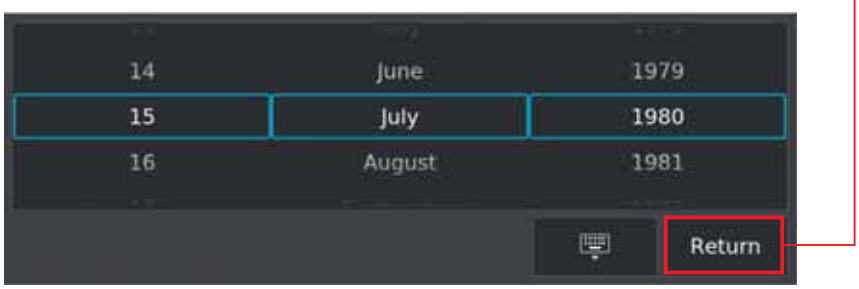
The following data **must** be entered:

Identifier: Enter the Patient Identifier

Last Name: Enter the Patient's last name

First Name: Enter the Patient's first name

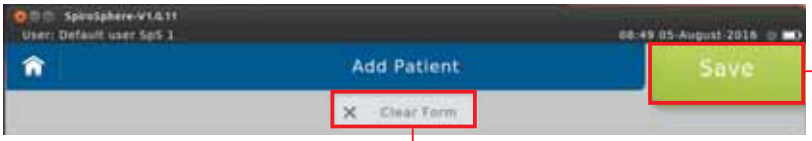
Date of Birth: Select appropriate Day, Month and Year of Birth and continue by tapping on <**Return**>.



Age: The Patient's age will be calculated automatically from the entered date of birth
Gender: Select appropriate gender
Height: Enter the Patient's height
Weight: Enter the Patient's weight
Ethnicity: Select the appropriate ethnicity

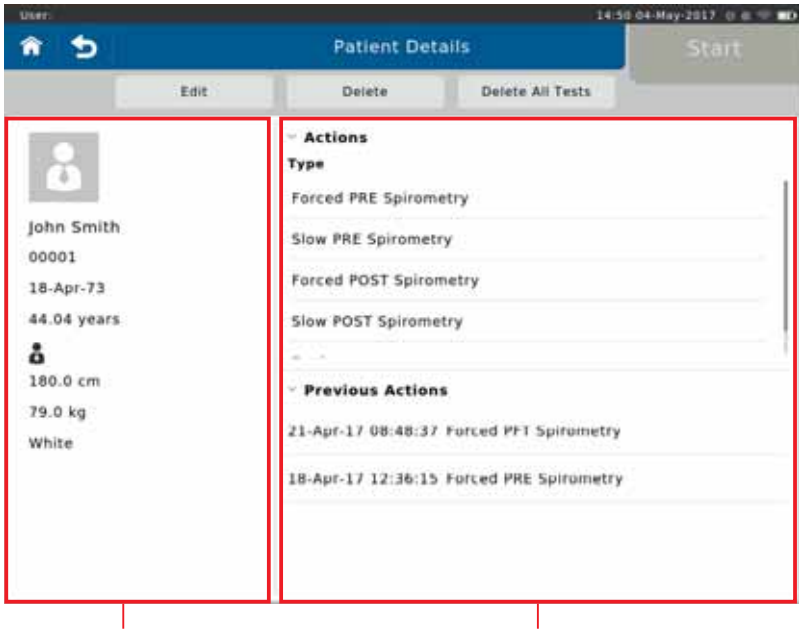
Additionally, there is an option to enter:
Technician: Enter the Technician's name
Physician: Enter the Physician's name
Set A Name 1:
Set A Name 2:

As soon as all required patient data is entered, tap on <**Save**> to save the patient to your patient directory.



*If you want to discard all data just entered, tap on <**Clear Form**>. All entry fields will be cleared.*

Screen display after patient data input:



Patient data

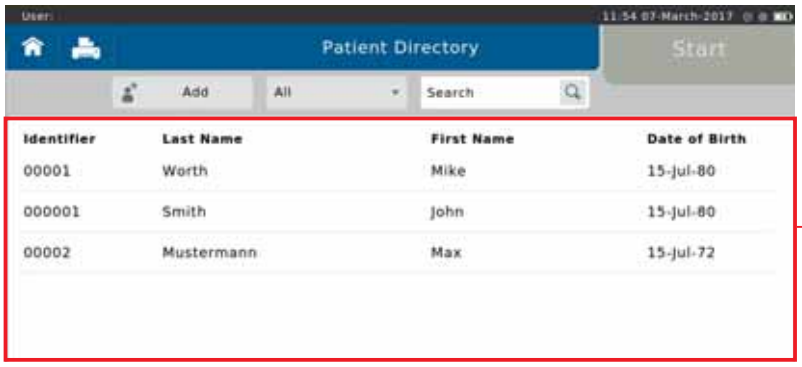
Available Actions (Type), and list of tests already performed (Previous Tests)

Search Patient

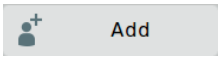
When a patient whose data is already stored in the database comes for another visit, you can reload his/her data from the patient directory. You do not have to enter the data again.

Tap on the "**Search Patient**" button on the Home Screen to open the list of all patient data saved in the database.

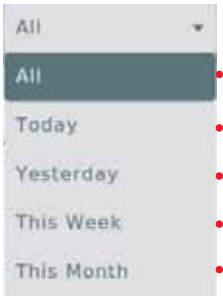
The following screen appears:



List of all patients



data of a new Patient can be entered



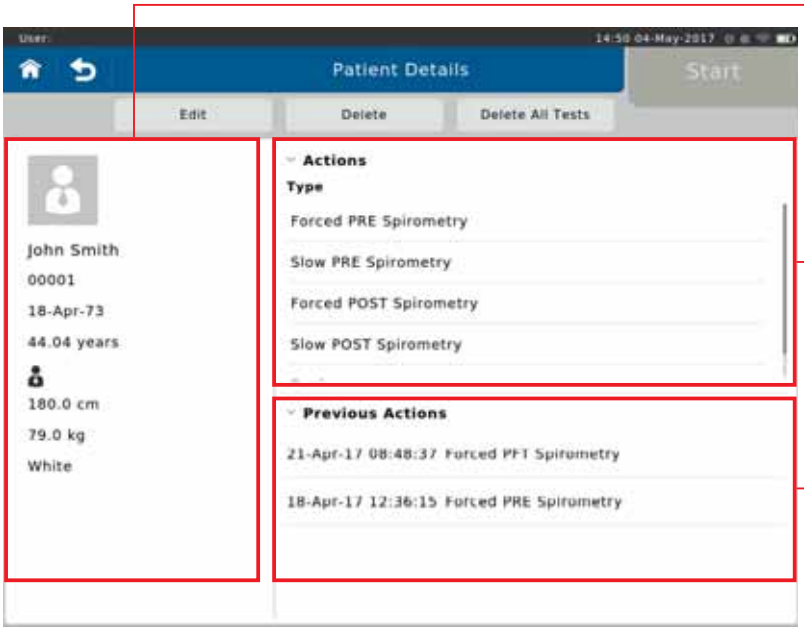
- Display **all** tested patients
- Display all Patients tested **today**
- Display all Patients tested **yesterday**
- Display all Patients tested **this week**
- Display all Patients tested **this month**

Search for specific Patients by entering his/her last name or ID. Entering the first letter or the first character of the patient's ID is sufficient as well: If e.g. "S" is entered, all patients whose last names start with "S" are displayed.

If a listed patient is selected, the following fly-out menu appears:

Start

Tap on <**Start**> to display the patient's personal data on the left.

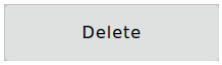


In the "**Actions**"section, all conductable actions are listed.

The "**Previous Actions**" section shows the actions already performed for the specific patient.

Edit

Tap on <**Edit**> to display the patient's demographic information. If incorrect patient data was entered or if the patient data need to be updated (e.g. due to weight or height change in children), the respective data can be edited and will be used for future tests.



Each patient can be completely deleted from the patient directory by tapping <**Delete**>.

A "**Warning**" appears:

Tapping on "**Yes**" will **irrevocably delete** the selected patient including all saved measurements performed for that patient!

Actions

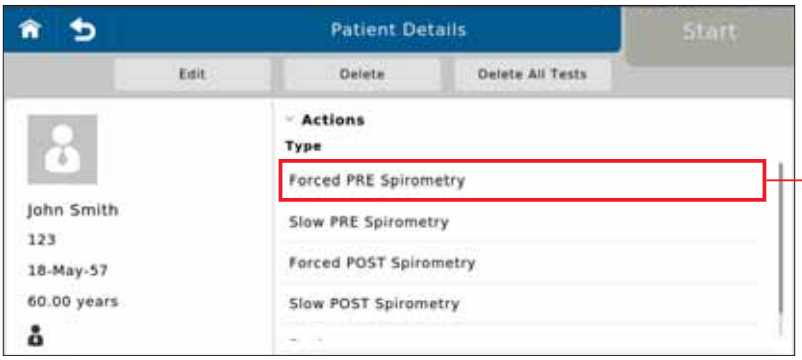
SpiroSphere is capable of performing different types of measurements.

The different options are displayed on the screen.

Forced PRE Spirometry	Forced Spirometry (Flow/Volume loop) pre bronchospasmolysis
Forced POST Spirometry	Forced Spirometry (Flow/Volume loop) post bronchospasmolysis
Slow PRE Spirometry	Slow Spirometry pre bronchospasmolysis
Slow POST Spirometry	Slow Spirometry post bronchospasmolysis

Preparing a Spirometry Measurement

Please observe the instructions for hygiene of your system. Verify that a new **ERT PT with mouthpiece** is attached in the SpiroSphere Sensor.

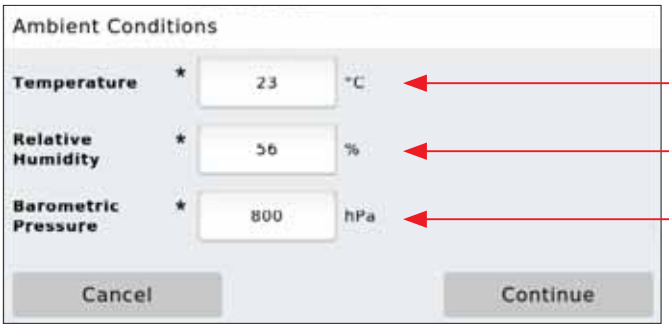


Select a measurement (e.g. <**Forced PRE Spirometry**>) via tapping.

Start

The measurement is started by tapping on <**Start**>.

The "**Ambient Conditions**" window appears:



Current room temperature (°C)

Current relative humidity (%)

Current barometric pressure (hPa)

The current ambient conditions are to be entered manually. In this case, the ambient data should be updated if the room temperature changed by more than 2°C or if relative humidity changed by more than 10%.

The ATP-BTPS correction factors for inspiratory and expiratory flows and volumes will be determined from the ambient data. Therefore, ambient data must be updated at regular intervals. Incorrect or imprecise ambient data will result in incorrect measurement results.

Continue

Tap on <**Continue**> to apply the ambient data entered.

Make the proper preparations according to ATS/ERS guidance.

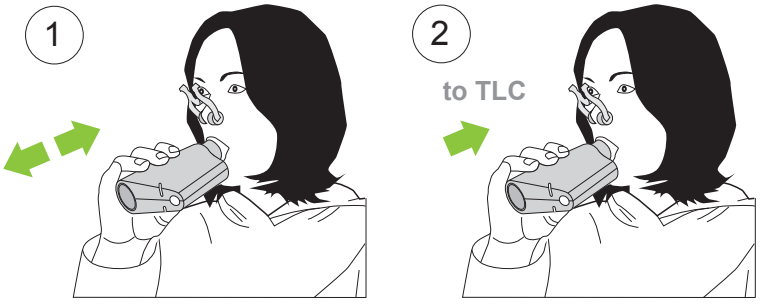
Perform a Forced Spirometry Measurement

When the test is started, an automatic zero adjustment of the sensor unit is performed. Hold the SpiroSphere Sensor still and wait for the zero adjustment to be completed before approaching the mouthpiece.

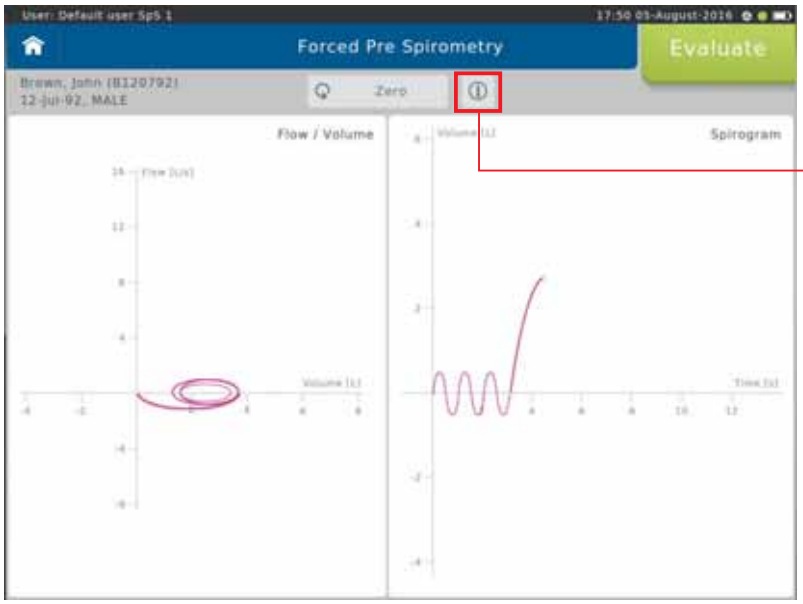
As soon as the zero adjustment is completed, the patient should close his/her nose with the nose-clip, take the mouthpiece between his/her teeth and seal his/her lips tightly around the mouthpiece. Check the correct position of the mouthpiece! For safety reasons, testing should be preferably done in the sitting position, using a chair with arms and without wheels.

Please note: During the whole examination the patient must stay on the mouthpiece.

The patient breathes normally (figure 1) until a steady tidal breathing is shown. From tidal breathing, the patient is instructed to inhale as deeply as possible (inhale to TLC - figure 2).

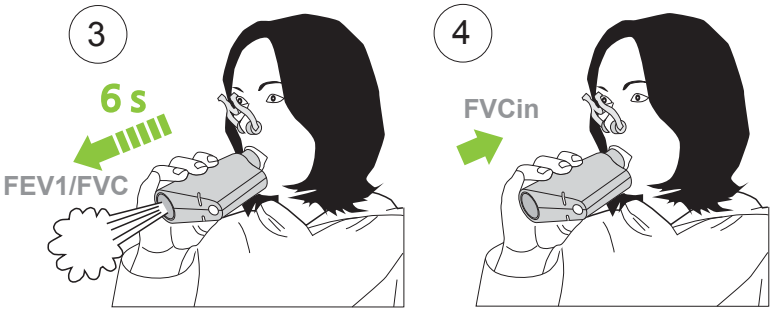


Screen display:

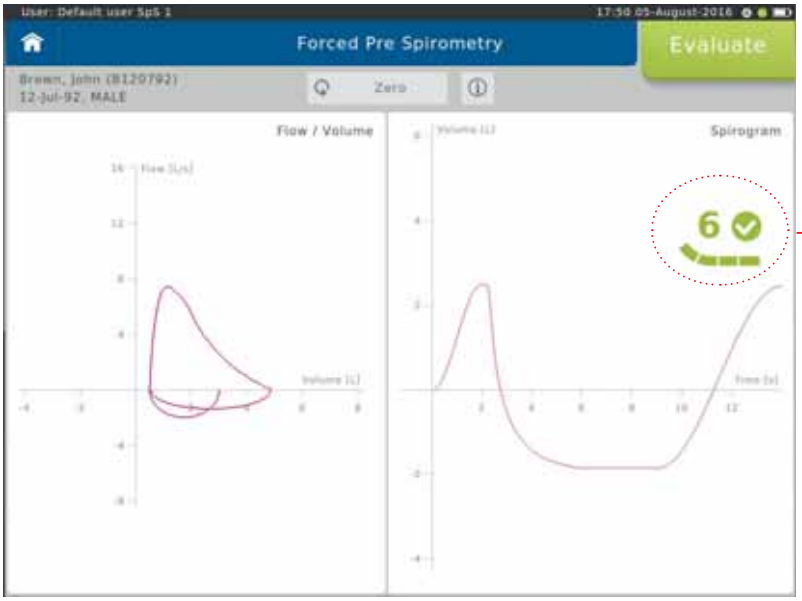


Tapping on the "i"-symbol will display information on the measurement procedure.

Without interruption, the patient should immediately exhale as fast and as much (FEV1) and as long (FVC) as possible (figure 3). According to the ATS/ERS guidelines, exhalation should be for a minimum of 6 sec for adults, and 3 sec for children. The maneuver is usually completed by an inhalation (figure 4).



Screen display:

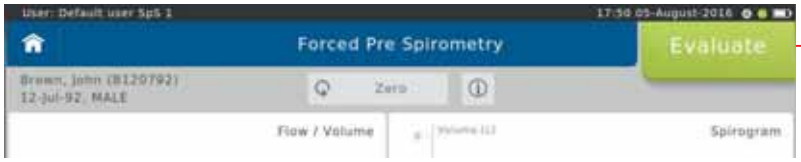


End of Test criteria is displayed as dynamic icon (time of exhalation and plateau).

Small tick indicates 6 seconds reached.

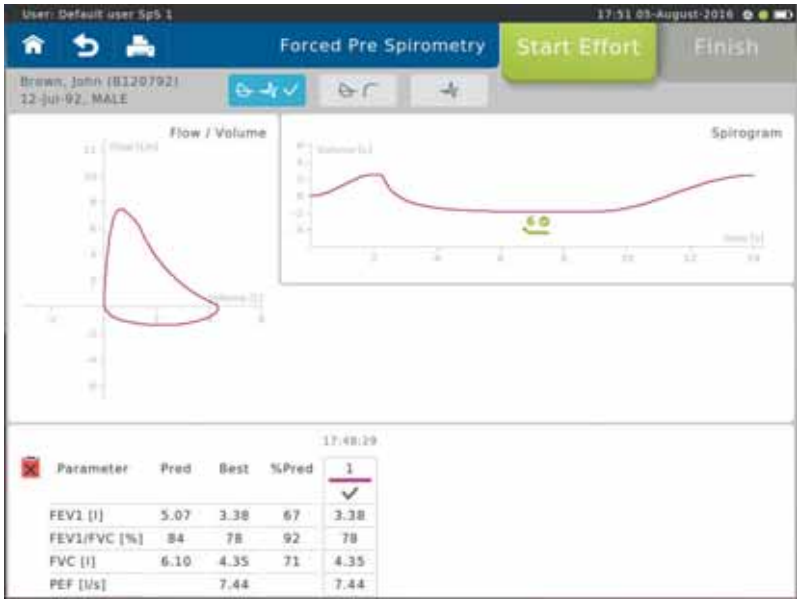
Large tick indicates 6 seconds reached and plateau.

Flow-Volume curve Volume-Time tracing



Tap <**Evaluate**> to end the first effort.

Screen display after the first effort:



The upper left part of the chart section shows the recording of the flow-volume loop. The upper right part shows the volume-time tracing.

The lower section of the screen displays the predicted values calculated from the patient data and the actual values measured from first effort.

Pred = Predicted value

Best = Best value of all valid efforts.

%Pred = Best value in % of predicted values

The quality of the flow-volume loop depends on the patient‘s cooperation. In order to assess repeatability and quality, it is recommended to perform at least 3 efforts according to ATS/ERS guidelines.
The results of the best and the second best effort for FEV1 and FVC may differ by ≤ 150 mL. For FVC ≤ 1 L a difference of ≤ 100 mL is valid*.

If necessary, it is possible to terminate the test prematurely.
In this case, a warning message is displayed.

Start the next effort by tapping on <**Start Effort**>.

Screen display after three efforts:

The "**Best**" column displays the best value out of all valid efforts.

Definition of the best effort depends on the Settings selected *(see: >Settings Spirometry >Forced Spirometry >Measurement).*

Scroll down to display further parameters (if applicable)

* 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

Change View:

Screen display flow-volume and tiffaneau curve:

Screen display volume-time curve:

Curves superimposed:

Return to Home Screen

Return to Patient Details

Print Report

Tap on the curve you want to be displayed.

The lower section displays the quality assessment according to ATS/ERS 2005 guidelines:

- ✓ = no acceptability errors
- △ = minor errors present
- ✗ = major errors present

Individual parameter Repeatability

- ↻ = Parameter repeatability criteria not met
- ↻✓ = Parameter repeatability criteria met

Overall Repeatability

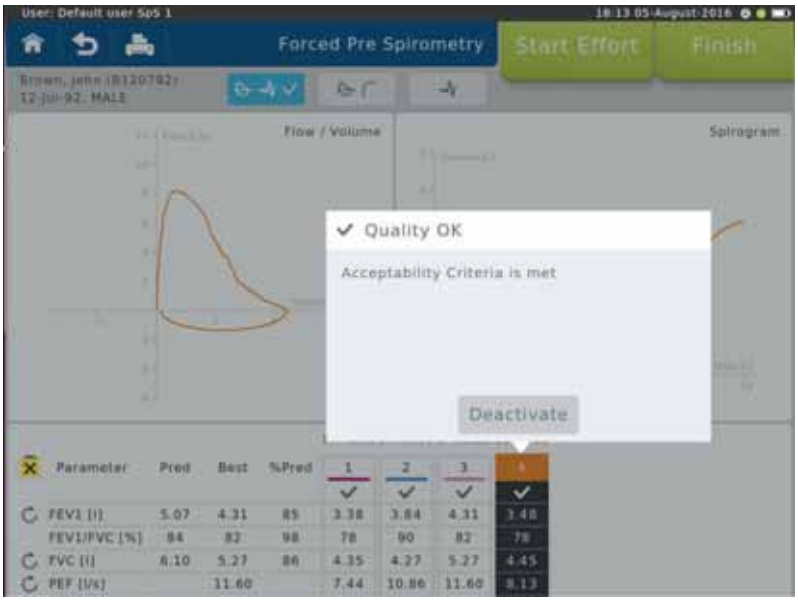
- ✗ = Not enough effort performed
- ✗ = Enough efforts, but one or more repeatability criteria are not met
- ✓ = Enough efforts and all repeatability criteria are met

Deactivate/reactivate efforts

If several efforts were performed, individual efforts (e.g. efforts with insufficient patient cooperation) can be deactivated. The system can also automatically deactivate efforts as a result of system detected ATS/ERS acceptability errors. Behaviour can be configured in Settings.

Procedure:

Mark the effort to be deactivated (in our example Effort 4). Following window appears:



Tap on <**Deactivate**>. Tapping on <**OK**> will deactivate the selected effort.
Successfully deactivated efforts will appear as a dashed line at the top of the column.

An effort deactivated by mistake can be reactivated again by tapping on the respective effort again. Tap on"**Reactivate**"in the following window to reactivate the effort.

Deactivated efforts will not be taken into consideration when calculating the Best Effort and Predicted Calculations.

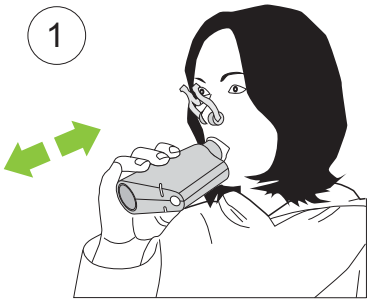
End and save the test by tapping on <**Finish**>.

Perform a Slow Spirometry Measurement

When the test is started, an automatic zero adjustment of the sensor unit is performed. Hold the SpiroSphere Sensor still and wait for the zero adjustment to be completed before approaching the mouthpiece.

As soon as the zero adjustment is completed, the patient should close his/her nose with the nose-clip, take the mouthpiece between his/her teeth and seal his/her lips tightly around the mouthpiece. Check the correct position of the mouthpiece! For safety reasons, testing should be preferably done in the sitting position, using a chair with arms and without wheels.

Make the proper preparations according to ATS/ERS guidance.



Performance of an "ERV Maneuver":

Tidal breathing should be continued for a longer period of time (figure 1). A stable breathing baseline is absolutely required to determine the lung volumes ERV and IC correctly.

Tidal breathing

Tapping on the "i"-symbol will display information on the measurement procedure.

The two columns displayed show how constantly the patient is breathing over the last five breathing cycles.

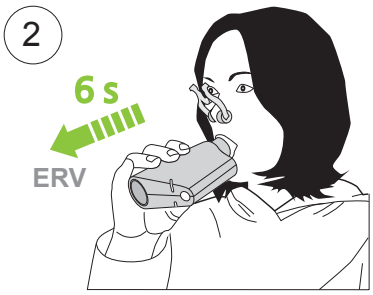
dVT = variation (coefficient of variation) of the tidal volume

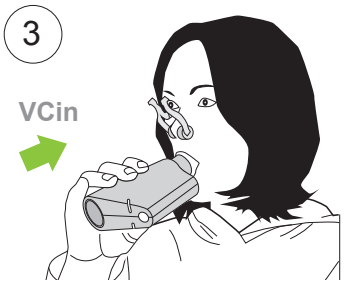
dFRC = variation of the breathing baseline

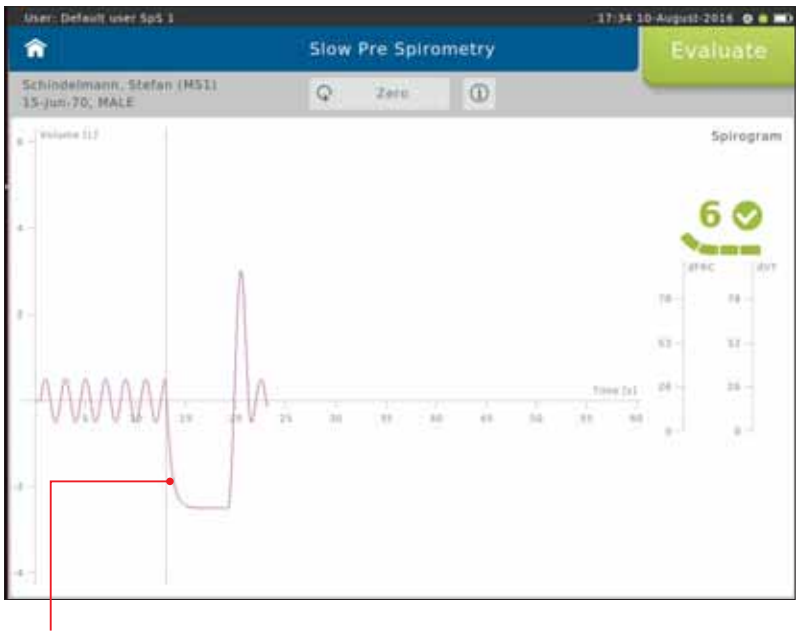
The lower the variation the more regular the breathing.

As soon as the display changes from "**red**" to "**green**", a stable breathing baseline has been reached.

The patient should exhale slowly (see "Note" below) and completely (ERV - figure (2)) followed by a slow and complete inhalation (VCin - figure (3)). Then, continue to breathe normally.







ERV/VCin

In order to reach the end-expiratory level the following two criteria must be complied with according to ATS/ERS.

1. Duration of expiration (ERV)
   Patients must exhale for at least 6 seconds.
2. End of Test Criteria (ERV)

Towards the end of the expiration it is important to motivate the patient to try hard. Within the last second of expiration the exhaled volume must not exceed 25 mL.

Tap on <**Evaluate**> to end the first effort.

Screen display after the first effort:

The upper section of the chart section shows the recording of the volume-time curve.

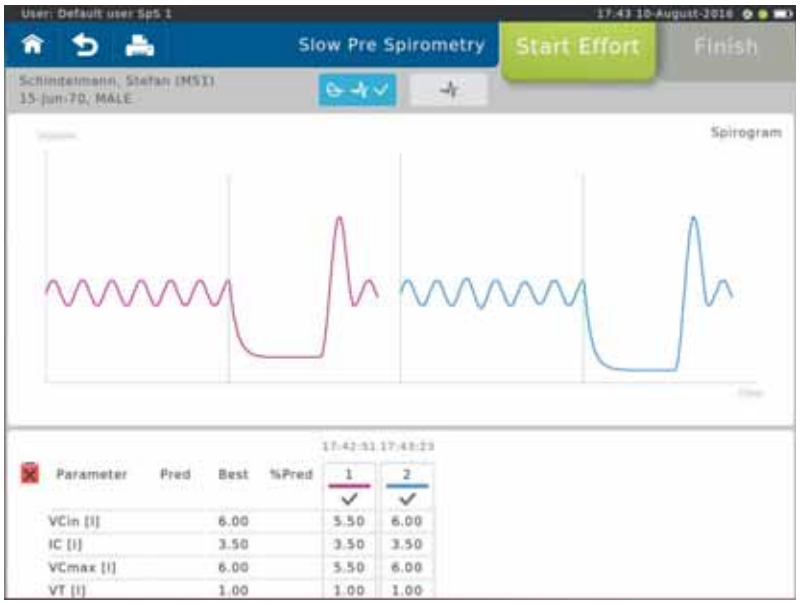
The lower section of the screen displays the predicted values calculated from the patient data and the actual values measured from first effort.

According to ATS/ERS criteria, at least three efforts should be performed. If the difference between the best and second best effort is greater than 0.150 L, further efforts should be performed.

If necessary, it is possible to terminate the test prematurely. In this case, a warning message is displayed to confirm that the test should be ended.

Start Effort Tap on <**Start Effort**> to start the next maneuver.

Screen display after two efforts:



The lower section of the screen displays the predicted values calculated from the patient data and the actual values measured during the test.

Pred = Predicted value

Best = Best values from all efforts

%Pred = Best value in % of predicted values

Scroll down to display further parameters (if applicable)

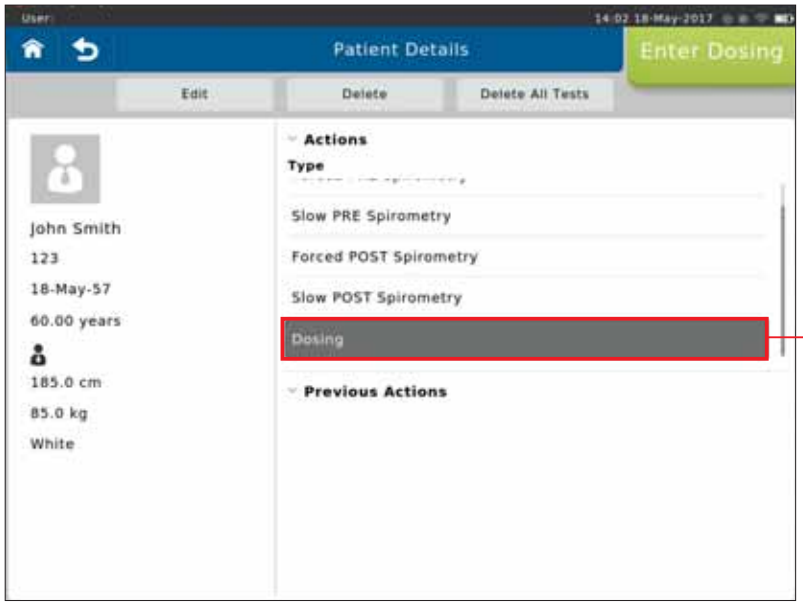
The "**Best**" column displays the best value out of all valid efforts.
Definition of the best effort = highest VCmax.

(see: >Settings Spirometry >Slow Spirometry> Measurement)

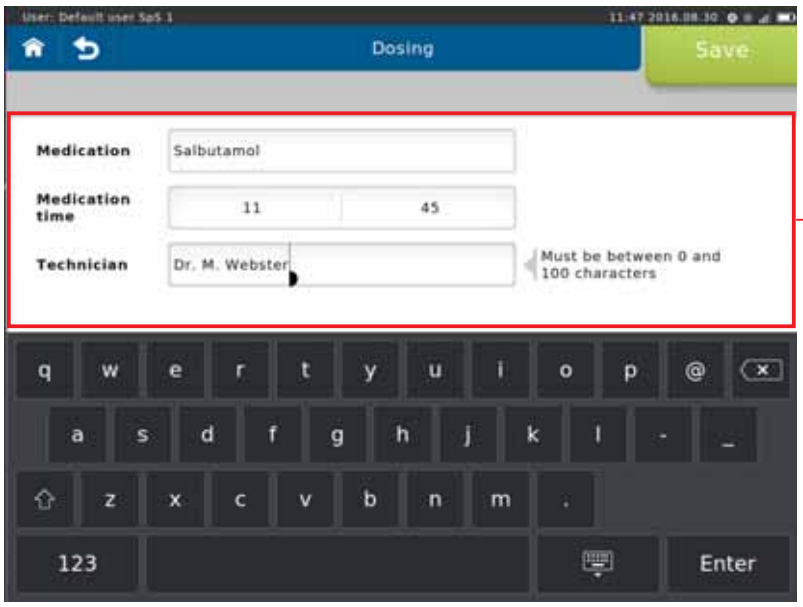
Medication Dosing Record

Before the **post**-measurement is started you can input Medication, the Medication time and the Technician name.

Tap <**Dosing**>.



Tap on <**Enter Dosing**>



The following data **can** be entered:

Medication: Enter the Medication, e. g. Albuterol/Salbutamol

Medication time: Enter the time the Medication was given, hh:mm

Technician: Enter the Technician name

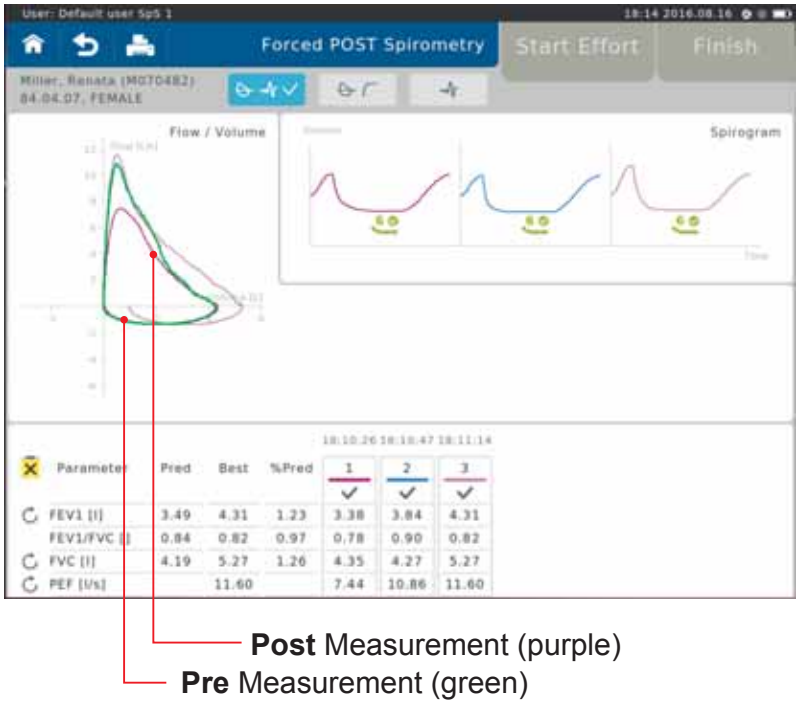
Tap on <**Save**> to save the dosing to your patient directory.

Perform a Post Spirometry Measurement

The Flow-Volume curve shows the immediate bronchospasmolytic effect. The expiratory portion of the Flow-Volume curve and consequently, maximal peak flow (PEF), forced expiratory volume after 1 sec (FEV1) as well as forced vital capacity (FVC) changes.

Screen display after the "**Pre Measurement**":

Screen display after the "**Post Measurement**":

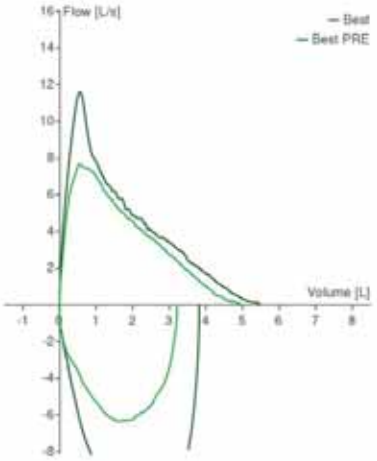


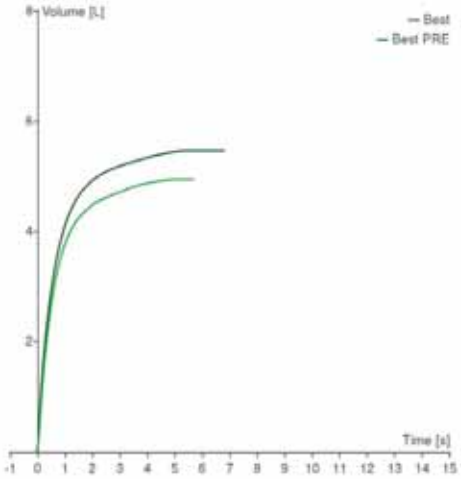
Pre-Post Report:

Best Effort Report

Patient Id:	3	**Date of Birth:**	06-Dec-82	**Height:**	183.0 cm
Last Name:	Bloggs	**Age:**	35 years	**Weight:**	
First Name:	Joe	**Gender:**	Male	**Ethnicity:**	White

Forced POST Spirometry 09-Aug-18 10:54:17





Ambient Conditions:	09-Aug-18 10:54:17	Temperature: 24 °C	Ambient Pressure: 980 hPa	Humidity: 60 %
Calibration Check:	not yet performed			
Linearity Check:	not yet performed			

Parameter	Pred	Pre	%Pred	Post	%Pred	Post%Pre
FEV1 [L]	4.53	3.79	84	4.13	91	9
FEV1/FVC [%]		77		75		-2
FVC [L]	5.58	4.95	89	5.47	98	11
PEF [L/s]	9.98	7.68	77	11.66	117	52
MMEF [L/min]	272	192	71	197	72	2
FVCin [L]		3.21		3.82		19
Error Code		BCDG				

ATS Error Codes

A	No repeatability. Less than 3 accepted forced measurements	G	PEF repeatability is unacceptable
B	FEV1 repeatability is unacceptable	H	Late peak flow detected
C	FVC repeatability is unacceptable	I	Coughing was detected in the first part of the expiration
D	Expiration time was too short (< 6 sec or < 3 sec if age < 10 years)	J	No valid forced measurement available
E	No plateau was detected at the end of the expiration	R	Abrupt End of Measurement
F	Back extrapolation volume was too large		

Predicted Authors

Knudson/Crapo

Template Version: 1.0 Page: 1 / 1 09-Aug-18 10:56:18

Adhoc Test

With the **Adhoc Test** application it is possible to perform a Spirometry measurement without having to register the patient beforehand.

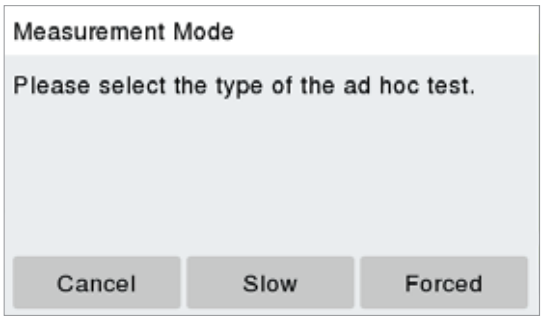
For example: An Adhoc test can be performed if a prompt measurement of a patient is urgently required (e.g. in an emergency situation).

It is possible to assign the measurements performed to a patient after the measurement has been completed or at some point later.

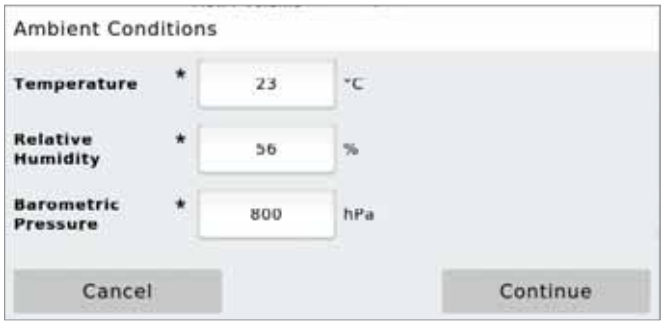
Perform an Adhoc Test

Tap on the "**Adhoc Test**" field on the Home Screen.

Please select the measurement mode. "Slow" or "Forced" spirometry:



The "**Ambient Conditions**" window appears and zeroing occurs:



Tap on <**Continue**> to apply the ambient data entered and perform three successive "Forced Spirometry" maneuvers as described. Once the test is completed, the following window appears:

Assign Adhoc Test now

Yes

Tap on <**Yes**>. The "**Patient Directory**" is displayed:

Tap on <**Add**> and enter the respective patient data (see chapter "**Add Patient**" for details).

Following window appears:

OK

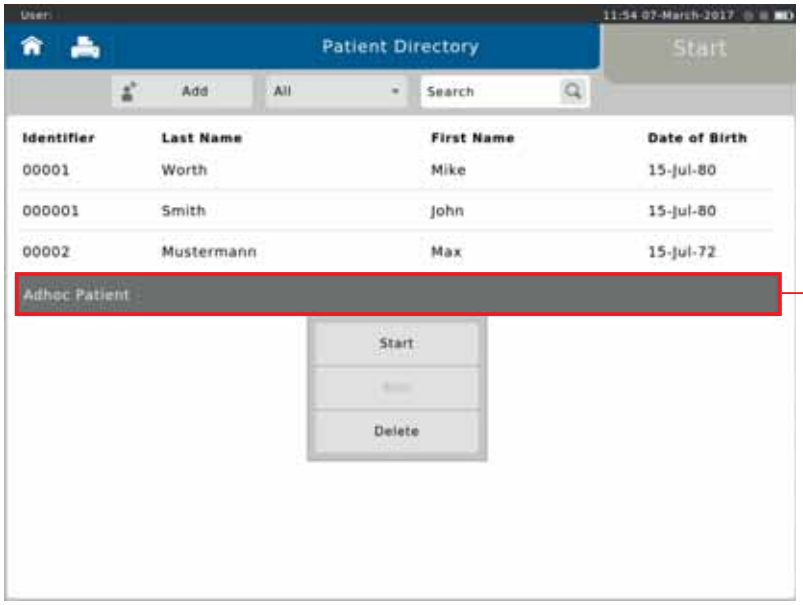
Finish by tapping <**OK**>.

Assign Adhoc Test later

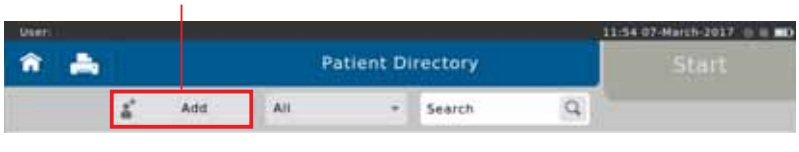
No

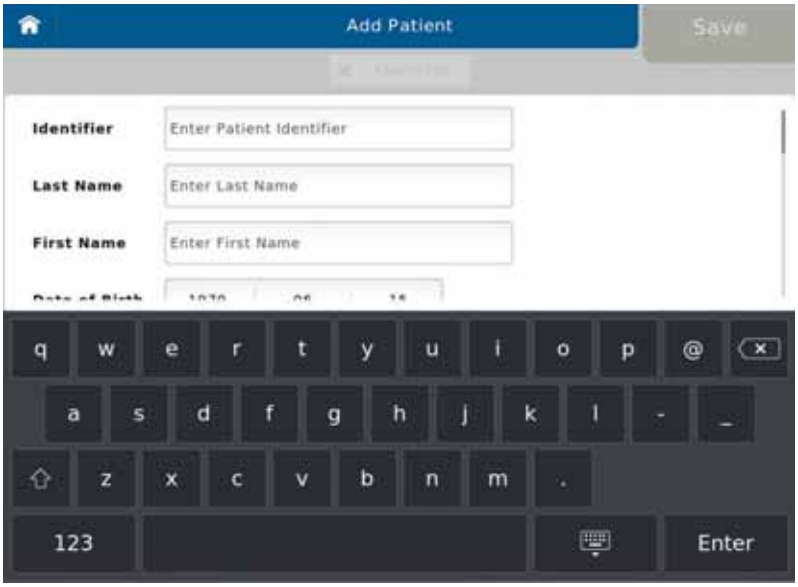
Tap on <**No**>.

The patient which is not registered yet will appear as "**Adhoc Patient**" in the "**Patient Directory**".
In order to assign a patient to the Adhoc test performed, tap on "**Adhoc Patient**".



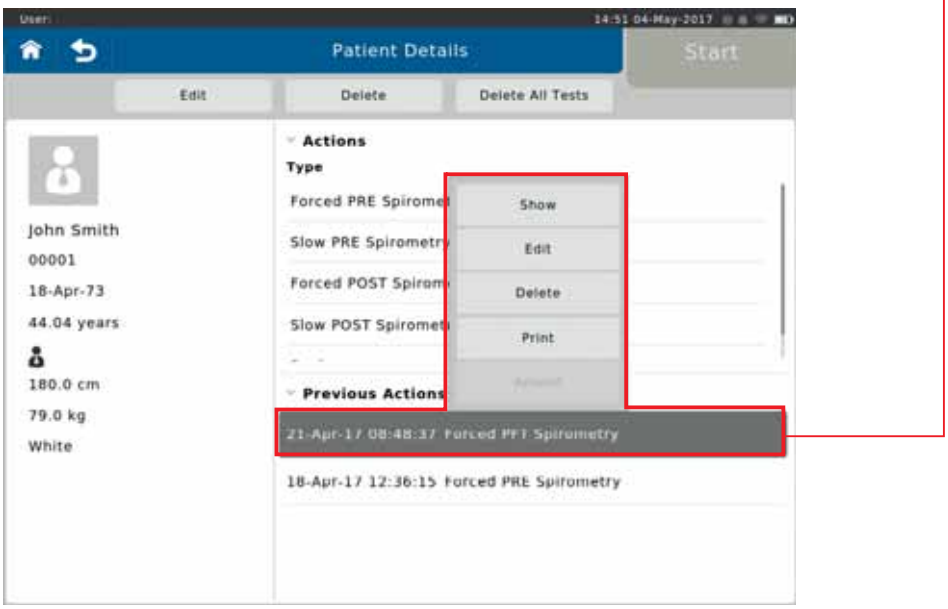
Tap on <**Add**> to enter the appropriate patient data.





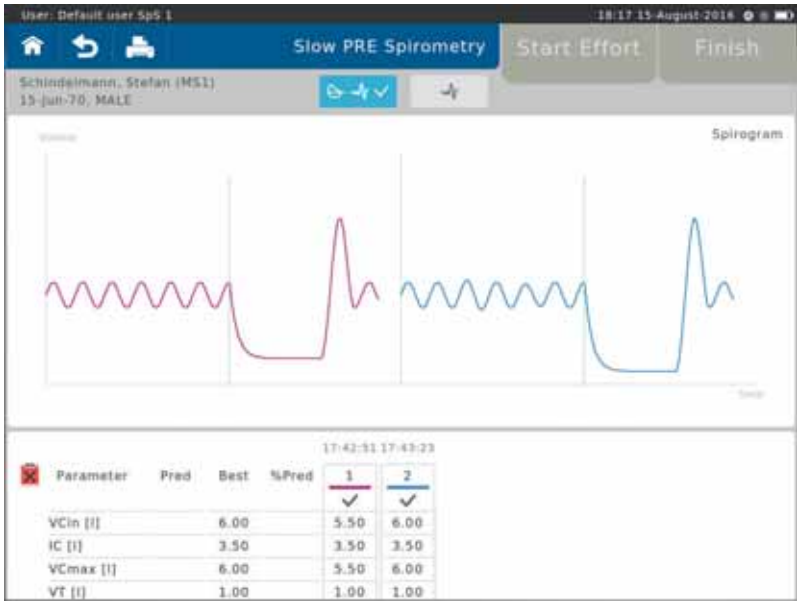
Show, Edit, Delete and Print Tests

Select a completed test. The following fly-out menu appears:



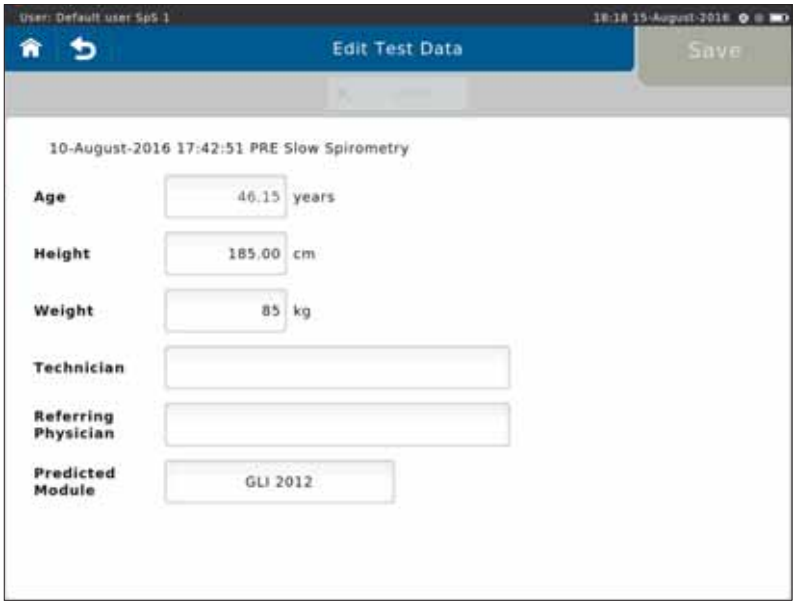
Show

Tap on <**Show**> to display the results of the selected test on the screen:



Edit

Existing patient data can be edited (if e.g. the patient's body weight or height (e.g. in children) has changed in the meantime) by tapping on <**Edit**>.



Delete

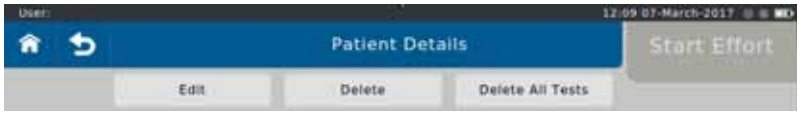
The selected test can be deleted with <**Delete**>:

Tapping on <**Yes**> will irrevocably delete the selected test!

Print

Tap on <**Print**> to print the selected test or send a PDF-report to a designated e-mail address.

For more detailed information, see chapter "**Print Recorded Results**".



Delete

The selected patient including all measurements performed with the respective patient can be deleted by tapping on <**Delete**>:

Tapping on <**Yes**> will irrevocably delete the selected patient and all respective tests!

Delete All Tests

Tap on <**Delete All Tests**> to delete all measurements performed with the selected patient:

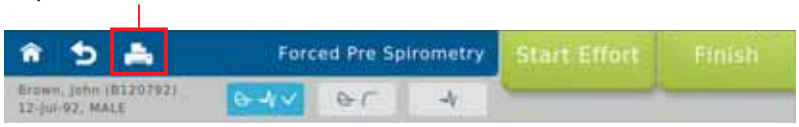
Tapping on <**Yes**> will irrevocably delete all tests assigned to the selected patient!

Print Recorded Results

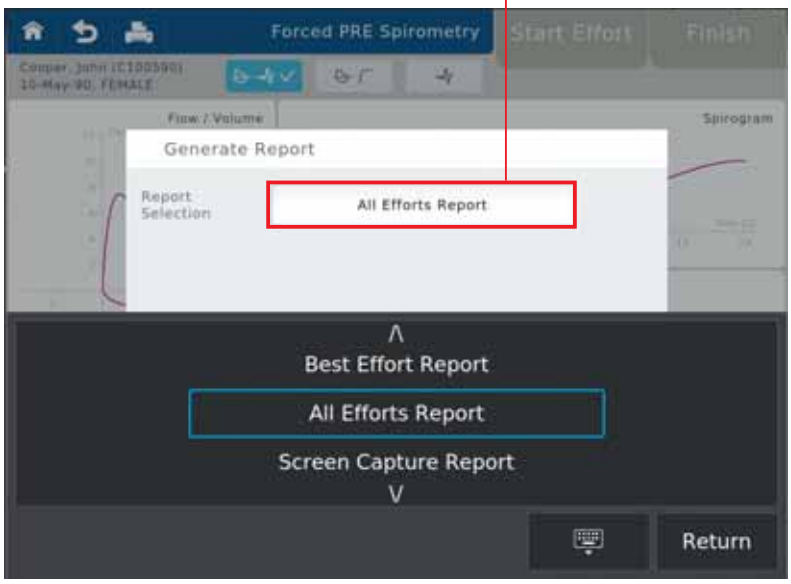
As soon as a measurement is completed, the results can be printed by means of a connected USB[*1] printer. It is also possible to create a PDF file which can be sent to a predefined e-mail address[*2] or saved to an USB stick.

Preset: send PDF to an e-mail address (see >Setting Report & Printing)

Tap on the Printer icon.



Tap on the Report Selection field.



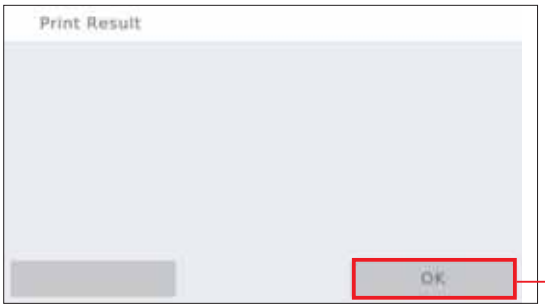
Best Effort Report
a report displaying the best effort is created

All Effort Report
a report displaying all efforts is created

Screen Capture Report
a screen capture report is created

Return

Tap on <**Return**> to create the report. The "**Print Result**" window appears:



Tap on <**OK**> to send the report to the predefined e-mail address.

The report will be sent to the email address defined on your SpiroSphere. The report label will include the date and identification number. The file will be password protected as defined.

SpiroSphere Report: BestEffortReport_20160815_155247+0200.zip

*[*1] For this option, an USB printer needs to be connected to the SpiroSphere*
*[*2] For this option, the SpiroSphere needs to be connected to the network*
*[*3] See chapter "Settings and Tools > Report & Printing"*

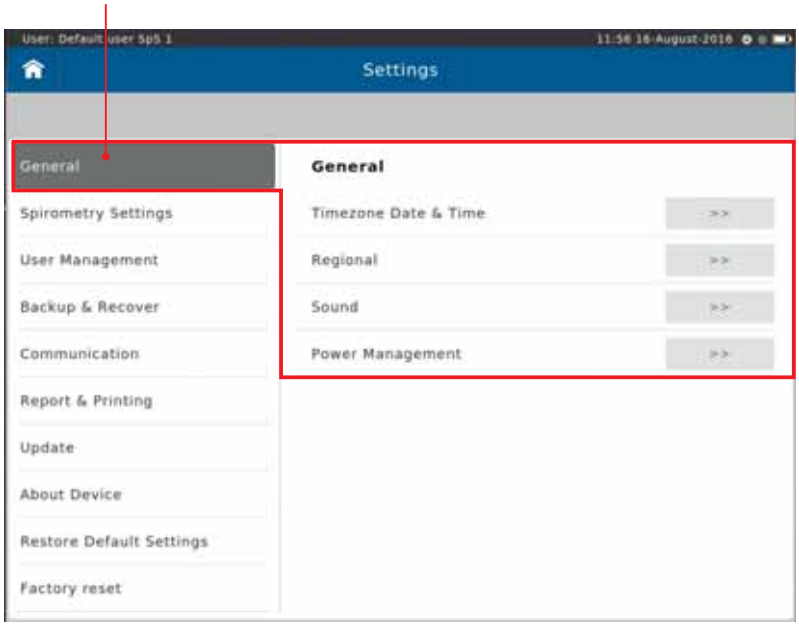
Settings and Tools

The following includes a short description of settings which are not required for daily routine work.

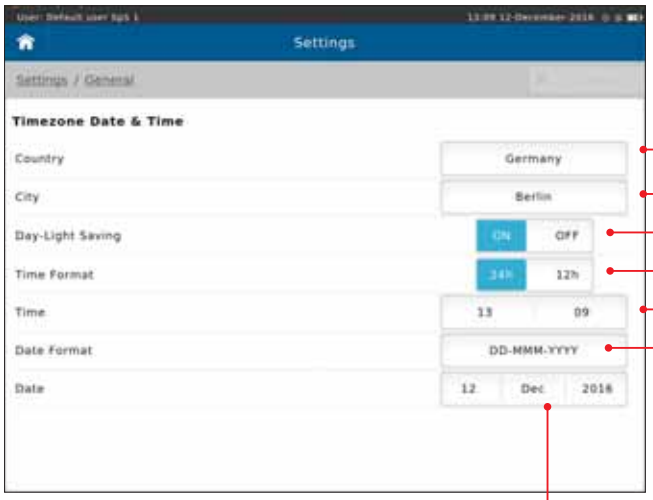
Tap on the "**Settings & Tools**" button on the Home Screen.
The following will appear:

General

Tap on "**General**"

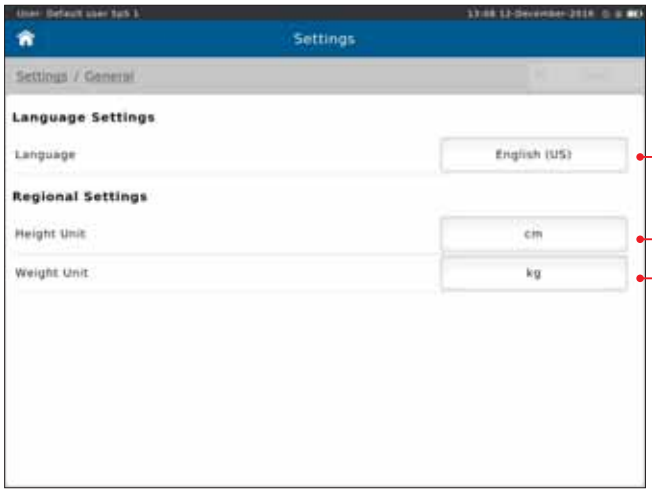


Timezone Date & Time



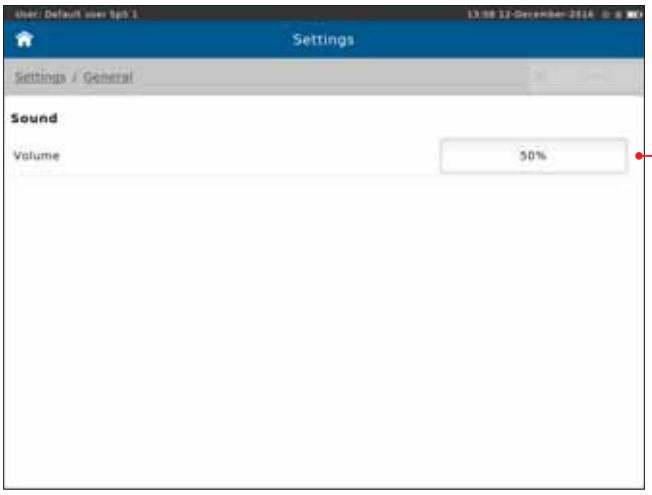
Options:	*Definition:*	*Choose/Preset:*
		select actual Country
		select timezone City
ON/OFF		ON
24h/12h		24h
		set actual Time
YYYY.MM.DD		2016.08.16
DD.MM.YYYY		16.08.2016 DD-MM-YYYY
DD-MMM-YYYY		16-AUG-2016
MM/DD/YYYY		08/16/2018
		set actual Date

Regional



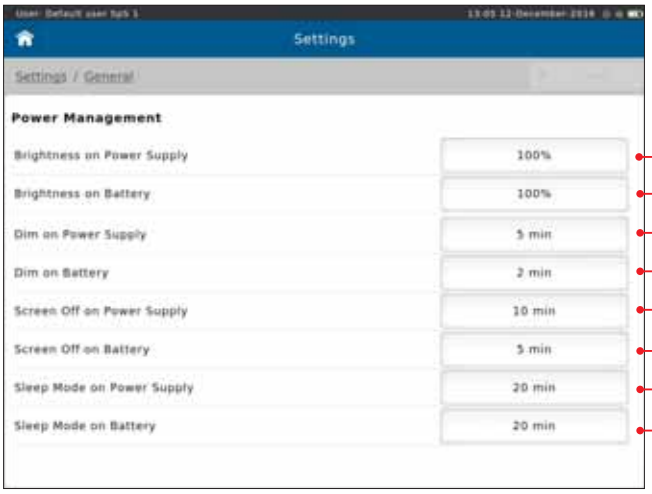
	Setting options:	*Preset:*
Language	English (US), German	English (US)
Height Unit	cm. in	cm
Weight Unit	kg. lb	kg

Sound



	Setting options:	*Preset:*
Volume	select	50%

Power Management

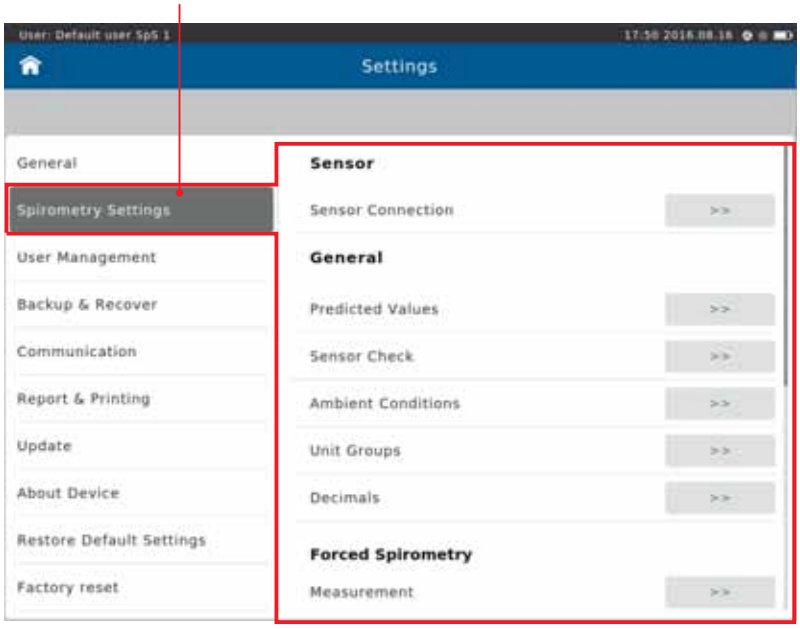


		Preset:
Brightness on Power Supply	select	100%
Brightness on Battery	select	100%
Dim on Power Supply	select	5 min
Dim on Battery	select	2 min
Screen Off on Power Supply	select	10 min
Screen Off on Battery	select	5 min
Sleep Mode on Power Supply	select	20 min
Sleep Mode on Battery	select	20 min

These settings influence the battery life of the SpiroSphere.

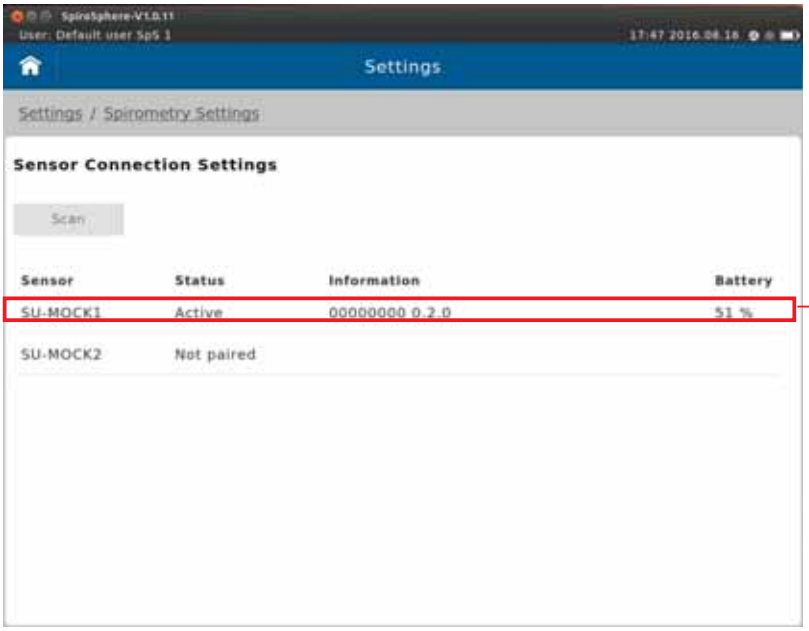
Spirometry Settings

Tap on "**Spirometry Settings**"



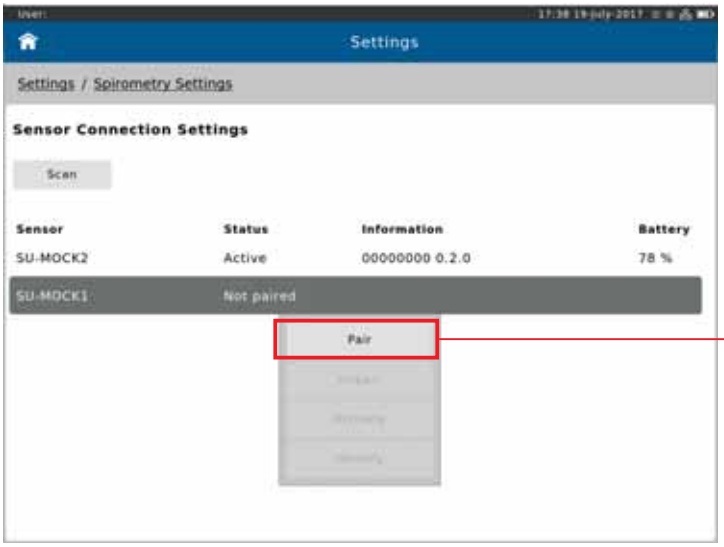
Spirometry Settings - Sensor

Sensor Connection

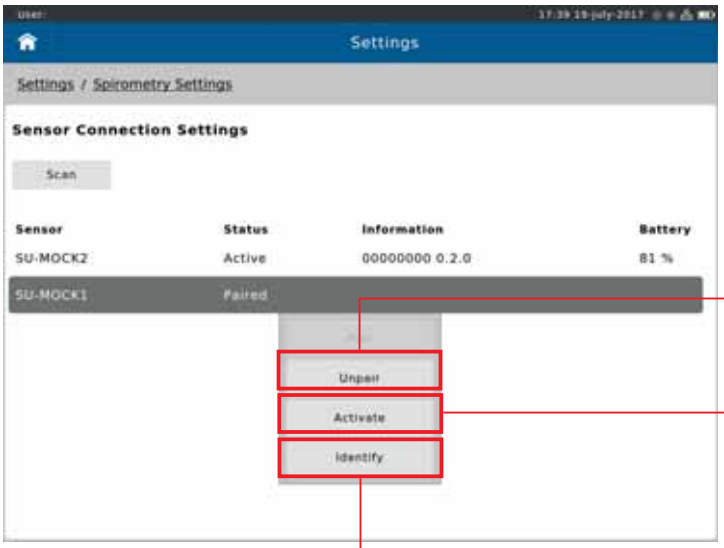


To make the SpiroSphere Sensor visible for pairing ensure it is powered on, and then remove and reinsert the SpiroSphere Sensor unit to the cradle.

Active:	The SpiroSphere Sensor is connected to the SpiroSphere via Bluetooth
Not paired:	The SpiroSphere Sensor is not connected to the SpiroSphere
Battery:	Indicates the battery status of the SpiroSphere Sensor



Select "**Pair**" to pair a new SpiroSphere Sensor



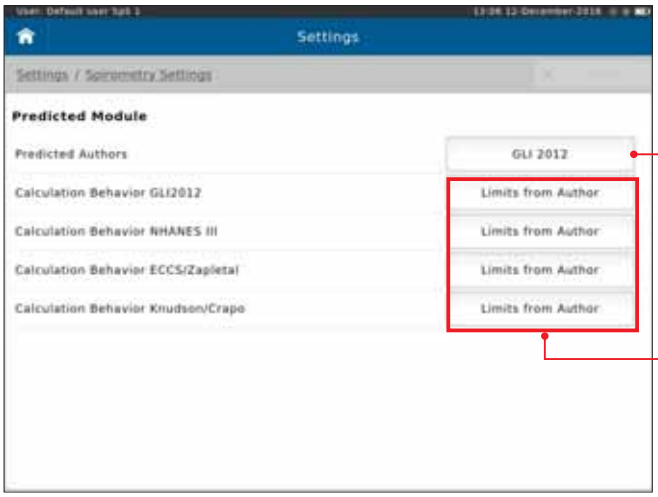
Select "**Unpair**" to unpair the SpiroSphere Sensor

Select "**Activate**" to make this SpiroSphere Sensor the active sensor for measurements

Select "**Identify**" to trigger an LED response on active SpiroSphere Sensor unit

Spirometry Settings - General

Predicted Values

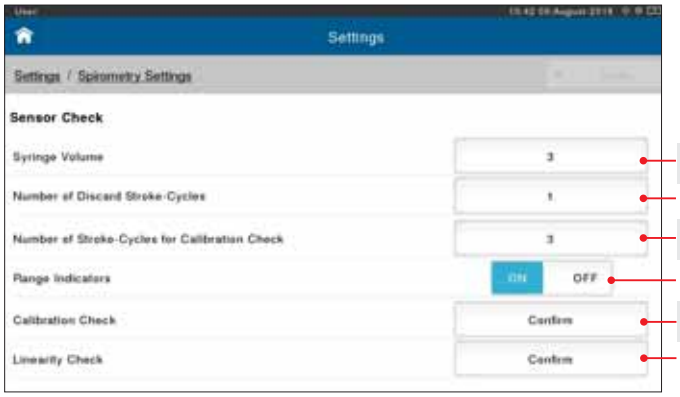


Setting options:	*Preset:*
None	GLI 2012
GLI 2012	
NHANES III	
ECCS/Zapletal	
Knudson/Crapo	
Extrapolate	
Limits from Author	Limits from Author
No calculation outside limits	

Module	Age range	Height range	Differentiation acc. to Race
GLI 2012	3-95 years	no limitation	Caucasian African American North East Asian South East Asian Other/mixed
NHANES III	8-80 years	110-200 cm	Caucasian African American Mexican American Asian-American is 0.88 of Caucasian (per MESA for FEV1, FVC)
ECCS/Zapletal	5-17 years (Zapletal) 18-70 years (ECCS 93)	107-182 cm (for Zapletal only)	Caucasian Oriental Hong Kong Chinese = 1.0 of Caucasian Orientals Japanese Americans = FEV1 0.89 of Caucasian, FVC = 1.0 of Caucasian Polynesians = 0.9 of Caucasians North Indians & Pakistanis = 0.9 of Caucasians African Descent = 0.87 of Caucasians Chinese (Female) = FEV1 0.93 of Caucasians, FVC = 1.0 of Caucasians Chinese (Male) = FEV1 0.95 of Caucasians, FVC = 0.94 of Caucasians
Knudson/Crapo	6-90 years	no limitation	Caucasian African-Descent = 0.88 of Caucasian (for FEV1 & FVC)

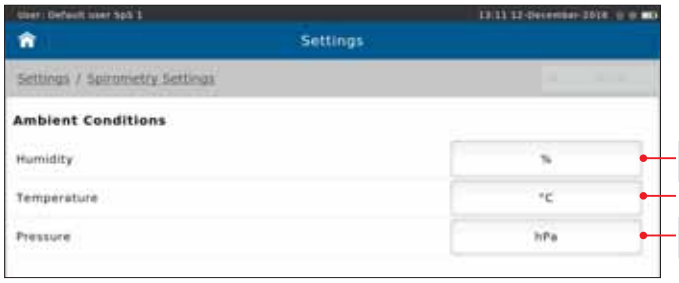
[1] For an age between 19 and 25, the calculation is based on the age of 25

Sensor Check



Setting options:	*Preset:*
1, 2, 3	3
1, 2, 3, 4	1
2, 3, 4, 5, 6, 7, 8	3
ON, OFF	ON
OFF, Confirm, Enforce	Confirm
OFF, Confirm, Enforce	Confirm

Ambient Conditions

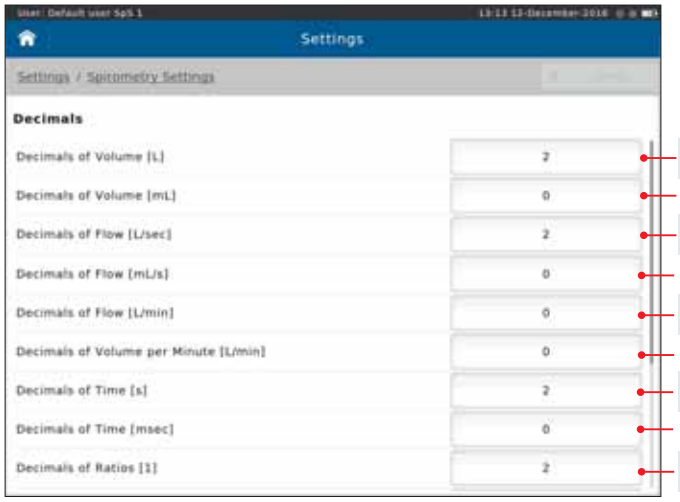


Setting options:	*Preset:*
%	%
°C, °F	°C
hPa, mmHg	hPa

Unit Groups

Setting options:	*Preset:*
mL, L	L
mL, L	mL
L/s, mL/s, L/min	L/s
L/s, mL/s, L/min	L/s
L/min	L/min
s, ms	s
s, ms	ms
1, %	%
L*L/s	L*L/s
Hz, 1/min	1/min

Decimals

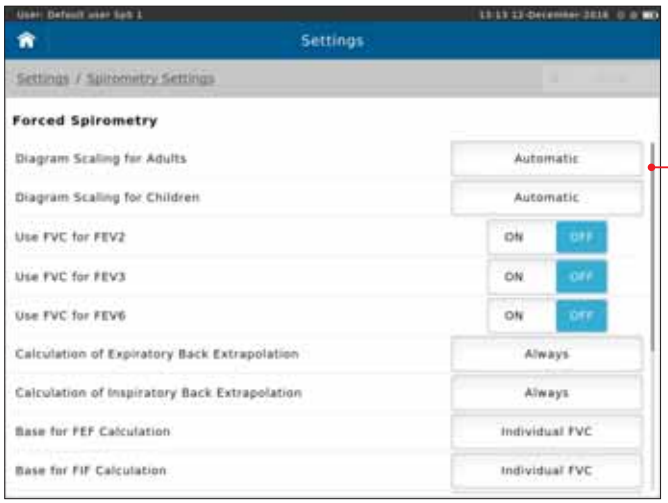


Possible Setting Options for Decimals:	*Preset:*
Decimals of Volume [L] - 0, 1, 2, 3	2
Decimals of Volume [mL] - 0	0
Decimals of Flow [L/Sec] - 0, 1, 2, 3	2
Decimals of Flow [mL/Sec] - 0	0
Decimals of Flow [L/min] - 0, 1	0
Decimals of Volume per Minute [L/min] - 0, 1	0
Decimals of Time [s] - 0, 1, 2, 3	2
Decimals of Time [msec] - 0	0
Decimals of Ratios [1] - 0, 1, 2, 3	2

Example:	Preset 0:	Preset 1:	Preset 2:
FVC [L]	5	5.1	5.10

Spirometry Settings - Forced Spirometry

Measurement



Scroll down to display further settings (if applicable)

	Setting options:	*Preset:*
Diagram Scaling Adult **Diagram Scaling Child**	Automatic 16 L/s, 12 L/s, 8 L/s , 4 L/s	Automatic

If “**Automatic**“ is selected and the breathing flow is greater or less than the preset flow axis, this axis will be rescaled automatically.

	Choose:	*Preset:*
FVC as FEV2	ON, OFF	OFF
FVC as FEV3	ON, OFF	OFF
FVC as FEV6	ON, OFF	OFF

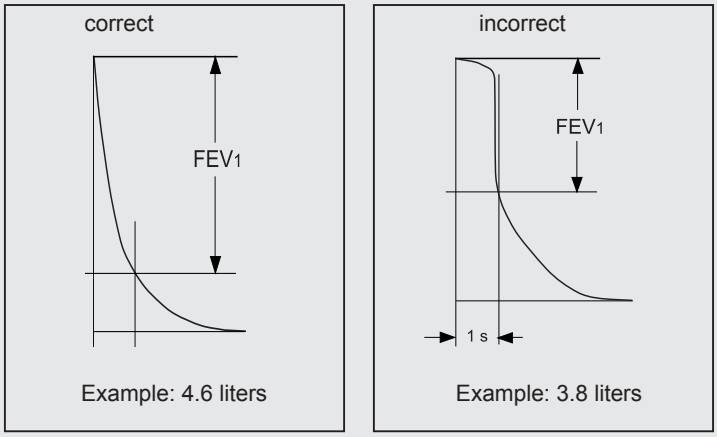
If “” is selected, the value for the respective parameter is used as the FVC value.

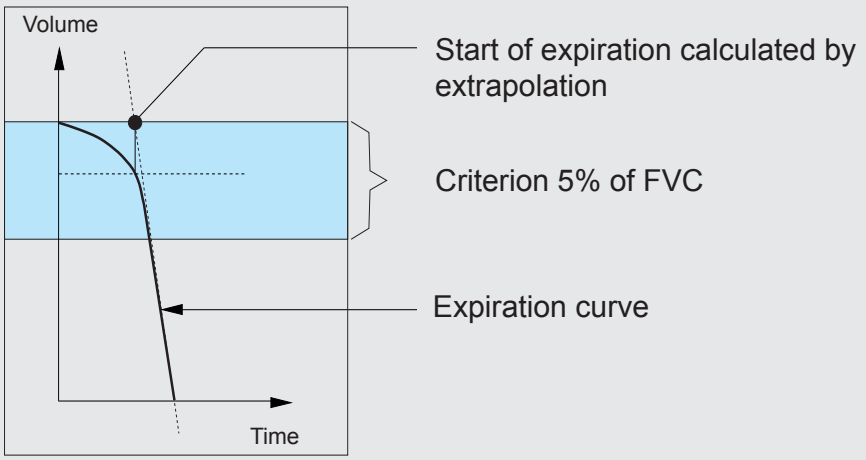
	Setting options:	*Preset:*
Expiratory Back Extrapolation **Inspiratory Back Extrapolation**	Always, Never	Always

Why Back Extrapolation?

A delayed start of the expiration in the forced expiration breathing maneuver provides incorrect results for various parameters.

Back extrapolation means that in case of a delayed expiration the system determines the correct start of expiration.





Why inspiratory back extrapolation?

In case of a delayed inspiration during the FIV1 breathing maneuver and if “always“ is preset, the system determines the correct start of inspiration.

FEF calculation Base **FIF calculation Base**	*Setting options:* individual FVC VC max	*Preset:* individual FVC
	If “**individual FVC**“ is selected, the FEF or the FIF values will be calculated based on FVC.	
Best Expiration	*Setting options:* FEV1 + FVC FEV1 FVC FVC + FERV1 + 1/3*PEF FEV0.5 + FVC FEV0.5	*Preset:* FEV1 + FVC
Best Inspiration	*Setting options:* FVCin + PIF FVCin + 0.1*PIF FVCin + FIV1 FVCin FIV1 Use best EX	*Preset:* FVCin + PIF
	If several breathing maneuvers are performed within one test cycle, the system determines the best breathing maneuver within this trial according to preset criteria.	
Summary default View	*Setting options:* Flow/Volume Tiffenau Spirogram	*Preset:* Flow/Volume
	If “**Flow/Volume**“ is selected, the result screen will display the flow-volume curve. If "**Tiffeneau**" is selected, the tiffenau curve will be displayed.	

Display Inspiratory

Setting options: ON, OFF

Preset: ON

ON means: the inspiratory portion of the Flow-Volume curve is displayed.

OFF means: the inspiratory portion of the curve will not be displayed.

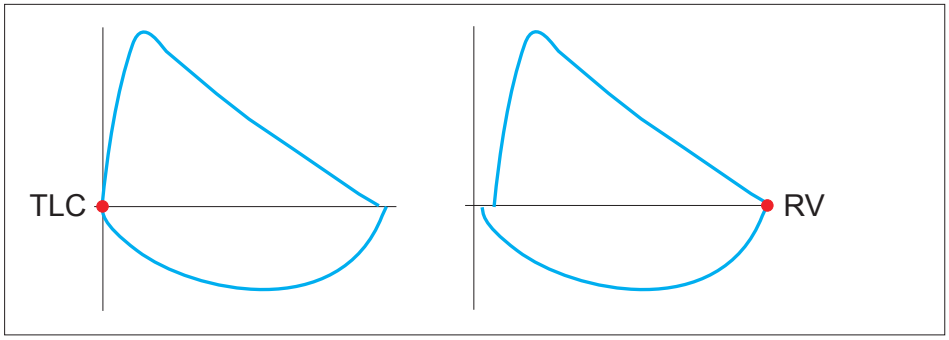
The setting can be changed during the measurement.

Inspiratory Position

Setting options: TLC, RV

Preset: TLC

The inspiratory and expiratory phase of the Flow-Volume curve can be referred to TLC or RV.

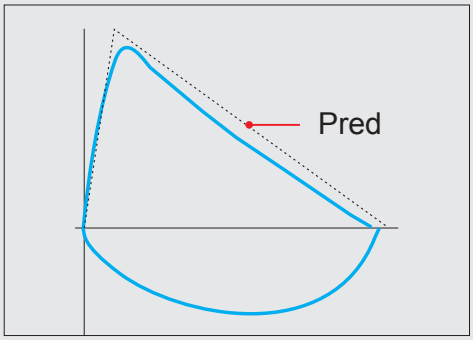


Display Predicted Curve

Setting options: ON, OFF

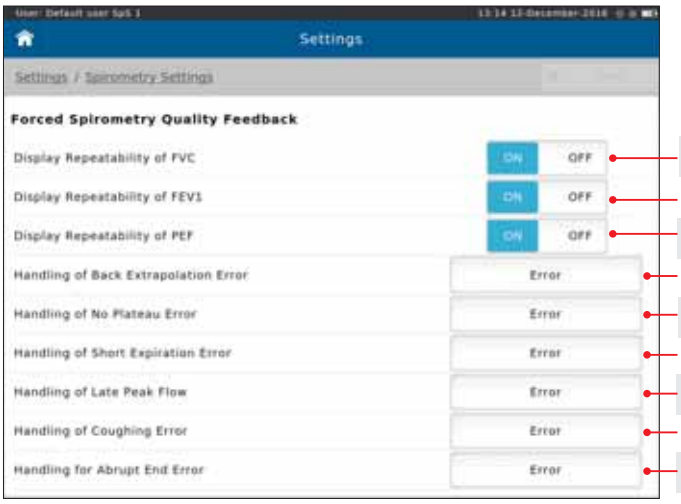
Preset: ON

If activated (**ON**), a predicted curve will be displayed in the diagram as reference.



Spirometry Settings - Forced Spirometry

Quality Feedback



	Setting options:	*Preset:*
Display Repeatability of FVC	ON, OFF	ON
Display Repeatability of FEV1	ON, OFF	
Display Repeatability of PEF	ON, OFF	
Handling of Back Extrapolation Error	Error, OFF, Warning, Confirmation	Error
Handling of No Plateau Error	Error, OFF, Warning, Confirmation	Warning
Handling of Short Expiration Error	Error, OFF, Warning, Confirmation	Warning
Handling of Late Peak Flow	Error, OFF, Warning, Confirmation	Error
Handling of Coughing Error	Error, OFF, Warning, Confirmation	Error
Handling for Abrupt End Error	Error, OFF, Warning, Confirmation	Error

As the quality of a spirometry measurement strongly depends on the patient's cooperation, the criteria defined by the ATS must be met. If the respective criteria are not met, they will be displayed in the results screen and finally documented in the report.

Quality Feedback documented in an "Example" report:

Environment conditions: 16.08.16 18:10:26 Temperature: 22 °C Pressure: 1010 hPa Humidity: 65 %

Parameter	Pred	Pre	%Pred	Post	%Pred	Post%Pre
FEV1 [l]	3.49	3.84	1.10	4.31	1.23	0.12
FEV1/FVC []	0.84	0.88	1.05	0.82	0.97	-0.07
FVC [l]	4.19	4.35	1.04	5.27	1.26	0.21
PEF [l/s]		10.86		11.60		0.07
MMEF [l/s]	3.72	5.39	1.45	3.93	1.06	-0.27
FVCin [l]		4.30		4.30		0.00
Error Code		ABG		BCG		

ATS error codes

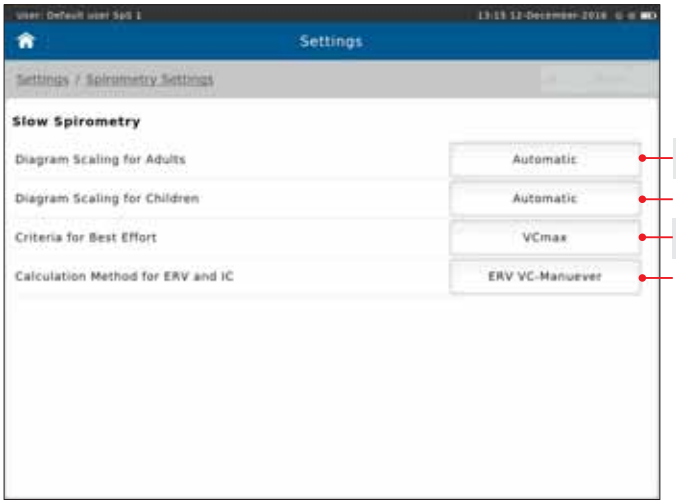
A	No repeatability; Less than 3 accepted forced measurements	F	Back extrapolation volume was too large
B	FEV1 repeatability is unacceptable	G	PEF repeatability is unacceptable
C	FVC repeatability is unacceptable	H	Late peak flow detected
D	Expiration time was too short (< 6 sec or < 3 sec if age < 10 years)	I	Coughing was detected in the first part of the expiration
E	No plateau was detected at the end of the expiration	J	Abrupt End of Measurement

ATS error codes

ABG means: errors A, B, G are present

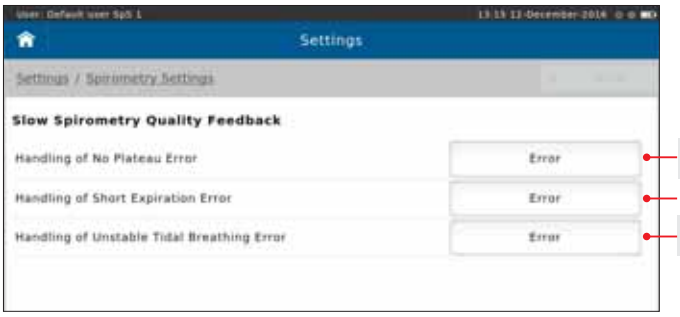
Spirometry Settings - Slow Spirometry

Measurement



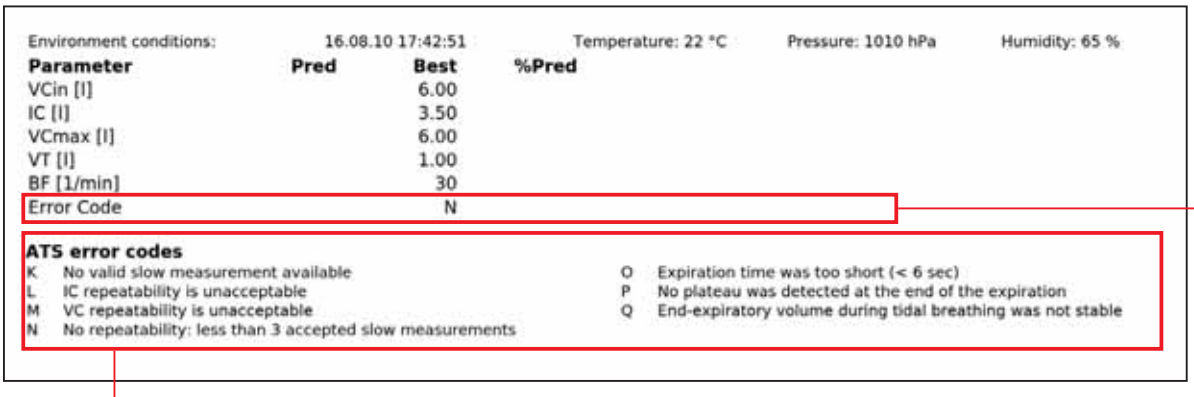
	Setting options:	*Preset:*
Diagram Scaling for Adults	Automatic, 12, 9, 6, 4 L	Automatic
Diagram Scaling for Children	Automatic, 12, 9, 6, 4 L	Automatic
Criteria for Best Effort	VCin, VCex, VCmax, IC, ERV	VCmax
Calculation Method for ERV and IC	ERV VC-, IC VC-Maneuver	ERV VC-Maneuver

Quality Feedback



	Setting options:	*Preset:*
Handling of No Plateau Error	Error, OFF, Warning, Confirmation	Warning
Handling of Short Expiration Error	Error, OFF, Warning, Confirmation	Warning
Handling of Unstable Tidal Breathing Error	Error, OFF, Warning, Confirmation	Error

Quality Feedback documented in an "Example" report:



Environment conditions: 16.08.10 17:42:51 Temperature: 22 °C Pressure: 1010 hPa Humidity: 65 %

Parameter	Pred	Best	%Pred
VCin [l]		6.00	
IC [l]		3.50	
VCmax [l]		6.00	
VT [l]		1.00	
BF [1/min]		30	
Error Code		N	

ATS error codes

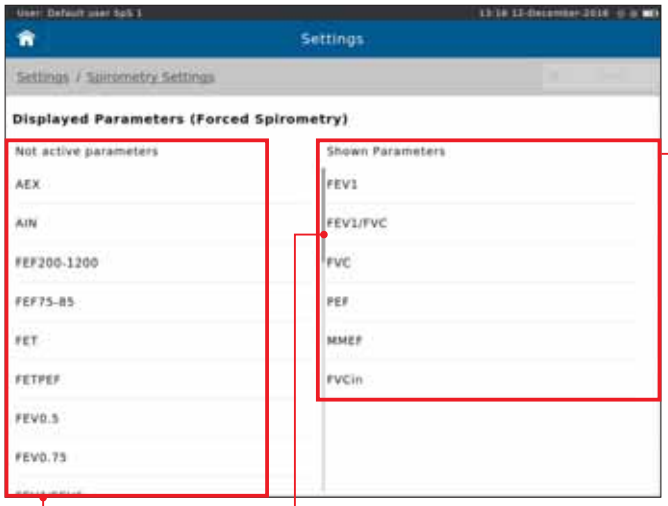
K No valid slow measurement available
L IC repeatability is unacceptable
M VC repeatability is unacceptable
N No repeatability: less than 3 accepted slow measurements
O Expiration time was too short (< 6 sec)
P No plateau was detected at the end of the expiration
Q End-expiratory volume during tidal breathing was not stable

ATS error codes

N means: the criteria N are not met

Parameter Selection

Forced Spirometry - Displayed Parameters



The"**Shown Parameters**" column displays the parameters shown in the result screen of the forced spirometry measurement.

Preset:

FEV1

FEV1/FVC

FVC

PEF

MMEF

FVCin

Scroll down to display further parameters (if applicable)

The"**Not active parameters**" column displays all parameters which can be selected to be shown during a measurement.

Add a parameter to the "Shown Parameters" column:

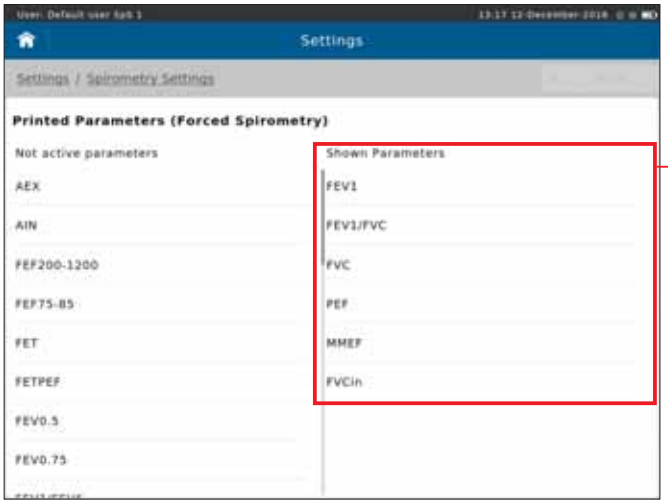
Double-tap on the required parameter in the "Not active parameters" column. The parameter will immediately be added to the "Shown Parameter" list.

Remove a parameter from the "Shown Parameters" column:

Double-tap on the parameter you want to delete.

Tap on <**Undo**> in order to undo the recent changes.

Forced Spirometry - Printed Parameters



The"**Shown Parameters**" column displays shown the printed parameters of the forced spirometry measurement:

Preset:

FEV1

FEV1/FVC

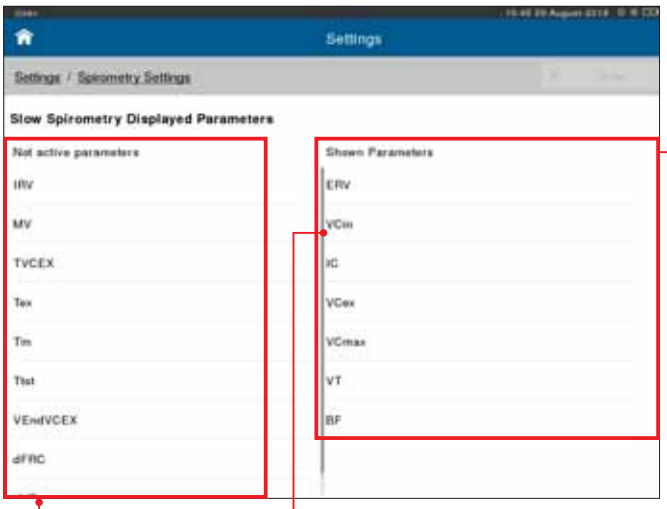
FVC

PEF

FEF25-75

FVCin

Slow Spirometry - Displayed Parameters



Scroll down to display further parameters (if applicable)

The "**Shown Parameters**" column displays the parameters shown in the result screen of the slow spirometry measurement.

Preset:

ERV

VCin

IC

VCmax

VT

BF

The "**Not active parameters**" column displays all parameters which can be selected to be shown during a measurement.

Add a parameter to the "Shown Parameters" column:

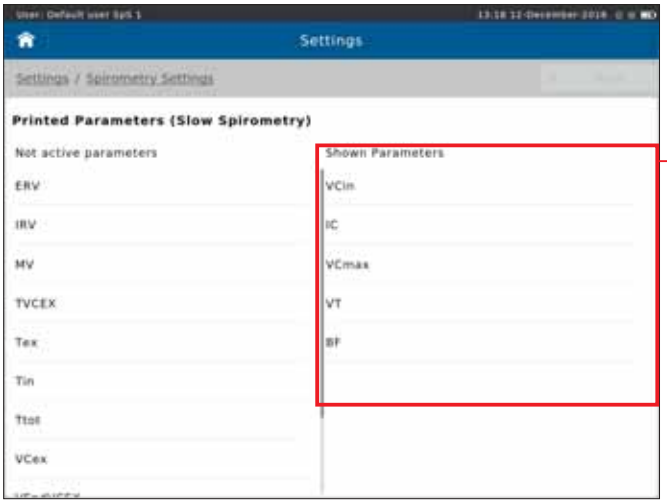
Double-tap on the required parameter in the "Not active parameters" column. The parameter will immediately be added to the "Shown Parameter" list.

Remove a parameter from the "Shown Parameters" column:

Double-tap on the parameter you want to delete.

Tap on <**Undo**> in order to undo the recent changes.

Slow Spirometry - Printed Parameters



The"**Shown Parameters**" column displays shown the printed parameters of the slow spirometry measurement:

Preset:

VCin

IC

VCmax

VT

BF

Resting ECG

SpiroSphere ECG allows recording of a 12-lead resting ECG measurement.

Information on ECG Recording

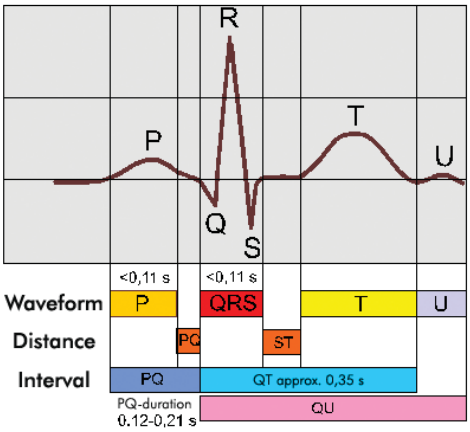
An electrocardiogram (ECG) is a graphic recording of the changes occurring in the electrical potentials (millivolt changes) at defined sites on the skin. The continuously changing electrical fields are the result of depolarization and polarization of the heart and are distributed in the body without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

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.

ECG Leads

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

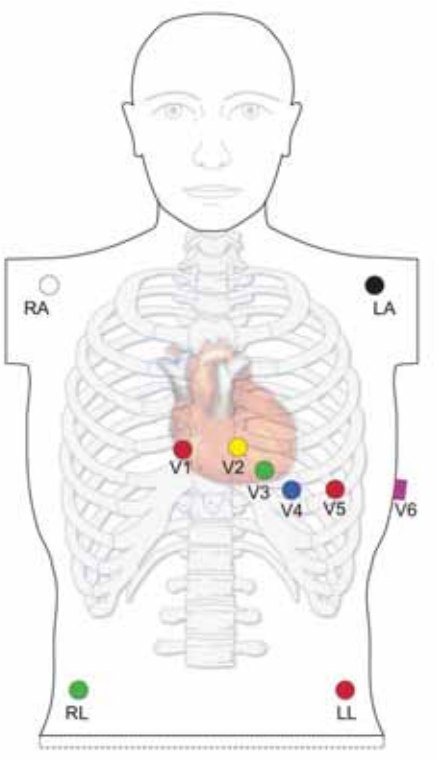
Preparing the subject‘s skin:

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.

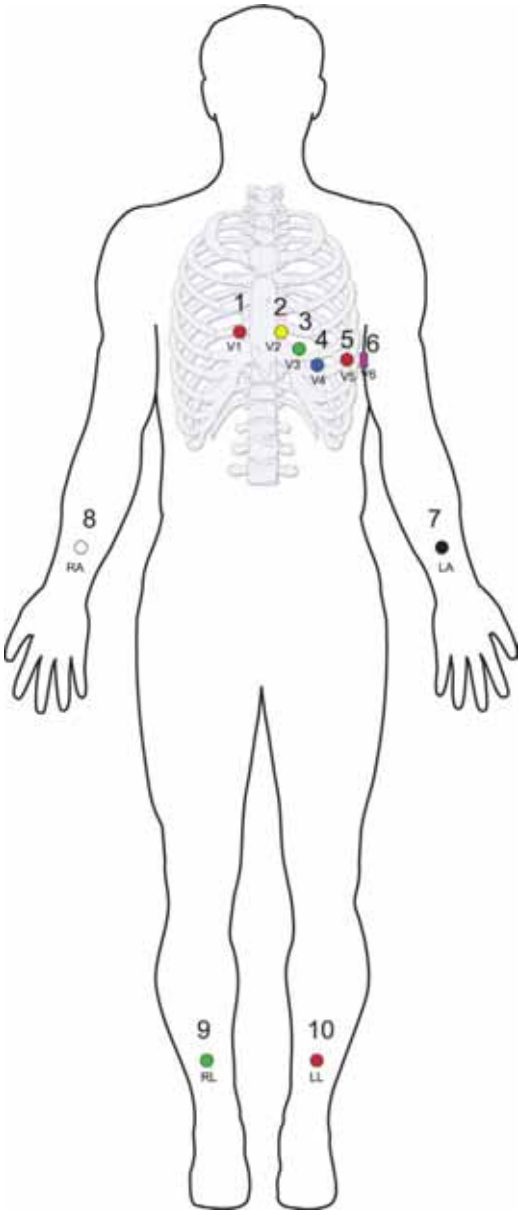
Correct electrode placement is important for acquiring a successful ECG recording.

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 wrist
RA	Right wrist
RL	Right ankle
LL	Left ankle

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

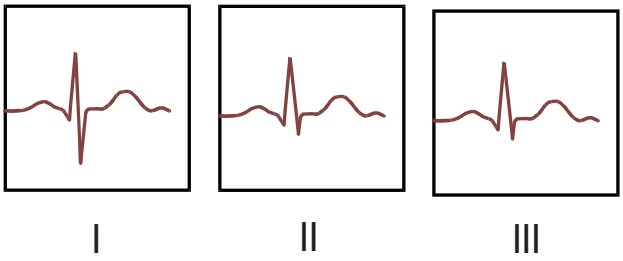
When connecting the electrodes to the ECG unit, the tiny and fast potential differences originating from the heart can be detected on the surface of the body between either two individual electrodes or between one individual electrode and a group of combined electrodes and recorded by SpiroSphere ECG.

The different measurement setups are commonly referred to as leads.

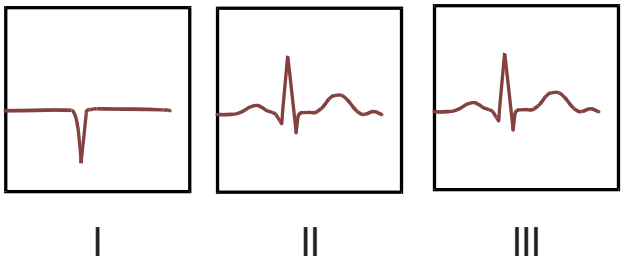
For a standard 12-lead ECG, four electrodes are placed at the limbs and six at the chest.

The 12 leads are:

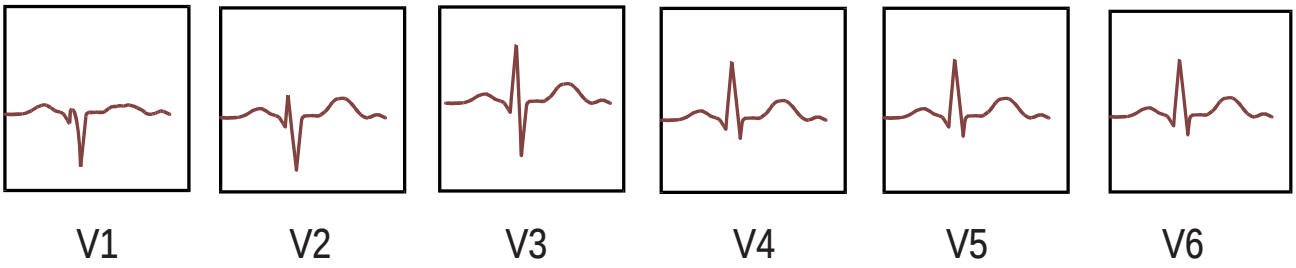
Three bipolar limb leads: I, II and III (according to **Einthoven**)



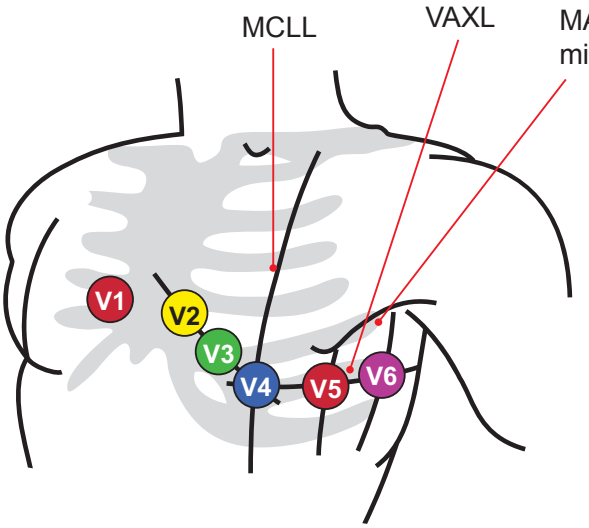
Three unipolar limb leads: aVR, aVL and aVF (according to **Goldberger**)



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

Lateral view of lead positions

Treatment of Isoelectric Segments within the QRS-Complex

The wave of depolarization is a spatial entity, which means that the onset of a wave will not be evident in all leads at the same time. Isoeletric sections starting at QRS onset of a complex are treated as part of the subsequent significant wave. Similarly, the isoelectric sections at the end of the QRS-complex are incorporated into the preceding significant wave.

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.

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 unit electrode cables with the electrodes.

⚠ CAUTION

- Adhesive electrodes are for single use only.
- Comply with the instructions for use of the elctrodes used.
- The electrodes must only be applied to intact skin.
- Do not use electrodes that have exceeded their expiration date or have dried electrode gel.

Insertion of Batteries/Rechargeable Batteries, Charge Level Indicator

To chage the battery, open the battery compartment cover and insert the battery or rechargeable battery matching the polarity indicated in the battery compartment. Close the battery compartment cover.

To determine if the battery needs replacement, see "Troubleshooting Guide".

CAUTION

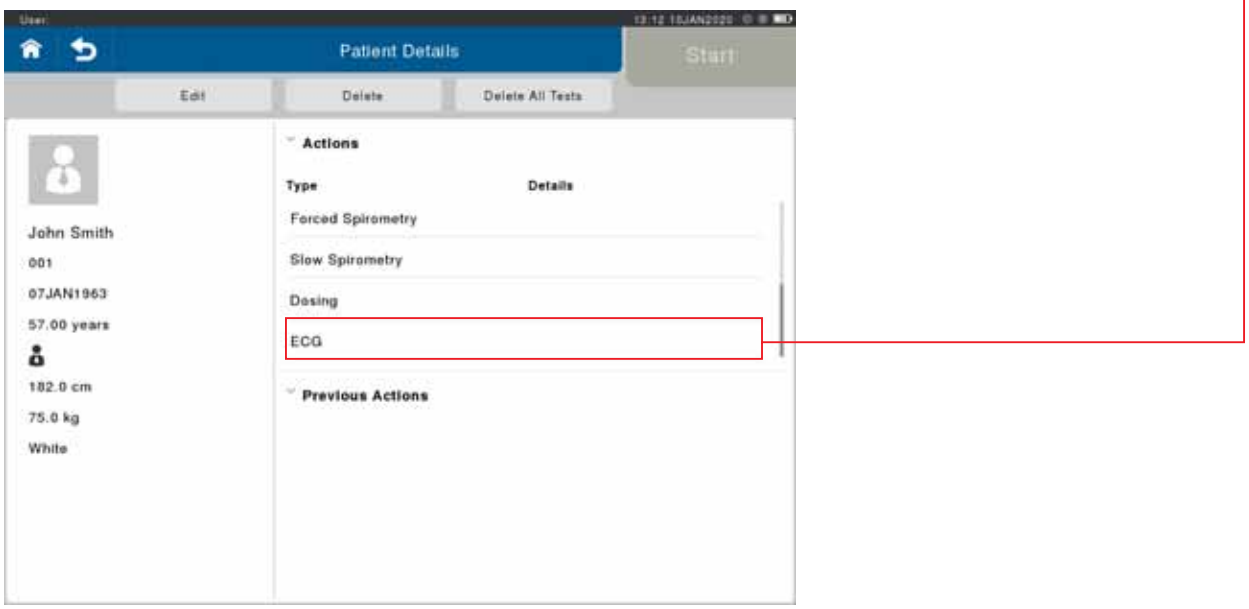
- Do not insert or change batteries while a patient is attached to the ECG device.
- Dispose of used batteries in accordance with the regulations of your country.
- Using a battery other than recommended by manufacturer, may shorten the device runtime of the ECG device and may affect the accuracy of the battery status indication.

Performing an ECG Recording

SpiroSphere ECG allows the recording of a 12-lead resting ECG measurement.

Add a <**New Patient**>, or <**Select a Patient**> from the "Search Patient" option.

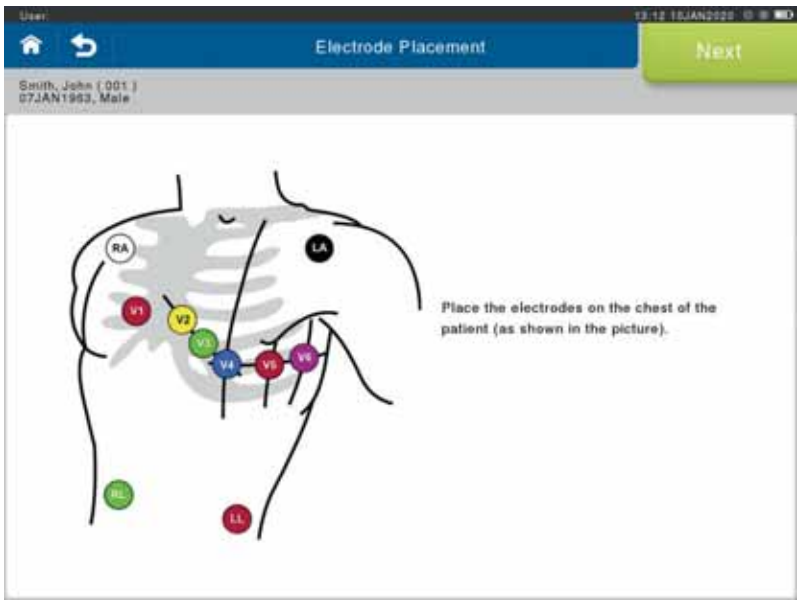
Scroll the list of Actions down to the action "ECG" within the Patient Details screen:



Power on the ECG unit by pressing the power button. The LED will turn blue indicating the ECG unit is powered on. If the battery is low, the LED will blink.

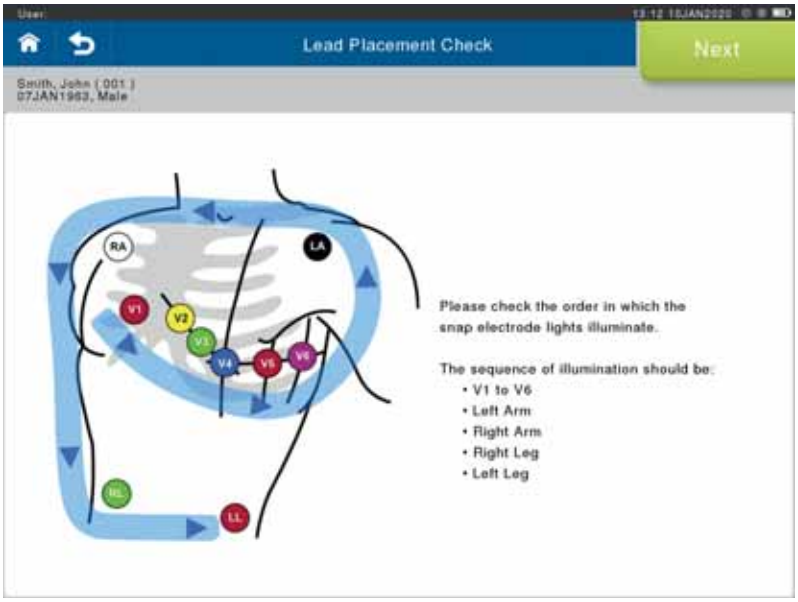
Select <**Next**> to continue.

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



Select <**Next**>.

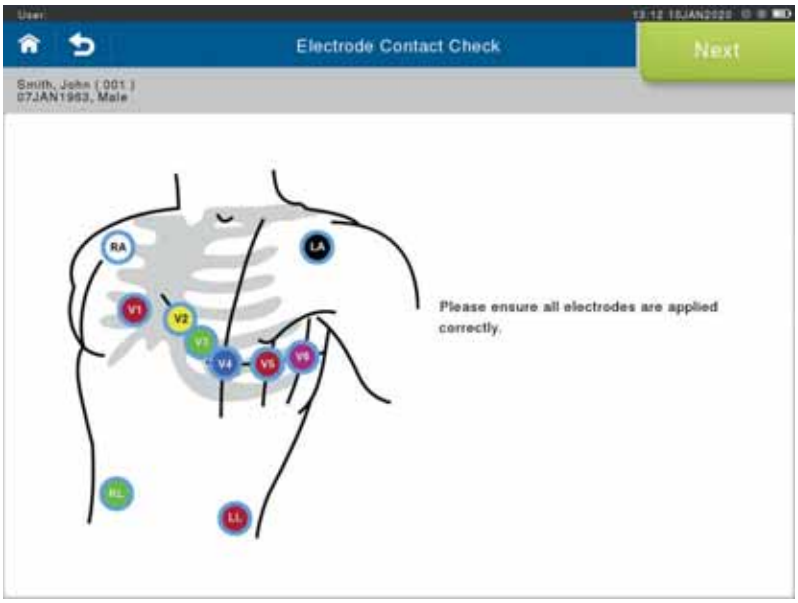
The system will illuminate the electrodes in a fixed sequence.



The electrodes can be visually checked (“running lights”), starting with “V1” and end with “LL”. Look for the “e” shape to confirm correct lead placement.

Press <**Next**>.

Prior to the ECG recording, an Impedance Check will be performed to confirm good contact with the skin. If a contact is poor, the respective electrode will blink on the screen:



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

CAUTION

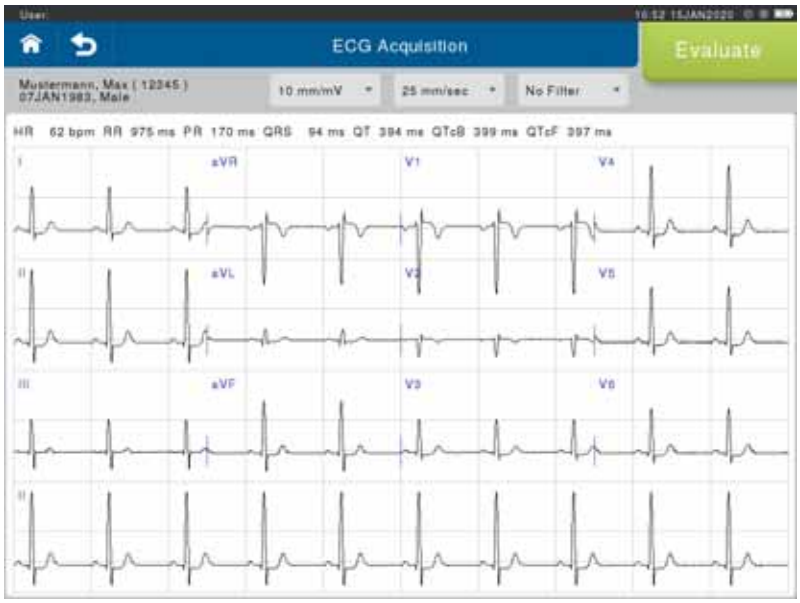
- Adhesive electrodes are for single use only.
- Comply with the instructions for use of the elctrodes used.
- The electrodes must only be applied to intact skin.
- Do not use electrodes that have exceeded their expiration date or have dried electrode gel.

Next

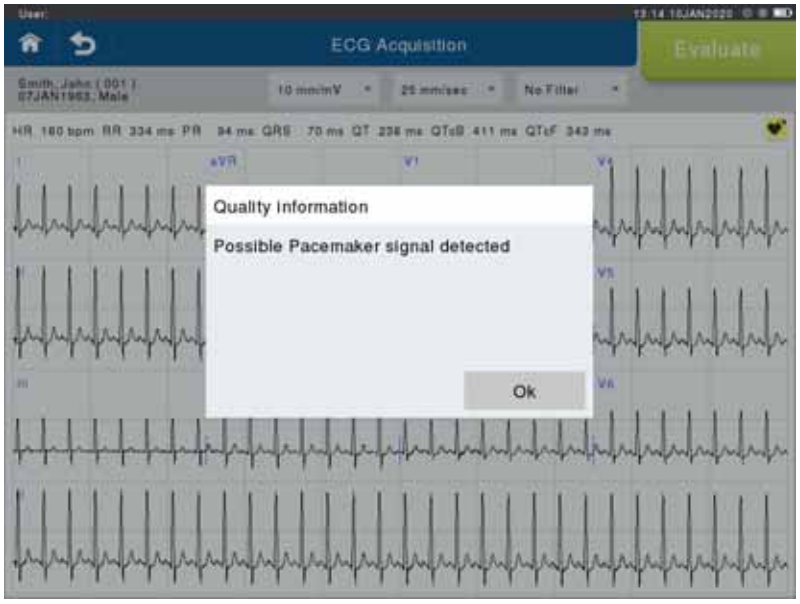
Correct the contact issue (if necessary) and press <**Next**> to start the ECG recording.

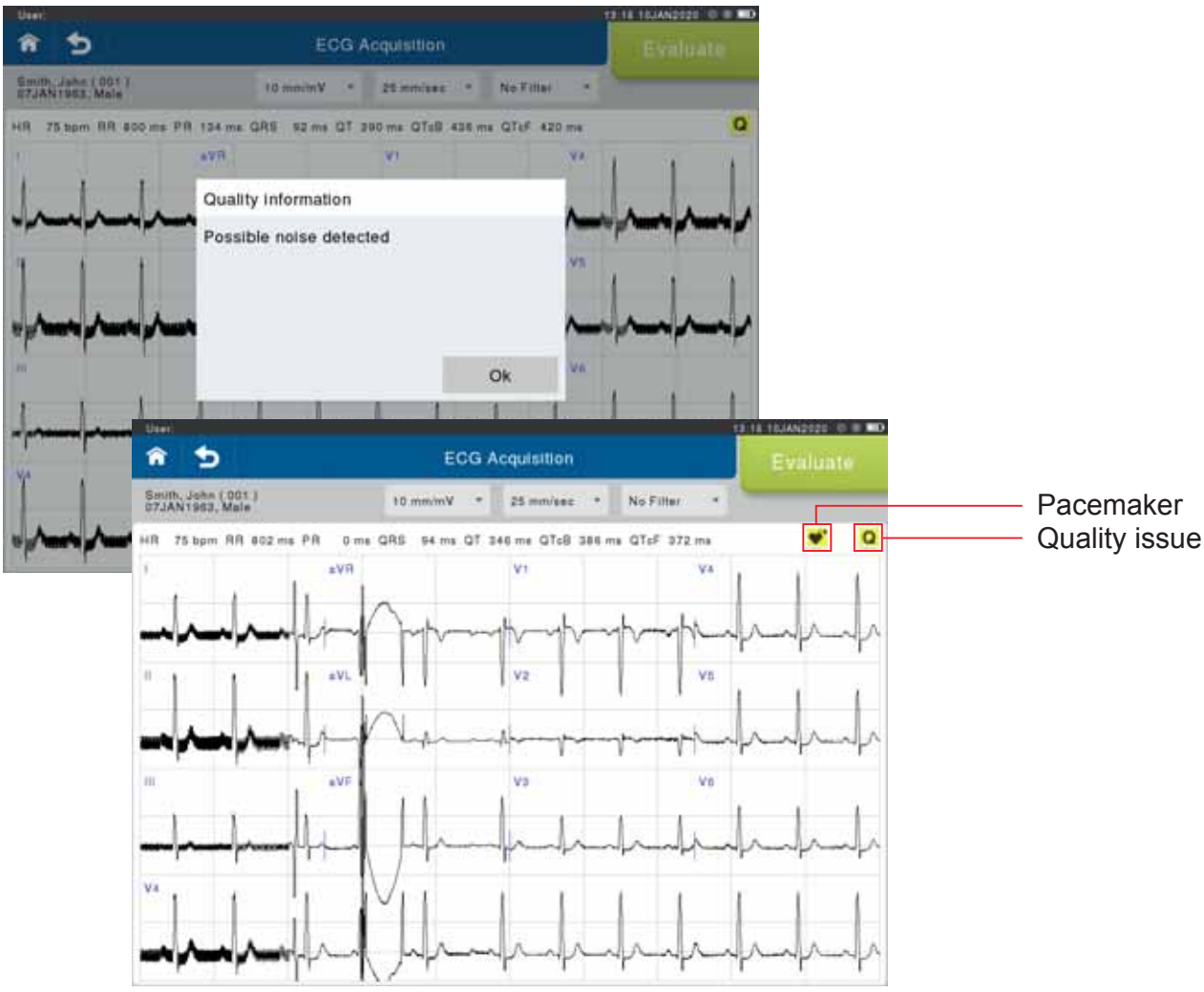
The ECG will begin to record.

The recorded ECG waveforms are displayed on the screen:



The system will also check for possible pacemaker presence as well as any quality issues. If detected, a message box will appear and an icon will display:





Scaling and Filter

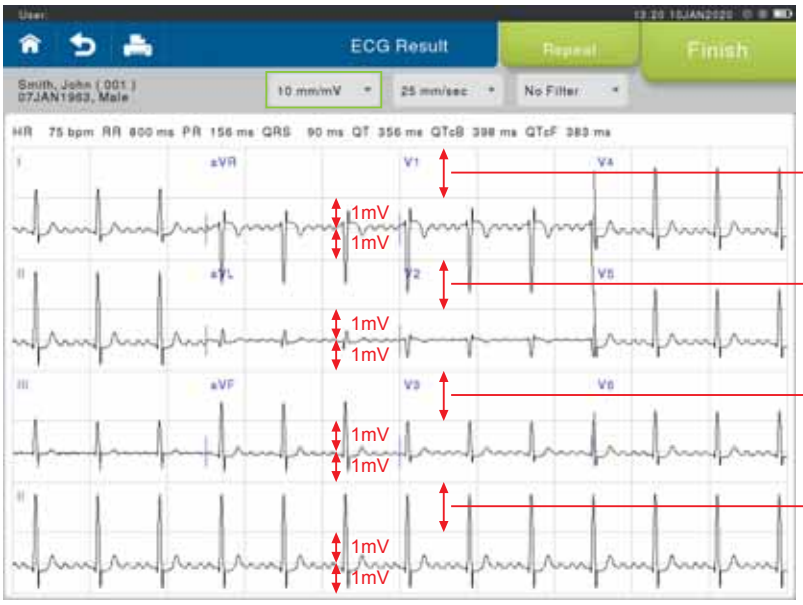
You can adjust the view of the online recording by changing the settings for Gain and Speed. You can also apply filters to the view.

Note: The on-screen scaling has been adapted to fit the aspect ratio of the display. It should not be used for direct on-screen measurement (e.g. using a ruler).

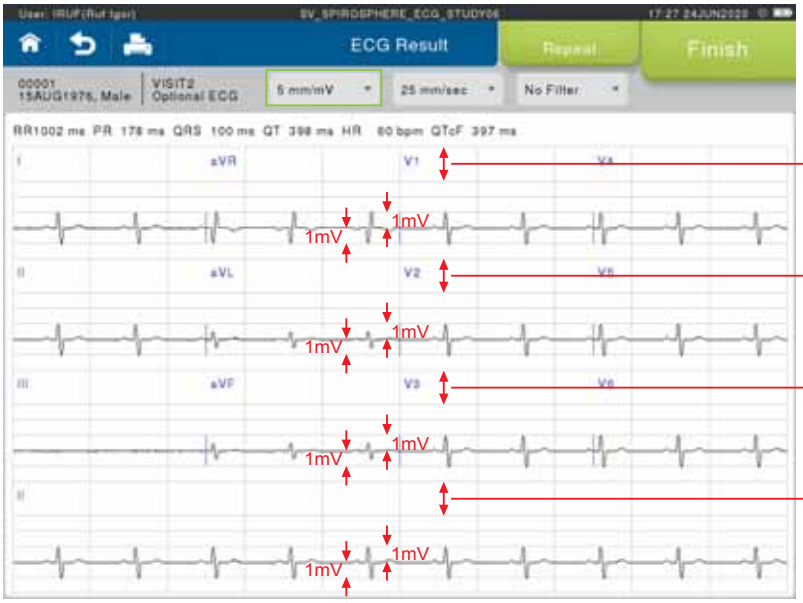
Gain:	5mm/mV, 10mm/mV
Speed:	25mm/sec, 50mm/sec
Filter:	No Filter, Line Filter, Muscle Filter, All Filter

It is possible to print with:
Gain: 10mm/mV or 5mm/mV
Speed: 25mm/s or 50mm/s
(depending on the configured on-screen display).

10 mm/mV Scaling



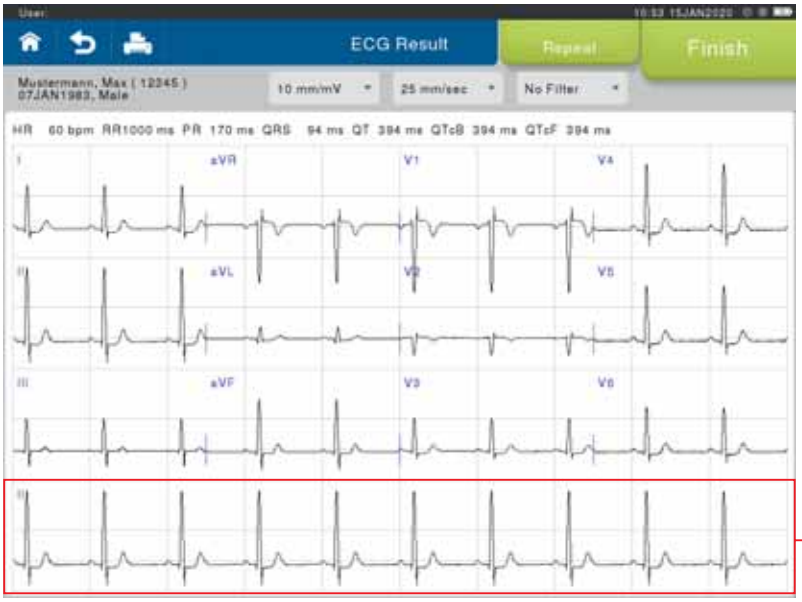
5 mm/mV Scaling



ECG Results

After 10 seconds the <**Evaluate**> button will become available to allow you to end your recording.

Inspect the recording quality of the signals. If the signals are free of drift and noise, press <**Evaluate**> to end the recording. The ECG Result screen will display:



The full 10-seconds of any lead can be displayed by touching the respective lead required to be shown. (in the example Lead II)

Note: The printed report will always show the full 10-seconds of Lead II, independent of that selected in the Online view or Results screen.

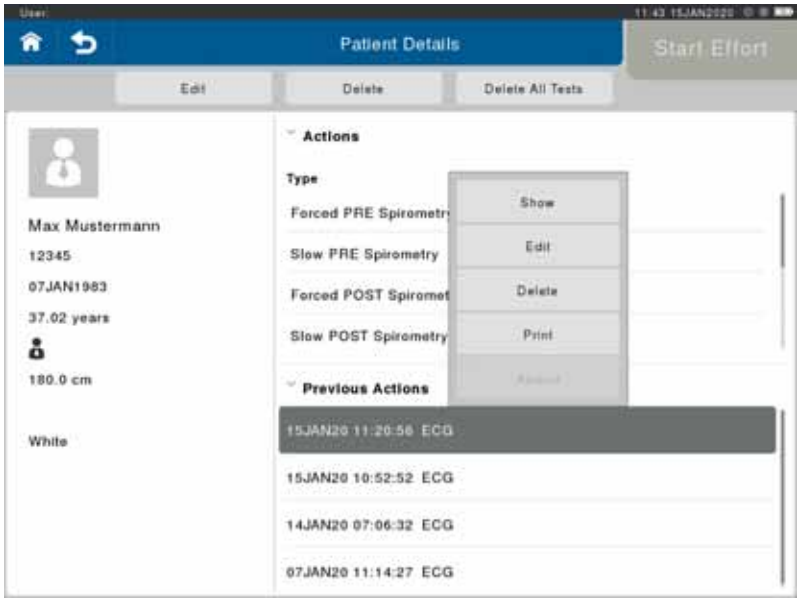
If the quality of the recorded data is not sufficient, a new ECG recording should be started prior to pressing <**Repeat**>.

The previously recorded data will be deleted and the ECG recording re-started.

If you are happy with the recording select <**Finish**> to save the ECG.

The ECG can be printed by selecting the <**Print**> icon.

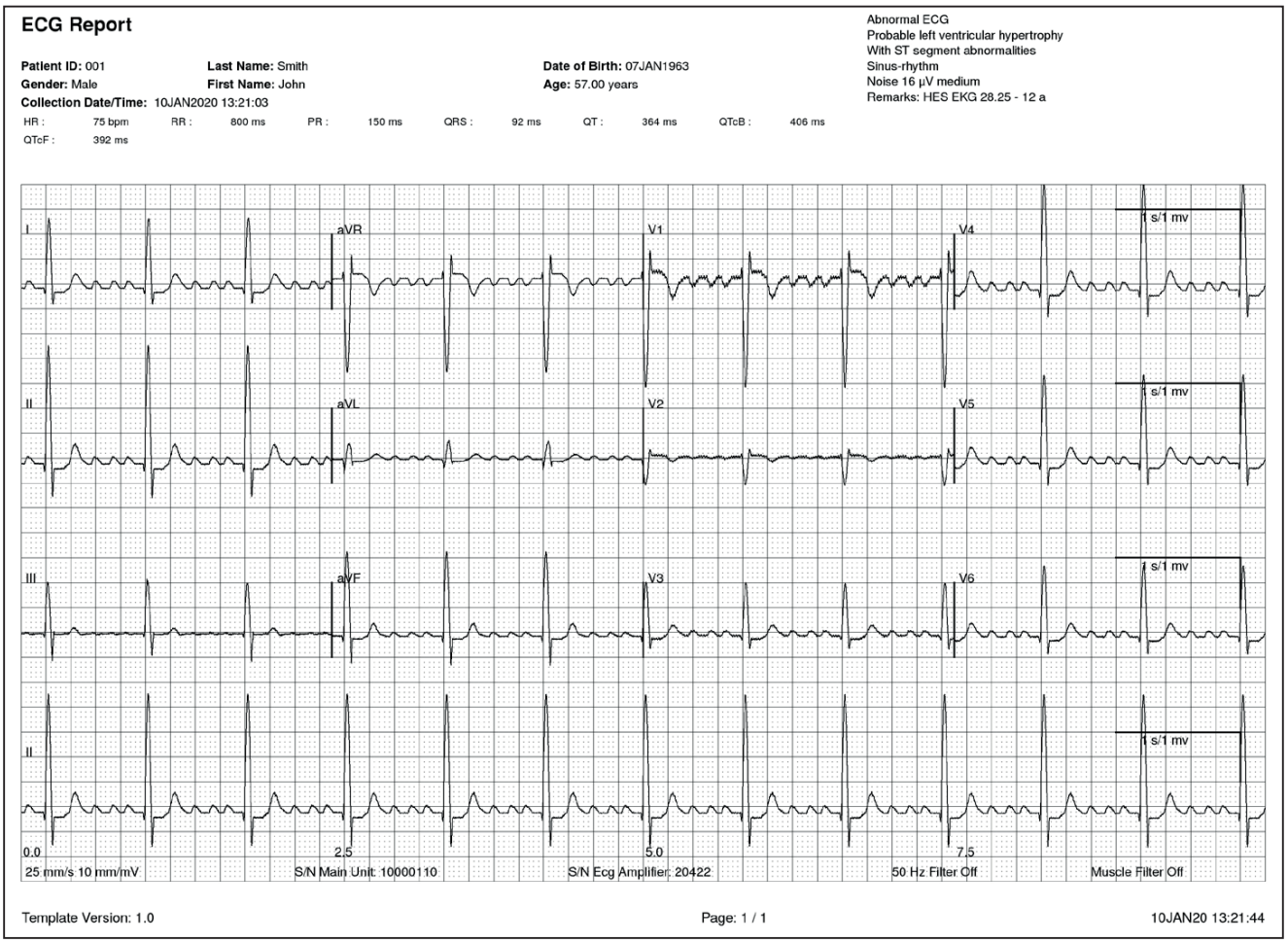
You can also print your ECG afterwards from the Patient Details screen, via the fly-out menu:



ECG Evaluation

The printed report will show the 12-lead ECG tracing, as well as information pertaining to the patient details, system calculated Interval Duration Measurements, Interpretation. These are provided as a guide only. Final clinical decision lies with the Physician.

It is possible to print with: Gain: 10mm/mV or 5mm/mV | Speed: 25mm/s or 50mm/s (depending on the configured on-screen display).



Interpretation according to HES®

SpiroSphere with 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.

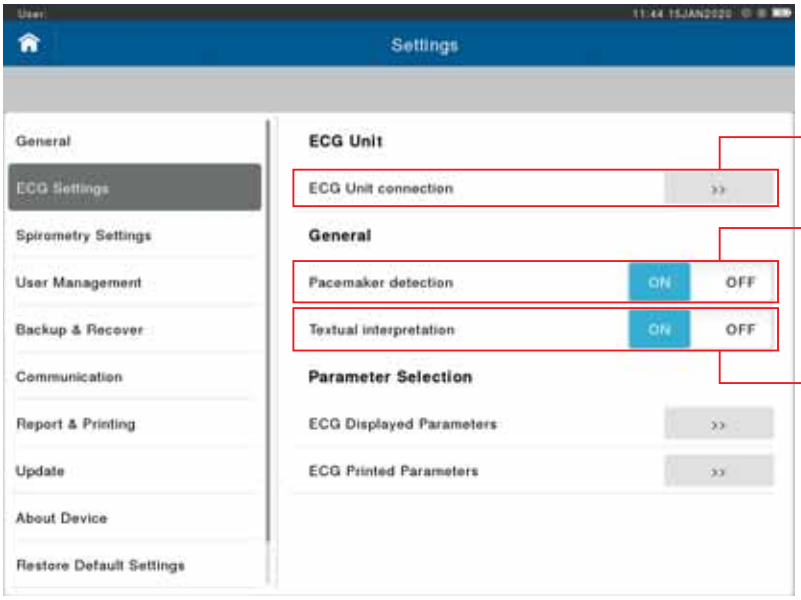
WARNING

A qualified physician has to reassess all SpiroSphere ECG measurements.

An interpretation by SpiroSphere with ECG is only significant when considered together with other clinical findings. ECG interpretation statements made by SpiroSphere with 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.

ECG Settings

Settings for ECG can be found under “ECG Settings”:

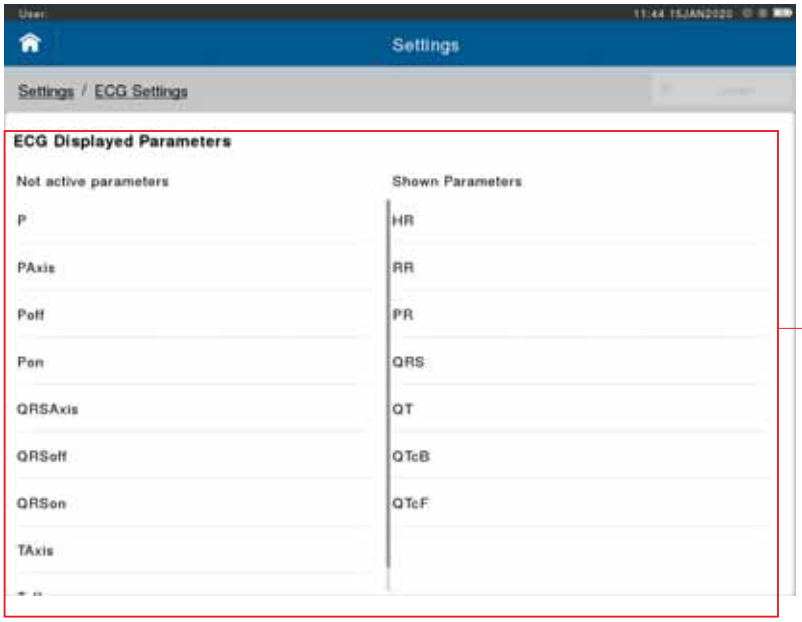


ECG Unit connection: Activate, Pair or Unpair an ECG Unit

Pacemaker detection: ON/OFF: Enables or disable check for Possible Pacemaker

Textual interpretation: ON/OFF: Enables or disables printing of the ECG computerised interpretation

ECG Displayed Parameters:

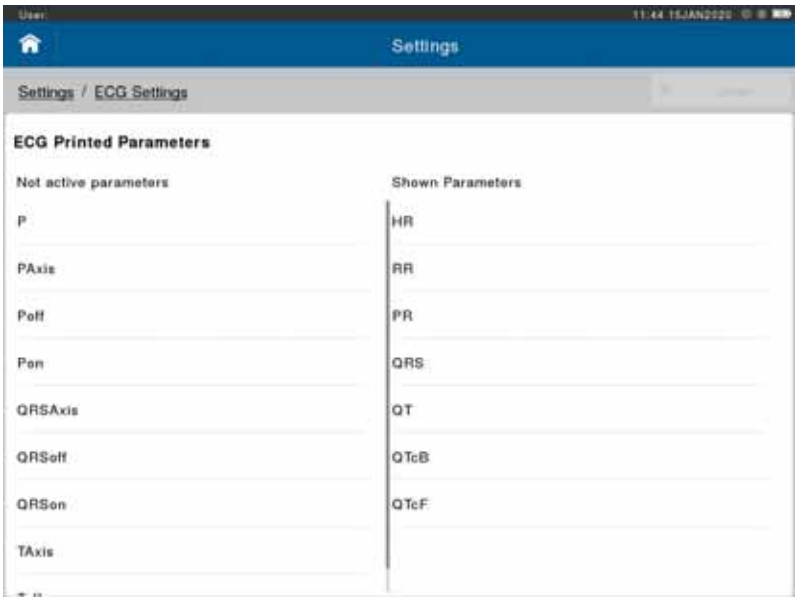


Up to seven (7) parameters can be selected for display during an ECG measurement.

They can be added or removed in this section, by either double tapping or dragging across the respective parameter to either Not active (not shown), or Shown Parameters

ECG Printed Parameters:

This configures the parameters that will be displayed on the printed ECG Report.



The parameters can be added or removed in this section, by either double tapping or dragging across the respective parameter to either Not active (not shown), or Shown Parameters.

The number of parameters printed is not limited.

Connecting an ECG Unit

Start the device by brief pressing the <**ON**> button.

The LED lights steady blue when the device is ready.

The ECG Unit will turn itself off after 10 minutes if it is not used.

Select “ECG Unit connection” from the ECG Settings menu.

1. On your ECG Unit press and hold the power button until the blue LED blinks fast. This will take approximately 20 seconds.
2. After further few seconds, the ECG unit will be listed in the above screen.
3. Select the ECG unit you wish to pair, and push “Pair” from the fly out menu:

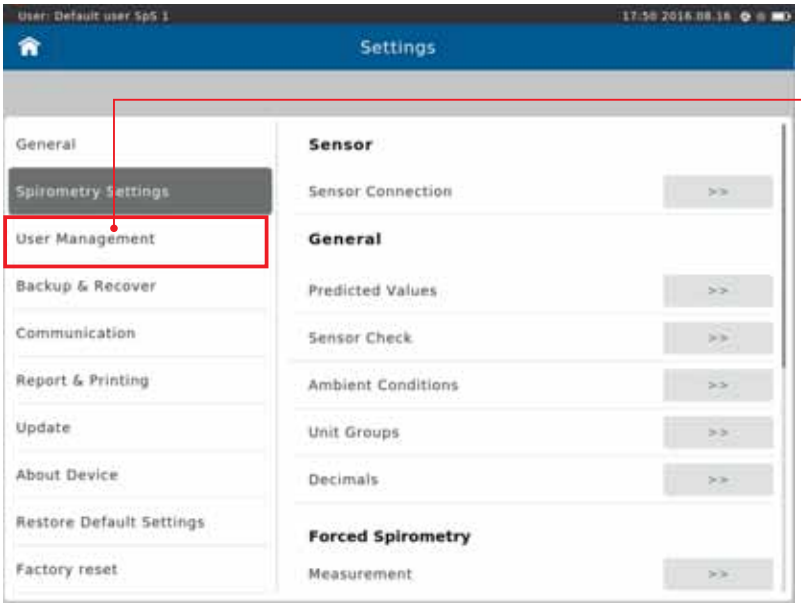
4. The ECG unit will then change to state “Active” and is ready to use.

⚠ CAUTION

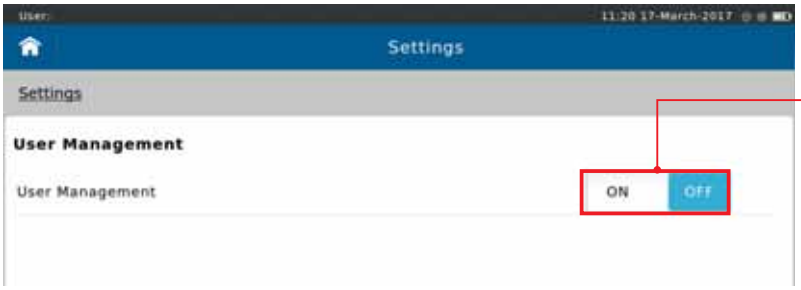
- The Bluetooth radio link has a limited range. The distance between the ECG unit and the receiving/display device can therefore impact the quality of the Bluetooth connection. Keep it as short as possible and free of objects between them. If the Bluetooth transmission fails for more than 10 seconds, the latest ECG data are erased and therefore lost for the recording.
- The separation of the point-to-point Bluetooth connection from another network (e.g. intranet, internet) is the responsibility of the operator. If the point-to-point Bluetooth connection is not active for more than 10 minutes, the connection will be terminated. Any ECG data not already transmitted from the ECG unit will be lost after 10 seconds (see above).

User Management

This tool enables an authorized person to create an Administrator account. The newly created administrator will then be able to create additional accounts for individuals authorized to work with the **SpiroSphere**. Additionally, it is possible to register your fingerprints in order to utilise the fingerprint reader for system access.

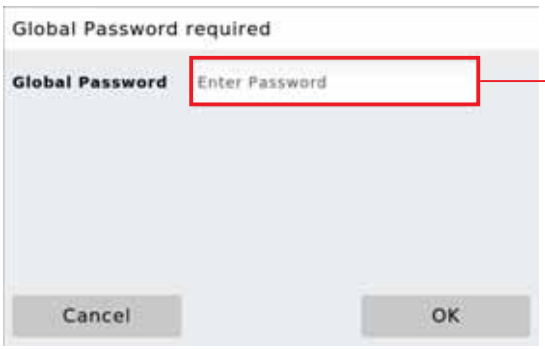


From "**Settings**" select "**User Management**"



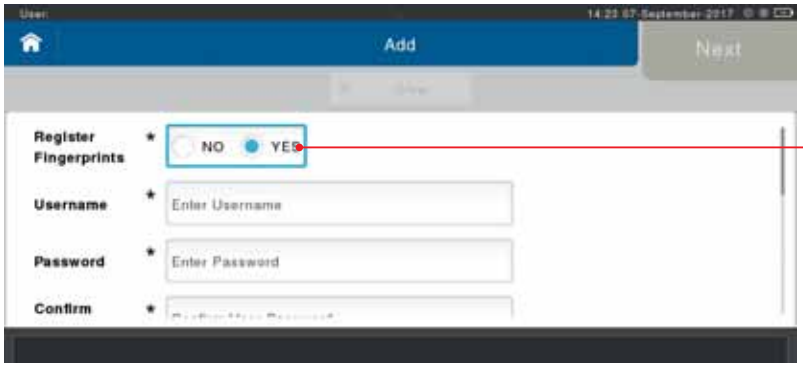
Tap "ON" the switch to activate User Management

The following screen appears:



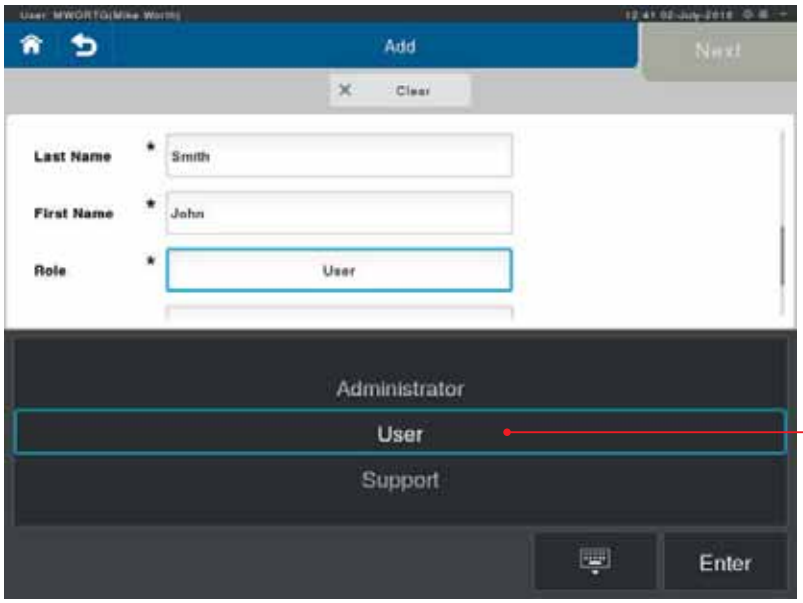
Enter the Global Password ("**691982**") and tap <**OK**>.

The following screen appears:



Select whether or wish to use your fingerprint reader for access to the system

Enter all the required information to create your user:



Options for role type:
Administator
User
Support

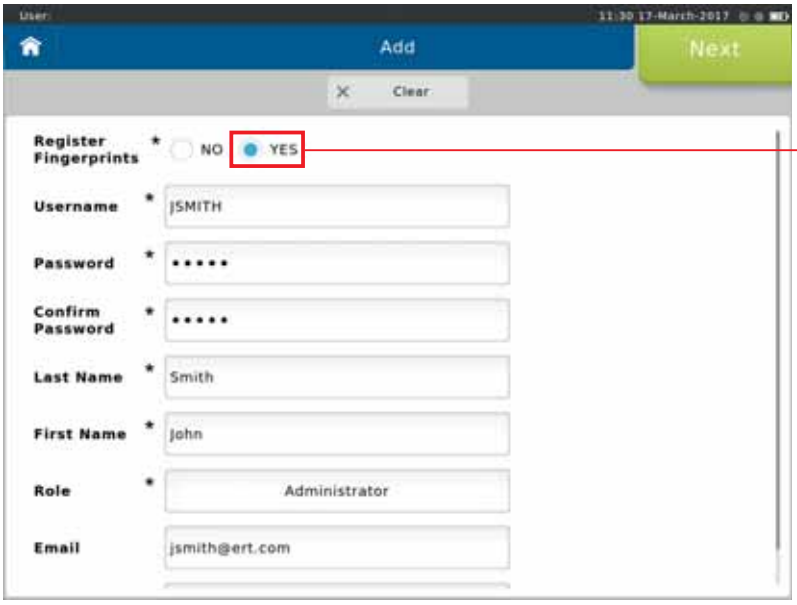
Enter the details for the user (for first user of the system this must be Administrator role).

Overview - who has which user rights:

Patients	Administrator	User	Support
New patient	X	X	
Search patient	X	X	X
View patient details	X	X	X
Change patient demographics	X	X	
View measurements	X	X	X
Perform measurements	X	X	
Print reports	X	X	X
Sensor Check			
Calibration Check	X	X	X
Linearity Check	X	X	X
Calibration CheckLog	X	X	X
Linearity CheckLog	X	X	X
Tools			
Create backup	X	X	X
View system info	X	X	X

System Administration			
Add or change user	X		X
Deactivate/activate user	X		X
Recover	X	X	X
Change date and time settings	X	X	X
Update software	X	X	X

Register fingerprints:



Select <**YES**> to register fingerprints.

Tap <**Next**> to move to the fingerprint registration.
(If you choose not to register fingerprints this button is labelled "**Save**".)

The following screen appears:

Tap the image of the finger you wish to register.

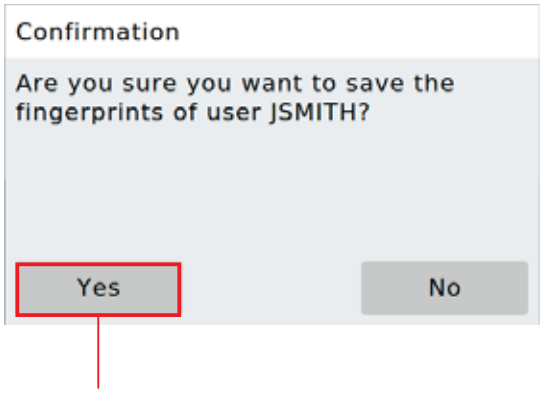
Place your finger on and off the fingerprint reader as per on-screen instructions (approx. 5 times) in order to register your fingerprint.

If the finger is not placed correctly, feedback is provided:

You may register as many fingers as you like.

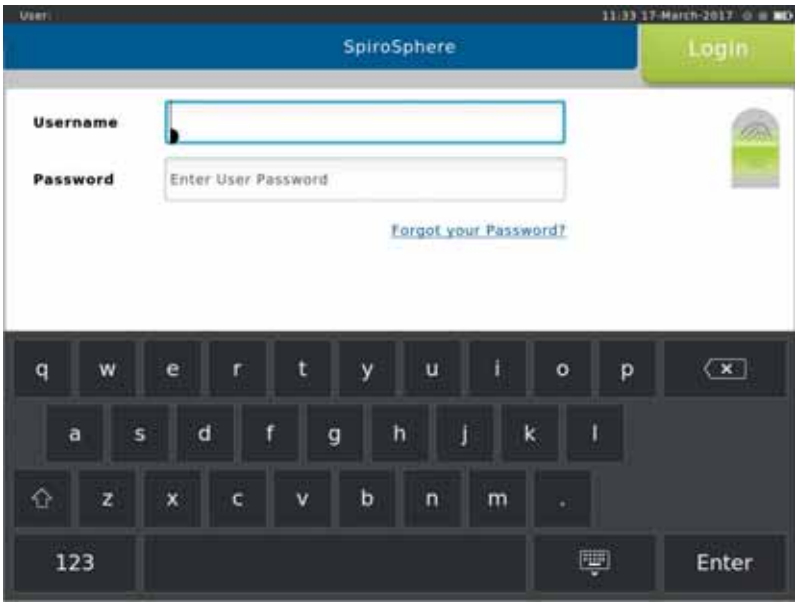
When finished tap <**Save**>.

The following screen appears:



Tap <**Yes**> to save the fingerprints of the respective user.

After saving the first user, you will be sent to the Login page:

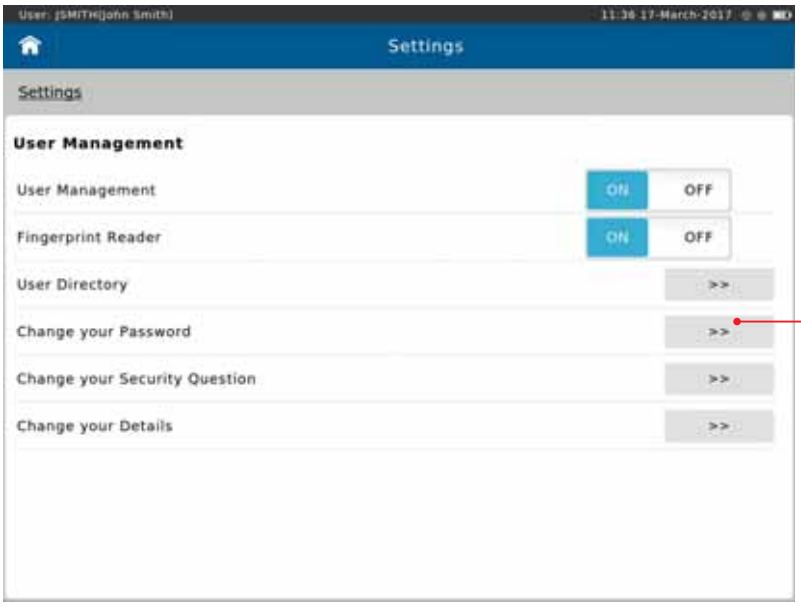


You can login via entry of Username and Password.

If you registered your fingerprint, you can use the fingerprint reader. Two touches are required (the first touch identifies the user, the second verifies the user).

User Directory

When User Management is active, additional items appear in the Settings screen:

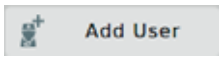


Select "**User Directory**"

The User Directory is displayed:

Add User

It is possible to add another new user from the User Directory.



To add a new user, tap <**Add User**>. Make the appropriate entries and, if desired, register fingerprints (see above).

Change Password

Tapping the currently logged in user in the directory will open a fly out menu:

Access to the User details, and Change password function is available

To set a new password, tap <**Change Password**>. The following screen appears:

Make the appropriate entries and tap <**Save**> to save the new password.

Edit User

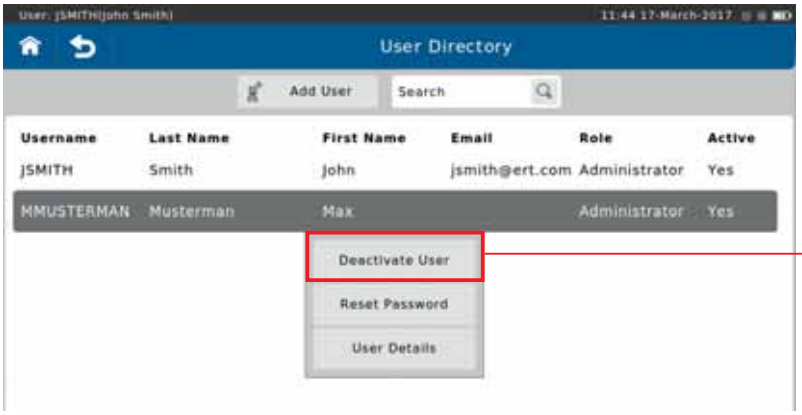
To edit the currently selected user, tap <**User Details**> in the fly out menu. The following screen appears:

Make the appropriate changes and tap <**Next**> to move to the fingerprint registration (see above).

(If you choose not to register fingerprints this button is labelled "**Save**".)

Deactivate User /Reset Password

An Administrator is able to activate/ deactivate a user and to reset the password (with a temporary password) for another user from the fly out menu in the User Directory.



Tap <**Deactivate User**> to deactivate the selected user.

To reset the password for another user, tap <**Reset Password**>. The following screen appears:

The user will be required to change their password upon their login.

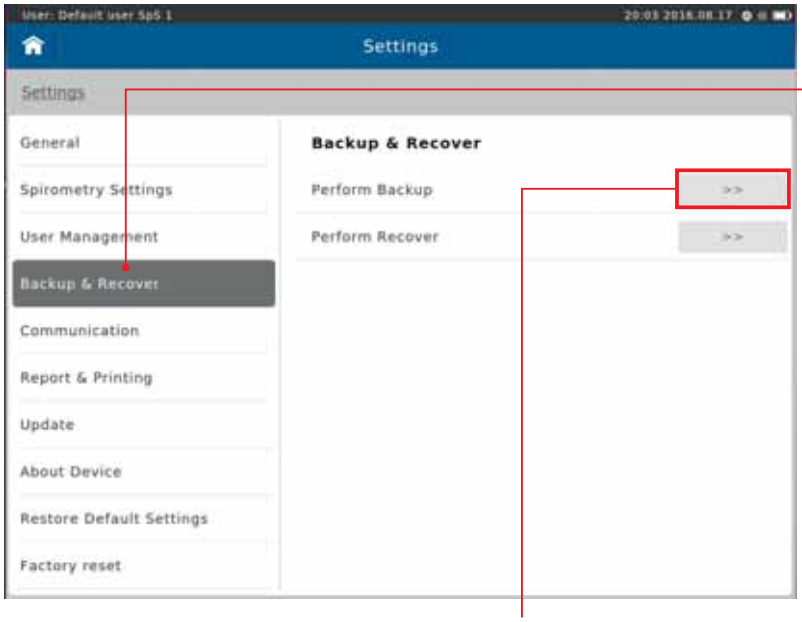
Change Security Question

From "**User Management Settings**" a Security Question and Answer can be defined for the current user.

Make the appropriate entries and tap <**Save**> to save the Security Question.

Backup & Recover

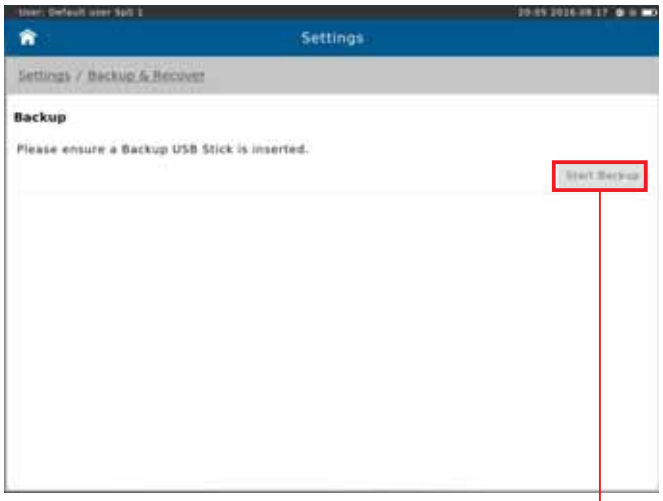
A backup of all saved patient- and test data should be performed and saved to a USB-Stick on a regular basis.

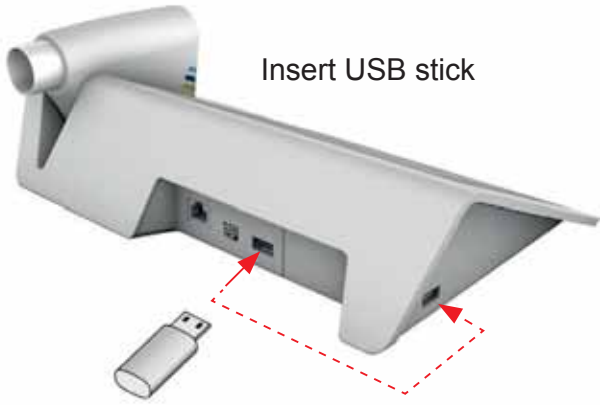


Tap on "**Backup & Recover**". Alternatively, tap on the "**No backup performed**" field on the Home Screen.

If "**Perform Backup**" is selected, the message "**Please ensure a Backup USB Stick is Inserted**" appears.

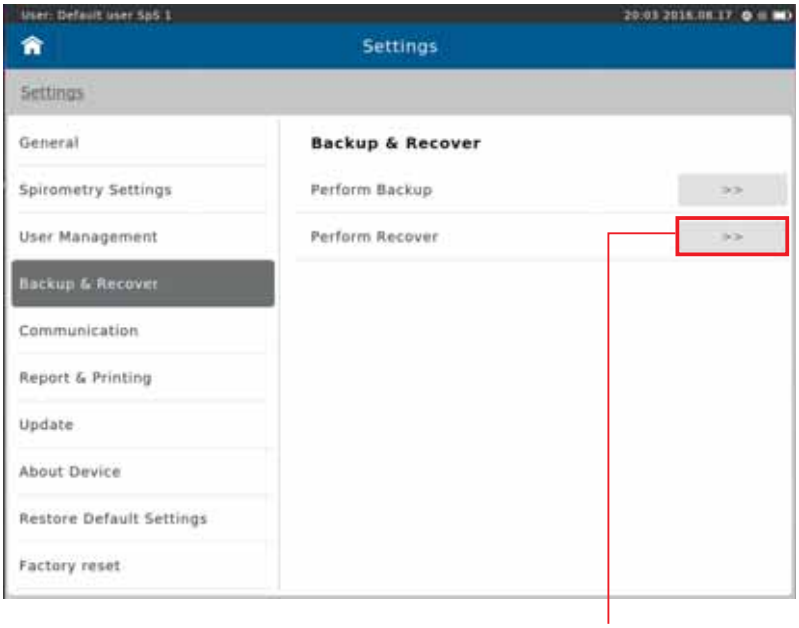
Backup





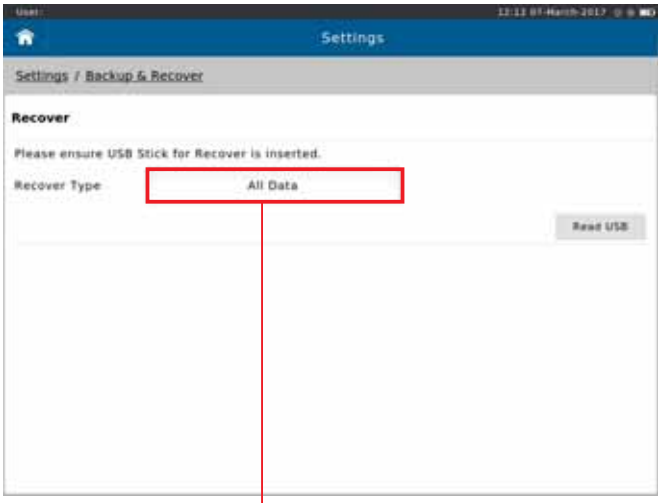
Insert USB stick

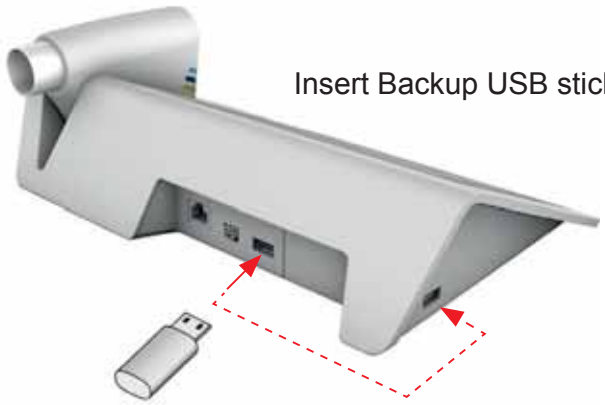
Tap on "**Start Backup**" to create a backup file and save it to the USB stick!



If “**Perform Recover**“ is selected, the message "**Please ensure USB Stick for Recover is Inserted**" appears.

Recover

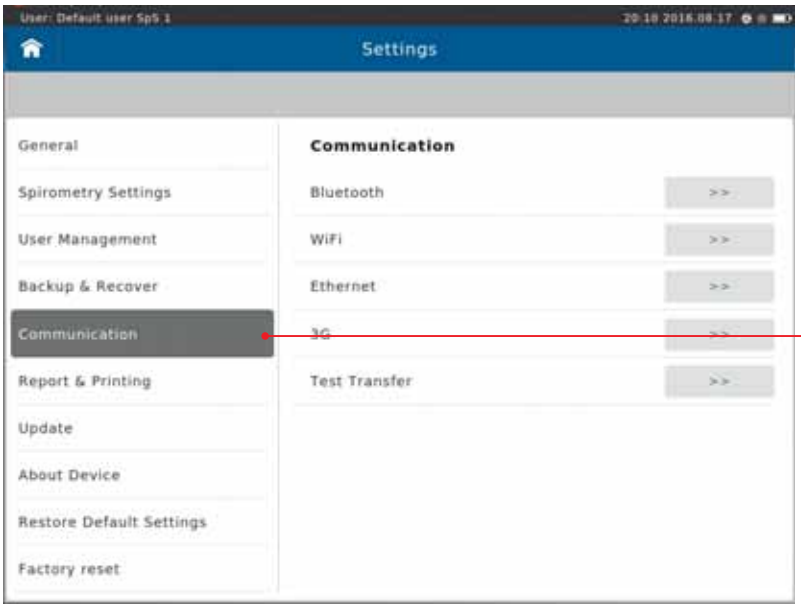




Insert Backup USB stick

Tap on “**All Data**“ to reload all data into the patient directory of your SpiroSphere.

Communication



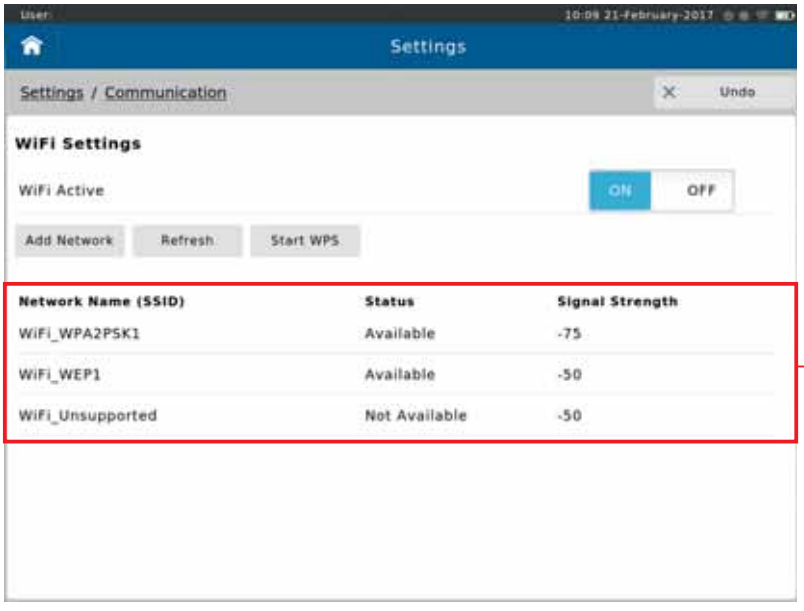
Tap on "**Communication**"

It is possible to configure the Communication settings from the Communication menu within Settings.

Select the Communication method to open the respective configuration settings.

Network Requirements

WiFi



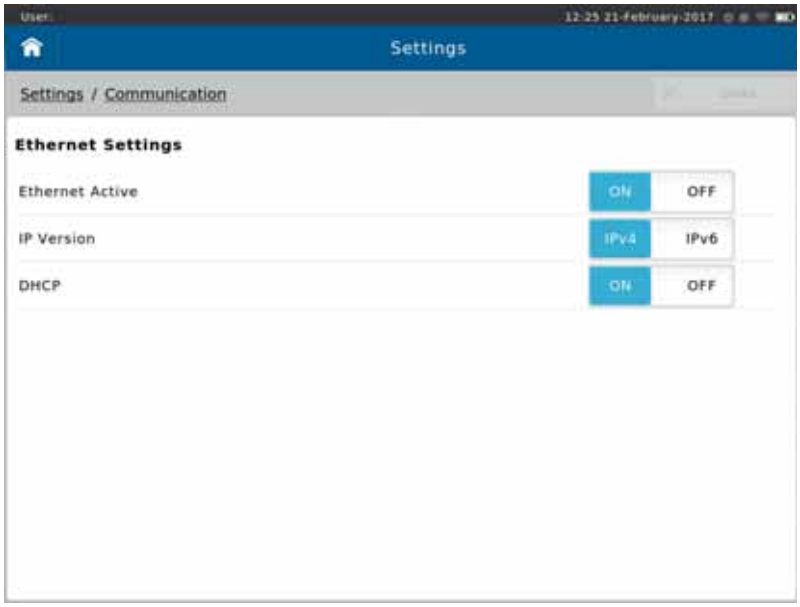
Tap on the desired WiFi network.

The following fly-out menu appears:

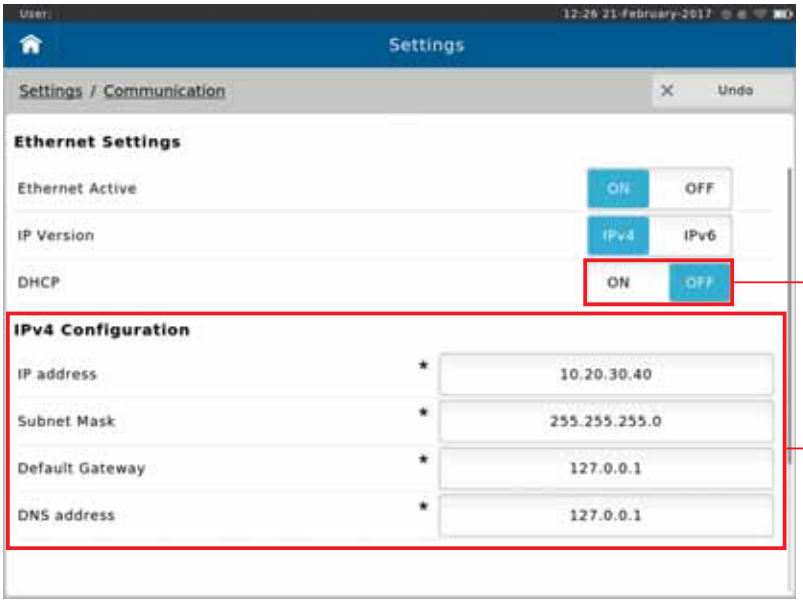
Tap <**Connect**> to initiate the connection.

Enter the password as applicable and tap <**Connect**>.

Ethernet

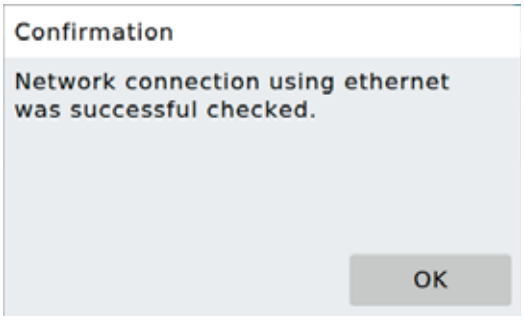


Choose the appropriate settings.

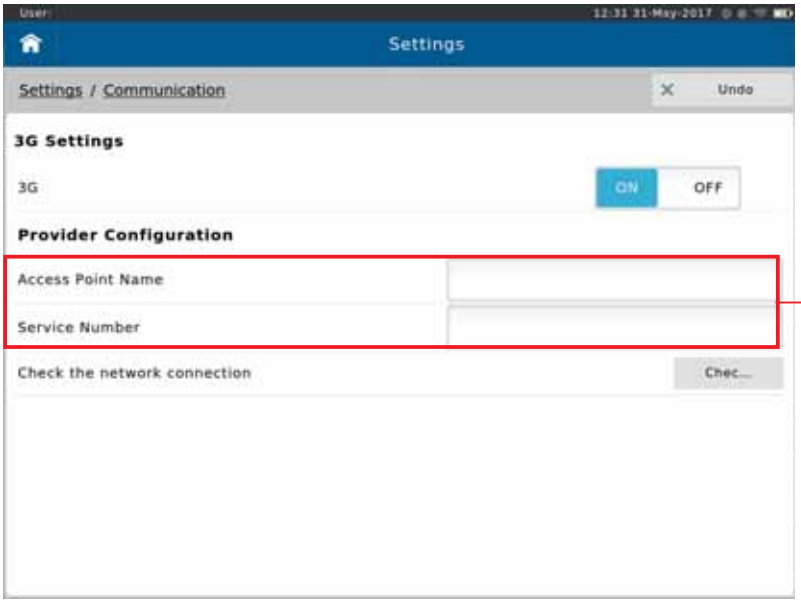


If DHCP is set on "**Off**", then you can manually enter the appropriate settings.

You can check the status of the connection by selecting "**Check the network connection**".
Upon confirmation of a successful connection, following message box is displayed:



3G (only applicable for optional 3G module)



Enter the appropriate Access Point Name and the Service Number.

Local IT Guide for Ethernet (LAN), WI-FI (WLAN) or optional 3G (Mobile Network)

The SpiroSphere system offers data transfer functionality via Ethernet (LAN), Wi-Fi (WLAN) or optional 3G (Mobile Network) which requires access to the Internet. 3G is only applicable for the optional 3G module.

Since the SpiroSphere system would for Ethernet (LAN) or WIFI (WLAN) be part of your local network, this guide explains how the system behaves and needs to be configured.

SpiroSphere is compliant to HIPAA regulations. There is no direct access to the operating system. Where User Management is enabled the responsible user of the data has to be able to control the access to the system.

How to configure Ethernet, Wi-Fi Access or optional 3G (Mobile Network)

In the "Settings & Tools" menu of the SpiroSphere system in the sub menu "Communication" Ethernet (LAN), Wi-Fi (WLAN) (or 3G Mobile Network) can be configured. The MAC addresses and IP addresses are visible within the "Settings & Tools" / "About Device" Information Screen. A check connection function helps to verify the network setup. A more detailed description of the possible configuration settings in the Settings & Tools menu can be found in the chapter "Settings & Tools" / "Communication" in this manual.

The following information describes the network settings and behavior of the SpiroSphere system.

How is SpiroSphere configured?

- Linux (32bit)
- No Third Party Application can be installed
- No Access to operating system
- No Access to an open web browser (no surfing)
- No Access to Bootloader
- No Network Registration (DNS)
- Firewall Activated (iptables), blocking all incoming traffic (except ping, ssh, DNS and DHCP, SMTP, FTP), preventing outgoing traffic except from authorized applications.
- Connected Media (USB) are checked against checksums before any content is accepted. No content form a USB stick is executed.

Which endpoints are accessed?

Data Transfer Check

- DNS (Local)
- DHCP (Local)
- Ping (localhost)
- Ping (ERT)
- FTP (Local)

Normal Operation

- DNS (Local)
- DHCP (Local)
- Ping (ERT)
- FTP (Local)
- SMTP (Local)

How the system behaves?

The network interfaces are only used when data needs to be transmitted.

Ideal Network Setup?

To satisfy common local network policies, a virtual or physically separated network with outgoing internet access is recommended. SpiroSphere does not require this separation.

How is the system updated?

Software components of the SpiroSphere system are made available by ERT.

Can the SpiroSphere system run without network access?
Yes. Alternatively, the data can be uploaded using a USB stick on a local Internet PC.

Specification of network connection
The SpiroSphere can be connected to an IT network in order to send a pdf report to a designated email address. In order to use this functionality, the SpiroSphere must be connected to an IT-network with TCP/IP connectivity via Ethernet, WLAN (or optional 3G) with routing to the Internet. The configuration of the necessary network settings is described in the "Settings and Tools" menu in the sub menu "Communication".

Add description and the configuration of the electronic report functionality can be found in the section "Report & Printing".

Safety hints
The integration of the SpiroSphere to an IT-network that includes other devices can incorporate risks to patient, operator or other persons. The user/ operator who integrates the SpiroSphere to the network is responsible to analyze, rate and handle those risk accordingly (eg. according IEC 80001-1).

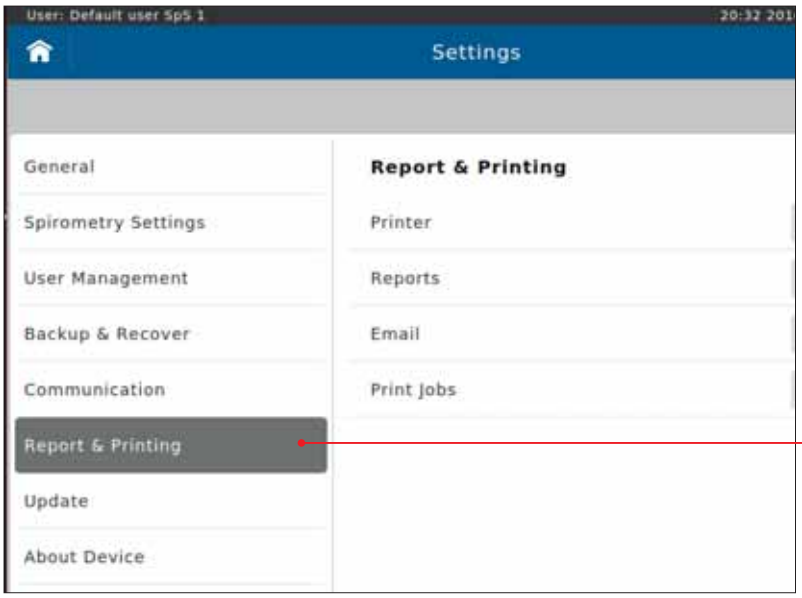
The following changes in the IT-network might lead to new risks and therefore it might be necessary that the user needs to reevaluate the analysis:

- Change of the infrastructure
- Integration of additional devices to the network
- Removal of device from the network
- Update of devices connected to the IT-network
- Upgrade of devices connected to the IT-network

If you have technical questions or require further assistance please feel free to contact our customer care.

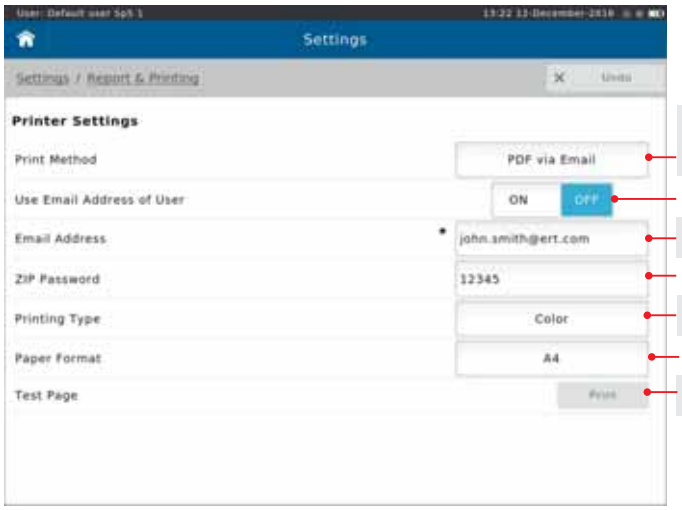
Report & Printing

SpiroSphere allows for reports to be printed with an external printer. In addition, SpiroSphere will allow the user to generate reports as a PDF-file which can be transferred to an external device (i.e. via a USB stick), or e-mailed to a specified recipient.



Tap on "**Report & Printing**"

Printer



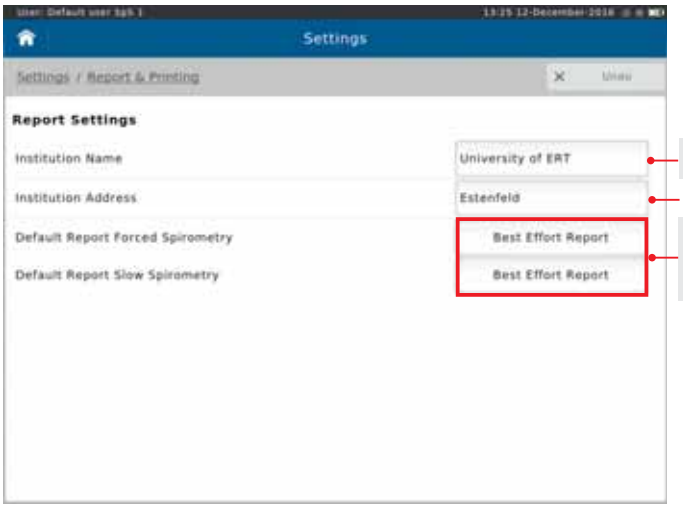
	Setting options:	*Preset:*
Print Method	Printer, PDF via Email, PDF via USB	PDF via Email
Use Email Address of User	ON, OFF	OFF
Email Address	see below	
ZIP Password	see below	
Printing Type	Color, Black & White	Color
Paper Format	A4, Letter	A4
Test Page	Send test page to Default Printer	

Email Address: Enter the Email address of the person the reports should be sent to.

Zip* File Password: Set the password the recipient is required to enter in order to open the "zip" folder.
See chapter "Print Recorded Results".

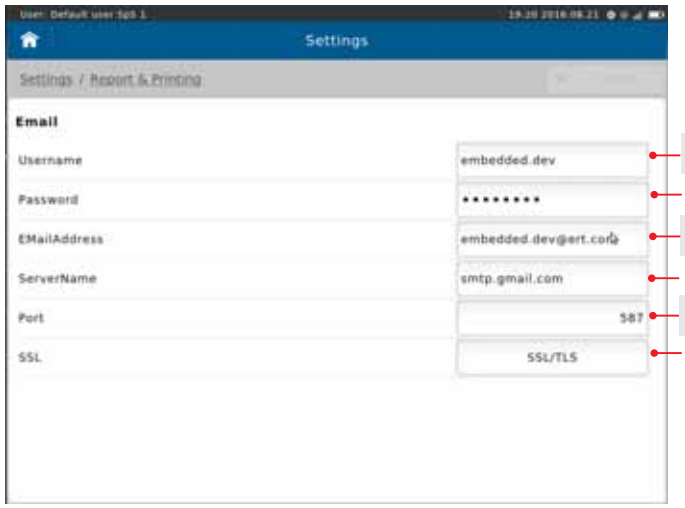
*ZIP is an archive file format that supports lossless data compression.
https://en.wikipedia.org/wiki/Zip_(file_format)

Reports



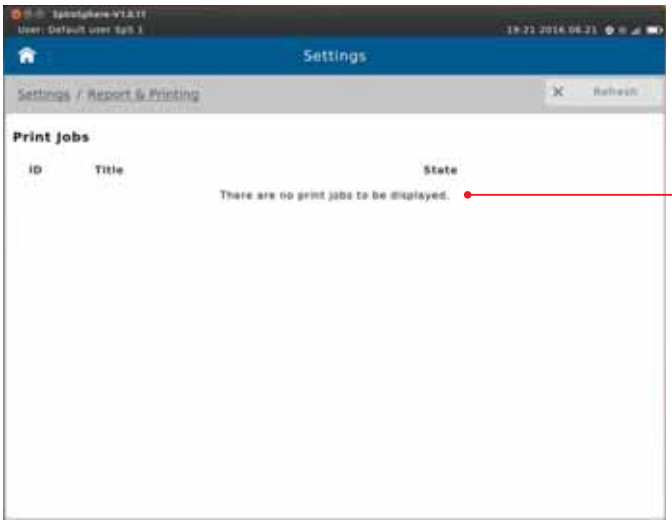
Setting options:	*Preset:*
Input Customer Name	
Input Customer Address	
Best Effort Report	Best Effort Report
All Efforts Report	

Email



- Input Username
- Input Password
- Input Email Address
- Input Server Name
- Input Port
- Input SSL

Print Job



- Print jobs state

Configuration of the Electronic Report Functionality

In order to send a pdf report the SMTP server configuration, the user name and password of an active Email Account and the destination Email address of the receiver must be set up in the Settings and Tools menu in the sub menu Report & Printing. The SpiroSphere will send the Email with the attached pdf report to the destination address by using the configured SMTP server.

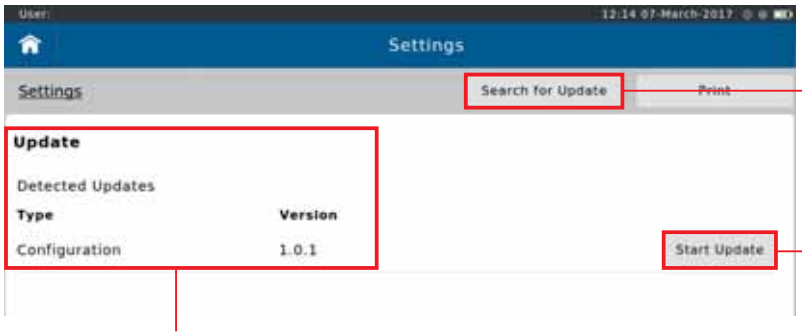
The pdf report is secured by a user configurable password, to ensure that the report could not be opened by other persons than the intended recipient.

As the SpiroSphere just sends data over the network there are no risk or hazards for the patient resulting out of the non availability of network services.

Update

The SpiroSphere is continuously improved and expanded. Necessary updates are stored on a USB stick.
Procedure: Insert the USB stick with the software update in one of the two USB slots.

USB Stick



Tap on <**Search for Update**>. The device will search for updates on the connected USB stick.

Tap on <**Start Update**> to begin the update process.

List of available updates

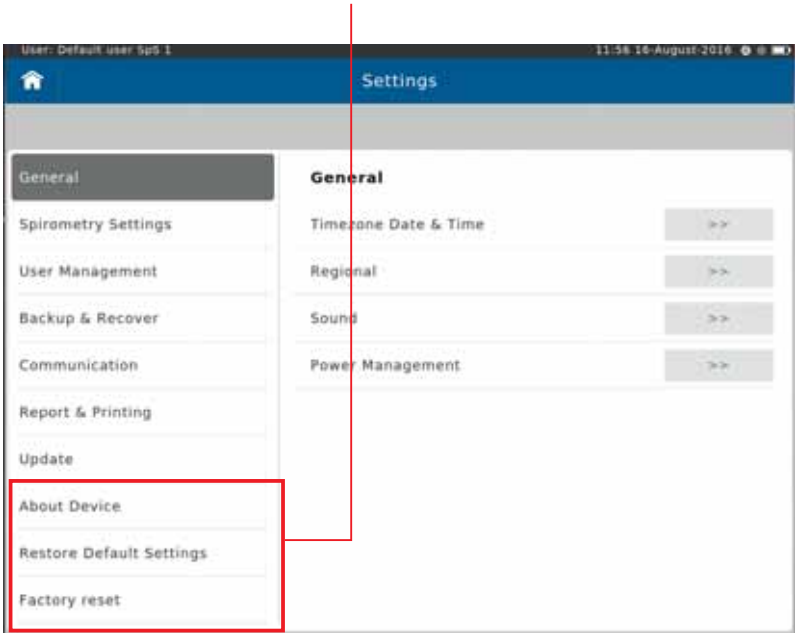
About Device

You can view system information under the About Device section.

Restore Default Settings

The system settings can be restored to the defaults using Restore Default Settings

Factory Reset



A detailed description of this tool is not part of this Instructions for Use.

Cleaning/Hygiene Spirometry

In the course of lung function testing, certain parts of the equipment can be contaminated by germs, which creates the risk that these germs can be transferred to the next test subject. For cross-contamination to occur, the test subject would need to be in direct contact with the contaminated object or transport media such as droplets or aerosols. Contaminated aerosols may be transported through the respiratory flow and may affect the next test subject.

Always be sure to disconnect the devices/systems from the mains power before cleaning or disinfecting.

The possible risk of infection can only be avoided if all of the contaminated parts are thoroughly disinfected!

In case of normal contamination all single-use items can be disposed of with the regular waste. In case of dangerous infectious diseases (e.g. tuberculosis, blood...) single-use items must be disposed of through hazardous waste.

How often should contaminated parts be exchanged?

	**Single-Use ERT PT with mouthpiece** Dispose after every patient **WARNING** Reuse may lead to patient infections.
	**Single-patient-use Nose clip** Dispose nose clips after every patient **WARNING** Reuse may lead to patient infections.
	**Disposable mouthpiece snorkel** Dispose mouthpiece snorkel after every patient **WARNING** Reuse may lead to patient infections. Disposable mouthpiece is to be used in combination with the tube portion of the ERT PT.

ERT PT and mouthpiece are parts for single use only. These parts must be disposed after each single use. If reused, infection may occur.

Reprocessing may deteriorate the part, resulting in reduced stability and leakage through micro cracks or releasing micro particles that could be inhaled. Should any of these parts be recycled and misused intentionally, ERT takes no responsibility nor can be made liable for the consequences arising from reusing these parts.

Surface Cleaning and Disinfection

Wiping disinfection

The surface disinfection of the **Main unit** and other contaminated surfaces, such as the **SpiroSphere Sensor**, must be performed on a regular basis (e.g. Main Unit daily).

If there has been direct contact with the skin or if the case history/diagnosis of the patient requires it, a surface disinfection has to be performed directly after the application.

DANGER

If the patient's history shows a dangerous infectious disease (e.g. tuberculosis), all parts which had been in direct or indirect contact with the patients must be disinfected.

Do not clean or disinfect the Main Unit or the SpiroSphere Sensor while the devices are in operation.

Precleaning and Disinfection

A thorough pretreatment/cleaning is a precondition for an efficient disinfection of contaminated parts. Protein residue on these parts might prevent an effective disinfection.

ERT recommends the following disinfectants:

Precleaning and Disinfection:

Product	Manufacturer	Concentration/Reaction time
mikrozid®sensitive wipes	Schuelke & Mayr GmbH	1 minute
CaviWipes	Metrex	1 minute

Procedure: Use the first cleaning wipe to cover all surfaces with the detergent. Repeat the procedure with a second wipe for disinfection. Let the surface dry.

Avoid fluid (eg. detergent) getting in contact with the connector inside of the guiding tube of the sensor unit.

Protein residue on parts which are to be disinfected prevents effective disinfection. Therefore all protein residue must be removed prior to disinfection. In case of persistent residues please use an appropriate tool (e.g. soft brush) to remove the residues.

Please observe the instructions with regard to concentration and reaction time!

If a different substance is used, please follow the manufacturer's instructions.

The use of detergents and disinfectants which have not been recommended by the manufacturer might damage the products.

The manufacturer's information on the cleaning of accessories provided separately must be observed!

With suspected tuberculosis or other resistant germs, the use of an appropriate disinfectant (CaviWipes, Reaction time >3 minutes) is required.

Avoid contaminated fluids (e.g. blood) to get into the SpiroSphere Sensor. In case of ingress of contaminated fluids, do not use the SpiroSphere Sensor anymore.

Disposal of Single Use Items / Damaged Reusable Items

Take precautions to avoid contaminating yourself (e.g. use gloves). All single patient use items can be disposed of as domestic waste if there is a normal degree of contamination. In case of dangerous infectious diseases (e.g. tuberculosis) it is necessary to dispose of the single patient use items in special designated containers.

In addition, please note country-specific disposal regulations.

Hygiene ECG

How often should contaminated parts be exchanged?

ECG electrodes are for single use only;
dispose after each subject

ECG electrodes are parts for single use only. These parts must be disposed after each single use. If reused, infection may occur.

Reprocessing may deteriorate the part, resulting in reduced stability and leakage through micro cracks or releasing micro particles. Should any of these parts be recycled and misused intentionally, ERT seeks no responsibility nor can be made liable for the consequences arising from reusing these parts.

The ECG unit and the electrode cables can be disinfected with a surface disinfectant (e.g. Incidin® Foam or Lysol® wipes), which is to be applied with a non-fuzzy, damp cloth.

Cleaning and Disinfection of the ECG Unit Surface

Clean the ECG unit only when switched off. Be certain that no liquids penetrate into the device.

Wipe the housing with a soft, moist cloth. Use Incidin® Foam or an equivalent means for disinfection such as Lysol® wipes. Follow the instructions regarding the use and exposure time of the disinfectant.

CAUTION

Never submerge the device into disinfectant or other liquids. This might result in device damage and/or consequently danger to the patient or operators.

Cleaning and Disinfection of the Cables

Wipe the cables with a soft, moist cloth to clean the device. Only use mild detergent in order to avoid damage. Pay attention not to pull too hard on the cables while doing this. Under no circumstances should the cables be submerged into liquids.

For disinfection, wipe the cables with a cloth saturated with Incidin® Foam or an equivalent means for disinfection such as Lysol® wipes. Follow the instructions regarding the use and exposure time of the disinfectant.

Lysol® is a registered trademark of the Reckitt Benckiser company.

Functional Check ECG

At each power-on, the medical device carries out an integrated self test. By means of this test the correct functionality of the following components is ensured:

- Voltage supply
- Memory
- Bluetooth module
- ADC for pacemaker detection
- ADC for ECG

An error condition in the Bluetooth connection is indicated by a quick double flashing of the blue LED. Error conditions of all other components are transmitted via the Bluetooth interface to the host PC.

⚠ CAUTION

Conduct a visual inspection of the medical device before each use. In case you should discover external damage at the device or the cables or in case the integrated self test fails, do not continue to operate the device. Contact the manufacturer Corscience or a specialist distributor authorized by Corscience to have the device repaired.

Troubleshooting Guide ECG

LED Status Chart		
LED code (blue)	System status	Possibility of intervention
Blue LED blinks slowly (1Hz)	Bluetooth connection active	-
Blue LED slow double blink	Battery almost empty	Replace battery
Blue LED blinks fast (3Hz)	Bluetooth pairing active	ECG unit can be paired from the according Settings menu
Blue LED on (solid)	Ready for operation	Start measurement in order to establish connection
Blue LED quick double blink	Start-up error, connection impossible	Replace battery, retry connection. If continuous failure contact ERT Customer Care

⚠ CAUTION

- The distance between the ECG unit and the SpiroSphere main unit impacts the quality of the Bluetooth connection. Keep it as short as possible and free of objects between both, e.g. furniture. If Bluetooth transmission fails for more than 10 seconds, the old ECG data are dismissed by the device and therefore lost for the recording.
- The separation of the point-to-point Bluetooth connection from another network (e.g. intranet, internet) is under the responsibility of the operator. In case the point-to-point Bluetooth connection is not served for more than 10 minutes the connection is terminated. The not yet transferred ECG data from ECG unit will be lost after 10 seconds (see above).

Malfunction	Cause of the Malfunction	Removal of the Malfunction
The ECG unit cannot be switched on.	Battery discharged below minimum power requirements.	Change battery for either a new or (re)charged one. Check polarity of the inserted energy source.
The ECG unit is not visible to the receiving Bluetooth devices.	There is already a Bluetooth pairing with another device.	Put the device into pairing mode. For this, press the button after power-on until the blue LED flashes. This indicates that the former pairing is removed and the device is visible in the Bluetooth vicinity.
No or fragmentary ECG data is transferred.	Radio communication is interrupted.	Reduce distance to receiving unit or remove a possibly existing obstacle.
	Device detects no ECG signal.	Check ECG cable application and restart the device. Remove and insert battery before restart if normal restart leads to the same malfunction.

Return of Goods in Medical Institutions

Recommendations for action -

for all staff members having contact with potentially contaminated returns.

Returns or returned goods are all products returned to the producer or the supplier, irrespective of whether or not they have been used, e.g. due to complaints, repair or maintenance. Those products might have had contact with biological substances or highly active pharmaceuticals (e.g. cytostatics, radioactive medicines) and could be contaminated by them. If in doubt, the goods to be returned should be treated as contaminated products.

Due to infectious agents, pathogens or pharmaceuticals, contaminated goods pose a potential hygienic risk for all persons having contact with the returns.

This leaflet provides guidance on minimizing the potential hygienic risk when handling returned goods. Among other things, this information is based on the legal standards of the Biostoff-Verordnung (= Biological Substances Regulation) and the Employment Protection Act (both valid in Germany). A more detailed reference list of applicable rules and regulations can be obtained from the BVMed (info@bvmed.de).

In order to protect your and our employees who handle contaminated parts and to optimally examine such parts, you should consider the following:

1. Assessment of returns before reshipment

Irrespective of whether or not a contamination risk is known, products which had direct or indirect contact with biological working substances (e.g. blood, secre-tions or other body fluids) or with highly active pharmaceuticals (e.g. gloves of the clinical or surgical staff) should be regarded as potentially dangerous to health.

According to the regulation on biological substances, substances of risk group 3 can cause severe illness in humans and pose a serious risk to staff members (e.g. tuberculosis or hepatitis). Substances of risk group 4 cause severe illness in
humans and pose a serious risk to staff members (e.g. Ebola or smallpox).
Regarding national and international regulations for the transport of potentially infectious substances (ADR, IATA-DGR), the **risk groups** 2 (e.g. staphylococcus aureus) **and 3** defined by the Biological Substances Regulation are classified as **Transport Category B.**

Products which are potentially contaminated by biological working substances of risk group 4 according to the regulation on biological substances as well as products which are potentially contaminated by pharmaceuticals posing a serious risk to health (e.g. X-ray contrast agents and cytostatics) must not be returned to the producer.

The following applies to products that are potentially contaminated by biological working substances of risk group 3 and 2 according to the regulation on biological substances and that are thus classified as Transport Category B:

Please contact ERT **before** returning the goods and observe the regulations for the transport of dangerous goods.

2. Cleaning

If the products had contact with biological working substances (for example blood or other body fluids), they have to be cleaned and disinfected in a combined cleaning and disinfection procedure, unless a differing agreement has been made with ERT.

As a rule, the products also have to be cleaned in order to minimize adhesions and bacterial contamination. Unless body fluids, tissue or contrast agents etc. have caused the product to be defective, deposits and adhesions should be removed carefully without damaging or altering the product, if possible. For this, refer to the notes on the preparation of products.

Products which have been contaminated by highly active pharmaceuticals have to be cleaned appropriately with tap water.

If in doubt, contact ERT for guidance on further actions!

3. Disinfection/Sterilization

After cleaning, the products have to be disinfected and/or sterilized (only if permitted for this medical product) in order to avoid harm to your and our employees.

If in doubt or in case of suspected material incompatibility, please consult ERT.

4. Packaging

To avoid any contamination, the cleaned and disinfected product has to be packed as follows:

a) Put it into a sealable primary packing.

Parts with sharp edges need to be packed particularly safe.

b) Put the primary packing in a waterproof secondary packing (if possible use hard packing material).

c) Pack the secondary packing with a neutral packing material.

For “**Packaging and labeling of non-contaminated products**“: see point 6.

5. Labeling

If a concrete risk of infection (e.g. HIV, Hepatitis B or C) is known to be present, this risk has to be noted on the packing of the returned goods and/or in the accompanying documents.

For "**Packaging and labeling of non-contaminated products**": see point 6.

6. Packaging and labeling of non-contaminated products

If the procedures described under point 2 and 3 are not applied, the contaminated product has to be returned in a combined packing complying with the packaging instruction P 650 ADR after contacting ERT, if necessary. Proceed as follows:

a) Put the product into a liquid-tight, sealable packing (e.g. tearproof plastic bag) (primary packing)

b) Put the primary packing into a (if possible, liquid-tight) protective packing (secondary packing); for liquid materials insert an adequate amount of absorbing material between the primary and the secondary packing.

c) Pack the secondary packing with an additional outer packaging (padded envelope or cardboard box).

d) Label the outer packaging with the corresponding UN no. 3373 for diagnostic or clinical samples and add the note:

"**Biologischer Stoff, Kategorie B/Biological Substance, Category B**"

7. Dispatch

Please note that non-decontaminated returns with suspected pathogens of risk group 3 are excluded from mailing. Diagnostic or clinical samples of UN no. 3373 which have been packed according to packing instruction P 650 are not subject to any further regulations on the transportation of dangerous goods and may be transported by a forwarding agent or a parcel service.

For this purpose use the accompanying shipping documents of the forwarding agent/carrier containing the corresponding valid transportation regulations, e.g. GGVSE (Road and Railway Dangerous Goods Regulation).

The product is then dispatched to the address indicated by the manufacturer.

Address:

eResearchTechnology GmbH
Sieboldstrasse 3
97230 Estenfeld, Germany
Tel: +49 9305 720-9891
www.ert.com

Certificate of Hygiene

This certificate must be attached to ANY product complaint, ANY return of medical products and accessories, ANY repair order and ANY return of studies.

Name of product: _____

REF (ERT item no.): _____

LOT (batch no.): _____

It is herewith confirmed by signature that (please mark appropriate box):

- ❑ the enclosed medical product had **no** contact with blood or other body fluids so that it is **hygienically safe**.
- ❑ the enclosed medical product had contact with blood or other body fluids during its use. The product has been cleaned and decontaminated as follows:
- ❑ Disinfection by wiping all accessible surfaces with

  Disinfectant: _____

  Concentration: _____

  Reaction time: _____
- ❑ Other procedure (please indicate):
- ❑ Steam sterilization (3 minutes at 134 °C or 15 minutes at 121 °C)
- ❑ the enclosed medical product could **not** be decontaminated.

  Reason:

  _____

  _____

Send returns to the following address:

eResearchTechnology GmbH
Abteilung Wareneingang
Sieboldstrasse 3
97230 Estenfeld
Germany

Sender's signature and address:

General Safety Precautions

The Instructions for Use is regarded as part of the instrument, and should always be kept on hand.

The Instructions for Use describes the present state of the device/system, including software and accessories, with regard to the fundamental requirements of the MDD 93/42/EEC and MDR (EU) 2017/745.

Exact adherence to the instructions issued is a prerequisite for perfect and intended functioning of **ERT** instruments.

WARNING

Deviation from Intended Use

Any non-observance of the procedures (such as preparation for a measurement and methods, disinfection procedures, use of accessories and replacement parts etc.) described in the Instructions for Use results in a deviation from intended use.

In case of a deviation from intended use, the operator/user has to supply proof of meeting all corresponding fundamental requirements.

The operator/user is responsible for performing the conformity assessment correctly and is also completely liable for defective products - i.e. the operator/user is liable for his/her modification of the medical product.

ERT only guarantees for the safety, reliability and functionality of the instrument if

- installation, extension, modifications, and repairs are exclusively carried out by personnel authorized for these tasks by **ERT**.
- the room in which the equipment is operated complies with the country-specific installation standard.
- the unit can be plugged into a socket with protective conductor system.
- the ambient conditions at the place of installation are suitable for the unit.
- the unit is used according to the Instructions for Use.

Unpack your medical device. Please check if the unit is damaged. If so, do not use it and return it for a replacement.

Patient Safety according to EN 60601-1

This medical device safely insulates the subject from the mains power supply as required in the safety regulations on leakage current according to EN 60601-1, **Type BF**. Nevertheless, a subject environment must be defined. The subject has to keep a distance of at least 1.5 m from all open interfaces and connectors of the SpiroSphere Main Unit to avoid any contact with electrical voltage.

The physician/operator must not touch any voltage-carrying parts (e.g. USB Plug, Ethernet Plug) and the subject at the same time.

CAUTION

The connection of further power-operated units to your **ERT** unit may cause all the leakage currents to add-up and the safety of the subject is reduced. Due to this, the connection of further units may only be carried out on consultation with the **ERT** Customer Care.

Accessory equipment connected to the interfaces must be certified according to the respective EN standards (e.g. EN 60950 or EN 60601-1).

Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard (IEC 60601-1). If in doubt, consult the technical service department or your local representative.

Use of Multi-Plug Sockets

Do not connect the medical device/system to multi-plug sockets.

WARNING

Radiated Interference

The ERT device meets the regulations according to EN 60601-1-2 (CISPR 11 Group 1 class B) regarding the interference radiated and received. The device should not be installed in the vicinity of high-frequency devices, X-ray equipment, motors or transformers with high installed power rating since electric or magnetic interference fields may falsify the result of measurements or make taking measurements impossible. Due to this, the vicinity of power lines is to be avoided as well. Existing environmental interferences may cause deviations of the measurement values without impairing the device's function. Therefore, it is recommended to keep a distance of about 2 meters from possible error sources when using the device.

This device should not be operated in immediate vicinity to or stacked with other devices since this could lead to an incorrect operation. However, if an operation in the described manner is necessary, this device as well as the other devices should be carefully observed to ascertain a proper operation.

Using other accessories, other transformers and other cables than those specified or provided by the device's manufacturer can result in increased electromagnetic radiation or reduced electromagnetic immunity of the device and can lead to an incorrect operation.

Portable RF communications equipment (transmitters) (including appropriate accessories such as aerial wires and external antennas) should be operated with a minimum distance of 30 cm (21 inch) to the SpiroSphere's components and cables specified by the manufacturer. Non-observance may lead to a reduction of the device's performance.

For further information see chapter
Electromagnetic Emission and Immunity and **Notes on EMC.**

DANGER

Ambient Conditions

The medical device must not be operated in rooms with the presence of flammable anaesthetic mixture with air or flammable anaesthetic mixture with oxygen or nitrous oxide. The medical device must be operated in rooms where only non-conductive pollution occurs; however, occasional temporary conductivity due to condensation is to be expected. The medical device is designed for operation in medically used rooms.

The medical device has to be effectively protected against moisture. Ventilation slots must be kept free of obstructions in order to enable air circulation.

CAUTION

Putting the Unit into Operation

Temperature changes may give rise to condensation in the device. Consequently, the device has to adapt to the ambient temperature before putting it into operation.

Always consult the nameplate on the device/system for compliance of the unit's own data with those of the local power supply system (mains voltage and mains frequency) before actually connecting the unit.

Connect only if all data comply!

Inspect the mains connection cable, plug, and receptacle for visible damages prior to establishing the connection. Damaged cables or plugs must be replaced immediately. Installation and assembly of the device must be done only in compliance with this Instructions for Use.

After the first setup or if the setup has been changed (e.g. exchanging of the SpiroSphere Sensor), a function test (e.g. calibration check) has to be performed.

The Main Unit must be placed outside the patient environment during measurement.

Medical Supervision

During the measurement the patient must not be unattended. A qualified physician must reassess all measurements. An interpretation by the medical device is significant only when considered together with other clinical findings. The performance of the spirometer can be affected by the patient spitting or coughing into the spirometer during expiration or by extremes of temperature, humidity and altitude.

WARNING

Cleaning and Hygiene

Prior to every application, all parts which come in contact with the patient and which are intended for reuse must be cleaned or disinfected (unless otherwise instructed).

Prior to taking measurements of a patient, his/her medical history is to be checked in order to avoid a contamination of the device and a resulting cross-contamination of the next patient.

While performing a calibration check, a new disposable Pneumotach must be used to prevent cross-contamination between the calibration syringe and the parts. This will prevent contamination of the syringe and allow for its reuse.

Always be sure to disconnect the devices/systems from the mains power before cleaning or disinfecting. The Main Unit corresponds to protection class IP21, the SpiroSphere Sensor to class IP20.

The device may not be soaked in liquid of any kind. Liquid inside the device/ system may lead to harm of the user and can destroy the device.

The device can be cleaned with a damp (but not soaked) cloth, which does not produce lint. More detailed information can be found under “Hygiene“ in this Instructions for Use.

Detergents and chemicals required for cleaning and disinfection must always be stored in specially marked containers to prevent any accidental improper use.

Biocompatibility

Component	Material
Mouth piece	Styrolution PS 454N HIPS
Housing parts of the sensor unit and the main unit	Cycoloy CX2244ME
PT-tube	Styrolution PS 454N HIPS

WARNING

Maintenance

No part of the medical device may be replaced by the customer.

Use only **ERT** approved accessories and spare parts for this medical device.

If applied parts (e.g. SpiroSphere Sensor) have been exposed to extreme mechanical stress, a function test (e.g. volume calibration check) has to be performed. If function is lost, the defective part is to be replaced. Damaged parts, e.g. frayed plugs, receptacles, a damaged handle, and defective cables should be replaced immediately by an authorized specialist or engineers from **ERT Customer Care.** The device must not be opened. If it is opened without authorization the guarantee entitlement expires. **ERT Customer Care** is always at your disposal with help and assistance in case of problems.

Before turning on the device/system you should always check whether the power cable, power plug, outlet and power input of the device are free from defects.

Before turning on the device/ system the following issues have to be checked visually on a daily basis:

- the display glass is undamaged
- the unit has not been mechanically stressed in the extreme (e.g. damage to the housing, the cable is made defective by running over it with a heavy object or dragging it)
- no liquid got inside the unit
- the SpiroSphere Sensor is not damaged
- cables and/or multiple connectors are not defective
- coverings are not broken

An unattended child should **not** get into contact with disposables, accessories and packing material as well as cleaning and disinfection substances.

Further safety-related checks in accordance with IEC 62353 have to be performed every 3 years by an authorized technician. These safety-related checks include the measuring of leakage current and insulation resistance and the visual checks as performed on a daily basis.

WARNING

Recurrent Test

Medical Electrical equipment needs a recurrent testing after repair of the equipment according to IEC 62353.

The calibration syringe itself has to be calibrated at regular intervals as determined by the manufacturer and as indicated on the syringe. The calibration syringe must be checked for an accuracy of ± 12 mL.

CAUTION

Recycling

Adhere to the national law of the country when disposing the medical device and its accessories.

Improper disposal of the device and/or its accessories can result in serious environmental hazards.

If you recognize or experience any serious incident that has occurred in relation to the device, you should report this to the manufacturer and the competent authority of your country.

Safety Precautions ECG

Read these instructions for use carefully. They are part of the device and must be available at all times. Do only use the device for the intended purpose described in this document (see chapter “Indications for Use“). If you recognize or experience any serious incident that has occurred in relation to the device, you should report this to the manufacturer and the competent authority of your country.

For your own safety as well as for the safety of your patients and according to the requirements of the FDA and Medical Devices Act, please observe the following:

General Cautions and Warnings

	CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.
	The medical device is only to be used by people who can guarantee proper operation based on their training or their knowledge, e. g. as a result of a training.
	Any claim to guarantee and liability expires if other than the equipment recommended in this instruction for use or original spare parts are used. Functional failure or non-biocom-patibility can result, if other than original or recommended parts and equipment is used.
	The medical device is not suitable for use in aircraft or moving vehicles.
	User must comply with the instructions given in this manual for avoiding infections and bacterial contaminations.
	Repairs must only be performed by the manufacturer or by factory trained personnel.
	Carry out a visual control of device, cables and the other equipment/accessories before each use. Do not use the device if obvious external damage or a failure of the self test is identified.
	Comply with the environmental conditions described in the technical data.
	Only use biocompatible and FDA or CE-certified electrodes, as applicable, with the medical device.
	Comply with the instructions for use of the applied electrodes at all times.
	Do not submerge the medical device into liquids, pour or splash it with liquids deliberately or expose it to rain. Should liquids penetrate into the device, do not operate it before a check of the customer support has been carried out.
	Do a functional check regularly.
	The medical device, other than the battery compartment, must only to be opened by factory authorized personnel. Opening the device by an unauthorized person will void all warranties.
	The manufacturer is not liable for the function of the medical device if the device is improperly maintained by the owner or the operator or if it is operated in a way that does not correspond with the intended use according to these instructions of use.

⚠	The signals emitted by the measuring device do not comply with the alarmstandard for medical electrical devices, DIN EN 60601-1-8.
⚠	All parts of the medical device, including the equipment, which come into contact with the patient when operating the device in accordance to the regulations, meet the applicable biocompatibility standards.
⚠	Packaging material can pose a risk of suffocation. Keep it inaccessible for children or dispose of it in accordance with the regulations.

Operation Cautions and Warnings

⚠	The medical device, especially the electrodes and cables, must only be used on healthy and intact skin.
⚠	Do not make any changes to the electrodes or the device during operation. That might result in incorrect measurements.
⚠	The device is not suitable for heart leads. When using a defibrillator the electrodes of ECG and defibrillator must not come into contact.
⚠	If a defibrillator is used, pay attention that no one has contact with the patient. Burns or other injuries might result.
⚠	It is not possible to operate the medical device in combination with HF devices, e. g. surgical units.
⚠	When monitoring critical patients, an alternative medical device must be kept available at all times in case of a device breakdown.
⚠	Avoid tensional load on the cables.
⚠	Only use biocompatible and FDA or CE-certified electrodes, as applicable, with the medical device.
⚠	Comply with the instructions for use of the applied electrodes at all times.
⚠	Assure that the electrodes are correctly applied. Incorrectly applied electrodes can adulterate the ECG and result in misinterpretations.
⚠	The skin at the application positions of the electrodes has to be clean and dry. Moisture can result in signal distortion. If using an inflammable skin cleansing agents, the skin must be dried completely as a means of precaution.
⚠	Conductive parts of the electrodes have to be kept away from other combustible parts.
⚠	**Electric Shock from Unconnected Electrodes:** As soon as at least one electrode or peripheral sensor is attached to a person, make sure that none of the other electrodes or peripheral sensors come into contact with any conductive material that might provide a return path to ground.

	Motion artefacts adulterate the measurements. They might result in an incorrect interpretation by the operator and, as a consequence, lead to a wrong or delayed therapy.
	When wearing other electronic devices, e. g. pacemakers, other implanted or body-worn devices, errors or mutual interaction might possibly occur. Pacemaker patients have to be monitored separately.
	Magnetic and electric fields can influence the function of the device. Keep a safe distance between the medical device and devices emitting HF radiation (e. g. mobile phones) as otherwise failures might occur (see chapter “Technical Data“).
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the medical device including cables. Otherwise, degradation of the performance of this equipment could result.
	Note that when using the device the electromagnetic radiation emitted might influence other electric devices in the vicinity.
	Use of accessories, transducers and cables other than those specified or provided by the manufacturer could result in an increased electromagnetic emission or decreased electromagnetic immunity of the medical device and result in improper operation.
	The medical device must not be operated in potentially explosive atmosphere.
	Check the settings of the signal strength before each use.
	When using the medical device, it is necessary to place the patient under constant monitoring.
	The medical device must not be used on children < 20 kg, infants and new-born.
	The medical device must not be used unattended on children younger than 4 years and disturbed patients. There is a danger of an aspiration of the electrodes.
	When operating heat therapy devices nearby disruptions from the radio transmission might arise.
	When wearing pacemakers, errors in the determination of the heart rate might possibly occur.
	A short circuits of the battery circuit can overheat the medical device. If the device feels warm, put it down immediately and remove the battery of energy. Do not use the medical device until it has been serviced by a factory trained represetative.
	Assure that the Bluetooth monitor which receives the measured data is paired to only the medical device to prevent loss of monitoring.
	ECG cables may wrapp around patients neck during sleep. So do not sleep with the device attached or fix the ECG cable close to the body.
	Do not change the battery while the medical device is connected to a patient.

⚠	Do not touch the device during shock release!
⚠	Do not use or store the device in dusty, wet or dirty environments. Make sure to always keep the environment conditions for storage and transport that are listed in the chapter “Technical Data”.
⚠	Take care in arranging subject and ECG electrode cables to avoid risk of subject entanglement or strangulation.
⚠	No adverse effects are known for the ECG amplifier itself. However, electrodes or electrode gel can lead to skin irritation on a transient basis. In rare cases, an allergic reaction has been observed to certain kinds of conductive electrode pastes.

Graphical Symbols

Applied Part of type CF, Defibrillation-proof (ECG unit cable variant)

Alternating current

Attention!

ON/OFF (device connected to/disconnected from the power supply system)

Follow the instructions for Use!

Year of Production

Manufacturer

Applied part of Type BF

Single use

Disposal of electronic devices in compliance with WEEE

Packaging can be recycled

Temperature limit

UDI Unique Device Identifier

MD Medical Device

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

SN Serial number

REF Reference number

IP20 Protection against intrusion of solids ≥ 12,5mm diameter; no protection against ingress of liquids

IP21 Protection against intrusion of solids ≥ 12,5mm diameter; protection against dripping water

CE 0123 CE sign with code number of the Notified Body.
The certified quality management system of eResearchTechnology GmbH corresponds to the international standard of ISO 13485.

Possible source of interference

The typeplate can be found at the rear side of the Main Unit.

The typeplate on the SpiroSphere sensor is positioned at the left side.

Typeplate including optional 3G module

Parts of the software are developed under the GPL software license. The source code of these parts can be obtained from **ERT.**

The conditions and a copy of the GPL can be obtained at: "http://www.fsf.org/licenses/gpl.html" or from: Free Software Foundation, Inc., 51 Franklin Street, Fifth Floor, Boston, MA 02110-1301, USA

This product is based in part on Evas, Copyright© 2000 - 2005 by Carsten Haitzler and various contributors, and on the work of the FreeType team.

The safety precautions and operational procedures indicated in this chapter refer to Germany. Different regulations and standards may apply to other countries.

Safety Precautions for Lithium Ion Rechargeable Batteries

The SpiroSphere Sensor is powered by an internal Lithium-Ion Polymer battery.

The SpiroSphere Main Unit can also be powered by an internal Litihium-Ion Polymer battery.

The following safety precautions are valid for Lithium-Ion batteries:

- Dispose of Lithium-Ion batteries according to local regulations.
- Do not shortcut the battery.
- Protect the battery against excessive heat!
- Protect the battery against direct sun light!
- Protect the battery against fire!
- Do not dismantle or manipulate the battery.
- Do not replace the battery. Improper replacement can lead to fire, excessive heat or explosion.
- The fluid in the battery is toxic and flammable - leaky batteries or batteries with dents must not be used any longer!
- Do not come in contact with the fluid in the battery. If the fluid comes in contact with your skin, immediately rinse the affected part with water and contact a doctor!
- To charge the SpiroSphere Sensor, use only the Main Unit Cradle and observe the instructions in the manual!
- To charge the Main Unit, use only the provided power supply.

USA

“This device complies with Part 15 of the FCC Rules. Operation is subjected to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including that may cause undesired operation.“

SpiroSphere - Main Unit: FCC-ID: 2AAUFSPS001 (for optional 3G module included)
2AAUFSPS003 (for optional 3G module excluded)

SpiroSphere - Sensor Unit: FCC-ID: 2AAUFSPS002

FCC Notice "Declaration of Conformity Information"

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Any changes or modifications not expressly approved by ERT could void the user's authority to operate the equipment.

Canada

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d’Industrie Canada applicables aux appareils radio exempts de licence. L’exploitation est autorisée aux deux conditions suivantes : (1) l’appareil ne doit pas produire de brouillage, et (2) l’utilisateur de l’appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d’en compromettre le fonctionnement.

SpiroSphere - Main Unit: IC: 11335A-SPS001 (for optional 3G module included)
11335A-SPS003 (MOD MU-SPS003) (for optional 3G module excluded)

SpiroSphere - Sensor Unit: IC: 11335A-SPS002

Exposure to radio frequency energy.

The radiated output power of this device meets the limits of FCC/IC radio frequency exposure limits. This device should be operated with a minimum separation distance of 20 cm (8 inches) between the equipment and a person’s body.

Frequency Band and Transmittet power:

3G (optional):

Frequency Band	Transmission Frequency Range	Maximum Output Power	Gain
UMTS B1	1922 to 1978 MHz	23 dBm (+/- 2dBm) Class 3bis	-1.74 dBi
UMTS B2	1852 to 1908 MHz	23 dBm (+/- 2dBm) Class 3bis	-1.1 dBi
UMTS B5	826 to 847 MHz	23 dBm (+/- 2 dBm) Class 3bis	-3.31 dBi
UMTS B6	832 to 838 MHz	23 dBm (+/- 2 dBm) Class 3bis	
UMTS B8	882 to 913 MHz	23 dBm (+/- 2 dBm) Class 3bis	
UMTS B19	832.4 to 842.6 MHz	23 dBm (+/- 2 dBm) Class 3bis	
GSM 850	824 to 849 MHz	2 Watts GSM, GPRS and EDGE	
E-GSM 900	880 to 915 MHz	2 Watts GSM, GPRS and EDGE	
DCS 1800	1710 to 1785 MHz	1 Watt GSM, GPRS and EDGE	-1.1dBi
PCS 1900	1850 to 1910 MHz	1 Watt GSM, GPRS and EDGE	

Bluetooth:

Frequency Band	Transmission Frequency Range	Maximum Output Power
2400 MHz (BT)	2402 to 2480 MHz	12 dBm

WiFi:

Frequency Band	Transmission Frequency Range	Maximum Output Power
2400 MHz (WiFi)	2412 to 2484 MHz	19 dBm

Wireless Charging:

Frequency Band	Transmission Frequency Range	Maximum Output Power
Qi (wireless charger)	112 to 205 kHz	37 dBm

Electromagnetic Emission and Immunity SpiroSphere ECG

Medical electrical equipment is subject to special precautions regarding electromagnetic compatibility (EMC). User must follow the EMC installation instructions and only use the device in the intended environment during operation.

The SpiroSphere meets the regulations according to EN60601-1-2 regarding the interference radiated and received. For more information, refer to the EMC tables of the instructions for use of your device/system.

The SpiroSphere is intended to be used in professional healthcare facility environment like doctor’s office or hospital.

SpiroSphere conforms to basic standard IEC 60601-1.

The essential performance of the device is the acquisition of spirometry and ECG signals and display on the Main Unit.

Electromagnetic irradiation can influence the device essential performance by the following:

• The maximum error (drift, uncertainty) of Flow measurements might be up to +/- 20ml/s

Electromagnetic irradiation can influence the ECG device essential performance by the following:

• The measurement signal might be influenced but will recover for use within 10s after the source of disturbance disappeared.

⚠ CAUTION

Electromagnetic Interference and Wrong Diagnosis

- The device must not be installed and used in the vicinity of high-frequency devices, X-ray equipment, motors or transformers with high installed power ratings since electric or magnetic interference fields may falsify the measurement.
- Do not perform measurements with the device directly next to other equipment or in combination with other devices in a stacked form as this may result in faulty operation.
- The SpiroSphere has been tested for radiated RF immunity only at selected frequencies. A use nearby emitters of other frequencies could result in improper operation. Keep a distance of about 2 meters from possible error sources when using the device.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the medical device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories, cables etc. other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Changes or modifications to the SpiroSphere may result in increased electromagnetic emissions or decreased electromagnetic immunity in relation to EMC performance.
- Devices that are connected to the SpiroSphere can also cause radiated interference. Therefore, you must follow the regulatory and safety related notes of the respective device manufacturer.
- Strong electromagnetic fields can disturb the measurement signal. Cellular phones, x-ray machines, thermal radio frequency treatment equipment, diathermy, electrocautery, and RFID, etc. produce strong electromagnetic fields. Make sure to keep devices that produce electromagnetic fields away from the SpiroSphere device.
- Make sure that the recommended distances to radio wave emitters are met.

If the measurement signal is lost or degraded due to electromagnetic disturbances, you need to relocate the device and repeat the measurement.

The use of accessories not recommended by ERT may result in an increased electromagentic radiation or a reduced interference immunity of the SpiroSphere.

SpiroSphere

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The SpiroSphere is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		
EMC Basic Standard	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The SpiroSphere uses RF energy for internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Class B	The SpiroSphere unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity	
The SpiroSphere is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Immunity Test	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV indirect contact ± 15 kV direct air ± 8 kV direct contact
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2700 MHz applied to 4 devices orientations each with vertical and horizontal antenna polarisation
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode
Conducted RF IEC 61000-4-6	3 V(rms) from 150 kHz to 80 MHz 6 V(rms) in ISM bands
Voltage dips IEC 61000-4-11	tested at 100 and 240 V power supply input lines < 5% @ 0.5 cycles and 45 degree sync angle steps < 5% @ 1 cycle <70% @ 25 cycles and 50 Hz <70% @ 30 cycles and 60 Hz
Short interruptions and voltage variations IEC 61000-4-11	tested at 100 and 240 V power supply input lines < 5% @ 250 cycles and 50 Hz < 5% @ 300 cycles and 60 Hz

ECG amplifier

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The ECG unit is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG unit should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The ECG unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The ECG unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ECG unit is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG unit should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8kV air	±8 kV contact ±2 kV, ±4kV, ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated, Radiofrequency, Electromagnetic Field Immunity IEC 61000-4-3	3 V/m 80 to 2700 MHz 80% AM at 1 kHz	3 V/m 80 to 2700 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment must be used no closer to any part of the ECG unit, including cables, than the recommend separation distance shown earlier
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m (50/60Hz)	30 A/m (50/60Hz)	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

Test Specifications for Immunity to RF Wireless Communications Equipment						
Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460; FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth; WLAN 802.11 b/g/n; RFID 2450; LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE: If necessary to achieve the immunity test level, the distance between the transmitting antenna and the ECG unit may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Bluetooth® Wireless Communication

Bluetooth is a wireless technology standard for exchanging data over short distances from fixed and mobile devices and building personal area networks (PANs). IEEE standardized Bluetooth as IEEE 802.15.1. The maximum output power the Bluetooth radio is 2.5mW. The typical range of operation is approximately 30 feet (10 meters). Bluetooth is used to pair the ECG unit with its data collection devices and transfer test data between them. Bluetooth links use encryption algorithms that are widely considered acceptably strong. The strength of Bluetooth security relies primarily on the length and randomness of the passkey used for Bluetooth pairing, during which devices mutually authenticate each other. The encryption procedure enables encryption of the data sent over the air-interface to prevent unintended eavesdropping.

COR12
CS10785

Assembled from tested components
Complete system not tested

Corscience GmbH
Hartmannstr. 65
91052 Erlangen
Germany
+49 9131 977986-0

FCC ID: T7VPAN10

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interferences, and (2) this device must accept any interference received, including interferences that may cause undesired operation.

FCC Notice "Declaration of Conformity Information"

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Bluetooth® is a registered trademark of Bluetooth SIG, Inc.

Canada

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

IC: 216Q-PAN10

Technical Data Spirometry

Dimension	31.5 x 19.5 x 7.5 cm (L x W x H)		
Weight	1.5 kg		
Screen Display	16.2 x 12.2 cm		
Medical	Model: GTM91099-3009-4.0-T2		
Power Supply	Input: 100 - 240 Vac, 50 - 60 Hz, 1.5 A Output: 5 V, 6 A Cable length: 1200 mm		
Battery	Main Unit	Built-in rechargeable lithium-ion battery 3.7 V, 5000 mAh. Battery will last under standard operating conditions for about 3 h. Full charging: 2 h Cycle life: 70% of rated capacity after 350 cycles	
	SpiroSphere Sensor	Built-in rechargeable lithium-ion battery 3.7 V, 640 mAh. Battery will last under standard operating conditions for about 3 days in standby and 2.5 h operation. Full charging: 2 h Cycle life: 70% of rated capacity after 500 cycles	
Protection Class	Power Supply	Class II	
	SpiroSphere Sensor	Internally powered	
Mode of Operation	Continuous		
Moisture Protection	Power Supply	IP42	
	Main Unit	IP21	
	SpiroSphere Sensor	IP20	
Applied Parts	ERT PT, SpiroSphere Sensor		Type BF
Application	Measuring Pulmonary Function		
Interface	USB	Data Transfer	
	Bluetooth	Data Transfer	
	WiFi	Data Tansfer	
	Ethernet	Data Transfer	
	3G (optional)	Data Transfer	
Measuring Principle	High-Quality Pneumotach		
Operating Ambient	Temperature:	+10 °C to +35 °C	
	Relative Humidity:	15 % to 90 %	
	Barometric Pressure:	700 to 1070 hPa	

Transport/Storage	Temperature:	-20 °C to +50 °C	
	Relative Humidity:	15 % to 90 %	
	Barometric Pressure:	600 to 1200 hPa	
Ambient unit		**Measuring range**	**Accuracy**
	Barometric pressure:	500 to 1100 hPa	± 2.5 hPa at 700 - 1060 hPa

Technical Data Flow Sensor

Measuring Range:	PEF:	0.1 to 16 L/s	
	FEV1 and FVC:	0.1 to 8 L	
Resolution:	PEF:	< 5 mL/s	
	FEV1 and FVC:	1 mL	
Accuracy:	PEF:	0.1 to 16 L/s:	± 10% of reading or ± 0.3 L/s
	FEV1 and FVC:	0.1 to 8 L:	± 3% of reading or ± 0.050 L
Resistance Spirometer	max. 135 Pa/L/s at 14 L/s		
Instantaneous Flow	0.1 – 14 L/s: +/- 5% or 0.2 L/s		

The expected operational lifetime of the SpiroSphere is 7 years.

Technical Data ECG

Feature	Value	
Product class according to 93/42/ EWG (MDD)	IIa	
Dimensions W x H x D in cm	8,0 x 9,3 x 2,1 (3.3 x 3.7 x 0.8 in)	
Weight, incl. cable / without cable	200 g (0.4 lbs) / 81 g (without battery)	
Temperature range Operation Temperature range Storage (without batteries)	T = 10 to 37 °C T = -20 to 50 °C	
Air pressure range Operation Air pressure range Storage (without batteries)	70 to 1060 hPa 600 to 1200 hPa	
Humidity (operation, storage, transport)	5 – 95% RH (not condensing)	
Power supply	1x AA (rechargeable) battery	
Runtime	> 5h with AA battery > 8h with rechargeable battery (2850mAh)	
Current consumption at 1,5 V - Operation / Idle	230 mA / 185 mA	
Data transmission	wireless, online with radio standard Bluetooth Protocol: SPP.	
Bluetooth®	Bluetooth® module	Panasonic PAN-1322-SPP
	Bluetooth® standard	V2.1 + EDR, class 2 device
	Output power	2.5 dBm, max. 4.5 dBm
	Frequency range	2400 - 2483.5 MHz
	FCC identifier	T7VPAN10
	IC identifier	216Q-PAN10
	Bluetooth® QD ID	B021246
Memory	Buffer memory for a 10-second ECG	

ECG unit manufactured by:

Corscience GmbH
Hartmannstr. 65
91052 Erlangen
Germany

Feature	Value
Classification according to 60601-1 - Protection type against electric shock - Protection level against electric shock	 Device with internal power supply Type CF
Electromagnetic compatibility (EMC) according to 60601-1-2 - Noise suppression - Immunity	 EN 55011 EN 61000-4 parts 2, 3, 6, 8
Protection level against access to hazardous parts and ingress of solid objects	IP20
Variants	12-channel EU cable; 12-channel US cable, 12-channel connector
Accuracy of the ECG signal	1,94µV/bit resolution (at sampling rate of 500Hz)
Filter	bandpass 0,05 Hz – 150 Hz no line filter (50Hz / 60Hz)
Electrodes	Standard ECG electrodes
Connection of the electrodes	4 mm snap, gilded
Shelf life	1 year for device
Product life	The product life is 5 years.
Radio transmission	Approved in accordance to RED directive transmitter module marked by CE, manufactured by Panasonic incorporated to OEM product.

Application	ECG Recording
ECG leads	acc. to Einthoven, Wilson, Goldberger
Bandwidth	0 - 150 Hz digital
Sampling rate per channel	500 Hz
Pacemaker detection	4000 Hz sampling rate
HR and pacemaker detection in ECG unit	
Resolution	1.94 µV/bit ECG, 15 bit
Power supply	1 x AA battery
Connection to electrodes	4 mm snap connector, gold-plated
Moisture protection	IP20
Electrode cable length	0.44 m / 0.81 m

Item Numbers of Disposables and Accessories

Use ERT accessories and spare parts only!

720254	Manual calibration syringe, 3 L
852353	Syringe Adapter D 28 mm, L 60 mm
892120	Plastic nose clip
892121	Nose clip pad "foam material", disposable, 100 pieces per pack
706000	ERT PT, incl. mouthpiece
706002	ERT PT, incl. mouthpiece (box of 10)
706003	ERT PT, incl. mouthpiece (box of 50)
892104	Disposable Mouthpiece Snorkel (pack of 30)
992951	ECG Electrodes - Extra Small, 25 per pack
992950	ECG Electrodes - Small, 50 per pack
992946	ECG Electrodes - Medium, 25 per pack

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