Instructions for Use

SpiroSphere®

781235
Version 00.16

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Indications for Use

The **SpiroSphere** is a diagnostic compact device to measure inspiratory and expiratory lung function parameters in adults and children. In addition the SpiroSphere can collect, store and transfer vital data from other external devices.

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

CAUTION Federal U.S. law restricts this device to sale by or on the order of a physician. (Rx only)

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.

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. 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, 3G and Ethernet.

The device can be used by physicians in the office or hospital as well as in occupational medicine.

Unpacking and Starting Operation

SpiroSphere is delivered with the following accessories*:

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

The "Return of Goods in Medical Institution/Certificate of Hygiene" is provided as a separate document/flyer.

WARNING **Death due to suffocation may occur if packing material is swallowed.**
Store packing material out of reach of children and dispose of properly!

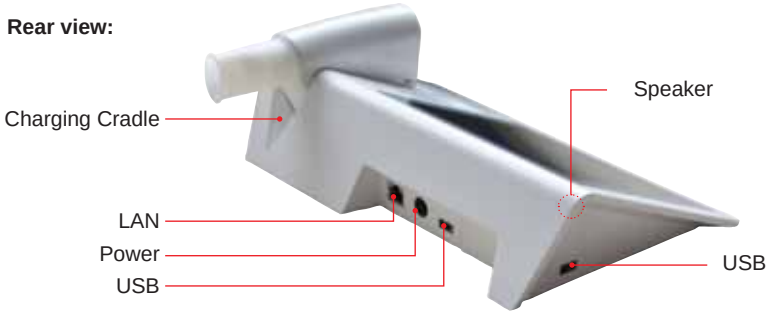
WARNING Use only **ERT** approved accessories and spare parts for this medical device.

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

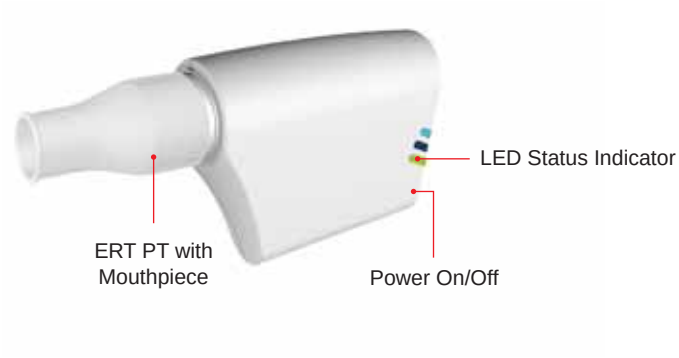
The SpiroSphere

Main Unit: **Front view:**

Rear view:



SpiroSphere Sensor:



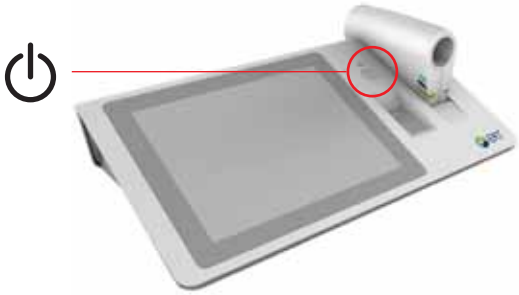
Power supply:

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.

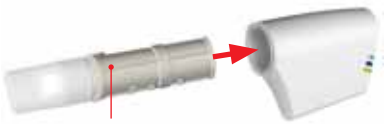
3. Use the Power On switch located at the front of the main unit to switch on the **SpiroSphere Main Unit**.



The operating status of the device is indicated via an LED on the main unit and on the SpiroSphere Sensor.

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.

5. Ensure an ERT PT is inserted into the **SpiroSphere Sensor**.



ERT PT with mouthpiece

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

WARNING 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 temperature of the SpiroSphere Sensor Unit can get up to 47°C.

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

Shut down

1. To switch off the **SpiroSphere Main Unit**, press the Power On/Off switch located at the front of the main unit. Disconnect the main unit from the power source.

2. Switch on the SpiroSphere Sensor by pressing the "**Power Off**" switch located at the back side of the SpiroSphere Sensor. Disconnect the SpiroSphere Sensor from the main unit.

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.

Troubleshooting

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 power socket

LED Status SpiroSphere Sensor

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

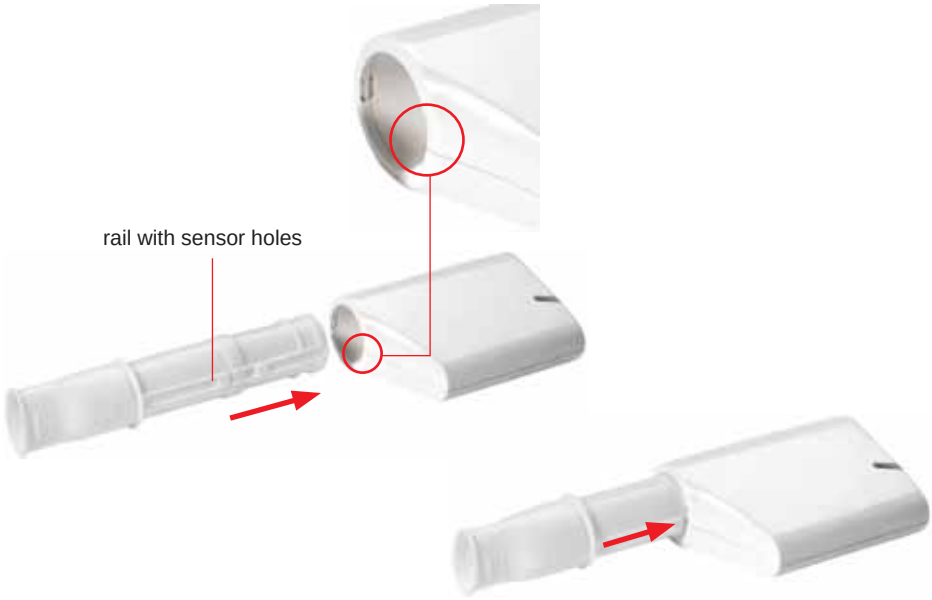
Orange LED On	Charging in cradle	
Orange LED Off	No charging/ charging complete in cradle	
Orange LED blinking slowly	Low battery	Put the SpiroSphere Sensor into the cradle of the Main Unit
Orange LED blinking fast		Indicates an error in the SpiroSphere Sensor

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

Error Messages

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:



The ERT PT should be inserted fully without force.

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**>.

2. Date & Time Settings

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

3. Sensor Settings

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**>.

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

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

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

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.

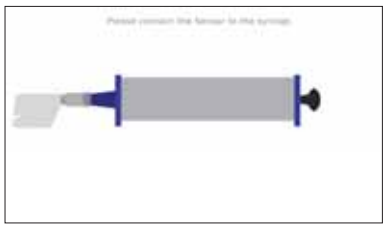
Tap <**Sensor Check**> to perform a sensor check.

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.

Calibration Check

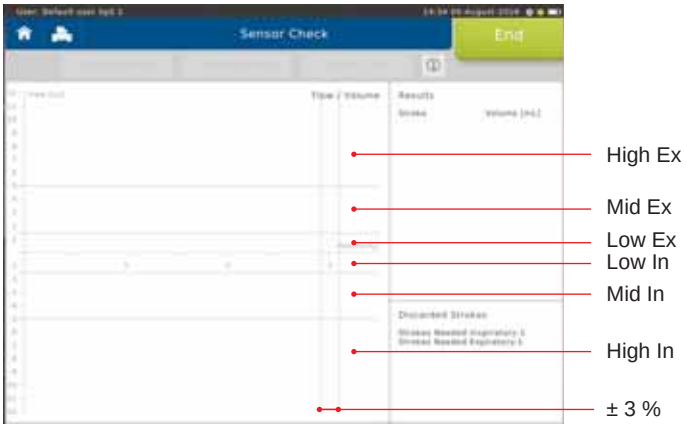
In order to perform a calibration check, tap on <**Calibration Check**>.
Following screen appears:



Ensure a new ERT PT (with mouthpiece removed) is connected to the 3 L calibration syringe via an adapter (as shown).

Proceed by tapping <**OK**>. A zero adjustment of the connected SpiroSphere Sensor will be performed automatically.

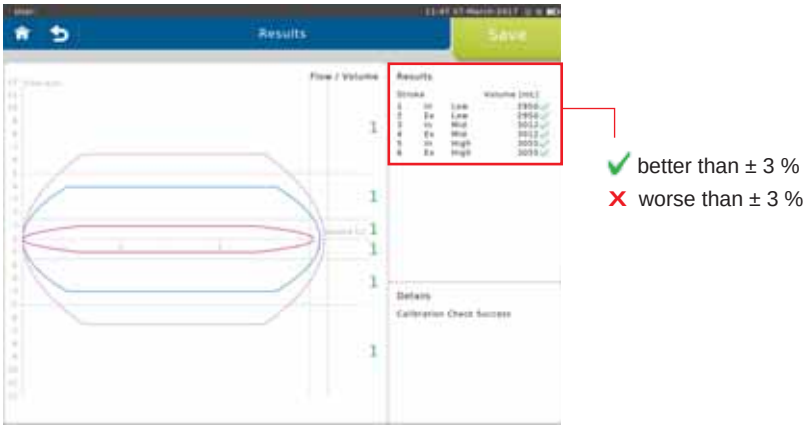
The **calibration check** is used to check the volume accuracy within 3 different flow ranges.
With each syringe stroke, the volume accuracy should be within ± 3 %.



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:



Save 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.

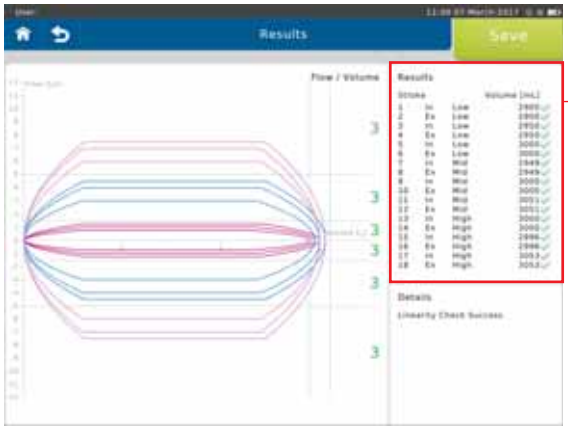
During a linearity check, volume accuracy at different flows is tested. Three syringe strokes at a low, three at a mid-range flow and three at a high flow are required.

With each syringe stroke, the volume accuracy should be within ± 3 %.

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:



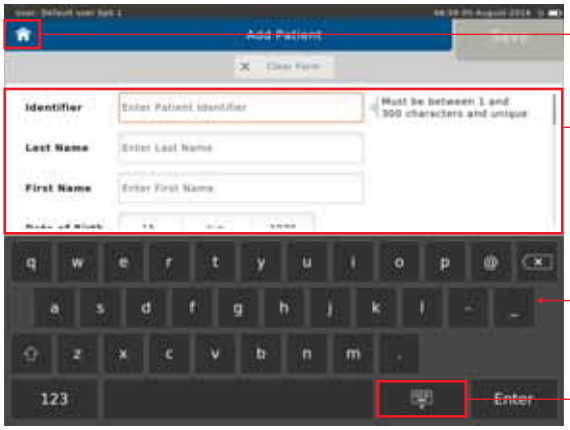
✓ better than ± 3 %
✗ worse than ± 3 %

Save 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

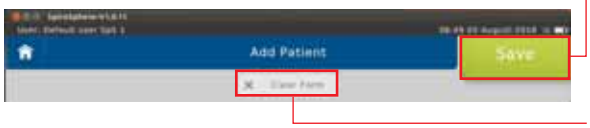
First Name: Enter the Patient's first name

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

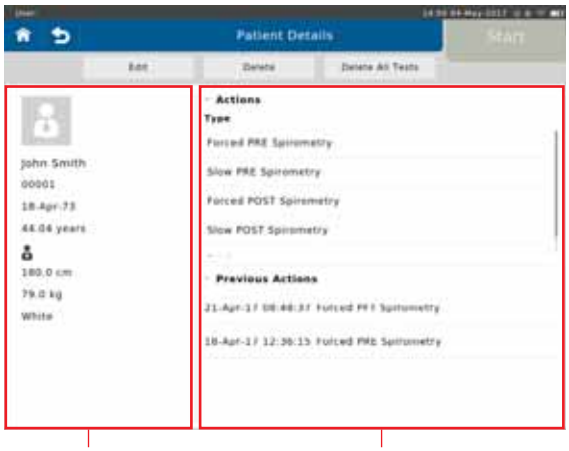
Additionally, there is an option to enter:
Technician: Enter the Technician's name
Physician: Enter the Physician's name
Set A Name 1:
Set A Name 2:

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)

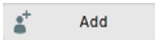
Search Patient

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.

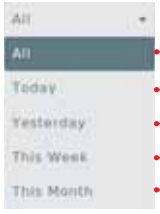
Tap on the "**Search Patient**" button on the Home Screen to open the list of all patient data saved in the database.

The following screen appears:

List of all patients



data of a new Patient can be entered



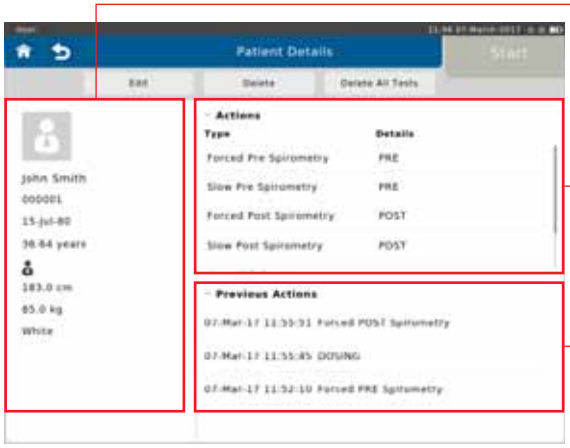
- Display **all** tested patients
- Display all Patients tested **today**
- Display all Patients tested **yesterday**
- Display all Patients tested **this week**
- Display all Patients tested **this month**

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
Dosing	Input Medication, Medication time and Technican

Preparing a 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:

WARNING The patient must not interact with the SpiroSphere Main Unit.

Current room temperature (°C)
Current relative humidity (%)
Current barometric pressure (hPa)

When the test is started, an automatic zero adjustment of the connected ERT PT 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!

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.

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

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%.

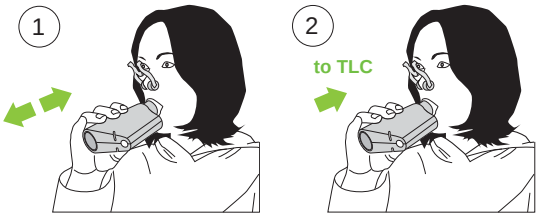
Continue Tap on <**Continue**> to apply the ambient data entered.

Perform a Forced Spirometry Measurement

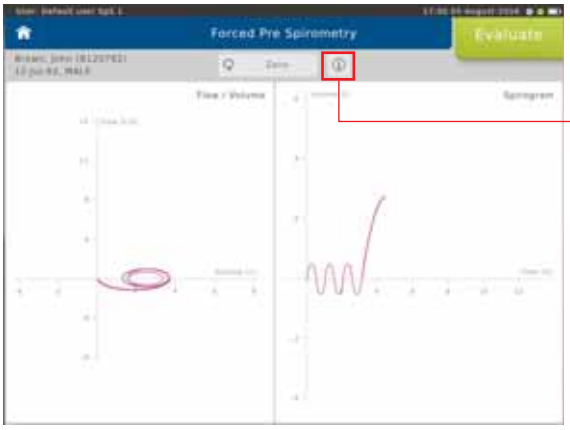
Make the proper preparations according to ATS/ERS guidance.

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

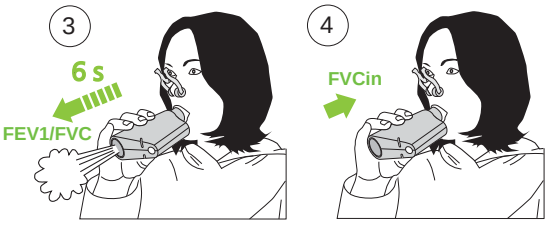
The patient breathes normally (figure 1) until a steady tidal breathing is shown. From tidal breathing, the patient is instructed to inhale as deeply as possible (inhale to TLC - figure 2).



Screen display:

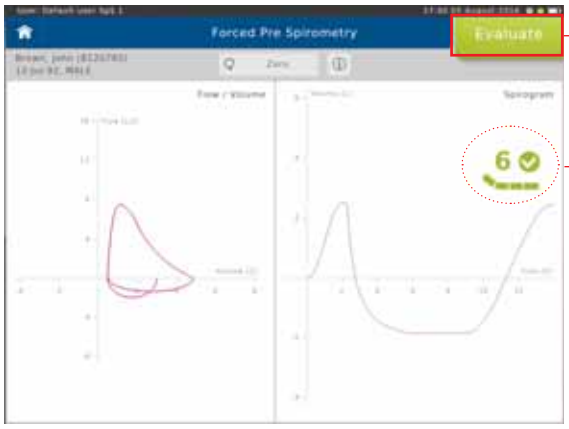


Tapping on the "i"-symbol will display information on the measurement procedure.



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:



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

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

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 (or < 5 %). 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 Effort

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)

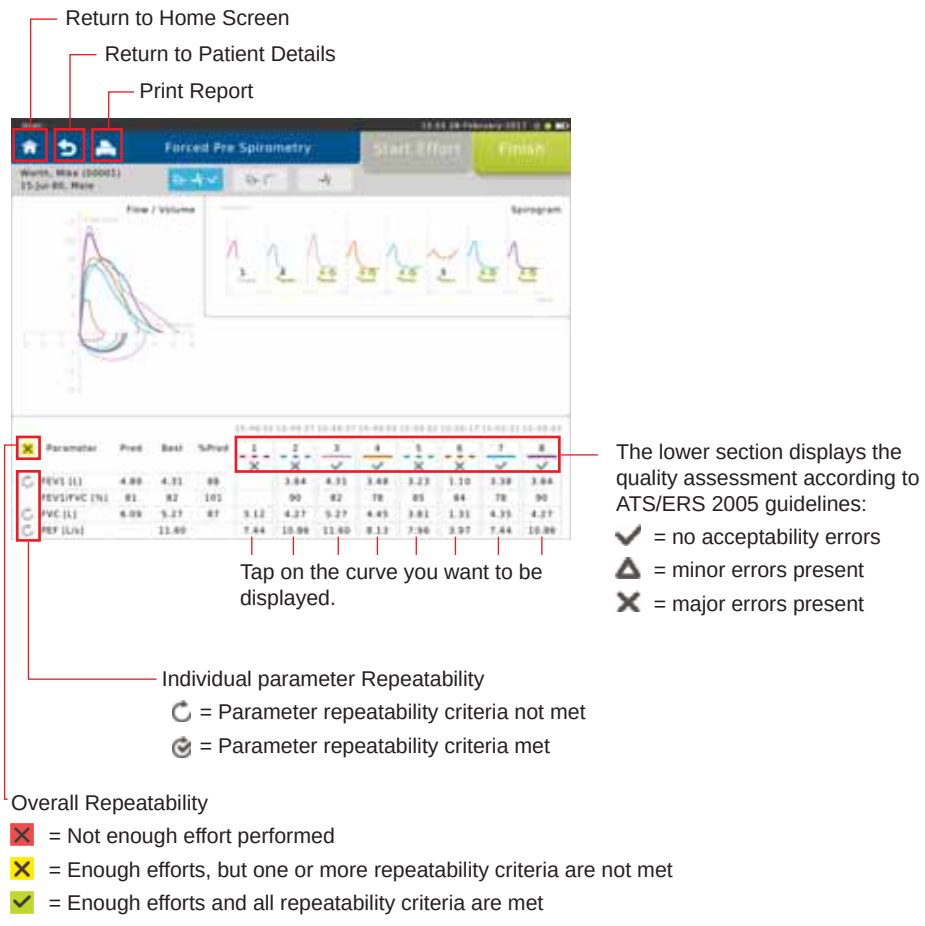
* Literature:
MR Miller et al. Series "ATS/ERS Task Force: Standardisation of Lung Function Testing", Standardisation of Spirometry, Eur Respir J 2005; 319-338. Copyright © ERS Journals Ltd. 2005

Change View:

Screen display flow-volume and tiffaneau curve:

Screen display volume-time curve:

Curves superimposed:



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.

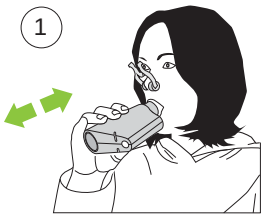
End and save the test by tapping on <**Finish**>.

Perform a Slow Spirometry Measurement

Make the proper preparations according to ATS/ERS guidance.

When the test is started, an automatic zero adjustment of the connected ERT PT 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!



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.

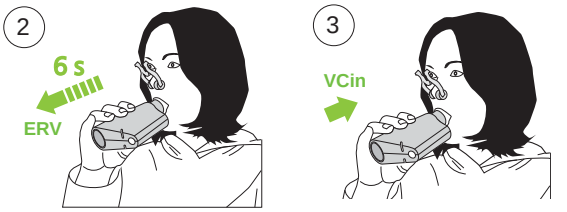
dVT = variation (coefficient of variation) of the tidal volume

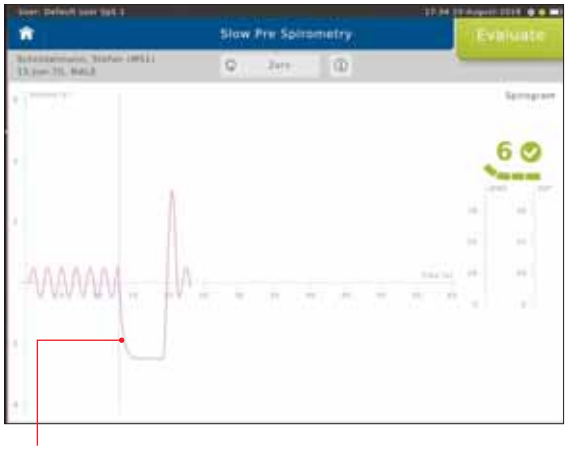
dFRC = variation of the breathing baseline

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)

Dosing

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

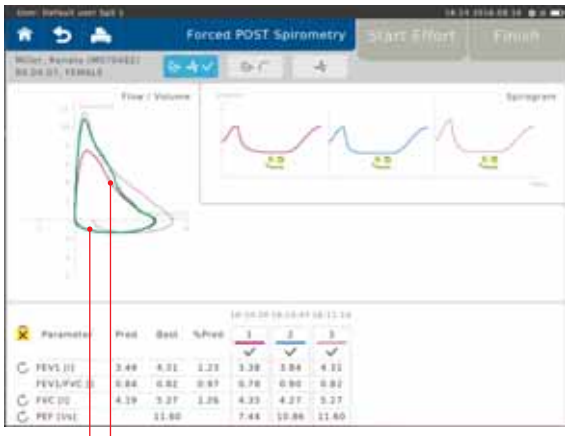
Tap on <**Save**> to save the dosing to your patient directory.

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**":



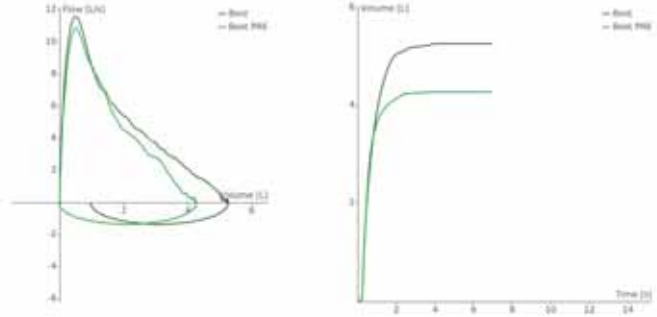
Post Measurement (purple)
Pre Measurement (green)

Pre-Post Report:

Best Effort Report

Patient Id:	M070482	**Date of Birth:**	84.04.07	**Height:**	170 cm
Last Name:	Miller	**Age:**	32.35 years	**Weight:**	69 kg
First Name:	Renata	**Gender:**	FEMALE	**Ethnicity:**	WHITE

Forced POST Spirometry 16.08.16 18:10:26



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

Template Version: 1.0 Page: 1 / 1 18:12:07 16.08.16

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

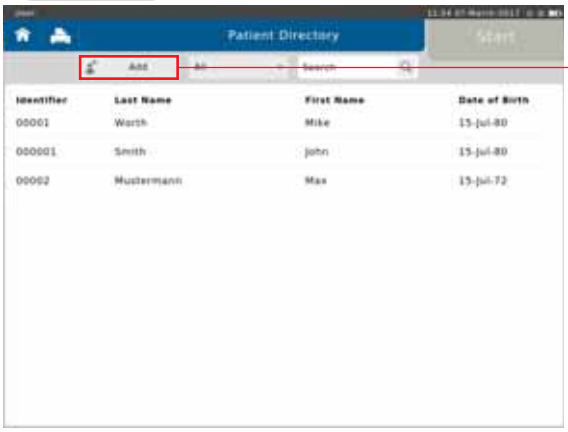
Tap on the "**Adhoc Test**" field on the Home Screen.

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

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



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

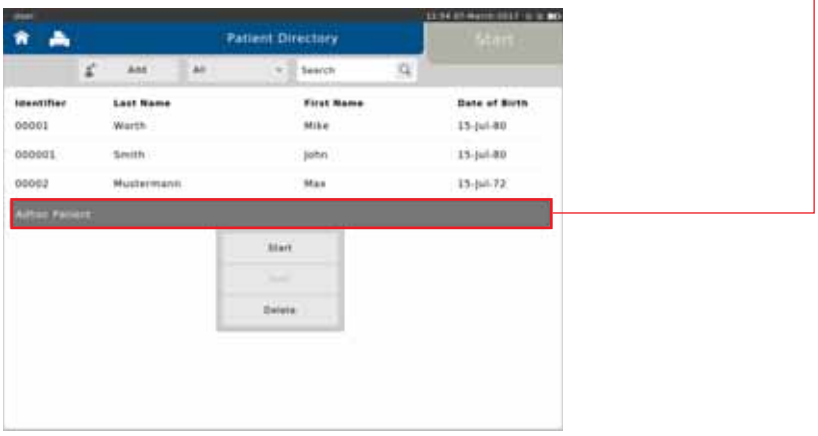
Following window appears:

Finish by tapping <**OK**>.

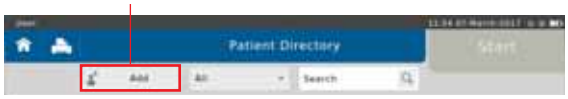
Assign Adhoc Test later

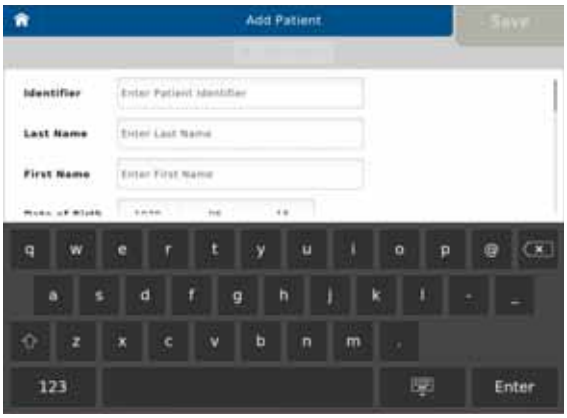
Tap on <**No**>.

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**".



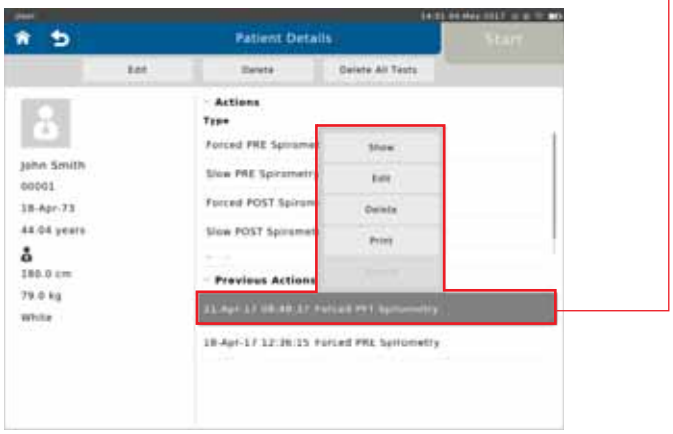
Tap on <**Add**> to enter the appropriate patient data.





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**>:

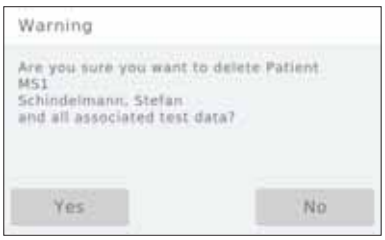
Tapping on <**Yes**> will irrevocably delete the selected test!

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 Patient**>:



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:

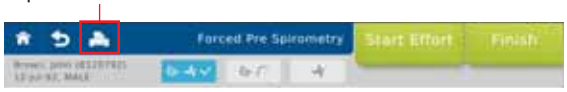
Tapping on <**Yes**> will irrevocably delete all tests assigned to the selected patient!

Print Recorded Results

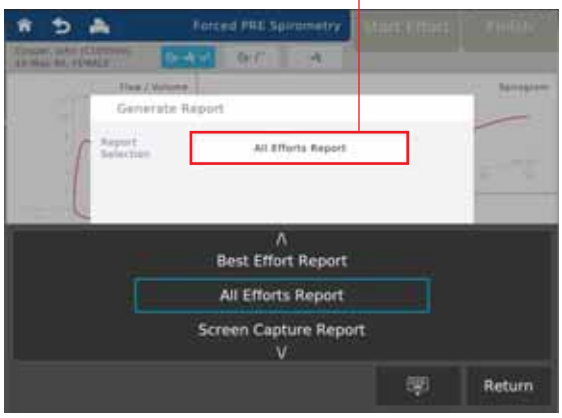
As soon as a measurement is completed, the results can be printed by means of a connected USB[*1] printer. It is also possible to create a PDF file which can be sent to a predefined e-mail address[*2] or saved to an USB stick.

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

Tap on the Printer icon.



Tap on the Report Selection field.

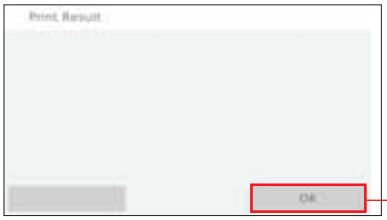


Best Effort Report
a report displaying the best effort is created

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"*

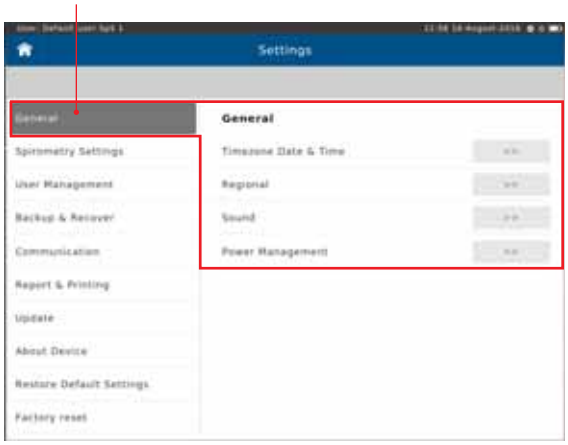
Settings and Tools

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

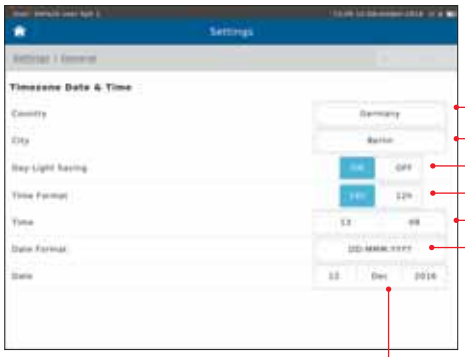
Tap on the "**Settings & Tools**" button on the Home Screen.
The following will appear:

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

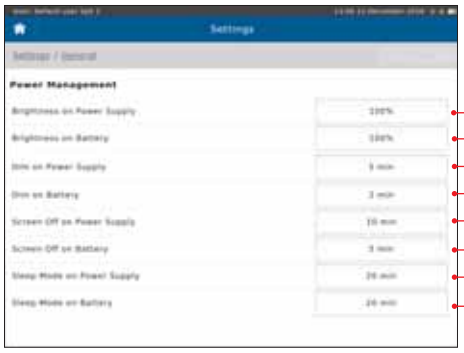
Regional

	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

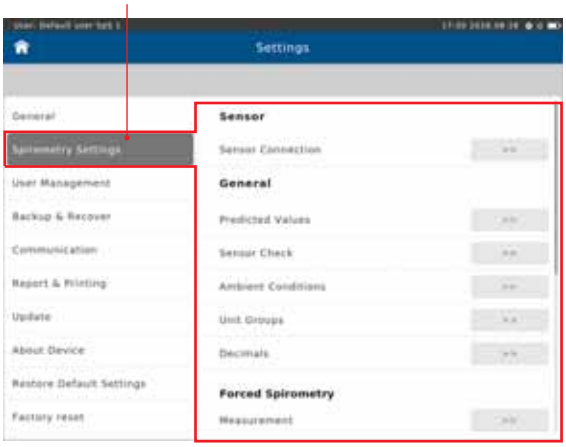


		Preset:
Brightness on Power Supply	select	100%
Brightness on Battery	select	100%
Dim on Power Supply	select	5 min
Dim on Battery	select	2 min
Screen Off on Power Supply	select	10 min
Screen Off on Battery	select	5 min
Sleep Mode on Power Supply	select	20 min
Sleep Mode on Battery	select	20 min

These settings influence the battery life of the SpiroSphere.

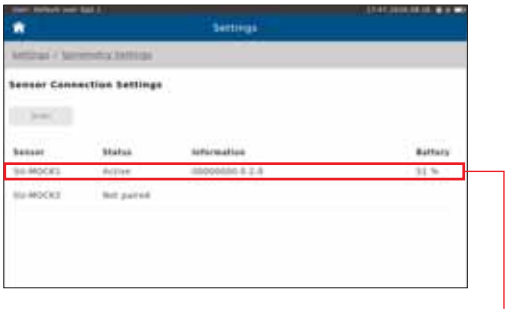
Spirometry Settings

Tap on "**Spirometry Settings**"



Spirometry Settings - Sensor

Sensor Connection



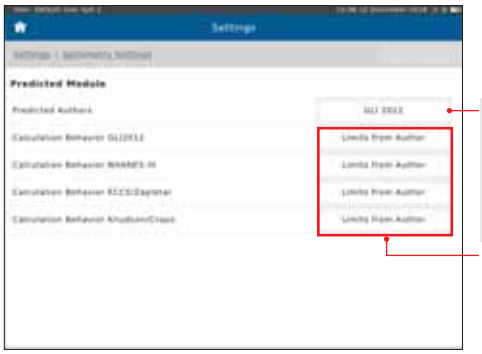
Active: The SpiroSphere Sensor is connected to the SpiroSphere via Bluetooth

Not paired: The SpiroSphere Sensor is not connected to the SpiroSphere

Battery: Indicates the battery status of the SpiroSphere Sensor

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	Ethnicity
NHANES III	8-80 years	110-200 cm	African-Descent Mexican-American all other groups
ECCS/Zapletal	5-17 years (Zapletal) 18-70 years (ECCS 93)	107-182 cm (for Zapletal only)	African-Descent 0.87 for volume (18 - ∞)
Knudson/Grapo	6-90 years	no limitation	African-Descent 0.88 for volume all other groups

[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, mL*L/s	L*L/s

Decimals

Setting options:	*Preset:*
0, 1, 2, 3, 4	2
0, 1, 2, 3, 4	0
0, 1, 2, 3, 4	2
0, 1, 2, 3, 4	0
0, 1, 2, 3, 4	0
0, 1, 2, 3, 4	0
0, 1, 2, 3, 4	2
0, 1, 2, 3, 4	0
0, 1, 2, 3, 4	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

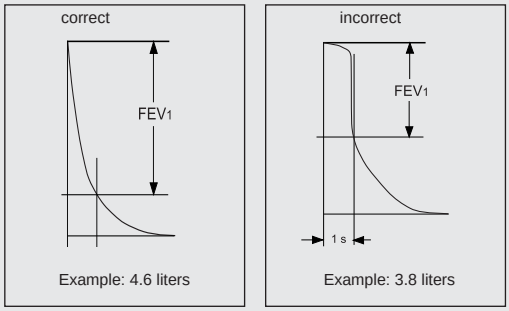
If "**ON**" is selected, the value for the respective parameter is used as the FVC value.

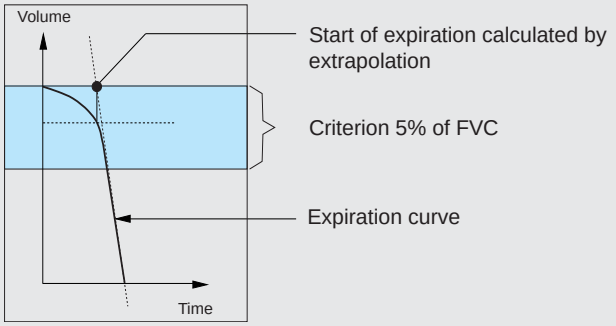
	Setting options:	*Preset:*
Expiratory Back Extrapolation **Inspiratory Back Extrapolation**	Always, Never	Always

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 computer 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 software 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.

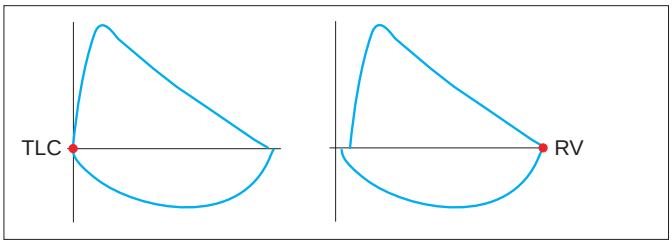
The setting can be changed during the measurement.

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.

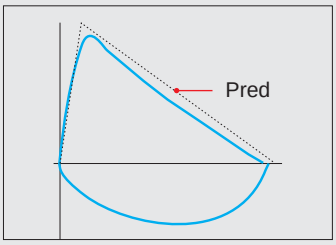


Display Predicted Curve

Setting options: ON, OFF

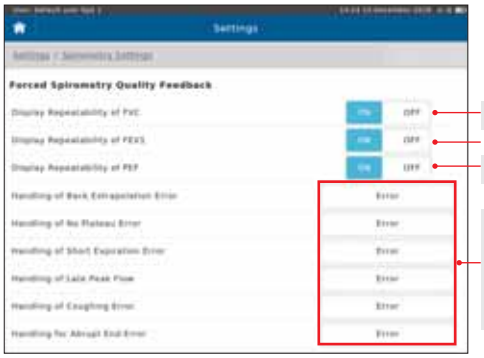
Preset: ON

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



Spirometry Settings - Forced Spirometry

Quality Feedback



Setting options:	*Preset:*
ON, OFF	ON
ON, OFF	
ON, OFF	
Error	Error
OFF	
Warning	
Confirmation	

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

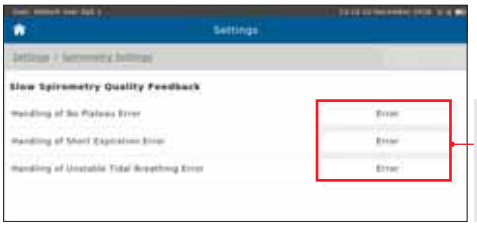
ABG means: errors A, B, G are present

Spirometry Settings - Slow Spirometry

Measurement

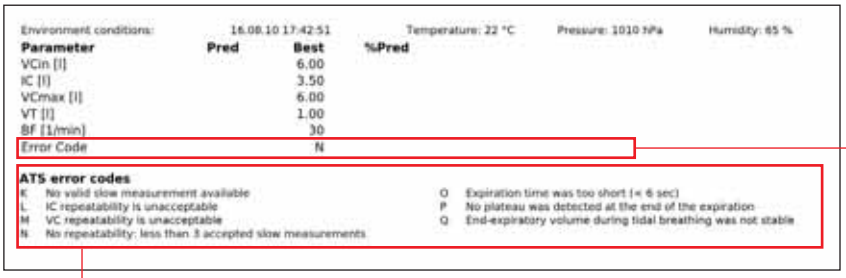
Setting options:	*Preset:*
Automatic, 12, 9, 6, 4 L	Automatic
Automatic, 12, 9, 6, 4 L	Automatic
VCin, VCex, VCmax, IC, ERV	VCmax
ERV VC-, IC VC-Maneuver	ERV VC-Maneuver

Quality Feedback



Setting options:	*Preset:*
Error	Error
OFF	
Warning	
Confirmation	

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

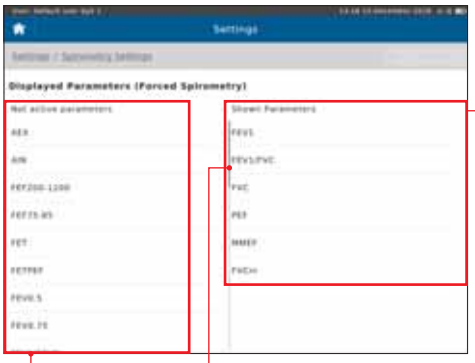
K No valid slow measurement available
L IC repeatability is unacceptable
M VC repeatability is unacceptable
N No repeatability: less than 3 accepted slow measurements
O Expiration time was too short (< 6 sec)
P No plateau was detected at the end of the expiration
Q End-expiratory volume during tidal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

ATS error codes

N means: the criteria N are not met

Parameter Selection

Forced Spirometry - Displayed Parameters



Scroll down to display further parameters (if applicable)

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

Preset:

FEV1

FEV1/FVC

FVC

MMEF

FVCin

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:

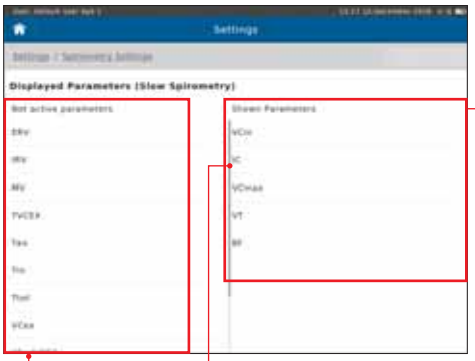
Double-tap on the parameter you want to delete.

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

Forced Spirometry - Printed Parameters

"see above"

Slow Spirometry - Displayed Parameters



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

Preset:

VCin

IC

VCmax

VT

BF

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.

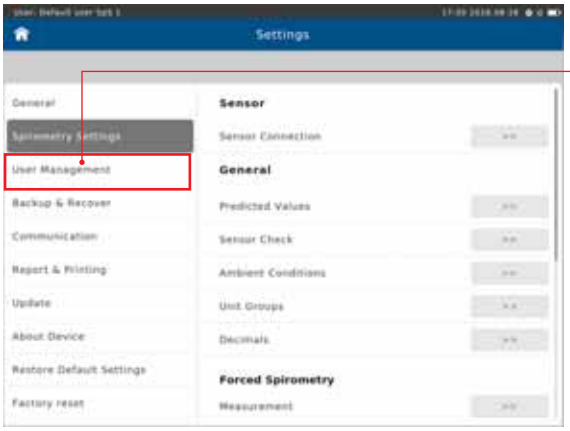
Tap on <**Undo**> in order to undo the recent changes.

Slow Spirometry - Printed Parameters

"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.



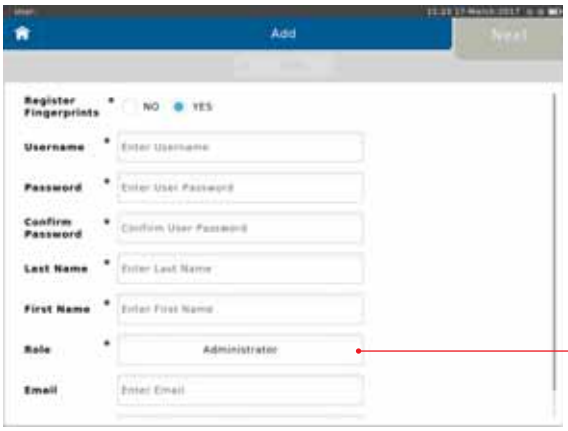
From "**Settings**" select "**User Management**"

Tap the switch to activate User Management

The following screen appears:

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

The following screen appears:



Options for role type:
Administator
User
Support

Enter the details for the user (for first user this must be Administrator role).
Optionally you can choose to register your fingerprints in order to utilise the fingerprint reader for system access.

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	X
Deactivate/activate user	X		X
Recover	X	X	X
Change date and time settings	X	X	X
Update software	X	X	X

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.

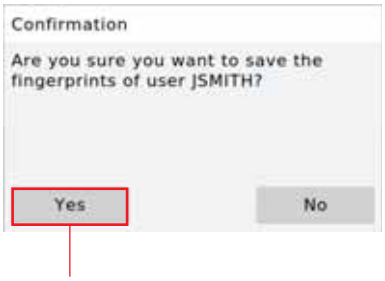
Place your finger on and off the fingerprint reader as per on-screen instructions (approx. 5 times) in order to register your fingerprint.

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.

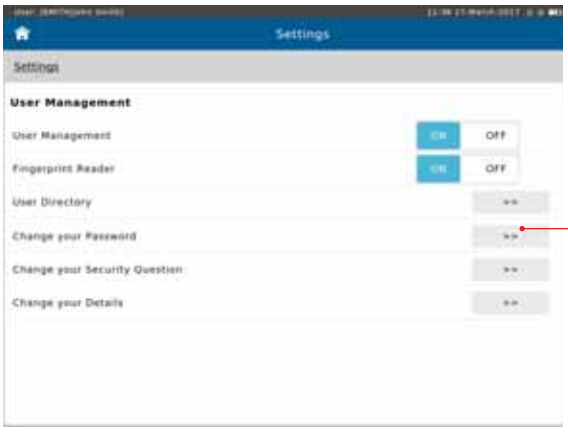
After saving the first user, you will be sent to the Login page:

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 a 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

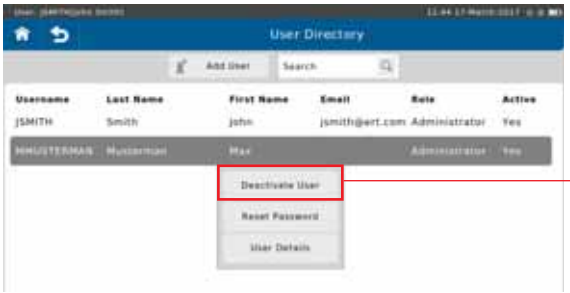
To edit the currently selected user, tap <**User Details**> in the fly out menu. The following screen appears:

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.

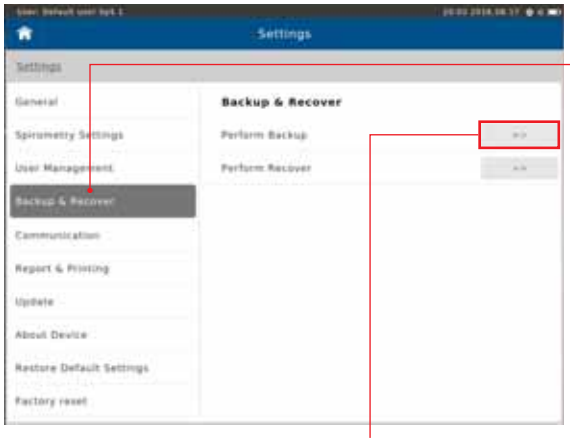
Change Security Question

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

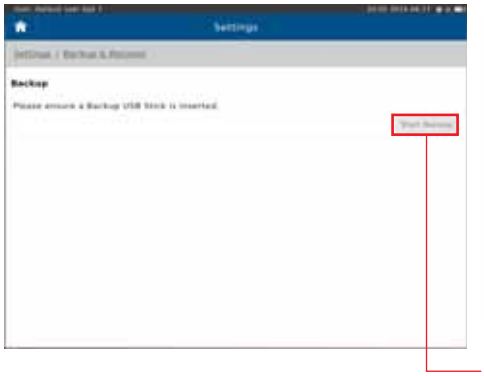
A backup of all saved patient- and test data should be performed and saved to a USB-Stick on a regular basis.



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

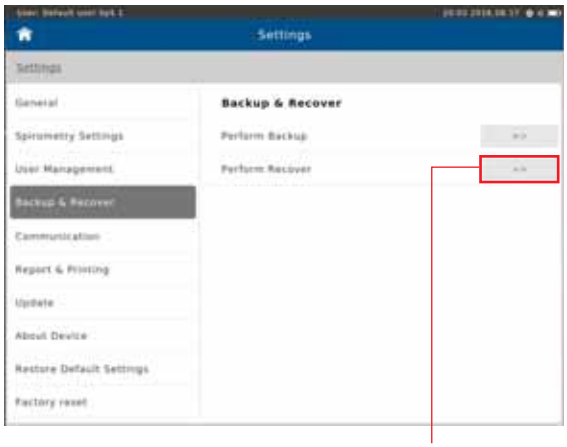
If "**Perform Backup**" is selected, the message "**Please ensure a Backup USB Stick is Inserted**" appears.

Backup



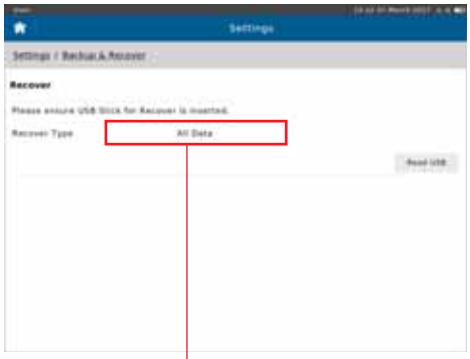
Insert USB stick

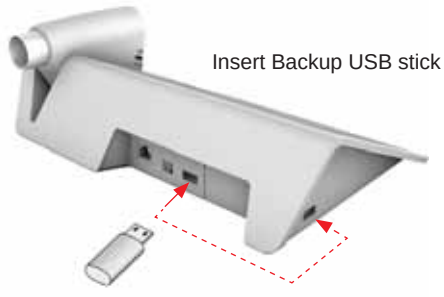
Tap on "**Start Backup**" to create a backup file and save it to the USB stick!



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

Recover

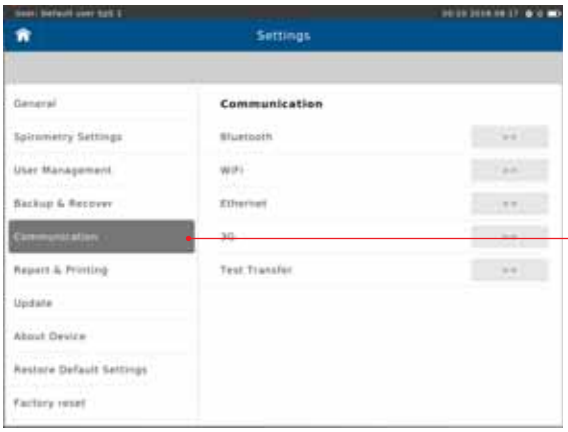




Insert Backup USB stick

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

Communication



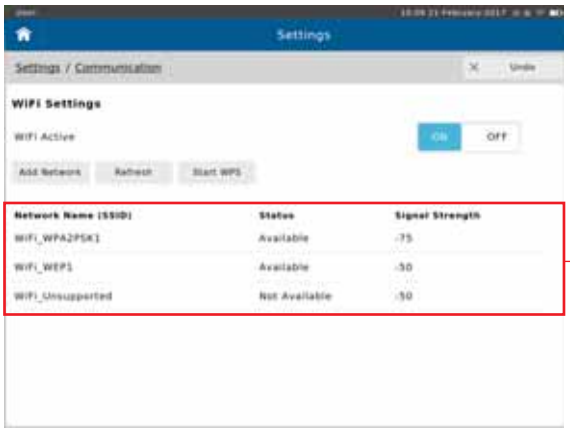
Tap on "**Communication**"

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.

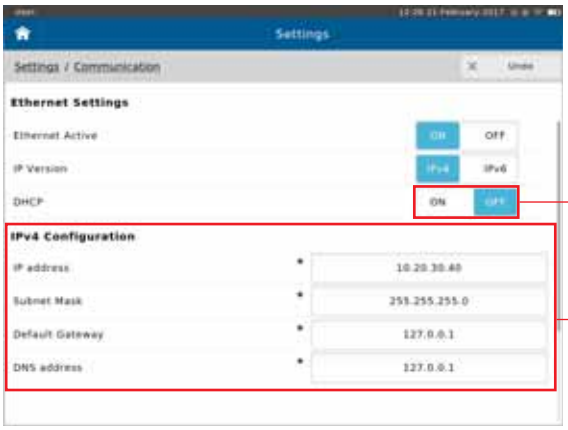
The following fly-out menu appears:

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

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

Ethernet

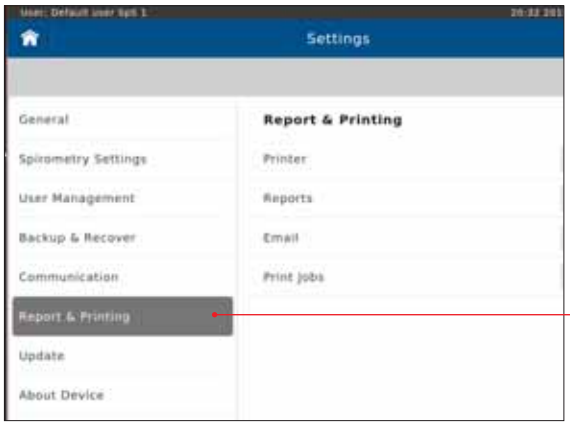
Choose the appropriate settings.



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

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**"

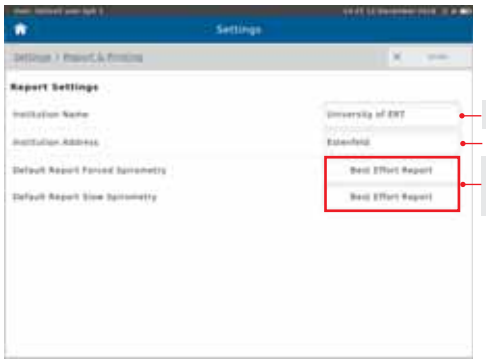
Printer

Setting options:	*Preset:*
Printer, PDF via Email, PDF via USB	PDF via Email
ON, OFF	OFF
see below	
see below	
Color, Black & White	Color
A4, Letter	A4
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".

Reports

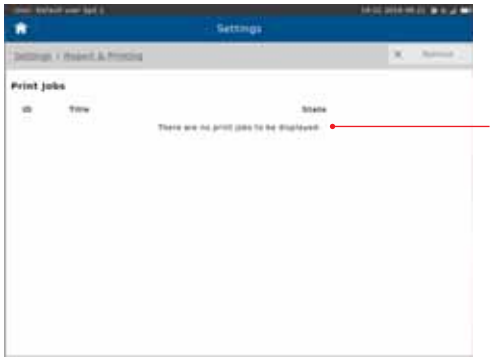


Setting options:	*Preset:*
Input Customer Name	
Input Customer Address	
Best Effort Report	Best Effort Report
All Efforts Report	

Email

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

Print Job



- Print jobs state

Update

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

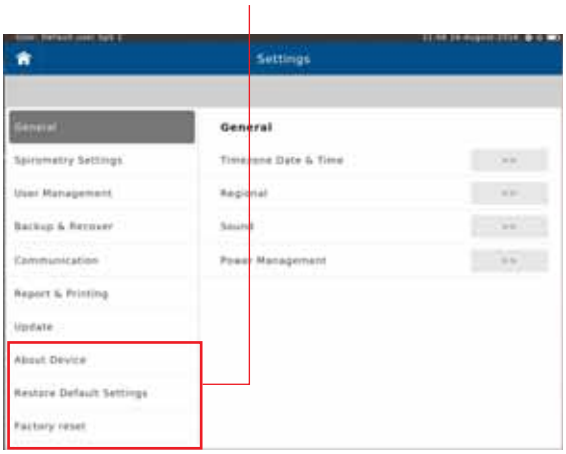
Tap on <**Start Update**> to begin the update process.

List of available updates

About Device

Restore Default Settings

Factory reset



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

Cleaning/Hygiene

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!

Hygiene Regulations:

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.

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

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.**

DANGER **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.

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 Sensor Unit. In case of ingress of contaminated fluids, do not use the Sensor Unit.

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.

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.

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.

CAUTION

Use of Multi-Plug Sockets

Medical devices/systems must only be connected to multi-plug sockets if all regulatory requirements are met.

- Additional mobile multi-plug sockets must not be connected to power sockets of medical devices/systems.
- Mobile multi-plug sockets of medical devices/systems must not be placed on the floor.
- Equipment (for example vacuum cleaner, radio, etc.) and devices which are not part of the medical device/system must not be connected to the 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.

WARNING

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.

WARNING

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.

WARNING

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.

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.

CAUTION

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

Contraindications

According to "ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING" (ERS Journals Ltd 2005) performing lung function tests can be physically demanding for a minority of patients. It is recommended that patients should not be tested within 1 month of a myocardial infarction. In rare cases spirometry testing can lead to syncope due to extensive exhalation.

In the S2 guideline "Spirometry" (German Airway League, German Respiratory Society and German Society of Occupational and Environmental Medicine, 2015), contraindications of spirometry are divided into absolute and relative contraindications:

Absolute contraindications for Forced Maneuvers

Acute, life threatening diseases of every description, e.g.

- Acute Myocardial Infarction
- Acute Fulminant Pulmonary Embolism

- Large Ascending Aortic Aneurysm
- Tension Pneumothorax

Relative contraindications for Forced Maneuvers

- Massive Pneumothorax (within the first weeks)
- Abdominal or Thoracic Surgery (depending on the findings 1 to 4 weeks post-operatively)
- Surgery of the Eyes, Brain, or Ears (variable, consultation with the surgeon)
- Special care must be taken when dealing with Hemoptysis of unknown origin

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.

CAUTION

Biocompatibility

Component	Material
Mouth piece	Styrolution PS 454N HIPS Biocompatibility of the material has been confirmed.
Housing parts of the sensor unit and the main unit	Cycoloy CX2244ME Biocompatibility of the material has been confirmed.
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.

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.

Graphical Symbols

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

Barometric pressure limits

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

Packaging can be recycled

Temperature limit

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 condensation

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.

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

SpiroSphere - Sensor Unit: FCC-ID: 2AAUFSPS002

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

SpiroSphere - Sensor Unit: IC: 11335A-SPS002

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	

ERT complies with EMC guidelines according to EN60601-1-2.

ERT can provide further information on EMC properties on request.

Notes on EMC according to EN60601-1-2

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

Guidance and Manufacturer's Declaration – Electromagnetic Emissions and Immunity	
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. 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.	
IEC 60601 directive	**Compliance level**
RF emissions CISPR 11	Group 1 Class B
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV indirect contact ± 15 kV direct air direct contact not possible
Radiated RF IEC 61000-4-3	10 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	0.5 kV differential mode 1 kV differential 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

Technical Data

Dimension	31.5 x 19.5 cm x 7.5 (L x W x H)		
Weight	1.5 kg		
Screen Display	16.2 x 12.2 cm		
Medical Power Supply	Model: GTM91099-3009-4.0-T2 Input: 100 - 240 Vac, 50/60 Hz, 1.5 A Output: 5 V, 6 A Cable length: 1200 mm		
Frequency	50 - 60 Hz		
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 transfer	
	Ethernet	Data Transfer	
	3G	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:	-10 °C to +50 °C	
	Relative humidity:	0 % 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.

Item Numbers of Disposables and Accessories

Use ERT accessories and spare parts only!

720254	Manual calibration syringe, 3 L
852740	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)
706002	ERT PT, incl. mouthpiece (box of 10)
706003	ERT PT, incl. mouthpiece (box of 50)

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