Zimmer
MedizinSysteme

Instructions for Use

Spiro*Four*

EN

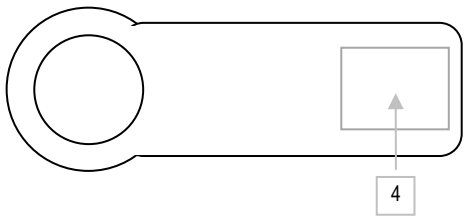
Schematic illustrations

Views / Operating elements

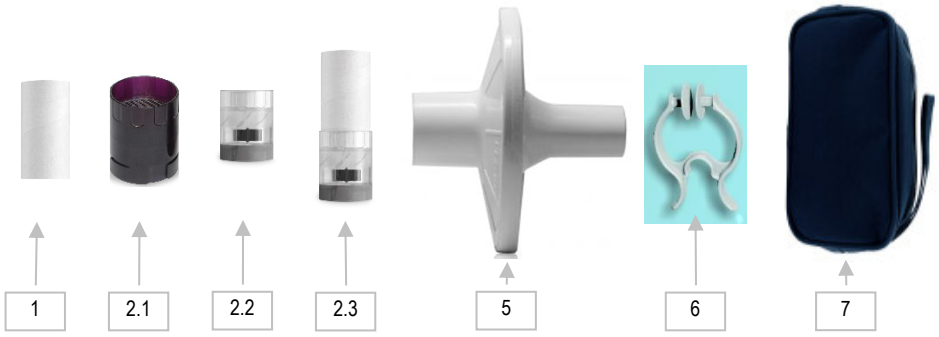
Views

Front

Back



Accessories



Operating elements

Front

1	Mouthpiece
2	Turbine
2.1	Reusable turbine
2.2	Disposable turbine without mouthpiece
2.3	Disposable turbine with mouthpiece
3	USB cable for connection with the PC (firmly connected)

Back

4	Identification plate

Accessories

5	Bacterial and viral filter
6	Nose Clip
7	Storage bag

Brief start-up instructions

Before using your Spiro ***Four*** …

- Read this manual carefully, plus all labels and other product information supplied.
- Check PC system requirements for compatibility with the device Operating system: Windows 7 (32bit/64bit); Windows 10 (32bit/64bit);
- Intel dual-core architecture or similar, at least 1.6 GHz. At least 4 GB RAM, 8 GB RAM is recommended. Hard disc drive with at least 5 GB of free space on the system partition. PCIe graphics card, 128 MB RAM, 1024 x 768 pixels, 24-bit colors.
- Spiro ***Four*** should only be connected to a computer manufactured in compliance with EN 60950.

The pulmonary function system Spiro ***Four*** contains the sensor Spiro ***Four*** with USB cable, optionally the disposable or reusable turbine and the DiagnostikSuite software.

Note

*Spiro **Four** can only be operated with the DiagnostikSuite software from Zimmer MedizinSysteme. Before you connect Spiro **Four** with the PC, the DiagnostikSuite must be correctly installed and configured on the PC. For more information, also see the DiagnostikSuite instructions for use.*

Connect Spiro *Four* with the PC

Install the device driver for Spiro ***Four***.
Connect Spiro ***Four*** to a free USB connection on the PC. The display for detecting a new peripheral device appears on the screen. Once the device has been correctly detected, it is ready for use and can be used with the DiagnostikSuite.

Interface configuration

Start the analysis software DiagnostikSuite on the PC and check and correct the interface configuration in DiagnostikSuite, if necessary.

Insert mouthpiece

- Insert the turbine in the intended socket and turn it clockwise as far as it will go.
- Insert the mouthpiece min. 0.5 cm deep into the turbine if it is not a disposable turbine with integrated mouthpiece.
- Secure the nose clips on the sides of the patient's nose so that no air can escape from the nostrils.

Select patient

Select the entry "**Open**" in the navigation area of DiagnostikSuite. Double-click to select the desired patient.

Prepare examination

In the navigation area, open the "**New"** tab and, for a new pulmonary function measurement, select the corresponding measurement which you want to perform.

Instruct patient

Instruct the patient on correct behaviour during the measurement and how to operate the device properly.

Measurement results

After a successful measurement, the measurement results and an assessment are displayed in DiagnostikSuite. To save, press the **"Save"** button.

Description of symbols

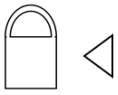
SN	Device serial number
REF	Item Number
	Manufacturer symbol
CE 0123	CE mark according to MDD (93/42/EEC)
	Symbol for electrical safety. In conformity with standard EN 60601-1, the device and its applied part correspond to type BF and accordingly protect the patient from electrical shock.
	Class II equipment symbol: as per EN 60601-1, the product complies safety requirements of Class II equipment
	WEEE Symbol; As laid down in the European Directive 2012/19/EEC requirements regarding the disposal of electrical and electronic devices.
IPX1	Information on protection against ingress of liquids. The label indicates the degree of protection against ingress of liquids (IPX1). The device is protected against vertically falling drops of water
Rx Only	Symbol for FDA regulation: use the device under the prescription of the physician
	Instruction for use symbol. Refer to instruction manual. Read this manual carefully before using the medical device.
	Manufacturing date of the device
	This symbol indicates “Danger” with regard to possible risks to people.
	This symbol indicates “Caution” with regard to possible material damage.
	Temperature limits: indicates the temperature limits to which the medical device can be safely exposed
	Humidity limitation: indicates the range of humidity to which the medical device can be safely exposed

Description of symbols

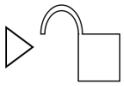
Pressure limitation: indicates the range of pressure to which the medical device can be safely exposed

Note instructions for use

USB interface



Turbine rotational direction locked



Turbine rotational direction unlocked

Do not reuse. If used more than once, cross infection may occur.

Content

Content

Valid for Spiro ***Four***.

These instructions for use are an integral part of the device. They must be stored with the device and kept accessible at all times for anyone authorised to operate this device.

Last updated: February 2022

If the instructions for use have become illegible, damaged or otherwise inaccessible to the user, a replacement must be requested from the manufacturer for the safe use of Spiro ***Four*** and made available to the user. This includes the information on the labels on the device.
The instructions for use can also be downloaded from our website
The present instructions for use have been prepared by Zimmer MedizinSysteme GmbH and checked for correctness. However, it does not claim to be complete. All information and data are subject to change without prior notice. We reserve the right to revise this document or change described product specifications at any time. There is no obligation to inform the customer about the changes.

Intended Use

1

Intended purpose

Spiro ***Four*** spirometer is intended to be used either by a physician, medical or paramedical staff or by the patient under supervision of a physician.
The device is intended to test lung function and can make:

- spirometry testing in people of all ages, excluding infants and neonates

Spiro ***Four*** calculates a series of parameters relating to human respiratory function.
The use of the device is usually "prescribed" by a doctor who is responsible for analysing and verifying the results and the data collected during the trial period.

Knowledge and experience required

The correct use of the device, the interpretation of the results and the maintenance of the device, with particular attention to disinfection (cross-contamination risk), all require qualified medical personnel.

Operating environment

Spiro ***Four*** has been designed for use in hospital setting, or in physician's office.
The device is not intended for use in an operating room nor in the presence of inflammable liquids or detergents, nor in the presence of inflammable anesthetic gases, oxygen or nitrogen.
The instrument is not designed to be used in direct air flow (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or any other chemical substances.
The user is responsible for ensuring that the device is stored and used in appropriate environmental conditions as specified in chapter 7.1, “Technical Data”.

Who can or must make the installation

The device requires installation by qualified personnel

Subject effect on the use of the device

A spirometry test should only be carried out when the subject is at rest and in good health, and thus in a suitable condition for the test. A spirometry test requires the collaboration of the subject since the subject must make a complete forced expiration, in order to have a meaningful test result.

Limitations of use - Contraindications

An analysis of the results of a spirometry test is not by itself sufficient to make a correct diagnosis of the subject’s clinical condition. A detailed clinical history of the subject is also required together with the results of any other test(s) suggested by a doctor.
Test comments, a test interpretation and suggested courses of treatment must be given by a doctor.
A spirometry test requires the collaboration of the subject. The results depend on the person’s capability to inspire and to expire all air completely and as fast as possible. If these fundamental conditions are not respected then the results obtained during spirometry testing will not be considered accurate, and therefore the test results are “not acceptable”.
The significance of a test is the responsibility of the medical personnel. Special attention should be given to testing elderly subjects, children and handicapped people.
The device should never be used when it is possible or probable that the validity of the results may be compromised due to any such external factors.

Application information

2

Prior to using the device on a patient, the user should become familiar with the instructions for use and individual treatment methods to be used as well as the indications / contraindications, warnings and application information. Additional sources of information about the diagnosis and treatment should be followed.

Inspect the device before use. If there is any damage, it must not be used.

The paper mouthpiece, the nose clip, bacterial and virus filter and the disposable turbine with mouthpiece in the equipment should be considered as disposable products. If used more than once, cross infection may occur.

Only accessories provided by Zimmer MedizinSysteme GmbH must be used.

The manufacturer cannot be held responsible for any damage caused by the user of the device failing to follow the instructions and warnings contained in this manual.

If the device is exposed to unsuitable environmental conditions, this could cause the device to malfunction and to give incorrect results.

Do not expose the turbine to a direct jet of water or air, and avoid contact with high temperature liquids.
Do not allow dust or foreign bodies to enter the turbine sensor, in order to avoid incorrect functioning and possible damage. The presence of any impurities (such as hair, sputum, threads etc.) within the body of the turbine sensor may seriously compromise the accuracy of the measurements.

General

Any symptoms of illness which the patient complains about must be considered prior to performing the spirometry. The medical staff prescribing the test must assess the patient's physical and mental abilities with regard to suitability for taking the test. The medical staff is obligated to assess the degree of patient cooperation for each individual test when evaluating the stored data. Proper spirometry execution requires the best possible cooperation by the patient. The test result depends on the ability to inhale the largest volume of air possible as well as to completely exhale the air as quickly as possible. If these conditions are not met, the spirometry results are not reliable or plausible. The final evaluation of the test is the responsibility of the physician. Special attention must be paid in the case of elderly or disabled persons and children.

Preparation

The optimal preparation of the patient, operation of the entire spirometry system as well as the preparation of the test and exclusion of disturbances have a significant influence on the quality of the pulmonary function testing.

In doing so, attention must be paid to the following:

- All devices must be ready for operation.
- The materials needed, such as nose clips, disposable mouthpiece, etc. must be on hand.
- The patient should not be cold. There must be a "stable climate".
- The patient must not be left unattended during the pulmonary function test.
- The corresponding respiratory manoeuvre should be explained to the

patient prior to the pulmonary function test.
- During the pulmonary function test, the patient's respiratory manoeuvre should be checked and action should be taken in the event of irregularities (such as the urge to cough, lack of patient cooperation or other disruptions).

Preconditions for spirometry

A spirometry session should take place with the following preconditions:

- Room temperature 18-22°C, relative air humidity 30-60%.
- Unnecessary medications, alcohol and stimulants – especially smoking – should be avoided on the day of the test.
- Continuous observation of the patient during the pulmonary function test.
- Discontinuation of the pulmonary function test if there are any criteria for discontinuation.
- Working defibrillator on hand, prescribed medications and resuscitation bag/intubation in the case of provocation tests.

Instructions and Information for the patient

The following instructions and information must be given to the patient:

- During the pulmonary function tests, active cooperation of the patient and optimal execution of the respiratory manoeuvres are very important.
- The patient should be standing up during the pulmonary function test.
- The patient should be relaxed and breathing calmly and should not talk.
- It is helpful for the pulmonary function test if the patient slightly leans his/her head back (clear throat, less salivation).
  The patient must hold the mouthpiece in his/her mouth such that no air can escape from the sides.

Warnings

Users of the device must be trained in how to use the system properly and have the appropriate skills.

Use in wet areas is not permitted and may in case of non-compliance lead to considerable damage and endanger both the patient and the user.

Dispose of the packaging material properly. Make sure that it is not accessible to children.

Merely evaluating the spirometry results without examining the patient is not sufficient for an interpretation of the patient's state of health. Rather, it is necessary to take into account the patient's past medical history as well as any other examinations which may have been ordered by the physician. Remarks, diagnoses and appropriate therapeutic treatments are the responsibility of the physician.

General safety information

- Spiro ***Four*** may only be operated in accordance with these instructions for use. Any other use is at the operator's responsibility.
- For maintenance measures, expansions, readjustments or modifications, the provisions of the German Medical Devices Act (MPG) and the Medical Device Operator Ordinance apply.
- According to the Medical Device Operator Ordinance, medical devices may be set up, operated and used only by persons who have the necessary training or knowledge and experience to do so.

For questions, please contact Zimmer MedizinSysteme GmbH.

Safety information for setup and installation

- Prior to putting the device into operation, the connection cables and the device should be checked for damage. Damaged cables must be immediately replaced. If the device is damaged, it must not be used and has to be secured against reuse.
- The environmental conditions indicated in the "Technical information" chapter must be observed.
- The computer and PC monitor must not be set up in the vicinity of the patient. The minimum distance to the patient must be 1.5 m; an exception to this is the use of a medical PC. Observe the standard EN 60601-1.
- Spiro ***Four*** must not be operated in rooms where there is a risk of explosion.

High-frequency energy (as sent from electronic devices) can impair the function of the device. For this reason, a safety distance (of several meters) should be maintained if other electronic devices are used in the same room and at the same time, such as a TV, radio, mobile phone, radio telephone, household electronic devices, etc.

In addition, the device may provide inaccurate measurements in the presence of strong electromagnetic sources, such as electric scalpels or electric knives or medical devices such as X-ray or diathermy devices, MRI machines, etc.

A minimum distance of 5 m must be ensured. Protective measures such as shielding wallpaper, shielding plaster or shielding curtains can reduce this distance.

Connection with other devices

- Additional equipment connected to the analogue and digital interfaces of the PC must demonstrably meet its corresponding EN specifications (e.g. EN 60950 for data-processing devices and EN 60601 for electro medical devices). In addition, all configurations must satisfy the system standard EN 60601-1-1.
- Devices may only be connected to each other or with parts of systems if it is ensured that the safety for the patient, the user and the environment is not impacted by this coupling.
- Provided that safe coupling is readily apparent from the device data, the user must determine, by contacting the respective manufacturers or inquiring with a qualified person, that the necessary safety for the patient, the user and the environment is not impaired by the intended coupling. Standard EN 60601-1-1 must be complied with in any case.
- Only original accessories and spare parts from Zimmer MedizinSysteme may be used.
- The use of components which are not included in the scope of delivery or not approved by Zimmer MedizinSysteme for Spiro ***Four*** may lead to measurement errors and malfunctions.

Hazards to persons

- Spiro ***Four*** should only used based on doctor's prescription. Spiro ***Four*** must not used for spirometry testing if the doctor has any reservations about the State of health or cooperation of the patient
- In order to avoid cross infections, all disposable articles like disposable turbine, nose clip, bacterial and virus filter or mouthpiece have to be disposed after any patient. Otherwise cross-contamination can occur.

Information about spirometry

- The device may not be used at the same time as high-frequency surgical devices. This may lead to burns.
- Before each use of the Spiro ***Four***, the user must check and ensure the functional safety and proper condition.
- The spirometry is to be evaluated by a physician. Be aware that any pulmonary function measurement can be affected by the patient’s body position, physiological constitution or other factors.

Risk of infection transmission

The device can be operated with two different turbines:

- Disposable turbine
- Reusable turbine

A disposable mouthpiece is necessary for a patient examination with the spirometer.
To avoid infection transmission from patient to patient, the reusable turbine must be thoroughly disinfected prior to each use (on a new patient) and the mouthpiece must be changed. If the disposable turbine is used, this and the disposable mouthpiece must be changed with each new patient. Please follow the cleaning and disinfection instructions in chapter 8.

The use of an antiviral filter is left to the physician to decide.

Warnings

The accuracy and hygiene characteristics as well as the proper functioning of the disposable turbine are only guaranteed if it has been stored closed in its original packaging.

The disposable turbine is made of plastic. It must be disposed in accordance with local regulations.

Proper function of the reusable turbine is only guaranteed if it is clean and free of foreign bodies. Insufficient disinfection can lead to the transmission of infections. Only in the case of personal use of the device, used by only one and the same patient, sufficient is periodic cleaning.

Hazardous substances

Spiro ***Four*** does not contain any materials from pharmaceutical substances or tissues of animal origin. Spiro ***Four*** does not emit any material or energy hazards for humans.

Risk of incorrect diagnosis

Patients should be informed about the rules regarding cooperation, appropriate handling of the device and the expected results.

Spiro ***Four*** provides only data for diagnostic decisions by a qualified physician. Spiro ***Four*** interprets the measured values and provides data which in any case must be validated by a qualified physician.

Performance Range

Spiro ***Four*** provides the ventilation profile and generates quality control as well as reproducibility of the spirometry performed for the patient. The automatic test evaluation provides for 11 levels based on the ATS (American Thoracic Society) classification. The best values from the measurement can be accessed easily and quickly. The target values can be selected from a target value list. Within the European Community, the values recommended by the ERS (European Respiratory Society) are usually used.

The measured values are shown on a personal computer (PC) in connection with the PC software DiagnostikSuite (optional). Spiro ***Four*** also monitors the patient's inspiration and expiration.

What does Spiro *Four* do?

Spiro ***Four*** achieves excellent measurement quality and is favoured because of its fast and safe handling as well as high reliability.
Spiro ***Four*** is a hand-held spirometer. It works connected to a personal computer.

What are the other benefits of Spiro *Four*?

- FVC, VC, IVC, MVV, PRE-POST measurements
- Compact dimensions and lightweight
- Maintenance-free
- Advanced evaluation of the spirometry tests.
- Temperature sensor for automatic BTPS conversion.
- Up to 30 functional parameters

Residual risks
If the device is used within its intended purpose, no other unacceptable residual risks are known besides the side effects and the warnings already mentioned.

Measurement principle

Flow and volume are measured by a turbine sensor, based on the principle of infrared light interruption. This principle guarantees a high degree of accuracy and reproducibility of the measured values and regular calibrations are omitted (are unnecessary).

Special features of the type of sensor:
- High degree of measurement accuracy even with low flow (end of expiration)
- Independent of moisture and gas-tightness

Spiro ***Four*** helps diagnose pulmonary diseases with the aid of "basic spirometry". This includes the following diagnostic methods:

- New recording of a spirometry (FVC measurement)
- New recording of a VC measurement ("slow spirometry")
- New recording of an MVV measurement
- Performing provocation tests
- Performing spasmolysis

The most important functional variables which are measured are

- Vital capacity (VC): the volume which can be maximally inhaled or exhaled, after maximum exhalation or inhalation has been performed. The inspiratory vital capacity (VCi) is determined as the maximum inhalation (inspiration) following a previous maximum exhalation (expiration) and is generally slightly larger than the expiratory vital capacity (VCe).
- Forced expiratory volume (FEV_1): The volume which can be maximally exhaled

in one second. The FEV_1 is a measurement of the width of the airways because the wider they are the more volume can be exhaled in a certain amount of time.

- The relative one-second capacity (known as the Tiffeneau value) is calculated from the FEV_1 and vital capacity (FEV_1/VC). The Tiffeneau value indicates the percent of vital capacity which can be exhaled in the first second of a maximum exhalation.
- Tidal volume (VT): Volume which can be inhaled or exhaled during a breath (for example, while at rest) Inspiratory reserve volume (IRV): Volume which can still be inhaled following a normal inhalation (inspiration).
- Expiratory reserve volume (ERV): Volume which can still be exhaled following a normal exhalation (expiration).

In addition, the respiratory flow rates during various degrees of filling of the lung are determined from the flow-volume curve:

- Peak flow: maximum respiratory flow rate during forced - that is, intentionally particularly forcefully performed exhalation
- MEF 75, MEF 50 and MEF25: MEF = maximal expiratory flow, that is, the maximum respiratory flow rate which can be achieved during exhalation and at 75, 50 and 25 percent of vital capacity. The MEF 50 is accordingly the maximal respiratory flow rate which is measured in the case of half of the maximally respirable volume.

Spiro ***Four*** is thoroughly tested during its production and therefore the product complies with the safety requirements and quality standards laid down by the Council Directive 93/42/EEC for medical devices.

After removing the device from its packaging, check that there is no visible damage. In case of damage do not use the device and return it to the manufacturer for replacement.

5.1. Interfaces

Note

*Spiro **Four** can only be operated with the Zimmer DiagnostikSuite software. Before you connect Spiro Four with the PC, the DiagnostikSuite must be correctly installed and configured on the PC. For more information, also see the DiagnostikSuite instructions for use.*

USB cable

Spiro ***Four*** is connected to the PC via the USB cable (3).
The PC must have a free USB port.

Check the USB cable and Housing of Spiro ***Four*** for damage before each use! If there are visible damages do not use the spirometer and contact the customer service.

Connect Spiro *Four* with the PC

Using the USB cable, connect the Spiro ***Four*** to a free USB interface on the PC.
During the first connection to be established, the driver, depending on the operating system is automatically installed or a request for installation of a driver is made. The device driver for Spiro ***Four*** is on the DiagnostikSuite installation stick.
In this case, follow the instructions on the PC monitor *(see also DiagnostikSuite instructions for use).*

The device is now ready for use and can be used with the DiagnostikSuite. Spiro ***Four*** thus becomes an intelligent sensor for flow and volume measurement. The measurement is performed in real time and is shown on the PC monitor.

5.2. Power supply

Power supply

As soon as Spiro ***Four*** is connected with the PC, it is supplied with current via the USB connection.

6.1. Switching on

Switching device on

As soon as Spiro ***Four*** is connected to an active USB connection, the device is switched on and ready for use; this is indicated by a short beep when the device is plugged in.

6.2. Spirometry test

Note

For preparation, please observe the information in the "Application information" chapter.

Introduction

During the test, the sensor is active even at very low flow rates. During the respiratory manoeuvre, Spiro ***Four*** emits acoustic signals (beeps) proportionally to the flow speed of the inhaled or exhaled air.
The user thus receives notification of when the flow speed goes to 0. The frequency of the beeps is between 6/sec and 0/sec.
A test is considered acceptable if the beep frequency at the end of the expiration time (known as FET) is very low or 0.

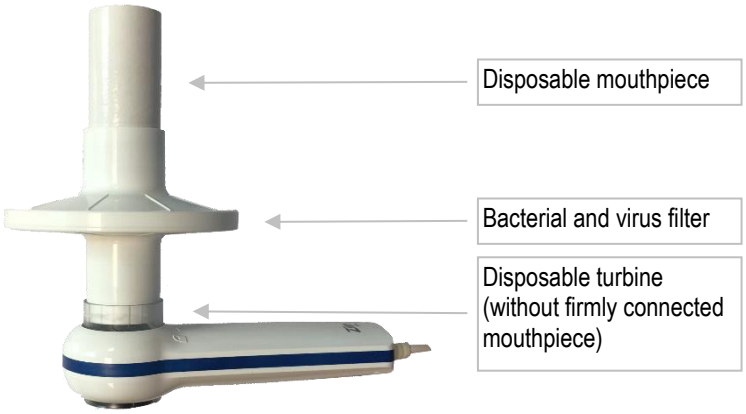
After 6 seconds from the start of forced expiration, Spiro ***Four*** emits a continuous beep.
This allows the physician to identify whether the patient has exceeded the necessary minimum expiration time.
This method is required by the most important international pneumonological associations.

This feature can also be used for maintenance and simple testing of Spiro ***Four***.

Implementation of the Bacterial and virus filters

To prevent the patients from the dissemination of viruses and bacteria during the spirometry examination a bacterial and virus filter can be inserted.

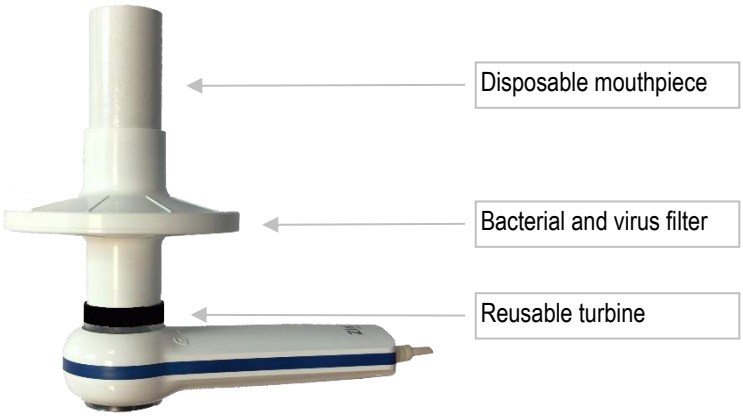
Configuration with disposable turbine



Note

Please note when using a bacterial – and virus filter the disposable turbine without the firmly connected mouthpiece is used.

Configuration with reusable turbine



Performing the spirometry

- Insert the turbine in the intended version and turn it clockwise as far as it will go.
- Insert the mouthpiece at least 0.5 cm into the turbine.
- Secure the nose clips on the sides of the patient's nose so that no air can escape from the nostrils.
- Enter the patient data via the software into the pc.
- Ask the patient to hold both ends of Spiro ***Four*** with two hands or to hold it like a mobile phone with one hand. The front must always be facing the patient.
- The patient takes the mouthpiece in his/her mouth; the mouthpiece must be inserted in the mouth until it is behind the dental arch (min. 2 cm) and the lips must be tightly closed around it so that no air can escape from the sides.
- It is recommended to perform the test with the patient standing and to have the patient slightly bend the upper body forward during the exhalation phase (expiration) to facilitate the outflow of air by compressing the abdominal muscles.
- Give a start command and perform the respiratory manoeuvre according to the type of pulmonary function measurement.

The following tests can be performed with the Spiro *Four*:

- FVC Forced vital capacity
- VC & IVC Slow vital capacity
- MVV Maximal voluntary ventilation

Influence of the patient on the test

A spirometry can only be performed if the patient is calm and in a good state of health or is in a state which is compatible with execution of the test. A spirometry test requires cooperation by the patient since the patient must perform a complete forced exhalation in order to obtain meaningful test results.

FVC test

To perform this test, attention must be paid to the phases displayed on the screen, in particular:

Slow maximal INHALATION
Deep and fast EXHALATION
Deep and fast INHALATION

Procedure

- To perform the test, the patient holds the mouthpiece of the spirometer between his/her teeth and the tongue is positioned below the mouthpiece.
- The patient is asked to close his/her lips tightly around the mouthpiece. In doing so, it should be ensured in particular that the lips at the corners of the mouth are tightly sealed against the mouthpiece.
- After taking several calm, even breaths, the patient should slowly inhale maximally. Then a forced, maximal exhalation is performed.
- To achieve the residual volume during forced expiration, it is necessary to exhale as long as possible until a clear plateau can be seen in the chronological volume progression. Spiro ***Four*** supports the patient in this with a series of individual beeps which slow down in accordance with the flow speed. If the required minimal expiration time of 6 seconds is reached, the Spiro ***Four*** indicates this with a continuous beep.
- Then the patient inhales fully and as fast as possible to determine the inspiratory vital capacity.
- Then a transition is made to respiration at rest. After a few breaths, the device is removed from the mouth.

If the inspiration data (FIVC; FIV_1, FIV_1%, PIF) are not needed, the rapid inspiration can be omitted.

The test can be performed over several cycles. In this case, Spiro ***Four*** automatically detects the best cycle (the largest FVC+FEV_1 values) and displays the accordingly measured parameters.

Note

For an accurate spirometry test, the air in the lungs must be completely exhaled.

VC test and ventilation profile

Prior to the test, have the patient breathe in and out calmly a few times.
At the start of the test, the patient continues breathing normally. After three to four respiratory phases (these should be similar in respiratory rate and depth), an acoustic signal (beep) indicates that the ventilation profile was measured and the measurement of the VC or IVC can be continued.

Slow expiratory vital capacity (VC)

After the acoustic signal (beep) sounds, slowly inhale as deeply as possible. Then slowly exhale as deeply as possible.

Slow inspiratory vital capacity (IVC)

After the acoustic signal (beep) sounds, slowly exhale as deeply as possible, and then slowly inhale as deeply as possible.

After the VC or IVC test, continue breathing normally with the device.
After three to four respiratory phases, you can end the test.

Note

The VC parameter is the maximum value of the measured EVC or IVC values depending on which of the two values was measured.

MVV test

This test is started with a series of consecutive, forced inhalations and exhalations as fast as possible, that is, the patient is to inhale and exhale several times as deeply and as quickly as possible.
The recommended respiratory rate is 30 inhalations and exhalations per minute.
The test ends automatically after 12 seconds.

Note

It is mandatory to replace the mouthpiece for each patient!

6.3. **Display of measured values**

Spirometry test results

The results and assessment of the spirometry test are provided by the DiagnostikSuite evaluation software. Please observe the corresponding instructions for use Dignostik Suite – Spirometry. The measurement values outputted from the spirometer and the calculated and outputted measurement values of the DiagnostikSuite Software take from Chapter 7.3.

7.1. Technical data

Energy supply	USB connection (5 V)	
Power consumption	max. 60 mA	
Interfaces	USB	
Measurement	Measurement method	Interruption of the infrared light/impeller
	Flow/volume meter	Bidirectional turbine
	Temperature sensor	Semiconductor (0-45°C)
	Measurable maximum volume	max. 10 L
	Flow measurement range	-16 L/s to +16 L/s
	Volume accuracy	± 2,5% or 50 mL
	Flow accuracy	± 5% or 200 mL/s
	Dynamic resistance at 12 L/s	<0.5 cm H_2O/L/s
Essential performances (compliant with EN 60601-1:2005 + A1:2012)	Error of displayed numeric value: Flow measurement percentage error< ± 5%	
Emission limits	CISPR 11 Group 1 Class B	
Electrostatic discharge protection	8kV contact, 15kV air	
Magnetic field immunity	30 A/m	
Radio Frequency Immunity	3V/m @ 80-2700 MHz	
Electrical safety	Type of protection against electrical shock	Protection class II
	Applied part (housing, turbine, mouthpiece)	Type BF
	Degree of protection against penetration of water	IPX1
	Protection against hazards due to ignition of combustible mixtures	No protection
	Level of safety in the presence of flammable anaesthetic gases, oxygen and nitrogen	The device is not suitable
	Operating mode	Continuous operation
Mechanical data	Dimensions (in mm) Width x height x depth	142 x 49.7 x 26 mm
	Weight	65 g

Environmental conditions

Storage conditions	-40°C to +70°C 10% to 95% relative humidity without condensation 500 hPa to 1060 hPa air pressure
Transport conditions	-40°C to +70°C 10% to 95% relative humidity without condensation 500 hPa to 1060 hPa air pressure
Operating conditions	+10°C to +40°C 10% to 95% relative humidity without condensation 700 hPa to 1060 hPa air pressure

Storage and transport

Please keep the packaging. The device should be shipped and stored only in the original packaging.

7.2. Quality information and reproducibility

Spiro ***Four*** also displays a series of comments related to the test.	
ERROR IN Vext and PEF If the extrapolated volume EVol is greater than 500 mL or greater than 5% of the FVC or if the PEFT (time until peak flow value) is more than 300 ms, the following message appears:	**START OF EXPIRATION TOO SLOW**
ERROR in the FET If the intended duration of the FET is not met, the following message appears:	**INSUFFICIENT LENGTH OF EXPIRATION <6 s**
FLOW ERROR If the last flow value in the F/V curve is greater than 200 mL/s, this indicates that the expiration is incomplete and the following message appears:	**EXHALE COMPLETELY**
Between two tests, the Spiro ***Four*** assesses the reproducibility of the following parameters:	
PEF, reproducible if the difference between the largest and smallest PEF value is ≤0.67 L/s; VC, reproducible if the difference between the largest and smallest VC value is ≤150 mL;	
If the FVC > 1.0 L, the following applies: FEV_1, reproducible if the difference between the largest and smallest FEV_1 value is ≤150 mL; FVC, reproducible if the difference between the largest and smallest FVC value is ≤150 mL;	
By contrast, if the FVC ≤ 1.0 L, the following applies: FEV_1, reproducible if the difference between the largest and smallest FEV_1 value is ≤100 mL; FVC, reproducible if the difference between the largest and smallest FVC value is ≤100 mL;	

7.3. Measurement parameters

Measurement parameters

Spiro ***Four*** records and processes the following parameters:

- FVC-Forced Vital Capacity
- FEV_1-Volume expired in the 1st second of the test
- FEV_6-Volume expired in the initial 6 seconds of the test
- PEF-Peak Expiratory Flow
- FEF2575-Flow ratio at 25% and at 75%
- FIVC Forced inspiratory vital capacity
- ELA-Estimated lung age
- *FVC-Best FVC
- *FEV_1-Best FEV_1
- *PEF-Best PEF
- *FIV_1/FIVC-Best FIV_1/FIVC x 100
- EVC-Slow vital capacity (expiratory)
- IVC-Slow inspiratory vital capacity

*= best values

Display parameters / evaluation parameters
(using evaluation software)

Parameter	Description	Unit
FVC	Forced vital capacity	L
FEV_1	Expiratory volume after 1 s of the test (one-second capacity)	L
FEV_1/FVC	FEV_1/FVC x 100	%
FEV_1/VC	FEV_1/best value from EVC and IVC x 100	%
PEF	Expiratory peak flow	L/s
FEF2575	Forced expiratory flow between 25% and 75% of vital capacity	L/s
FEF25	Forced expiratory flow at 25% of FVC	L/s
FEF50	Forced expiratory flow at 50% of FVC	L/s
FEF75	Forced expiratory flow at 75% of FVC	L/s
FEV_6	Forced expiratory volume during the first 6 test seconds	L
FEV6 %	FEV6/FVC x 100	%
FET	Duration of forced expiration	s
EVol	Extrapolated volume (also known as VEXT)	mL
FIVC	Forced inspiratory vital capacity	L
FIV_1	Inspiratory volume after 1 s of the test	L
FIV_1/FVC	FIV 1%	
PIF	Peak inspiratory flow	L/s
ELA	Estimated lung age	Years

VC parameters

Parameter	Description	Unit
VC	Best value from IVC and EVC	L
EVC	Expiratory vital capacity	L
IVC	Inspiratory vital capacity	L
IC	Inspiratory capacity (best value from EVC and IVC) - ERV	L
ERV	Expiratory reserve volume	L
TV	Tidal volume: Mean value of the volume of air moved	L

	per respiratory cycle during respiration at rest	
VE	Respiratory minute volume	L/min
RR	Respiratory rate	Breath/min
Ti	Mean inspiratory duration during respiration at rest	s
Te	Mean expiratory duration during respiration at rest	s
TV/ti	Mean inspiratory flow during respiration at rest	L/min
ti/Ttot	te/ (ti+te)	\

MVV parameters

Parameter	**Description**	**Unit**
MVV	Maximal voluntary ventilation	L/min

7.4. Correction factor

Information on calculating the correction factor

According to the publication “Standardised Lung function Testing” (European Respiratory Society, Vol 6 Supplement 16, March 1993), the air exhaled from the mouth has a temperature of approx. 33/34°C.

The exhaled flow and the volume must be increased by 2.6% in order to correspond to the BTPS conditions (37°C).
This is derived from the BTPS factor of 1.026 for a temperature of 33°C and means a correction of +2.6%.
In practice, the BTPS factor for the expiration flow and the volume is therefore 1.026 (constant).
In the case of the inspiratory volume and the flow, the BTPS factor depends on the environmental temperature (inhaled air = environmental temperature).
Example: For an environmental temperature of 20°C and a relative humidity of 50%, the BTPS factor is 1.102. This corresponds to a correction requirement of + 10.2%.

Inhaled volumes and flows are automatically corrected. Spiro ***Four*** has an internal temperature sensor and can calculate the BTPS values from it.
If a 3-L calibration pump is used and if Spiro ***Four*** is correctly calibrated, the FVC value (pump) is: 3.00 (FVC) x 1.026 (BTPS) = 3.08 L (BTPS).

If the environmental temperature is 20°C, this yields the following FIVC (pump) value: 3.00 (FIVC) x 1.102 (BTPS) = 3.31 L (BTPS).
The volume of the calibration pump indicated by the device is converted into BTPS conditions. For this reason, the increase in the results, based on the expected values, does not represent an error.

Cleaning and disinfection

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General

Two types of turbine can be used with the Spiro ***Four***:

- Disposable turbine
- Reusable turbine

Both guarantee measurement accuracy and have the major advantage of not requiring any periodic calibration. To maintain the properties of the turbine, it must be cleaned and disinfected after each use (applies only to the reusable turbine).

This measure also guarantees perfect hygiene and thus the best safety conditions for the patient.

The disposable turbine must be replaced for each patient!

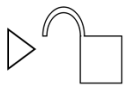
Information on cleaning

- Before cleaning, the device must be switched off and disconnected from the PC.
- The Spirometer and all of the accessories are not intended for any kind of sterilization
- Do not use any cleaning agents or disinfectants which contain alcohol or solvents.
- Under no circumstances should the device be immersed in a fluid or subjected to heat sterilization with water, steam or air. Protect the device from spray or spilled fluid. Spiro ***Four*** has no separate protection against leaking liquids or the penetration of water or other liquids.
- The device has no special protection against leaking liquids or the penetration of water or other liquids. If the device was immersed in a liquid or a liquid was spilled on it, it should in no case be put back into operation. If liquid has penetrated the device, contact Zimmer customer service.
- Do not expose the device to extreme heat or radiation nor to any long periods of direct sunlight.

Reusable Turbine rotational direction unlocked

To ensure the functionality of the turbine and avoid a cross-infection, it must be cleaned and disinfected after each use. Prevent the penetration of dust and other foreign bodies. The turbine could be damaged or its correct operation could be impaired. The inside of the turbine is to be periodically checked for contamination and foreign bodies, such as lint or hair. This could prevent the movement of or block the movable impeller of the turbine flow meter and thus lead to inaccurate measured values.

To do this, turn it counter-clockwise out of its socket and take note of the direction indicated by the symbol of the open padlock, printed on the front of the device.



Cleaning the Reusable Turbine

Immerse the turbine completely in cold water and move the turbine back and forth to loosen any minor soil inside the turbine.
Leave the turbine in the water until the visible heavy soil has loosened.

Cleaning and disinfection

Disinfecting the Reusable Turbine

Immerse the turbine completely in cold disinfectant solution and move the turbine back and forth to loosen any minor soil inside the turbine.
Leave the turbine in the disinfectant solution for as long as indicated in the respective manufacturer's information.
Rinse the turbine by briefly immersing it in clean water.

Note

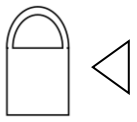
To avoid irreparable damage to the turbine, no cleaning or disinfection fluids containing alcohol or oils should be used. Do not immerse in hot water or hot solutions. Do not hold the turbines under a direct stream of water or another liquid in order to clean it. If no cleaning fluid is available, the turbine must at least be cleaned with clean water.

Remove the turbine from the spirometer, place it on a dry surface with the axis in a vertical position and allow the turbine to dry completely.

Under no circumstances should the turbine be placed on a heater, in the over or dried with a hot air blower (hairdryer or similar)!

Reusable Turbine rotational direction locked

Before reinstalling the turbine in Spiro ***Four***, the movement of the impeller in the turbine should be checked.
To do this, hold the turbine in a horizontal position and move it slowly from right to left and vice-versa.
In doing so, the impeller in the turbine should rotate freely. If the rotation is obstructed, the measurement accuracy cannot be guaranteed. In this case, the turbine should be replaced with a new one.
Once the turbine has dried, it can be used in Spiro ***Four*** again. Place the turbine back in its socket and ensure that the sieve is facing upwards.
Turn the turbine clockwise as far as it will go such that it snaps into the inside of the socket and take note of the direction indicated by the symbol of the closed padlock, printed on the front of the device.



Check that the turbine is working properly, as described above. If the turbine demonstrates irregularities, replace it with a new one.

Cleaning the Housing

Clean the housing by wiping it with a soft cloth and a commercially available plastic cleaner or with a water-moistened cloth. Ensure that no liquid penetrates the device.

Disinfecting the Housing

Disinfect the housing after each patient contact. For disinfection, wipe the housing with a soft cloth and a device disinfectant suitable for plastic. Observe the instructions for use of the respective manufacturer. Ensure that no liquid penetrates the device. Do not use spray disinfectants.

CE mark

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The device has the CE mark

CE 0123

in accordance with the EC directive 93/42/EEC.

Manufacturer

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89231 Neu-Ulm, Germany
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Fax +49 (0)731. 9761-299
www.zimmer.de

10.1. Scope of delivery

Scope of delivery	Item no.*	Amount	Description
	7420	1	Device Spiro ***Four***
	57.391.010	1	Reusable turbine**
	57.200.020	1	Device pouch
	57.510.910	1	Nose clip (100 pcs)
	433	1	Disposable cardboard mouthpiece with filter (100 pcs / package)**
	10.102.598	1	Instructions for use
	57.391.1010	1	Disposable turbine with cardboard mouthpiece (60 pcs)**

*Subject to technical changes

** Depending on the ordered variant, the scope of delivery includes either the reusable turbine and disposable cardboard mouthpiece with filter (100 pcs) or disposable turbines with cardboard mouthpiece (60 pcs).

10.2. Accessories

To ensure reliable function of the spirometry system, only original accessories from Zimmer MedizinSysteme may be used.

List of accessories

	Item no.*	Description
	57.510.910	Nose clip (Disposable, 100 pcs)
	433	Disposable cardboard mouthpiece with filter (100 pcs)
	57.392.000	Disposable cardboard mouthpiece without filter
	57.200.020	Device pouch
	57.391.100	Disposable turbine, 100 pieces
	57.392.100	Disposable turbine
	57.391.010	Reusable turbine
	57.203.020	Bacterial & virus filter, plastic, 50 pieces

*Subject to technical changes.

Additional accessories are available from Zimmer MedizinSysteme.

Device combination

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Spiro ***Four*** can be combined with the DiagnostikSuite evaluation software.
Anyone who combines devices against these guidelines and thus creates a medical system does so under his/her own responsibility.
When combining devices, observe the specifications of standard EN 60601-1. In doing so, please note the information in chapter 3 “Warnings”.

Note: *The installation, start-up and operation of the connected devices are described in the respective instructions for use.*

Guarantee

Zimmer MedizinSysteme GmbH can guarantee the safe, reliable and trouble-free function of the device only if the points below have been complied with:

- Spiro ***Four*** may only be operated in accordance with the instructions for use.
- Repairs, expansions, readjustments, installations or modifications to the device may only be performed by Zimmer MedizinSysteme or by persons authorized by Zimmer MedizinSysteme. The guarantee regarding the device/accessories becomes void if the purchaser or a third party performs work or interventions of any type on the system without prior approval from Zimmer MedizinSysteme.
- Spiro ***Four*** may only be used with accessories and spare parts from Zimmer MedizinSysteme.
- No maintenance work may be carried out on the spirometer or DiagnstikSuite during operation.

Regular inspection of the device

To maintain the uninterrupted functioning and to guarantee the safety of users and patients, it is necessary to regularly check the device and any accessories used, especially the patient cable. The user must ascertain the safe function of the device prior to each use.

12.1. Maintenance

The following work must be performed periodically:

- Cleaning and inspection of the reusable turbine flow meter
- Changing the disposable turbine after completing the examination on a patient
- Cleaning and disinfection of the Housing

Note

The maintenance work listed in the instructions for use must be carried out with the utmost care.
Failure to follow the instructions detailed here can lead to measurement errors or incorrect evaluations of the measured values.

12.2. Calibration

General

The Spiro ***Four*** turbine with the infrared interruption principle works mechanically. Since this is not affected by either air pressure, density or temperature, regular calibration of Spiro ***Four*** is not necessary.

The turbine flow sensor does not require calibration but needs only a regular cleaning. If a calibration must be made then the following guidelines should be carefully noted.
Calibration can be made using a 3 litre calibration syringe.

In line with the publication "Standardised Lung Function Testing" of the European Respiratory Society (Vol 6, Supplement 16, March 1993), the air expired from the mouth is at a temperature of circa 33/34 °C.

The expired flow and volume, to be converted to BTPS conditions (37 °C) must be increased by 2.6% - this is derived from the BTPS factor of 1.026 at a temperature of 33°C, which represents a correction of 2.6%. In practice the BTPS factor for the expired flow and volumes is therefore constant and equal to 1.026.
For the inspired volumes and flows, the BTPS factor depends upon the ambient temperature as the air inspired is at ambient temperature.
For instance at an ambient temperature of 20°C with relative humidity at 50%, the BTPS factor is 1.102, a correction of +10.2%.
The correction of the inspired volumes and flows is made automatically as the machine has an internal temperature sensor; the BTPS values are thus calculated.
If a 3L syringe is used to make the calibration and if Spiro Four is calibrated correctly then the FVC (syringe) value will be:
3.00 (FVC) x 1.026 (BTPS) = 3.08 L (FVC at BTPS).
If the ambient temperature is 20°C, the FIVC (syringe) value will be:
3.00 (FIVC) x 1.102 (BTPS) = 3.31 L (FIVC at BTPS).
The user must be aware that the volume of the syringe shown by the machine is converted to BTPS conditions, so that the "increase" of the results with respect to the expected values does not constitute an error.
For instance, if the calibration procedure is carried out with measured data:

FVC = 3.08 L and FIVC = 3.31 L at an ambient temperature of 20°C the resulting correction factor becomes:
EXPIRATION .00%
INSPIRATION .00%
This does not represent an error, but is a logical consequence of the explanation detailed above.

Functional test

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Prior to initial start-up, perform a function test to check the functionality of the pulmonary function analysis system.

DiagnostikSuite functional test (optional)

- Connect Spiro ***Four*** to the PC and start your practice management software or DiagnostikSuite. Select a patient and start with him/her.
- Check and, if necessary, correct the interface configuration under “Options/System/Devices”.
- In DiagnostikSuite, start a test using the FVC measurement button and follow the instructions of the assistant on the PC monitor.
- After a successful measurement, the measurement results and assessment are displayed. Check these for plausibility.

In the event of malfunction or visible damage, do not use the pulmonary function measurement system. Contact Zimmer customer service.

Legal notice

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The device is not listed in either in attachment 1 or in attachment 2 of the MPBetreibV (Medical Device Operator Ordinance).

In Germany, the German Social Accident Insurance (DGUV) Regulation 3 (Electrical systems and equipment), as amended, must be observed.

Note: This information applies to the operation of the unit in Germany. Please consider divergent national regulations in your country, if applicable.

Reporting

All serious incidents associated with the product are to be reported to the manufacturer and the competent authority of the state in which the user and/or the patient is located.

Error messages / troubleshooting / disposal / Service

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Malfunctions and corrections

In the event of technical problems or interference, observe the explanations, descriptions and solutions in these instructions for use.

If you require support or if there is interference which cannot be corrected, please contact your sales consultant or, for matters of urgency, please contact the factory directly.

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm
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Telephone +49 731 / 9761 - 291

Diagnostic hotline:
Telephone +49 731 / 9761 - 115
Fax +49 731 / 9761 - 4443

You can also receive support via email: support@zimmer.de
Visit us online at: http://www.zimmer.de

You will help us solve the problem if you have the following information at hand:

- Accurate description of the problem
- Serial number of Spiro ***Four***

Typical sources of error

The following causes may be responsible for inaccurate measurements or inaccurate evaluations of measured values and non-evaluable results:

- Human errors, mistakes on the part of the user.
- Use of the device outside of the intended use described in the instructions for use.
- Use of the device despite functional problems.
- Improper handling.
- Dirty or damaged reusable turbine.
- Turbine is not correctly engaged.

Malfunction	Possible cause	Remedy
The data from the spirometry test are implausible.	The turbine doesn't rotate correctly	Clean the turbines and check them for proper function. If necessary, replace all turbines with new ones.
	The test is performed in a wrong way	Repeat the test following the indications on the screen, like described by the DiagnostikSuite
	Incorrect ambient conditions, such as drafts or high humidity	Führen Sie die Spirometrie in einem Bereich durch, in welchem die spezifizierten Umgebungsbedingungen eingehalten werden.
Spiro *Four* is not communicating with the PC.	The USB cable is not correctly connected	Check whether the connection cable on the PC and Spiro Four is correctly inserted.
	The driver doesn't work correctly	▪ Check the presence of the device in the list of USB devices connected. ▪ Try to remove and connect the device.
	Wrong interface set.	▪ Check whether the correct interface is set in DiagnostikSuite.
	Interface problem of the operating system	▪ Check in the Windows device manager whether there is a general problem with the USB connection. ▪ If necessary, use another USB interface. ▪ Check the functionality of the desired interface with another device connected via USB.

15.1. Service

No service work may be carried out by the user. Service work may only be performed by trained service personnel.

Zimmer MedizinSysteme GmbH provides Circuit diagrams, parts lists, descriptions, calibration instructions or other informations on request. With these, parts of the device could be repaired from the service personnel, if these are classified as repairable.

15.2. Disposal

Disposal

Spiro ***Four*** should not be discarded via household waste or public facilities. Contact Zimmer MedizinSysteme in this regard.

Appropriate collection containers are to be used to dispose of accessories, replaceable parts and wear parts.

Disposable and rechargeable batteries should not be discarded in household waste under any circumstances. NiCd batteries are to be considered hazardous waste in any case. Disposable and rechargeable batteries are to be disposed of in accordance with the German Battery Act.

The respective provisions are to be followed. Zimmer MedizinSysteme is not responsible for any direct and indirect damage resulting from failure to comply with the above measure.

Note

In foreign (European) countries, disposal is handled by dealers authorised by Zimmer MedizinSysteme.

Manufacturer's EMC declaration

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The Spiro ***Four*** was developed according to the recognised rules of engineering; the information on use as intended of the components was taken into account. The Manufacturer's EMC declaration was prepared according to standard IEC 60601-1-2:2014.

The Spiro ***Four*** should not be operated near active HF surgical devices, Electro surgical devices or magnetic resonance imaging devices which can cause significant electromagnetic interference.

The Spiro ***Four*** is exclusively intended and has been tested for professional healthcare facilities, such as hospitals.

The Spiro ***Four*** does not have any key performance features which could be impaired through electromagnetic interference.

WARNING: The use of this device next to or stacked with other devices should be avoided since this could lead to faulty operation. If such use is necessary, the device as well as the other devices should be continuously observed to ensure that they are working normally.

The electromagnetic compatibility of the Spiro ***Four*** device was tested on the original device with the connected USB-cable.

WARNING: The use of accessories and cables which are not specified or provided by the manufacturer of this device can lead to increased electromagnetic interference emissions or decreased electromagnetic immunity of this device, resulting in improper operation.

The Spiro ***Four*** device does not contain any exchangeable components or other parts which lead to worsening of the EMC.

WARNING: Portable HF communication devices (including peripheral devices such as antennas) should be used at a distance of at least 30 cm (12 inches) from any part of the Spiro ***Four*** device; this includes cables indicated by the manufacturer. There may otherwise be a loss of performance of this device.

The device was tested for HF immunity with selected frequencies only. Transients with other frequencies occurring in the vicinity can lead to malfunctions. The tested frequencies are listed in Table 4.

The Spiro ***Four*** device does not contain any components which can age during the life of the device or which can lead to worsening of the electromagnetic compatibility. Thus no maintenance is necessary.

All tests according to standard EN 60601-1-2:2015 were performed. Other standards and regulations on electromagnetic compatibility were not applied.

Table 1

Guidance and Manufacturing Declaration- Electromagnetic Emissions		
The device Spiro *Four* is intended for use in the electromagnetic environment specified below. The customer or user of the device Spiro *Four* should ensure that it is used in such environment.		
Emission Measurement	**Compliance**	**Electromagnetic Environment-Guidelines**
RF Emissions in accordance with CISPR 11	Group 1	The device Spiro ***Four*** must emit electromagnetic energy in order to ensure its intended function. Nearby electronic equipment may be affected.
RF Emissions in accordance with CISPR 11	Class B	The device Spiro ***Four*** is suitable for use in all establishments, including domestic establishments and those directly connected to the public supply network that also supplies buildings used for domestic purpose.
A Emissions of Harmonics in accordance with IEC 61000-3-2	not applicable	
Emissions of voltage fluctuations/ flickers in accordance with IEC 61000-3-3	not applicable	

Table 2

Guidance and Manufacturing Declaration- Electromagnetic Immunity			
The device Spiro Four is intended for use in the electromagnetic environment specified below. The customer or user of the device Spiro Four should ensure that it is used in such environment.			
Immunity Tests	**IEC 60601- Test Level**	**Compliance Level**	**Electromagentic Environment-Guidlines**
Electrostatic Discharge (ESD) in accordance with IEC 61000-4-2	± 8 kV Contact Discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air Discharge	± 8 kV Contact Discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air Discharge	Floors should be made from wood, concrete or ceramic tiles. If floor are covered with synthetic material, the relative humidity must be at least 30 %
Electrical fast transient/ burst in accordance with IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	not applicable	The supply voltage quality must correspond to that of a typical commercial or hospital environment.
Surges in accordance with IEC 6100-4-5 -Line-to-Line-	± 0,5 kV, ± 1 kV	not applicable	
Surges in accordance with IEC 6100-4-5 -Line-to-Earth-	± 0,5 kV, ± 1 kV, ± 2 kV	not applicable	

Guidance and Manufacturing Declaration- Electromagnetic Immunity			
The device Spiro Four is intended for use in the electromagnetic environment specified below. The customer or user of the device Spiro Four should ensure that it is used in such environment.			
Immunity Tests	**IEC 60601- Test Level**	**Compliance Level**	**Electromagentic Environment- Guidlines**
Voltage dips in accordance with IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	not applicable	--
	0 % U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	not applicable	
Voltage interruptions accordance with IEC 61000-4-11	0% UT; 250/300 cycle	not applicable	
Magnetic filed of supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m 50 Hz oder 60 Hz	30 A/m 50 Hz	Magnetic fields at mains frequency should have the typical values found in a business or hospital environment.
Note: U_T is the mains AC Voltage before application of the test level			

Table 3

Guidance and Manufacturing Declaration- Electromagnetic Immunity			
The device Spiro *Four* is intended for use in the electromagnetic environment specified below. The customer or user of the device Spiro *Four* should ensure that it is used in such environment.			
Immunity Test	**IEC 60601-Test Level**	**Compliance Level**	**Electromagnetic Environment - Guideline**
Conducted Disturbances induced by RF fields according IEC 61000-4-6	3 V 0,15 MHz to 80 MHz 6 V in ISM Band between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz to 80 MHz 6 V in ISM Band between 0,15 MHz und 80 MHz 80% AM bei 1 kHz	**In the vicinity of devices, bearing the following symbol, interference is possible:** 
Radiated RF EM fields according IEC 61000-4-3	**3 V/m 80 MHz-2,7 GHz 80% AM to 1 kHz**	**3 V/m 80 MHz-2,7 GHz 80% AM at 1 kHz**	

Table 4

Electromagnetic immunity to HF radio communication equipment						
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Energy (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ± 5kHz Derivation 1kHz Sine	2	0,3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18Hz	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 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 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0,2	0,3	9
5500						
5785						

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Spiro*Four*

Instructions for Use

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EN 10102598 0222 I Version 8 I