CLARIO.

Instructions for Use

iSpiro® Ultrasonic Sensor

782200USEN | Version 01.00

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1. INTRODUCTION

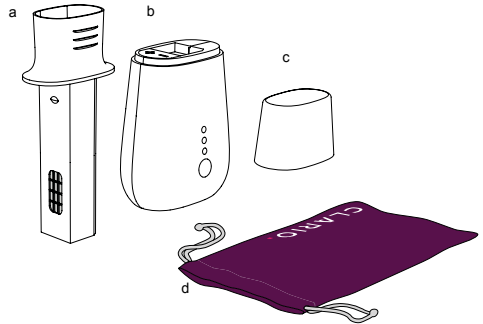
1.1 Product Description

The iSpiro Ultrasonic Sensor is a portable spirometer that is capable of pairing via Bluetooth with smart devices to perform a spirometry test. The iSpiro Ultrasonic Sensor detects the volume and flow moving through the device to record spirometry data. The device is powered by standard 2 x AAA Alkaline batteries. The iSpiro Ultrasonic Sensor is used in combination with the SpiroWay® mouthpiece.

1.2. What's in the box?

Your iSpiro Ultrasonic Sensor box contains:

- iSpiro Ultrasonic Sensor Device (b)
- SpiroWay® (a)
- iSpiro Ultrasonic Sensor Cap (c)
- Carrying pouch (d)
- Instructions for use
- Quick-Start Guide
- AAA Batteries



⚠ CAUTION

Please check that there is no visible damage on any device components. If any damage is present, do not use or attempt to repair the device but contact the manufacturer directly.

1.3. Indications for Use

The iSpiro Ultrasonic Sensor is intended to be used by adults and children over 5 years old in physician's offices, clinics and home setting to conduct basic lung function and spirometry testing.

1.4. Restrictions, Contraindications and Possible Adverse Effects

Diagnosis of medical conditions or prescription of treatments can only be made by a qualified healthcare professional who may use results obtained with the iSpiro Ultrasonic Sensor as adjunct information when performing a full medical examination that has taken into consideration your clinical history and other test results.

The iSpiro Ultrasonic Sensor must be used by a single user at any one time. If the iSpiro Ultrasonic Sensor will be transferred to and used by a new user, it must be cleaned and disinfected according to the information given in this user manual before use.

A SpiroWay® mouthpiece must not be shared between users, including family members.

Spirometry tests should only be performed if you are not experiencing any shortness of breath, are in good health and capable of performing a lung function test. Test results may otherwise be unreliable.

Failure to perform the required breathing maneuver correctly during a test may lead to inaccurate and unacceptable results. More information about how to perform a spirometry test correctly is described in this user manual.

The device should not be used if test accuracy and/or reliability is jeopardized by these or other external factors.

Spirometry tests can be physically demanding. The forced expiratory maneuver used in spirometry increases intrathoracic, intraabdominal, and intracranial pressures. Potential risks of spirometry are primarily related to maximal pressures generated in the thorax and their impact on abdominal and thoracic organs, venous return and systemic blood pressure, and expansion of the chest wall and lung. The physical effort required can increase myocardial demand. Caution must be used if you have medical conditions that could be adversely affected by these physiological consequences. Although such risks are likely to be minimal for spirometry in most patients, the potential risks associated with testing should always be weighed against the benefit of obtaining information about lung function. Spirometry should be discontinued if you experience pain during the maneuver. If you have any of these potential contraindications, please seek spirometry testing in primary care settings or pulmonary function laboratories where you will be under the supervision of healthcare professionals and there may be access to emergency care if needed.

Patients aged 5 years old and over and physicians are the intended operators of the iSpiro Ultrasonic Sensor device. A competent adult should assist patients (children or older patients) who may need assistance.

Relative Contraindications for Spirometry.

Due to increases in myocardial demand or changes in blood pressure;

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

Due to increases in intracranial/intraocular pressure;

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

Due to increases in sinus and middle ear pressures;

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

Due to increases in intrathoracic and intraabdominal pressure;

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

Infection control issues;

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

If you have or suspect having any of the conditions above, consult your healthcare professional before using the iSpiro Ultrasonic Sensor.

2.OPERATION

Mode of Operation: There are no minimum or maximum limits to the period of device use ('on' time) or disuse ('off' time). The device will time-out and automatically switch off if it is not actively used for a period of time. Batteries of the device should be removed if it will not be used for more than a month.

2.1. Operation Conditions

The required operation conditions for the iSpiro are:

- Temperature: +15°C to +35°C
- Relative Humidity: 30% to 85%
- Pressure: 700 hPa to 1060 hPa

The iSpiro should only be used within the ambient temperature, relative humidity and ambient pressure ranges given above. The device should remain within this range for at least 1 hour before use.

2.2. Storage / Transport Environment

The required storage conditions for the iSpiro are:

- Ambient temperature: -20°C to +60°C
- Relative Humidity: 5% to 85%
- Pressure: 700 hPa to 1060 hPa

The required transport conditions for the iSpiro Ultrasonic Sensor are:

- Ambient temperature: -20°C to +60°C
- Relative Humidity: 5% to 85%
- Pressure: 700 hPa to 1060 hPa

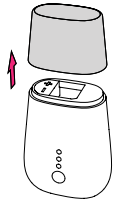
The iSpiro should not be used in the presence of inflammable liquids or detergents, nor in the presence of inflammable anesthetic gases (oxygen or nitrogen).

2.3. Setting Up Your Device

ASSISTANCE: If you need assistance setting up, using or maintaining your iSpiro please contact your doctor, study investigator or Customer Care.

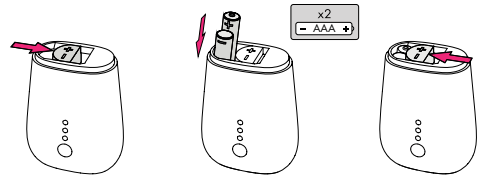
1

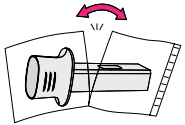
Remove the cap from the iSpiro Ultrasonic Sensor device.



2

Slide open the battery cover, insert the AAA alkaline batteries in the correct orientation, slide the battery cover back to the closed position.



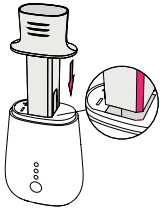


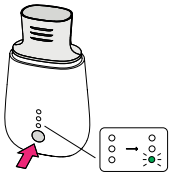
3

Take the SpiroWay out of the bag.

4

Insert the SpiroWay® mouthpiece into the spirometer as shown below and keep pushing until you hear a click.





5

Open the device by pressing the button.

2.4. Device Indicators

There are 3 LED lights located on the front of the device. The LED lights may be turned on or flashing various colors in various patterns. The LED lights indicate the current status of the device. Please see the following information for guidance on LED light indications.

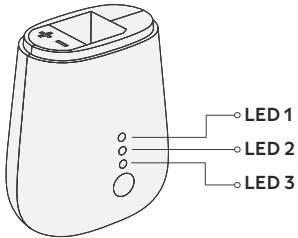
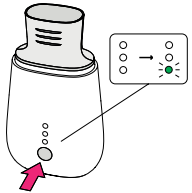


Table 2: Device Led Indicators

LED Display	Indication/s
None of the LEDs are on	The device is switched off
LED indicators are consecutively flashing green.	The device is switching on
LED number 3 is constantly flashing green.	The device is switched on
LED number 2 is fading blue.	The device is connected to the app. Bluetooth connection has been established.
LED number 2 and LEDs 1 and 3 together are flashing yellow in turn.	The zero flow level adjustment is in progress.
LED number 1 is constantly blue.	The device is ready for a test.
During a test, LED number 2 is constantly flashing blue.	The test has timed-out (there has been no inhalation/exhalation over a while)
All LEDs are flashing red.	The zero flow level adjustment setup has been unsuccessful. (Mouthpiece is removed)
All LEDs are flashing red.	There is a foreign object between the sensors. (Check device error in troubleshooting section)
LEDs are consecutively flashing yellow.	Over-the-air connection is being established.
LED number 3 flashes red three times.	Battery low warning.
LEDs flash in reverse order and remain switched off.	The device is switching off.

2.5. Turn on and off

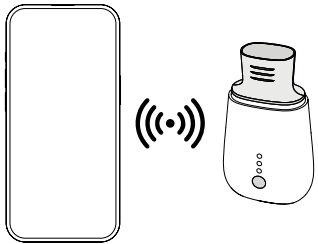


1

To connect the iSpiro Ultrasonic Sensor with your device press the power key button on the iSpiro Ultrasonic Sensor.

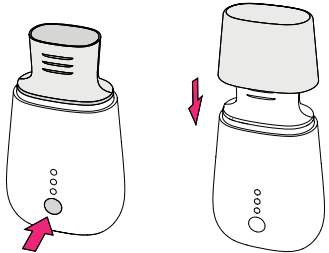
2

Before starting a spirometry test with a patient, ensure that the spirometer is connected to the smart device.



3

After completing your spirometry session, switch off the device by pressing the power key. Use the cap to protect the mouthpiece from contamination when the device is not in use.



2.6. How to perform a Lung function test

For instructions on how to perform the maneuver, please see the related Instructions for Use of the mobile application. Lung function test should be conducted according to ATS standards (see Graham B, Steenbruggen I, Miller M, et al. Standardization of spirometry 2019 update. An official American Thoracic Society and European Respiratory Society technical statement. Am J Respir Crit Care Med. 2019; 200:e70-e88).

3.MAINTENANCE

Handle the iSpiro Ultrasonic Sensor and SpiroWay mouthpiece with care. Do not use the device or its accessories if they are visibly damaged, particularly if there is damage to the filters on the mouthpiece or deformation of the mouthpiece itself. Store the iSpiro Ultrasonic Sensor and SpiroWay in dust-, dirt-, and moisture-free conditions. Before each use, always check that the device is free from contaminants and does not have any visible damage.

3.1 Performance and calibration

The iSpiro Ultrasonic Sensor is provided to the user factory-calibrated and does not require routine re-calibration. If you suspect performance errors in the iSpiro Ultrasonic Sensor, cease use of the device and test your lung function in a clinical setting to verify the results . Devices with confirmed performance errors should be returned to Clario.

3.2 Cleaning and disinfection procedure

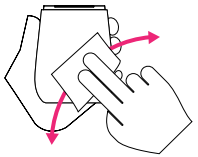
You should clean the iSpiro Ultrasonic Sensor body and cap at least once a week or whenever the device is visibly contaminated.
You MUST perform the cleaning step before performing the disinfection step. Cleaning will prevent the physical buildup of contaminants on device surfaces and remove larger debris. Disinfection kills and destroys pathogens such as bacteria, viruses, or other microorganisms which might still be present on device surfaces after initial cleaning.

1

Wash Hands

Before beginning the procedure, wash hands thoroughly with soap and water.

2



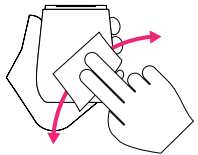
Perform Cleaning

First, remove the SpiroWay® from the iSpiro Ultrasonic Sensor device. Using a disinfectant wipe, wipe all accessible surfaces of the device and cap using moderate pressure (as shown) for at least 30 seconds to remove contaminants. Be gentle and use care when wiping the sensors to avoid damaging them.

CAUTION

Prevent any excess liquids contained within the wipes from entering the components of the iSpiro Ultrasonic Sensor. Never immerse the product in water or any other liquid solution.

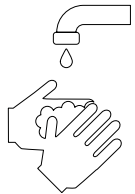
3



Perform disinfection

To disinfect the device and cap use a fresh disinfectant wipe to wipe over all accessible surfaces again using moderate pressure and for the contact time recommended by the wipe manufacturer.

4



Wash Hands

Wash hands thoroughly after performing a cleaning or disinfection procedure, and before handling the cleaned or disinfected components again for packing and storage.

3.3. Cleaning and disinfection agents

The following cleaning/disinfectant agent/s may be used to clean and disinfect this device: CaviWipes™ disinfecting towelettes (Active ingredients: Isopropanol (17.2%) and Ammomium Chloride), which can be purchased at:

3.4. Cleaning the SpiroWay

To clean the SpiroWay® Mouthpiece once a week and whenever visibly soiled;

- Add dishwashing detergent (e.g. those containing 5-15% anionic surfactant, 5% nonionic surfactant) to warm water to create a soapy solution.
- Shake the mouthpiece gently in the soapy solution.
- Hold the mouthpiece under running tap water to rinse, do not rub
- Leave the mouthpiece upright on a clean lint-free cloth at room temperature until it is completely dry

Do not insert the SpiroWay® mouthpiece into your iSpiro Ultrasonic Sensor device until it is completely dry

The SpiroWay® should be replaced every 3 months.

DANGER

The SpiroWay® mouthpiece must be replaced and the device thoroughly disinfected if user has used the mouthpiece whilst having or suspected of having a dangerous infectious disease.

The SpiroWay® must be replaced immediately if the filters are damaged or whenever a risk of contamination is suspected.

WARNING

Risk of Cross-Contamination

The SpiroWay® mouthpiece is indicated for single-patient-use only to prevent any potential of cross-contamination.

DANGER

Thorough cleaning and disinfection of the iSpiro Ultrasonic Sensor device must be performed prior to the dedication of the iSpiro Ultrasonic Sensor device to a new user. A new mouthpiece must be used by the new user.

3.5. Batteries

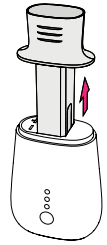
The iSpiro Ultrasonic Sensor device operates with 1.5V AAA Alkaline batteries. The battery life of the iSpiro Ultrasonic Sensor is approximately 12-18 months, assuming daily use of the device. The battery charge level is continuously monitored by the device. The device will not turn on if the battery charge level is low and will make a beeping sound to notify you.

⚠

The batteries of the device should be removed if the device is not going to be used for more than a month.

3.5.1. Instructions for battery replacement

1. Remove cap and SpiroWay® mouthpiece from the device.

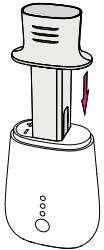


2. Slide battery cover to open position.

3. Remove the empty batteries.

4. Insert new batteries in the correct orientation.

5. Slide the battery cover back to the closed position.

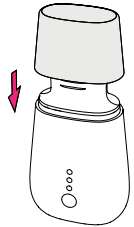


6

Insert the SpiroWay® in the right orientation. Your device is now ready to use.

7

Place cap on device to protect mouthpiece from contamination during storage.



3.6. Disposal of iSpiro Ultrasonic Sensor

This product is not to be discarded as regular household waste but should be discarded as electronic waste in accordance with local regulations and returned to a collection point of recycling for electric and electronic devices.

Used batteries should be disposed of in designated battery recycling containers in accordance with local laws and regulations.

4. TROUBLESHOOTING

Problem	Cause	Solution
Device not turning on	Multiple possible causes	Check battery orientation and correct polarities
		Remove the AAA batteries, wait 30 seconds and reinstall AAA batteries
		Replace AAA batteries
		Check that battery cap is in the lock position, or if the cap is broken, contact manufacturer
iSpiro Ultrasonic Sensor cannot connect to a smart device via Bluetooth®	The smart device is out of range	Bring your smart device closer to the iSpiro® device
	Smart device Bluetooth® is disabled	Enable Bluetooth® on your smart device
	Bluetooth® connection not working properly	Your smart device will need Bluetooth® version 4.0 or higher. Find and select iSpiro Ultrasonic Sensor from the list of detected devices.
Test results are inconsistent	SpiroWay® mouthpiece is dirty	Clean SpiroWay® to ensure that the lumen is not obstructed or replace with a new mouthpiece
	SpiroWay® mouthpiece is damaged	Replace SpiroWay®
	SpiroWay® mouthpiece is installed incorrectly	Refer to the user manual for proper installation of SpiroWay®
The test does not start - Cannot set up zero flow level adjustment	Direct air flow through on the iSpiro Ultrasonic Sensor device	Close the cap of the iSpiro Ultrasonic Sensor to avoid effects of environmental flow
		Place the device on a flat surface
		Remove causes of direct air flow e.g. air conditioner, opened window, fan, etc.
Test starts before you start blowing	Rough handling of the device	Keep the device as stable as possible after starting a test
Device disconnected during test	The device is turned off accidentally or due to rough handling during use	Switch the device on again and proceed with a new test
	Bluetooth® connection disrupted	Reconnect the device and proceed with a new test

For any other technical queries please call Clario's Customer Care.

5. SIGNS AND SYMBOLS

The following signs and symbols provided for the safe use and storage of your iSpiro Ultrasonic Sensor

SYMBOL	EXPLANATORY TEXT
	Indicates the medical device manufacturer
	Date when the medical device was manufac-tured
REF	Manufacturer's catalog/reference number for the device
SN	Manufacturer's serial number
LOT	Manufacturer's batch/lot code
	Device should not be used if the package has been damaged or opened and user should consult the instructions for use for additional information
	Device that needs protection from light sources
	Device that needs protection from moisture – Keep dry, keep away from rain
	Indicates the temperature limits to which the medical device can be safely exposed

SYMBOL	EXPLANATORY TEXT
	Indicates the range of humidity ot which the medical device can be safely exposed
	Indicates acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Device that may be used multiple times (multiple procedures) on a single patient
	Attention!
	Applied part of Type BF
	Instruction manual/booklet must be read
IP22	IP22: N1=2, Protected against solid foreign objects of 12,5 mm Ø and greater; N2=2, Protection against vertically falling water drops when ENCLOSURE tilted up to 15°
	Possible source of interference

SYMBOL	EXPLANATORY TEXT
	Separate collection for waste of electrical and electronic equipment. Do not dispose of battery in municipal waste.
	Packaging is recyclable.
Rx Only	CAUTION: FEDERAL U.S. LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
AAA	On battery powered equipment
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.
FC	Meets FCC requirements per 47 CFR Part 15 Sensor unit FCC ID: 2AAUFISPIRO1
IC	ICC Identification Number Sensor Unit IC ID: 11335A-ISPIRO1
	Presents hazards in all MR environments.
MD	Medical Device
UDI	Unique Device Identifier

6. TECHNICAL FEATURES

6.1.Summarized technical data

Flow / Volume Measurement Method	Ultrasonic pulse transit-time measurement
Power Supply	2 x 1.5V AAA Alkaline or rechargeable batteries
Dimensions	110 x 63 x 41 mm
Weight (With batteries)	90 g
Weight (Without batteries)	67 g
Flow range	0 - 14 L/s
Maximum volume measured	10 L
Volume accuracy (Average)	± 2.50 % or 0.05 L
Flow Accuracy (Average)	± 10.00 % or 170 mL/s
Highest Expiratory Impedance*	48.54 Pa*s/L
Volume resolution	1 mL
Flow resolution	1 mL/s
Medical device class	Class IIa
Wireless connection	BLE 4.2

*Tested according to ISO26782 Annex B

6.2. Device Parameters

The iSpiro Ultrasonic Sensor records the following spirometry data:

Parameters	Definition	Unit
FVC	Forced Vital Capacity — The volume of air that can forcibly be blown out after full inspiration	L
$FEV_{0.75}$	Forced Expiratory Volume within 0.75 seconds: The volume of air that can forcibly be blown out within 0.75 seconds, after full inspiration.	L
FEV_1	Forced Expiratory Volume within 1 second	L
FEV_3	Forced Expiratory Volume within 3 seconds	L
FEV_6	Forced Expiratory Volume within 6 seconds	L
$FEV_{0.75}$/FVC	The ratio of $FEV_{0.75}$ to FVC	--
FEV_1/FVC	The ratio of FEV_1 to FVC	--
FEV_3/FVC	The ratio of FEV_3 to FVC	--
FEV_6/FVC	The ratio of FEV_6 to FVC	--
PEF	Peak Expiratory Flow — The maximal flow rate achieved during the maximally forced expiration initiated at full inspiration.	L/s
MMEF	Mean Mid-Expiratory Flow — synonymous with FEF_{25-75}	L/s
FEF_{25}	Forced Expiratory Flow at 25% of vital capacity — synonymous with MEF_{75}	L/s
FEF_{50}	Forced Expiratory Flow at 50% of vital capacity — synonymous with MEF_{50}	L/s
FEF_{75}	Forced Expiratory Flow at 75% of vital capacity —synonymous with MEF_{25}	L/s
FEF_{25-75}	Forced Expiratory Flow from 25% to 75% of vital capacity — synonymous with MMEF	L/s
MET_{25-75}	Mid-Expiratory Time — synonymous with FET_{25-75}	s
$FEV_{0.75}/FEV_6$	The ratio of $FEV_{0.75}$ to FEV_6	--

Parameters	Definition	Unit
FEV_1/FEV_6	The ratio of FEV_1 to FEV_6	--
FEF_{50}/FVC	The ratio of FEF_{50} to FVC	1/s
MMEF/FVC	The ratio of MMEF to FVC	1/s
FET	Forced Expiratory Time	s
BEV	Back extrapolated volume	L
FIV_1	The forced inspiratory volume within 1 second	L
FIVC	Forced inspiratory vital capacity	L
PIF	Peak inspiratory flow	L/s
FIF_{25-75}	Forced inspiratory flow at 25% of vital capacity — synonymous with MIF_{75}	L/s
FIV_1/FIVC	The ratio of FIV_1 to FIVC	--
R50 (FEF50/FIF50)	The ratio of flow at 50% of expiration and flow at 50% of inspiration — synonymous with FEF50/FIF50	--
VC	Vital capacity, from slow expiration	L
VCin	Inspiratory vital capacity, from slow inspiration	L
VCex	Expiratory vital capacity, from slow expiration	L
ERV	Expiratory reserve volume	L
IRV	Inspiratory reserve volume	L
IC	Inspiratory capacity from end of tidal breathing	L
Rf	Respiratory frequency	1/min
VT	Tidal Volume	L
MVV	Maximum voluntary ventilation	L/min
MVV6	Maximum plat voluntary ventilation for 6 seconds	L/min
MVVtime	Duration of the trial in seconds	s

7. SAFETY WARNINGS AND PRECAUTIONS

7.1.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, will 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 safety symbols used in this user manual.

			General Warning Sign
			General mandatory action sign

7.2 List of safety warnings and precautions

	Special warning should be given by handlers of the device to elderly, pediatric or differently-abled users prior to use of the device.
WARNING	Do not use this device for any other purpose than its intended use to avoid potential dangers or harm to users. This device is not recommended for children under the age of 5.
CAUTION	If any damage is present on the device or its components upon initial unboxing of the product then do not use the device as this may affect device performance and return it to the supplier.
CAUTION	Take care when inserting the mouthpiece into the device to avoid physical injury and/or damage to the device.
WARNING	Do not use this device or its accessories if any parts are damaged, detached or blocked to avoid risk of choking or asphyxiation during use.
	In case of adverse events related to device use, immediately cease further use to avoid harm or damage and notify relevant local authorities and the manufacturer.
	Maximal inflation is unnatural; you may not have achieved it before, and it may seem somewhat uncomfortable.

⚠	Regardless of the data presented on this device, cease testing if you feel unwell or have respiratory illness symptoms and contact your healthcare provider immediately.
❗	Medications and treatments based on device results must be directed only by a qualified doctor.
❗	For your safety, if there is an excessive decrease in your FEV1 value then cease use of the device and inform your healthcare provider.
❗	Do not perform more than 8 spirometry trials in one spirometry session. If you experience pain or sensations of dizziness during testing, cease device use and rest and inform your healthcare provider.
❗	Do not walk or run whilst performing a lung function test with the iSpiro Ultrasonic Sensor for your safety and to avoid result inaccuracies.
⚠ CAUTION	Do not perform a spirometry test with food or objects in your oral cavity as this may lead to risk of choking.
❗	Do not share your iSpiro Ultrasonic Sensor or SpiroWay® with any other users, including family members, to prevent the transmission of infectious material. The device must be cleaned and disinfected, a new mouthpiece must be used, and a new account must be created for a new user of the device.

⚠	Remove all batteries when the device will not be used for prolonged periods of time to prevent damage to the device through battery leakage or oxidation.
⚠	To protect the environment, dispose of the product only through local EPA or WEEE collection facilities.
⚠ CAUTION	Check the mouthpiece airway for foreign materials before each use to prevent risk of choking and to avoid measurement inaccuracies.
⚠ CAUTION	Coughing or spitting into the device may cause incorrect readings.
⚠ CAUTION	Keep the device dry. The limited Ingress Protection (IP22) rating of the iSpiro Ultrasonic Sensor device case will not prevent damage from water leaking into the case and damaging electronics.
⚠ CAUTION	Do not use accessories not described in this user manual to prevent damage to the device, measurement inaccuracies or risk of affecting electromagnetic performance.
⚠ CAUTION	Do not touch the filters on the mouthpiece and do not use if filters have been damaged. Damage to filters may result in measurement inaccuracies.
⚠ CAUTION	Device accuracy can be affected by extremes of temperature, humidity and altitude. Use, store and transport your device only as specified in this user manual.
⚠ CAUTION	The device may give inaccurate readings if operated in the presence of strong electromagnetic sources, such as electrosurgical equipment, magnetic resonance imaging devices or computed tomography (CT) equipment.

⚠ CAUTION	Do not use the device in the presence of direct air currents (e.g. wind), sources of heat or cold, direct sun rays, or other sources of light or energy (such as heaters or radiators), dust, sand, or any other chemical substances as these conditions can affect the performance or the expected life of the iSpiro Ultrasonic Sensor device.
⚠ CAUTION	If your device is damaged or malfunctioning, contact the manufacturer or distributor if purchased from a reseller. Unauthorized repairs will terminate the product warranty and may result in a faulty device.
❗	Follow all data security warnings and recommendations for your personal smart device as per it's manufacturer's instructions to protect your personal data.
⚠ CAUTION	Do not share your iSpiro Ultrasonic Sensor account information with unauthorized parties. This will help protect your personal data.
❗	iSpiro Ultrasonic Sensor devices may be affected by electromagnetic interference. Please read EMC information and precautions provided in this user manual before use.
❗	Do not use iSpiro Ultrasonic Sensor devices in the presence of external portable and mobile radio frequency (RF) communications equipment as this may affect data transmission.
❗	Keep your iSpiro Ultrasonic Sensor device away from strong sources of magnetic and RF fields such as large electric motors, amateur radio transmitters, radar, anti-theft systems, stereo speakers, cell phones, and radio frequency identification (RFID). Television and radio transmitters could cause interference if the device is used close to them.
❗	Federal Law (USA) restricts this device to sale by or on the order of a physician.

7.3.Safety information regarding electromagnetic compatibility

The iSpiro Ultrasonic Sensor should not be operated at the same time as electrical devices with a high RF power output (e.g. HF surgical equipment) during intended use.

The iSpiro Ultrasonic Sensor may be affected by portable wireless communications equipment such as antennas, wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, etc. A minimum distance of 30 cm (12 inches) should be kept between these and any part of the iSpiro Ultrasonic Sensor.

Use of accessories or components (e.g transducers) other than those specified by the manufacturer may result in increased emissions or decreased immunity of the iSpiro Ultrasonic Sensor. The iSpiro Ultrasonic Sensor should not be used adjacent to or stacked with other equipment. If this is unavoidable the configuration in which it is used should be monitored closely to ensure that the device continues to function normally.

If there are electromagnetic fields from other electrical devices nearby whilst the iSpiro Ultrasonic Sensor is being used, the device may fail to respond or not function as normal. To restart the iSpiro Ultrasonic Sensor, turn the device off and on again. If the problem persists, move the device away from sources of electromagnetic interference as described in the EMC compatibility section of this user manual.

7.4.IT Networks

Connection of the mobile application to an IT network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties.
Subsequent changes to the IT network could introduce new risks and require additional analysis.
Changes to the IT network include:

- changes in the IT network configuration,
- connection of additional items to the IT network,
- disconnecting items from the IT network,
- update of equipment connected to the IT network, and
- upgrade of equipment connected to the IT network.

It is the user's responsibility to identify, analyze, evaluate, and control these risks.
IEC 80001-1:2021 provides guidance to address these risks.

8.ORDERABLE ACCESSORIES

- SpiroWay® 4-Pack
(Ref number: 892115)
- iSpiro Ultrasonic Sensor Cap
(Ref number: 707014)
- iSpiro Ultrasonic Sensor Pouch
(Ref number: 707013)

9. TERMS OF WARRANTY

The SpiroWay Mouthpiece is the applied part of the iSpiro Ultrasonic Sensor device. To purchase these accessories please contact your local distributors or Clario.
The iSpiro Ultrasonic Sensor hardware is guaranteed against manufacturing defects for a period of 24 months effective from the date of purchase, upon the provision of an invoice or sales receipt. The service life of the iSpiro Ultrasonic Sensor (includes spirometer, cap and carry pouch) and is 5 years from purchase. The service life of the Spiroway mouthpiece is 3 months from first use. There are no user serviceable parts in the iSpiro Ultrasonic Sensor product.

The customer must return goods for replacement or repair at the customer's expense to the authorized supplier or manufacturer. The product must be returned with a clear written explanation of the fault or problem.
This warranty does not apply, at the discretion of the manufacturer, in the following cases:

- Improper installation or operation of the device
- Use of the product for purposes other than those specified in this user manual
- Damage due to failure to follow instructions
- Damage due to unauthorized repair, modification or reconfiguration performed on the device

- Damage caused by falls, hit, lack of proper care or maintenance
- Damage caused by abnormal physical or electrical stress or defects of the electric supply (battery cell) or of equipments
- If the serial number is altered, deleted, removed or rendered illegible

In any case, the entire liability of İnofab Sağlık Teknolojileri A.Ş. under the provision of this agreement shall be limited to the amount paid by the customer for the product.

10. ELECTROMAGNETIC COMPATIBILITY

Meeting the requirements for EMC (electromagnetic compatibility) and preventing the unsafe use of the device, medical devices including the iSpiro Ultrasonic Sensor manufactured by Clario conform to the EN60601-1-2 standard which defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices. For details, please see the following tables:

Table 1: Emission table for IEC 60601-1-2

Guidance and manufacturer's declaration – electromagnetic emissions		
iSpiro Ultrasonic Sensor battery-operated spirometer devices are intended for use in the electromagnetic environments specified below. Users of these devices should assure that it is used in such environments.		
Emission Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	iSpiro Ultrasonic Sensor uses RF energy for its internal function. Its Radio Bluetooth, BLE module also complies with the national regulations. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. However, a separation distance of 30 cm shall be maintained.
RF emissions CISPR 11	Class B	The iSpiro Ultrasonic Sensor devices are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	Emissions are not applicable because iSpiro Ultrasonic Sensor does not connect to mains supply but operates with AAA batteries.

Table 2: Immunity (Stimulation mode) table according to IEC 60601-1-2

Guidance and manufacturer's declaration – electromagnetic immunity			
iSpiro Ultrasonic Sensor battery-operated spirometer devices are intended for use in the electromagnetic environment specified below. Users of these devices should assure that it is used in such an environment.			
Immunity Test Standard	IEC 60601 test level	Compliance level	Recommended separation distance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8 kV, ±15 kV Air	±8 kV contact ±2, ±4, ±8 kV, ±15 kV Air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
iSpiro Ultrasonic Sensor battery-operated spirometer devices are intended for use in the electromagnetic environment specified below. Users of these devices should assure that it is used in such an environment.			
Immunity Test Standard	IEC 60601 test level	Compliance level	Recommended separation distance
Radiated RF IEC 61000-4-3	385 MHz 27 V/m 450 MHz 28 V/m 710, 745, 780 MHz 9 V/m 810, 870, 930, 1720, 1845, 1970, 2450 MHz 28 V/m 5240, 5500, 5785 MHz 9 V/m 80 MHz to 2.7 GHz 10 V/m	27 V/m 28 V/m 9 V/m 28 V/m 9 V/m 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the iSpiro Ultrasonic Sensor devices including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Recommend separation distance d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iSpiro Ultrasonic Sensor devices are used exceeds the applicable RF compliance level above, the iSpiro Ultrasonic Sensor device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the iSpiro Ultrasonic Sensor device.
[b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment.

iSpiro Ultrasonic Sensor devices are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of iSpiro Ultrasonic Sensor devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iSpiro Ultrasonic Sensor device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter	
	80 MHz - 800 MHz $d = 0.35\sqrt{P}$	800 MHz - 2500 MHz $d = 0.7\sqrt{P}$
0.01 W	0.035 m	0.07 m
0.1 W	0.11 m	0.22 m
1 W	0.35 m	0.7 m
10 W	1.11 m	2.21 m
100 W	3.5 m	7 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

11. BLUETOOTH WIRELESS COMMUNICATIONS

Bluetooth is used to pair the iSpiro Ultrasonic Sensor with smart devices and transfer test data between them. Bluetooth data transfer involves the widely trusted use of pre-shared key authentication and encryption algorithms. The strength of Bluetooth security depends heavily on the length and randomness of the passkey used for Bluetooth pairing. Initial pairing involves mutual authentication between devices where a link key is set up between them for later authentication and encryption. Encryption of data sent between devices prevents unintended or malicious interference. Each iSpiro Ultrasonic Sensor will connect to the smart device it is paired with and will not be confused with other Bluetooth radio communications.

Frequency Band:	2400 Mhz
Transmission Frequency Range:	2402 - 2480 Mhz
Max Output Power:	0.7 dBm
Antenna gain:	5.3 dB

12. FCC / IC NOTICE

USA

iSpiro Ultrasonic Sensor
FCC ID: 2AAUFISPIRO1

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

Canada

iSpiro Ultrasonic Sensor
Sensor Unit IC: 11335A-ISPIRO1

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.

13. MANUFACTURER INFORMATION

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