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MANUAL DE USO • USER'S MANUAL
MANUEL DE L'UTILISATEUR • MANUAL D'US
MANUAL DE UTILIZAÇÃO • MANUALE D'USO

DATOSPIR *aira*

ESPIRÓMETRO • SPIROMETER
SPIROMÈTRE • ESPIRÒMETRE
ESPIRÓMETRO • SPIROMETRO

CE 0318

511-D00-MUM · Rev 2.02 · 2024-05

ES EN
FR CA
PT IT

DATOSPIR *aira* User's Manual
Revision: 511-D00-MUM Rev 2.02

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DISCLAIMER
SIBEL S.A.U. is responsible for the security, reliability and performance of this equipment only if:
• The place where the system is installed or used meets the requirements for electrical installations IEC and other applicable regulations.
• The repairs, revisions or modifications, in warranty or not, are made by technical staff **of SIBEL S.A.U**
• The device is used by qualified staff in accordance with the recommendations stated in this User's Manual.

INDEX

DATOSPIR *aira* has been developed by the RDI department of SIBEL, S.A.U in cooperation with the Pneumology Service oh Hospital de la Santa Creu and Sant Pau of Barcelona, according to the standardization criteria of International Institutions: **ATS/ERS TASK FORCE 2019** (American Thoracic Society / European Respiratory Society) and National Institutions: **SEPAR** (Sociedad Española de Neumología y Cirugía Torácica).

CE 0318 **PRODUCT IN COMPLIANCE WITH MEDICAL DEVICE REGULATION (EU) 2017/745 (CLASS IIa)**

Revised
Fecha: 2024-05
Technical Director

Approved
Date: 2024-05
Sales Director

1. SAFETY

DATOSPIR *aira* has been designed for maximum safety. The complete use instructions should be read before proceeding to operate with the system. Failure to do so may result in injuries to the user or the patient and damage to the device and/or accessories.
Report any serious incident to the manufacturer and competent authority.

1.1 INTENDED USE

Measurement of lung flows and volumes for the diagnostic and control of respiratory diseases (Asthma, COPD, etc.).
The following conditions must be considered:
- Use in a health center or similar indoor use (not for outdoor use).
- Not intended for home use or for use in moving transport vehicles.

1.2 INTENDED USER

DATOSPIR *aira* has been designed for its use by health professionals, being supervised or instructed by a physician. Specific training in the spirometry technique is recommended. The Bronchoconstriction test must be supervised by a technician qualified in this technique. The user must be familiar with the device functioning before using it on patients. All the required information for the correct use of the device is available in this User Manual. Although the patient can handle the device while blowing, the software application must be managed by a physician or a trained technician in spirometry.
Contact with SIBEL, S.A.U. or your dealer for more information about the technique or the product.

1.3 INDICATIONS FOR USE

Spirometry is a helpful tool for assessing medical conditions such as asthma, Chronic Obstructive Pulmonary Disease (COPD) or other respiratory diseases.

DATOSPIR *aira* is indicated to be used for the diagnosis and control of respiratory diseases like asthma, Chronic Obstructive Pulmonary Disease (COPD) or other respiratory diseases The spirometer is also indicated for evaluating the health status of individuals in occupational medicine, for assessing preoperative risk or for medicolegal assessment.

DATOSPIR *aira* is a useful tool for providing an accessible and accurate diagnosis of respiratory diseases. It also allows the clinical management of respiratory patients and an early identification of individuals at risk of developing respiratory diseases.

1.4 INTENDED PATIENT POPULATION

DATOSPIR *aira* is indicated for patients older than 4 years, with weight over 15 Kg and height over 90 cm, and with a mental and physical condition allowing the performance of the forced maneuver.

1.5 LIMITATIONS FOR USE

The analysis of the results of a spirometry test is not enough to make a correct diagnostic about the clinical condition of the patient. Interpretation of tests must be complemented by the clinical history or other test that the doctor considers appropriate for deciding the correct treatment.
The collaboration of the patient is required to make a spirometry test. Complete forced expiration is necessary to obtain significant FVC values. The physician must assess the patient's ability to perform these tests. Pay special attention to children, the elderly and people with disabilities.
Medical staff must consider the symptoms showed by the patient. The acceptability of atest is the responsibility of the sanitary staff.

1.6 CONTRAINDICATIONS

No contraindication has been identified for spirometry tests. However, special precautions must be considered when performing these tests in patients with medical conditions that could be adversely affected by maximal pressures generated in the thorax during the forced maneuvers.

1.7 SIDE EFFECTS

Some patients may occasionally experience exhaustion during the test performance. In such case, the test must be stopped and the patient condition re-evaluated.

1.8 ESSENTIAL OPERATION

The acquisition and sending of flow samples to the external software is considered to be an essential operation in order to comply with the specified accuracy and / or indicate whether the maneuver is correct.

1.9 RESIDUAL RISKS

According to the application of the EN ISO 14971 standard, all risks related to the use of the **DATOSPIR** *aira* equipment have been reduced to maximum, as much as possible.
It is important to read carefully all indications of use, contraindications, warnings and recommendations provided in this manual.

1.10 ⚠ WARNINGS

Use **DATOSPIR** *aira* only with the accessories provided by the manufacturer or dealer, or those that meet the specifications of this manual. The use of other accessories with **DATOSPIR** *aira* can reduce the product's safety or affect the accuracy of measurements.
Handle accessories by their strongest parts (e.g. the connectors when manipulating the USB cable). **DO NOT** get them wet or expose them to very abrupt changes of temperature.

DO NOT apply excessive stress to the accessories. In particular, avoid pulling or bending any part of the cables.

DO NOT disconnect the cable from the device by pulling the cable. You can damage the device or accessories reducing the product's safety. Hold always the cable by the connector.

DO NOT use deteriorated accessories (USB cable or connectors with broken cases) since there is risk of cramps.

DO NOT use deteriorated batteries since there is risk of burns, skin irritation, sensitization.

Please contact with SIBEL, S.A.U. or your dealer to get new accessories.

DATOSPIR *aira* system is prepared to work at room temperature. **DO NOT** expose the system to heat sources or direct sunlight. Temperature changes can cause condensation.

In case of device over-heating during use, immediately turn off the device and please contact SIBEL's After Sales Service or your dealer.

Keep your device protected from shock and vibration. It can be damaged or function incorrectly.

Always transport the device and accessories inside the carrying bag. It provides protection against small accidental impacts.

In case of receiving **DATOSPIR** *aira* with a deteriorated packaging, DO NOT use the device and please contact your courier agency, dealer or SIBEL S.A.U. After Sales Service.

DO NOT use **DATOSPIR** *aira* outdoors.

DO NOT use **DATOSPIR** *aira* in moving transport vehicles.

ELECTRICAL RISK

DATOSPIR *aira* is **NOT** intended to be used with other energy sources that are not covered in this manual.

DO NOT try to open the device. In case of malfunction or unexpected operation, please contact SIBEL S.A.U. After Sales Service or your dealer.

According to EN60601-1, the equipment is classified as a continuous operation mode, and due to its intended use, it is considered as applicable part in its entirety.

RISK OF ELECTRICAL SHOCK

DATOSPIR *aira* is designed to be used in conjunction with a software application, such as W20s Spirometry Software, running on an external device. This device must fulfill the low voltage Directive (particularly EN 60950-1 standard) and EMC Directive (particularly EN 55022, EN 61000-3-2, EN 61000-3-3 and EN 55024 standards).

DO NOT connect **DATOSPIR** *aira* to other devices in order to keep product safety.

Temporary immersion of any device part is NOT allowed. MAY CAUSE ELECTRIC DISCHARGE.

Contact of liquids with the internal parts of the device and the connectors must always be avoided.

RISK OF EXPLOSION

DO NOT use the device in an explosive environment or in the presence of flammable anesthetics or gases of any kind. MAY CAUSE EXPLOSION.

RISK OF CONTAMINATION

Cleaning instructions in this manual must be carefully followed.

Perform cleaning, disinfection and maintenance of device and accessories with the specified frequency and following the instructions in this manual in order to keep product's safety.

DO NOT use mouthpieces or other consumables from manufacturers that have not checked their biocompatibility, since it could endanger the patient's health.

RISK OF INTERFERENCE

DO NOT use the system in an MRI (Magnetic Resonance Imaging) environment.

DO NOT use the system in the presence of radio equipment, such as mobile phones, transmitters and similar equipment generating radio frequency emissions. Follow the recommendations regarding the separation distance specified in the manufacturer's declaration on electromagnetic compatibility in this manual.

1.11  DISPOSAL OF ELECTRICAL AND ELECTRONIC DEVICES BY DOMESTIC USERS IN THE EUROPEAN UNION

 **DO NOT** dispose **DATOSPIR** *aira* spirometer, accesories and / or batteries with household waste. Deliver it in a designated collection point for recycling in accordance with the legal requirements of your country.

Single use accessories (disposable Lilly transducers, mouthpieces, filters and spares) must be disposed according national regulations of potentially infected products.

The device uses NiMH or Alkaline batteries.

Information on proper recycling of the product and its disposable accessories is available on Technical Service of SIBEL S.A.U. or at your supplier.

2. INSTALLATION INSTRUCTIONS

2.1 INTRODUCTION

Spirometry is the most common of the Pulmonary Function Tests and allows the measurement of the amount (volume) and/or speed (flow) of air that can be inhaled and exhaled by a subject.

The **DATOSPIR** *aira* spirometer works in conjunction with an external software application (for example W20s). When the subjects blows through the transducer (Turbine, Fleisch or Disposable), it can operate in modes 1) or 2):

1. Device acquires the flow signal and sends it via USB or Bluetooth to the software. The software application calculates spirometric parameters from the acquired flow samples.

2. Device acquires the flow signal, transforms it to L/s and sends it via USB or Bluetooth to the software. When the spirometry maneuver finishes, device also calculates parameters and adjusts graph. Parameters and graphs are sent to the external software under request. This mode is only available for FVC tests.

The Pulmonary Function Tests that the **DATOSPIR** *aira* can perform are:

- FVC: Forced Vital Capacity
- VC: (Slow) Vital Capacity
- MVV: Maximum Voluntary Ventilation
- FVC, VC and MVV with bronchodilation response
- FVC with bronchoconstriction response (challenge test)

From these spirometric tests, a set of parameters are calculated and evaluated by the software using interpretative algorithms.

2.2 MAIN FEATURES

DATOSPIR *aira* is a portable device avaliable with different kinds of transducers: Fleisch, Turbine or disposable Lilly.

DATOSPIR *aira* is powered with two AAA NiMH or Alcaline batteries or through the USB port when connected to a computer

It allows real-time connection via **Bluetooth** or **USB** to any PC (Personal Computer) running **W20s Spirometry Software**.

DATOSPIR *aira* has 4 models with the following functionalities:

DATOSPIR AIRA T
DATOSPIR AIRA D
DATOSPIR AIRA F
DATOSPIR AIRA BASIC T

FUNCTIONALITIES	F	D	T	Basic T
Fleisch transducer				
Disposable transducer				
Turbine transducer				
USB connection				
Bluetooth				
Program upgrade by USB				
W20s Spirometry Software				
W20s Bronchoconstriction option				

Included Optional Not included

The device has been manufactured under strict quality controls. However, accidents may occur during transportation or storage; so it is convenient to make an initial review of the condition of the equipment and its accessories before installing it. Do not dispose the packaging before confirming the correct functioning of the device.

2.3 PACKING LIST

COD. 09884 Cant. 1ud.  DATOSPIR AIRA F

COD. 09883 Cant. 1ud.  DATOSPIR AIRA D

COD. 09885 Cant. 1ud.  DATOSPIR AIRA T

COD. 09886 Cant. 1ud.  DATOSPIR AIRA BASIC T

COD.	QTY.		PRODUCTS, ACCESSORIES AND COMPONENTS	F	D	T	BASIC T
	1		Quick start guide				
09090	2		AAA Alkaline batteries				
09106	1		USB cable Micro B Type, PC connection				
02692	1		Nose clip bag (5u)				
09085	1		Carrying bag				
09887	1		W20s spirometry software				
--	1	---	Bronchoconstriction Option				
09718	5		Disposable transducer with filter				
09698	(*)		Bacterial-viral filter				

COD.	QTY.		PRODUCTS, ACCESSORIES AND COMPONENTS	F	D	T	BASIC T
06186	1		Fleisch transducer				
06187	3		Fleisch filters				
03175	1		Turbine transducer				
05636	1		Disposable adapter to calibration syringe 3L				

(*) DATOSPIR AIRA F and DATOSPIR AIRA T: 5 u. / DATOSPIR AIRA BASIC T: 1 u.

Incluided Optional Not incluided

2.4 OPTIONAL PARTS

COD.	PRODUCTS AND ACCESSORIES	T	F	D	Basic T
02692	Nose clips bag 5 u.				
03169	Disposables transducers bag 50u.				
01149	Pediatric mouthpiece adapter				
08290	Calibration syringe (3 L)				
COD.	**COMPONENTS AND SPARE PARTS**				
01145	Bluetooth PC adapter				
07155	Transducer support				
09084	Lanyard				

Optional Not incluided

2.5 CALIBRATION

⚠ **Verify the device calibration daily. Otherwise you can obtain incorrect measurements.**

Connect the calibration siringe output to the transducer input by the same side for blowing to verify the calibration.

Consult the User's Manual of the **W20s Spirometry Software** to obtain more information about the calibration or verification procedure.

3. INSTRUCTIONS FOR USE

Install the **W20s Spirometry Software** to use the device with a PC. Consult the **User's Manual of W20s Software.**

Then, connect the USB cable with ⇠ the connector indicated with and the other side to the computer.

If you have acquired a model with Bluetooth, connect the **Bluethooth adapter** to the PC and install the included software. Consult the user's manual of the Bluetooth adapter.

You can link the spirometer to another device via Bluetooth. The pairing code are the last 6 digits of the serial number.

3.1 USE OF THE DEVICE

⚠ **Before using the system, it is necessary to keep the device at a stable temperature so it can make a good measure of the ambient temperature.**

⚠ **It is recommended using a nose clip when performing the spirometry maneuvers to avoid airflow leaks through the patient's nose.**

DO NOT bite the mouthpiece or antibacterial / virus filter when performing spirometry maneuvers. Otherwise, the product's safety can be reduced.

It is recommended NOT performing more than eight spirometry maneuvers in order to avoid patient exhaustion (ATS/ERS 2019).

Start the W20s Software and connect the device by Bluetooth or USB. Then, select the Spirometer model and the type of connection in the Links screen (consult the W20s User's Manual).

To turn the device on or off, press and hold the key puntil the green LED lights up and release the key.

To save energy, the equipment includes an auto-off system that shuts down the equipment after three minutes without communications with the W20s spirometry software.

1. TRANSDUCER PLACEMENT:

2. MANEUVER PERFORMANCE:

⚠ Use the lanyard according to the following instructions. Otherwise, the product safety can be reduced.

It is recommended use the lanyard to avoid device falls if the patient drops it accidentally. Check that the wristband has no knots and put it around the patient's wrist, without being too loose or too tight.

⚠ Turbine and Fleisch transducers and reusable mouthpieces must be disinfected before using them in new patients or disposable mouthpieces or antibacterial /

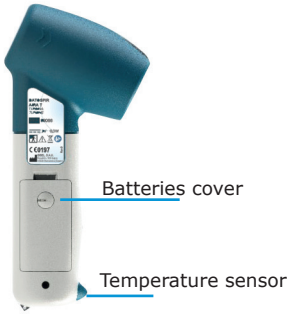
antivirus filters must be used in order to avoid the risk of contamination or cross-infection.

Use disposable mouthpieces or antibacterians filters if you suspect about contamination risk.

Place the transducer onto the cradle when it is not being used to avoid falls. If you have to travel with the device, consult the paragraph TRANSPORT AND STORAGE.

For information on test quality results, please consult the user's manual of the W20sSpirometry Software.

3.2 CONTROL AND CONNECTORS DISTRIBUTION



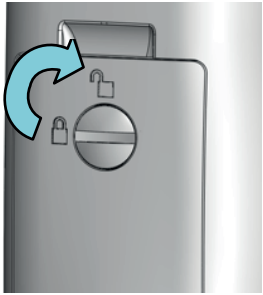
3.3 BATTERY: INSTALLATION AND CHARGING

DO NOT use battery types different from the ones specified in this manual.

Respect the polarity indicated in the battery placement. If not, the device will not turn on.

DATOSPIR *aira* can work with two AAA alkaline batteries or two rechargeable Ni-Mh 1.2V 800mAh batteries. In both cases, the approximate autonomy with normal use is 5 days.

Use a coin to turn the screw to unblock the battery cover to remove the battery. Then, replace them according to the polarity indicated on the housing.



3.4 VISUAL INDICATIONS AND WARNINGS

Indicator	Warning	Description
1 s ...	Device on	
0,2 s ...	Activated communications	Transferring data
0,1 s ...	Recovery mode	It allows updating the firmware (only USB)
0,2 s ...	BIOS Mode	It allows restoring the firmware when the communication is interrupted (USB only)
0,1 s ...	Measurement error	Internal measurement error. Restart the device or contact Technical Support
1 s ...	Low battery	Replace the batteries

⚠ When "MEASUREMENT ERROR" visual indication is detected repeatedly, switch off the device and contact SIBEL S.A.U. After Sales Service or your dealer.

It is recommended to change the battery before performing more spirometry maneuvers when "LOW BATTERY" visual indication is shown. Previous maneuvers will not be lost since they are stored in the W20s Spirometry Software.

3.5 TRANSPORT AND STORAGE

A carrying bag is included in all models of **DATOSPIR** *aira* that allows storing the device and most of its accessories for and easy transportation. The device can be stored in this bag while not in use. It is recommended to remove the batteries if the device will be not used for a week or longer.

3.6 FIRMWARE UPDATE

To update the device's firmware to a new version connect the device to the PC via USB cable and send the new firmware using the W20s software (see process description in the W20s user's manual). When the update is complete, turn off the device and now it is ready for use.

If the device does not respond as expected, you can enter into the RECOVERY MODE by holding down the key ⏻ for a few seconds until the visual indicator blinks rapidly in green. Then, you can update the firmware using the W20s software.

In case that the communication is interrupted during the firmware update, the device will enter into the BIOS MODE after restart. This mode allows updating again the firmware, following the procedure described previously.

If you cannot update the firmware, contact SIBEL S.A.U. After Sales Service or your dealer.

4. CLEANING AND MAINTENANCE

Do not use abrasives substances or solvents. The device can be damaged.

DATOSPIR aira spirometer requires, like other electromedical equipment, maintenance aimed at assuring patient safety as well as operator and environment safety; and at ensuring reliability and accuracy of the functions for which it has been developed.

4.1 SPIROMETER CLEANING

Clean the spirometer with a cloth moistened with water and neutral soap or with 96º alcohol or 0.1% sodium hypochlorite solution (equivalent to a 1:50 dilution of bleach in water if the bleach concentration is 5%). Dry the remaining moisture. Make sure no liquid or foreign material enters the equipment nor connectors or connections, especially in the pressure ports of the disposable transducer handle (wipe the handle downwards).

4.2 TRANSDUCER DISINFECTION

The transducer is the main part exposed directly to the patient. Therefore, it is necessary to keep it in perfect physical and hygienic conditions.

To disinfect the transducer, proceed as follows:

A) FLEISCH TRANSDUCER

1. Remove the filter and then the transducer by slightly pressing the tab to release it from its housing.
2. Immerse the transducer and filter in a orthophthaldehyde solution, CIDEX® OPA, or in a disinfectant solution based on peracetic acid, hydrogen peroxide or N-Duopropenide according to the concentration defined by the manufacturer (refer to the disinfectant manufacturer's instructions).
3. Rinse with distilled water.
4. Shake the transducer to remove residual water, dry it at room temperature and assemble again.

B) TURBINE TRANSDUCER

1. Remove the transducer by slightly pressing the tab to release it from its housing.

⚠ **DO NOT rinse the turbine under the stream of tap water. The turbine can be damaged.**

2. Immerse the transducer in a orthophthaldehyde solution, CIDEX® OPA (or in a disinfectant solution based on peracetic acid, hydrogen peroxide or N-Duopropenide according to the concentration defined by the manufacturer (refer to the disinfectant manufacturer's instructions). Rinse with distilled water.

3. Reliability depends on the condition of the turbine. Inspect it for possible damage.

4. Dry it at room temperature and assemble again.

It is recommended to have several transducers to replace them while disinfecting the transducers already used.

If an antibacterial filter is used with the Fleisch or Turbine transducers, the disinfectant solution indicated in step 2 can be replaced with soapy water (neutral soap).

C) DISPOSABLE LILLY TRANSDUCER

⚠ **DO NOT reuse Disposable transducer, disposable mouthpieces, disposable filters or disposable spares for filters. Otherwise, there is risk of cross-contamination between patients.**

⚠ DO NOT disinfect the disposable accessories. The use of disinfectant products can affect the accessories integrity inducing a loss of accuracy in the measurement.

Lilly disposable transducer does not need any cleaning. It is for single use. It must be disposed once used by the patient.

4.3 PREVENTIVE MAINTENANCE

The preventive maintenance include those actions aimed at keeping the device in good condition of use.

Actions to be performed by the user:

1. Perform an internal review of the device periodically by accessing the **DEVICE MAINTENANCE / CHECK** menu (this operation can be performed through the W20s Software).

2. Check that the connections, accessories and external elements of the device are in good condition for use and there are no damages. Pay special attention to the cable and USB connector.

3. Check the calibration daily and calibrate when required (this operation can be performed through the W20s Software).

4. Define the period between maintenance and calibrations in the CUSTOMIZATION MENU of the device. The device will warn every time it is turned ON if the period is exceed. If "0 days" is set, there will be no warning (this operation can be performed through the W20s Software).

If there is any anomaly that cannot be solved, contact SIBEL S.A.U. After Sales Service or your dealer.

Actions to be performed by qualified staff:

The **European Regulation of Medical Devices (EU) 2017/745** recommends that medical devices should be regularly checked and calibrated to assure the reliability of its funtions and the safety for the patients and users.

This technical verification must be done every year following the Adjustment and Verification Procedure of **DATOSPIR** *aira*, defined by the manufacturer SIBEL S.A.U.

This procedure must be performed by manufacturer's Technical Service staff or the dealer. This one must have written autoritation of SIBEL S.A.U. to perform the maintenance. The manufacturer **IS NOT** liable for malfunction or damage in the device due to of faulty maintenance performed by non certified staff.

Contact SIBEL S.A.U. **After Sales Service to recieve more information about different types of PREVENTIVE MAINTENANCE available.**

4.5 CORRECTIVE MAINTENANCE

Corrective maintenance consists in repairing the device when it is no longer in service; leaving it in good conditions for use.

If there is any failure in the device contact the SIBEL S.A.U **After Sales Service**, specifying the anomaly occurred.

SIBEL S.A.U **After Sales Service**
Tel. +34 93 433 54 50
sat@sibelmed.com

5. TECHNICAL SPECIFICATIONS

Medical device classification	Class IIa

	Fleisch	Turbine	Lilly Disposable (without transducer)
Weight (g)	182	173	124
Dimensions (cm)	18 x 9 x 5	18 x 9 x 5	15,5 x 10 x 3,5

Comunications	PC: USB 2.0 and 3.0, Bluetooth 5.0 (BR/EDR/LE)			
Batteries	2 batteries AAA rechargeables Ni-Mh 1.2V 800 mAh / 2 Alkaline batteries AAA (Recommended)			
Use conditions	Temperature: 5 to 40 ºC Humidity: 15 % to 90 % (Non-condensing) Pressure: 700 to 1060 hPa. (525 to 795 mmHg / 3000 to -380 m aprox.)			
Recommended conditions of measurement		Peak expiratory flow (EN ISO 23747:2015)	Forced expiratory volumes (EN ISO 26782:2009+AC:2009)	ATS/ERS
	Temp	10-35 ºC	17-35 ºC	>17 ºC
	Hum	30-75 % (non-condensing)		
	Pres	850-1060 hPa (638 to 795 mmHg / 1500 to -380 m aprox.)		
Transport and storage	Temperature: 0 to 50 ºC (*) Humidity: < 90 % (Sin condensación)			
Internal temperatura sensor	5 to 40 ºC ± 1 ºC			
User life	7 years			

(*) The device suports from -25ºC to 70ºC, but the temperature is limited due to the transducers with filters (model D) and the bacterial-viral filters (models F and T).

RANGES AND MEASURES

The most demanding value among ATS-ERS 2019, EN ISO 26782:2009 + AC:2009 and EN ISO 23747:2015 is specified.

	Fleisch	Turbine	Lilly Disposable	Lilly Disposable with filter
Measurement range (BTPS) Flow Volume	0 to ±16 l/s 0 to 16 l			
Flow resistance 14 l/s (cmH_2O / l/s)	<1,4	<0,6	<1,2	<1,5
Measurement accuracy (BPTS) Volume Flow PEF	2,5% or 50 ml 3% o 150 ml/s 10% or 170 ml/s			
Temporal accuracy	0,50%			
Volume resolution	<10ml	<10ml	<10ml	<10ml
Frequency of sampling	100Hz	100Hz	100Hz	100Hz
Transducer life	1400 disinfect. or 3 years	1400 disinfect. or 3 years	Only one use (Expir. 3 years)	Only one use (Expir. 5 years)

6. APPLICABLE LEGISLATION AND STANDARDS

- European Medical Device Regulation (EU) 2017/745
- ROHS Directive 2011/65/EU
- Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE).
- Directive 94/62/EC on packaging and packaging waste.
- Regulation (EC) 1272/2008 on classification, labeling and packaging of substances and mixtures (REACH)
- Implementing Regulation (EU) 2021/2226 regarding electronic instructions for use of medical devices
- Quality System (EN ISO 13485:2016+A11:2021, EN ISO 9001:2015)
- Risk Management (EN ISO 14971:2019 + A11:2021)
- Safety of medical equipment (EN 60601-1:2006+AC:2010+A11:2011+A1:2013)
- Electromagnetic Compatibility (EN 60601-1-2:2015)
- Bluetooth 5.0 Class II (EN 300328 v2.1.1:2016)
- Biocompatibility: Biological evaluation of medical devices (EN ISO 10993-1:2020, EN ISO 18562-1:2020, EN ISO 18562-2:2020 y EN ISO 18562-3:2020)
- Usability (EN 60601-1-6:2010+A1:2015 and EN 62366-1:2015 + A1:2020)
- Medical Device software (EN 62304:2006+AC:2008+A1:2015)
- Documentation and information (EN ISO 20417:2021, EN ISO 15223-1:2021)
- Spirometers for measuring forced expiratory volumes (EN ISO 26782:2009+AC:2009)
- Spirometers for peak expiratory flow (EN ISO 23747:2015)

Spirometry Recommendations

- ATS / ERS:

Graham BL 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(8):e70–88.

- SEPAR: García-Rio F et al. SEPAR regulations. Spirometry. Arch Bronconeumol 2013;49(9):388-401.

- NLHEP: Ferguson et al. Office Spirometry for Lung Health Assessment in Adults. Chest 2000;117:1146-1161.

7. SYMBOLS

SN — SERIAL NUMBER

MANUFACTURER (manufacturer date, name and adress of manufacturer)

LOT — LOT NUMBER

REF — PRODUCT'S REFERENCE

DATE OF EXPIRY

DO NOT REUSE

TEMPERATURE LIMIT

HUMIDITY LIMITATION

ATMOSPHERIC PRESSURE LIMITATION

CONSULT INSTRUCTIONS FOR USE

WARNING, RISK IDENTIFIED

WARNING, IDENTIFIED RISK

MD — MEDICAL DEVICE

STAND-BY

APLICABLE PART BF

WASTE DISPOSAL OF ELECTRICAL / ELECTRONIC WASTE

DIRECT CURRENT

Annex 1. ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions		
DATOSPIR *aira* is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment..		
Emissions test	**Compliance**	**Electromagnetic environment - Guidance**
RF (Radiated) emissions CISPR 11 (EN 55011)	Grupo 1 Clase B	
RF (Conducted) emissions CISPR 11 (EN 55011)	Not applicable	**DATOSPIR** *aira* works with batteries.
Harmonic emissions EN-IEC 61000-3-2	Not applicable	**DATOSPIR** *aira* works with batteries.
Voltage fluctuations / Flicker emissions EN-IEC 61000-3-3	Not applicable	**DATOSPIR** *aira* works with batteries.

Guidance and manufacturer's declaration – electromagnetic emissions			
DATOSPIR *aira* is intended for use in the electromagnetic environment specified below. The costumer or the user of **DATOSPIR** *aira* should assure that it is used in such an environment. Tests EN-IEC 61000-4-4 y -4-5 are applicable to AC/DC power inputs, and input/output signal. Test EN-IEC 61000-4-6 additionally applies to patient connections. Test EN-IEC 61000-4-11 only applies to AC power inputs.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –Guidance**
Electrical fast transient/burst EN-IEC 61000-4-4	±2 kV for power supply lines and earth ±1 kV for input/output lines Frecuency 100 kHz	Not applicable Not applicable	**DATOSPIR** *aira* works with batteries. The input/output line cables are shorter than 3 meters long.
Surge EN-IEC 61000-4-5	±0.5, ±1 kV differential mode (Line to line). ±0.5, ±1, ±2 kV common mode (Line to ground).	Not applicable Not applicable	**DATOSPIR** *aira* works with batteries.
Conducted RF EN-IEC 61000-4-6	3 Vrms de 150KHz a 80 MHz 6 Vrms in ISM bands 80% AM a 1kHz	3 Vrms	
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11	0% Ut ; 0.5 cycles: 0º, 45º, 90º, 135º, 180º, 225º, 270º y 315º. 0% Ut; 1 cycle 70% Ut; 25/30 cycles: 0º 0% Ut ; 250/300 cycles (5 segundos)	Not applicable	**DATOSPIR** *aira* works with batteries.
NOTE Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
DATOSPIR *aira* is intended for use in the electromagnetic environment specified below. The costumer or the user of **DATOSPIR** *aira* should assure that it is used in such an environment. Below mentioned tests are applicable to enclosure. Additionally, test EN-IEC 61000-4-2 is applicable to input/output signal and patient connections.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN-IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV, air	±8 kV contact ±2, ±4, ±8, ±15 kV, air	
Radiated RF EN-IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	3 V/m	
Proximity fields from RF communications EN-IEC 61000-4-3	(View following table).		Portable and mobile RF communications equipment should be used no closer than 30cm to any part of **DATOSPIR** *aira*, including cables. The distance is calculated according to: $d = \left[\frac{6}{E}\right]\sqrt{P}$ where P is the output power rating of the transmitter in watts (W), d is the recommended separation in meters (m) and E is the immunity level in V/m.
Power frequency (50 / 60 Hz) magnetic field EN-IEC 61000-4-8	30 A/m	30 A/m	Only applicable to devices sensitive to magnetic fields.

Proximity fields EN-IEC 61000-4-3					
Frecuency (MHz)	Band (MHz)	Modulation	Power (W)	Distance (m)	E (V/m)
385	380-390	Pulso 18Hz	1.8	0.3	27
450	430-470	FM D:+/-5kHz 1kHz sinus	2	0.3	28
710 745 780	704-787	Pulso 217Hz	0.2	0.3	9
810 870 930	800-960	Pulso 18Hz	2	0.3	28
1720 1845 1970	1700-1990	Pulso 217Hz	2	0.3	28
2450	2400-2570	Pulso 217Hz	2	0.3	28
5240 5500 5785	5100-5800	Pulso 217Hz	0.2	0.3	9

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