Instructions for use

RESMON First

THE FIRST MINI OSCILLOMETER

(Ref: RT1105)



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Software version: 2.0.x

RESTECH
RESPIRATORY TECHNOLOGY

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Introduction

Thank you for purchasing **FIRST**, the first hand held oscillometer. **FIRST** is a **smart, compact and portable device** that permits to monitor quickly the respiratory functionality using the **forced oscillation technique**. Thanks to its innovative design, **FIRST** allows healthcare professionals to measure lung function, oxygen saturation and heart rate everywhere.



Before using the **FIRST**, make sure to carefully read these instructions for use.

The important **symbols** that you will find in these instructions for use are:



Warning! symbol: indicates a potentially hazardous situation, which, if not avoided, could cause death or serious injury



Caution! symbol: indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices



Note symbol: indicates important information related to the usage of the device

Clinical information

Intended Purpose

Device for monitoring respiratory function.

Intended Use

FIRST is intended to measure respiratory system impedance using the Forced Oscillation Technique. FIRST is intended for use with pediatric and adult patients 3 years of age or older. The device is designed to be used by pulmonologists, general practitioners, nurses, respiratory therapists, laboratory technologists, medical researchers and similarly trained personnel in hospitals, clinics, private physician offices, pharmacies and health-check centers.

Contraindications

The use device is contraindicated in subjects with known sensitivities or allergies to the following components: ABS (acrylonitrile butadiene styrene), Silicone, Stainless Steel, Polypropylene, Acrylic, Polycarbonate, Nylon, Aluminum and PET (polyethylene terephthalate) and in any operators or subjects who are not explicitly indicated in the paragraph “Intended Use”.

Complications

RESTECH is not aware of any complications due to the device used under its intended use.

Undesirable side effects

RESTECH is not aware of any undesirable side effects due to the device used under its intended use.

Descriptive information

Description of the device

FIRST is a medical device designed for assessing mechanical impedance through the use of the Forced Oscillation Technique, also known as Oscillometry. Oscillometry is a non-invasive approach to measuring the mechanical properties of the respiratory system. During the measurement, small pressure oscillations are applied to the respiratory system to elicit an oscillatory flow in and out of the lungs to allow the measurement of respiratory impedance (Zrs). Zrs, in turn, measures how difficult is for the pressure oscillations to move air in and out of the respiratory system and comprises two distinct components: resistance (Rrs) and reactance (Xrs). **FIRST** measures Rrs and Xrs over multiple breaths by utilizing a sinusoidal pressure stimulus at 5 Hz.

One of the most appealing aspects of oscillometry from a clinical perspective is that it allows for measurements to be taken during a patient's normal breathing, without the need for any forced effort. This feature makes oscillometry especially well-suited for monitoring individuals who may have limited ability to fully cooperate, such as the elderly or severely ill patients with limited forced capacity.

FIRST also enables a non-invasive assessment of oxygen saturation and heart rate through the principles of pulse oximetry.

Device Composition

MAIN COMPONENTS OF THE FIRST



OTHER PARTS SUPPLIED WITH THE DEVICE

- **Test object**, a component of the **FIRST** with a known impedance used to verify the factory calibration of the device



- Type-A to Type-C **USB cable**
- **Wall adapter** for recharging the device battery
- **Carrying bag**

Disposables not supplied with the device

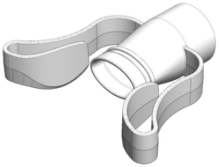
Warning! Use only **CE-marked bacterial/viral filters and nose-clips** having the characteristics specified below

The following disposables are **not supplied with the FIRST** but are required to perform the measurement correctly.

- **Single-use nose-clip**: any medical CE nose-clip suitable for pulmonary function measurements
- **Single-use bacterial/viral filter**: any medical CE filter suitable for pulmonary function measurement that meets the following specifications:
  - Resistance at tidal flows: <0.7 $cmH_2O \cdot s \cdot L^{-1}$
  - Inner diameter of the device-side connector: 30 mm
  - Viral and bacterial filtration efficiency: >99.99% at 30 L/min

Furthermore, the following optional disposable component can be connected to the bacterial/viral filter having a patient-side outer diameter of 30 mm.

- **Single-use cheek holder (REF RT4155):** it provides support for the patient's cheeks during an oscillometry measurement as an alternative to using their hands.



Note: These items are intended for single use and, therefore, must be changed after each subject. For a proper disposal of filters and nose-clips used during the measurements, follow the safety instructions reported on their instructions for use and the additional provisions and regulations of your hospital or institution.

Instructions for your safety



Warning! To reduce the risk of fire and electrical shock and prevent electrical interference, use only components supplied with the device.



Warning! Do not use the device in an oxygen-enriched environment



Warning! Do not replace the internal battery. If you suspect a malfunction of the battery, please contact your local distributor



Warning! The use of a nose clip and bacterial/viral filter is mandatory for a correct execution of the measurement and to avoid the risk of cross-contamination between tested subjects



Warning! Do not open the device. There are no user adjustable components in it.





Warning! The FIRST device is MR Unsafe. The device presents a projectile hazard.



Warning! The FIRST device shall not be used in operating rooms.



Caution! While charging, only connect the device to extension cords and outlet strips that meet all the specifications outlined in IEC 60601-1. Avoid attaching different outlet strips to the device's outlet strip, and refrain from placing the outlet strip on the floor. Furthermore, refrain from plugging any other devices that are not associated with **FIRST** into the same outlet strip.



Caution! Do not expose the device to condensing humidity



Caution! The wall adapter supplied with device is compliant with IEC 60601-1. Do not use other wall adapters for recharging the device. If the wall adapter is damaged or lost, please contact your local distributor.



Caution! Use of components other than those provided by the manufacturer or in configurations different from those reported in this manual or which fail to comply with the specifications indicated above may alter the performances of the device. If any accessories are damaged or lost, please contact your local distributor.



Caution! RESTECH recommends paying particular attention to the subject's positioning during the measurement to ensure that the upper airways are not obstructed, either partially or entirely, by the tongue or teeth.



Caution! The **battery** used in this device may present a **risk of fire or chemical burn** if mistreated. **Do not disassemble**, heat above 50°C or incinerate.



Caution! Do not crash the device, disassemble or dispose it of in fire



Caution! Factors that may degrade the performance or accuracy of the pulse oximeter include: excessive ambient light, residues (grease, oil, etc.) or moisture in the light path, **excessive pressure applied on the sensor's cover**, **movement of the finger placed on the sensor's cover**, **cold hands**, blood flow restrictors (blood pressure cuffs, infusion lines, tight rings, etc.), low hemoglobin concentration, carboxyhemoglobin, methemoglobin, dysfunctional hemoglobin



Caution! Your organization is in charge of keeping the passwords for devices secure.



Caution! The device shall be fully recharged at least every two months to prevent any potential deterioration of the internal battery.

General precautions



Caution! Failure to observe the precautions listed below may cause risks for the subject, for the user, or the loss of integrity of the device.

- Handle with care. Rough handling or misuse could cause hardware and electrical damage
- Cover the device when not in use, as dust may cause improper function of the device
- Do not occlude either side of the breathing pathway. The occlusion may worsen the quality of the measurement and may cause over-heating of the device
- Applying excessive pressure to the touchscreen may result in screen damage and compromise the display's integrity
- Make sure that the sensor channels and breathing pathway remain unobstructed, as any blockage can lead to a substantial alteration in the measured parameters and yield unreliable results
- Should the chassis be damaged, contact the distributor (see section *User information*)
- In case the display is damaged or malfunctioning, contact the distributor (see section *User information*). The touchscreen and the on-screen instructions are essential for the correct utilization of the device
- If the packaging is damaged at the time you receive the device, contact your distributor before using it (see section *User information*).

Turn on / off the device and the home screen

- To **turn on** the device: press and hold the *ON/OFF Button* on the display of the device for **3 seconds** and then wait for the device to finish its loading process and the *Home Page* is displayed:



The *Home Page* (and all the subsequent screens) have a green *Header* reporting the following information:
- Date
- Level of battery charge

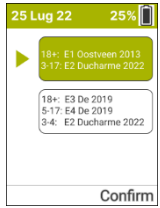
The top right icon ( ) allows you to **change the device settings**, the top left icon ( ) allows you to **navigate the internal archive**, the bottom icon allows you to **perform a new measurement**

- To **turn off** the device: press and hold the *ON/OFF Button* on the display of the device for **3 seconds**

Change device settings

From the **settings page** (see section *Turn on / off the device and the home screen*), you can:

- Change **date and time**
- Change the device **language**
- Change the device **units of measurement**
- Make a **calibration check**
- Enable or disable the **head position check**
- Visualize the device information: 1) **device serial number**, 2) current date and time, 3) firmware version, 4) calibration ID and 5) language pack loaded onto the device
- Change the **device password** to access your **desktop software**; the default password is PASSWORD.USER
- Change barometric pressure at which the device is used
- Change the reference equations: you can choose between two sets of reference equations:
  - SET#1:
    - E1 - Oostveen et al., (Eur Respir J., 2013) for age 18+,
    - E2 - Ducharme et al., (Pediatr Pulmonol, 2022) for age 3-17.
  - SET#2:
    - E3 - De et al. (Eur Respir J, 2019) for age 18+
    - E4 - De et al. (Indian J. of Pediatr, 2020) for age 5-17,
    - E2 - Ducharme et al., (Pediatr Pulmonol, 2022) for age 3-4.



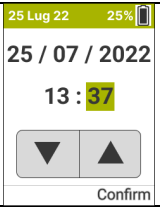
Press the right button *Next* ◉ to move to the next page of settings and the left button *Home* ◉ to return to the *Home Page*.

Caution! Make sure to **change the default password!** The minimum length for the new password is 12 characters or numbers.

Caution! Before using the device, make sure to **set the barometric pressure to the one of your current location!**

Note: Instructions to make a calibration check are reported in section *Daily Calibration Check*.

Note: To change the date and time, touch the value that you want to modify (for example, the minutes), use the arrows to increase or decrease the value and then press the button ◉ *Confirm* to confirm



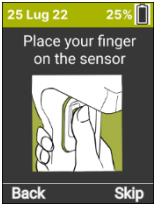
Perform a new measurement

From the **measure page** (see section *Turn on / off the device and the home screen*), you can start a new measurement. Each measurement consists of different steps, as reported below.

Measurement of pulse oximetry and heart rate

Note: You can **skip** pulse oximetry and heart rate measurements by pressing the ◉ *Skip* button on the right

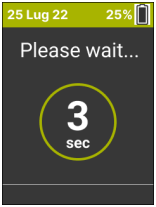
Note: The **FIRST** is **not** equipped with any alarm system for the detection of oxygen saturation or pulse rate

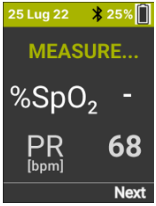


Request the subject to position one of their fingers on the pulse oximeter. If necessary, assistants, guardians, or caregivers can provide assistance with this task. Ensure that the sensor is fully covered by the finger; if it is not, instruct the subject to try a different finger

Note: Make sure that the subject **hand / finger is not cold**, otherwise the sensor will not measure pulse oximetry values

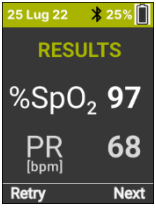
Note: Do not press too hard the cover lens with the finger, otherwise the sensor will not measure pulse oximetry values





Once the finger is properly positioned, the pulse oximetry measurement will initiate automatically, and within a few seconds, the display will present the initial readings for oxygen saturation (SpO2, in %) and heart rate (PR, in beats per minute). These values will continue to refresh (update time: 1s) as long as the subject maintains their finger on the sensor and the signal is of sufficient quality. Values of SpO2 and/or PR are not displayed on screen when the measured signals are low quality.

Note: Do not move the finger and **do not press too hard the cover lens** during the measurement, this will help maintain good-quality signals



Ask the subject to remove the finger once the displayed data have stabilized, typically after approximately 10-15 seconds. This action will prompt the results screen to appear.

To repeat the measurement, press the *Retry* button on the left. Alternatively, to proceed to the next phase of the measurement, use the *Next* button on the right

Daily Calibration Check

Note: This step is needed only once every day, at the first daily startup the device. In case the daily calibration has already been performed, this step is automatically skipped and you will be directed to the next one.

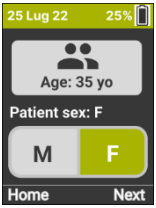
Note: If the barometric pressure is changed from settings, the device will ask to repeat the calibration check before starting a new measurement.

Insert the **Test Object** supplied with the device (see section *Device Composition*) into the inlet of the breathing pathway with a gentle rotation movement. Press the ◉ *Next* button on the right to start the calibration check. If this check is successful, you will move to the oscillometry measurement.

Caution! Do not occlude the test object during the calibration check procedure.

Oscillometry measurement

Note: Oscillometry measurements must be performed with the subject in **sitting position**



Insert the subject age and sex, by pressing the correspondent buttons on the display. Press the ◉ *Next* button on the right to confirm the data. Then, insert the height and weight by pressing the correspondent buttons on the display. Press the ◉ *Next* button on the right to confirm the data.





Before performing the first measurement of a session, you can review and change the preset reference equations (for details, see paragraph *Change device settings*).

Press the ◉ *Confirm* button on the right to confirm the data.



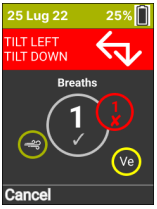
Connect the filter to the inlet of the breathing pathway. Press the *Start* button on the right to start the measurement of the filter and wait a few seconds.

Caution! Ensure the subject does not breathe into the filter during this operation



1. Ensure that the subject is seated comfortably and wears a nose clip (not included with the device)
2. Confirm that the subject maintains a tight seal around the filter mouthpiece with their mouth during the measurement
3. Verify that the subject refrains from obstructing the airflow by placing their tongue or teeth between the mouth and the filter or the cheek holder inlet; the tongue should be positioned below the filter or cheek holder mouthpiece
4. Ask the subject to use their hands to support their cheeks. If the cheek holder is used (see section *Disposables not supplied with the device*) the patient can keep their hands resting along the body.
5. Position the subject's head slightly upward
6. Initiate the measurement by pressing the Start button on the right and instruct the subject to breathe normally into the device
7. After a few breaths without artifacts, the device will activate the fan and starts the recording of oscillometry data.





Throughout the measurement, the display will indicate if the subject's head is not correctly positioned; the device will emit a buzz, and the screen will display instructions to adjust the head position (either more upright or more downward or more towards the left of the right). Head position check can be disabled from the settings page of the device (see section Change device settings).

Caution! If you have turned off the head position check (see section Change device settings), ensure that the subject maintains the proper posture throughout the measurement to prevent any unwanted artifacts.

8. During the measurement, the display will also show the number of valid breaths (i.e., the breaths without artifacts) in the center of the screen, and the number of discarded breaths on the right side. The count of valid breaths increases when the head position is correct and the airflow is ≤ 1 L/s. In such cases, the symbol in the bottom left corner of the screen is green. If this symbol turns yellow or red, encourage the subject to breathe more calmly and relaxed.

9. The measurement will conclude automatically when either 10 artifact-free breaths are detected or when 90 seconds have elapsed from the start of the test. You may conclude the measurement by pressing the Save button after detecting a minimum of 5 valid breaths, provided the real-time average ventilation for these valid breaths is less than 18 L/min. In such cases, a green (Ve < 16 L/min) or yellow symbol will be displayed in the bottom right corner of the screen. If this symbol turns red, it indicates higher ventilation rates, and you should encourage the subject to breathe more calmly and relaxed.

10. After concluding the measurement, you have the option to either initiate a new measurement within the same session (with a maximum limit of 5 measurements per session) or return to the Home Page.



After exiting a measurement session, it is possible to add a **Custom Subject ID** to the session. The ID can be an alphanumerical string of no more than 8 digits. Once the ID has been inserted, press the *Save* button on the right to save this information. Press the *Skip* button on the left to skip the insertion of the ID.

Caution! Avoid inserting personal data in the Subject ID field.

Note: The results obtained through oscillometry are displayed on the screen as explained in section *Error! Reference source not found.* within these instructions for use

Note: You can add new measurements to any open sessions as long as they contain fewer than 5 recorded measurements and were initiated during the same day. To access these sessions, refer to the Archive page (see section *Error! Reference source not found.*).

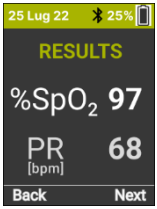
Note: It is possible to use the **same subject ID for more than one session.**

Note: It is possible to change the **subject ID assigned to a session** by navigating the Archive menu (see section *Error! Reference source not found.*), but only if the session is still open.

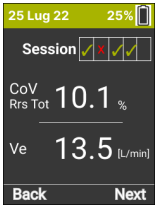
Navigate the internal archive

From the **archive page** (see section *Turn on / off the device and the home screen*), you can review the last 15 measurement sessions. Press the right button ◉ *Next* to move to the next page of the archive and the left button ◉ *Home* to return to *Home* Page. In the archive page **touch the session button** that you want to review.

Each **session button** contains the following information: date and time of the session, number of oscillometry measurements of the session (in square brackets), custom session ID (if available), sex and age of the patient tested in that session.
After pressing a session button, the following information is displayed (press the right button ◉ *Next* to move to the next page of the selected session and the left button ◉ *Back* to return to the previous page):

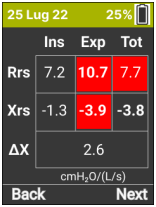


This page reports oxygen saturation and heart rate detected during the first measurement of the session

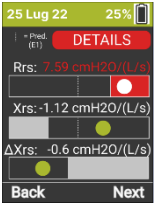


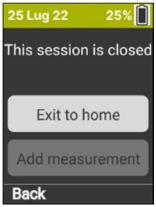
Total number of oscillometry measurements performed, up to a maximum of five per each session; the ones used for calculating the mean results are marked with a green tick, those discarded with a red cross. Quality control parameters of the measurement session (inter-measurement **coefficient of variation** (CoV) of the selected measurements (green tick) and **mean ventilation** (Ve) are reported in this screen

Note: If the session CoV is >10% in adults and 15% in children, the *Technical Standards on Oscillometry* (Eur Respir J, 2020) recommend to add new measurements to the session (if less than 5 measurements have been performed). Ve above 18 L/min may indicate that the measurements were not performed at tidal breathing.

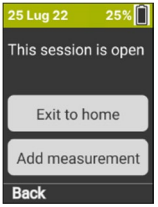


This screen displays the average total resistance (Rrs) and reactance (Xrs) and the difference between inspiratory and expiratory reactance (ΔXrs) in numerical format (in $cmH_2O \cdot s \cdot L^{-1}$). The bars below Rrs and Xrs show circles indicating the corresponding z-scores, calculated using the selected reference equations (indicated in the up-left corner of the screen between parenthesis). These circles indicate whether Rrs and Xrs are within the normal range or in the abnormal region; if abnormal, this latter region is displayed in red. The central vertical lines represent the predicted values of Rrs and Xrs. The bar below ΔXrs shows a circle indicating the measured absolute value. A value above 2.8 $cmH_2O \cdot s \cdot L^{-1}$ suggests the presence of tidal expiratory flow limitation. By pressing the DETAILS button, you can access the inspiratory ("Ins") and expiratory ("Exp") values of Rrs and Xrs, which are provided in absolute values and with the specified units of measurement. Values displayed against a red background fall outside the normal ranges established with the reference equations mentioned above. DETAILS button is red if any of the abovementioned parameters is outside of the normal ranges.





To go back to the Home Screen, press the *Exit to Home* button. If the measurement session took place during the day and involved fewer than 5 recorded measurements, you can also include additional measurements in this session by selecting the *Add measurement* button.



Caution! The device can visualize a maximum of 15 measurement sessions; new sessions are visualized on a first-in-first-out basis, thus the oldest sessions are progressively replaced by the newest ones. For each session, the subject's age, sex and, optionally, custom ID are saved, hence they can be considered pseudo-anonymized.
To preserve the data of your subjects, it is recommended to make a copy of it by downloading them into your computer, as described in section *Exporting, saving and printing the measurement results*.

Charging the device

The battery charge status is consistently shown in the display's header. Upon device startup or the commencement of each new measurement, the device checks the battery level. It will notify

you if the remaining charge is insufficient for conducting any new measurements, or if it may suffice for just a single measurement but not for an entire measurement session.

To charge the battery of your FIRST, you need to use the **wall adapter provided with the device**. Connect the **USB cable provided with the device** to the wall adapter and connect the wall adapter to a wall socket. Once a valid power source has been detected the device will display the percentage of battery charge. **If this screen does not display during the recharging, contact your local distributor.**

Note: During the charging process, measurements and screen navigation are disabled.

Exporting, saving and printing the measurement results

You can export and save the results of the measurements obtained with the FIRST device to your PC through the **desktop software**. Register your product on www.restech.it to download your copy of the software. Unzip the downloaded file and move the extracted folder to your preferred path on the PC. Then, connected the FIRST to your PC using **the provided USB cable and double click on the software icon**.

The USB port of the FIRST allows data upload to the **desktop software** (outgoing direction/functionality), as well as incoming data functionality (password management/control).



Sessions data

Data downloaded from device 23051M001 on 20/10/2023, 13:04:30

	Date	ID	Sex	Age	SpO_2 [%]	HR [bpm]	#	R_{tot} CoV [%]	Ve [L/min]	R_{tot}	X_{tot}	ΔXrs	Report
1	2023-06-06 14:07		M	40	97	70	1	1.4	5.4	2.68	-0.65	-0.78	
2	2023-06-04 17:41	CHILD	M	15	-	-	1	3.0	10.2	3.26	-0.58	-0.23	
3	2023-08-07 17:41	TUG	M	40	97	97	2	9.3	10.4	3.23	-0.22	0.57	
4	2023-05-31 9:10		M	29			3	**11.3**	5.2	2.59	-0.19	0.04	
5	2023-05-30 15:12		M	67	-	-	3	2.6	15.2	**4.02**	**-1.63**	0.83	
6	2023-05-29 11:48		F	51	-	-	3	7.8	6.4	**5.19**	-0.84	-0.07	
7	2023-05-28 09:10		M	8	-	-	4	**15.2**	13.1	4.09	-1.26	-0.97	

Upon startup, insert the *device password* (see section *Change device settings*) to access the list of stored measurements on the FIRST device (up to 200 sessions). Values for Rrs and Xrs that fall outside the normal range will be displayed with a red background. Additionally, any CoV of Rrs exceeding the recommended threshold (10% for adults and 15% for children) will also be highlighted in red. By clicking on the top-right icon, you can personalize the report layout by adding your organization logo and name. You can also set default names for the physician and technician who conducted the test or completed the report and change the language of the user interface.

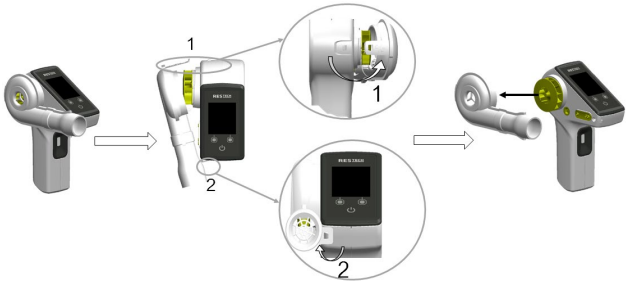


Select the **report icon** for a chosen session to view the data in a comprehensive manner. Here, you have the option to input personal information such as your name, the subject's name, last name, and ethnicity, along with additional notes covering factors like smoking history, the purpose of the test, or any additional remarks. Subsequently, you can generate a printout of the measurement results using the layout depicted on the right-hand side of the page.

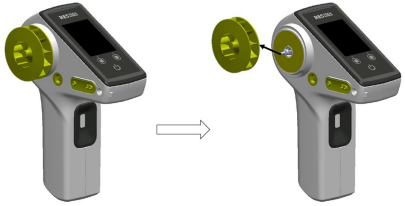
Note: During the connection with the PC, measurement and screen navigation are disabled.

Note: To uninstall the desktop software, simply delete the program folder.

How to disassemble and reassemble the device



To **disassemble the device**, detach the *breathing pathway* by first disconnecting the flap from the rear side of the device (1) and then from the frontal side (2)



Detach the *fan* by pulling it from the *motor shaft*

To **reassemble the device**, repeat the previous steps in the opposite order, paying attention to keep the fan parallel to the main body while reinserting it into the *motor shaft*.

Cleaning and disinfection

Upon concluding measurement sessions with a subject, the device must be cleaned and disinfected to uphold its performance and mitigate potential biological risks due to accumulation of bacteria or viruses. Please adhere closely to the provided cleaning and disinfection instructions reported below.

⚠	**Caution! Turn off the device** before initiating the cleaning and disinfection procedure (see section *Turn on / off the device and the home screen*)
⚠	**Caution!** The use of a bacterial/viral filters reduces the contamination of the parts behind it. However, a thorough cleaning and disinfection of the device still has to be performed.
⚠	**Caution!** During the cleaning and disinfection process for the device, employ gloves that are legally approved and of the suitable type and length. Also, ensure the use of eye protection and gowns that are resistant to fluids.

Dispose of the bacterial/viral filter, nose clip and cheek holder

Bacterial/viral filters, the nose clips and the cheek holder are single-use items and therefore, it is mandatory to replace them after each patient!
The use of a bacterial/viral filter with the characteristics indicated in section *Disposables not supplied with the device* is mandatory to perform a measurement. Filters, nose clips and cheek holder can be disposed of as domestic waste if they show normal degree of contamination. In all other cases (e.g., tuberculosis) dispose them of in special containers.

Clean the device

Wipe the device and its components with a soft cloth moistened with distilled water.

Disinfect the device

Between patients, wipe the device and its components with a cloth moistened with alcohol or disinfecting ethanol (95%). Do not squeeze the wipes too much to avoid frothing.



Warning! If there is reason to believe that the internal components of the device may be biologically contaminated, in addition to the standard cleaning and disinfection process outlined above follow also the subsequent procedure

1. **Disassemble** the *breathing pathway* and the *fan* from the main body of the device (see section *How to disassemble and reassemble the device*).
2. **Dip** the **fan** and the **breathing pathway** in a disinfectant solution (sodium hypochlorite solution at 0,5% - 5 g/L) for 10 minutes. Then, thoroughly rinse the parts with distilled water until no traces of disinfectant remain.
3. **Shake off** any excess of water and let the device and its detached components (i.e., the **fan** and the **breathing pathway**) dry separately on a clean surface
4. **Inspect the sensor channels** to ensure there is no debris within them. Any leftover material can be delicately eliminated using a toothpick, being careful not to damage the rubber in the process
5. **Reassemble** the *breathing pathway* and the *fan* (see section *How to disassemble and reassemble the device*).

Note: Before utilizing the aforementioned disinfectants and for the appropriate disposal post-use, it is advisable to carefully review the usage instructions provided on the package insert. Be sure to adhere to the manufacturer's safety recommendations. In addition to the guidelines detailed in this section, please also comply with the regulatory directives and hygiene standards mandated by your institution.

Drying and Visual Inspection

Make a visual inspection on the device before utilizing it again. If you notice residues or impurities repeat the cleaning and disinfection procedure. If you notice damaged surfaces, deformations, cracked seals, discolorations or corrosions **do not use the device** and contact your local distributor.



Warning! Use the device only if the *breathing pathway* and the *fan* are completely dry and no water residues are present.

List of the units of measurement

	Available units of measurements	
Physical quantity	**Default format**	**Other available format(s)**
Date format	dd/mm/yyyy	-
Height	cm	in
PR	Bpm	-
spO_2	%	-
Weight	kg	lbs
Rrs, Xrs, ΔX	$cmH_2O \cdot s \cdot L^{-1}$	

Symbols and abbreviations

Symbols

Screen header	
	Battery charge status (icon representation)
25%	Battery charge status (percentage)
25 Lug 22	Date

Screen buttons	
	Confirmation/selection button
	Power on/stand by button

Device labelling			
	Manufacturer		Minimum and maximum allowed storage and transport relative humidity (%)
	Model		Minimum and maximum allowed storage and transport temperature (degrees Celsius)
	CE mark	Rx Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Catalogue number		No low-level SpO2 alarm present
	Production date (YYYY-MM-DD)		Refer to Instructions for Use
	Class II equipment	**IP22**	Degree of protection

	Waste of electrical and electronic equipment according to WEEE Directive 2012/19/EU		UDI GS1 Datamatrix
	Type BF applied parts	MD	Medical device
SN	Serial number		

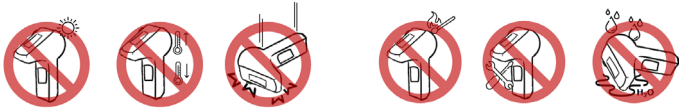
Abbreviations

CoV	Coefficient of variation
PR	Pulse rate
Rrs insp	Mean inspiratory resistance
Rrs exp	Mean expiratory resistance
Rrs or Rrs tot	Mean resistance of the whole breath
%SpO_2	Peripheral capillary oxygen saturation percentage
Ve	Ventilation
Xrs insp	Mean inspiratory reactance
Xrs exp	Mean expiratory reactance
Xrs or Xrs tot	Mean reactance of the whole breath
ΔXrs	Difference between mean inspiratory and mean expiratory reactance at 5 Hz

Maintenance and storage

Maintenance

When you finish using the device, **clean and disinfect** it as reported in section *Cleaning and disinfection*, put it in its carrying bag and keep it in a dry and clean environment, away from heat sources or direct sunrays. Avoid exposing the device to temperatures outside those reported in section *Technical specifications*.



A **periodic maintenance** is recommended for the **fan** and the **breathing pathway**. Conduct a visual check of the **FIRST** device at least once a week. If you detect any signs of damage, deformities, seal cracks, discoloration, or corrosion, please get in touch with your local distributor and do not use the device.

Storage Conditions

Recommended temperature:	-20 - +40°C
Recommended relative humidity:	30 - 75% non-condensate
Recommended barometric pressure:	700 – 1060mbar

Caution! The use, storage or transport of the device outside of recommended ranges may alter its performances and decrease accuracy of data

How to return a defective device

If you need to send your device back to RESTECH, follow these guidelines to ensure the safety of both yourself and our employees who will be handling it, and to facilitate a comprehensive inspection of all its components.

- The device must be thoroughly **cleaned** and **disinfected** with the **extraordinary disinfection procedure** reported in section *Cleaning and disinfection* in order to remove residues and biological contaminants as far as possible.
- **Contact your local distributor before shipment** to get the correct return address and the packing instructions. See section *User information*.

Information for disposal for private users, companies and healthcare institutions

Disposal of the device and of its components

The FIRST is an *electrical equipment* that must be disposed of by following your national or local regulations. Contact the distributor for further details. In the European Union, the device shall be disposed of according to WEEE Directive 2012/19/EU. In other Countries, it shall be disposed of by following the local/national regulations.

	This symbol on the product and/or on the accompanying documentation is valid only in the European Union and specifies that the electrical equipment is not designated for common garbage. A proper disposal of this product will contribute to conservation of resources and avoid potentially negative effects on human health and the environment. In the case of improper disposal penalties could be applied according to local and national regulations.

Disposal of the packaging

The packaging of the FIRST device shall be disposed of by following your national or local regulations. Contact your local distributor for further details. For the European Union, the recycling codes are the following:

 **PAP 20** CARTON BOX	 **LDPE 4** DEVICE AND COMPONENT BAGS
PAP 20: Corrugated fiberboard	LDPE 4: Low density polyethylene

Electromagnetic compatibility

The FIRST device complies with the IEC 60601-1-2:2014+AMD1:2020 standard (immunity and emissions).
Further information on the accordance with the standard is available on request contacting the manufacturer, see section *User information*.
The compliance with the above standard guarantees the safety of the device but special attention should be paid in the following situations:

	**Warning!** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
	**Warning!** Electromagnetic interference (EMI) from devices such as radiofrequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), near-field communication (NFC) systems, wireless power transfer (WPT) systems, and 5G cellular networks that may be near the FIRST device could result in heightened electromagnetic emissions or reduced electromagnetic immunity, potentially causing malfunction. If proximity to these emitters is unavoidable, the FIRST device should be monitored to ensure it is functioning correctly



Warning! Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation



Warning! Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the FIRST device

Troubleshooting and error messages

Troubleshooting

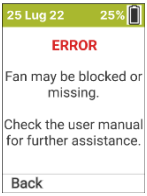
The table provided below outlines the typical issues that can arise during device use. To address these problems, refer to the troubleshooting options listed in the same order as they are presented for their resolution. For other problems not listed below, contact your local distributor (see section *User information*).

The device does not start the measurement	1. Reattempt the measurement by following the guidance provided in the *Oscillometry measurement* section, with specific attention to wearing the nose clip and preventing leaks around the filter or mouthpiece. The *fan* will begin moving after detecting a few breaths 2. Confirm that the *breathing pathway* is properly assembled (refer to the *How to disassemble and reassemble the device* section) 3. Examine the breathing pathway for any signs of cracks or deformities 4. Get in touch with your local distributor (refer to *User information* section) if the issue persists
The touchscreen is unresponsive	Contact the local distributor (see section *User information*)
The device does not start up	1. Charge the device, see section *Charging the device* 2. Get in touch with your local distributor (refer to *User information* section) if the issue persists
The daily calibration check has failed	The device is not measuring the expected value of the Test Object. 1. Ensure that you are using the Test Object provided with the device 2. Ensure that the *Test Object* is securely plugged in, that the *breathing pathway* is correctly linked to the device, and that neither the *breathing pathway* nor the *sensor channels* are obstructed. Then, rerun the test 3. Ensure that the set barometric pressure is correct.

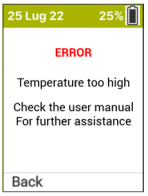
	4. Get in touch with your local distributor (refer to *User information* section) if the issue persists

Error messages

Here are a few errors you might encounter while using the FIRST device, along with potential solutions. If you encounter any on-screen errors not covered in the list below, please get in touch with your local distributor (see section *User information*).



The fan maybe blocked or missing.
Switch off the device and re-assemble the breathing pathway and fan.
If the problem is still present after turning on the device, contact the local distributor.



Temperature of the device too high.
Switch off the device and wait a few minutes.
If the problem is still present after turning on the device, contact the local distributor.

Technical specifications

Flow measurement	Type	Pressure drop across a resistive element; pressure measurement by mass flow principle
	Range	± 1.5L/s
	Linearity	< ± 1%FS in the range ± 1.5L/s
Mouth Pressure	Range	± 15 cmH_2O
	Linearity	≤ ± 1.5%FS in the range ± 5 cmH_2O
	Resolution	0.00046 cmH_2O
Test signals	Amplitude	Max 3 cmH_2O peak-to-peak
	Within-breath protocols	5Hz
Accuracy of the measurement	For impedance parameters	≤ ±0.1 $cmH_2O \cdot s \cdot L^{-1}$ or ≤ ±10% of the measured value
	For volume parameters	≤ ±50 mL or ≤ ±2.5% of the measured value
Impedance magnitude range at	5Hz	0 – 25 $cmH_2O \cdot s \cdot L^{-1}$

<table>
<tr><td>specified frequency</td><td colspan="3"></td></tr>
<tr><td>Calibration and calibration check</td><td colspan="3">Factory calibration according to international recommendations. Calibration check with a test object (supplied with the device).</td></tr>
<tr><td>Total load to the subject</td><td colspan="3"><1 $cmH_2O \cdot s \cdot L^{-1}$ in the flow range (± 1L/s) and frequencies of normal breathing</td></tr>
<tr><td>Device dead space</td><td colspan="3"><23.2 mL</td></tr>
<tr><td>Applied parts</td><td colspan="3">Inlet of the device and cover lens of the pulse oximeter</td></tr>
<tr><td>Display</td><td colspan="3">2’’color display with capacitive touchscreen</td></tr>
<tr><td>Electrical specifications</td><td colspan="3">Power supply:
- Wall adapter (for recharging the internal battery only): 100-240 V, 50/60 HZ:
<table>
<tr><th>Plug type</th><th>Model and manufacturer</th><th>Input /output</th></tr>
<tr><td>A</td><td>SWI10B-5-NW-I38; CUI Inc.</td><td>10 W input AC/ 5VDC 2A output</td></tr>
<tr><td>C</td><td>SWI10B-5-EW-I38; CUI Inc.</td><td>10 W input AC/ 5VDC 2A output</td></tr>
<tr><td>D</td><td>FOX-6-X-USB (1899496) + plug 1847521; FRIWO GmbH</td><td>7 W input AC/ 5VDC 1.4A output</td></tr>
<tr><td>G</td><td>FOX-6-X-USB (1899496) + plug 1847543; FRIWO GmbH</td><td>7 W input AC/ 5VDC 1.4A output</td></tr>
</table>
- Internal battery: rechargeable 7.2 V, 3.35 Ah, Li+ battery.</td></tr>
<tr><td>Expected battery duration from full charge</td><td colspan="3">- Device in stand-by: ≥ 15 days
- Device during SpO2 and Heart Rate measurements: ≥30hrs
- Device during oscillometry measurements: ≥100 tests of 90s each</td></tr>
<tr><td>Dimensions</td><td colspan="3">17x14x8 cm</td></tr>
<tr><td>Weight</td><td colspan="3">450 g</td></tr>
<tr><td>Operating Conditions</td><td colspan="3">Optimal temperature: 5 - 40°C
Optimal relative humidity: 15 - 95% non-condensing
Optimal barometric pressure: 700 – 1060mbar</td></tr>
<tr><td rowspan="3">Pulse oximeter and heart rate

The pulse oximeter is classified as a class I laser product</td><td rowspan="2">Wavelength (λ):</td><td>IR light 870-900 nm</td><td rowspan="2">Power:</td><td>IR light: 6.5 mW</td></tr>
<tr><td>Red Light: 650 - 670 nm</td><td>Red Light: 9.8 mW</td></tr>
<tr><td>%SpO_2 Update time – no motion</td><td colspan="3">1s</td></tr>
<tr><td>%SpO_2 Range – no motion</td><td colspan="3">70-100%</td></tr>
</table>

according to the IEC 60825-1:2014	*%SpO_2 Accuracy – no motion (A_{rms}*)*	*≤ 3.3% of the reference value*
	Heart Rate Accuracy – no motion*	*≤ 2.8% of the reference value*

* The +/- A_{rms} accuracy encompasses about 68% of the population. SpO2 and Heart Rate (HR) accuracy testing was conducted during induced hypoxia study on 10 adult healthy, male and female, non-smoking, I to V Fitzpatrick phototype subjects. The measured saturation value (SpO2) and HR of the FIRST was compared to SpO2 and HR of a laboratory co-oximeter in the range 70 – 100%. Accuracy data is calculated using the root-mean-square (A_{rms} value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

User information

Incident Reporting

If a **serious incident** occurred in relation to the use of the device, it shall be promptly **reported to the Manufacturer** using the contacts below *and* to the **Competent Authority** of the Country where the incident occurred.

Other User Assistance Information

For other information and requests of technical support, please contact your local distributor using the contacts below.

MANUFACTURER **RESTECH Srl** Via Melchiorre Gioia, 61-63 20124 Milano – Italy Web: www.restech.it Email: support@restech.it Tel: +39 02 3659 3690	**TECHNICAL ASSISTANCE / LOCAL DISTRIBUTOR** (Contacts and/or company's stamp)

Other information

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Notes

Names of persons mentioned in the context of this document are fictitious and any resemblance to living or deceased persons is purely incidental and not intended.
If there are any uncertainties or mistakes, the original version of this manual is the English one and should be regarded as such.

Declaration of conformity

The present device is classified as a medical device class IIa according to the European Regulation MDR 2017/745. The device has been designed in accordance with the requirements of the IEC 60601-1:2005+AMD1:2012+AMD2:2020 and its deviations ANSI/AAMI ES60601-1:2005 (R2012) (USA), CSA IEC 60601-1:2005+AMD1:2012 (Canada), JIS T 0601-1:2012 (Japan) and KS C 60601-1:2011 (South Korea).

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RESTECH

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