RESMON

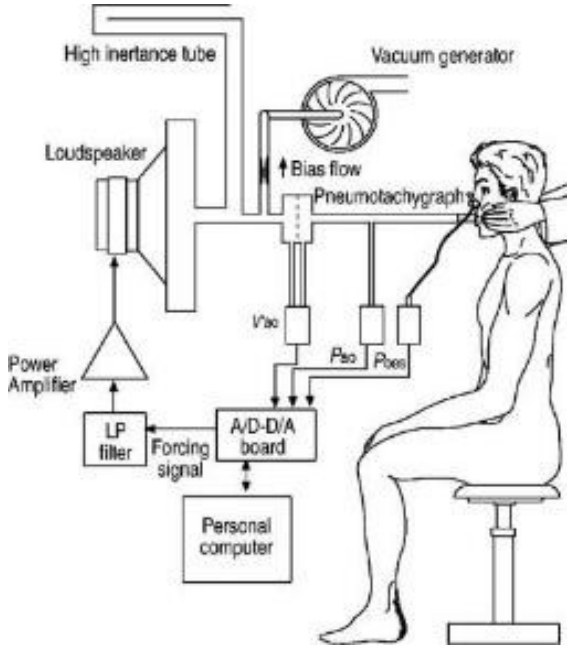
First

THE FIRST MINI OSCILLOMETER

"The Hand Held oscillometer could be a revolution in pulmonary function testing"

NEW HANDHLED TECHNOLOGY FOR OSCILLOMETRY DEVICES

STATIONARY device TECHNOLOGY



- Bigger actuators (e.g., loudspeaker);
- Uses a high inertance tube;
- Uses a bias flow to reduce dead space;

HANDHELD TECHNOLOGY

(patent nr WO2012014024A1)

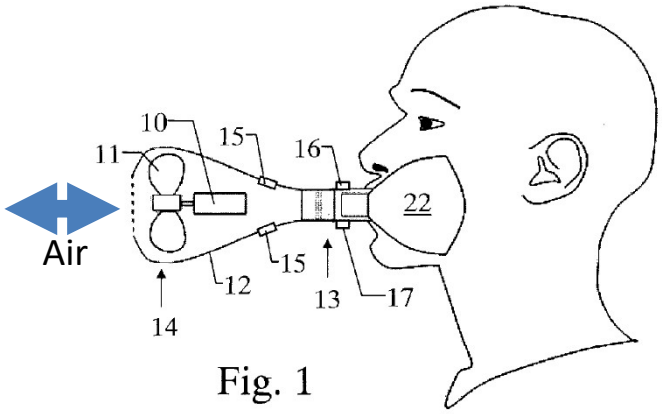


Fig. 1

- A fan/blower/turbine produces the flow oscillations, while the patient can breathe through it;
- No need of additional tubes;
- Dead space can be very limited.

Even if the current technologies allow for compact size and reduced weight of the components, there is a limit to the minimum size and cost associated to this setup

This design allows the manufacturing of small, lightweight and inexpensive oscillometry device.

FIRST: the FIRST MINI OSCILLOMETER

RESMON First

THE FIRST MINI OSCILLOMETER

Main features:

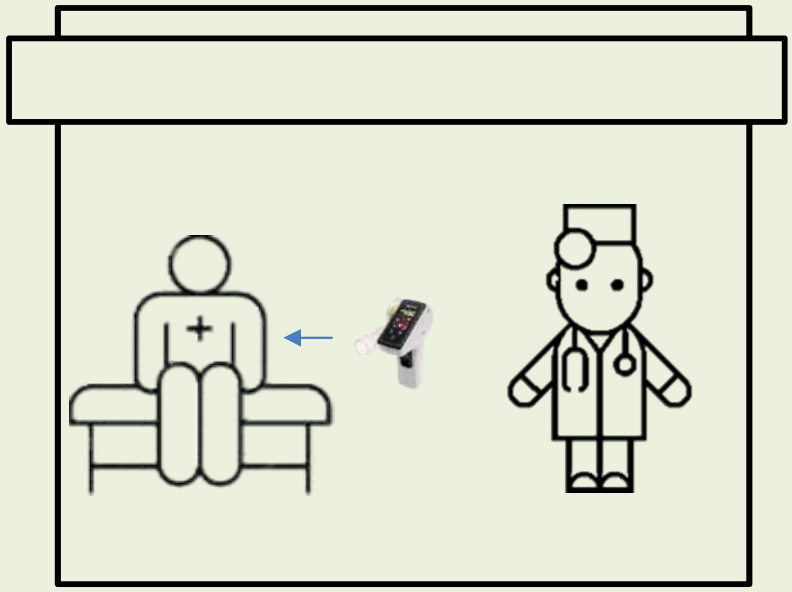
- ✓ Standalone, portable system
- ✓ Fan-based system for the measurement of respiratory impedance at 5 Hz and breathing pattern
- ✓ Integrated PulseOxymetry SpO2 sensor
- ✓ Integrated accelerometer for control of patient position during the test
- ✓ Battery powered, (rechargeable by USB-C, i.e. phone charger), one full charge about 100 measurements
- ✓ Weight <400 gr
- ✓ Data can be downloaded into the RESMON PRO v3 device for further analysis of more parameters, that are recorded but not displayed on the FIRST, or into the DATA VIEWER app for PC

Measured parameters (with CoV% and color coded warnings) :

- ✓ **3 Lung function (oscillometry) parameters :** within-breath and total Resistance and Reactance (INSP, EXP and TOT), tidal Expiratory Flow limitation (**ΔXrs, patented)**
- ✓ **Breathing pattern:** Minute ventilation (VE)
- ✓ **SpO2 and Heart rate (spot check)**

APPLICATION 1: QUICK EVALUATION OF LUNG FUNCTION IN THE HOSPITAL, private clinic, specialist, even at remote locations.

1. The physician uses FIRST as a portable tool for quick evaluation, bedside visits, or measurement on the field.
2. The physician inputs the patient's basic information into the FIRST device.
3. The physician guides the patient through a brief measurement session. Following international ERS technical standards, they collect three measurements, a process that takes just a few minutes.
4. Device displays Rrs, Xrs, and DXrs results, highlighting anomalies.
5. If RESMON PRO FULL v3 is available, the physician can upload data and analyzed for trends, or the PC Data Viewer app can be utilized.



Immediate onscreen results

Data upload on the RESMON PRO FULL and/or On the desktop data viewer

APPLICATION 1/A: Respiratory and neuromuscolar patients rehabilitation. EVALUATION OF SECRETION REMOVAL SESSIONS

1. Before any secretion removal session, the physiotherapist uses the FIRST device to establish a baseline understanding of the patient's airway condition.
2. The physiotherapist carefully administers the secretion removal procedure, ensuring the patient's comfort and safety.
3. Right after the intervention, the physiotherapist turns to the FIRST device again. It allows her to conduct an immediate evaluation to gauge the effectiveness of the secretion removal. The device provides critical data, helping her determine if further intervention is necessary.

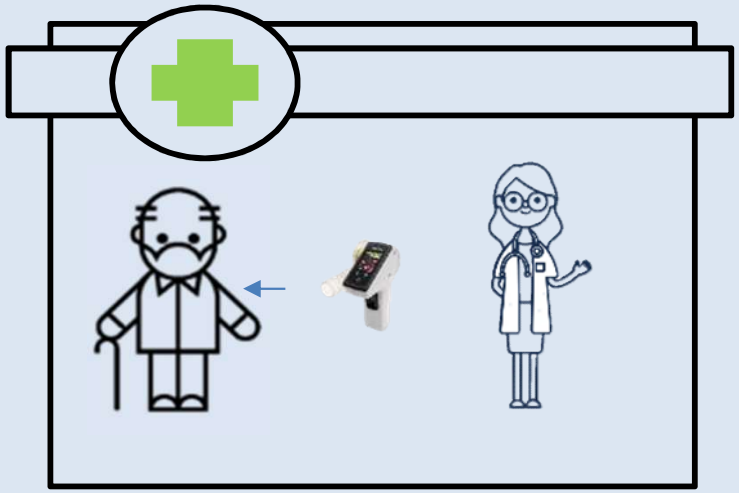
BEFORE

AFTER

Data upload on the RESMON PRO FULL and/or On the desktop data viewer

APPLICATION 2: PRIMARY CARE SCREENING (General Practitioner, Family Pediatrician, Pharmacy) and OCCUPATIONAL MEDICINE screening

1. A patient walks into the clinic with respiratory symptoms or risk factors that raise concerns.
2. The physician gathers important information about the patient's medical history to understand the patient's condition.
3. The physician enters the patient's anthropometric data into the FIRST device.
4. The physician guides the patient through a brief measurement session. Following international ERS technical standards, they collect three measurements, a process that takes just a few minutes.
5. Device displays Rrs, Xrs, and DXrs results, highlighting anomalies.
6. The physician uses these results to support her diagnostic hypothesis. Depending on the findings, she might decide to refer the patient to a pulmonologist for further assessments. A basic report can be printed to share with the specialist.



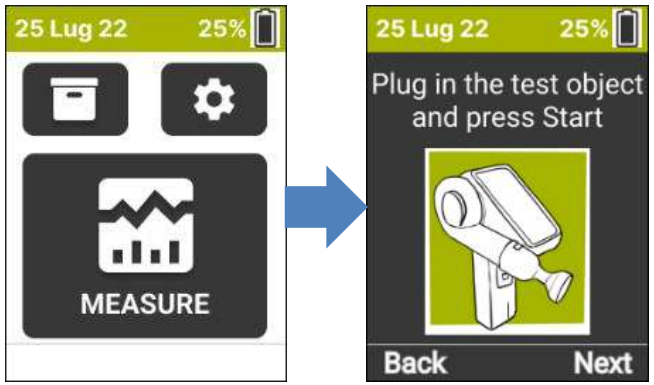
Immediate onscreen results

AND

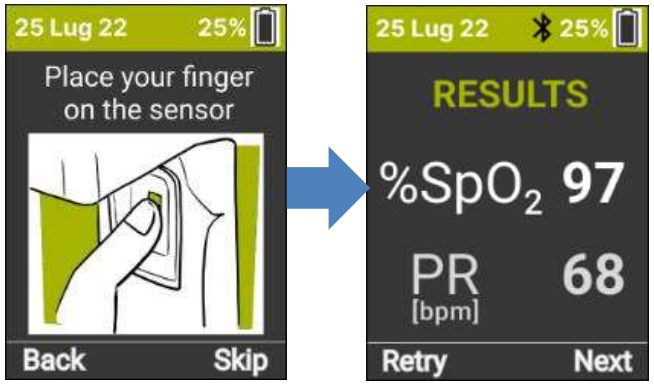
***PC data viewer app*, Reads the memory of FIRST, add patient info, notes, comments,and print with user printer, saves PDF report**

FIRST User Interface : ONLY 6 steps to easy assess lung function

1 ***Power on and daily device verification***



2 ***Measure SpO2 and Pulse rate***

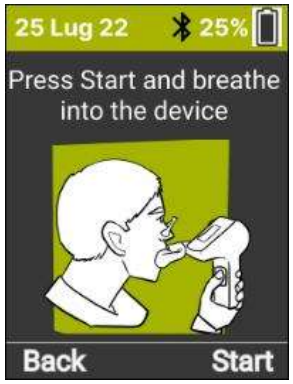


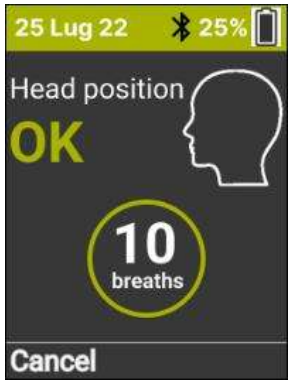
3 ***Enter patient anthropometric info for determination of predicted data from published equations***

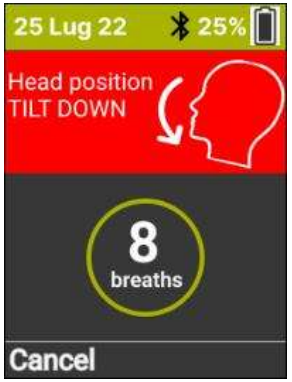
FIRST User Interface : ONLY 6 steps to easy assess lung function

4

Perform measurement (10 accepted breaths) with filter, verify patient neck position

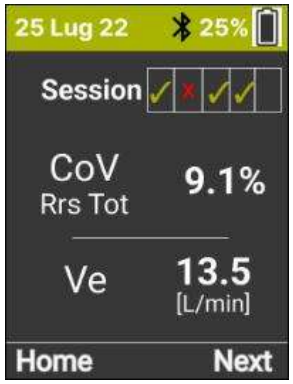


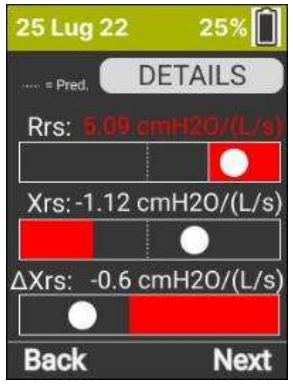




5

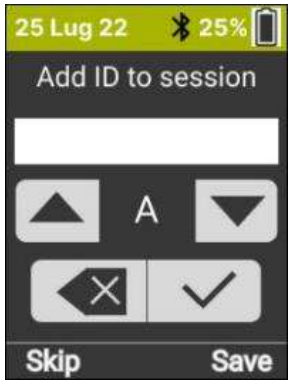
Data evaluation, valid measurements and session Rrs, Xrs and EFL with "quickscreen" and "Details"





6

Enter patient ID for data printout and/or export to Resmon Full V3 (only for clinical report edit/printing)



RESTECH

FIRST - data viewer, desktop software

- ✓ Available for WINDOWS, Soon available for macOS
- ✓ Reads the memory of the FIRST : 15 sessions (up to 5 measurements) displayed on screen, 20 in the internal memory

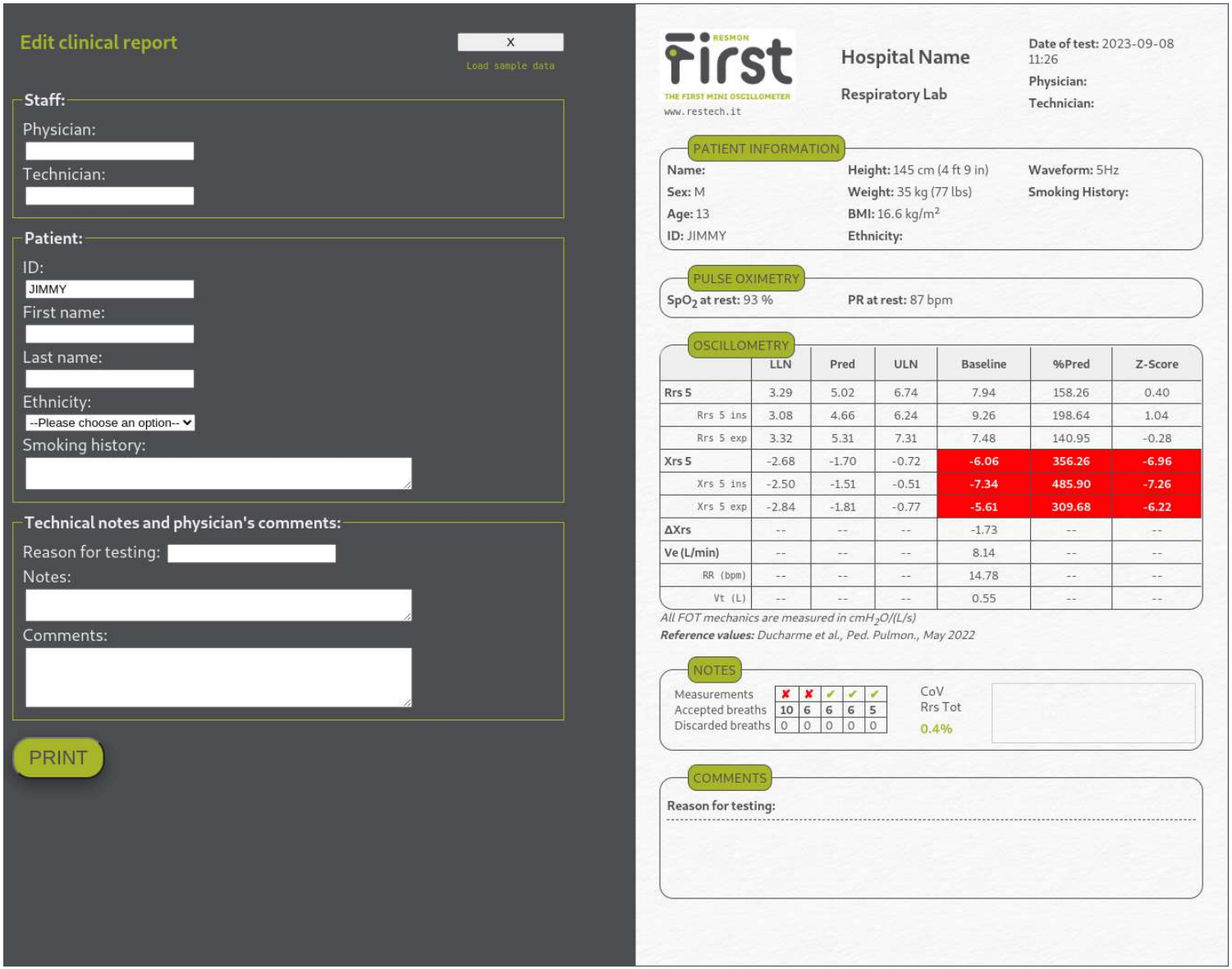
Sessions data

	Date	ID	Sex	Age	SpO_2 [%]	HR [bpm]	#	R_{tot} CoV [%]	Ve [L/min]	R_{tot}	X_{tot}	ΔXrs	Report
1	2023-10-03 15:51	MAT	M	32	96	71	2	9.7	15.2	3.40	-1.15	-0.62	
2	2023-09-29 21:05	ELK01	M	7	-	-	2	2.3	14.6	6.17	-3.10	0.03	
3	2023-09-29 20:48	SAM01	M	4	-	-	2	5.6	6.1	8.86	-4.48	1.38	
4	2023-09-28 18:16	BOND	M	60	-	-	2	1.1	14.7	3.22	-1.31	0.12	
5	2023-09-22 12:07	AE	M	47	93	84	2	7.1	11.2	3.98	**-1.74**	0.66	
6	2023-09-22 11:26		M	47	98	78	3	**11.7**	12.2	4.52	**-2.13**	1.17	
7	2023-09-22 10:57	PA	M	48	93	71	2	4.4	13.2	3.08	-0.67	-0.36	
8	2023-09-21 18:01	GHI	M	60	95	73	2	5.7	7.1	**3.32**	**-2.01**	0.68	
9	2023-09-21 17:56		M	35	-	-	1	0.0	14.0	3.08	-1.21	-0.52	

FIRST - data viewer, desktop software

MAIN FEATURES

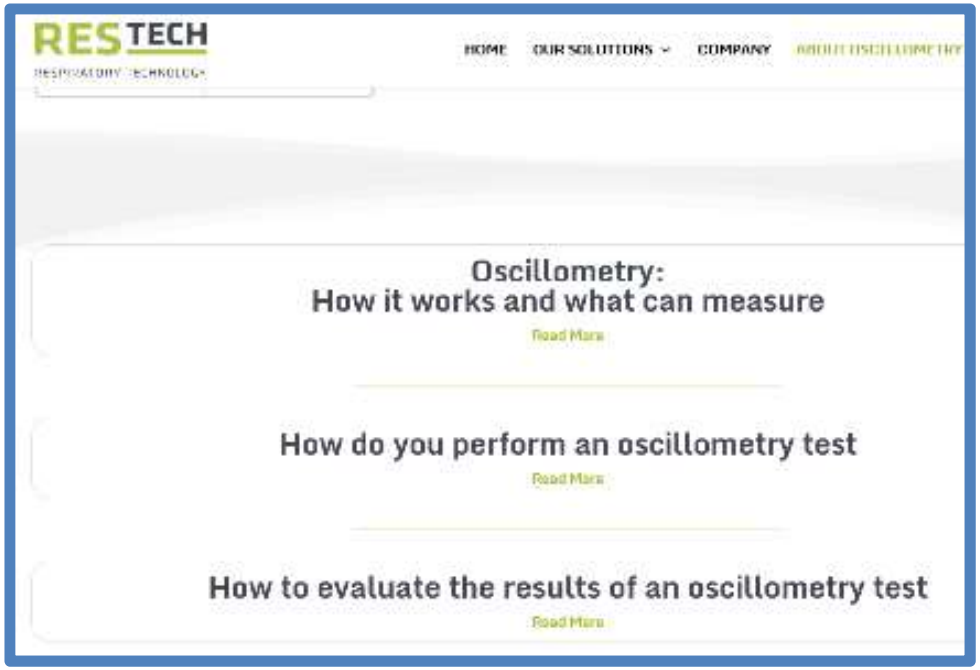
- ✓ Inclusion of patient data
- ✓ Inclusion of technician and physician notes
- ✓ Generation of PDF report for archiving or printing
- ✓ Available for WINDOWS
- ✓ Soon available for macOS



The new RESTECH website :

www.restech.it

- The products (FIRST and Resmon Pro Full V3), with videos, fields of applications, parameters, specifications, videos of the devices in use
- The Company
- For software updates, downloads of FIRST DATA VIEWER APP
- About OSCILLOMETRY – a great educational page with :



Links to the products pages :

FIRST : www.restech.it/project/first/

V3 : www.restech.it/project/resmon-pro/


RESTECH
As simple as breathing
RESMON
First

Resmon FOT products
COMPARATIVE MATRIX

Version 2 – 4th Oct 2023

	First	RESMON PRO FULL
General description and uses		
Automatic breath identification with auto discard of breaths affected by artifacts	YES, NOT EDITABLE	YES, with viewing of the selected breaths with manual selection of breaths and recalculation of the results
Automatic selection of the best 3 measurements that minimizes session variability (CoV)	YES, NOT EDITABLE	YES, EDITABLE: user can enable/disable individual measurements within a session.
Memory storage	> 200 FOT sessions (of up to 5 measurements each)	> 15.000 FOT sessions (of up to 5 measurements each).
Meets 2020 ERS Respiratory Oscillometry technical standards	YES	YES
Measurement age range	pediatric and adult patients 3 (4 in the US) years of age or older	pediatric and adult patients 3 (4 in the US) years of age or older.
Reference equations	Pre-set reference equations covering the entire age range. Not user selectable (ref manual for details)	User-selectable reference equations among a set of 7 different equations for different age ranges and ethnicities
Periodic software updates	N/A to the final user	Regular yearly release of free update distributed to the final user
Internal database	N/A	Relational database allowing storage, searching, editing and review of patients and session data.
Programmable user accounts	N/A	Up to 9 user-defined accounts customizable with specific settings (testing stimulus, duration, clinical report option, preferred reference equations, graph settings)

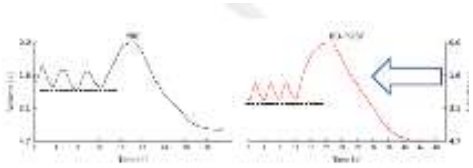
	First	RESMON PRO FULL
Modes and measured parameters		
Single frequency mode	5 Hz	5 Hz, 6 Hz, 8 Hz, 10 Hz
Multi frequency mode	N/A	5-11-19Hz Pseudo Random Noise (5-37 Hz)
Within breath mode	YES	YES
Slow spirometry	N/A	Provides IC and VC with GLI 2020 predicted values
Oscillometry parameters	✓ "within breath" (Insp, Exp and Tot) : single frequency Rrs, Xrs at 5 Hz and EFL	✓ "within breath" (Insp, Exp and Tot) : Rrs, Xrs at all frequencies and EFL ✓ Spectral parameters: Ax and Fres, R5-19
Breathing pattern parameters	VE, RR	VE, RR, Vt, Ti/Tot, VT/Ti, Vt/Te
Closing volume parameters	N/A	Closing Volume (Cvrot) and Critical reactance point (Xcrit)
Specific airway conductance (sGrs)	N/A	YES
Within-breath TIDAL loop analysis	N/A	YES
Saturation and Heart rate	YES	N/A
Reporting and data export		
Clinical report	Basic PDF report of single session generated with the support of an external DATA VIEWER APP.	Programmable PDF report including patient demographics, pre and post sessions, bar charts, frequency spectra, tidal loops and numerical values. Programmable Trends report for monitoring patient progress over time
DATA export/import	✓ Export memory to Resmon V3 for integration into V3 data base, V3 trending and V3 Data output export in CSV/XLS. ✓ CSV data output available through DATA VIEWER PC app	✓ complete CSV/XLS data output ✓ Raw data files ✓ Data import/EXPORT from EXPAIR and BreezeSuite software ✓ Integrated HL7 protocol (under development) ✓ Data import from FIRST device ✓ Direct connection with PS printers

RESMON PRO FULL-V3

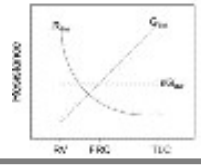
Not just a special FOT device but a HUB for many diagnostic tests and modules

Within-breath FOT, Rrs, Xrs and Tidal EFL (expiratory flow limitation)

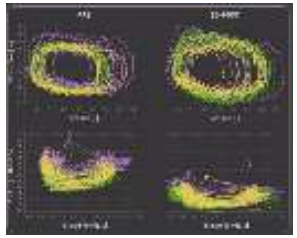
Slow Vital Capacity with Hyperinflation analysis (IC and SVC)



Specific conductance sGrs, by manual input of TLC or FRC, with lung subdivisions graphs and number

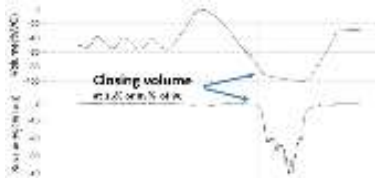


Tidal breathing loops, Flow, Volume, Rrs, Xrs and Zrs



Closing Volume (Xcrit) by FOT, during SVC testing

available in 2023



Full data integration with MGCD/Medisoft PFT, FeNO, Body Box, DLCO, etc.

Neonatal/Infant option with FOT and Tidal Breathing loop graphics and numerical parameters

available in 2024

FIRST, the stand-alone mini-oscillometer, with data upload into Resmon PRO FULL V3

available in 2023

RESTECH

Oscillometry – medical applications

Clinical settings: \ **Possible uses:**	Level of obstruction	Reversibility test	Airways clearance assessment
Pulmonary departments including POST- COVID spec units	✓	✓	✓
Pediatric departments, including off site testing (schools etc.)		✓	✓
Respiratory and Neuro Rehabilitation, Thoracic surgery, physiotherapy	✓		✓
Respiratory Allergy, adult & pediatric		✓	
Occupational medicine, including off site testing (workplace, factories, etc.)	✓	✓	
Cystic fibrosis units			✓

Why should I use oscillometry ?

1 Faster testing

Oscillometry testing requires 3 measurement of 5-10 breaths each for a total of about 5 minutes

2 More comprehensive

Oscillometry provides a more comprehensive assessment of lung function, including small airways that spirometry may miss.

3 Less effort required

Oscillometry requires less effort from the patient, making it more suitable for children and elderly patients.

4 More sensitive to changes

Oscillometry is more sensitive to subtle changes in lung function, making it better for detecting early signs of respiratory disease, even over time.

5 Accepted and standardized

FOT is now internationally standardized, by published technical standards, with reccomendations, measurements rules and thresholds for significant response to treatment

BETTER RESPIRATORY DIAGNOSIS !!!

RESTECH

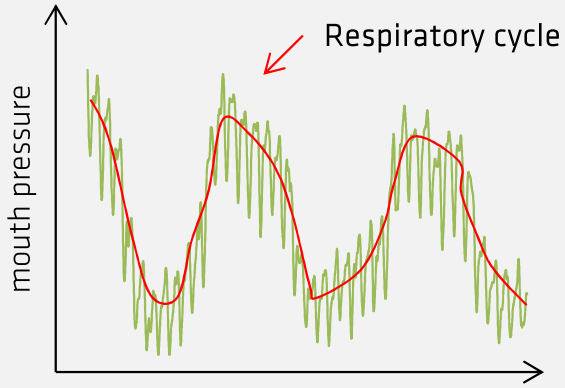
Supplemental educational material

Forced oscillation technique (FOT,oscillometry)

Basic principles:

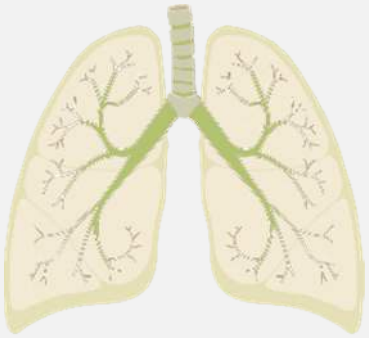
An **external small oscillatory pressure** is applied to mouth, **during normal breathing** and flow and pressure at the airways opening (usually mouth) are measured in real time.

Oscillometry measure quantifies how easy is for the air to move in and out the respiratory system and is represented using RESPIRATORY RESISTANCE and **REACTANCE**



RESISTANCE (Rrs):

- ✓ **measures the degree of airway obstruction** at tidal volume
- ✓ Can be used in pediatric and adult population as a surrogate of spirometry in bronchial reversibility tests



REACTANCE (Xrs):

- ✓ enables the clinician to determine how effectively the lung can be ventilated in its distal areas or **how well air reaches the peripheral areas.**

- ✓ **Within breath changes of Xrs** (ΔXrs = Xexp-Xisp) detects tidal expiratory flow limitation

ADVANTAGES:

- ✓ The test can be executed even in **absence of medical supervision**
- ✓ **Suitable test for children, elderly, severe patients, home monitoring, self-assessment of lung function, screening, measurement during noninvasive ventilation**

RESTECH

Oscillometry: suggested readings and courses

King GG, Bates J, Berger KI, et al. Technical standards for respiratory oscillometry. Eur Respir J. 2020;55(2):1900753. doi:10.1183/13993003.00753-2019

Kaminsky DA, Simpson SJ, Berger KI, et al. Clinical significance and applications of oscillometry. Eur Respir Rev. 2022;31(163):1-19. doi:10.1183/16000617.0208-2021

2022 – An ERS free, online CME course on oscillometry:

https://www.ersnet.org/news-and-features/news/cme-online-oscillometry-forced-oscillation-technique-in-the-assessment-of-respiratory-disease/

RESTECH

ATS 2022 - VALIDATION

In-vitro Validation Of A Novel Handheld Oscillometry Device

D. Bizzotto[1], P. P. Pompilio[2], A. Gobbi[2], R. L. Dellacà[1]

Rationale

The forced oscillation technique (FOT), or oscillometry, uses the flow-response to high-frequency, low-amplitude pressure oscillations applied at the airway opening to evaluate respiratory mechanics during spontaneous breathing. It requires minimal patient cooperation, making this technique ideal for home monitoring [1] and in-field lung function testing. However, current oscillometry devices are too complex, cumbersome, and expensive for large scale applications. Recently, a new small handheld FOT device based on a miniaturized fan for generating a sinusoidal forcing waveform has been developed. This study aims to evaluate the performances of this novel technology on an in-vitro setting.

Methods

The accuracy of oscillatory parameters measured by the handheld FOT device (FOT HH, see Figure 1, RESTECH SRL, Milano, Italy) using 5 Hz pressure waveforms was evaluated against a commercially-available oscillometric device for ambulatory use (FOT PRO, Resmon PRO FULL, RESTECH SRL, Milano, Italy).

Figure 1: Handheld FOT device

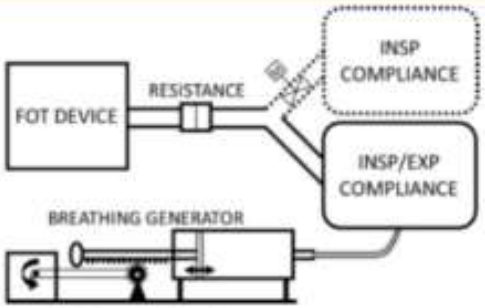


Figure 2: Experimental setup

The comparison was done in vitro by using a specifically-developed breathing test lung. It consisted of mesh-type resistances (Hans Rudolph, Shawnee, KS, USA) connected to glass bottles and a piston-type servocontrolled volume generator used to reproduce human pre-recorded breathing patterns (Figure 2).

The tests were performed on several combinations of two resistances (5 and 15 cmH_2O*s/l) and three glass bottles (3, 5 and 15 l, leading to a reactance of approximately -10.5, -6.9 and -2.3 cmH_2O*s/l, respectively) to simulate different degrees of lung disfunction. Each condition was measured under two different breathing patterns (1: Vt 0.4 l, RR 17 bpm, Ti 1.60 s; 2: Vt 0.28 l, RR = 23.5 bpm, Ti 1.19 s). Within-breath changes of Xrs, hallmark of patients with tidal Expiratory Flow Limitation [2], were simulated by using an electrically-controlled valve activated synchronously with the breathing phase to close the connection of an additional gas bottle during expiration, leading to a decreased expiratory compliance.

Results

The performance of the novel device is reported in the Table I as linear regression parameters and average errors. The correlation coefficient was always > 0.99.

Table I: Linear regression parameters and relative errors between FOT HH and FOT PRO.

	Linear Regression (FOT HH vs. FOT PRO)			Error (FOT HH vs. FOT PRO)		
	R^2	Slope (CI 95%)	Intercept (CI 95%)	mean (%)	std (%)	Range max-min (%)
R_{insp}	1.000	0.98 (0.97;1.00)	-0.28 (-0.48;-0.07)	-4.4	1.7	7.2 - 2.8
R_{exp}	1.000	0.92 (0.90;0.95)	0.24 (-0.16;0.65)	-5.5	1.6	8.0 - 2.9
R_{tot}	1.000	0.95 (0.94;0.96)	-0.01 (-0.18;0.17)	-5.0	0.3	5.5 - 4.6
X_{insp}	1.000	1.11 (1.09;1.12)	0.31 (0.24;0.39)	2.3	5.3	7.4 - 4.3
X_{exp}	0.999	0.99 (0.92;1.05)	-0.01 (-0.47;0.46)	-1.9	5.3	5.4 - 1.7
X_{tot}	1.000	1.04 (1.00;1.08)	0.14 (-0.13;0.41)	0.1	3.8	5.6 - 0.9
ΔX	0.999	1.04 (0.94;1.15)	0.07 (-0.41;0.54)	5.5	5.5	13.9 - 1.5

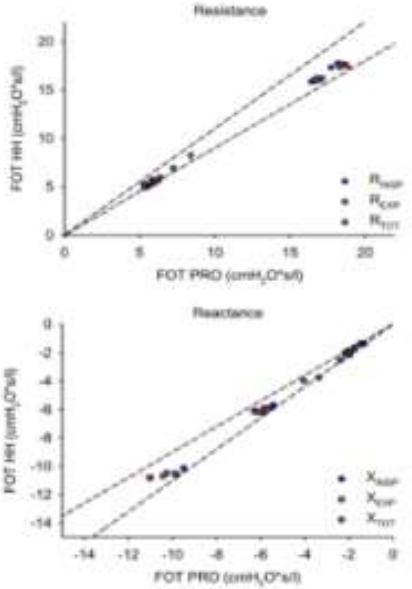


Figure 3: Comparison of resistance and reactance measured by the FOT HH and FOT PRO. Dashed lines represent ± 10% error.

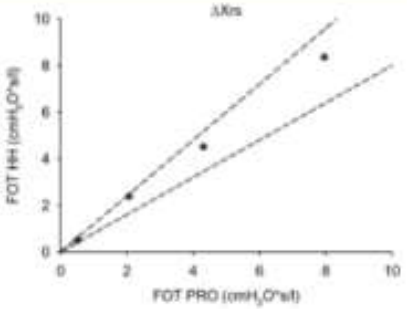


Figure 4: ΔXrs measured by the FOT HH and FOT PRO. Dashed lines represent ± 20% error.

Discrepancies of Rrs and Xrs were always within the 10% limit of agreement (Figure 3), satisfying current FOT technical standards [3]. The maximum error for ΔXrs was lower than the limit of 20% (Figure 4).

Conclusions

The novel fan-based approach allows accurate measurements of oscillatory mechanics with a handheld compact, portable and more accessible device, opening new applications for the diagnosis and management of respiratory conditions outside the lung function test laboratory.

References

1. Walker et al. AJRCCM 2018
2. Dellacà' et al. ERJ 2004
3. King et al. ERJ 2020

Disclosures

P.P., A.G. and R.D. are co-founders and serve as board members of RESTECH s.r.l.

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Accuracy of impedance measurements of a novel handheld oscillometry device

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Introduction

The forced oscillation technique (FOT), or oscillometry, is a noninvasive method to assess lung function during quiet tidal breathing.

FOT is gaining popularity as a complementary or alternative tool to spirometry for assessing physiological dysfunctions of the respiratory system at their early stages.

Moreover, since it requires minimal patient cooperation, this technique has been used for remote patient monitoring programs [1-2] and potentially usable for lung function testing outside the pulmonary function test lab.

Despite these advantages, current oscillometry devices are relatively cumbersome and expensive for large scale applications.

This study aims to evaluate the performances of a recently developed small handheld FOT device based on a miniaturized fan for generating a Pseudorandom Noise (PSRN) forcing waveform[3] an in-vitro setting.

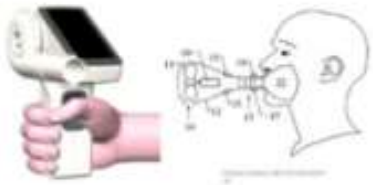

Figure 1: Handheld FOT device

References:
1. Walker et al., J Allergy Clin Immunol 2016
2. Dellacà et al., ERJ Open Res 2017
3. WO2021/251833 - System and method for measuring the mechanical impedance of the respiratory system

Methods

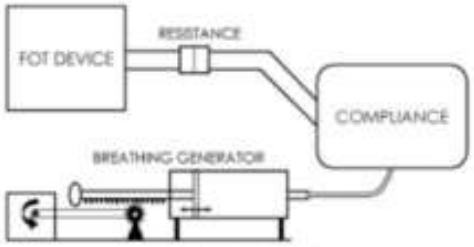

Figure 2: Experimental setup

The handheld device (FOT HH) has been validated against a commercial oscillometry device (Resmon Pro Full V3, Restech srl, Italy) using an active test lung that comprises multiple combinations of resistances and reactances among:

- Two resistance values
  - 5 cmH_2O*s/L
  - 15 cmH_2O*s/L
- Three glass bottles
  - 3 L (Xrs = -10.5 cmH_2O*s/L)
  - 5 L (Xrs = -6.9 cmH_2O*s/L)
  - 15 L (Xrs = -2.3 cmH_2O*s/L)

During the tests, a flow-volume simulator was used to reproduce pre-recorded breathing patterns:

1. VT = 0.40 L, RR = 17.0 bpm, TI = 1.60 s;
2. VT = 0.28 L, RR = 23.5 bpm, TI = 1.19 s

The tests were performed using PSRN (5-11-19 Hz) excitation signal for both oscillometry devices.

Results

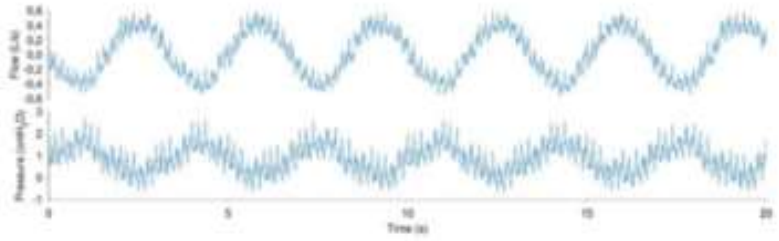

Figure 3: Example of flow and pressure signals during the oscillation of the PSRN using the handheld FOT device.

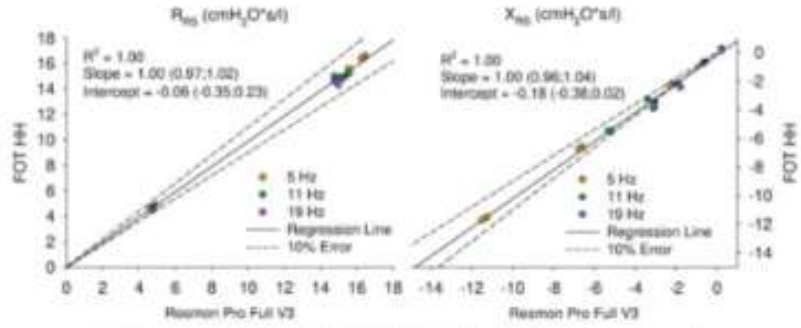

Figure 4: Comparison of resistance and reactance measured by the FOT HH and Resmon Pro Full V3.

The fan/blower-based handheld oscillometer provides accurate measurements of respiratory resistance and reactance using PSRN at 5-11-19 Hz.

With a patient breathing load < 1 cmH_2O*s/L and an overall dead space of ~17 ml, the handheld oscillometer is suitable for oscillometry applications in adult and pediatric range.

TECHRESS

Novel miniaturized handheld oscillometry device provides accurate measurement of respiratory impedance.

Conclusions:

- The novel fan-based oscillometry device is accurate and smaller, more lightweight, and less expensive compared to current devices;
- These features enable new applications of oscillometry outside the lung function test laboratories (e.g., home monitoring, points of care, GPs, pharmacies, etc.).

RESMON First

THE FIRST MINI OSCILLOMETER