RESTECH
RESPIRATORY TECHNOLOGY

spin off
POLITECNICO DI MILANO

Instruction Manual
Resmon PRO™ FULL

(ref: RT1100)

Device for the assessment of lung function

Please review this manual before utilizing the device

Revision 20 – July 2019

This revision of the instruction manual has been released from software version 6.1.1.

CE 0051

Copyright

Notes

Names of persons mentioned in the context of this manual are fictitious and any resemblance to living or deceased persons is purely incidental and not intended.

In case of ambiguities and/or errors, the English version of this manual is to consider the original.

Declaration of conformity

The present device is classified as a medical device class IIA according to the MDD 93/42/EEC. The device has been designed in accordance with the requirements of the EN 60601-1:2006 3rd Ed / IEC 60601-1 3rd Ed and following editions.

Restech Srl
Via Melchiorre Gioia, 63
20124 Milano – Italy
Web: www.restech.it
Email: support@restech.it

CE 0051

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Table of contents

Symbols in the Instruction Manual

SYMBOLS FOR NOTES ON SAFETY

Please note that specific passages of this Instruction Manual are clearly marked as safety notes.

 CAUTION

CAUTION 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

NOTE indicates important or useful information on use.

OTHER SYMBOLS / ICONS

Additional icons are reported on the device and used in the Instruction Manual:

WHERE YOU FIND IT	SYMBOL	MEANING
Device Screen		Go to Home Page
		Go to Previous Page
		Browse the Database
		Make a New Test
Device Labeling		Manufacturer
		Type B Applied Part
		CE Mark
	IP21	Degree of protection provided by enclosure

	Rx Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
		Consult Instruction Manual
		Direct Current Power Supply
Device Back Lid		Ethernet
		USB
		Landline Modem (if available)

List of abbreviations

f_{res}	Resonant frequency
BMI	Body Mass Index
BTPS	Body Temperature and Pressure, Saturated
CV	Coefficient of Variation
ERV	Expiratory Reserve Volume
IC	Inspiratory Capacity
PSRN	Pseudo Random Noise
RR	Respiratory Rate
Rinsp	Mean Inspiratory Resistance
Rexp	Mean Expiratory Resistance
Rtot	Mean Resistance of the whole breath
Rrs	Respiratory Resistance
R5	Resistance at the Frequency of 5 Hz
R_{5-19}	Difference between inspiratory resistance at 5Hz and 19Hz
SD	Standard Deviation
SVC	Slow Vital Capacity
Ti	Inspiratory Time
Te	Expiratory Time
Ttot	Total Duration of the Breath
VC	Vital Capacity
Ve	Ventilation
Vol	Volume
Vt	Tidal Volume
Vt/Ti	Mean Inspiratory Flow
Vt/Te	Mean Expiratory Flow
Xinsp	Mean Inspiratory Reactance
Xexp	Mean Expiratory Reactance
Xtot	Mean Reactance of the whole breath
Xrs	Respiratory Reactance
X5	Reactance at the Frequency of 5 Hz
Z	Respiratory Impedance
ΔXrs	Difference Between Mean Inspiratory and Mean Expiratory at 5 Hz
ρ	Coherence

List of the units of measurement

PHYSICAL QUANTITY	AVAILABLE UNITS OF MEASUREMENTS (For more information see section *CHANGE USER SETTINGS*)		
	Default format	Other available format(s)	
BMI	Kg/cm^2		
Date format	dd/mm/yyyy	mm/dd/yyyy	yyyy/mm/dd
f	Hz		
Height	cm	in	
R/X/Z	$cmH_2O \cdot s \cdot L^{-1}$		
RR	bpm (breaths per minute)		
Room Humidity	%		
Room Pressure	mmHg		
Room Temperature	°C		
Ve	L/min		
Vt, Vol, VC, SVC and IC	L		
Vt/Ti	L/s		
Vt/Te	L/s		
Weight	Kg	lbs	

Descriptive Information

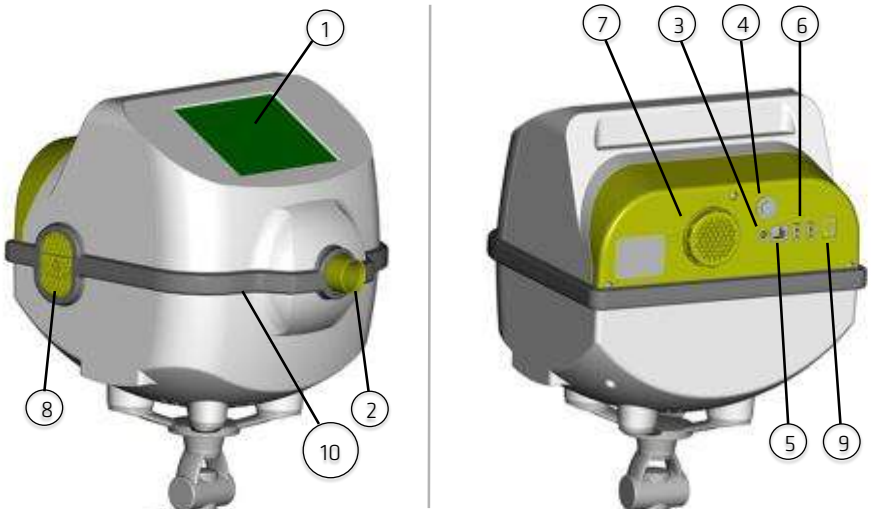
INDICATIONS FOR USE

The Resmon PRO FULL is intended to measure respiratory system impedance using the Forced Oscillation Technique (FOT). Resmon PRO FULL is intended for use with pediatric and adult patients 4 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, and private physician offices.

DESCRIPTION OF THE DEVICE

Resmon PRO FULL is a device for the assessment of the mechanical impedance based on the Forced Oscillation Technique (FOT). FOT is a non-invasive method for measuring the mechanical properties of the respiratory system and is not intended to be used as a stand-alone diagnostic device. With FOT, the respiratory system is stimulated by pressure oscillations, which evaluate its mechanical response in terms of impedance. Impedance is the complex ratio between pressure and flow estimated at the frequency of the stimulating signal, ranging from a simple sinusoid wave or a composite of different frequencies. The first approach is utilized for tracking swift changes in respiratory impedance. Examples of this would include breath changes in lung mechanics or outcome measurements of specific interventions. The latter is used to assess the frequency dependency of impedance (related to the degree of lung heterogeneity) and identify the parameters of mathematical models of the respiratory system. The most attractive feature of FOT from a clinical stand point is that the measurement occurs during a patient's normal breathing pattern, with no forced effort required. FOT is particularly suitable for monitoring non-cooperative patients, such as elderly patients or very severely ill patients with limited forced capacity.

DEVICE STRUCTURE



1. Touchscreen Display and Screen Cover
2. Barrier Filter Connection
3. Power Supply Outlet
4. Power On Button
5. Ethernet Port
6. USB Port
7. Cover of the Air Filter
8. Inlet of Ambient Air
9. Landline Modem (Optional)
10. Silicone Seal

ACCESSORIES

The following accessories are included with the device:

1. Instruction Manual
2. Test Object (A test fixture with a known impedance that is used to verify the factory calibration of the device) (Figure 1)

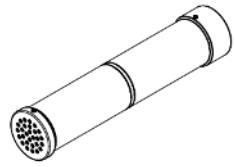


Figure 1 - Test Object

3. Device Holder
4. Stylus (quantity of 2)
5. Ethernet Cable
6. USB Cable
7. Power Supply

POWER SUPPLY SPECIFICATIONS
Mod: FW7405M/15 FRIWO Geratebau GmbH
Input frequencies: 50-60Hz
Input voltage: 100-240 V
Output voltage: 15 V DC
Maximum current: 3.0 A
Polarity: ⊖—◉—⊕

CAUTION	THE POWER SUPPLY PROVIDED BY THE MANUFACTURER IS COMPLIANT WITH EN 60601-1. DO NOT USE A NON-COMPLIANT POWER SUPPLY. IF THE POWER SUPPLY IS DAMAGED OR LOST CALL THE DISTRIBUTOR (SEE SECTION *User Assistance Information)*

CAUTION	USE OF ACCESSORIES OTHER THAN THOSE PROVIDED BY THE MANUFACTURER OR IN CONFIGURATIONS DIFFERENT FROM THOSE REPORTED IN THIS MANUAL MAY ALTER THE PERFORMANCES OF THE DEVICE. IF ANY ACCESSORIES ARE DAMAGED OR LOST CONTACT THE DISTRIBUTOR (SEE SECTION *User Assistance Information)*

DISPOSABLES

The following disposables are not supplied with the device but are required to perform testing procedure correctly. For further information on their use with the device, please see section *Preparing the device for a test session*..

1. Nose-clip: any nose-clip suitable for pulmonary function tests.
2. Anti-bacterial anti-viral barrier filter: any filter suitable for pulmonary function tests that meets the following specifications:
    a. Resistance must be < 0.7 $cmH_2O \cdot s \cdot L^{-1}$ at 1 L/s
    b. The inner diameter of the connector must be 30mm
    c. Viral and Bacterial filtration efficiency > 99.99% at 30 L/min

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

To increase the comfort of the patient, you may consider connecting a single use, single patient mouthpiece or mask to the filter on the patient's side. Any mouthpiece suitable for

pulmonary function test or mask that allows the exclusion of the nose and that can be connected to your filters can be used. The use of mouthpieces/masks is not mandatory. For a proper use and disposal of mouthpieces/masks, follow the instructions for use of their manufacturers and the additional provisions and regulations of your hospital or institution.

 CAUTION	THE USE OF DISPOSABLES WHICH FAIL TO COMPLY WITH THE SPECIFICATIONS INDICATED ABOVE MAY REDUCE THE ACCURACY OF THE MEASUREMENTS. THE MANUFACTURER RECOMMENDS SPECIAL ATTENTION TO THE PATIENT'S POSTURE DURING TESTING TO ASSURE THAT THE UPPER AIRWAYS ARE NOT PARTIALLY OR COMPLETELY OCCLUDED BY THE TONGUE OR BY THE TEETH. FOR MORE INFORMATION ABOUT THE POSTURE SEE SECTION *PREPARE THE PATIENT FOR THE TEST*.

Instructions for your safety

 CAUTION	ONLY CONNECT THE RESMON PRO FULL TO EXTENSION CORDS OR OUTLET STRIPS IF THEY ARE COMPLIANT WITH ALL THE REQUIREMENTS OF EN 60601-1-1. DO NOT CONNECT OTHER OUTLET STRIPS TO THE OUTLET STRIP OF THE RESMON PRO FULL. DO NOT PUT THE OUTLET STRIP ON THE FLOOR. OTHER DEVICES THAT ARE NOT PART OF THE RESMON PRO FULL SHOULD NOT BE PLUGGED TO THE OUTLET STRIP.

 CAUTION	TO REDUCE THE RISK OF FIRE AND ELECTRICAL SHOCK AND PREVENT ELECTRICAL INTERFERENCE, USE ONLY ACCESSORIES PROVIDED WITH THE DEVICE.

 CAUTION	DO NOT EXPOSE THE DEVICE TO CONDENSING HUMIDITY.

 CAUTION	DO NOT OPEN THE DEVICE. THERE ARE NO USER ADJUSTABLE COMPONENTS IN THE DEVICE.

General precautions

CAUTION	FAILURE TO OBSERVE THE PRECAUTIONS LISTED BELOW MAY CAUSE RISKS FOR THE PATIENT, 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 openings on the bottom of the device. The occlusion may worsen the quality of the measurement and may cause over-heating of the device.

- Pressing hard on the touch-screen could damage the screen and display integrity.

- Always use an antibacterial filter in order to avoid cross-contamination among patients.

- Ensure that the metal mesh of the flow sensor is not occluded. An occlusion of the mesh could result in a significant change in the measured parameters and produce unreliable results.

- If the holder should become damaged, remove the device from the holder and contact the distributor (see section *User Assistance Information*). If the device

falls from the holder, this could injure the subject or user and cause malfunctions of the device itself.

- Should the chassis be damaged, disconnect it from the power supply and contact the distributor (see section *User Assistance Information*).

- In case the display is damaged or malfunctioning, contact the distributor (see section *User Assistance Information*). The display buttons and instructions are essential for the proper use of the device.

- If the packaging is damaged at the time you receive the device, contact the distributor before using it (see section User Assistance Information).

- Do not use the device in oxygen rich environments.

- The use of this device could be contraindicated in patients with known sensitivities or allergies to the following components: ABS (acrylonitrile butadiene styrene), Silicone, Stainless Steel, Polypropylene, Acrylic, Polycarbonate, Nylon, Aluminium and PET (polyethylene terephthalate).

Technical specifications

Flow measurement	Mesh type	
	Range	± 2L/s
	Linearity	< ± 2% in the range ± 1.5L/s
Mouth pressure	Range	± 2.5 kPa
	Linearity	0.05 %fs
	Resolution	0.015 cmH_2O
Test signals	Amplitude	Max 3 cmH_2O peak-to-peak
	Within-breath protocols	5Hz, 6Hz, 8Hz, 10Hz and 5-11-19Hz
	Frequency-dependence protocols	5-37Hz Pseudo-Random Noise (PSRN)
Accuracy of the measurement	For impedance parameters	$\leqslant$ 0.1 $cmH_2O{\cdot}s{\cdot}L^{-1}$ or $\leqslant$ 10% of the measured value
	For breathing pattern parameters	$\leqslant$ 10% of the measured value
	For volume parameters	**≤ ±**100 mL or **≤ ±**3.5% of the measured value
Impedance magnitude range at specified frequency	5Hz, 6Hz or 8Hz	0 – 25 $cmH_2O{\cdot}s{\cdot}L^{-1}$
	10Hz	0 – 21.4 $cmH_2O{\cdot}s{\cdot}L^{-1}$
	5-11-19Hz	0 – 15 $cmH_2O{\cdot}s{\cdot}L^{-1}$
	PSRN	0 – 8.8 $cmH_2O{\cdot}s{\cdot}L^{-1}$
Calibration and calibration check	• Factory calibration according to international recommendations + auto-zeroing of the sensors before each test • Calibration check with a test object (supplied with the device) and with a 3L calibration syringe (not supplied with the device), required for the measurement of slow spirometry volumes	
Total load to the patient	0.25 - 0.49 $cmH_2O{\cdot}s{\cdot}L^{-1}$ in the frequencies of normal breathing (0.1 – 1 Hz)	
Device dead space	35 mL	
Applied Part/s	Inlet of the device	

Connectivity	2 USB full speed (2.0) to connect external USB flash memories or printers. Note: Resmon PRO FULL is compatible with some postscript printers. Please contact the distributor (see section *User Assistance Information*) to know the list of verified USB printers.	
	Ethernet 10/100	
Display	5.7'' LCD backlight touchscreen display	
Electrical specifications	Power supply	100-240V, 50/60 Hz 60W input AC / 15VDC 3A output power supply (supplied with the device)
	Stand-by current	250 mA
	Average current during the measurement	1500 mA
Dimensions	89 x 55 x 26 cm	
Weight of the box	9 Kg	
Noise (measured at a distance from the device equal to the average distance of the patient's ear from the device while making a test – Phonometer: SL4023 SD – Class II – Time Constant: Slow)	Type A Filter	< 64 dB rms

Electromagnetic compatibility

During the immunity testing described below Resmon PRO FULL was found to operate without interference.

The information contained in this section (such as separation distances) is in general specifically written with regard to the Resmon PRO FULL. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes:
Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the remainder of the instructions for use this device.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

 CAUTION	USE ONLY LAN CABLES (ref. RT3031) AND USB CABLES (ref. RT3032) APPROVED BY THE MANUFACTURER. FOR TECHNICAL ASSISTANCE CONTACT THE LOCAL DISTRIBUTOR (SEE SECTION *User Assistance Information)*.

Care should be taken if the equipment is used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic *Emissions*		
This Resmon PRO FULL is intended for use in the electromagnetic environment specified below. The user of the Resmon PRO FULL should assure that is used in such an environment.		
Emissions	*Compliance according to*	*Electromagnetic environment*
RF emissions (CISPR 11)	*Group 1*	*The Resmon PRO FULL uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
CISPR Emissions Classification	*Class B*	*The Resmon PRO FULL is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.*
Harmonic emissions (IEC 61000-3-2)	*Not Applicable*	
Voltage fluctuations / flicker (IEC 61000-3-3)	*Complies*	

Electromagnetic Immunity			
The Resmon PRO FULL is intended for use in the electromagnetic environment specified below. The user of the Resmon PRO FULL should assure that is used in such an environment.			
Immunity against	**IEC 60601-1-2 test level**	**Compliance level (of this device)**	**Electromagnetic environment**
Electrostatic discharge, ESD (IEC 61000-4-2)	*Contact discharge: ± 6 kV* *Air discharge: ± 8 kV*	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients / bursts (IEC 61000-4-4)	*Power supply lines: ± 2 kV* *Longer input/output lines: ± 1 kV*	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges on AC mains lines (IEC 61000-4-5)	*Common mode: ± 2 kV* *Differential mode: ± 1 kV*	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	*3 A/m*	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
Voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	*<5% U_T (>95% dip in U) for 0.5 cycle* *40% U_T (60% dip in U) for 5 cycles* *70% U_T (30% dip in U) for 25 cycles* *<5% U_T (>95% dip in U) for 5 s*	*<5% U_T (>95% dip U_T) for 0.5 cycle* *40% U_T (60% dip in U) for 5 cycles* *70% U_T (30% dip in U) for 25 cycles* *<5% U_T (>95% dip in U) for 5 s*	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Resmon PRO FULL requires continued operation during power mains interruptions, it is recommended that the Resmon PRO FULL be powered by an uninterruptible power supply or a battery.
NOTE UT is the a.c. mains voltage prior to application of test level			

Electromagnetic Immunity			
The Resmon PRO FULL is intended for use in the electromagnetic environment specified below. The customer or the user of the Resmon PRO FULL should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF *RF coupled into lines* *(IEC 61000-4-6)*	*150 kHz to 80 MHz*	*3 Vrms*	Portable and mobile RF communications equipment should be used no closer to any part of the Resmon PRO FULL, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. **Recommended separation distance** d=1.2/√P
Radiated RF *(IEC 61000-4-3)*	*3 V/m* *80 MHz – 2.5 GHz*	*3 V/m*	d=1.2/√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theorectically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Resmon PRO FULL is used exceeds the applicable RF compliance level above, the Resmon PRO DIARY should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Resmon PRO FULL.

[b] Over the frequency range 150 kHz to 80 MHz, field strenghts should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the equipment

The Resmon PRO FULL is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Resmon PRO FULL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipments (transmitters) and the Resmon PRO FULL as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitters in meters		
	150 kHz – 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Setup

CHOOSE THE RIGHT PLACE FOR SETUP

Place the device on a horizontal surface in a cool, dry environment with a controlled temperature, as suggested in the section *Operating and Storage Conditions*. Identify a proper place for the setup next to an electrical outlet. Other setup configurations are not permitted by the manufacturer.
The device should then remain in the same place after setup.

CAUTION	DO NOT PLACE THE DEVICE IN SUCH A POSITION THAT MAY HINDER THE ABILITY TO DISCONNECT THE DEVICE FROM THE POWER SUPPLY.

ASSEMBLING THE HOLDER

Figure 2 shows the holder and its components.

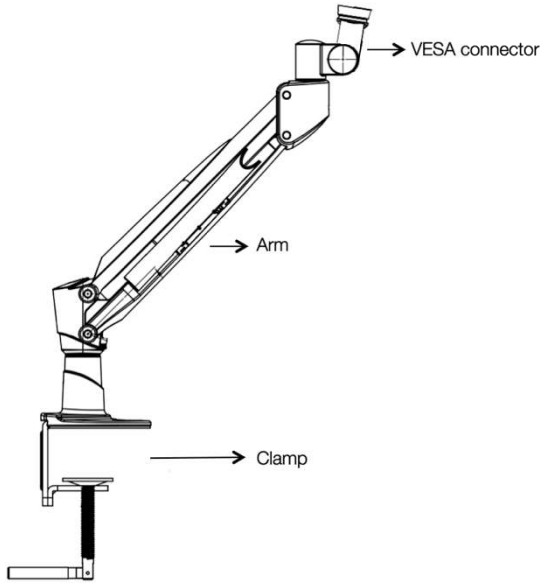


Figure 2 - Arm Bracket

1. **Tighten the clamp to the desk surface.** Use the protection pad provided with the device to protect the surface.

CAUTION	IF THE HOLDER IS NOT FIRMLY ATTACHED TO THE SURFACE (DESK OR TABLE) THE DEVICE MAY FALL CAUSING POSSIBLE DAMAGE TO THE DEVICE OR USERS. FASTEN THE CLAMP SECURELY BEFORE USING THE DEVICE.

CAUTION	THE DESK OR TABLE MUST BE OF ADEQUATE DIMENSIONS AND WEIGHT TO SECURELY PREVENT THE DEVICE FROM TIPPING OVER.

2. **Connect the arm to the clamp** as shown in Figure 3.

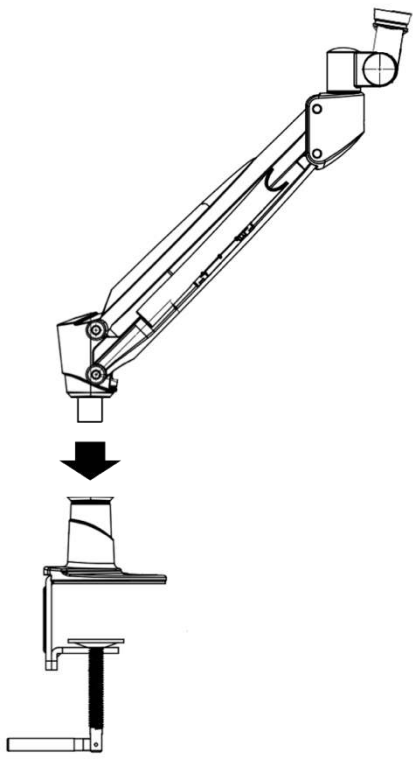


Figure 3: Insert arm bracket into opening on the clamp

CAUTION	PAY ATTENTION WHEN INSERTING THE ARM INTO THE CLAMP TO AVOID INJURY TO HANDS OR FINGERS.

3. **Adjust the orientation of the VESA connector** as shown in Figure 4. To do it, loosen the nut with the tool provided with the device, change the orientation to be between 5 and 10 degrees as shown in Figure 4 and then tighten the nut again.

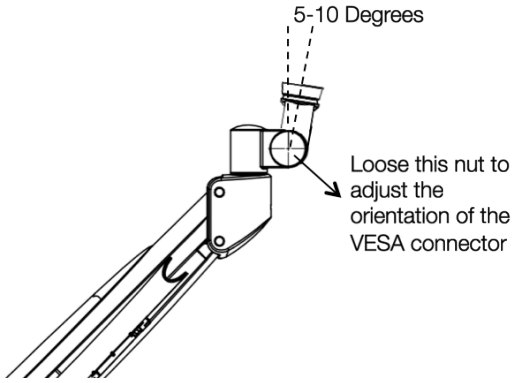


Figure 4 – Adjust the orientation of the VESA connector

CAUTION	PAY ATTENTION WHEN ADJUSTING THE ORIENTATION OF THE VESA CONNECTOR TO AVOID INJURY TO HANDS OR FINGERS.

CAUTION	A CORRECT SETUP OF THE VESA CONNECTOR WILL GUARANTEE AN EFFECTIVE CLEANING OF THE DEVICE (SEE SECTION *Cleaning*). IT WILL ALSO HELP THE PATIENT ASSUME A PROPER POSTURE DURING THE TEST (SEE SECTION *Preparing the patient for a test*).

FASTEN THE DEVICE TO THE ARM

On the bottom of the device there is a connector (see Figure 5). Pull the round pin and turn it counter-clockwise to open. Connect the arm to the connector, turn it clockwise to close and lock it in place. The connector has a shape that allows only one orientation of the device and a complete closing of its lock.

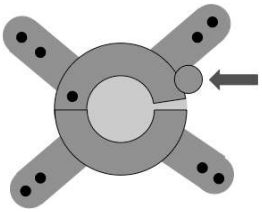


Figure 5: VESA connector, the arrow indicates the safety locker that should be properly engaged to guarantee a secure connection between the device and the holder.

CAUTION	MAKE SURE THAT THE SAFETY LOCK IS PROPELY LOCKED BEFORE USING THE DEVICE.

CAUTION	IF THE HOLDER IS DAMAGED, DO NOT USE THE DEVICE. REMOVE THE DEVICE FROM THE HOLDER AND CONTACT THE DISTRIBUTOR (SEE SECTION *User Assistance Information).*

MOUNT/REMOVE THE SILICONE SEAL

CAUTION	TO AVOID CONTAMINATION OF THE DEVICE AND CROSS-INFECTION AMONG PATIENTS THE SILICONE SEAL MUST BE USED. FOR MORE INFORMATION ON THE CLEANING AND DISINFECTION PROCEDURES, SEE SECTION *Cleaning* .

To mount the silicone seal, insert it into its housing starting from the front side (Figure 6). Peel off the internal adhesive layer and attach it to the surface of the device. Check that no gaps are left between the device and the silicone seal, especially around the inlet of the device and its front parts.

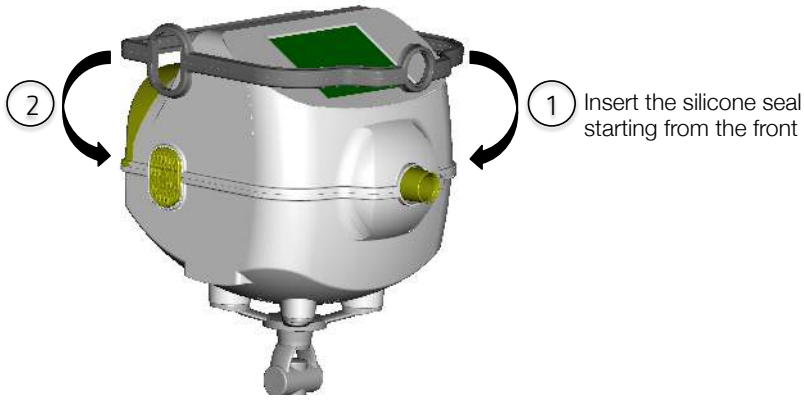


Figure 6 – Mount the silicone seal

To remove the silicone seal, pull it slightly upward starting from the backside of the device (Figure 7). Even if the silicone seal is in a good state, it is recommended to replace it once every three months.

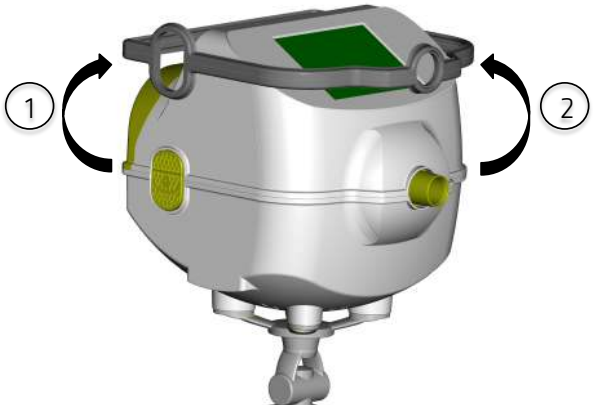


Figure 7 – Remove the Silicone Seal

MOUNT/REMOVE THE SCREEN COVER

CAUTION	TO AVOID CONTAMINATION OF THE DEVICE AND CROSS-INFECTION AMONG PATIENTS THE SCREEN COVER MUST BE USED. FOR MORE INFORMATION ON THE CLEANING AND DISINFECTION PROCEDURES, SEE SECTION *Cleaning* .

To mount a new screen cover, peel it off and apply it to the display (Figure 8). Be sure that its borders are completely glued to the surface of the device. To remove the screen cover, pull it up slightly (Figure 8).

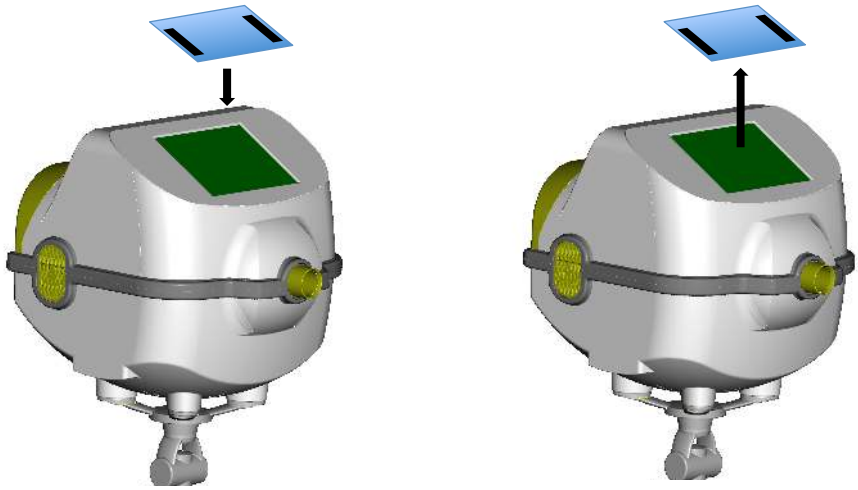


Figure 8 – Mount (left) and remove (right) the Screen Cover

NOTE	PLEASE DO NOT DISPOSE OF THE PACKING MATERIAL. REUSE IT IF THE DEVICE NEEDS TO BE SHIPPED AGAIN, FOR EXAMPLE FOR SERVICING. IF THERE IS A PROBLEM, CONTACT THE LOCAL DISTRIBUTOR (SEE SECTION *User Assistance Information*).

Turning on/off the device

TURNING ON THE DEVICE

Plug the device into the power supply and connect this to the power supply outlet.

CAUTION	THE POWER SUPPLY PROVIDED BY THE MANUFACTURER IS COMPLIANT WITH EN 60601-1. DO NOT USE THE DEVICE WITH A NON-COMPLIANT POWER SUPPLY. IN CASE OF DAMAGE OR LOSS OF THE POWER SUPPLY CONTACT THE DISTRIBUTOR (SEE SECTION *User Assistance Information*).

Press the *POWER ON BUTTON* in the back of the device and hold for a second. After few seconds, the screen displays RESMON PRO (Figure 9). Wait until the system loading is complete before moving forward.

Figure 9 – System Loading

TURNING OFF THE DEVICE

To turn the device off go to the *HOME PAGE* display screen by pressing the *HOME BUTTON* in the header, select *LOGOUT* and then select *SHUTDOWN*. The message shown in Figure 10 will be displayed.

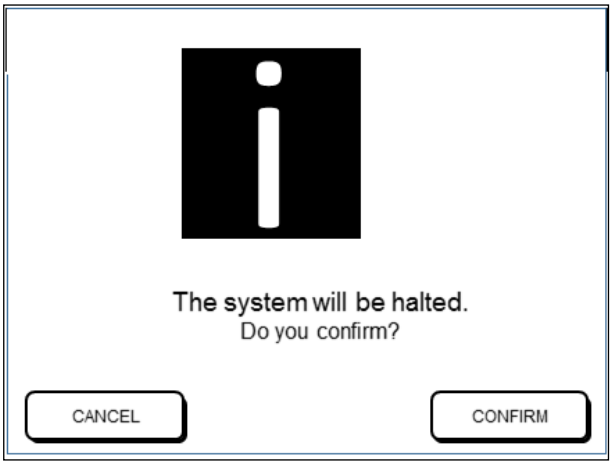


Figure 10 – Power Off Screen

Press *CONFIRM* to power off the device.

CAUTION	IN ORDER TO GUARANTEE ELECTRICAL SAFETY, WHEN THE DEVICE IS NOT IN USE UNPLUG THE POWER SUPPLY. THE GREEN LED “ON” INDICATES THAT THE POWER SUPPLY IS PLUGGED IN. THIS LIGHT SHOULD BE OFF WHEN THE DEVICE IS NOT BEING USED.

First log-in and the *ADMIN* account

When the device is turned on the log in page will display (Figure 11). At first log-in only the ADMIN user is present.

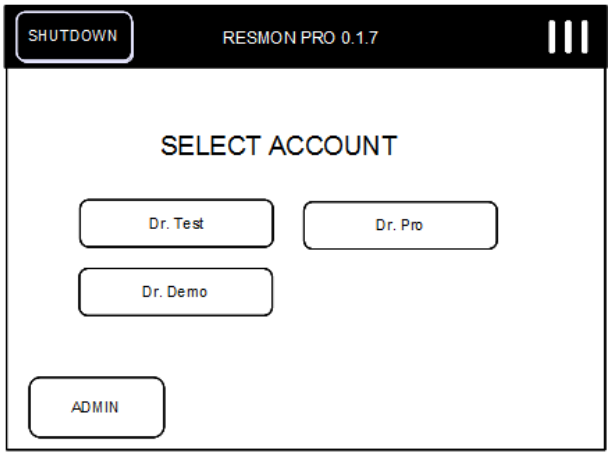


Figure 11 - Select Account

Press the ADMIN button and enter the password. The default password for ADMIN is 12345.

CAUTION	THE ADMIN USER CAN MODIFY THE MAIN CONFIGURATIONS OF THE DEVICE. CHANGE THE PASSWORD OF ADMINISTRATOR AFTER FIRST LOG-IN. PRESS *ACCOUNTS – RESET PASSWORD – ADMIN* AND TAKE NOTE OF THE NEW PASSWORD. FOLLOW THE SAFETY REGULATIONS OF YOUR INSTITUTION TO MANAGE THIS PASSWORD.

ADMIN is enabled to modify the device settings but not to perform measurements nor to access the database. In order to perform testing with the device it is necessary to create additional user accounts. ADMIN login brings to the Settings Page (Figure 12). Select *LOGOUT* in the header bar if you want to exit Settings Page.

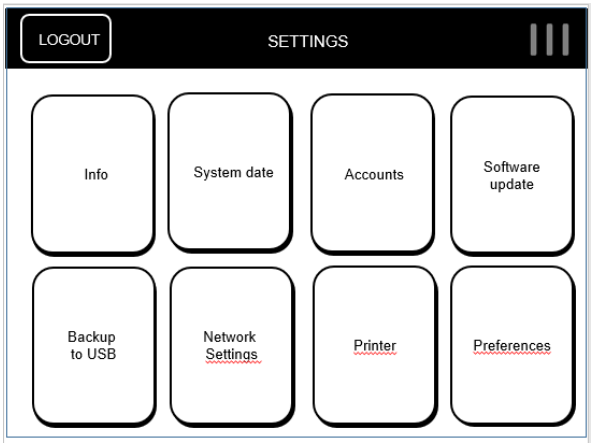


Figure 12 - Admin Settings

INFO

Press *INFO* to see the distributor contact information, system date, software and firmware versions, first installed version, the serial number of the device and the disk usage (Figure 13). For devices sold in the US, the license name is followed by '*US*' in brackets.

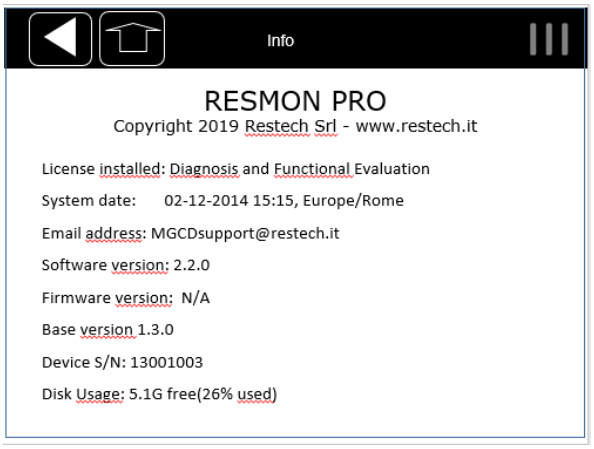


Figure 13 – Information Page

SYSTEM DATE

Press *SYSTEM DATE* to set the DATETIME format or your current TIMEZONE (Figure 14).

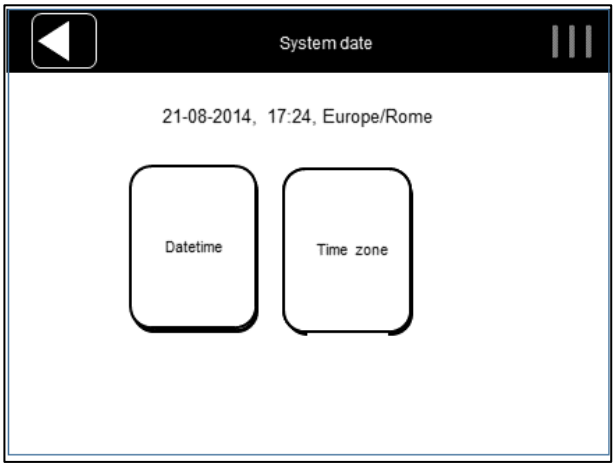


Figure 14 – System date options

DATETIME allows you to set the date and time of the system. The default display format is DD-MM-YYYY hh:mm, but it can be changed in the user Settings Page screen.
After entering the new date and time, additional controls will be performed by the device; for instance, if you try to insert a system date which is in the past when compared with the latest recorded event, you will get the following message: *System date seems incoherent – is this system date correct?* You will have to double check and confirm the system date, or to go back and adjust its value to the correct one.

CAUTION	PAY MAXIMUM ATTENTION WHEN CHANGING SYSTEM DATE AND TIME BECAUSE THIS MAY HAVE AN IMPACT ON THE ACCURACY OF THE NEXT TESTS.

If you set a system date that is in the future, the periodic backup of your data made automatically by the device will be affected and after several reboots (at least ten) without reinserting a correct date and time the backup functionality will cease to work properly. This is a KNOWN ISSUE: if you entered a wrong system date and subsequently rebooted your device more than ten times without correcting it, contact your local distributor for technical assistance (for further information see section *User Assistance Information*).

TIMEZONE allows you to select your time zone. The default is CET (UTC+1).

Base your selection on the *city* of interest: this is more accurate than the UTC offset, which could be biased by whether DST (*Daylight Saving Time*) is currently in use in a given time zone.

ACCOUNTS

Select *ACCOUNTS* to create, remove, modify or set the permission of an account. The following screen will display (Figure 15).

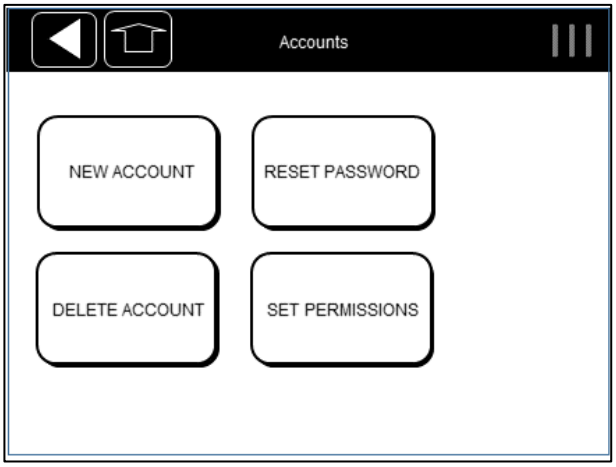


Figure 15 – Account management screen

- Select *NEW ACCOUNT* to create a new user. Enter the user name (max 25 characters). Press *NEXT* enter a user-password with a numerical keyboard (5-digit password required). Press *NEXT* to confirm.

There are three kinds of users: ADMIN, STANDARD, and PRO. The ADMIN is always present and cannot be deleted. Functionality is based on the user account that is currently logged in. The following table summarizes default user settings.

USER TYPE	ADMIN	PRO	STANDARD
Back-Up	✓		
Create And Modify Account	✓		
Update Device Software	✓		
Change Network Settings	✓		
Modify Customer Name	✓		
Select Language	✓		
Display Info	✓	✓	✓
Modify System Date	✓	✓	✓
Change Units Of Measurement		✓	✓
Change Date Format		✓	✓
Perform Device Test		✓	✓
Select Waveform		✓	
Select Test Duration		✓	
Execution Of The Test		✓	✓
Database Browsing		✓	✓
Database Exporting		✓	✓
Enable reference equations	✓		
Selection of the reference equation set		✓	✓
Enable anonymization of patients	✓		

All existing accounts will be listed to assign permissions: the highlighted users are the PRO users. By default, a new user is a STANDARD user. To change its status to PRO, click on the user name. Press *CONFIRM* to return to the Settings page.

A maximum of ten users can be created. When attempting to add users beyond this amount the following message will be displayed: *You cannot add another account.*

Usernames are unique identifiers; therefore, you cannot have two users with the same username. If you try to add an account with an existing username you will get the error *Username already in use*.

- Select *DELETE ACCOUNT* to remove a user account. The list of all the accounts will be shown. After selecting the one to delete you will be asked to confirm the

operation. Once confirmed, the following message will appear: *Account deleted*. Press *NEXT* to go back to the Settings Page.

- Select *RESET PASSWORD* to modify the password of a current user. A list of all users will be displayed on the screen. Select the account to modify its password. Press *NEXT* to go back to the Settings Page.

- Select *SET PERMISSIONS* to assign functionalities to the user. The list of all the accounts will be shown. Select the account to edit permissions. You can:

    - Change between PRO and STANDARD functionalities

    - Enable or disable REFERENCE EQUATIONS. If disabled, reference values will not be displayed on test results and test reports

    - Enable or disable DATA ANONYMIZATION. If enabled, data will be anonymized before exportation, i.e. name and surname will not appear on the test reports and in all exported files and filenames

SOFTWARE UPDATE

Select *SOFTWARE UPDATE* to install a new software release. The update must be copied in the root of a USB memory stick, which must be plugged in the USB port.

- If the USB memory stick is not inserted, you will see the following message: *DEVICE NOT FOUND. Please insert a USB drive and try again*. Press *BACK* to go to the Settings Page.

- If the USB memory is inserted but no valid updates are detected you will get the following message: *No suitable update files detected. Make sure to have a certified software update on your USB drive*. Press *BACK* to go to the Settings Page.

- If the USB memory is inserted and more than four valid updates are present you will get the following message: *Too many updates found – the limit is 4*. Remove old update files from the USB memory stick.

- If the USB memory is in place and up to four valid software updates are detected you will get: *Software update detected. Would you like to proceed with the*

installation? Press *CONFIRM* to install the software update. At the end of installation process press *REBOOT* and wait for the reboot to complete.

CAUTION	SOFTWARE UPDATES ARE DIGITALLY SIGNED. CORRUPTED OR TAMPERED SOFTWARE UPDATES WILL NOT BE DISPLAYED.

BACKUP AND RESTORE OF PREVIOUS BACKUPS

BACKUP TO USB

Insert a USB memory stick into the USB port and select *BACKUP AND RESTORE* and then *BACKUP TO USB* to start copying data from the device (Figure 16).

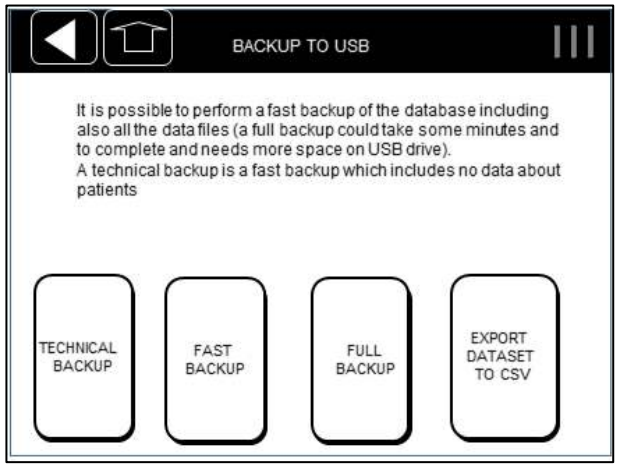


Figure 16 – Backup Options

- Select *TECHNICAL BACKUP* to save a backup of technical information only, excluding personally identifiable information.
- Select *FAST BACKUP* to create a dump of the device database and other utility files (e.g. log files).
- Select *FULL BACKUP* to backup raw data, the dump of the device database and other utility files (e.g. log files).

- Select *EXPORT DATASET TO CSV* to create a csv file containing all the measurements available on the device database with patients' data and calculated parameters.

If a USB memory stick is not plugged in you will get the following message: *Device not found. Please insert a USB memory stick and try again*. Press *BACK* to get back to the Settings Page.

If there is not enough space on the USB memory you will get the following message: Not enough disk space. Please, free some memory on the USB device and try again, or use a different USB memory with more free space. Press BACK to get back to the Settings Page.

CAUTION	TO NOT LOSE YOUR DATA, IT IS RECOMMENDED TO MAKE PERIODICALLY FULL BACKUPS OF THE DEVICE AND TO ARCHIVE THEM ACCORDING TO THE REGULATIONS OF YOUR INSTITUTION.

CAUTION	AFTER A BACKUP, THE USB MEMORY STICK MAY CONTAIN CONFIDENTIAL DATA. MAKE SURE TO PROTECT ITS CONTENT FROM UNAUTHORIZED ACCESS FOLLOWING THE REGULATIONS OF YOUR INSTITUTION.

RESTORE OF PREVIOUS BACKUPS

Insert into the device a USB memory stick with the FULL BACKUP file that you want to restore: you can either place it into the root folder or in the RESTECH_DUMP folder, which is the default location for the backup files exported from the device.

Select *BACKUP AND RESTORE* and then *RESTORE* to start the process of copying data into the device.

If more than one FULL BACKUP is found, only the latest (most recent) backup will be considered for the restore. You will be able to see the details of the selected file, including date and time of creation.

Notice that FAST and TECHNICAL BACKUPS, if present, will be ignored.

If at least one FULL BACKUP file is found into the USB memory stick, the following information will be displayed on screen (Figure 17) after some processing time: filename,

serial number of the device from which such backup file originated and the date and time of backup creation.

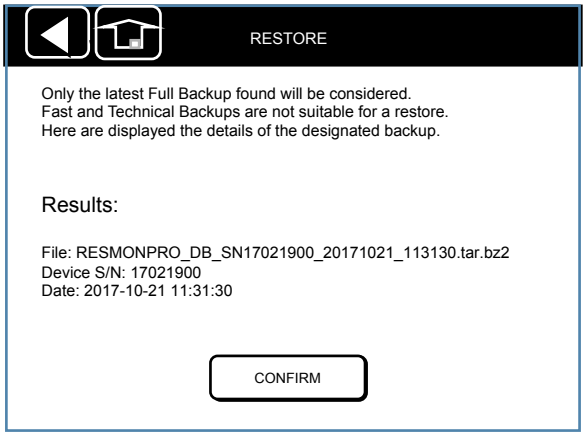


Figure 17 - Restore of a backup file

If all this information is correct and corresponds to the backup file that you want to restore, select *CONFIRM* to continue. The device will perform some additional controls to ensure the file is valid and compatible. If the controls are passed, you will be reminded that all data currently on the device will be overwritten.

Select again the button *CONFIRM* only if you are sure you want to proceed with the restore of the database.

CAUTION	ALL DATA ON YOUR DEVICE, INCLUDING ALL PATIENT DATA, WILL BE OVERWRITTEN WITH THE CONTENTS OF THE BACKUP FILE. THIS OPERATION CAN NOT BE REVERTED. PROCEED ONLY IF YOU ARE ENTITLED TO DO SO BY YOUR INSTITUTION.

You are now asked to enter the ADMIN password for security purposes.

If the password is correct, the device will replace the current data with that contained in the backup file. This may take some time.

At the end of this procedure, select RELAUNCH to restart the software (Figure 18) with the restored database. Should you need further assistance, please contact your local

distributor for technical assistance (for further information see section *User Assistance Information*).

Figure 18 - Restore Complete

NETWORK SETTINGS

The *NETWORK SETTINGS* menu (Figure 19) is used to set network parameters and to allow the communication of the device with an external web service. The screen also reports the current configuration of the system: notice that you can choose whether to use a static (manual) network configuration, or a configuration automatically received by the network through the DHCP protocol.

CAUTION	USE THE DEVICE IN TRUSTED NETWORK ONLY AND CONFIGURE THE NETWORK PARAMETERS FOLLOWING THE SAFETY REGULATIONS OF YOUR INSTITUTION.

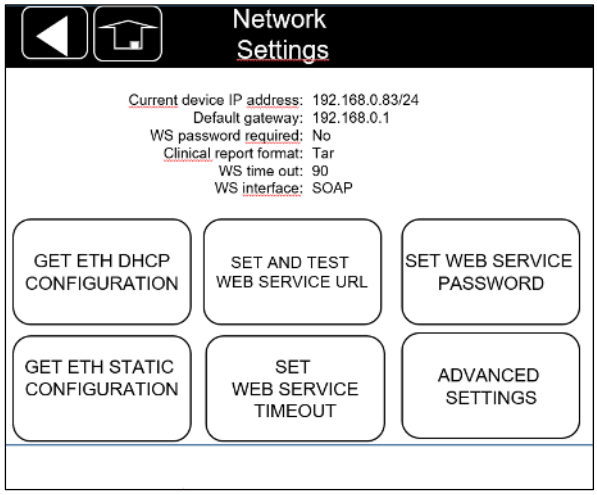


Figure 19 – Network Settings Options

- Select *GET NETWORK CONFIGURATION VIA DHCP* to request a network configuration to a DHCP server over the wired network. If you correctly receive a configuration, the “dhcp” configuration is saved. Your network must be have an active DHCP server for this feature to work correctly, otherwise the device will not receive any configuration.

- Select *SET A STATIC NETWORK CONFIGURATION* to insert manually the network parameters (IP ADDRESS, NETWORK MASK, DEFAULT GATEWAY). When entering IP addresses, a syntax check is performed. Be sure to enter valid IPv4 addresses in the format of *A.B.C.D* where all A,B,C and D are numbers between 0 and 255. If you save all your parameters, the “static” configuration is saved.

- Select *SET AND TEST WEB SERVICE URL* to insert the service URL used in *SYNC* mode (see *SECTION WEB SERVICE COMMUNICATION PROTOCOL*). After entering the URL, a connection test is automatically performed and you will be shown a message with its result. The URL is composed of three separated parts:

    - The IP address or hostname of the server

    - The path to the Web Service on the server

    - The Web Service name

The maximum length of each field is 39 characters. Default values are provided. In the last field, you can omit the ".SVC?WSDL" extension and it will be automatically added. SOAP and REST web services are supported.

- Select *SET WEB SERVICE TIMEOUT* to set the maximum waiting time for web service operations to complete, used in *SYNC* mode. The default is 90 seconds.

- Select *SET WEB SERVICE PASSWORD* to set a password to access and download visits.
- Select *ADVANCE SETTINGS* to select the test report format: .pdf or .tar.

PRINTER

Press *PRINTER* to visualize the name of the USB printer connected to the device and to print a test page. In case the printer is compatible, the test page will be printed correctly. If no printer is connected, the error message *No printer detected* will be displayed.

PREFERENCES

Press *PREFERENCES* and then select:

- *LANGUAGE*, to change the software language. The default is English. The language will change immediately.

- *SET CLINICAL REPORT HEADING* to insert the facility information. This name will be displayed on the header of clinical reports.

Verification of the Factory Calibration

Your device has been calibrated by the manufacturer according to the European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines on FOT equipment and on volume measurements. Nonetheless, the device will automatically ask you to *verify* that the device is calibrated.
Starting from software version 6.0.0, the verification of calibration consists of a two-step procedure: the device will ask you to verify the Slow Spirometry volumes factory calibration first and then the FOT factory calibration.
The verification of the slow spirometry volume calibration is optional and you can always skip it. However, if not performed, the measurement of the slow spirometry volumes will not be available during the test. Slow Spirometry features could be disabled by the manufacturer: in such case, it won't be asked to perform the verification of the slow spirometry volume calibration.

NOTE	IF YOU UPGRADED YOUR DEVICE SOFTWARE FROM VERSIONS BELOW 6.0.0 AND WANT TO PERFORM SLOW SPIROMETRY MEASUREMENTS, CONTACT YOUR LOCAL DISTRIBUTOR. SEE SECTION *User Assistance Information*. SLOW SPIROMETRY MEASUREMENTS CAN NOT BE ENABLED IN THE U.S.

HOW TO PERFORM THE VERIFICATION OF THE FACTORY CALIBRATION

The verification of the factory calibration can be performed by any PRO and STANDARD user (see section First log-in and the *ADMIN* account) this option is available in the SETTINGS section (see section CHANGE USER SETTINGS).

Select DEVICE TEST to perform a verification of the factory calibration.

Verification of the Slow Spirometry factory calibration

The verification of the Slow Spirometry factory calibration consists in measuring increasing flows generated with a 3L calibration syringe and in comparing the resulting volumes with the nominal value of the syringe, i.e. 3L.

The Verification of the Slow Spirometry factory calibration is successful when the measured error on volume is below 100 mL.

From the user Settings page (see section *CHANGE USER SETTINGS*), select *DEVICE TEST*. The instructions to perform the Slow Spirometry verification will appear on the screen (Figure 20).

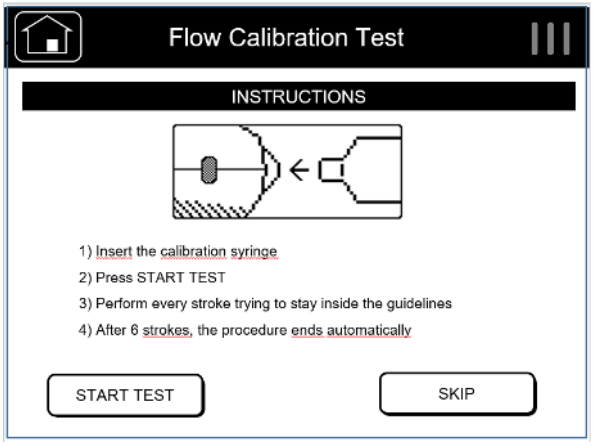


Figure 20 - Instructions for the Slow Spirometry volumes verification

If you press SKIP, you will jump to the verification of the FOT calibration (see section *Verification of the FOT factory calibration*). The measurement of the slow spirometry volumes will not be available until a successful verification of the slow spirometry volumes is done.

Connect a 3L volume calibration syringe (not supplied with the device) to the device inlet and make sure that no leaks are present around it and that the syringe is completely empty.

CAUTION	USE ONLY 3L VOLUME CALIBRATION SYRINGES THAT CARRY A VALID CALIBRATION CERTIFICATE. DO NOT USE CALIBRATION SYRINGES WITH VOLUMES DIFFERENT FROM 3 L.

Press START TEST and wait for 3 seconds during the auto-zeroing of the flowmeter. Move the syringe piston in and out six times and maintain the flow within the dotted lines displayed on screen (Figure 21). A counter on the right side of the screen will increase automatically at the end of each run.

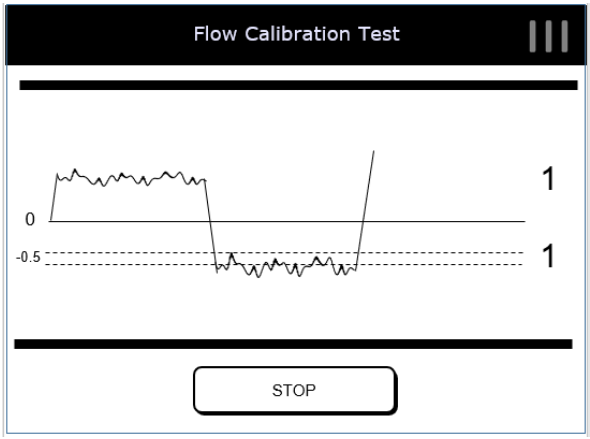


Figure 21 – Example of flow tracing during the slow spirometry volume verification

The verification results are reported as in Figure 22.

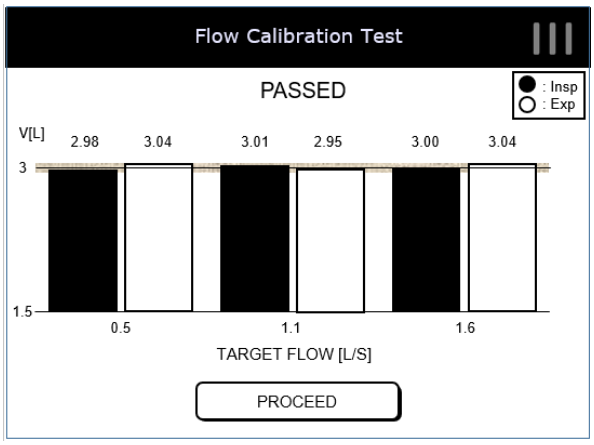


Figure 22 – Slow Spirometry verification results

Results can be:

- *PASSED*: volume measurements are within 100 mL of the 3L syringe, as recommended by international guidelines on volume measurements. Bars on screen represent the volumes (in liters) measured during each run (Insp = inspiration, corresponds to filling the syringe with air, Exp = expiration, corresponds to emptying the syringe) Press PROCEED to verify FOT calibration.

- *FAILED*: the Slow Spirometry volume verification was not successful because at least one of the volumes measured during this procedure was not within 100 mL of the theoretical value (3 L).

CAUTION	IF THE RESULT OF THE SLOW SPIROMETRY VERIFICATION IS *FAILED* REPEAT THE TEST. IF IT FAILS AGAIN, YOU WILL NOT BE ALLOWED TO MAKE ANY SLOW SPIROMETRY MEASUREMENTS ON THE SUBJECT BECAUSE THEY WOULD BE UNRELIABLE. CONTACT YOUR LOCAL DISTRIBUTOR (SEE SECTION *User Assistance Information*).

Verification of the FOT factory calibration

Verification of the FOT calibration is accomplished by measuring the resistance and reactance of the Test Object supplied with the device at all stimulating waveforms and comparing them with their counterparts measured during factory calibration.
This Verification is successful when the measured error on impedance at all stimulating waveforms is below 9%. Such value guarantees that the next measurements are accurate within the limits reported in section *Technical specifications*.

If the device is not calibrated properly, you will not be allowed to make any FOT measurements on subjects. Should this be the case, the device must be recalibrated: contact your local distributor for technical assistance (for further information see section *User Assistance Information*).

CAUTION	TO PERFORM THE FOT CALIBRATION VERIFICATION, USE ONLY THE TEST OBJECT PROVIDED BY THE MANUFACTURER.

NOTE	HOW TO READ THE CODE OF THE TEST OBJECT The resistance and reactance spectra of the Test Object are two lines which theoretical slopes are 0 $cmH_2O \cdot s^2 \cdot L^{-1}$ and 0.17 $cmH_2O \cdot s^2 \cdot L^{-1}$, respectively, and theoretical intercepts of 2.50 $cmH_2O \cdot s \cdot L^{-1}$ and 0 $cmH_2O \cdot s \cdot L^{-1}$, respectively. Their actual values are printed on the Test

Object label (the CODE) and are also reported in the Test Object Report supplied with the device.

The CODE is a 20-digit number with the following format:

ABCD – EFGH – JKLM – NOPQ – RSTU

Where:

A = sign of the resistance spectrum slope (0 = positive, 1 = negative)
BCD = slope of the resistance spectrum (2 digits precision)
E = sign of the resistance spectrum intercept (0 = positive, 1 = negative)
FGH = intercept of the resistance spectrum (2 digits precision)

J = sign of the reactance spectrum slope (0 = positive, 1 = negative)
KLM = slope of the reactance spectrum (2 digits precision)
N = sign of the reactance spectrum intercept (0 = positive, 1 = negative)
OPQ = intercept of the reactance spectrum (2 digits precision)

RSTU = checksum

For example, this CODE can be: 0000 – 0245 – 0017 – 0001 – 0065

And corresponds to:

Slope of the resistance spectrum = 0 cmH2O/(L/s^2)
Intercept of the resistance spectrum = 2.45 cmH2O/(L/s)
Slope of the reactance spectrum = 0.17 cmH2O/(L/s^2)
Intercept of the reactance spectrum = 0.01 cmH2O/(L/s)

Insert the last 4 digits of the preloaded code (Figure 23). The code (CODE) is reported on the label of the Test Object.

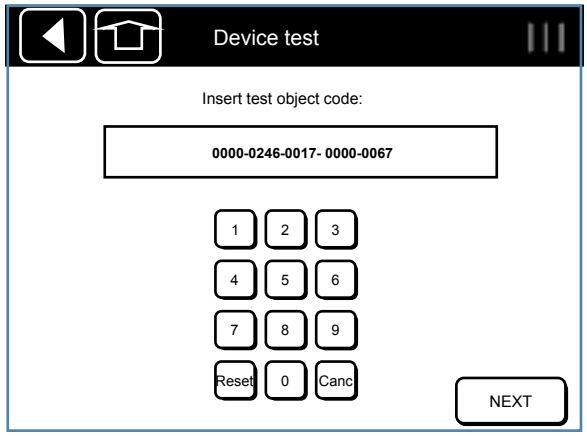


Figure 23 – Insert Code for the Identification of the Test Object

If the code is correct, you will see the instructions to perform the FOT verification (Figure 24Take the Test Object out of its bag, connect it to the device and press *START TEST*.

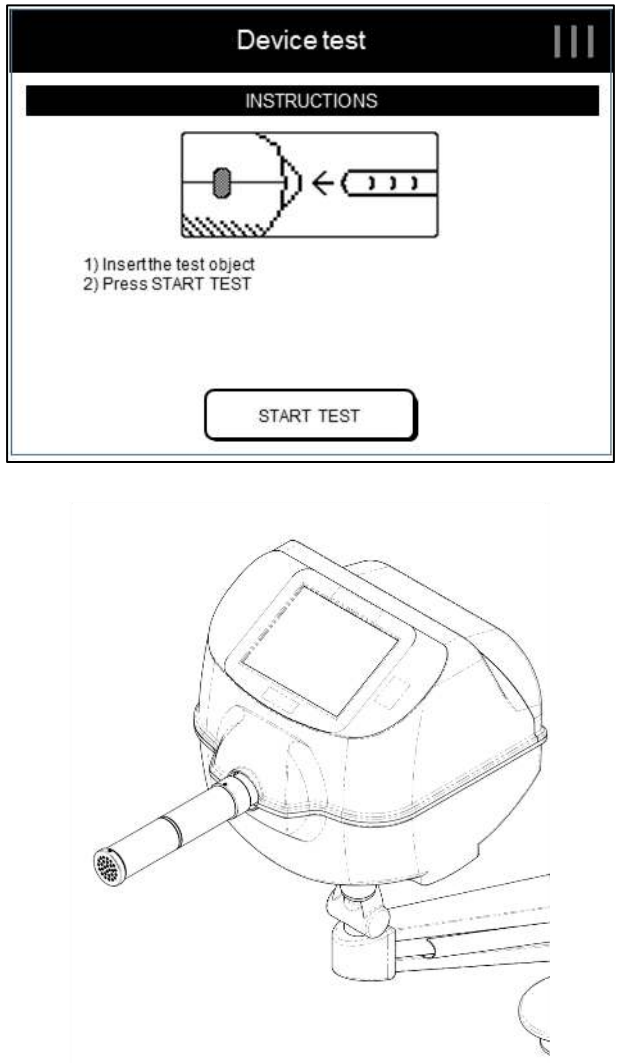


Figure 24 - Instructions for the Calibration Verification and connection of the Test Object

The duration of the calibration Verification is 90 seconds and can be cancelled at any time by pressing *STOP*.

This test is performed for all stimulating waveforms, i.e. 5Hz, 6Hz, 8Hz, 10Hz, 5-11-19Hz and PSRN signals. Then, resistance and reactance spectra are derived and compared with the resistance and reactance spectra measured in factory immediately after calibration and stored into the device.

Test results are reported as in Figure 25.

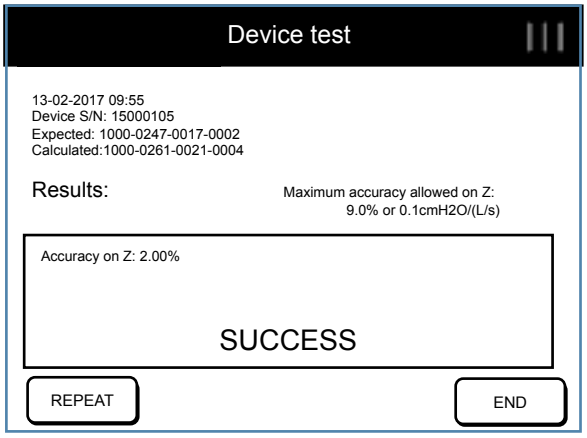


Figure 25 – Calibration Verification Results

This report includes the date and time of the test, the serial number of the device, the expected and measured codes of your Test Object. The Calibration Verification can provide the following results on screen:

- SUCCESS: the FOT Verification has been successful because the measurement has a coherence at all stimulation waveforms that is greater than 95% and the measured impedance has an error within the range of acceptability recommended by the international guidelines.
- *COHERENCE ERROR*: *please try again:* the FOT Verification has not been successful because the measurement has a coherence less than 95% at least at one of the stimulating waveforms. This may indicate a measurement error or a failure of the device.
- *FAILURE*: the FOT Verification has not been successful because impedance at least at a given stimulating waveform differs more than 9% from the expected value.

CAUTION	IF THE RESULT OF THE CALIBRATION VERIFICATION IS *FAILURE* OR *COHERENCE ERROR* REPEAT THE TEST. IF IT FAILS AGAIN, YOU WILL NOT BE ALLOWED TO MAKE ANY MEASUREMENTS ON SUBJECTS BECAUSE THEY WOULD BE UNRELIABLE. CONTACT YOUR LOCAL DISTRIBUTOR (SEE SECTION *User Assistance Information*).

At the end of this procedure, disconnect the Test Object, put it again in its bag and keep it stored in a dry and clean place until the next Verification of the Factory Calibration.

Operating instructions

If the user is not logged in as ADMIN, the Home Screen () will be displayed (Figure 26).
You can always press the *LOGOUT* button to log-out.

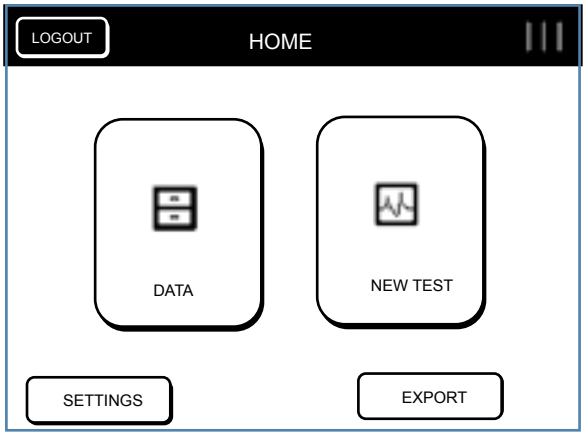


Figure 26 – Home Page

From the Home Screen:

1. Press SETTINGS to change the user settings.
2. Press DATA () to enter the database.
3. Press NEW TEST () to perform a new test.
4. Press EXPORT to export all test performed using the current account to a CSV file onto a USB memory stick.

CHANGE USER SETTINGS

If you enter the SETTINGS as a PRO user, the following page will be loaded (Figure 27):

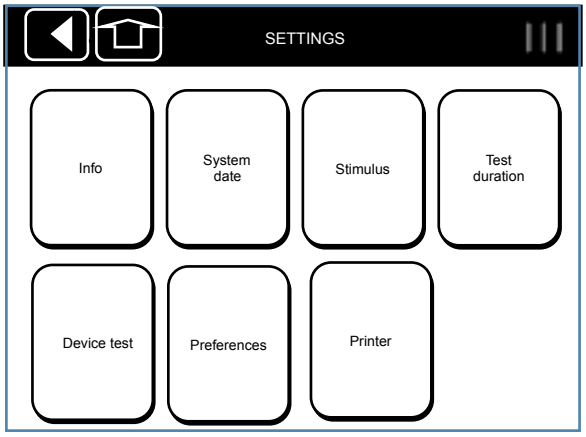


Figure 27 – Settings for a PRO User

INFO

See section First log-in and the ADMIN account.

SYSTEM DATE

See section First log-in and the ADMIN account.

STIMULUS

Select *STIMULUS* to select the stimulating waveform. The following page will be shown (Figure 28):

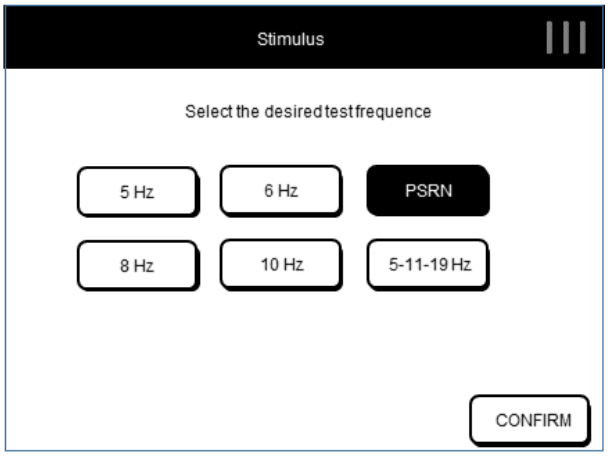


Figure 28 – Selection of the stimulating waveform

The stimulating waveforms available are:

- Sinusoidal signal at 5, 6, 8 or 10 Hz
- Multi-frequency signal at 5-11-19 Hz
- Pseudo-random noise (PSRN) including selected frequencies in the range 5-37 Hz

The highlighted button indicates the waveform currently active. To change the waveform select the desired stimulus and press *CONFIRM* to go back to the Settings Page.

For further information on the choice of the stimulating waveform, see section CHANGE USER SETTINGS

TEST DURATION

Press *TEST DURATION* to select the maximum duration of the measurement (Figure 29). You can select the maximum duration in terms of minutes (available choices are 1, 3, 5 or 10 minutes) or in terms of total number of breaths without artefacts (available choices are 10, 15, 20 or 30 breaths). If you select the latter option (maximum duration in terms of accepted breaths), the measurement will end automatically when the number of breaths set here is reached.

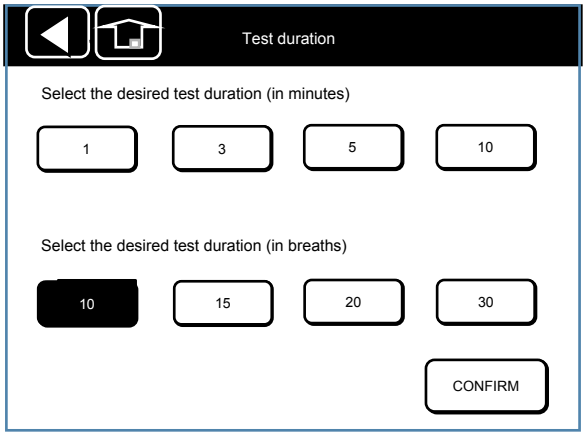


Figure 29 – Selection of the test duration

The highlighted button corresponds to the current selection. To change the maximum duration of the test select the desired time press *CONFIRM* to go back to the Settings Page.

NOTE	IF THE SELECTED STIMULUS IS PSRN, IT IS NOT POSSIBLE TO CHOOSE THE TEST DURATION, WHICH IS INSTEAD FORCED TO BE 1 MINUTE.

DEVICE TEST

See section Verification of the Factory Calibration.

PREFERENCES

Select *PREFERENCES* to set:

1. The measurement units of weight and height:
   - International System format (cm and Kg)
   - Imperial Units format (in and lbs).

2. The date format, choosing among the following formats:

- day-month-year (DD/MM/YYYY, default)
- month-day-year (MM/DD/YYYY)
- year-month-day (YYYY/MM/DD)

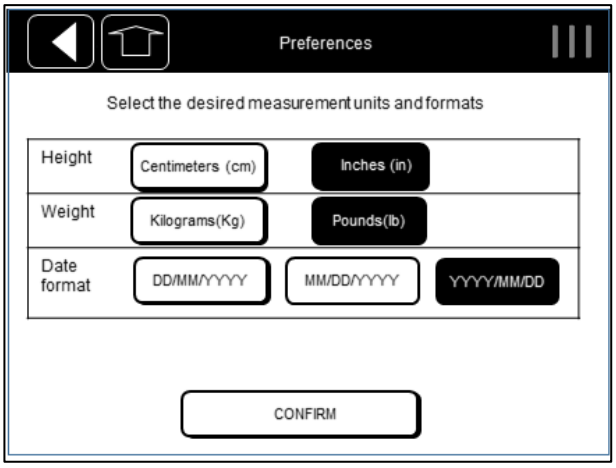


Figure 30 – Preferences options

Press *CONFIRM* to go back to the Settings Page.

NOTE	IF YOU ACCESS THE SETTINGS SCREEN AS A STANDARD USER, THE SELECTION OF THE STIMULUS AND DURATION OF THE TEST WILL NOT BE AVAILABLE OPTIONS.

PRINTER

Press *PRINTER* to visualize the name of the postscript USB printer connected to the device and to print a test page.
Before printing the test page, be sure that the printer model has been verified for use with the device, that the printer is turned on and that the USB cable is connected. If you need any help, contact your local distributor for technical assistance (for further information see section *User Assistance Information*).

CRITERIA FOR SELECTING THE STIMULATING WAVEFORM

The default stimulating waveform is 5-11-19 Hz. It allows measuring the within-breath respiratory impedance at three frequencies and, at the same time, provides an estimate of the frequency dependence of resistance and reactance within the limits of accuracy up to 15 $cmH_2O \cdot s \cdot L^{-1}$.

You can change the stimulating waveform from your SETTINGS page (see section *CHANGE USER SETTINGS*) to measure the subject impedance at a different frequency.

The choice of a single frequency sinusoidal waveform (5, 6, 8 or 10Hz) may be useful to increase the maximum measurable impedance, from 15 $cmH_2O \cdot s \cdot L^{-1}$ of the 5-11-19 Hz stimulating waveform up to 25 $cmH_2O \cdot s \cdot L^{-1}$ (see below). Instead, the choice of the pseudo-random noise stimulating waveform (PSRN) may be useful if you are interested in studying the frequency dependence of resistance and reactance with a frequency resolution higher than that provided by the 5-11-19 Hz signal.

The maximum values of respiratory impedance that can be measured at a specific stimulating waveform within the 10% accuracy limit (as required by international guidelines on FOT equipment) have been established by the manufacturer. They are reported in section Technical specifications and summarized in the table below.

Stimulating Waveform	Maximum impedance measurable within the 10% accuracy limit
5 Hz	25 $cmH_2O \cdot s \cdot L^{-1}$
6 Hz	25 $cmH_2O \cdot s \cdot L^{-1}$
8 Hz	25 $cmH_2O \cdot s \cdot L^{-1}$
10 Hz	21.4 $cmH_2O \cdot s \cdot L^{-1}$
5-11-19 Hz (default)	15 $cmH_2O \cdot s \cdot L^{-1}$
PSRN	8.8 $cmH_2O \cdot s \cdot L^{-1}$

At the end of the test, the device notifies you automatically if the limits reported above have been exceeded (see also section *PERFORMING A NEW TEST SESSION*).

In this case, the test is automatically discarded. Repeat the test with another stimulating waveform that allows the measurement of impedances higher than those allowed with the current stimulating waveform (see table above). To change the stimulating waveform, press SETTINGS from your HOME page and then STIMULUS (see *section CHANGE USER SETTINGS*).

Values of impedance above 25 $cmH_2O \cdot s \cdot L^{-1}$ are unlikely within the intended population. However, if you encounter these values, repeat the test and pay attention to the posture of the subject. For further information, see section *Preparing the patient for a test*. If you are using a single sinusoidal stimulating waveform and the device warns you again that the measured impedance exceeded the limits of accuracy, this measurement has to be considered unreliable and the device should not be used for further FOT measurements on this subject.

PERFORMING A NEW TEST SESSION

NOTE	INTERNATIONAL GUIDELINES SUGGEST PERFORMING THREE TO FIVE MEASUREMENTS ON A SUBJECT FOR THE EVALUATION OF THE RESPIRATORY IMPEDANCE.

A test session on a given subject and with a given session label (see below) may be composed of one single test or multiple tests (up to five). If a test session includes less than five tests, you can continue adding new tests, provided that the last one is performed no later than 20 minutes after the previous one. After this time, the session is automatically closed and you will need to start a new one.

Each test may be enabled for the measurement of the slow spirometry volumes only if a successful slow spirometry verification has been performed before during the same day. For further information see section *Verification of the Factory Calibration*.
The measurement of the slow spirometry volumes is not available if the selected stimulating waveform is pseudo-random noise (PSRN).

To perform a new test session from the Home Screen press the *NEW TEST* button ( ).

The verification of the factory calibration must be checked every day. The verification of the FOT factory calibration is mandatory while the verification of the slow spirometry volumes calibration is optional. If the verification of the FOT factory calibration has not been made yet, or if previous verification was unsuccessful (see section *Verification of the Factory Calibration*), you will be noticed to perform it before starting the test session (Figure 31).

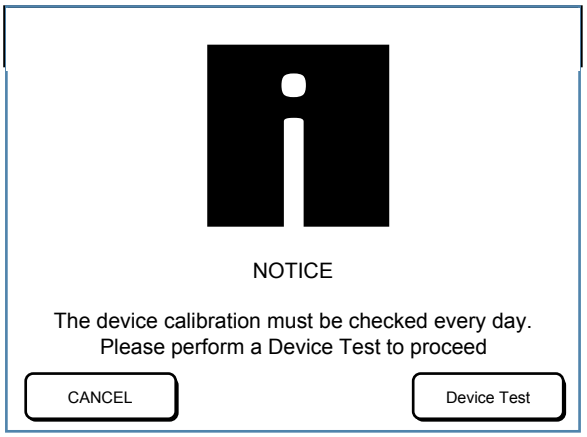


Figure 31 – Notice to make a device test

You can perform a new test session on a new patient or on a patient already in the database.

Performing a test session on a patient already in the database

The Patient Search screen will be displayed (Figure 32).

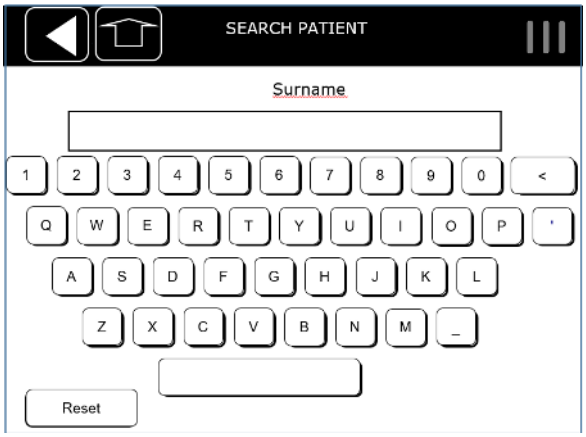


Figure 32: Search patient screen

Type in the patient information using the keyboard on the screen. You need to enter at least one letter to proceed. Press *NEXT*. Patients whose surname begins with the letters entered are shown in a table format (Figure 33).

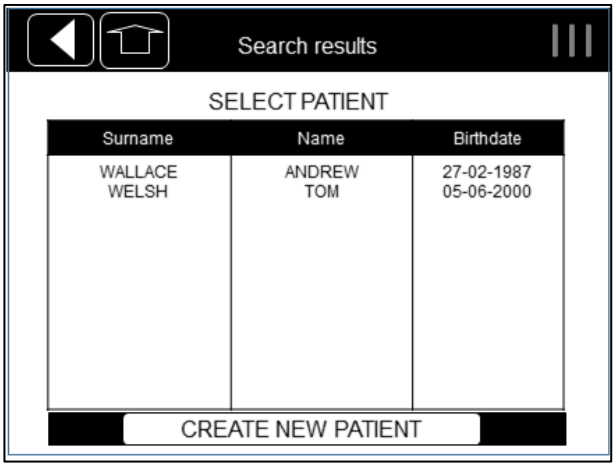


Figure 33 – Results of the patient search

If several results are present, you can scroll the pages using the arrows on the right. Press on the row corresponding to the patient to highlight and open the patient file. You can edit patient's height and weight and room parameters (temperature, pressure and relative humidity) if they have changed since the last visit (Figure 34). To insert or modify data press the correspondent text entry box and enter the correct value.

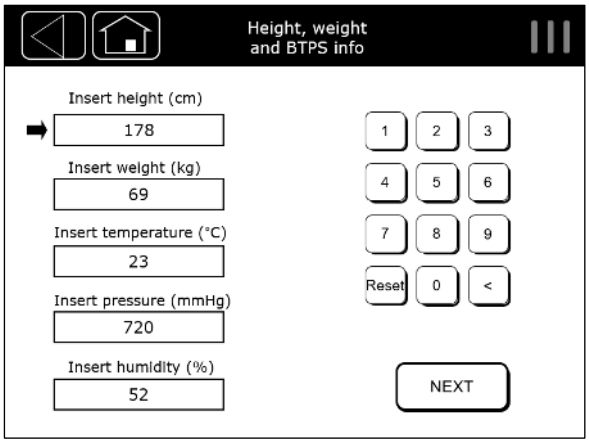


Figure 34 – Edit patient and room conditions

CAUTION	AS RECOMMENDED BY INTERNATIONAL GUIDELINES, ROOM PARAMETERS WILL BE USED TO APPLY THE BTPS CORRECTION TO THE CALCULATION OF SLOW SPIROMETRY VOLUMES. MAKE SURE TO ENTER AND/OR EDIT THESE VALUES CORRECTLY TO AVOID INACCURATE RESULTS.

Performing a test session on a new patient

If the patient is not present in the database, press *CREATE NEW PATIENT* at the bottom of the Result Table (Figure 33).
A keyboard will be displayed to enter the patient unique identification code (ID). If you enter a patient ID which is already present you will get the following message: *This ID already exist: please provide a unique identifier for each patient*.

Press *NEXT* to insert the patient SURNAME.
Press *NEXT* to insert the patient FIRST NAME.
Press *NEXT* to insert the patient DATE OF BIRTH.
Press *NEXT* to select the patient GENDER.
Press *NEXT* to select the patient phenotype: CAUCASIAN, ASIAN, BLACK, HISPANIC, NORTHERN ASIAN, SOUTHERN ASIAN or UNSPECIFIED.

A summary of the inserted data will be displayed. Press *CONFIRM* to accept and to insert the anthropometric data (height and weight) and the room parameters at the time of visit (Figure 34). An arrow indicates the active field. Press on the text entry box to activate the desired field. The *NEXT* button will appear only once both fields are filled up.

Labeling a test session

After inserting a new patient or selecting an existing patient, you will enter the screen showed in Figure 35. This screen summarizes the patient's demographic and the stimulus waveform that will be used for the next measurement. You can add here a label to the test, to easily recognize and recall it later. For example, this label may refer to a test performed before or after taking a medication (bronchoconstrictor or bronchodilator).
For further information, see section *CLINICAL REPORTS*.

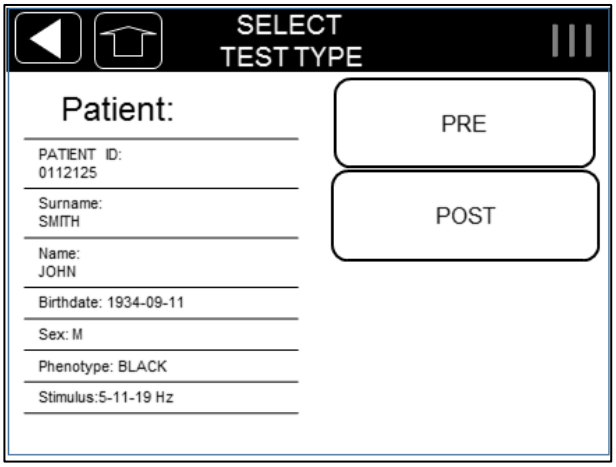


Figure 35 – Test Selection Options

Select the desired label for the test, PRE or POST; if you select POST, three more options will be displayed: BRONCHO-CONSTRICTOR, BRONCHO-DILATOR and OTHER. Selecting OTHER will open up a keyboard to enter a custom label for this test.

Please note that the device does NOT perform bronchodilation or bronchoprovocation testing and no clinical thresholds are provided for these tests.

Preparing the device for a test session

You can connect now a single-use bacterial/viral filter to the inlet on the device.
The use of bacterial/viral filters is mandatory to perform a test.
The selection of a filter with the characteristics reported in section *DISPOSABLES* will guarantee a proper connection to the inlet of the device without leaks. To increase the comfort of the patient you may also consider to connect a mouthpiece to the filter with the characteristics reported in section *DISPOSABLES.* The use of mouthpieces is not mandatory.

Once the test type has been chosen, you access the filter measurement screen (Figure 36). The filter has intrinsic impedance that is added to the patient's own impedance and that can be subtracted at the end of the test before displaying the results.

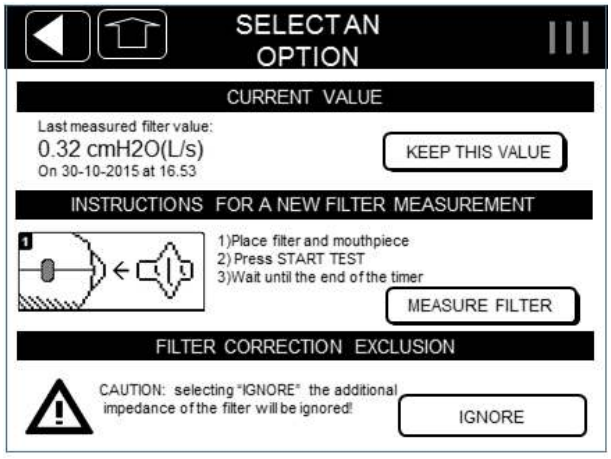


Figure 36 – Filter Measurement

- Select *KEEP THIS VALUE* to apply the filter correction indicated on the left. If N/A is displayed here, no previous value has been measured at the stimulating waveform that you are going to use.

- Select *MEASURE FILTER* to measure the impedance of a new filter at the frequency of the stimulating waveform. Insert the filter before pressing this button. Do not attach anything to it. If the measured value is below the range of acceptability (0.1 – 1 $cmH_2O/(L/s)$) you will get the following message: "*Filter impedance very low or missing filter*". If the measured value is above the range of acceptability you will get the following message: "*The filter impedance is outside the recommended range"*.

- Select *IGNORE* to not apply the correction for the filter impedance.

Notice that in case the daily calibration check has not been performed yet, a notice screen will ask you to complete the Device Test before proceeding, as shown in Figure 37 (see section *Verification of the Factory Calibration*).

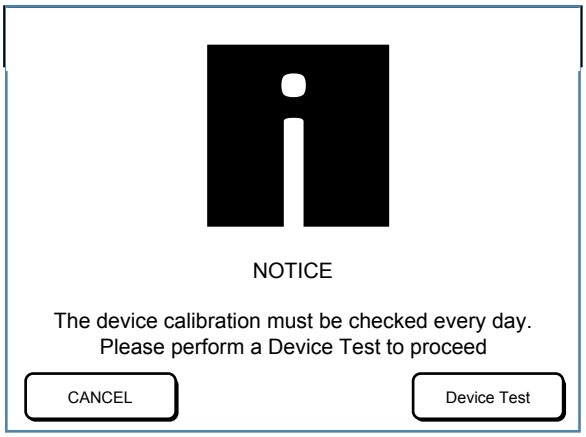


Figure 37 – Daily device calibration check

Then, wait for the sensors' calibration and filter measurement procedure to complete (Figure 38 - Sensors calibration).

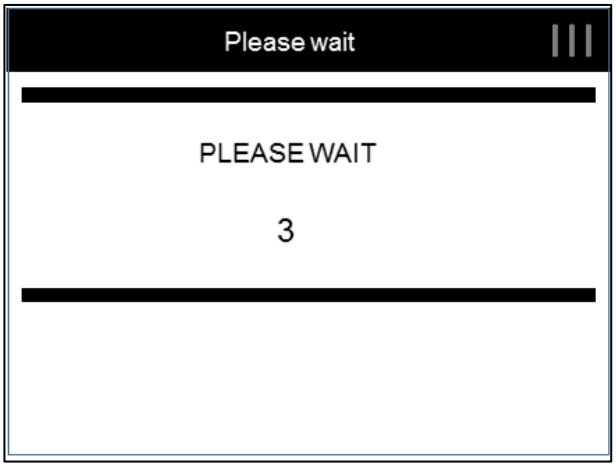


Figure 38 - Sensors calibration

CAUTION	DO NOT TOUCH THE DEVICE DURING CALIBRATION. DO NOT OBSTRUCT THE INLET OF THE DEVICE DURING CALIBRATION. ANY ERROR IN CALIBRATION MAY CAUSE ERRORS IN THE IDENTIFICATION OF BREATHS, INSPIRATIONS AND EXPIRATIONS, AND THE COMPUTATION OF BREATHING PATTERN PARAMETERS.

CAUTION	IF THE FILTER MEASUREMENT RESULTS IN A *COHERENCE ERROR,* REPEAT THE MEASUREMENT. IF IT STILL DOES NOT SUCCEED, CONTACT THE DISTRIBUTOR (SEE SECTION *User Assistance Information*).

Once the filter has been measured and sensors are calibrated successfully, the instructions for execution of the test will display (Figure 39). The vignettes shown remind you to insert the filter, wear the nose-clip, hold the cheeks, and let the patient breathe normally through the filter. For further information on the use of the filter and the nose-clips please refer to their instructions for use.

To begin the test, press *START TEST*.
Notice that in case the daily calibration check has not been performed yet, a notice screen will ask you to complete the Device Test before proceeding, as shown in Figure 39 (see section *Verification of the Factory Calibration)*.

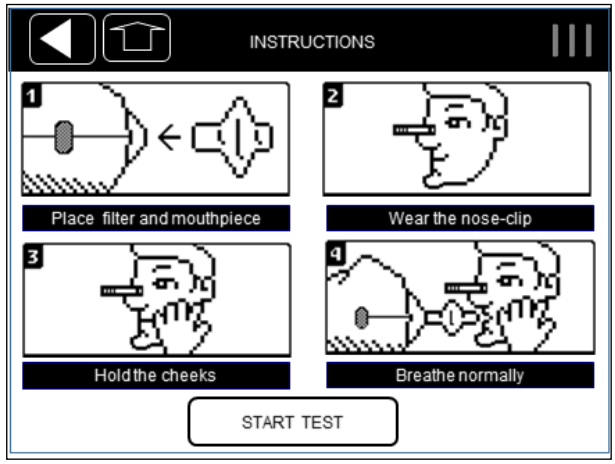


Figure 39 - Test instructions

CAUTION	IF THE PATIENT FAILS TO USE THE NOSE-CLIP, HOLD THE CHEEKS OR KEEP PROPER POSTURE, THE MEASUREMENT MAY PRODUCE INACCURATE RESULTS. REVIEW THE *CORRECT POSTURE* SECTION AND BE AWARE OF THE PATIENT'S POSTURE FOR THE DURATION OF THE TEST.

CAUTION	FAILURE TO USE A FILTER OR USING THE SAME FILTER BETWEEN PATIENTS MAY CAUSE CROSS-CONTAMINATION. IF YOU SUSPECT THAT THE DEVICE IS CONTAMINATED BECAUSE A SUBJECT HAS NOT USED A FILTER, CONTACT THE DISTRIBUTOR (SEE SECTION *User Assistance Information*). ALL THE COMPONENTS OF THE BREATHING CIRCUIT CAN BE REPLACED.

CAUTION	THROUGHOUT THE TEST PROCEDURE, THE ACTUATOR WILL GENERATE THE PRESSURE WAVE STIMULUS REQUIRED FOR LUNG FUNCTION MEASUREMENTS. A SLIGHT SENSATION OF THESE OSCILLATIONS IS NORMAL. MOREOVER, AN AIR BLOWER WILL CONTINUOUSLY REMOVE THE EXHALED AIR IN ORDER TO AVOID CARBON DIOXIDE ACCUMULATION. A SLIGHT NOISE ASSOCIATED WITH THE AIR MOVING WITHIN THE BREATHING CIRCUIT IS NORMAL.

Preparing the patient for a test session

Figure 40 shows the correct posture to keep during the test.

Figure 40 - Correct posture for test execution

- Place a chair in front of the device. Be sure a bacterial/viral filter is connected properly to the device.

- The patient should be sitting, back straight and neck slightly flexed upward. Adjust the height of the device so that correct patient position is assured.

CAUTION	PAY ATTENTION WHEN ADJUSTING the height and inclination of the device TO AVOID THE HAZARD OF INJURY TO HANDS OR FINGERS.

- Attach a nose-clip to the patient.

CAUTION	NOT USING THE NOSE-CLIP MAY CAUSE INACCURATE MEASUREMENTS. IF THE TIDAL VOLUMES ARE MUCH LOWER THAN EXPECTED, REPEAT THE MEASUREMENT PAYING PARTICULAR ATTENTION TO AVOID LEAKS FROM THE NOSE AND MOUTH.

- Ensure the patient has his/her mouth tightly sealed around the filter during the test.

- Be sure that the patient does not occlude the airway by putting his/her tongue or teeth in between the mouth and the filter.

 CAUTION	IF THE RESISTANCE VALUES ARE MUCH HIGHER THAN EXPECTED, REPEAT THE MEASUREMENT PAYING PARTICULAR ATTENTION TO OCCLUSIONS. OBSERVING LARGE VARIATIONS IN REAL-TIME REACTANCE CAN INDICATE THAT THE TONGUE OR TEETH ARE OBSTRUCTING THE AIRWAY.

- To get higher quality of the measured signals ask the patient to refrain from closing their glottis during the test.
- During the test it is necessary to hold the patient's cheeks in order to improve the accuracy of the measurement.

 CAUTION	NOT HOLDING THE SUBJECT'S CHEEK MAY CAUSE INACCURATE MEASUREMENTS.

Performing a test session

A test session includes up to five single tests, provided that they are performed on the same subject, by the same account, with the same label and within 20 minutes of each other.
For each test, FOT parameters will be measured during tidal breathing at the selected stimulating waveform. If the measurement of slow spirometry volumes has been enabled and a successful slow spirometry verification has been performed the same day (see section *Verification of the Factory Calibration*) you are also allowed to measure slow spirometry volumes (inspiratory capacity, IC and slow vital capacity, SVC).

Measurement of FOT parameters

If you have chosen a single frequency stimulating waveform (5, 6, 8 or 10Hz) or a multi frequency stimulating waveform (5-11-19 Hz)

During the test real time tracings will be displayed (Figure 41).

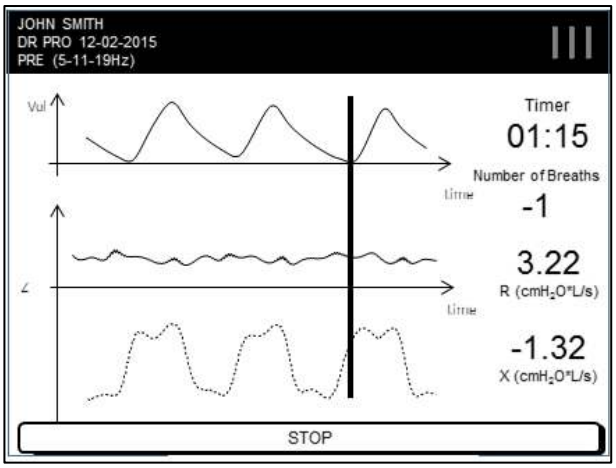


Figure 41 - Real-time tracings for volume and impedance

The top chart will display the tidal volume (Vol, unit of measurement: liters), the chart on the bottom will show the impedance (Z, unit of measurement: $cmH_2O/(L/s)$) in the form of resistance (solid line), and reactance (dashed line). In case of multi frequency stimulating waveform, the tracings displayed on the screen during the test are those at the lowest frequency (5 Hz). The right side of the screen will report, from the top: the remaining time to the end of the test (mm:ss), the number of accepted breaths, the mean inspiratory resistance (R) and the mean inspiratory reactance (X) of the last accepted breath.

The number of accepted breaths starts from -3, as the first 3 breaths are not used for the calculation of impedance but only to optimize the amplitude of the stimulating waveform to the patient being tested. This also allows the patient to adapt to the device with a normalized breathing pattern.

If a successful slow spirometry verification has been performed on the same day, the device will enable the measurement of the slow spirometry volumes after five breaths are accepted. A button MEASURE SVC will appear on the bottom right side of the screen (Figure 42). At this point, you may choose to either continue with the measurement of the FOT parameters until the timer countdown is completed or until you reach the selected

number of accepted breaths (see section *CHANGE USER SETTINGS*) or you can switch to the measurement of slow spirometry volumes (see section *Measurement of the slow* spirometry).

Any time, you can press *STOP* to end the test.

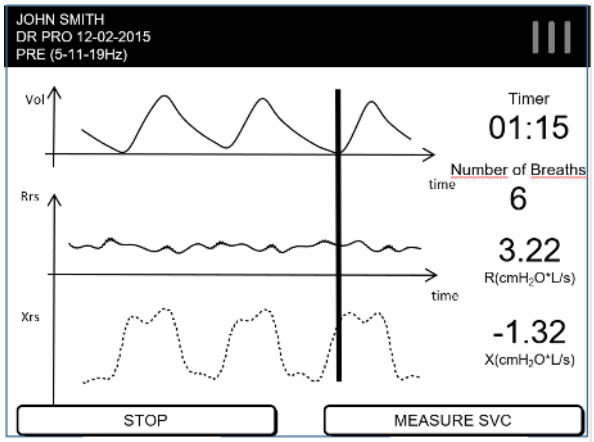


Figure 42 - After 5 accepted breaths, the option to measure SVC is available

NOTE	THE MINIMUM NUMBER OF BREATHS REQUIRED AFTER THE AMPLITUDE OPTIMIZATION FOR THE RESULTS TO APPEAR IS FIVE. IF THE TEST IS STOPPED BEFORE FIVE ACCEPTED BREATHS AN ERROR SCREEN WILL ALLOW YOU EITHER TO *REPEAT* THE TEST OR TO RETURN TO THE HOME SCREEN.

NOTE	IF THE MEASUREMENT OF THE SLOW SPIROMETRY VOLUMES IS NOT ENABLED (I.E. THE BUTTON MEASURE SVC DOES NOT APPEAR ON THE SCREEN AFTER FIVE ACCEPTED TIDAL BREATHS), PLEASE PERFORM A SUCCESSFUL SLOW SPIROMETRY VERIFICATION FIRST (SEE SECTION *Verification of the Factory Calibration*) AND ENSURE THAT YOUR DEVICE HAS BEEN ENABLED FOR SLOW SPIROMETRY MEASUREMENTS. FOR FURTHER INFORMATION CONTACT YOUR DISTRIBUTOR (SEE SECTION *User Assistance Information*).

If you have chosen a pseudo-random noise stimulating waveform (PSRN)

During the test the wording "*Breathe normally*" will display along with the time remaining and the number of valid breaths.
The number of accepted breaths starts from -3, as the first 3 breaths are not used for the calculation of impedance, but only to optimize the amplitude of the stimulating waveform to the patient being tested. This also allows for the patient to adapt to the device with a normalized breathing pattern.

Any time, you can press *STOP* to end the test.

NOTE	THE MINIMUM DURATION OF A PSRN TEST REQUIRED FOR THE RESULTS TO APPEAR IS 30 SECONDS. IF THE TEST IS STOPPED BEFORE 30 SECONDS AN ERROR SCREEN WILL ALLOW YOU EITHER TO *REPEAT* THE TEST OR O RETURN TO THE HOME SCREEN.

NOTE	THE MEASUREMENT OF THE SLOW SPIROMETRY VOLUMES IS NOT ALLOWED WITH THE PSRN STIMULATING WAVEFORM.

Measurement of the slow spirometry volumes

Current slow spirometry volumes calculated and displayed by the device are the inspiratory capacity (IC) and the slow vital capacity (SVC).
After pressing the MEASURE SVC button (see section *Measurement of FOT parameters*) the device will guide you through the measurement of these parameters (Figure 43). The volume tracing (V, in liters) will be displayed on the screen as a solid line, the reactance tracing (X, in $cmH_2O \cdot L \cdot s^{-1}$) at the selected stimulating waveform will be displayed as a dashed line.

NOTE	IF THE SELECTED STIMULATING WAVEFORM IS 5-11-19 HZ, THE REACTANCE TRACING WILL BE CALCULATED AND DISPLAYED AT 5 HZ ONLY DURING THE MEASUREMENT OF SLOW SPIROMETRY VOLUMES.

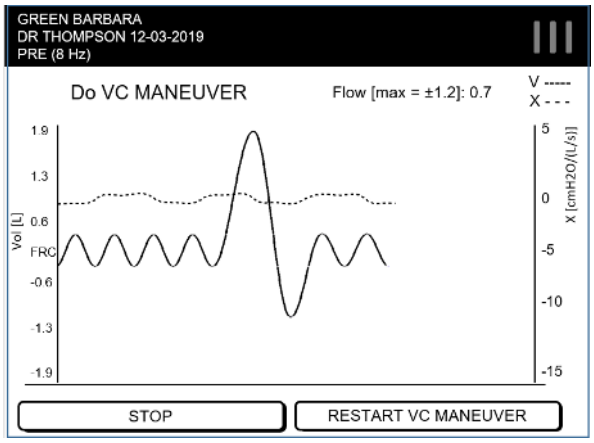


Figure 43 - Slow Spirometry screen

First, the subject is required to make at least three tidal breaths for the calculation of the Expiratory Reserve Volume (ERV). A breath counter on the top left side of the screen will assist you during this first step.

CAUTION	ENSURE THE SUBJECT PERFORMS AT LEAST 3 TIDAL BREATHS BEFORE STARTING THE SLOW SPIROMETRY MANEUVER, OTHERWISE THE RESULTS MAY BE INACCURATE.

After three tidal breaths are accepted, the sentence “Do VC Maneuver” will appear on the top left side of the screen (Figure 44).

CAUTION	ALWAYS WAIT FOR THE DEVICE TO DISPLAY THE MESSAGE “DO VC MANEUVER” BEFORE ASKING THE SUBJECT TO START THE SLOW SPIROMETRY MANEUVER, OTHERWISE THE RESULTS MAY BE INACCURATE.

CAUTION	DO NOT ASK THE SUBJECT TO MAKE MORE THAN ONE SLOW SPIROMETRY MANEUVER WITHIN EACH TEST, OTHERWISE THE RESULTS MAY BE INACCURATE.

The Slow Spirometry maneuver consists of a gentle deep inspiration from ERV until maximal volume is reached (this phase is used to calculate the IC), followed by a gentle expiration until no more air can be blown out (this phase is used to calculate the SVC).

NOTE	IF THE SUBJECT AIRFLOW IS ABOVE 1.6 L/S DURING THE MANEUVER (THE FLOW VALUE IS DISPLAYED ON THE TOP RIGHT PART OF THE SCREEN), THE DEVICE WILL WARN YOU WITH THE FOLLOWING MESSAGE “FLOW TOO HIGH”. YOU NEED TO REPEAT THE MANEUVER. ASK THE SUBJECT TO BREATHE MORE SLOWLY

At the end of this phase, the subject is required to return to breath normally at his/her operating volumes and make at least one more tidal breath.

If you need to cancel and to repeat the maneuver, press RESTART VC MANEUVER (Figure 43). This will cancel the current maneuver.

At any time, you can press *STOP* to end the test.

At the end of each test, a summary of the results will be displayed on the screen. See section *Presentation of the results*

Adding a new test while performing a session of measurements

After reviewing the test results (see section *Presentation of the results*), you can either save or discard the test (see section *Accept or discard the test*).

If you SAVE the test, you will be able to PRINT the clinical report of this test, export it on a PDF or export the PDF report and all raw data (Figure 44).
You can also add a new test to this open test session by pressing the button ADD TEST (up to five single tests can be added to a given test session) or end the current measurement by pressing the button END.

You can start a new test session by pressing the button ADD SESSION.

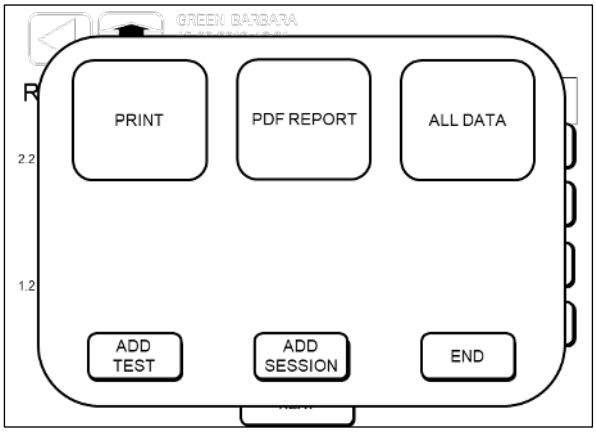


Figure 44 - Adding a new test to the current session

NOTE	IF YOU PRESS END, THE TEST SESSION WILL NOT BE CLOSED. IT WILL REMAIN OPEN FOR 20 MINUTES AND YOU CAN STILL ADD SINGLE TESTS TO THAT SESSION. FOR FURTHER INFORMATION, SEE SECTION User Assistance Information

Adding a test to an open session from the HOME page

A test session on a given subject and with a given test label can be reopened if the previous test has been done not earlier than 20 minutes ago and if the test session contains less than five single tests.

A test session can be reopened in two ways:

- From the database: from the HOME screen select DATA, then select the subject by pressing the correspondent row and, finally, the test session you want to reopen. The current test session results will be displayed on screen. Press NEXT and, in the screen reported in Figure 45, press ADD TEST.

- From the new test button: from the HOME screen, select NEW TEST, insert the subject surname and select him/her from the list displayed on screen. If an open test session for that specific subject and selected stimulating waveform exists,

you can either open a NEW SESSION or ADD TEST to the existing one (Figure 45).

Figure 45 - Adding a test to an existing session

Presentation of the results

Results of each test can be reviewed on screen at the end of the measurement. The results will include FOT data and, if available, slow spirometry volumes.

You can always SAVE or DISCARD the test (see section *Accept or discard the test*). If you SAVE the test, it will be automatically added to the test session, which you can review thereafter.

You can also always review the saved test sessions and each single test contained by browsing the database (for further information, see section *BROWSING THE DATABASE*).

Results of a single test

CAUTION	IF THE MEASURED IMPEDANCE IS OUTSIDE THE 10% ACCURACY LIMIT AT THE SELECTED STIMULATING WAVEFORM, AT THE END OF THE TEST YOU WILL BE NOTIFIED WITH THE MESSAGE REPORTED IN Figure 46 AND YOU WILL NOT BE ABLE TO SAVE THE TEST. PRESS END TO GO TO THE HOME PAGE. USE THE TABLE REPORTED IN THIS MESSAGE TO SELECT A STIMULATING WAVEFORM THAT ALLOWS THE MEASUREMENT OF HIGHER IMPEDANCES, THEN REPEAT THE TEST. FOR FURTHER INFORMATION, SEE SECTION *CRITERIA FOR SELECTING THE STIMULATING WAVEFORM*

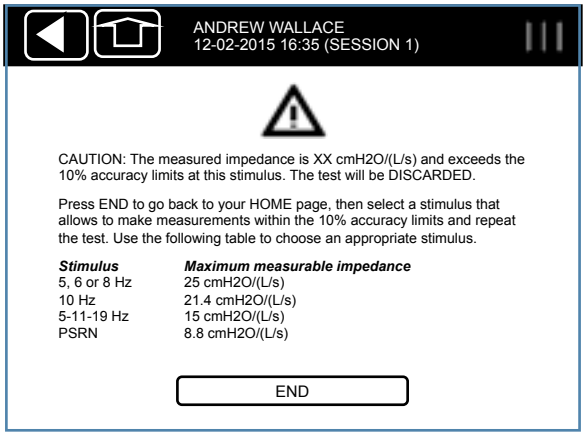


Figure 46 - Notification of measured impedance above accuracy limits

If the measured impedance is within the 10% accuracy limits, on the top of the screen the following parameters will be reported:

- The type of stimulus at which the measurement has been performed
- The number of accepted breaths (% of the total number of breaths)
- Minute ventilation (Ve, expressed in L/min). Data is reported as mean ±SD
- *Within-test* coefficient of variation of the total respiratory resistance at the lowest stimulating frequency available (CV, expressed in %). If the CV is greater than 15% it will be highlighted.

The presentation of resistance and reactance data will vary depending on the selected stimulus.

If you have chosen a single frequency stimulating waveform (5, 6, 8 or 10Hz)
The results are reported as in Figure 47.

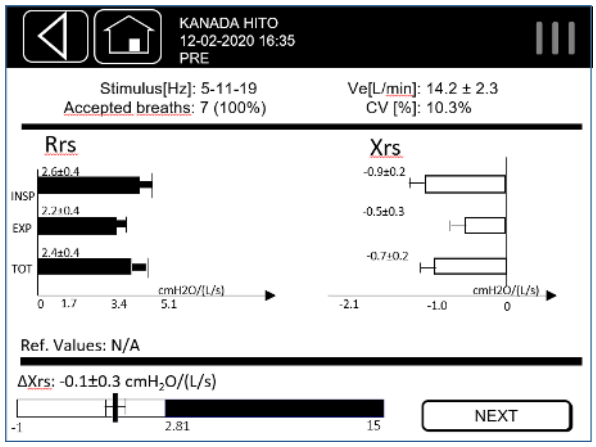


Figure 47 - Results of a single frequency test

- The bar plot on the left reports the mean and standard deviation of the Resistance (INSPiratory, EXPiratory and TOTal), calculated based on all the accepted breaths of the test. The shaded area represents the normality range calculated according to the reference equation selected and reported below the graphs. In case the reference equations have been disabled (see section *CHANGE USER SETTINGS*), the shaded area will not be displayed.

- The bar plot on the right reports the mean and standard deviation of Reactance (INSPiratory, EXPiratory and TOTal), calculated from all the accepted breaths of the test. The shaded area is the normality range calculated according to the reference equation reported below the graph. In case the reference equations have been disabled (see section *CHANGE USER SETTINGS*), the shaded area will not be displayed.

- If you used a stimulating waveform at 5 Hz, an additional horizontal bar on the bottom of the screen will display as a vertical line the mean ΔXrs calculated from all the accepted breaths of the test. ΔXrs is the difference between the mean inspiratory and the mean expiratory reactance and it is an index of expiratory flow limitation (*Dellacà et al., ERJ, 2004*). A threshold of 2.81 $cmH_2O/(L/s)$ is used to classify flow limited and non-flow limited breaths (*Dellacà et al., ERJ, 2004*). The white part of the bar represents the normality range, the blue shaded part indicates the presence of expiratory flow limitation.

Press *NEXT* to continue.

If you have chosen a multi frequency stimulating waveform (5-11-19Hz)

In addition to the results displayed for a single frequency stimulating waveform (Figure 47) an additional graph is displayed (Figure 48).

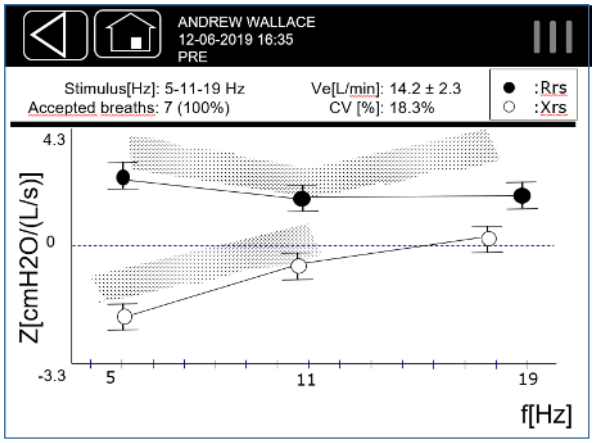


Figure 48 - Results of a 5-11-19 Hz test

Values of mean inspiratory resistance (full circles) and reactance (empty circles) at the frequencies of the stimulating waveform are displayed. Normality ranges are reported as a shaded area for the available stimulating frequencies.

Press *NEXT* to continue.

If you have chosen a pseudo-random noise stimulating waveform (PSRN)

The results are reported as in Figure 49.

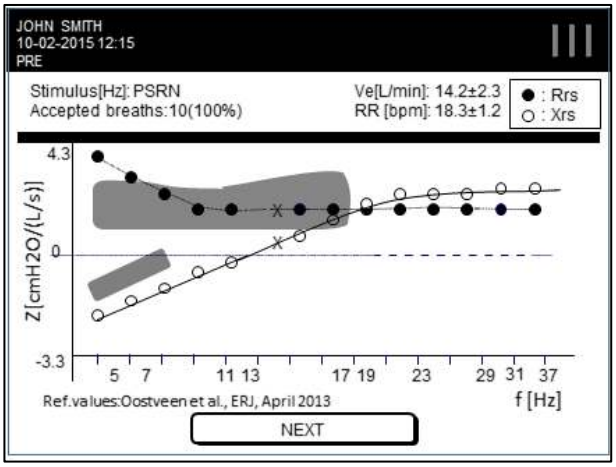


Figure 49 - Results of a PSRN test

Values of total resistance (full circles) and reactance (empty circles) at the frequencies of the stimulating waveform are displayed. When a PSRN stimulus is used the device uses coherence as an index of the quality of the data. If resistance and reactance at a specific frequency are marked with an 'X', the coherence at that frequency is <0.95 and, therefore, these data points must be considered cautiously when interpreting data. This is highlighted also in the final test report (see section *CLINICAL REPORTS*).
Normality ranges are reported as a shaded area for the available stimulating frequencies.

Press *NEXT* to continue.

If the subject has performed a slow spirometry maneuver
Results are reported as in Figure 50.
On the top right of the screen the following parameters are displayed:

- Vital capacity (VC) in L
- Percentage of the predicted VC according to the selected reference equation (reported as apex)
- Inspiratory capacity (IC) in L

The graph represents the slow spirometry maneuver. The dotted line is drawn at the Expiratory Reserve Volume (ERV).

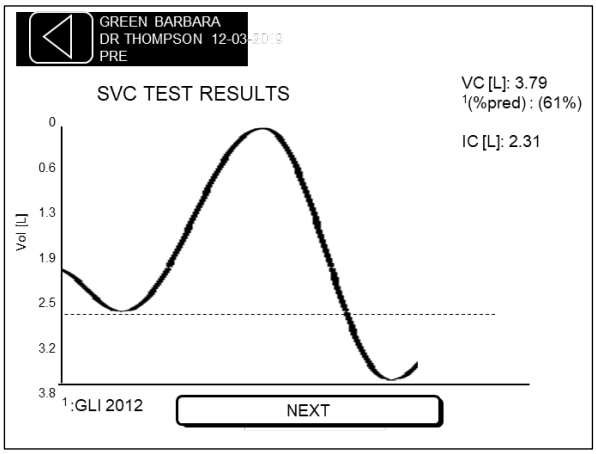


Figure 50 - Results of a Slow Spirometry test

Results of a test session

Each single test is automatically added to a test session. Pooled results of a test session are displayed on screen after reviewing data from each single test performed or they can be recalled from the device database.
The results of a test session displayed on screen include both a summary of FOT parameters measured during the session (Figure 51) and one of the slow spirometry parameters, if measured (Figure 52).

Summary of a FOT test session

The example of Figure 51 shows results of a FOT test session with four single tests. The top side of the screen reports the mean (M) value and the *inter-test* coefficient of variation (CV) of Rtot and the mean of Xtot calculated from the selected tests of the session. The mean values of Rtot and Xtot correspond to the full squares reported in the graphs in the lower part of the screen. The single tests selected for the computation of the mean and CV are displayed as full circles in the same graph, while their error bars represent their *within-test* standard deviation. Dotted lines in each graph represent the *inter-test* variability of the measurements and has been defined as the greatest between 0.5 $cmH_2O \cdot s \cdot L^{-1}$ and 15% of the mean Rtot (or Xtot).
You can always select or deselect a single test by pressing the corresponding button number on the right side of the screen. The mean values of Rtot and Xtot, the CV of Rtot and the position of the dotted lines in the graphs will update automatically.

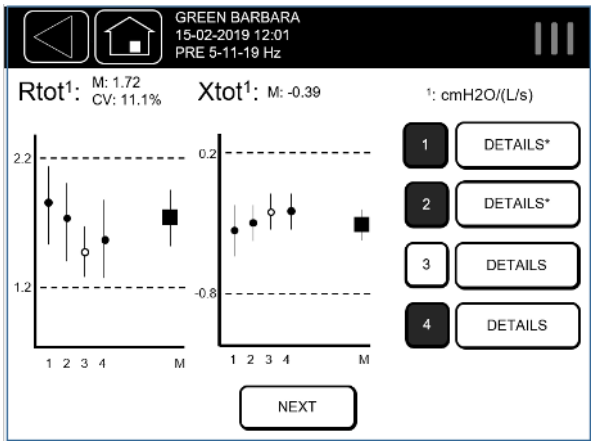


Figure 51 - FOT results for a test session

If you want to review the results of a single test press the button DETAILS. For further information see section *Results of a single test*. Single tests that include both FOT and slow spirometry measurements are marked with an asterisk '*' placed inside the DETAILS button (Figure 51).

Guide to the selection of the FOT tests within a session

NOTE	IT IS RECOMMENDED TO MAINTAIN THE *INTER-TEST* CV OF RTOT BELOW 15%. VALUES ABOVE 15% WILL BE HIGHLIGHTED ON SCREEN

The three most reproducible tests are automatically selected (i.e. highlighted in blue in the results screen of Figure 51).
You can always select or deselect a single test by pressing the corresponding button number on the right side of the screen.

NOTE	FOR EACH TEST SESSION, A MAXIMUM OF THREE TESTS CAN BE SELECTED AT THE SAME TIME.

If the test session contains at least one slow spirometry measurement press NEXT to review the summary data. Otherwise press END to exit the summary screen of the test session or EXPORT to send the entire test session results to a printer or to a USB memory.

Summary of a slow spirometry test session

The example of Figure 52 shows results of a slow spirometry test session with three slow spirometry maneuvers. The top side of the screen reports the selected value of Slow Vital Capacity (VC) and the mean (M) value and *inter-test* coefficient of variation (CV) of Inspiratory Capacity (IC), calculated from the selected tests of the session. The VC and the mean value of IC correspond to the full squares reported in the graphs in the lower part of the screen. The single tests selected for the computation of these values are displayed as full circles in the same graphs. Dotted lines in each graph are drawn at ±0.15 L from the selected VC or from the mean IC or ±0.10 L if the measured parameter is below 1 L..
You can always select or deselect a single test by pressing the corresponding button number below each graph. The squared symbols in the graphs of VC and IC and the position of the dotted lines will update automatically.

If you want to review the results of a single test press the button DETAILS. For further information see section *Results of a single test*. The number on the left side of the DETAILS button corresponds to the test number reported on the x-axes of the graphs.

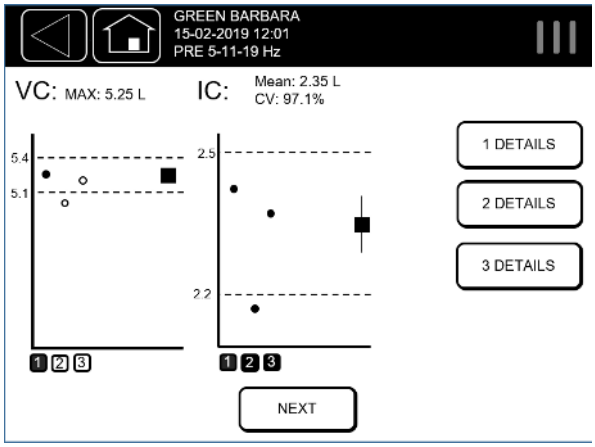


Figure 52 - Slow Spirometry results for a test session

Guide to the selection of the slow spirometry maneuvers within a session

By default, the highest measured VC volume is selected and highlighted among those performed in a test session (Figure 53). For the IC, the three most reproducible tests are automatically selected (i.e. highlighted in blue in the results screen of Figure 52). You can

always select or deselect a single test by pressing the corresponding button number at the bottom of each graph.

NOTE	FOR EACH TEST SESSION, A MAXIMUM OF THREE TESTS IC VALUES CAN BE SELECTED AT THE SAME TIME.

Accept or discard the test

After the presentation of the results of a single test, you can always choose to either *SAVE* or *DISCARD* the test.

- Select *DISCARD* to delete the data of the current test. You will be asked to *CONFIRM* or *CANCEL* your selection. If you CONFIRM to delete the test, you can either go back to the Home Screen (*HOME*) or *REPEAT* the test.

- Select *SAVE* to save the test onto the internal memory of the device. If you decide to save the test, the next screen will allow you to print the report using the postscript USB printer connected to the device, export the report of the test in a PDF format, export the whole data (ALL DATA), ADD a new TEST to the existing test session (if there are less than five single tests within the open session) or END the measurements (Figure 53).

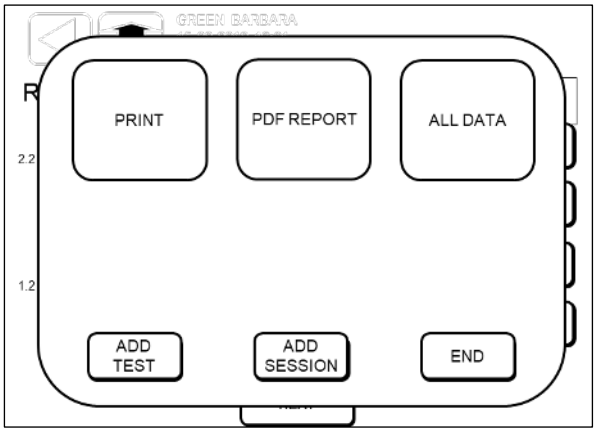


Figure 53 - Print or export results

- Select *PRINT* to print the clinical report. Be sure to have a verified postscript USB printer connected the device. Two options are available: *SINGLE* or *COMPARE*. Press *SINGLE* to create the report of the currently displayed session. Press *COMPARE* to compare the results of the currently displayed session with a former test session. The device will display a table with all the test sessions performed by the same patient using the same stimulating waveform. Press the row corresponding to the test session that you would like to compare. The results of the selected session will be displayed, see section *Presentation of the results*. Press *NEXT* to confirm and continue. Further details are reported in section *CLINICAL REPORTS.*

If the printer cable is not plugged in you will get the following message: *No printer detected. Please connect a printer and turn it on*. Connect the printer, turn it on and press the button *PRINT* again.

 CAUTION	THE PRINTED TEST REPORT CONTAINS CONFIDENTIAL DATA. MAKE SURE TO PROTECT ITS CONTENT FROM UNAUTHORIZED ACCESS FOLLOWING THE REGULATIONS OF YOUR INSTITUTION.

- Select *PDF REPORT* to export the clinical report. Be sure to have a USB memory stick inserted into the device. Two options are available: *SINGLE* or *COMPARE*. Press *SINGLE* to create the report of the currently displayed session . Press *COMPARE* to compare the results of the currently displayed session with a former test session. The device will display a table with all the sessions performed by the same patient using the same stimulating waveform. Press the row corresponding to the test session that you would like to compare. The results of the selected session will be displayed, see section *Presentation of the results*. Press *NEXT* to confirm and continue. Further details are reported in section CLINICAL REPORTS.

If a USB memory stick is not plugged in you will get the following message: *Device not found. Please insert a USB memory stick and try again*. Press *BACK* to get back to the Export Page.

If there is not enough space on the USB memory you will get the following message: Not enough disk space. Please, free some memory on the USB device and try again, or use a different USB memory with more free space. Press BACK to get back to the Export Page.

 CAUTION	THE USB MEMORY STICK CONTAINS CONFIDENTIAL DATA. MAKE SURE TO PROTECT ITS CONTENT FROM

UNAUTHORIZED ACCESS FOLLOWING THE REGULATIONS OF YOUR INSTITUTION.

- Select *ALL DATA* to export the session data. Two options are available: *SINGLE* or *COMPARE*. Press *SINGLE to* create a clinical report in PDF format for the currently displayed test session, and an archive with its data files. An archive (.tar file) will be exported for each test of the session. Press *COMPARE* to export the data of the currently displayed session and those of a former session, and to create a comparative clinical report (see section *CLINICAL REPORTS*.) An archive (.tar file) will be exported for each test of any session. The device will display a table with all the test sessions performed by the same patient using the same stimulating waveform. Press on the row corresponding to the test session that you would like to compare. The results of the selected session will be displayed, see section *Presentation of the results*. Press *NEXT* to confirm and continue.

Description of exported data

An archive (.tar) file exported from a test session contains up to six different files.

1) .xml file

This file is always present and contains structured information about the patients and the results of the tests.

2) .dat file

This file includes raw data sampled or calculated at 200Hz. The meaning and header of each column change according to the stimulating waveform used for the test, as reported in the following table.

Single frequency (5, 6, 8, 10Hz) stimulating waveform

Column number	*Column Title*	*Parameter*
1	Pressure	Raw Pressure
2	Flow	Raw Flow
3	Filtered flow	Tidal Breathing Flow
4	Rf	Within-breath Resistance at *f* Hz
5	Xf	Within-breath Reactance at f Hz
6	#	Sample Counter

Multi frequency (5-11-19Hz) stimulating waveform

Column number	*Column Title*	*Parameter*
1	Pressure	Raw Pressure
2	Flow	Raw Flow
3	Filtered flow	Tidal Breathing Flow
4	R5	Within-breath Resistance at 5Hz
5	X5	Within-breath Reactance at 5Hz
6	R11	Within-breath Resistance at 11Hz
7	X11	Within-breath Reactance at 11Hz
8	R19	Within-breath Resistance at 19Hz
9	X19	Within-breath Reactance at 19Hz
10	#	Sample Counter

PSRN stimulating waveform

Column number	*Column Title*	*Parameter*
1	RP	Raw Pressure
2	RF	Raw Flow
3	FF	Tidal Breathing Flow
4	#	Sample Counter

3) .mxn file

This file is organized in a n-by-3 matrix, where each row represents the n-th breath accepted by the device during the FOT measurement while the three columns contain the sample number correspondent to the beginning of inspiration, end of inspiration and end of expiration, respectively (Figure 54).Unless a breath has been discarded, the beginning of the inspiratory phase coincides with end of expiratory phase of the previous breath.

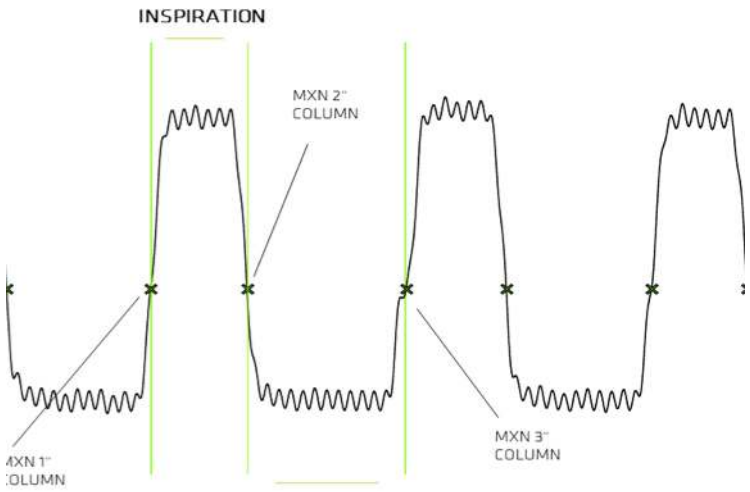


Figure 54 - Flow (from the .dat file) with superimposed .mxn points for a breath

4) .tr file

This file contains the average tracings of Volume, Resistance, Reactance and their standard deviation as a function of time (Figure 55). The tracings are resampled. First column is the Time base, second and third columns are the mean and standard deviation of the Resistance, fourth and fifth columns are the mean and standard deviation of the Reactance, sixth and seventh columns are the mean and standard deviation of the tidal Volume.
If a multi-frequency (5-11-19Hz) stimulating waveform has been used, Resistance and Reactance are reported only at 5Hz.
If a PSRN stimulating waveform is used, second to fifth columns are padded with zeros.

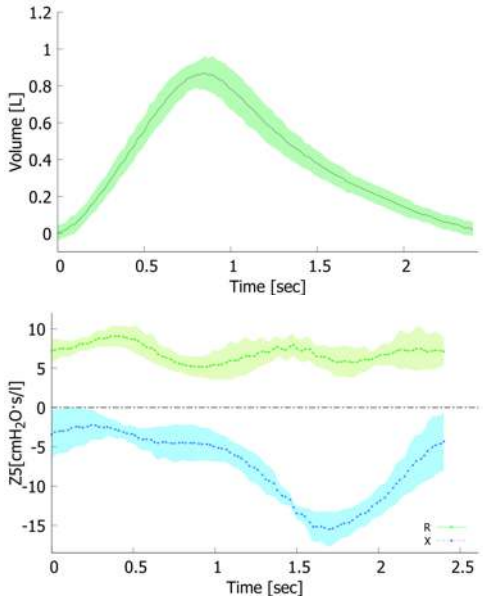


Figure 55 - Left: Average Tidal Volume and Standard deviation.
Right: Average Resistance and Reactance and their standard deviations (obtained from a .tr file)

CAUTION	THE USB MEMORY STICK CONTAINS CONFIDENTIAL DATA. MAKE SURE TO PROTECT ITS CONTENT FROM UNAUTHORIZED ACCESS FOLLOWING THE REGULATIONS OF YOUR INSTITUTION.

5) _VC.dat file

This file is only present if a slow spirometry maneuver has been performed. It includes raw data sampled or calculated at 200Hz during the maneuver. The meaning and header of each column will change according to the stimulating waveform used for the test, as reported in the following table. These VC files are not available if a PSRN stimulating waveform was used since it is impossible to perform a SVC maneuver with such stimulus.

Single frequency (5, 6, 8, 10Hz) stimulating waveform		
Column number	*Column Title*	*Parameter*
1	Pressure	Raw Pressure
2	Flow FOT	Raw Flow
3	Flow SVC	Flow calibrated for SVC
4	Filtered Flow	Tidal Breathing Flow
5	Rf	Within-breath Resistance at *f* Hz
6	Xf	Within-breath Reactance at f Hz
7	Volume	Raw Volume
8	#	Sample Counter

Multi frequency (5-11-19Hz) stimulating waveform		
Column number	*Column Title*	*Parameter*
1	Pressure	Raw Pressure
2	Flow FOT	Raw Flow
3	Flow SVC	Flow calibrated for SVC
4	Filtered Flow	Tidal Breathing Flow
5	R5	Within-breath Resistance at 5Hz
6	X5	Within-breath Reactance at 5Hz
7	R11	Within-breath Resistance at 11Hz
8	X11	Within-breath Reactance at 11Hz
9	R19	Within-breath Resistance at 19Hz
10	X19	Within-breath Reactance at 19Hz
11	#	Sample Counter

6) _VC.mxn file

This file is organized in a n-by-3 matrix, where each row represents the n-th breath accepted by the device during the slow spirometry maneuver, while the three columns contain the sample number corresponding to the beginning of inspiration, end of inspiration and end of expiration.

BROWSING THE DATABASE

From the Home Screen press *DATA* ( ) to enter the database.

Search for a patient

A table will be displayed with the list of all patients present in the database (Figure 56).

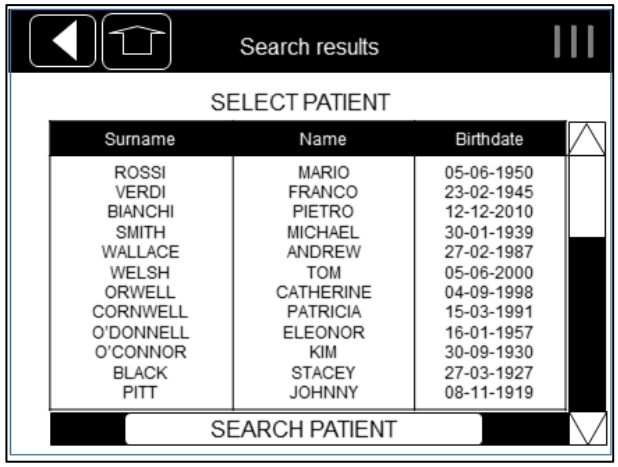


Figure 56 - Patients listing

If the number of patients is greater than ten, on the right of the table a scrolling bar will be displayed. Press the up and down arrows to scroll through all the patients.

Press *SEARCH PATIENT* to find a specific patient. Insert the patient surname or the initial part of it. As you enter the first letter the *NEXT* button will be displayed.

- If no patients' surname begins with the inserted letters, you will get the message: *PATIENT NOT FOUND*.
- If any patients' surname starts for the entered letters, a table with the list of these patients will be displayed. To select the desired patient press the corresponding row of the table.

Select the test session to recall

Once you have selected one patient from the database, a table with the list of all the sessions performed by that patient will be displayed. For each test session the following details are reported: date and time of the test, the type of stimulating waveform, the session label with an optional asterisk '*', the name of the physician who supervised the test and the number of tests included in each session (Figure 57). The asterisk indicates that at least a slow spirometry maneuver has been performed within the test session. To select a test session, press the corresponding table row. A summary of the test session will be displayed. For more information see section *Presentation of the results*.

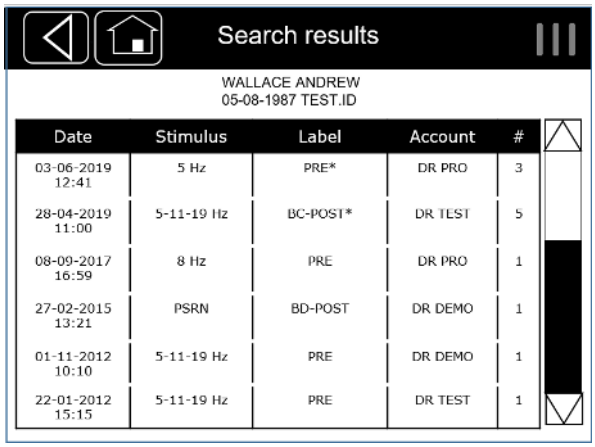


Figure 57 - Session results

CLINICAL REPORTS

A clinical report can be created for each single test or for an entire test session. It can be created immediately after the end of a measurement or by recalling a previously saved session from the database. A clinical report can contain data of one single session or compare the results of two different sessions.
Clinical reports can be either printed or exported to a USB memory stick. The file format is PDF. For more information about data export, see section *Presentation of the results*.

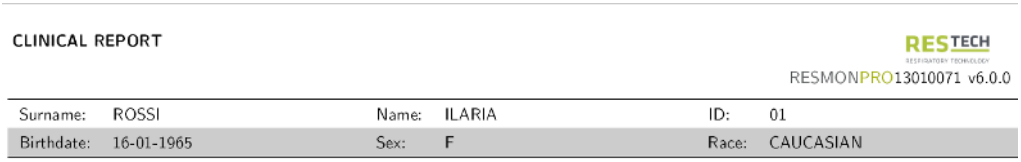
Clinical reports are organized into six sections:

1. Personal data
2. Measurement details
3. FOT charts
4. Numeric results
5. Footnotes
6. Slow spirometry data (optional)
7. Average tidal volume and impedance tracings (only for single-test clinical reports)

NOTE	IN SINGLE-TEST REPORTS THE MEAN, STANDARD DEVIATION AND COEFFICIENT OF VARIATION ARE *INTRA-TEST*, IN TEST-SESSION REPORTS THEY ARE *WITHIN-TESTS.*

1. Personal data

This section reports patient information (Figure 58).


CLINICAL REPORT

RESTECH

RESMONPRO13010071 v6.0.0

Surname:	ROSSI	Name:	ILARIA	ID:	01
Birthdate:	16-01-1965	Sex:	F	Race:	CAUCASIAN

Figure 58 - Personal data section

- Surname
- Name
- Birthdate
- Gender
- Race

2. Measurement details

This section includes information and details related to the test session (Figure 59).

		PRE				
Age $[years]$		28				
Weight $[kg]$		79				
Height $[cm]$		183				
BMI $[Kg/m^2]$		23.59				
		Date	Z filter $[cmH2O/(L/s)]$	Selection		
				FOT	VC	IC
TEST 1		02-07-2019 17:28	0.37	√	×	√
TEST 2		02-07-2019 17:30	0.37	×	×	×
TEST 3		02-07-2019 17:32	0.37	√	×	√
TEST 4		02-07-2019 17:35	0.37	√	√	×
TEST 5		02-07-2019 17:37	0.37	×	×	√
Account		GOOFY				
Prediction Equation	FOT	Oostveen et al., ERJ, April 2013[A]				
	SVC	GLI 2012				
Software version		6.1.0-rc6				

Figure 59 - Measurement details section

- Test type/label (PRE, POST, BC-POST, BD-POST or Custom Label).

- Age, Weight, Height and BMI at the date of the test. Measurement Units are in square brackets.
- One row for each test of the session reporting:
    - The date and time of the test
    - The mean impedance value of the bacterial/viral filter that has been used for the measurement. If no value is reported here, no correction for the bacterial/viral filter has been applied to the final result;
    - A checkmark (√) to signal which tests are selected to calculate the mean values of FOT parameters and slow spirometry volumes (√ = selected, x = not selected). The selection of tests can be different between FOT parameters and slow spirometry volumes (IC and SVC)
- Name of the Account used to perform the test session
- The equation for predicted values used to calculate the range of normality of FOT (if enabled, see section *CHANGE USER SETTINGS*) and slow spirometry volumes (if available)
- The software version used to collect data of the test session

Reference equations

Reference equations allow the determination of the normal range of respiratory parameters. Two sets of reference equations are available and both cover different age ranges for the patients. They are summarized in the following table and all of them are taken from studies published on peer reviewed international journals. It is possible to completely disable reference equations for a given account, see section First log-in and the *ADMIN* account.

Reference equations: Set 1		
Reference equation	**Used for patients with the following age range**	**Available Reference Values***
Calogero et al, Pediatric Pulmonology, 2010	Children (<= 7 yrs old)	• Using a single frequency stimulating waveform: o Resistance at 6, 8 and 10Hz o Reactance at 6, 8 and 10Hz

Ducharme et al, Chest, 1998	Children (8-17 yrs old)	• Using a single frequency stimulating waveform: o Resistance at 6, 8 and 10Hz
Oostveen et al, Eur Respir J., 2013	Adults (> 18 yrs old)	• Using a single frequency stimulating waveform: o Resistance at 5, 6, 8 and 10Hz o Reactance at 5, 6, 8 and 10Hz • Using a multi-frequency stimulating waveform: o Resistance at 5, 11 and 19Hz o Reactance at 5 and 11Hz • Using a PSRN stimulating waveform: o Resistance between 5 and 23Hz o Reactance between 5 and 13Hz o Resonant Frequency (Fres)
Quanjer et al, Eur Respir J, 2012 (GLI)	Children (4-17 yrs old) and Adults	• Slow Vital Capacity
Reference equations: Set 2		
Reference equation	**Used for patients with the following age range**	**Available Reference Values***
Calogero et al, Pediatric Pulmonology, 2013	Children (<= 12 yrs old)	• Using a single frequency stimulating waveform: o Resistance at 6, 8 and 10Hz o Reactance at 6, 8 and 10Hz
Ducharme et al, Chest, 1998	Adolescents (13-17 yrs old)	• Using a single frequency stimulating waveform: o Resistance at 6, 8 and 10Hz
Oostveen et al, Eur Respir J., 2013	Adults (>= 18 yrs old)	• Using a single frequency stimulating waveform: o Resistance at 5, 6, 8 and 10Hz o Reactance at 5, 6, 8 and 10Hz • Using a multi-frequency stimulating waveform: o Resistance at 5, 11 and 19Hz o Reactance at 5 and 11Hz • Using a PSRN stimulating waveform: o Resistance between 5 and 23Hz

		○ Reactance between 5 and 13Hz • Resonant Frequency (Fres)
Quanjer et al, Eur Respir J, 2012 (GLI)	Children (4-17 yrs old) and Adults	• Slow Vital Capacity

* If the reference equation is not available for a given stimulating waveform and/or parameter and/or subject's age, the corresponding confidence interval (C.I.) and percentage predicted (%Pred) values (see below) wil not be displayed on clinical reports.

3. FOT charts

FOT graphs from a test session where a single frequency stimulating waveform (5, 6, 8 or 10Hz) is used

Refer to Figure 61.

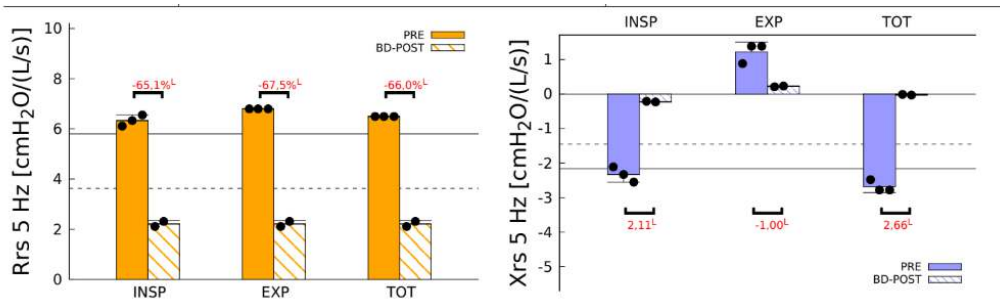


Figure 60 - Bars for resistance and reactance

- Bars on the left chart of Figure 60 represent the mean and standard deviation of INSPiratory, EXPiratory and TOTal resistance calculated from the selected single tests within a test session (see section *Performing a test session*).
  Bars on the right chart represent the mean and standard deviation of INSPiratory, EXPiratory and TOTal reactance calculated based on the selected tests within a session (see section *Performing a test session*). The dots on each bar represent the mean values of the FOT parameters of each selected test of the session.

- Bars with different color patterns placed side by side are used for paired comparisons between test sessions. By default, the test session labelled as PRE is plotted first. In case of coinciding labels of the two selected test sessions, the graph legend shows the date time, and the older session is plotted first. The black solid line represents the upper limit of normality, and the black dotted line represents the lower limit of normality computed based on the selected reference equations (for further information see previous section).

- If you used a 5 Hz stimulating waveform, an additional graph on the bottom of the page is displayed (Figure 61). This graph shows as an arrow the mean and standard deviation of ΔXrs calculated over all the tests of the session. Black dots represent the mean ΔXrs of individual tests results. ΔXrs is the difference between the mean inspiratory and the mean expiratory reactance and it is an index of expiratory flow limitation (*EFL*) during tidal breathing (*Dellacà et al., ERJ, 2004*). A threshold of 2.81 $cmH_2O/(L/s)$ is used to classify a patient as flow limited or non-flow limited during tidal breathing (*Dellacà et al., ERJ, 2004*). If such arrow is in the green part of the graph the patient has no flow limitation during tidal breathing. An arrow in the red part of the graph indicates the presence of *EFL*.

In comparative reports, one arrow per test session is reported. Each test session is identified by its label.

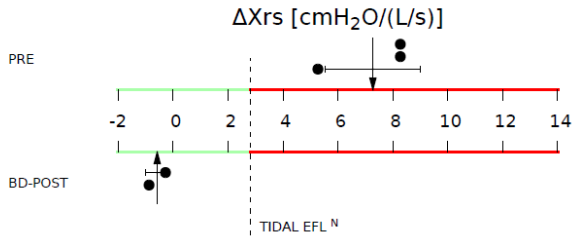


Figure 61 - Expiratory Flow Limitation (EFL) during tidal breathing

FOT graphs from a test session where a multi-frequency stimulating waveform (5-11-19 Hz) is used

In addition to the charts reported when a single frequency stimulating waveform is used (Figure 60 and Figure 61) where data are the resistance and reactance at 5Hz), a new chart with values of inspiratory resistance (orange solid line) and inspiratory reactance

(blue solid line) at the frequencies of the stimulating waveform is reported at the bottom of the page (Figure 62).
Results from the single tests are reported as dashed lines. Error bars at each stimulating frequency represent the standard deviation of the selected single tests. Black lines represent the upper limit of normality for the resistance, and the lower limit of normality for the reactance, based on the selected reference equations (for further information see the previous section).
In comparative clinical reports, the chart of each test session is identified by its label.

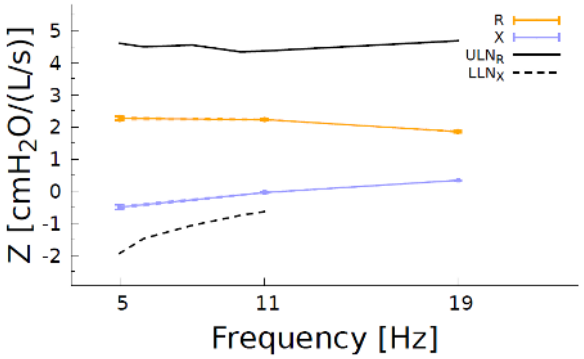


Figure 62 - Inspiratory resistance and reactance spectra

FOT graphs from a test session where a PSRN stimulating waveform is used

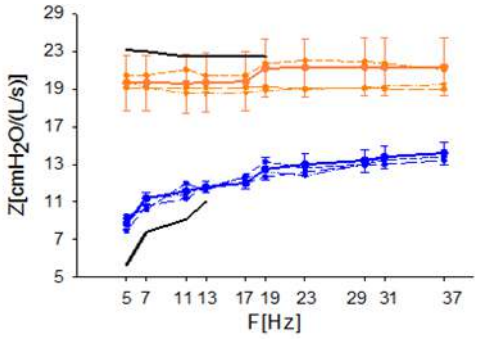


Figure 63 - Inspiratory resistance and reactance spectra in a PSRN test

Figure 63 shows an example of the chart reported on the clinical report when a PSRN stimulating waveform has been used. Solid lines represent the mean inspiratory resistance (orange) and reactance (blue) of the test session. Results from the single tests are reported as dashed lines. Error bars at each stimulating frequency represent the standard deviation of the selected tests. Black solid lines represent the upper limit of normality for the resistance and the lower limit of normality for the reactance, based on the selected reference equations (for further information see the previous section). When a PSRN stimulus is used the device uses the coherence as a data quality index. The symbol *X* indicates the data points with a coherence < 0.95.
In comparative clinical reports, the chart of each test session is identified by its label

4. Numerical results

This section of the clinical report contains the impedance and breathing pattern parameters. For each parameter and each test of the session, results are reported as follows:

- Mean (M) and coefficient of variation (CV)
- Z-score
- Predicted value and percentage of the predicted value, calculated based on the reference equation selected for the session. If the predicted values are not available, this column is filled with N/A

In comparative clinical reports, numerical results are reported for each test session and identified by the session label. Comparative clinical reports also include an additional column containing the absolute and percentage change between the parameters of the two sessions (CHG).

<u>Impedance parameters for single (5, 6, 8, 10Hz) or multi-frequency (5-11-19Hz) stimulating waveforms:</u>

- *Rinsp*: mean inspiratory resistance
- *Rexp*: mean expiratory reactance.
- *Rtot*: mean resistance of the whole breath.
- *Xinsp*: mean inspiratory reactance.
- *Xexp*: mean expiratory reactance.
- *Xtot*: mean reactance of the whole breath.

- ΔXrs: difference between mean inspiratory and expiratory reactance at 5Hz., which indicates the presence of expiratory flow limitation when greater than 2.81 $cmH_2O/(L/s)$ (*Dellacà et al., ERJ, 2004*). Available only when the test has been done with a 5Hz or 5-11-19Hz stimulating waveform.
- *FL%*: percentage of flow-limited breaths. Available only when the test has been done with a 5Hz or 5-11-19Hz stimulating waveform.
- R_{5-19}: difference between inspiratory resistance at 5Hz and 19Hz. This value is an index of heterogeneity of the obstruction within the lungs. Available only when the test has been done with a 5-11-19Hz stimulating waveform.

Impedance parameters for PSRN stimulating waveform:

- *Rrs*: mean total resistance of the respiratory system at every frequency contained in the PSRN stimulating waveform. Mean values are computed only over all the accepted breaths.
- *Xrs*: mean total reactance of the respiratory system at every frequency contained in the PSRN stimulating waveform. Mean values are computed only over all the accepted breaths.
- *Fres*: resonant frequency, which is the frequency at which reactance is null. This parameter is not available in the US.
- R_{5-19}: difference between resistance at 5Hz and 19Hz. This value is an index of heterogeneity of the obstruction within the lungs.

Breathing pattern parameters

CAUTION	THE ACCURACY OF BREATHING PATTERN PARAMETERS IS 10%. BREATHING PATTERN PARAMETERS SHOULD BE USED ONLY FOR AN OVERALL EVALUATION OF THE QUALITY OF THE TEST. IF YOU NOTICE ABNORMAL VALUES IT IS RECOMMENDED TO REPEAT THE TEST.

- *Ti*: duration of inspiration.
- *Te*: duration of expiration.
- *Ti/Ttot*: ratio between inspiratory time and total breath duration.
- *RR*: respiratory rate.
- Vt: tidal volume.

- Vt/Ti: mean inspiratory flow.
- Vt/Te: mean expiratory flow.
- Ve: minute ventilation.

5. Footnotes

This section contains an explanation of all the footnotes found within the clinical report. The footnotes are lettered from *A* to *Q* as follows:

A: Reference values determined on a Caucasian population.
The reference equations used had been determined on a Caucasian population.

B: According to patient's data at the time of the most recent test between the two compared ones.
When two test sessions are compared, the predicted values are calculated using the anthropometric data of the most recent test session.

C: Value out of range. (Dellacà et al.. ERJ, May 2004)
ΔXrs value > 2.81 $cmH_2O/(L/s)$, indicating expiratory flow limitation, according to “Dellacà et al, ERJ May 2004”.

D: CAUTION! No details about the previous device test.
No verification of the factory calibration has been done on the device before making the test in question (note valid only for tests made with software versions < 2.5.0)

E: CAUTION! Previous device test was unsuccessful (performed on dd-MM-yyyy at HH:mm).
Previous verification of the factory calibration failed (note valid for tests made with software versions < 2.5.0)

F: Previous device test was successful (performed on dd-MM-yyyy at HH:mm)
Previous verification of the factory calibration was successful.

CAUTION	IF THE CALIBRATION VERIFICATION OF A TEST MADE WITH A PREVIOUS SOFTWARE VERSION IS NOT AVAILABLE, OR IF IT WAS UNSUCCESSFUL, RESULTS OF THIS TEST ARE UNRELIABLE.

G: No data about normal variability at this frequency are available

The coefficient of repeatability (CR) between the two tests at the specified stimulating waveform is not available (the values are not highlighted in red).

H: Value out of the predicted range according to selected prediction equation
The measured values are out of the normal range according to the chosen reference equation.

L: Change greater than normal variability.
The variation between the two selected tests is above the Coefficient of Repeatability (CR), according to the chosen reference equation.

**: Coherence value (ρ) < 0.95:* Rrs and Xrs should be considered cautiously at *this* frequency.
Fres is also reported in red and asterisked if for its computation values of Xrs with a low coherence have been used (Fres is not available for devices sold in the US).

M: *Inter-test variability > 15%*
The inter-test variability is greater than 15% according to the coefficient of variation.

N: Dellacà et al., ERJ, May 2004
Threshold indicating the presence of tidal expiratory flow limitation. (Dellacà et al. ERJ, May 2004). ΔXrs value > 2.81 $cmH_2O/(L/s)$

P: Short time repeatability threshold not applicable: tests taken in different days
CHG threshold is not applicable in a compared report where the two tests were taken in different days.

Q: Intra-test variability > 30%
the intra-test variability is greater than 30% according to the coefficient of variation.

6. Slow spirometry data (optional)

This section of the clinical report is available only if at least one slow spirometry maneuver has been performed within the selected test session. Slow spirometry data are reported both as a chart and in table format.
In the example of Figure 64, solid lines represent the first slow spirometry maneuver of a session, dotted lines represent the second maneuver and dashed lines the third one. In comparative clinical reports each test session is identified by the test session label. The first session is plotted using black lines, the second session is plotted using red lines.

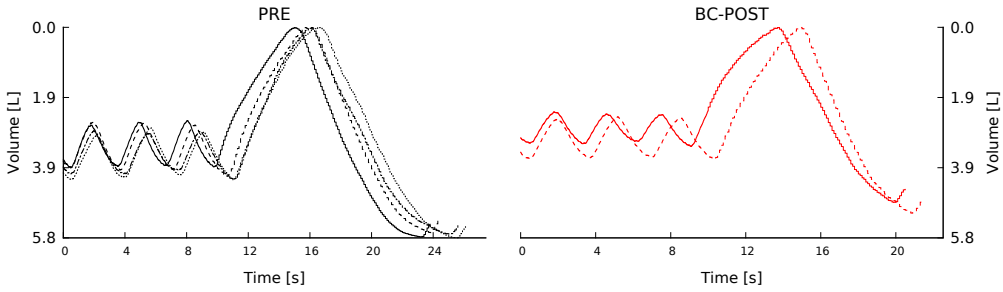


Figure 64 - Slow Spirometry chart

For the slow vital capacity (VC), results are reported as follows:

- Selected VC value from the available slow spirometry maneuvers of test session
- Z-score
- Predicted value and percentage of the predicted value, calculated based on the reference equation selected for the session. If the predicted values are not available, this column is filled with N/A

For the inspiratory capacity (IC) results are reported as:

- Mean (M) and coefficient of variation (CV) of the selected slow spirometry maneuvers of the test session
- Z-score
- Predicted value and percentage of the predicted value, calculated based on the reference equation selected for the session. If the predicted values are not available, this column is filled with N/A

7. Average tidal volume and impedance tracings (only for single-test clinical report)

This section contains the following graphs (Figure 65Figure 64 - Slow Spirometry chart):

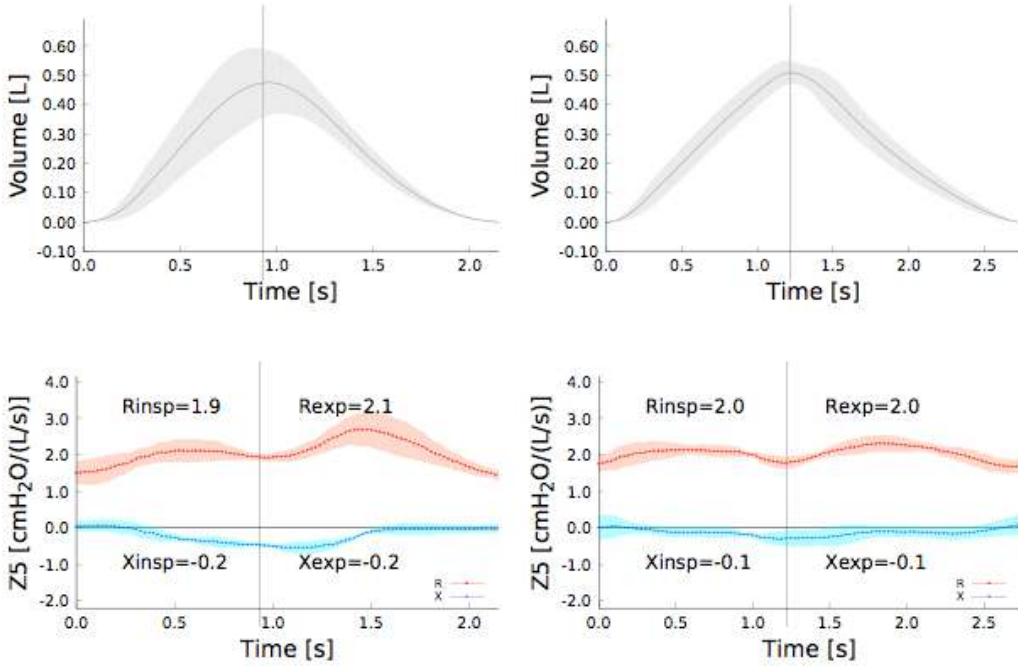


Figure 65 – Average Volume, Resistance and Reactance.
Shaded areas are the standard deviations.

- *Volume*: the solid line is the average tidal volume calculated on the accepted breaths for the selected test. The shaded area is the standard deviation of all the accepted breaths. This graph provides a visual information about the breathing pattern of the patient during the test. Discontinuities both on the average and the standard deviation are generally due to a poor measurement quality.
- *Resistance (R) and Reactance (X)*: the solid lines are the average within-breath R and X calculated on the accepted breaths for the selected test. The shaded areas are the standard deviations of all the accepted breaths. This graph provides visual information about the breathing pattern of the patient during the test. Discontinuities both on the average and the standard deviation or large standard deviations are generally due to a poor measurement quality. Within-breath R and X graphs are not reported when a PSRN stimulating waveform is used.

WEB SERVICE COMMUNICATION PROTOCOL

Resmon PRO FULL supports a proprietary communication protocol to exchange data with a remote SOAP/REST Web Service for downloading patient's demographic and test settings (stimulating waveforms and test duration), and to upload test results (raw data and parameters) through the same protocol.

Therefore, the Resmon PRO FULL can be used in three modes of operation:

1. OFF-LINE MODE: this is the standard stand-alone operation. All the tests performed offline by the Resmon PRO FULL can be transferred to a remote web service across the network when a proper network connection is established.

2. ON-LINE MODE: patients' demographic and test settings can be downloaded from a Web Service over the network to the Resmon PRO FULL. Once a new test has been performed, its results are immediately sent back to the Web Service.

3. RETRIEVE LIST MODE (POD-like use): a list containing patients' demographic and test settings, created on a remote Web Service, is downloaded on the Resmon PRO FULL, allowing the user to disconnect the device afterwards, move it to another room and load the list in off-line mode.

 CAUTION	THE MANUFACTURER OF THE RESMON PRO FULL IS NOT LIABLE FOR ANY ERRORS IN THE DATA DISPLAYED OR STORED BY THE REMOTE WEB SERVICE.

Off-Line Mode

This is the standard stand-alone mode of operation. All saved tests will be added in a list of files to be synchronized. For further information on how to synchronize such data see section On-Line Mode.

On-Line Mode

CAUTION	USE THE DEVICE IN TRUSTED NETWORKS ONLY AND CONFIGURE THE NETWORK PARAMETERS FOLLOWING THE SAFETY REGULATIONS OF YOUR INSTITUTION.

1. Connect the device to the network by an Ethernet cable.

CAUTION	USE ONLY ETHERNET CABLES (ref. RT3031) APPROVED BY THE MANUFACTURER. FOR TECHNICAL ASSISTANCE CONTACT THE LOCAL DISTRIBUTOR (SEE SECTION *User Assistance Information*).

2. Select *GET NETWORK CONFIGURATION VIA DHCP* and then *SET AND TEST WEB SERVICE URL* from your *ADMIN* account. Wait for a network configuration to be received. For further information see section *First log-in and the ADMIN account*.

3. On the Home Screen, you will see two new buttons: *SYNC* and *GET LIST* (Figure 66). Notice that if no tests need to be synchronized (for example because they have already been synchronized during a recent connection to the network) the SYNC button will not be present.

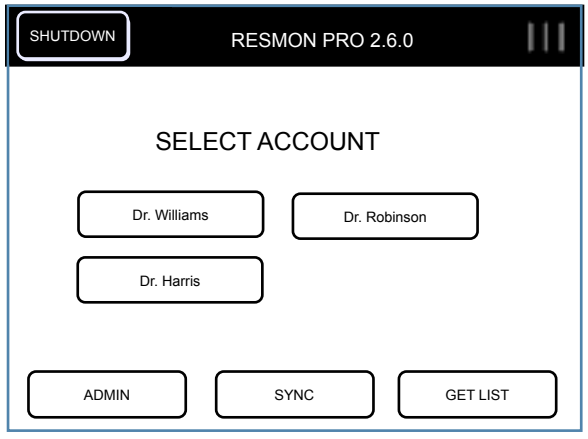


Figure 66 - Home Screen with network cable plugged in

- Select *GET LIST* to download the list of tests from the remote web service. For each test, demographic data (SURNAME, NAME and DATE OF BIRTH) of the associated patient are reported (Figure 67).

  If there is only one test in the list, the screen will be skipped and you will be automatically brought to:

  - The filter measurement workflow if the web service sent the test label to the device together with the other visit's data
  - The label selection screen in case the web service did not include this information in the list

If a problem occurs, for instance because the web service is not responding within the set timeout, an error will be displayed: *Cannot retrieve list*. Check that the Web Service is online and that the URL has been properly set. For further information see section *First log-in and the ADMIN account*.

If the Web Service encounters a problem, *error E105* will display. The code shall be completed by the details about the issue, provided by the Web Service. In case of need, contact the distributor (see *section User Assistance Information*).

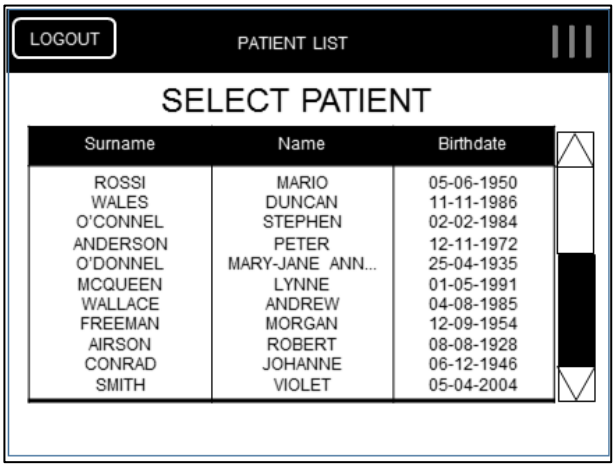


Figure 67 - Patients list downloaded from web service

Some of the patients on the downloaded list can appear as "canceled out" (Figure 68). This happens in two circumstances:

1. Syntax Error in personal data, due to an unsupported character, that need to be corrected on the remote interface (Figure 68). Unsupported characters are: / ‘ “ for Patient ID, while \ is not allowed in any fields.

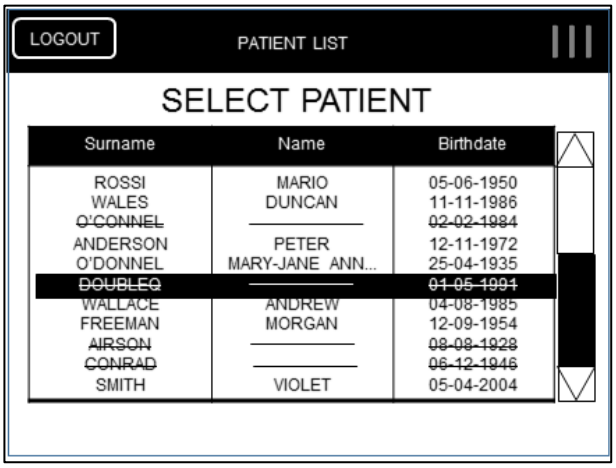


Figure 68 - Patients list with syntax errors

2. Conflicting data, due to identical Patient ID but inconsistencies in other fields. The device will ask to merge the information (Figure 69, Figure 70). If data do not belong to the same patient despite the same Patient ID, this must be edited on the remote interface.

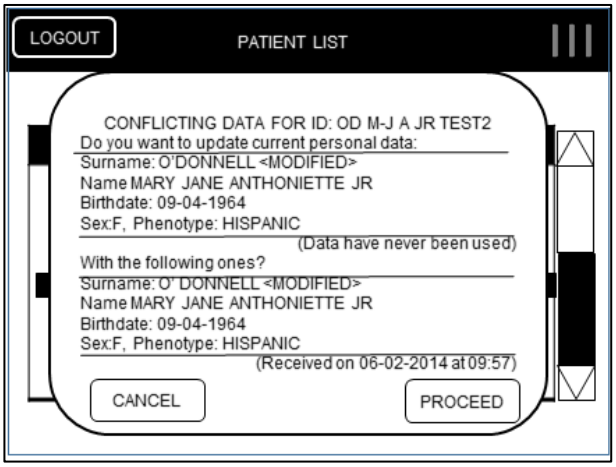


Figure 69 - Conflicting data

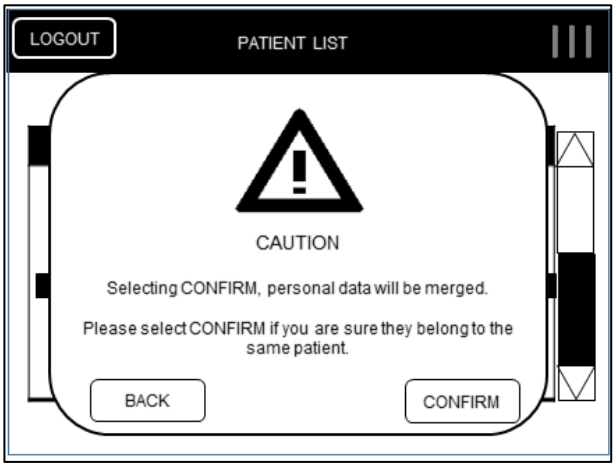


Figure 70 - Data merge

Once you selected a patient from the list, the associated test will appear on the screen. To continue with the test follow the instructions reported in the section *Labeling a test.* Notice that, in case the web service included the label with the other data, the labeling will be skipped and you will proceed with the filter measurement and the FOT test.

At the end of the test, two behaviors are supported according to the web service request.

In case the web service is configured to request a quick measurement, results will not be displayed on the device itself: the test will automatically be SAVED and transferred to the web service.

Otherwise, the device will ask you to *SAVE* or *DISCARD* the test. When saving, the device will try to synchronize the measurement with the Web Service.

In both cases, if the syncing is successful, it will be possible to *REPEAT* the test or to *END* the operation.

- Press *REPEAT* for multiple repetitions of the test within a few minutes, for example 3 to 5 recordings.

- Press *END* to conclude the test on the selected patient.

- Select *SYNC* to synchronize data on the Web Service. All the tests not yet synchronized will be sent over the network to a remote Web Service, which will send back a confirmation message. The syncing process will take some time depending on the amount of tests to be transferred. A progress indication will be shown on screen in the form of the number of tests that have been synchronized over the total. If the synchronization is successful select *PROCEED* to end this operation (Figure 71, Figure 72).

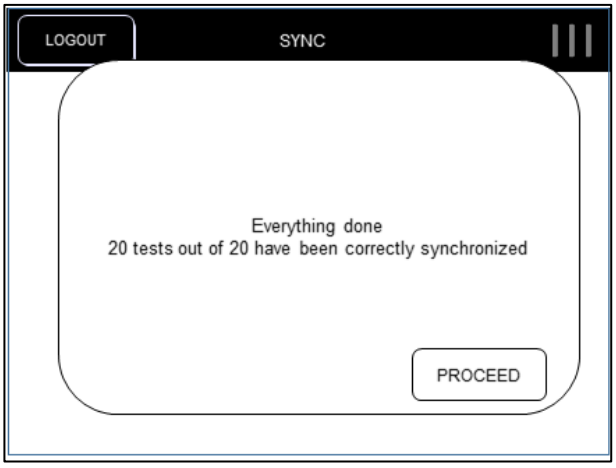


Figure 71 - End of synchronization

Figure 72 - Successful sync operation

If the synchronization fails press *RETRY* to try again or *CANCEL* to cancel the operation (Figure 73).
Tests will be transferred the next time an attempt of SYNC will be done.
Additional details may be present below the SYNC FAILURE message, according to whether or not the Web Service had been able to send diagnostics reports to the device.

Figure 73 - Sync was not successful

Retrieve a List When Offline

To display a list of tests (downloaded while the device was online) when the device is offline select *LOAD OFFLINE LIST* from the Home Screen (Figure 74).
The button *GET LIST* becomes *LOAD OFFLINE LIST* as soon as the network cable is disconnected from the device; it turns back to be *SYNC* as soon as the network cable is plugged in once again. If no list is present and no network cable is plugged in, no button is shown.

Press *LOAD OFFLINE LIST* to open a screen with the download date of the list and a list of visits. After a visit is selected from the list, follow the same procedure reported in the section *On-Line Mode* to perform a test.

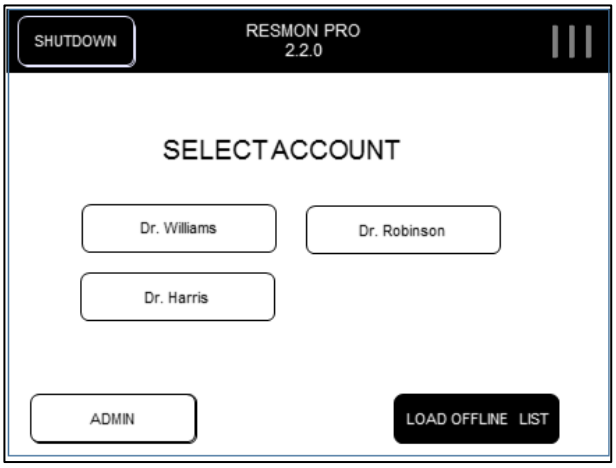


Figure 74 - Load a patient list when the device is offline

Cleaning

In the course of lung function tests some parts of the device can be contaminated by germs and may cause cross-infection among subjects. The device should not be sterilized. An effective cleaning and disinfection is in most cases sufficient.
This device corresponds to the safety level IP 21. Therefore, the device can be cleaned with a damp (not soaking) cloth that does not produce lint.

The reprocessing instructions described in this section have been successfully validated by the manufacturer and render the Resmon PRO FULL, if previously used or contaminated, fit for a subsequent single use.

The following wipes have been successfully tested by Restech SRL for the CLEANING of the device:

Commercial Name*: CaviWipes #13-1100*
Manufacturer: *Metrex Research, LLC*
Classification: *Intermediate disinfectant*
Short Description: *CaviWipes are towelettes to be used as cleaner and disinfectant.*
Website: *www.metrex.com*

The following wipes have been successfully tested by Restech SRL for the DISINFECTION of the device:

Commercial Name: *Super Sani-Cloth (EPA Reg. No. 9480-4)*
Manufacturer: *PDI*
Classification: *Intermediate disinfectant*
Short Description: *Super Sani-Cloth is an EPA registered disinfectant that is effective against several bacteria and viruses.*
Website: *www.pdipdi.com*

Before using the above towelettes and for a proper disposal after their use, read the instructions for use reported on the package insert. Make sure to observe the safety precautions of the manufacturer.

In addition to the instructions given in this section, observe the legal provisions and hygiene requirements of your institution.

Should you require further assistance, contact the distributor (see section *User Assistance Information).*

 CAUTION	DURING CLEANING AND DISINFECTION THE DEVICE MUST BE TURNED OFF.

 CAUTION	WHEN CLEANING AND DISINFECTING THE DEVICE, USE LEGALLY MARKETED GLOVES OF APPROPRIATE TYPE AND LENGTH, EYE PROTECTION AND FLUID-RESISTANT GOWNS.

 CAUTION	USE ONLY EPA (UNITED STATES ENVIRONMENTAL PROTECTION AGENCY) REGISTERED CHEMICALS FOR CLEANING/DISINFECTION OF THE DEVICE.

 CAUTION	THE RISK OF INFECTION CAN BE AVOIDED ONLY IF THE FOLLOWING INSTRUCTIONS ARE OBSERVED AND IF ALL THE CONTAMINATED PARTS ARE DISINFECTED CAREFULLY.

REPROCESSING INSTRUCTIONS TO BE FOLLOWED AFTER EACH PATIENT

After each patient and before the next use, follow the instructions below for a safe and effective reprocessing of the device:

1. Dispose of the bacterial/viral filter and nose clip
2. Clean the device surface thoroughly
3. Disinfect the device
4. Wipe the device surface with distilled water to remove chemical residues
5. Dry the device
6. Make a visual inspection

1. Dispose of the bacterial/viral filter and nose clip

Bacterial/viral filters and nose clips are single-use items. Replace the bacterial/viral filter and the nose clip after each patient!

The use of a bacterial/viral filter with the characteristics indicated in section *DISPOSABLES is* mandatory to perform a test. You can use any filter for pulmonary function test having the specifications reported in section *DISPOSABLES*.

The use of a nose clip is mandatory to perform a test.

Filters and nose clips 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.

CAUTION	THE USE OF A FILTER REDUCES THE CONTAMINATION OF THE PARTS BEHIND IT. HOWEVER, THOROUGH CLEANING AND DISINFECTION STILL HAVE TO BE PERFORMED.

CAUTION	IF YOU SUSPECT THAT THE DEVICE IS CONTAMINATED (FOR EXAMPLE BECAUSE A SUBJECT HAS NOT USED A FILTER), CONTACT THE DISTRIBUTOR (SEE SECTION *User Assistance Information*). ALL THE COMPONENTS OF THE BREATHING CIRCUIT CAN BE REPLACED.

2. Clean the device surface thoroughly

A thorough manual cleaning of the device at the point-of-use is mandatory to facilitate the next disinfection procedure and it is intended to protect the user.

After each patient, dispense one CaviWipes towelette and wipe the whole surface of the device until it is wetted to remove debris and biodurden (Figure 75). Do not squeeze the wipes too much to avoid frothing. Pay particular attention to the parts around the silicone seal and the inlet of the device because they are those at higher risk of contamination.

Then, discard used towelette following the legal provisions and hygiene requirements of your institution.

CAUTION	NEVER CLEAN THE DEVICE WITH METAL BRUSHES, STEEL WOOD OR OTHER SCRUBBING MATERIALS.

3. Disinfect the device

You will need to use three Super Sani-Cloth towelettes as described below.

Dispense the first Super Sani-Cloth towelette and wipe the (precleaned) plane surfaces of the device until they are wetted to disinfect it (Figure 75). Do not squeeze the wipes too much to avoid frothing. Allow treated surfaces to remain wet for a full 2 minutes. This is also the contact time recommended by the manufacturer.

Dispense the second Super Sani-Cloth towelette and wipe the (precleaned) silicone seal and the parts around the inlet of the device. These are the parts at higher risk of contamination. Do not squeeze the wipes too much to avoid frothing. Allow treated surfaces to remain wet for a full 2 minutes.

Then, dispense the third Super Sani-Cloth towelette and repeat the disinfection of the silicone seal and the parts around the inlet of the device as described above.

Discard used towelettes following the legal provisions and hygiene requirements of your institution.

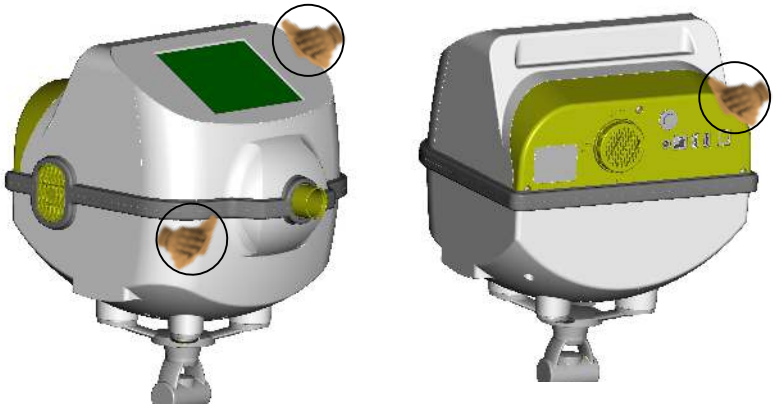


Figure 75 - Clean and disinfect the device

4. Wipe the device surface with distilled water to remove chemical residues

Dampen a clean cloth that does not produce lint with distilled water and wipe the surface of the device thoroughly until it is wetted to remove chemical residues after disinfection (Figure 75). Do not squeeze the cloth too much to avoid frothing.

5. Dry the device

Use a new clean cloth that does not produce lint to dry the whole surface of the device immediately after.

6. Make a visual inspection

Inspect the whole device surface after cleaning and disinfection. If you notice some residues or impurities repeat the cleaning and disinfection procedure (steps 2 to 5).

Inspect the silicone seal after the cleaning and disinfection. If you notice damaged surfaces, deformations, cracked seals, discolorations or corrosions dispose of it and replace this component. For further information, see section *Setup.*

REPROCESSING INSTRUCTIONS TO BE FOLLOWED AT THE END OF A MEASUREMENT SESSION

At the end of a measurement session, ideally once a day, follow the instructions below for a safe and effective reprocessing of the device:

1. Remove the screen cover
2. Clean the device surface thoroughly
3. Disinfect the device
4. Wipe the device surface with distilled water to remove chemical residues
5. Dry the device
6. Make a visual inspection
7. Mount a new screen cover
8. Perform a calibration verification

1. Remove the Screen Cover

Remove the screen cover by pulling it up slightly (for further information see section *Setup*) and dispose it off. It can be disposed of as domestic waste if it shows normal degree of contamination. In all other cases (e.g. tuberculosis) dispose it of in special containers.

2. Clean the device surface thoroughly

Dispense one CaviWipes towelette and wipe the whole surface of the device, including the parts under the screen cover, until it is wetted to remove debris and biodurden (Figure 75). Do not squeeze the wipes too much to avoid frothing. Pay particular attention to the parts around the silicone seal and the inlet of the device because they are those at higher risk of contamination.

Then, discard used towelette following the legal provisions and hygiene requirements of your institution.

CAUTION

NEVER CLEAN THE DEVICE WITH METAL BRUSHES, STEEL WOOD OR OTHER SCRUBBING MATERIALS.

3. Disinfect the device

You will need to use three Super Sani-Cloth towelettes as described below.

Dispense the first Super Sani-Cloth towelette and wipe the (precleaned) plane surfaces of the device, including the parts previously protected by the screen cover until they are wetted to disinfect it (Figure 75). Do not squeeze the wipes too much to avoid frothing. Allow treated surfaces to remain wet for a full 2 minutes. This is also the contact time recommended by the manufacturer.

Dispense the second Super Sani-Cloth towelette and wipe the (precleaned) silicone seal and the parts around the inlet of the device. These are the parts at higher risk of contamination. Do not squeeze the wipes too much to avoid frothing. Allow treated surfaces to remain wet for a full 2 minutes.

Then, dispense the third Super Sani-Cloth towelette and repeat the disinfection of the silicone seal and the parts around the inlet of the device as described above.

Discard used towelettes following the legal provisions and hygiene requirements of your institution.

4. Wipe the device surface with distilled water to remove chemical residues

Dampen a clean cloth that does not produce lint with distilled water and wipe the surface of the device thoroughly until it is wetted to remove chemical residues after disinfection (Figure 75). Do not squeeze the cloth too much to avoid frothing.

6. Dry the device

Use a new clean cloth that does not produce lint to dry the whole surface of the device immediately after.

7. Make a visual inspection

Inspect the whole device surface after cleaning and disinfection. If you notice some residues or impurities repeat the cleaning and disinfection procedure (steps 2 to 5).

Inspect the silicone seal after the cleaning and disinfection. If you notice damaged surfaces, deformations, cracked seals, discolorations or corrosions dispose it of and replace this component. For further information, see section Setup.

8. Mount a new screen cover

Peel off a new screen cover and apply it to the display. For further information, see *section Setup*. Be sure that its borders are completely glued to the surface of the device.

9. Perform a calibration verification

Perform a calibration verification and verify that it is passed before reusing the device. For further information, see section *Verification of the Factory Calibration.*

REPROCESSING INSTRUCTIONS TO BE FOLLOWED IN CASE OF SUSPECTED HIGH DEGREE OF CONTAMINATION

If you suspect that a high degree of contamination (e.g. tuberculosis) has occurred follow the instructions below for a safe and effective reprocessing of the device:

1. Remove the bacterial/viral filter
2. Remove the screen cover
3. Remove the silicone seal

4. Clean the device surface thoroughly, including the parts previously protected by the screen cover and the silicone seal
5. Disinfect the device, including the parts previously protected by the screen cover and the silicone seal
6. Wipe the device surface with distilled water to remove chemical residues
7. Dry the device
8. Make a visual inspection
9. Mount a new silicone seal
10. Mount a new screen cover
11. Perform a calibration verification

Please refer to the previous paragraph for details about the cleaning and disinfection. Please refer to section *Setup* for details about replacement of the screen cover and of the silicone seal.

Discard bacterial/viral filter, screen cover, silicone seal and used towelettes following the legal provisions and hygiene requirements of your institution.

Maintenance

MAINTENANCE PROCEDURES TO BE DONE BY THE USER

Calibration Verification

It is recommended to verify that the device is calibrated daily using the procedure described in the section *Verification of the Factory Calibration*.

 CAUTION	TO PEFORM THE CALIBRATION VERIFICATION, ONLY USE THE TEST OBJECT PROVIDED BY THE MANUFACTURER.

Replacement of the Air Filter

The air filter is located on the back side of the device, closed by its cover.
The air filter keeps the interior of the unit free of dust.

It is recommended to change the air filter yearly.

To change the filter, turn the cover clockwise. Remove the filter and place the new one on the inside of the cover. Then, place the cover in its original housing and rotate it counterclockwise, following the direction indicated by the arrow "*CLOSE*".

 CAUTION	USE ONLY AIR FILTERS PROVIDED BY THE DISTRIBUTOR.

 CAUTION	DO NOT COVER OR OCCLUDE THE AIR FILTER. THIS MAY CAUSE INTERNAL HEATING OF THE DEVICE AND MAY AFFECT THE MEASUREMENT.

CAUTION	WHEN REPLACING THE AIR FILTER, VERIFY THAT THE COVER IS TIGHT. IF NOT, DUST MIGHT OCCLUDE THE PNEUMOTACHOGRAPH SCREEN AND THE MEASUREMENTS MAY BE AFFECTED.

Replacement of the Silicone Seal and Screen Cover

The silicone seal and screen cover are intended to avoid contamination of the device and cross-infection among patients. For further information see section Cleaning .

Replace the silicone seal:

- If you notice damaged surfaces, deformations, cracked seals, discolorations or corrosions
- If you suspect that a high degree of contamination (e.g. tuberculosis) has occurred
- After 3 months after the last replacement, even if the silicone seal is still in a good state

Replace the screen cover:

- At the end of a measurement session, ideally once a day.
- If you suspect that a high degree of contamination (e.g. tuberculosis) has occurred

MAINTENANCE PROCEDURES TO BE DONE BY QUALIFIED PERSONNEL

CAUTION	WITH THE EXCEPTION OF THE MAINTENANCE PROCEDURES INDICATED IN THE PREVIOUS PRARAGRAPH, SERVICE ON THE DEVICE MUST BE PERFORMED ONLY BY QUALIFIED PERSONNEL. IN CASE OF NEED, CONTACT THE DISTRIBUTOR (SEE SECTION *User Assistance Information*).

How to return a defective device or safely dispose it of

If your Resmon PRO FULL needs to be returned to the manufacturer, follow these instructions to protect your and our employees who will handle it and to allow our employees an optimal inspection of all its parts.

1. The device must be thoroughly cleaned in order to remove residues as far as possible. For further information see section *Cleaning .*
2. As parts of the device may have had contaminated with biological substances, disinfect it following the instructions reported in section *Cleaning* .
3. Before shipment **always contact the distributor** (see section *User Assistance Information*) to get the following information:
    a. The address for returns
    b. The packing instructions

The Resmon PRO FULL is electrical equipment that must be disposed of following national regulations. Contact the distributor for further details (see section *User Assistance Information*).

Information for disposal for private users, companies and healthcare providers in the European Union

	This symbol on the product and/or on the accompanying documentation 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.

Information for disposal outside European countries
The symbol above is valid only in the European Union.
For disposal of this device, please contact the distributor and ask for proper disposal instructions (see section *User Assistance Information*).

Operating and Storage Conditions

OPERATING CONDITIONS

Optimal temperature: 5 - 40°C
Optimal relative humidity: 30 - 75% non-condensing
Optimal barometric pressure: 700 – 1060mbar

STORAGE AND TRANSPORT CONDITIONS

Recommended temperature: -30 - +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.

Troubleshooting

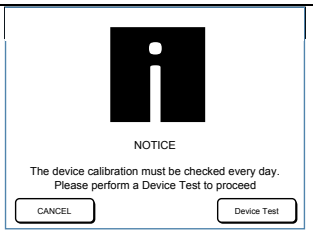
Below is reported a list of the most common problems that may occur during the normal use of the device and possible solutions. Should you encounter any unlisted problems or have any further questions, contact the distributor (see section *User Assistance Information*).

PROBLEMS RELATED TO THE RESULTS OF THE TEST

PROBLEM	SOLUTION
The patient's resistance or reactance are different (higher or lower) than the values that you expected	Be sure that the patient maintains a correct posture, is wearing a nose clip, is holding his/her cheeks, or the operator is holding his/her cheeks. Make sure there are not leaks from the nose or mouth. Repeat the test. If the problem persists, perform a Calibration Verification to exclude any problems with the calibration of the device.
You can not find the results of the last test performed	You might have pressed the button *DISCARD* and then *CONFIRM* at the end of the test, following the notice message: "The test will be discarded. Confirm?". Repeat the test and press *SAVE* at the end of the test.

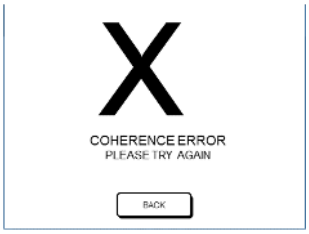
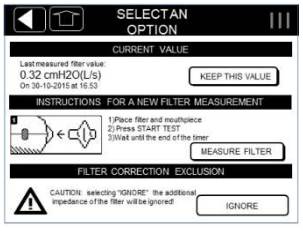
PROBLEMS RELATED TO THE CALIBRATION VERIFICATION

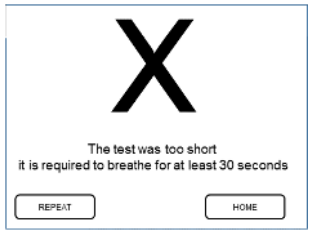
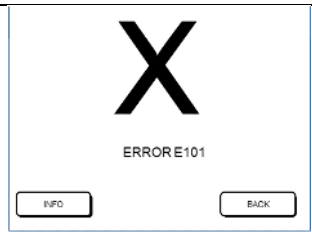
MESSAGE	SCREENSHOT	SOLUTION
Wrong Calibrator Code		Be sure of using the Test Object provided with the device. Check that all the digits entered correspond to those printed on the Test Object label.

MESSAGE	SCREENSHOT	SOLUTION
Coherence Error – Please Try Again		Be sure of using the Test Object provided with the device. Check that the Test Object is not occluded and that is connected firmly to the inlet of the device without leaks.
The device calibration must be checked every day. Please perform a Device Test to proceed.		Press button Device Test, connect the Test Object and run a verification of the factory calibration.

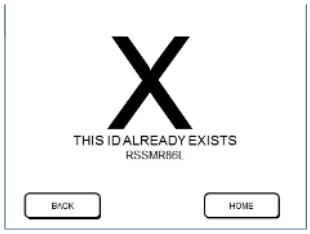
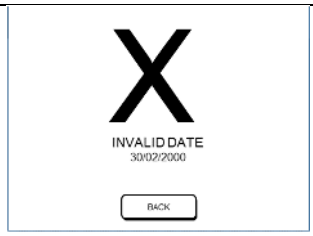
PROBLEMS RELATED TO THE MEASUREMENT

MESSAGE	SCREENSHOT	SOLUTION
The filter impedance is outside the recommended range		The device has measured a filter impedance that is greater than $1 cmH_2O \cdot s \cdot L^{-1}$. Check that: 1. The filter has the characteristics specified in section *Descriptive Information.* 2. The filter is not occluded. 3. The patient is not breathing trough it while measuring its value If the problem persists perform a Calibration Verification to verify that the device is calibrated.

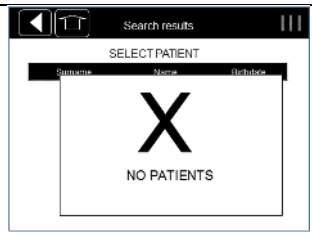
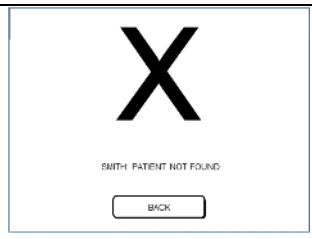
MESSAGE	SCREENSHOT	SOLUTION
Filter impedance very low or missing filter		The device has measured a filter impedance that is lower than 0.1cmH_2O·s·L^{-1}. Check that: 1. The filter has the characteristics specified in section *Descriptive Information.* 2. The filter has been connected firmly to the inlet of the device without leaks and that the filter is not broken. Then, repeat the filter measurement using a new filter. If the problem persists, make a Calibration Verification to verify that the device is calibrated.
Coherence Error – Please Try Again		Check that the filter is not occluded and that is connected firmly to the inlet of the device without leaks. Try to repeat the measurement of the filter. If still unsuccessful, make a Calibration Verification to verify that the device is still calibrated.
CAUTION: selecting “IGNORE” the additional impedance of the filter will be ignored!”		If you press IGNORE the measured parameters will include also the filter value. No automatic correction will be applied.

MESSAGE	SCREENSHOT	SOLUTION
The test was too short – it is required to breathe for at least 30 seconds		This error might appear when using a PSRN stimulating waveform. The device has automatically identified and discarded breaths with artifacts (cough, glottis closure, etc.) that have been discarded due to their low coherence value. Repeat the test trying to avoid such artifacts.
Not enough breaths detected – Required number of breaths: at least 5		This error might appear when using a single-frequency or multi-frequency stimulating waveform. During the test the device has automatically discarded breaths with artifacts (cough, glottis closure, etc.) and the total number of accepted breath has not reached the minimum required (5). Make again the test and make sure that the breath counter on the screen has reached at least 5 valid breaths before stopping the test.
Error 101		This is an internal communication error that might occur during the test. Turn off the device and on again and repeat the test.

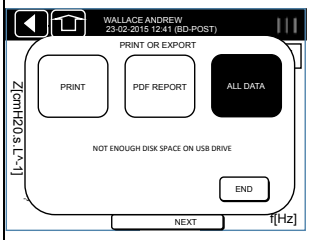
PROBLEMS RELATED TO THE INSERTION OF NEW PATIENTS

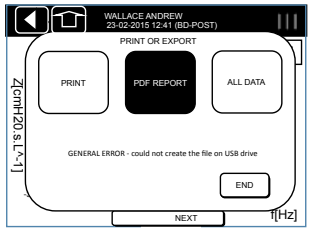
MESSAGE	SCREENSHOT	SOLUTION
This ID already exists (ID)		You are trying to insert a new patient with an ID that is already in use for another existing patient. Patient ID must be unique. Change the ID if you want to insert a new patient. Otherwise recall it from the database.
Invalid Date		You are trying to insert a date of birth with an incorrect format. Default format is dd/mm/yyy. To change the default format, see section *Change User Settings.*

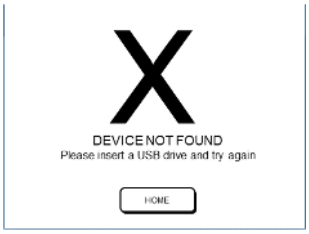
PROBLEMS OCCURRING WHEN BROWSING THE DATABASE

MESSAGE	SCREENSHOT	SOLUTION
No Patients		You are browsing the database but no patients have been inserted yet. Be sure to confirm the insertion of a new patient before browsing the database.
(Surname) – Patient Not Found		No matching patients have been found. Check the surname and try again.

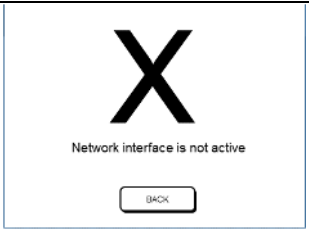
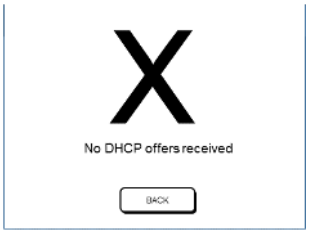
PROBLEMS OCCURRING WHEN EXPORTING DATA ONTO A USB DRIVE

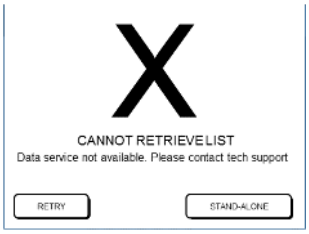
MESSAGE	SCREENSHOT	SOLUTION
Not Enough Disk Space on USB drive		The space on the USB drive is not enough to allow a complete export of the test data. Disconnect the USB drive and delete or move unnecessary files to other media supports. Then, reinsert the USB drive into the device and repeat the operation. Alternatively, use another USB drive.
Not Enough Disk Space on USB drive – Required Space on USB drive (kilobytes): (space)		The space on the USB drive is not enough to allow a complete export of the backup data. Disconnect the USB drive and delete or move unnecessary files to other media supports. Then, reinsert the USB drive into the device and repeat the operation. Alternatively, use another USB drive. **KNOWN ISSUE**: Pressing the 'Back' button two times will display an

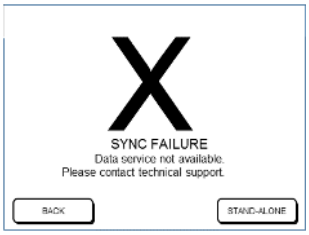
MESSAGE	SCREENSHOT	SOLUTION
		empty alert screen. Press the 'Home' button in the screen header to go back to the Admin menu.
GENERAL ERROR - could not create the file on USB drive		This is an unexpected error that might happen when the device is trying to save a clinical report on the USB drive. Try to export again the data on the same USB drive. If the problem persists: 1. Use the other USB port of the device 2. Verify that the USB drive is formatted FAT32 3. Verify that the USB drive is not write-protected 4. Use another USB drive.
GENERAL ERROR - could not create the file on USB drive		This is an unexpected error that might happen when the device is trying to save a file on the USB drive. Try to export again the file on the same USB drive. If the problem persists: 1. Use the other USB port of the device 2. Verify that the USB drive is formatted FAT32 3. Verify that the USB drive is not write-protected 4. Use another USB drive.

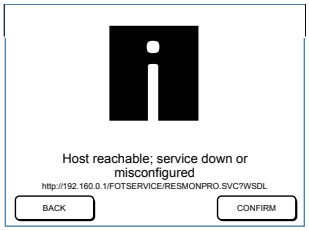
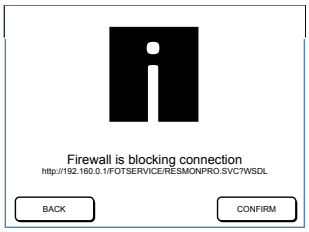
MESSAGE	SCREENSHOT	SOLUTION
DEVICE NOT FOUND – Please insert a USB drive and try again		Check that the USB drive is correctly inserted into one of the two USB slots. Then, wait a few seconds a repeat the operation. If the problem persists: 1. Use the other USB port of the device 2. Verify that the USB drive is formatted FAT32 3. Verify that the USB drive is not write-protected 4. Use another USB drive.

PROBLEMS RELATED TO THE WEBSERVICE

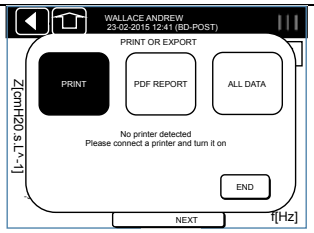
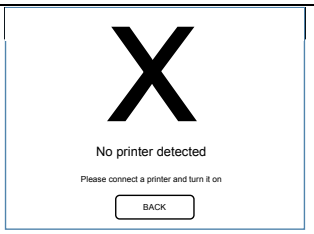
MESSAGE	SCREENSHOT	SOLUTION
CAUTION! Selecting CONFIRM, personal data will be merged. Please select confirm only if you are sure that they belong to the same patient.		The same ID appears to belong to two patients who have some discrepancies in other generalities. Verify the two entries refer to the same person and select CONFIRM, otherwise modify the patient ID on the remote system
Network interface is not active		A network connection was not found. Check that a network cable is correctly inserted, that the green LED close to the network connector is on or blinking and try again.
No DHCP offers received		Connection timed out with no answer from the network. If the device is connected directly to a computer check that the network interface of the computer is up and running and that the network cable is correctly inserted. If the device is connected to your hospital/institution network check that the network cable is correctly inserted. If the problem persists contact the network administrator.

MESSAGE	SCREENSHOT	SOLUTION
CANNOT RETRIEVE LIST – Data service not available. Please contact tech support.		The list of measurements can not be downloaded because the device seems not to be connected to the network. If the device is connected directly to a computer check that the network interface of the computer is up and running and that the network cable is correctly inserted. If the device is connected to your hospital/institution network check that the network cable is correctly inserted. If the problem persists contact the network administrator.
SYNC FAILURE – Cannot contact web service at specified URL		The tests have not been synchronized due to a timed out connection. If the device is connected directly to a computer check that the network interface of the computer is up and running and that the network cable is correctly inserted. If the device is connected to your hospital/institution network check that the network cable is correctly inserted. If the problem persists contact the network administrator.
SYNC FAILURE (error message)		The solution depends on the actual error message that is displayed. In most cases, close patient's information on the remote interface and try again to synchronize data.

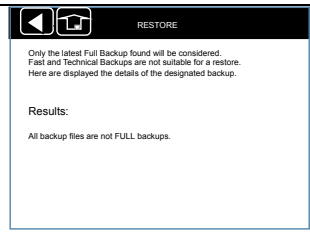
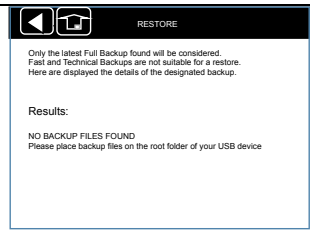
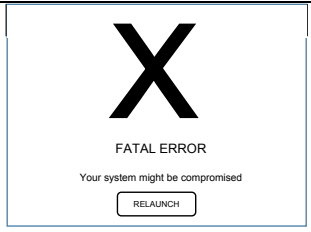
MESSAGE	SCREENSHOT	SOLUTION
SYNC FAILURE – Data service not available. Please contact technical support.		If the device is connected directly to a computer check that the network interface of the computer is up and running and that the network cable is correctly inserted. If the device is connected to your hospital/institution network check that the network cable is correctly inserted. If the problem persists contact the network administrator.
The following URL is not responding [URL]		The connection between the device and the web service is missing. Check the web service is running and verify connection settings on both the Resmon PRO FULL and your computer. Press *CONFIRM* to continue.
Host seems down.		When checking the WebService connection after setting its URL, this error appears when there is a network problem in reaching the computer hosting the web service. • The host may be disconnected from the network • The network configuration may be erroneous • The network cable may be damaged • The host may be protected by a firewall dropping ping requests while the web service is not active

MESSAGE	SCREENSHOT	SOLUTION
Host reachable; service down or misconfigured.		When checking the WebService connection after setting its URL, the machine where the service is installed is reachable. However, the service itself doesn't seem to be running. Please check the location and name of the WebService has been entered correctly.
Firewall is blocking connection.		When checking the WebService connection after setting its URL, the device cannot reach the service because a firewall (on the machine where the service is installed) is configured to block incoming connections. Check the firewall rules on your server.

PROBLEMS RELATED TO THE PRINTING

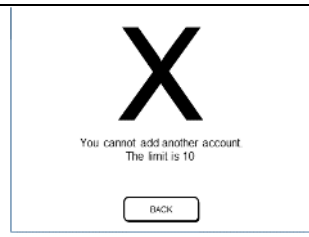
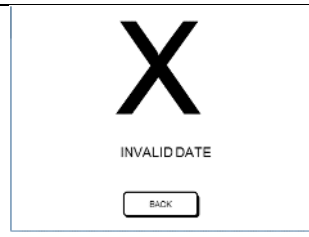
MESSAGE	SCREENSHOT	SOLUTION
Printer not detected. Please connect a printer and turn it on.		Connect a postscript USB printer to the device and turn it on. Contact the local distributor for the updated list of verified USB printers.
No printer detected. Please connect a printer and turn it on.		Connect a postscript USB printer to the device and turn it on. Contact the local distributor for the updated list of verified USB printers.

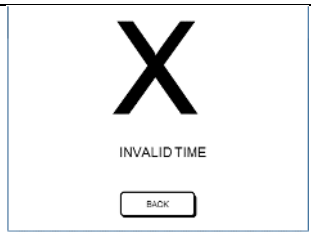
PROBLEMS RELATED TO THE RESTORE OF A BACKUP FILE

MESSAGE	SCREENSHOT	SOLUTION
All your backup files are not FULL backups.		You copied only fast and/or technical backup files in the USB drive, when performing a restore. Restore operations only work with Full Backup files.
NO BACKUP FILES FOUND. Please place backup files in the root folder of your USB drive.		You are trying to restore from a backup files, but the system did not detect any backup file in the USB drive connected to the device.
Backup file incompatible with this device.		You copied a full backup on its USB drive correctly, but the backup is not compatible with its device.
This is not a valid backup file.		You copied a full backup on its USB drive correctly, but the backup is compromised or damaged.
FATAL ERROR: you system might be compromised.		An unrecoverable error happened during the restore operation of a correct backup file. The system may function correctly for most operations, but some part of its database or data files may be damaged or missing. In case of

MESSAGE	SCREENSHOT	SOLUTION
		need contact the technical assistance.

OTHER PROBLEMS RELATED TO THE DEVICE

MESSAGE / PROBLEM	SCREENSHOT	SOLUTION
Internal temperature is too high. Please turn off the device, wait five minutes and try again		The temperature inside the device is above a safety threshold. You are not allowed to make a new test. To allow the device to cool down, press the *SHUTDOWN* button to turn the device off and wait 5 minutes before turning it on again
Username already in use (USERNAME)		If you want to add another user to the device choose another username. The username must be unique. Otherwise, login as the existing one.
Wrong Password		The password to login as a user or admin is incorrect. Try again or reset password. See Section *First log-in and the ADMIN account.*
You cannot add another account. The limit is 10.		The maximum number of accounts allowed is 10. If you want to add another account you must delete an existing one. See Section *First log-in and the ADMIN account.*
Invalid Date		You are trying to insert a date with an incorrect format. Default format is dd/mm/yyy. To change the default format, see section *Change User Settings.*

MESSAGE / PROBLEM	SCREENSHOT	SOLUTION
Invalid Time		You are trying to insert a time with an incorrect format. Time is expressed as HH:MM (24-h format). Check time is consistent with the above format and try again.
SYSTEM DATE SEEMS INCOHERENT - [date] is this system date correct?		The date stored into the device seems to be not coherent with other saved data and/or tests. Press EDIT to modify the system date or CONFIRM if the date that appears on screen is correct. If the problem presents again, contact the assistance.
Once you have plugged the device into an electrical outlet, it does not turn on	//	Be sure the power cord is connected to the device properly, that the cable is properly connected to the power supply, and that the power-on button has been pressed for at least a half second.
The device or the touch screen do not respond to your inputs	//	Wait a few seconds. If the device fails to respond, turn it off by pressing the power-on button for at least seven seconds, and then turn it on again.
Periodic backups not cancelled		If the user sets the wrong system date, the periodic backups are not cancelled. A user may set a system date in the future. A backup of data is made at every reboot up to 10 backups. If the user reboots for 10 times without fixing the system date, the backup system will stop, older backups will be kept instead of newer ones. To correct, enter a current date in the system.

User Assistance Information

Model: Resmon PRO FULL (ref. RT1100)

MANUFACTURER
 Restech Srl Via Melchiorre Gioia, 63 20124 Milano – Italy Web: www.restech.it Email: support@restech.it Fax: +39 02 3659 3692
TECHNICAL ASSISTANCE / LOCAL DISTRIBUTOR (Contacts and/or company's stamp)