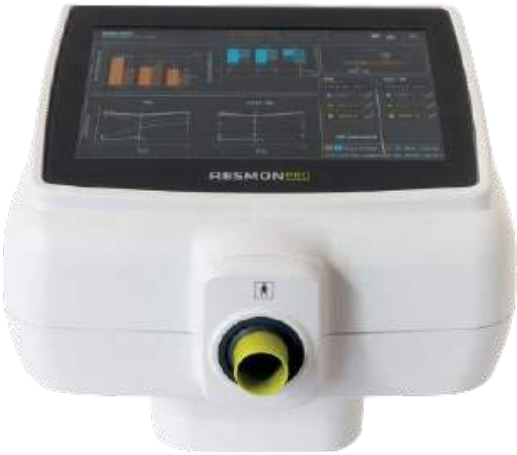
RESTECH
RESPIRATORY TECHNOLOGY

Instructions for Use

Resmon PRO FULL

(REF: RT1100)

Oscillometry Device



Please review this document before using the device.

Revision 35 – July 2026
Software version: 23.1.x

℞ ONLY

CE 0051

Copyright

Notes

Names of persons mentioned in the context of this document are fictitious and any resemblance to living or deceased persons is purely incidental and not intended.
In case of ambiguities and/or errors, the English version of this manual is to consider the original.

Declaration of Conformity

The Resmon PRO FULL is classified as a medical device class IIa according to the European Regulation MDR 2017/745. The device has been designed in accordance with the requirements of the IEC 60601-1:2007/A1 2012/A2 2020 and its deviations AAMI/IEC 60601-1:2005 + AMD 1:2012, CAN/CSA-C22.2 No. 60601-1:14, JIS T 0601-1:2017.

Manufacturer information

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

Table of Contents

1 Symbols in the Instructions for Use

1.1 Symbols for notes on safety

Please note that specific passages of this Instructions for Use are clearly marked as safety notes.

Warning! Indicates a potentially hazardous situation, which, if not avoided, can cause death or serious injury.

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.

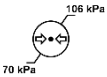
Note: indicates important or useful information on use.

1.2 Labeling / Symbols and icons

The icons on the device labels and used in the Instructions for Use, are listed in Table 1.

Where you find it	Symbol	Meaning
Device Screen		Shutdown
		Go to Previous Page
		Browse the Database
		Make a New Measurement
Device Label		Manufacturer
		Type BF Applied Part

Where you find it	Symbol	Meaning
	CE	CE Mark
		Waste of electrical and electronic equipment according to WEEE Directive 2012/19/EU
	Rx Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
		Refer to Instruction for Use
		Direct Current Power Supply
		Class II equipment
	IP20	Degree of Protection
	REF	Catalog Number
		Production Date (YYYY-MM-DD)
	SN	Serial Number
	MD	Medical Device
		Unique Device Identifier (UDI), GS1 Datamatrix
	#	Model
Device Back Lid		Ethernet port
		USB port
	HDMI	HDMI port

Where you find it	Symbol	Meaning
		Direct current power supply
		Power ON/OFF button
	 DO NOT COVER	Do not cover
Front Cover		Type BF applied part
Package Label		CE Mark
		Serial Number
		Catalog Number
		Medical Device
	Rx Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
		Manufacturer
		Production Date (YYYY-MM-DD)
		Unique Device Identifier (UDI), GS1 Datamatrix
		Minimum and maximum allowed storage and transport temperature (degrees Celsius)
		Minimum and maximum allowed storage and transport relative humidity (%)
		Minimum and maximum allowed storage and transport atmospheric pressure (kPa)

Symbols in the Instructions for Use

Where you find it	Symbol	Meaning
		Refer to the Instructions for Use (this document)
	1 unit	Shipping Information
	#	Model

Table 1

2 List of abbreviations

AX_{insp}	Area of inspiratory reactance
AX_{exp}	Area of expiratory reactance
AX_{tot}	Area of total (whole-breath) reactance
BMI	Body Mass Index
BTPS	Body Temperature and Pressure, Saturated
CoV	Coefficient of Variation
CR	Coefficient of Repeatability
CV_{FOT}	Closing Volume (detected by FOT)
ERV	Expiratory Reserve Volume
FRC	Functional residual capacity
$Fres_{insp}$	Resonant frequency of inspiratory reactance
$Fres_{exp}$	Resonant frequency of expiratory reactance
$Fres_{tot}$	Resonant frequency of total (whole-breath) reactance
GLI	Global Lung Initiative
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
R_{ei}	Resistance at the end of inspiration
R_{ee}	Resistance at the end of expiration
R5	Resistance at the frequency of 5 Hz
R_{5-19}	Difference between resistance at 5Hz and 19Hz
$R_{5-19,\ insp}$	Difference between inspiratory resistance at 5Hz and 19Hz
$R_{5-19,\ exp}$	Difference between expiratory resistance at 5Hz and 19Hz
SD	Standard Deviation
sG_{rs}insp	Specific inspiratory conductance of the respiratory system
sG_{rs}exp	Specific expiratory conductance of the respiratory system
sG_{rs}tot	Specific conductance of the respiratory system during the whole breath
RV	Residual Volume
RV/TLC	Ratio between residual volume and total lung capacity
SVC	Slow Vital Capacity
Ti	Inspiratory Time
Te	Expiratory Time
TLC	Total Lung Capacity
Ttot	Total Duration of the Breath

VC	Vital Capacity
Ve	Minute ventilation
Vol	Volume
Vt	Tidal Volume
Vt/Ti	Mean Inspiratory Flow
Vt/Te	Mean Expiratory Flow
X_{crit}	Reactance value at CV_{FOT}
Xinsp	Mean Inspiratory Reactance
Xexp	Mean Expiratory Reactance
Xtot	Mean Reactance of the whole breath
Xrs	Respiratory Reactance
X_{ei}	Reactance at the end of inspiration
X_{ee}	Reactance at the end of expiration
X5	Reactance at the frequency of 5 Hz
Z	Respiratory Impedance
ΔXrs	Difference between Xinsp and Xexp at 5 Hz
ΔR	Difference between R_{ee} and R_{ei}
ΔX	Difference between X_{ee} and X_{ei}

Table 2

3 List of the units of measurement

Physical quantity or parameter	**Available units of measurements (See also *Change user settings*)**			
	Default format	*Other available format(s)*		
BMI	$kg \cdot m^{-2}$			
Date format	dd/mm/yyyy	mm/dd/yyyy		yyyy/mm/dd
f	Hz			
Height	cm	in		
R, X, Z, X_{crit}	$cmH_2O \cdot s \cdot L^{-1}$	$hPa \cdot s \cdot L^{-1}$		$kPa \cdot s \cdot L^{-1}$
sGrs	$cmH_2O^{-1} \cdot s^{-1}$	$hPa^{-1} \cdot s^{-1}$		$kPa^{-1} \cdot s^{-1}$
Respiratory rate, RR	breaths per minute, bpm			
Room Humidity	%			
Room Pressure	mmHg	hPa	mbar	psi
Room Temperature	°C	°F		
Ve	$L \cdot min^{-1}$			
Vt, Vol, VC, SVC, IC, TLC, ERV, FRC and CV_{FOT}	L			
Vt/Ti	$L \cdot s^{-1}$			
Vt/Te	$L \cdot s^{-1}$			
Weight	kg	lbs		
AX	$cmH_2O \cdot L^{-1}$	$hPa \cdot L^{-1}$		$kPa \cdot L^{-1}$

Table 3

4 Descriptive Information

4.1 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 3 years of age or older. The device is designed to be used by pulmonologists, general practitioners, nurses, respiratory therapists, laboratory technologists, medical researchers and similarly trained personnel in hospitals, clinics, and private physician offices.

4.2 Contraindications

The device is contraindicated in patients with known sensitivities or allergies to the following components: ABS (acrylonitrile butadiene styrene), Silicone, Stainless Steel, Polypropylene, Acrylic, Polycarbonate, Nylon, Aluminum and PET (polyethylene terephthalate) and in patients not mentioned in the previous section. The device can be used only by persons indicated in the previous section.

4.3 Description of the device

Resmon PRO FULL is a device for the non-invasive assessment of the mechanical impedance of the respiratory system based on the Forced Oscillation Technique (FOT) - also known as *oscillometry* - and of lung volumes.
With FOT, the respiratory system is stimulated by pressure oscillations to evaluate its mechanical response in terms of impedance. Impedance is the complex ratio between the pressure and flow measured at the mouth and estimated at the frequency of the stimulating signal; it is usually further decomposed into its real part (the resistance, Rrs) and its imaginary part (the reactance, Xrs).
The Resmon PRO FULL uses the following stimulating signals:

- Single sinusoid at 5 Hz, 6 Hz, 8 Hz or 10 Hz
- Multi-frequency signals at 5 -11-19 Hz
- Pseudo Random Noise (PSRN), which contains the sinusoids having all the prime frequencies in the range of 5 -37 Hz

A FOT measurement is conducted during a patient's normal breathing, without requiring any forced effort; therefore, it is particularly suitable for monitoring non-cooperative patients, such as elderly patients or ill patients with limited forced capacity.

Resmon PRO FULL also allows the measurement of slow spirometry parameters, including inspiratory capacity (IC), slow vital capacity (SVC) and the closing volume (CV_{FOT}, i.e., the

volume of air in the lungs where the Xrs tracing changes its slope during an SVC maneuver). Absolute lung volumes (e.g., the residual volume, RV, or total lung capacity, TLC) can be calculated from the measured slow spirometry values by simple arithmetic operations provided that either the patient's functional residual capacity (FRC) or the TLC are inputted by the operator.
Alterations of the measured parameters (i.e. deviations from their normal range) provide clinical information to the physician to support the diagnosis and/or follow-up of obstructed and/or restricted respiratory diseases.

4.4 Device structure

1. Touchscreen Display
2. Front Cover
3. Device Inlet
4. Inlet of Ambient Air

Figure 1 - Device front view

5. Ethernet Port
6. USB Ports
7. Micro-HDMI Port
8. USB OTG port
9. Power on Button
10. Power Supply Inlet
11. Air Blower Filter Cover

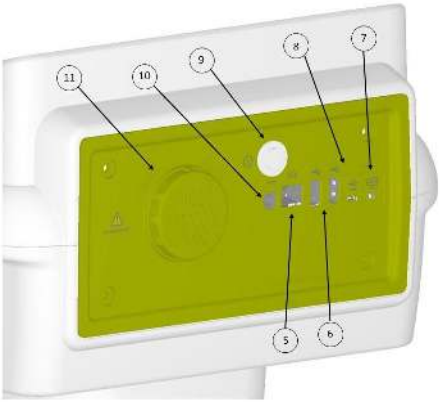


Figure 2 - Device back view

4.5 Components supplied with the device

1. **Test Object:** it is a component of the Resmon PRO FULL with a known impedance used to verify the factory calibration of the device (Figure 3).

Figure 3 - Test object

2. **Calibration and Titration reports**
3. **USB pen drive**

4. **Resmon CART (REF: RT1106, optional):** the cart is an optional component combining the characteristic of the *device holder* with the possibility to transport the device. The cart supplied with the device is an EU MDR Class I medical device (Figure 4).

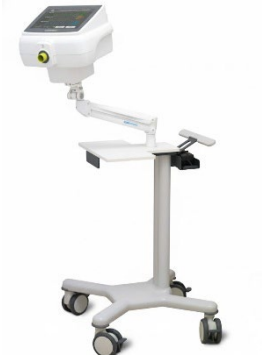


Figure 4 - Resmon CART

5. **Air blower filte**r (2 pieces) supplied the device for the periodic maintenance activities. See section *Maintenance*

6. **Device Holder** (Figure 5)**:** it permits to support the device during the measurements. Its design allows the user to adjust the device height and angle to perform the test with the patient in the correct position.

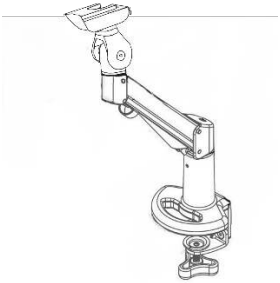


Figure 5 - Device Holder

7. **Power Adapter**

Model:	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:	

Warning! The power supply provided by the manufacturer is compliant with IEC 60601-1. Do not use a non-compliant power supply. If the power supply is damaged or lost contact your local distributor.

Caution! Use of accessories or components 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 or components are damaged or lost contact your local distributor.

4.6 Disposables

The following single-use items are required for measurement but are not included with the device:

- **Nose-Clip:** any standard nose-clip suitable for pulmonary function testing.
- **Bacterial/Viral Filter:** the use of legally marketed filter specifically intended for pulmonary function testing is mandatory. It must meet the following specifications:
  - Resistance: <1 $cmH_2O \cdot s \cdot L^{-1}$ at 1 L/s
  - Connector Inner Diameter: 30 mm
  - Device-Side Connector Length**:** 2 - 6 cm
  - Patient-Side Mouthpiece/Connector Length:
    - Filter with Rounded Shape: 4 - 6.5 cm
    - Filter with Squared Shape: 2.8 cm
  - Filtering Section:

Rounded Shape		Squared Shape	
Diameter:	8 - 9.5 cm	Side:	6.5 cm
Length:	0.5 - 1.2 cm	Length:	2 cm

  - Filtration Efficiency: >99.99% (Viral & Bacterial) at 30 L/min

4.6.1 Optional Disposables

- Mouthpiece or Face Mask: for patient comfort, a single-use mouthpiece or mask may be connected in series to the bacterial/viral filter at the patient side. Any commercially-available mouthpiece or face mask suitable for pulmonary function testing and compatible with the filters reported in section above can be used to perform the measurements with the device.

- **Cheek Holder** (**REF RT4155**): this optional, single-use component (Figure 6) connects to the filter to support the patient's cheeks during oscillometry measurements, serving as an alternative to using their hands.

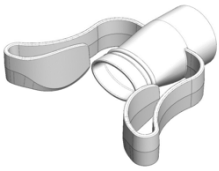


Figure 6 – Cheek Holder

4.6.2 Usage and Disposal

- All disposables are single-use and must be changed for each new patient.
- Dispose of used filters, nose-clips, and mouthpieces/masks according to the manufacturer's instructions and your institution's regulations.
- The cheek holder can be disposed of as domestic waste under normal contamination. In specific cases (e.g., tuberculosis), it must be disposed of in dedicated special waste containers.

4.7 External cables and electrical equipment

The following cables and electrical equipment can be connected to the Resmon PRO FULL:

- Ethernet port: connect only equipment compatible with IEEE 802 standard
- USB ports and USB-OTG port: connect only equipment compatible with USB 2.0 (“high-speed”) standard
- Micro-HDMI port: connect only equipment compatible with HDMI 1.4 standard

4.8 Shipping Box Composition

The Resmon PRO FULL is shipped as follows:

▪ Resmon PRO FULL main unit	(1 piece)	See section *Description of the device*
▪ Test Object	(1 piece)	See section *Components*
▪ Device Holder	(1 piece)	See section *Components supplied with the device*
▪ Power Supply	(1 piece)	See section *Components supplied with the device*
▪ USB pen drive	(1 piece)	See section *Components supplied with the device*
▪ Air Blower filter	(2 pieces)	See section *Components supplied with the device*
▪ Instruction for use (this document)	(1 piece)	

Optionally:

▪ Resmon CART	(1 piece)	See section *Components*

5 Warnings

Warning! To ensure electrical safety and regulatory compliance, any device, extension cord, or power strip connected to the Resmon PRO FULL's ports must strictly adhere to the IEC 60601-1 standard. The device's power strip must be kept off the floor and must not be connected in a series with other power strips. Only components belonging to the Resmon PRO FULL device should be plugged into its dedicated power strip.

Warning! To prevent electrical interference and reduce the risk of fire or electrical shock, use only the official components and accessories provided with this device. The use of unauthorized parts is strictly prohibited and may create a hazardous situation.

Warning! Do not expose the device to condensing humidity.

Warning! Do not open the device. There are no user adjustable components in the device. Only authorized personnel can open the device.

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

Warning! Do not use the device in an **MRI environment.**

Warning! No modifications to Resmon PRO FULL are allowed without the manufacturer's authorization.

Warning! To prevent a choking hazard, keep all parts with dimensions less than 31.7 mm (1.25 inches) in diameter and 57.1 mm (2.25 inches) in length out of the reach of children under three years old at all times.

6 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:** Avoid rough handling or misuse to prevent hardware and electrical damage.
- **Protect from dust:** Cover the device when not in use to prevent malfunctions caused by dust.
- **Keep air blower inlet clear:** Do not block the openings on the bottom of the device to ensure proper ventilation and prevent overheating.
- **Use touchscreen gently:** Do not press hard on the touchscreen to avoid damaging the display.
- **Avoid liquid contact:** Keep liquids away from the device. If a spill occurs, immediately disconnect the power and wipe the exterior with a soft cloth
- **Prevent cross-contamination:** Always use a new bacterial/viral filter for each patient.
- **Check for allergies**: The use of this device could be contraindicated in patients with known sensitivities or allergies to the components reported in section *Contraindications*
- **Ensure clear flowmeter:** Check that the flowmeter's metal mesh is not blocked, as obstructions can produce unreliable results.
- **Check for physical damage:** If the main body (chassis) is damaged, stop using the device, disconnect it from power, and contact your local distributor (see section *User Information*) to prevent injury or malfunction.
- **Check the display:** If the display is damaged or not working correctly, contact your local distributor (see section *User Information*), as a functional screen is essential for proper operation.
- **Inspect Packaging on Arrival:** If the packaging is damaged upon delivery, do not use the device and contact your local distributor immediately (see section *User Information*).

7 Setup

7.1 Device placement

Select a stable, horizontal surface for the device that is close to an electrical outlet and located in a cool, dry, temperature-controlled area (refer to the *Operating and Storage Conditions* section for exact specifications). Once installed, the device must remain in this location. No other setup configurations are permitted.

Caution! Ensure the device is placed in a location where access to the power plug for disconnection is never obstructed.

7.2 Resmon PRO FULL with Device Holder

7.2.1 Assembling the holder

Figure 7 shows the holder and its components.

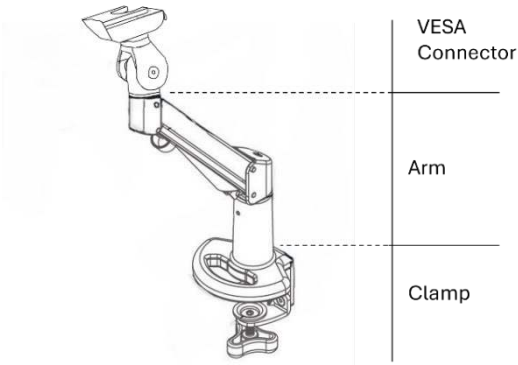


Figure 7 - Arm Bracket

1. **Tighten the clamp to the surface** (e.g., desk or table)**.** Use the protection pad provided with the holder to protect the surface.

Warning! Ensure the holder's clamp is securely fastened to a stable surface. An improperly attached holder can cause the device to fall, posing a risk of serious injury to users and causing significant equipment damage.

Warning! The support surface must provide complete stability for the device, being of sufficient size and strength to prevent it from tipping over.

Warning! Pay attention during the arm insertion in the clamp to avoid damage to things and people.

2. **Adjust the orientation of the VESA connector** as shown in Figure 8. To do it, loosen the bolt (indicated by the arrow) with the hex key provided with the device, change the orientation to be between 5 and 10 degrees as shown in Figure 8 and then tighten the bolt again.

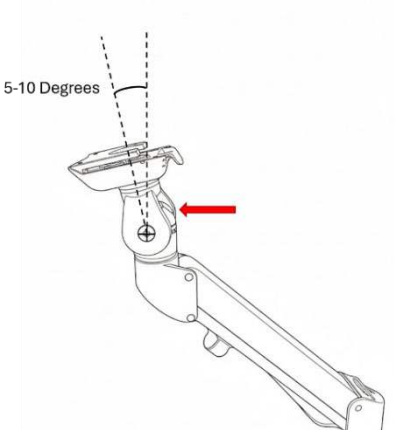


Figure 8 - Adjust the orientation of the VESA connector

Warning! 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 also guarantee an effective cleaning of the device (see section *Cleaning and disinfection*). It will also help the patient assume a proper posture during the measurement (see section *Preparing the patient for a measurement session*).

3. **Fasten the device to the arm**. On the bottom of the device there is a fitting. To attach the device to the holder, slide the fitting onto the VESA connector until you hear a “click”, indicating that the device is securely attached (see Figure 9).

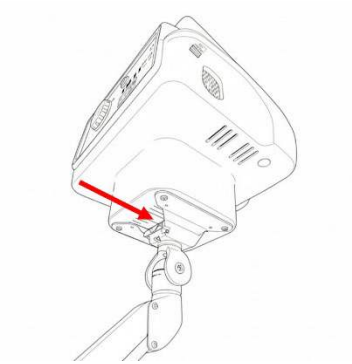


Figure 9 - VESA fitting

Warning! Make sure the device is properly fixed on the holder before using it.

Warning! If the holder is damaged, do not use the device. Remove the device from the holder and contact your local distributor (see *User Information*).

7.3 Resmon PRO FULL with Resmon CART

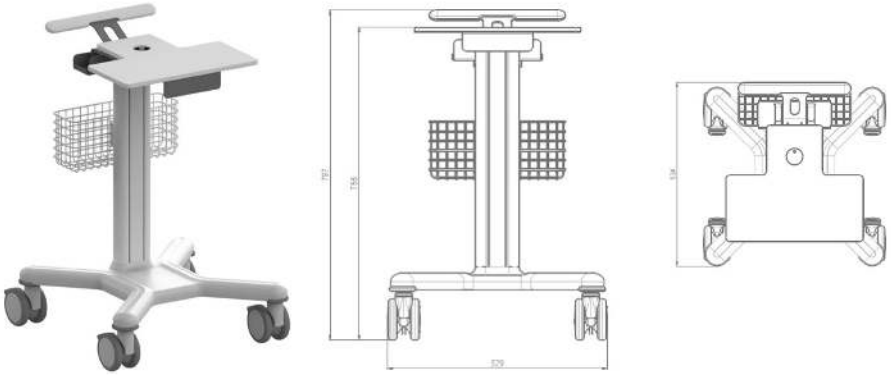


Figure 10 - Resmon CART

The Resmon CART is an optional component of Resmon PRO FULL designed to facilitate transportation of the main device. It is classified as a Class I medical device under the EU MDR 2017/745 Regulation. For a visual reference and detailed dimensions, please see Figure 10.

Caution! To ensure safe and correct setup, the Resmon CART must be assembled exclusively by authorized personnel and in strict accordance with the "Instructions Manual – Resmon CART" supplied together with the cart.

8 Turning on/off the device

8.1 Turning on the device

Connect the power adapter to the device, and then plug the power cord into a wall outlet.

Press the *Power on Button* in the back of the device and hold for a second. Wait until the device loading is complete before moving forward.

8.2 Turning off the device

To turn the device off go to the *Login* page, then press the *Shutdown* button  on the top left corner. Press *Confirm* to power off the device.
If the device cannot be turned off directly from the touchscreen display, it is always possible to turn the device off by pressing the *Power on Button* for at least 5 seconds.

Warning! To ensure electrical safety, disconnect the power cord from the mains outlet whenever the device is not in use. The green LED on the external power adapter unit indicates that the device is connected to the electrical mains. This light should be off when the device is not being used.

9 Admin account and device settings

When the device is powered on, the login screen appears. You will see two default accounts for taking measurements: STANDARD (with a preset stimulus at 5-11-19Hz) and PRESCHOOLER (with a preset stimulus at 8Hz).
To change device settings, you must use the separate *Admin* account. This account is limited to changing device settings and cannot perform measurements or access patient data.

To configure the device, you must first log in as an administrator:

- Select the *Admin* button on top right corner ( )
- Enter the default password: 12345
- This will open the *Settings* panel (Figure 11).

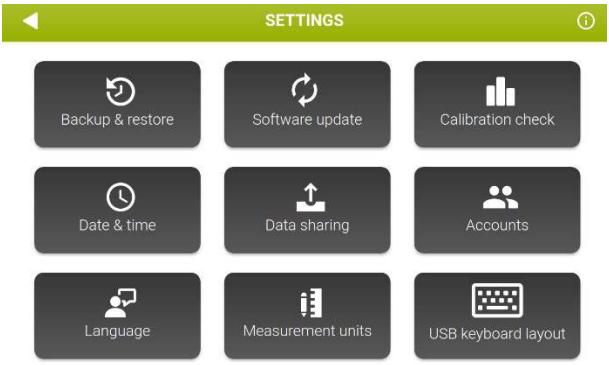


Figure 11 – Settings panel

Caution! To prevent unauthorized access, the default Admin password must be changed during your first login to the *Settings* panel. Please refer to the *Accounts* section for instructions.

When you have finished, select *Logout* button on the top left corner of the header bar to return to the login screen.

9.1 Info

Press the *Info* icon ( ) on top right corner to view detailed device and support information, including (Figure 12):

- System date,

- Support contact details,
- Software versions,
- Disk space usage,
- Initial installed software version,
- Device serial number.
- Firmware version

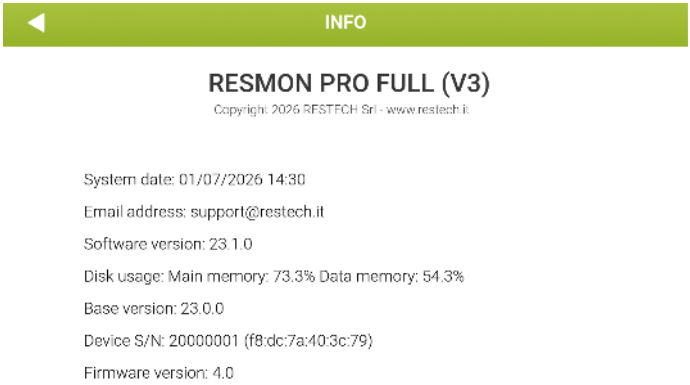


Figure 12 - Information Page

9.2 Accounts

From the *Settings* panel (Figure 11), select *Accounts* to open the *Accounts* panel (Figure 13), where you can create, modify, or remove user profiles.

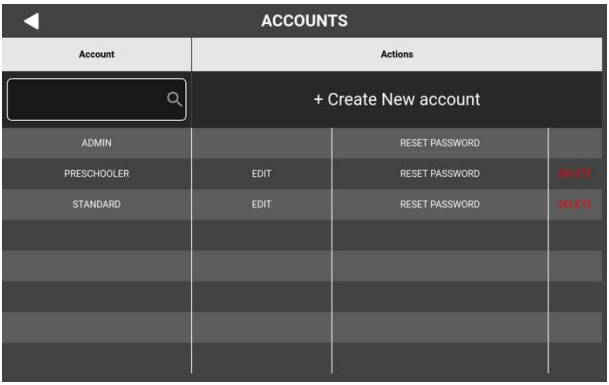


Figure 13 – Accounts panel

9.2.1 *Create a New User Account*

1. Select the + *Create new account* button to open the *New Account* panel (as shown in Figure 14).
2. Enter Credentials:
   - **Account name**: Choose a unique name (up to 25 characters).
   - **Password:** Create a password (5-32 digits) and enter it a second time in the confirmation field.
3. Configure Permissions: Use the buttons on the right to set the following options for the user account:
   - **Reference Equations**: When enabled, results are displayed alongside preset reference values (see section *Change user settings*). Default setting is ON.
   - **Anonymize Archive**: When enabled, the patient names, surnames and birth dates are hidden on all test reports and in exported files and file names. Default setting is OFF.
4. Once finished, press *Next* and create the account.

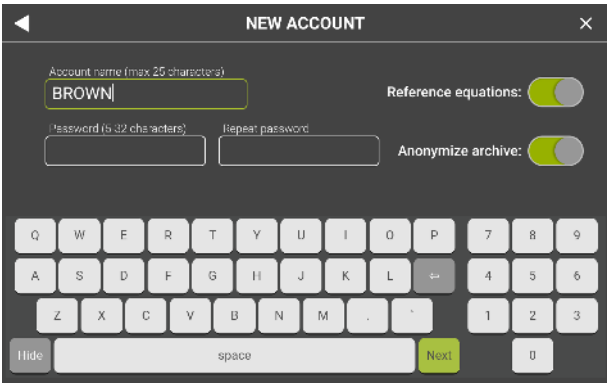


Figure 14 - Create a new account

Each username must be a unique identifier. The device will not allow you to create two accounts with the same username. If you attempt to use an existing name, the error "*Account already exists*" will be displayed.

9.2.2 *How to Delete an Account*

1. From the *Accounts* panel (Figure 13), select the *Delete* button next to the username of the account you wish to remove.
2. Confirm the action when prompted, then press *OK* to return to the *Accounts* panel.

9.2.3 How to Reset a Password

1. From the *Accounts* panel (Figure 13), select the *Reset password* button next to the relevant account (including *Admin*) to be modified.
2. Enter the new password and repeat it to confirm.
3. Press *Next* to continue. Confirm the action when prompted to save the change and then press *OK* when the password reset confirmation message is displayed.

9.2.4 How to Edit an account

From the *Accounts* panel (Figure 13), select the *Edit* button next to the relevant account to modify the following account settings:

- Account name
- Enable/disable the **Reference equations**
- Enable/disable the **Anonymize archive**

9.3 Backup, restore and merge

Selecting the *Backup & Restore* button, accessible from the *Settings* panel (Figure 11), you can perform a complete backup of the device's data, restore the device from a previous backup, or merge the information from a previous backup with the device's data. Remember to insert a USB memory stick into an available USB port.

Figure 15 - Backup and restore

9.3.1 Backup to USB

The Admin account can perform three different types of backup by selecting the desired option from the screen (Figure 16):

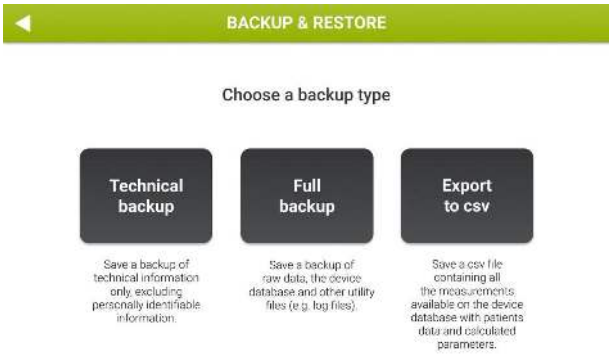


Figure 16 - Backup options

- *Technical Backup:* Saves only non-sensitive technical information. This option excludes all personally identifiable patient data and is typically used for troubleshooting or technical support.
- *Full Backup:* Creates a complete copy of all data on the device. This includes the full patient database, raw measurement data, and system utility files (e.g., logs). This is the standard option for creating a complete archive or for database restoration or merge (see section below *Restore a previous backup or Merge*).
- *Export to CSV:* Exports clinical data into two separate spreadsheet-compatible (.csv) files for analysis: the *Measurements* and the *Sessions* csv. The Measurements .csv file includes all measurement results, while the Sessions .csv file reports the mean values of the measurements within each session (for the selected measurements).

Caution! Make periodic full backups to not lose your data. Archive data according to the regulations of your institution.

Caution! The USB drive may contain confidential data after backup. Protect its content from unauthorized access following the regulations of your institution.

Note: from software version 21.0.0, the Resmon PRO FULL supports USB drives with AES-XTS encryption.

9.3.2 Restore a previous backup or Merge

By selecting the RESTORE button from *Backup & Restore* panel (Figure 15) you can restore backups created from:

- A Resmon PRO FULL V3
- A Resmon PRO FULL V2 (only if it was updated to software version 6.0.0 or newer before the backup was made)

or merge the device's data with the information belonging to:

- A Resmon PRO FULL V3
- A Resmon PRO FULL V2 (only if it was updated to software version 6.0.0 or newer before the backup was made)

Before you begin, ensure you have a USB drive containing a valid full backup file.

Note: if multiple backups are on the USB drive, the device will automatically detect and use the most recent one only. The device will display details of the latest backup found (file name, source serial number, and date) as reported in Figure 17.

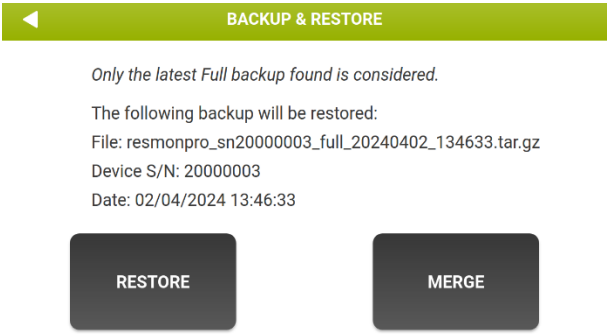


Figure 17 - Restore from backup

Press *Restore* or *Merge* to start, enter the Admin password and confirm.

Caution! The RESTORE procedure will permanently delete the current data on your device. This action cannot be undone. We suggest to make a Full Backup of your patient data before performing such operation.

If patient data is already present in your device, the RESTORE operation will overwrite all of your data, while the MERGE operation will try to import the new data and store it besides the current data. In case the MERGE operation finds some conflicting information between the two datasets, it will ask you to resolve them before proceeding. See the *Troubleshooting* section for more details.

Once the restore or merge is successful, a confirmation screen will appear. Select *Reboot* to restart the device with the new data.

9.4 Software Update

From the *Settings* panel (Figure 11) by pressing *Software update* button, you can install a new software release. You should copy the update file to the root directory of a USB drive and insert it into the device. From the menu, select the file, and press *Install*. Once the "Update installed!" message appears, press *OK* to complete the process.

Note: all software updates are digitally signed. Corrupted or tampered software updates will not appear in the list.

9.5 Date & time

From the *Settings* panel (Figure 11) press *Date & time* button to set them (Figure 18).

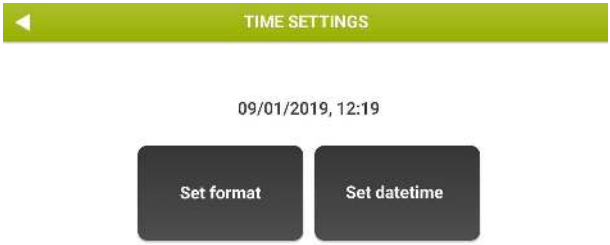


Figure 18 - System date options

You can customize the display by choosing a date format (DD/MM/YYYY, MM/DD/YYYY, or YYYY/MM/DD) and a time format (12 or 24-hour). The default formats are DD/MM/YYYY, 24-hour. To ensure data integrity, the device automatically validates any new date entered. If you set a date that is earlier than the last recorded event, a warning message will ask you to either confirm the new date is correct or go back and adjust the value.

Caution! Pay maximum attention when changing system date and time because this may have an impact on the accuracy of the next measurement.

9.6 Language

From the *Settings* panel (Figure 11) press *Language* to change the software language. The device's default language is English. When a new language is selected, the change is applied instantly throughout the device.

9.7 Measurement units

From the *Settings* panel (Figure 11) select *Measurement units* to set (Figure 19):

- Height units: centimeters (default) or inches
- Weight units: kilograms (default) or pounds
- Temperature: Celsius (default) or Fahrenheit
- Barometric pressure: hectopascals (default), millibars, pounds per square inch, millimeters of mercury
- Mouth pressure: hectopascals, kilopascals, centimeters of water (default)

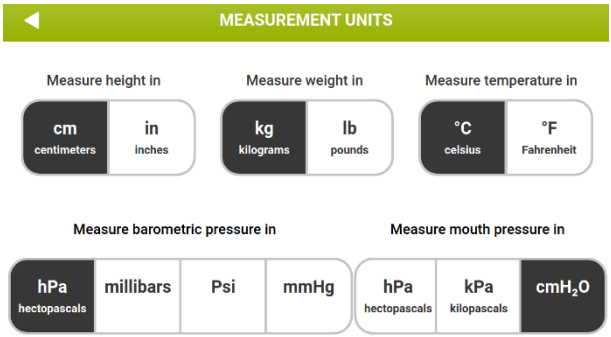


Figure 19 - Measurement units screen

Select the desired measurement units and press the *Back button* ( ) to return to *Settings* panel.

9.8 USB keyboard layout

From the *Settings* panel (Figure 11) press *USB keyboard layout* to select the layout for an external USB keyboard from the options listed below (Figure 20, Table 4):

us:	American keyboard layout
fr:	French keyboard layout
es:	Spanish keyboard layout

latam:	Latin-American Spanish keyboard layout
it:	Italian keyboard layout
be:	Belgian keyboard layout
pl:	Polish keyboard layout
gb:	United Kingdom keyboard layout
nl:	Dutch keyboard layout
ca:	Canadian keyboard layout
jp:	Japanese keyboard layout
de:	German keyboard layout

Table 4

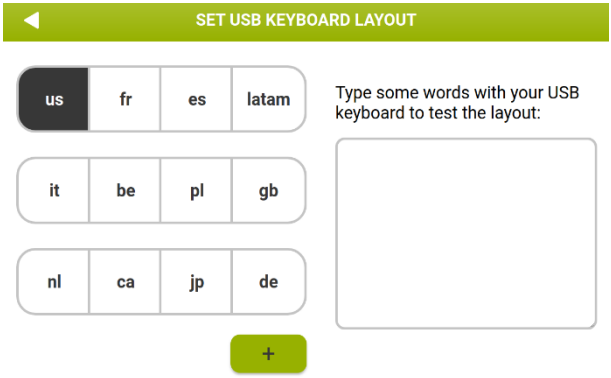


Figure 20 - USB keyboard layout screen

Press the green "+" button to add a different keyboard layout from the options reported on the screen.
Once you have chosen a layout, connect a corresponding keyboard and use the text box on the right to verify the selection.

9.9 Data Sharing

From the *Settings* panel (Figure 11) select *Data sharing* to configure the following:

- **Report heading:** press *Report heading* to see the heading of the clinical reports. The heading can be modified by pressing *Change text* (you can also add the *Lab* name under the *Hospital* name) or *Change logo*. Insert the new text and press *Next* to confirm. Choose the logo among *RESTECH logo*, *No logo* (blank space) or *Custom logo* importing a file named "logo.png" from a USB drive, then press *Confirm*.
- **Printer:** press *Printer* to visualize the name of the USB printer connected to the device. Press *Test printer* and print a test page.

If the printer is compatible, the test page will be printed correctly.
If no printer is connected, an error message “Printer not found” will be displayed.
The Resmon Pro supports standard Postscript printers as well as driverless printers (AirPrint and IPP Everywhere). Ask your distributor for some names of compatible models.

9.9.1 USB-OTG

Press *USB-OTG* to select the preferred method for sharing data via the USB-OTG port (micro-USB data cable) between the two supported options:

1. *Share data with an external personal computer*: You can share a clinical report as a PDF directly to a personal computer by connecting it to the USB-OTG port. This feature works without needing to install any special software on your computer.

Note: please make sure to use a **micro-USB data cable** when connecting Resmon PRO FULL to external computers.

2. *Share data with third party software*: This option allows for real-time communication between the Resmon PRO FULL and a third-party software via the USB-OTG port. Only third-party software that implements Restech’s proprietary protocols is supported (see *Technical specifications*). To enable this functionality:
    1. Select *Sharing Data with third party software* (Figure 21)
    2. Three more buttons are now displayed: *Ping*, *Sync* and *Sync and Delete* (Figure 21)
    3. Press *Ping* to verify the connection between the device and the third-party software. The Resmon PRO FULL is connected to the third-party software if a success screen is returned.

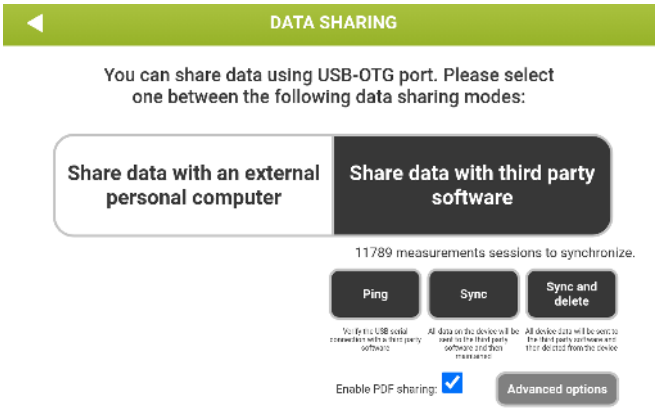


Figure 21 - Options available for sharing data with 3rd party software

Once the connection is verified, it is possible to synchronize the patient's data on the internal database with the third-party software as follows:

4. Select *Sync* to only synchronize data. The synchronization can be performed on measurements of the current day, last week or all data.
5. Select *Sync and delete* to synchronize and delete data from the internal database. The Synchronization can be performed on measurements of the current day, last week or all data (Figure 22). Once data synchronization is ended, the data on the device will be deleted.

Caution! The *Synch and delete* procedure will permanently delete the current data on your device. This action cannot be undone. It is suggested to make a Full Backup of your patient data before performing such operation.

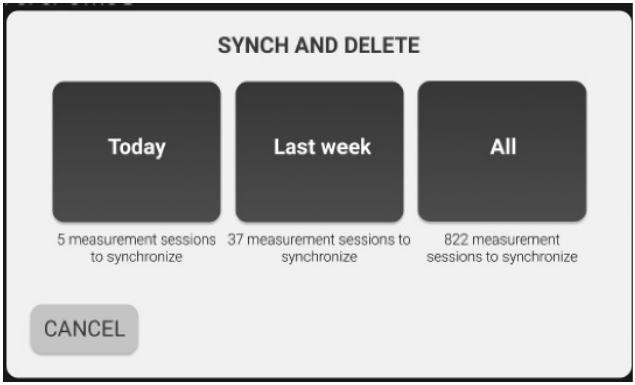


Figure 22 - Synchronization selection

By default, the clinical report in PDF format is always shared with the third-party software. Since this slows down the data transmission, you the PDF report is not needed, the checkbox on the same screen can be used to disable its transmission.

An *Advanced options* button is also present. Advanced options allow receivers that are still using the V1 protocol to modulate the transfer speed by adjusting the size of the data chunks and the delay between chunks. Changing these values may result in a slower but more reliable data transfer. In case you are experiencing data loss or data corruption, consider increasing the delay between chunks and decreasing the chunk size.

9.9.2 Network

Press *Network* to share data with third party software through an Ethernet cable connection. To connect the device:

1. Choose the web service protocol implemented by the third-party software in use
2. Enable the network using the slider button on the upper-right corner of the display (Figure 23). Notice that this will disable the USB-OTG option to share data with third-party software, in case it was enabled.
3. Insert the information requested to connect the Resmon PRO FULL with the third-party software:
    a. Figure 23 shows the network parameters; the Resmon Pro will make requests to the third-party web service to exchange medical data. You can use the DHCP protocol if your network supports it.
    b. The "*Enable sharing PDF*" button on the bottom-left side of the display, if checked, allows the transfer of the clinical report in PDF format. The PDF report can either be transferred through the ethernet cable together with the numerical results (HIS/EMR) or on a separate channel over USB-OTG data cable (BreezeSuite)
4. Select the Ping button to verify the connection between the device and the third-party software.

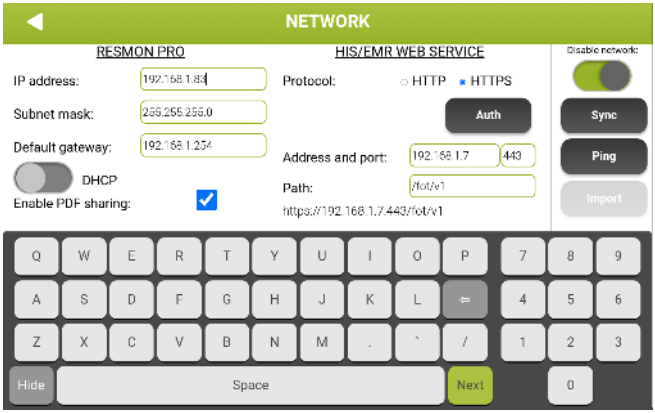


Figure 23 - Network settings

The *Sync* button can be used to transfer all sessions at once. The Synchronization can be performed on measurements of the current day, last week or all data. In case of HIS/EMR the PDF report can be included for all sessions. There's an option to also delete all data from the internal database.

Caution! The *Sync and delete* procedure will permanently delete the current data on your device. This action cannot be undone. It is suggested to make a Full Backup of your patient data before performing such operation.

[For BreezeSuite software only] The *Import* button can be used to import a network configuration from a backup file (*full* or *technical*) exported by a previous generation device (Resmon PRO FULL V2) that was already connected to the same third-party software (BreezeSuite). Simply place a USB drive containing such backup and press the *Import* button.

9.9.3 Network authentication

Select HTTPS for a secure connection between the device and the third-party software: this will ensure all data in transit is encrypted.
Mutual authentication over TLS can also be setup.

- *Server authentication*: the Resmon PRO FULL can verify signatures of public certification authorities. In case you make use of a private CA, you check *Use explicit CA certificate to authenticate the server* and click on "Import CA certificate": the device will look for a 'cacert.crt' file in PEM format on the USB drive plugged into the device. After the import, details about the CA certificate will be displayed.
    - If you enforce certificate revocation on your network, you can check *Enforce OCSP revocation check* and the device will refuse revoked certificate. Revocation check is only supported over the OCSP protocol.
- *Client authentication*: you can authenticate the Resmon PRO FULL by exporting a *certificate signing request*, signing the request with your CA private key and then importing the signed certificate from a USB drive. After the import, details about the Resmon PRO FULL certificate will be displayed.

10 Calibration check

Your device has been calibrated by the manufacturer according to the European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines. The device will automatically prompt you to verify this calibration through a two-part process, the FOT calibration verification and Slow Spirometry calibration verification.

10.1 Verification of the FOT calibration

The device will automatically remind you to check the factory calibration every day. You can also start this process manually at any time from the *Settings* panel by selecting *Calibration check*.

Caution! Use only the test object provided by the manufacturer to perform the FOT calibration.

To start the verification of FOT calibration, enter the last 4 digits of the Test Object code found on the label into the pre-loaded code on the device (Figure 24). Press *Next* to verify the code.

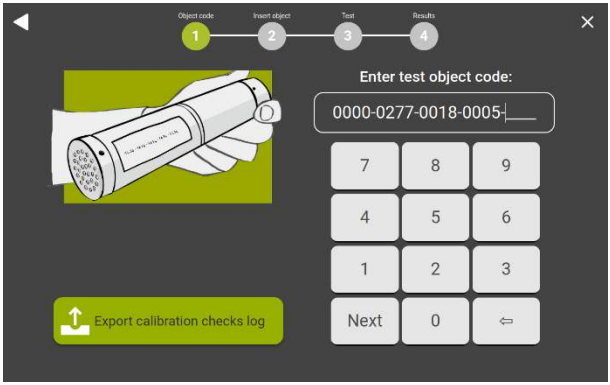


Figure 24 - Insert Code for the Identification of the Test Object

If the code is correct, you will see the instructions to perform the verification.
Connect the Test Object to the device and press *Start*.
The duration of the Calibration Verification is 80 seconds + 5 seconds for sensors' zeroing and can be cancelled at any time by pressing *Cancel*.
This procedure verifies the device's calibration by testing its response to a range of stimulating frequencies (i.e. 5Hz, 6Hz, 8Hz, 10Hz, 5-11-19Hz) and complex waveforms (i.e., pseudo-random noise). The test measures the test object's current resistance and

reactance and compares these values to the original factory-calibrated data stored in its memory.
The on-screen results indicate whether the calibration is still valid:

- *Test passed*: The device is properly calibrated. This result is given when the measurements are highly consistent (coherence is greater than 95%) and accurate (the impedance error is within 10%) across all tested signals.
- *Failure*: The device is out of calibration. This occurs if the measured impedance for at least one of the test signals differs by more than 10% from the stored factory 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 patients because they would be unreliable. Contact your local distributor (see section *User 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 FOT Calibration Verification.

10.2 Verification of the Slow Spirometry calibration

The verification of the Slow Spirometry calibration is optional and can be performed at the end of the FOT calibration check.
To start the verification, press the *Volume check for SVC* button. The on-screen instructions for performing the Slow Spirometry verification will then appear (Figure 25). If this step is skipped, the Slow Spirometry measurement functions will be disabled.

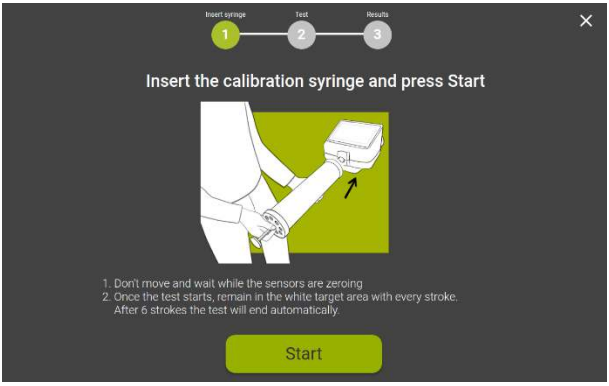


Figure 25 - Instructions for the Slow Spirometry volumes verification

The test uses a standard **3L calibration syringe** to push air through the device at various speeds. The device measures the total volume of air from the syringe and compares it to the expected 3L value.

Note: any commercially-available syringe suitable for pulmonary function testing can be used to perform the calibration check of slow spirometry parameters

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

Note: if the syringe does not properly fit in the device inlet, remove the front cover.

Caution! Use only 3L volume calibration syringes that carry a valid calibration certificate. Do not use calibration syringes with volumes different from 3L.

Press *Start* and wait for 3 seconds during the auto-zeroing of the flowmeter.

Figure 26 - Example of flow tracing during the slow spirometry volume verification

Move the syringe piston in and out six times. As you do this, keep the flow within the highlighted white area as shown on the screen (Figure 26).
On the right side of the screen a counter will track the number of strokes. The screen will display the measured volume in real time and will highlight any inaccurate results in **red**.

Figure 27 - Slow Spirometry verification results

At the end of the test (Figure 27) results can be:

- *Test passed*: verification is successful if all volume measurements are within **90 mL** of the 3L syringe's value (i.e., measured volume error is less than 3% of the syringe's value) in line with the 2019 ATS/ERS guidelines[1].
- *Test failed*: the verification fails if **any single measurement** deviates by more than 90 mL from the expected 3L syringe's value.

Caution! Repeat the test if the result of the slow spirometry verification is *failed*. If the test fails again, you will not be allowed to make any slow spirometry measurements on the patient because they would be unreliable.

1 American Thoracic Society. "Standardization of spirometry 2019 update an official American Thoracic Society and European Respiratory Society technical statement." Am J Crit Care Med 200.8 (2019): E70-E88

11 Operating instructions

To perform the user login, select an account (Figure 28), insert the password and press *Next*.

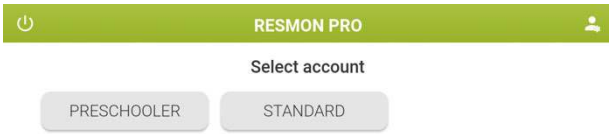


Figure 28 - Account displayed in the Login screen

After the user login, the *Home* screen will be displayed (Figure 29). You can always press the *Logout* button ( ) on the top right corner to log-out.

Figure 29 - Home screen

From the *Home* screen**:**

1. Press the *Settings* button ( ) to access the user settings.
2. Press the *Export* button ( ) to export the CSV archives containing all measurements and sessions performed with that account.
3. Press *Archive* to enter the database.
4. Press *Measurement* to perform a new measurement session.

11.1 Change user settings

When you open the *Settings*, the following page will be displayed (Figure 30):

Figure 30 - Settings screen

11.1.1 Stimulus frequency

Select *Stimulus frequency* to change the stimulating waveform. The following screen will be shown (Figure 31):

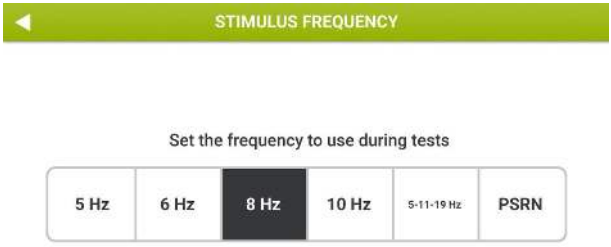


Figure 31 - Selection of the stimulating waveform

The available stimulating waveforms are:

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

The highlighted button indicates the currently active waveform. Select the desired stimulus and press the Back button ( ) to return to Settings.

For more information on selecting the stimulating waveform, see following section.

11.1.2 Criteria for selecting the stimulating waveform

The device uses a specific signal, or "stimulating waveform", to measure respiratory impedance. While the default setting is usually sufficient, you can choose a different waveform for specific clinical applications from the *Settings* page.

- **Default (5-11-19 Hz):** The standard multi-frequency signal used for general-purpose measurements.
- **Single-Frequency (5Hz, 6Hz, 8Hz, or 10Hz)**:
  - ✓ **Best for:** Analyzing impedance changes that occur *within breaths* at specific frequencies; frequencies higher than 5Hz allow better separation of the signal generated by the Resmon PRO FULL from the signals generated by tidal breathing of the patient.
- **Pseudo-Random Noise (PSRN)**:
  - ✓ **Best for:** When you need a more detailed analysis of how resistance and reactance are affected by frequency.
    - This waveform offers a much higher frequency resolution than the default signal.
    - This signal does not include within breath analysis (insp, exp).

Please note that each waveform has a maximum impedance value it can measure while maintaining the 10% accuracy required by international technical standards (King et al., Eur Respir J., 2020). These limits, established by the manufacturer, are detailed in the *Technical specifications* section and summarized in Table 5 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	25 $cmH_2O \cdot s \cdot L^{-1}$
5-11-19 Hz (default)	25 $cmH_2O \cdot s \cdot L^{-1}$
PSRN (5Hz, 7Hz, 11Hz, 13Hz, 17Hz, 19Hz, 23Hz)	25 $cmH_2O \cdot s \cdot L^{-1}$
PSRN (29Hz, 31Hz)	15 $cmH_2O \cdot s \cdot L^{-1}$
PSRN (37Hz)	6.8 $cmH_2O \cdot s \cdot L^{-1}$

Table 5

At the end of a measurement, the device will automatically notify you and discard the results if the patient's impedance was too high for the selected waveform's accuracy range (Figure 32 - see also section *How to start a new measurement session*).

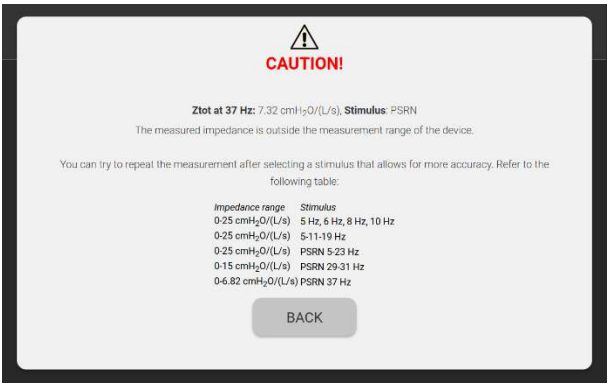


Figure 32 - Out of range measurement warning

If the device notify that the measured impedance is out of range for the current stimulation frequency you should repeat the measurement using a different waveform that is designed to handle higher impedance values (refer to Table 5 above).

Impedance values above 25 $cmH_2O \cdot s \cdot L^{-1}$ are rare. If you see a reading this high:

- Carefully check that the patient's posture is correct (see section *Preparing the patient for a measurement session*).
- After correcting any issues, repeat the test.

If, after following the steps above, you are using single-frequency or 5-11-19Hz waveform and the device still warns that the impedance limit was exceeded, the measurement must be considered unreliable. In this situation, you should not use the device for any further FOT measurements on this patient.

11.1.3 Measurement duration

Press *Measurement duration* to change the duration of the measurement (Figure 33).

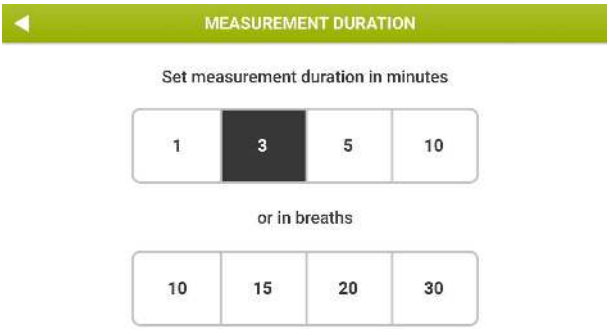


Figure 33 - Selection of the measurement duration

You can configure the measurement to last for a specific duration (1, 3, 5, or 10 minutes) or until a defined number of valid breaths are recorded (10, 15, 20, or 30). If the breath-count option is selected, the test will stop automatically when the target is reached or after a maximum of 10 minutes, whichever occurs first.

Note: if the selected stimulus is **PSRN**, the measurement duration cannot be modified and is limited to a maximum of 90 seconds.

11.1.4 Calibration check

See section 10 (*Calibration check)* of this document.

11.1.5 Reference equations

Reference equations define the normal ranges for respiratory parameters. Several sets of reference equations are available, covering different age ranges and patient ethnicities. You can select which set of reference equations the device uses to analyze the data (Figure 34). They are summarized in Table 6 and all of them are taken from studies published on peer reviewed journals. It is possible to completely disable reference equations for a given account, see section *Accounts*.

Reference equation	**Used for patients with the following age range**	**Available Reference Values***
Calogero et al, Pediatric Pulmonology, 2010	Children (3-6 yrs old)	- Resistance at 6, 8 and 10Hz - Reactance at 6, 8 and 10Hz

Calogero et al, Pediatric Pulmonology, 2013 (default)	Children (2-13 yrs old)	- Resistance at 6, 8 and 10Hz - Reactance at 6, 8 and 10Hz - Fres
De et al, Indian J of Pediatrics, 2020	Children (5-17 yrs old)	- Resistance at 5, 11 and 19Hz - Reactance at 5, 11 and 19Hz - R5-19
Ducharme et al, Chest, 1998	Adolescents (3-17 yrs old)	- Resistance at 6, 8 and 10Hz
De et al, Lung India, 2020	Adults (18-81 yrs)	- Resistance at 5, 11 and 19Hz - Reactance at 5, 11 and 19Hz - R5-19
Ducharme et al., Pediatr Pulmonol, 2022 (default)	Children (3-17 yrs old)	- Resistance and Reactance at 8 Hz - Resistance and Reactance at 5,11,19 Hz - AX at 5,11,19 Hz - R5-19
Oostveen et al, Eur Respir J., 2013	Adults (18-80 yrs)	- Resistance from 5 to 23 Hz - Reactance from 5 to 13 Hz - Resonant Frequency (Fres) - AX
Veneroni et al., Respiration, May 2024	Adults (20.8-86.3 yrs)	- Resistance at 5-11-19 Hz - Reactance at 5-11-19 Hz - Impdedance (Z) at 5 Hz - R5-19 - AX - Resonant frequency (Fres) - Delta Xrs
Valach et al., ERJ Open Res, 2025 (default)	Adults (18-90 yrs)	- Resistance at 5-11-19 Hz - Reactance at 5-11-19 Hz - Impdedance (Z) at 5 Hz - R5-19 - AX - Resonant frequency (Fres)
Quanjer et al, Eur Respir J, 2012 (GLI)	Children and Adults (3-95 yrs old)	- Vital Capacity (VC)

Hall et al, Eur Respir J, 2020 (GLI) (default)	Children and Adults (5-80 yrs old)	- Vital capacity (VC= - Inspiratory capacity (IC) - Total lung capacity (TLC) - Functional residual capacity (FRC) - Residual volume (RV) - Expiratory reserve volume (ERV) - Residual volume to total lung capacity ratio (RV/TLC)

Table 6: Reference equations available in the Resmon PRO.

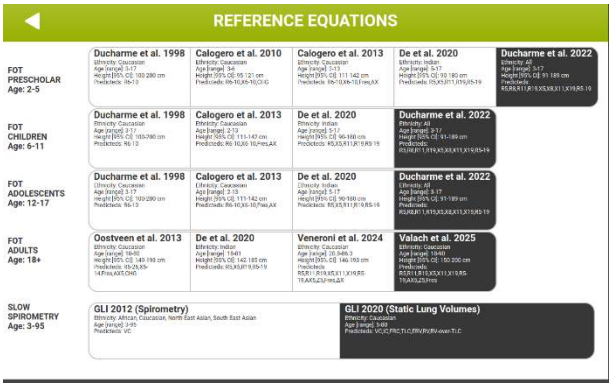


Figure 34 - Choose the set of Reference equations

11.1.6 Info

See section 10 (*Admin account*) of this document.

11.1.7 Graphs Settings

In this section (Figure 35), you can configure the parameters that will be displayed during a FOT measurement, as well as those that will appear in the Trend (see section *Trend report*) and Loop charts (see section *Loops charts*).

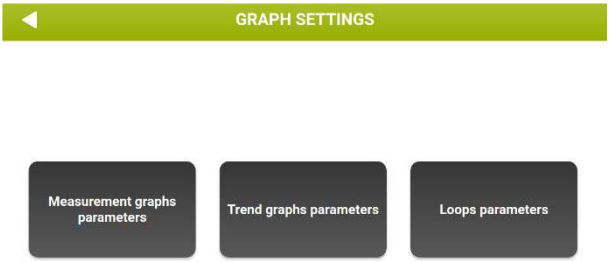


Figure 35 - Graph Settings Options

- *Measurement graphs parameters*: This setting allows you to modify the graphs displayed on the *live measurement screen* (see section *Performing a measurement*) and on the *breath selection screen* (see section *Review and edit of single FOT measurement*). The default values are those displayed in Figure 36.

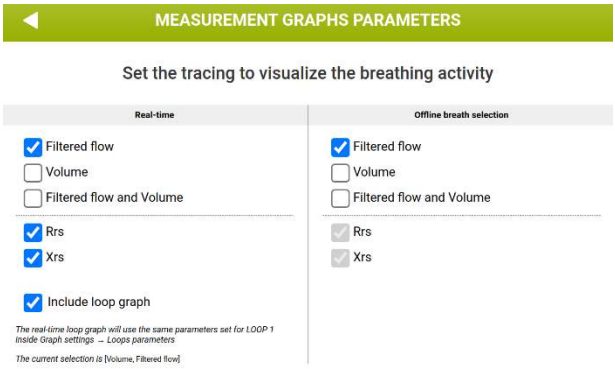


Figure 36 – Measurement graphs parameters

- *Trend Graph Parameters*: this section (Figure 37) allows you to select the parameters that will be displayed in the trend graphs for tracking data over time.

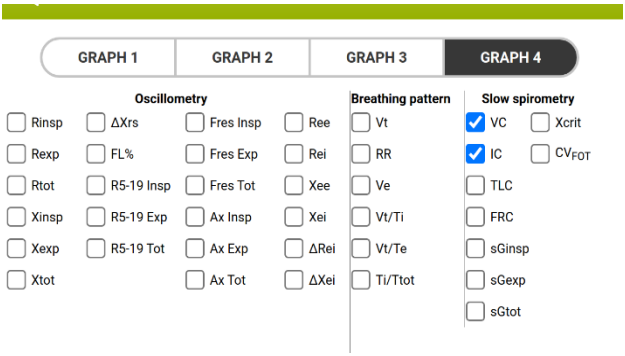


Figure 37 - Trend graph variables selection screen

You can setup up to 4 trend graphs by selecting for each of them 1 or 2 parameters to display. A graph will not be shown if no parameters are selected for it.
All your changes are saved automatically when you leave this screen with the button.

- *Loops parameters*: this option (Figure 38) allows you to choose which parameters are used to create the Loop charts (see *Results of a measurement session*). The Loop charts are disabled by default.

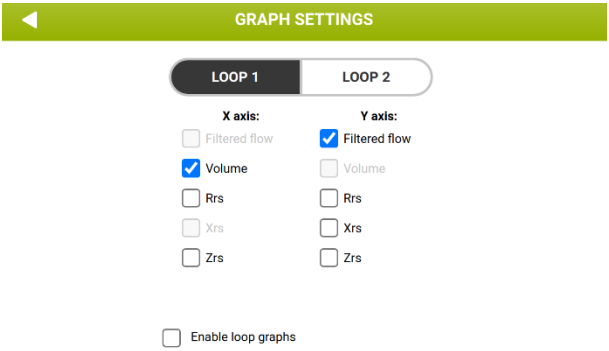


Figure 38 - Loop Parameters setting

You can setup the x- and y-axis of up to 2 loop charts.

Note: if the *Enable loop graphs* option on the bottom part of this screen or parameters are not selected, the Loops charts will not be displayed on screen nor they will be printed on the clinical report. See also section *Clinical Reports*.

The selection will be automatically saved at the closing of the screen with the button.

11.1.8 Clinical report

This setting determines the type of report that will be exported. You can choose from the following:

- Complete report: A complete clinical report containing all the parameters measured with the current session (see section *Complete Clinical Report*).
- Simplified report (default): A reduced clinical report that includes the most significative parameters (see section *Simplified Clinical Report*).

11.2 How to start a new measurement session

A session is a group of measurements, consisting of at least one FOT measurement.

Note: ERS technical standards on FOT suggest performing three to five measurements for each session on a patient for the evaluation of the respiratory impedance.

To perform a new measurement session from the *Home* screen (Figure 29), press the *Measurement* button.

Before you can start a measurement session, a daily calibration check is required. FOT Calibration is mandatory (see section *Calibration check*). The device will require you to perform it and pass it once per day before allowing any patient measurements (Figure 39).

Figure 39 – The Home screen showing the information message for the daily calibration check.

The calibration check of the volume is mandatory only if you want to perform slow spirometry and CV_{FOT} measurements (for further information see section *Verification of the Slow Spirometry calibration*), otherwise, the display will report the message shown in Figure 40.

Figure 40 - Home screen showing that the impedance calibration check was performed, while the volume calibration check was not.

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

11.2.1 Performing a measurement session on a new patient

After pressing *Measurement*, the *Search Patient* screen will be displayed.
If the patient is not already present in the database, press + *Create a new patient* on the lower part of the screen (Figure 41).

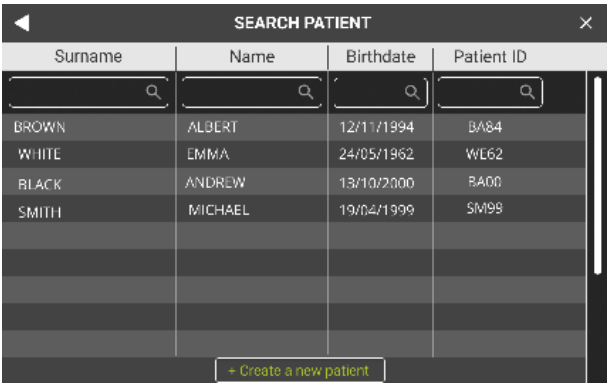


Figure 41 - Archive with the Create new patient button

A new screen (Figure 42) allows you to enter the following data for the patient:

- Surname
- Name
- Birth sex (Male, Female)
- Birthdate (according to the format chosen in Date & time)
- Optionally, birth weight and gestational age
- Ethnicity (Caucasian, Asian, African, Hispanic, Northeast Asian, South East Asian, Japanese, Indian or Other)
- Patient 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*". You can click on *AUTO* to generate a random unique ID.

Figure 42 - Patient's data

Click *Next* to continue to the section for entering anthropometric and environmental data (Figure 44).

11.2.2 Performing a measurement session on a patient already in the database

To find a patient, use the on-screen keyboard to enter part of their surname (at least one letter is required) and press *Next*. A list of matching patients will then be displayed in a table. (Figure 43).

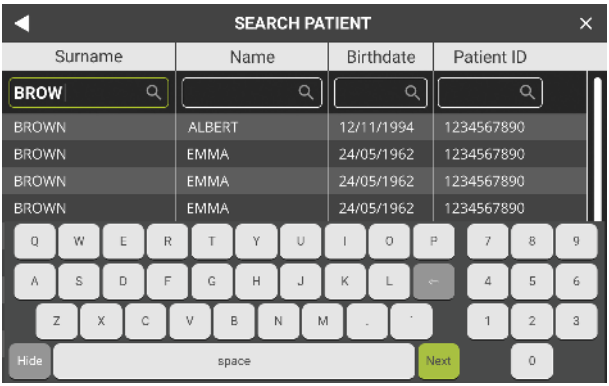


Figure 43 - Results of the patient search

If multiple patients are found, scroll to the correct one and tap their row to open their file. The screen will show the patient's last recorded height and weight, which you can edit by tapping the text box (Figure 44). The current environmental conditions (temperature, pressure, humidity) are taken automatically by the embedded sensor, but can also be manually updated before you proceed.

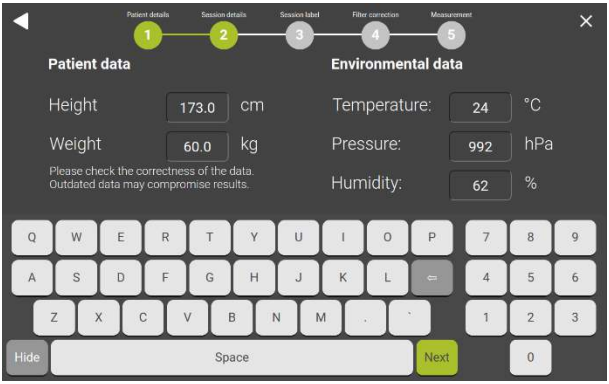


Figure 44 - Edit patient anthropometric data and room condition

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.

11.2.3 Performing a measurement session using Scheduled Visits (from third-party software)

When connected via USB or Ethernet to a third-party application that has scheduled visits (see *Data Sharing* section), the device will display the screen shown in Figure 45.

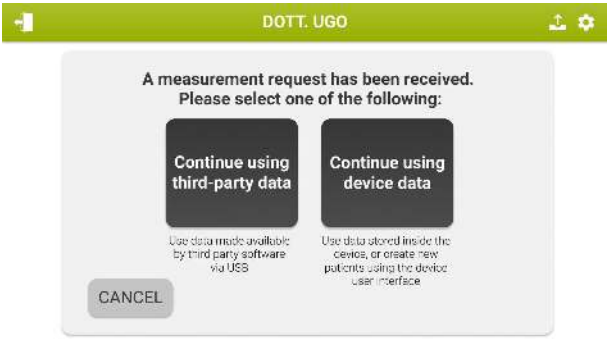


Figure 45 - Visits Scheduled

Press *"Continue using device data"* to use the device local database adding a new session of measurements on already existing patients (see *Performing a measurement session on a patient already in the database)* or insert a new patient before performing a new session of measurements (see section *Performing a measurement session on a new patient*).
Press "*Continue using third-party data*" to display a list of scheduled visits. You can then select a visit to begin the measurement (Figure 46).

The Resmon PRO FULL enables the import of the following data from a compatible third-party software and for each patient contained in the list:

- Patient ID, name, surname, birth sex, ethnicity
- Patient weight and height
- Required stimulating waveform (5, 6, 8, 10, 5-11-19Hz or PSRN)

Figure 46 - Scheduled Visits

Note: after you download data from the third-party software, the device stores the list of scheduled visits until their results are shared back. This means that even if you unplug the cable, clicking on the *Measurement* button will always show you the list of pending visits. If you don't need some of the pending visits, you can delete them persistently by clicking the recycle bin button on the top-right corner of the screen, and select the visits you want to remove.

Note: if there are no scheduled visits (empty list) the Resmon Pro will skip this screen and go directly to the internal database.

If a scheduled visit appears in red (Figure 46), it means there is a data mismatch (like a conflicting Patient ID) that you need to fix, or another kind of problem, like an unsupported character in patient name. Tap the red visit, and a pop-up will open to show you the problem (Figure 47).

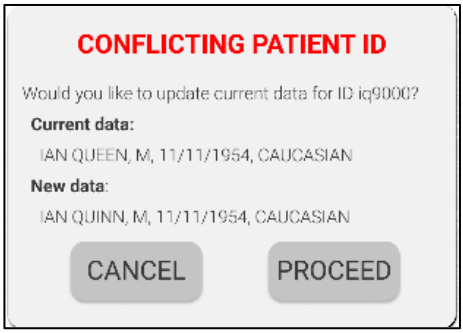


Figure 47 - Pop-up message

Note: while measurement data is automatically saved to the device's archive, it does not automatically sync back to the third-party software. You must manually share the results by following the instructions in the *Print, export or share the results* section.

Note: to prevent data sharing errors, do not modify patient demographics on the Resmon PRO FULL for any visit scheduled by an external software.

11.2.4 Labeling a measurement session

On the next screen (Figure 48), you can add an optional label to the measurement to help you recognize it later. For instance, you could use a label like "*Post treatment*" to mark a test taken after administering a bronchodilator (see the *Clinical Reports* section for more information). If you select PRE, the session will use the “PRE” label. Select POST to change the label or to define a custom label (Figure 48).

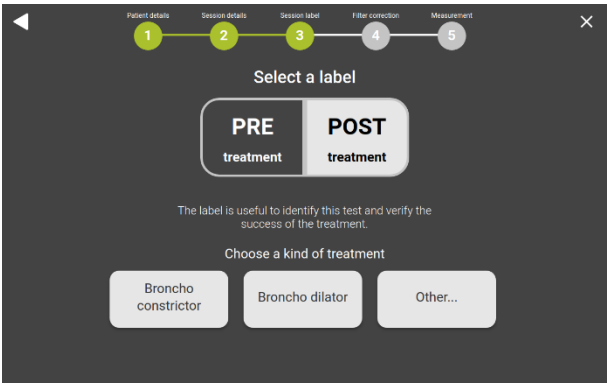


Figure 48 - Post treatment selection options

Note: while you can label a measurement as "PRE" or "POST", please be aware that the device itself is only for measurement. It does **not** conduct the actual bronchodilation or bronchoprovocation test.

11.3 Preparing the device for a measurement session

Before each test, you must connect a new bacterial/viral filter; an optional mouthpiece/face mask or cheek holder can be added for patient comfort (refer to the *Disposables* section for recommended types).

After you select the measurement session labeling, the device will take you to the filter viral/bacterial screen (Figure 49). For this step, connect the filter and all other components

(e.g., mouthpiece/face mask or cheek holder) in series, exactly as they will be used for the test. This quick measurement is necessary for the device to measure the combined impedance of the components and automatically remove their effect from the patient's final results.

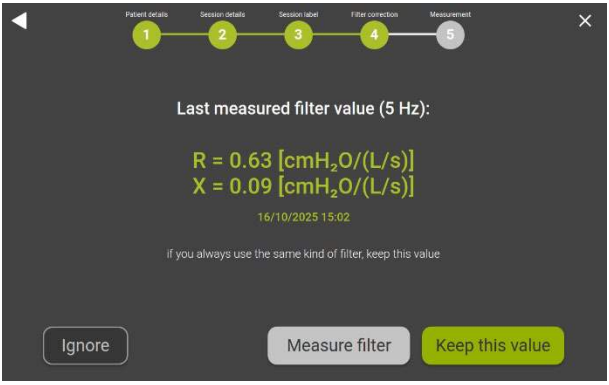


Figure 49 - Filter Measurement

On this screen (Figure 49), you must choose how to handle the filter impedance correction. Select one of the following options:

- **Keep this value:** This applies the filter correction value that was previously measured and stored. If "N/A" is displayed, it means no value has been saved for the currently selected waveform.
- **Measure filter:** This measures the impedance of a new filter.
    1. First, connect a new filter (including the mouthpiece/check holder).
    2. Then, press on *Measure filter*.

Caution! An error message will appear if the measured value is outside the acceptable range of 0.1 – 1.0 $cmH_2O/(L/s)$. Using values outside this range may compromise measurement accuracy.

- **Ignore:** This continues the measurement without applying any *software correction* for the filter's impedance.

Caution! Choosing *Ignore* does not mean you can skip using a physical filter. A filter is still **mandatory** for all tests. This option simply means you are responsible for manually accounting for the filter's effect on the final results.

After making your selection, please wait for the procedure to complete (Figure 50).

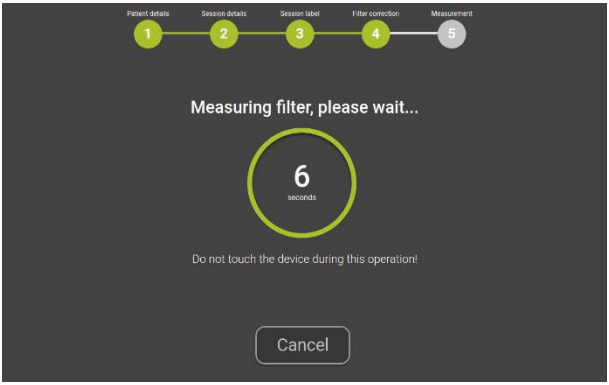


Figure 50 - Sensors auto-zeroing and filter impedance measurement

Caution! To ensure accurate results, do not touch the device or block its inlet while the sensors are resetting and the filter is being measured. Any interference during this critical step can cause errors in breath detection and lead to unreliable measurements.

If a *coherence error* occurs during the filter measurement, try the measurement again. If it fails a second time, contact your local distributor.
Once the filter measurement is successful, you will see the patient preparation screen (Figure 51).

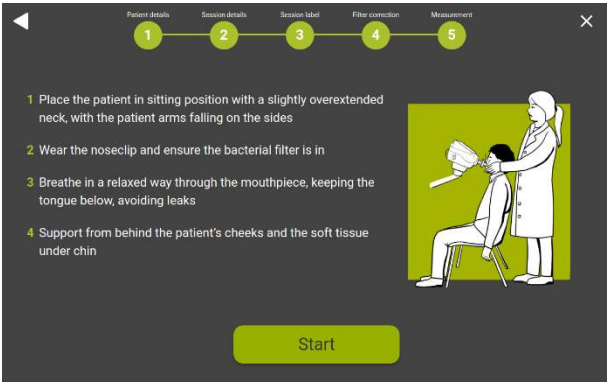


Figure 51 - Instructions for the execution of the measurement

11.4 Preparing the patient for a measurement session

The screen in Figure 51 reminds you to ensure and follow the precautions reported below:

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

Caution! To avoid inaccurate measurements, you must use only disposables that comply with the required specifications reported in section *Disposables*.

- 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 (Figure 52).

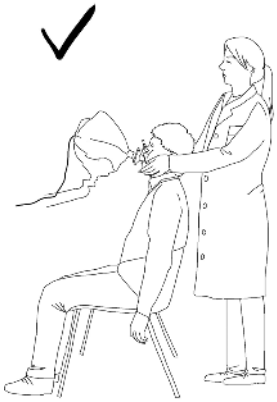


Figure 52 - Correct position for FOT measurement

Warning! 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. The use of a nose clip is mandatory to perform a measurement.

Caution! Not using the nose-clip can lead to inaccurate measurements. If you see unexpectedly low tidal volumes, it indicates a probable air leak from the nose or mouth. You should repeat the measurement, paying close attention to ensure a proper seal.

- Ensure the patient has his/her mouth tightly sealed around the filter during the measurement.
- Be sure that the patient does not occlude the airway by putting his/her tongue or teeth in between the mouth and the filter.

Figure 53 - Correct position of the tongue during the FOT measurement

Caution! If you see unexpectedly high resistance values or large variations in real-time reactance, the patient's tongue or teeth are likely causing an airway obstruction. In this case, instruct the patient on the correct technique, pay close attention to the patient's posture and repeat the measurement, ensuring their upper airway remains clear and not obstructed by their tongue or teeth during the measurement.

- To get higher quality of the measured signals, ask the patient to refrain from closing their glottis during the measurement.
- During the measurement, it is necessary to hold the patient’s cheeks or apply the cheek holder in order to improve the accuracy of the measurement.

Caution! Not holding the patient’s cheeks or not applying the cheek holder may cause inaccurate measurements.

Instruct the patient to begin breathing normally through the device then press *Start* to begin the measurement.

Caution! For the measurement to be accurate, the patient must wear the nose-clip, keep their cheeks supported, and maintain proper posture. If they don't, the results may be unreliable. Please monitor the patient for the duration of the test.

Caution! To avoid cross-contamination, a new filter must be used for every patient. Reusing filters or performing a test without one can contaminate the device. If you suspect contamination has occurred, contact your local distributor for assistance. All parts of the breathing circuit can be replaced.

Caution! If the air blower is not working properly, immediately stop using the device and contact your local distributor. For contact information, please see *User Information* section

Caution! Do not cover the air blower inlet on the back of the device as reported in the applied labeling (please see *Labeling / Symbols and icons* section)

Note: during the measurement, it is normal to feel a slight vibration from the pressure waves the device uses to test the lungs. It is also normal to hear a quiet sound from a blower that continuously clears exhaled air from the breathing tube. Both of these are expected parts of the device's operation.

11.5 Performing a measurement

A measurement session can include up to five tests for a single patient. A new test can be added as long as it is performed within 20 minutes of the previous one. If this 20-minute period of inactivity is exceeded, the session closes automatically, and a new session must be started for any subsequent measurements.
Each test records FOT parameters during tidal breathing. If enabled and calibrated on the same day, slow spirometry volumes (IC and SVC) and CV_{FOT} can also be measured.

11.5.1 Measurement of FOT parameters

Single frequency (5, 6, 8 or 10Hz) or multi frequency stimulus (5-11-19 Hz)

During the measurement, real time tracings will be displayed (Figure 54).

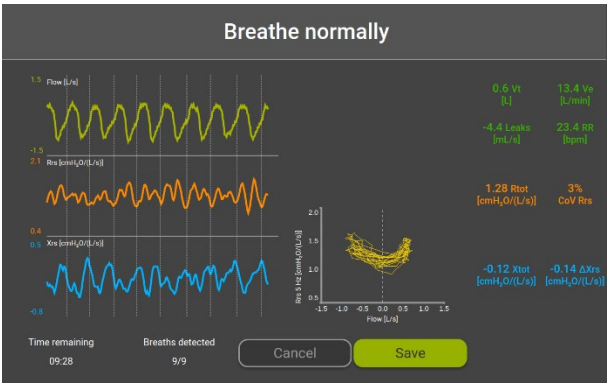


Figure 54 - Real-time tracings for volume and impedance

The plots display the following data, from top to bottom:

- **Flow** [L/s] or **Volume** [L] (or both), depending on the user settings (see section *Graphs Settings*)
- **Resistance (Rrs)** [cmH_2O/(L/s), hPa/(L/s), or kPa/(L/s)] (to change measurement units see section *Measurement units*)
- **Reactance (Xrs)** [cmH_2O/(L/s), hPa/(L/s), or kPa/(L/s)]

For 5–11–19 Hz stimulation, only the tracing corresponding to the lowest frequency (5 Hz) is displayed.
If the real-time visualization of loop graphs has been enabled (see section *Graphs Settings*), the first loop (i.e., LOOP1) will be showed as reported in Figure 54.

On the right side of the screen, the following values are shown:

- Mean tidal volume (Vt) of the accepted breaths and mean minute ventilation (Ve)
- Leaks, expressed in mL/s, and respiratory rate (RR) in breaths per minute
- Mean total resistance (Rtot) of the accepted breaths and the mean coefficient of variation of total resistance (CoV Rrs)
- Mean total reactance (Xtot) and the difference between inspiratory and expiratory reactance (ΔXrs) – available only for 5 Hz and 5-11-19 Hz – of the accepted breaths

At the bottom of the screen, the following values are displayed:

- Remaining time until the end of the measurement (mm:ss)
- Number of accepted breaths over the total of detected breaths

The first three breaths of each measurement are automatically discarded to allow for an initial acclimatization phase.

If the daily *slow spirometry calibration check* was performed, an *Add SVC* button will appear on-screen after five accepted breaths (Figure 54). This gives you the choice to either continue the current measurement until the timer countdown is completed or until you reach the selected number of accepted breaths (see section *Change user settings*) or switch to performing a Slow Vital Capacity (SVC) test (see section *Measurement of slow spirometry volumes*). You can end and save the FOT measurement at any time by pressing *Save*.

Note: to get a valid result, please ensure at least five breaths are accepted after the initial setup phase. If you stop the measurement early, an error will occur, prompting you to either *Restart* the test or *Exit* to the *Home* screen

Note: if the *Add SVC* button is missing, you need to perform a successful daily slow spirometry verification (see section *Calibration check*) and confirm that the spirometry feature is enabled on your device (this feature may be disabled in some Countries). If the button still does not appear, contact your local distributor for support.

Pseudo-random noise stimulus (PSRN)

During the measurement, the real time tracing of the flow (L/s) or volume (L) will be displayed along with the Mean tidal volume (Vt) of the accepted breaths and mean minute ventilation (Ve)

Any time, you can press *Cancel* to end the measurement. 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 30 seconds of measurement. A button *Add SVC* will appear on the bottom right side of the screen. At this point, you may choose to either continue with the measurement of the FOT parameters until the timer countdown is completed or you can switch to the measurement of slow spirometry volumes (see section *Measurement of slow spirometry volumes*). After at least 30 seconds of measurement, you can press *Save* to end the measurement.

Note: a PSRN measurement must run for at least 30 seconds to be valid. If you stop the test early, an error screen will give you the option to either *Restart* the measurement or return to the *Home* screen.

11.5.2 Measurement of slow spirometry volumes

After at least five accepted breaths have been recorded during the oscillometry measurement, an *Add SVC* button appears at the bottom-right corner of the screen if the daily verification of slow spirometry has been completed successfully. Click this button to start the slow spirometry measurement.

Note: during the measurement of slow spirometry volumes, the stimulating waveform is set to the same frequency as the oscillometry measurement for single-frequency waveforms (5, 6, 8, or 10 Hz). For oscillometry recorded using 5–11–19 Hz or PSRN waveforms, the stimulating waveform is performed at 5 Hz.

The slow spirometry measurement begins immediately after the oscillometry measurement. To ensure reliable volume measurements, instruct the patient to continue breathing normally without disconnecting from the device. A real-time graph displaying the traces of volume (green) and reactance (blue) will appear on the screen (Figure 55).
Follow the on-screen instructions to obtain a valid inspiratory capacity (IC), vital capacity (VC), and closing volume (CV_{FOT}).
The test will prompt the user to perform at least three consecutive stable breaths, which will be used to establish a volume baseline for calculating the IC. Once breath stability is detected, a horizontal dashed line will appear over the end-expiratory volumes of the stable breaths, and a message at the top of the screen will indicate that the patient can proceed with the SVC maneuver.
The SVC maneuver consists of a full inspiration (up to total lung capacity (TLC)) followed by a deep exhalation (down to residual volume). Because the SVC maneuver is also used to calculate the Closing Volume, the flow must be maintained below 1.5 L/s. If the flow exceeds this limit during the IC phase, the IC will be discarded and not computed. If the flow exceeds 1.5 L/s during the deep exhalation, the device will prompt the user to restart the entire SVC maneuver from the beginning. A colored panel on the right side of the screen displays the real-time flow to help ensure it remains below the 1.5 L/s threshold.
To ensure a reliable CV_{FOT} measurement, the expiratory phase of the SVC maneuver should last at least 15 seconds or include a plateau (volume variation below 0.025 L for at least 1 second). The plateau is automatically identified and represented with a horizontal dashed line (Figure 55). Once at least one of these conditions is met, a *Save* button will appear at the bottom-right corner of the screen. Click this button to save and conclude the maneuver (note: the button will be yellow if the IC was not valid (Figure 56), or green otherwise). Similarly, if the expiratory flow exceeds 1.5 L/s during the expiratory phase of the SVC, the process will automatically restart after 5 seconds. Once the SVC maneuver is complete, instruct the patient to breathe normally and then disconnect from the device.
During the SVC measurement, the reactance trace provides visual feedback on the quality of the measurement for computing CV_{FOT}. The Xrs signal should remain stable until the patient reaches their closing volume (near RV). Sudden drops in Xrs during the inspiratory or expiratory phases may indicate glottis closures, in which case the SVC measurement should be restarted by clicking the *Restart SVC* button.

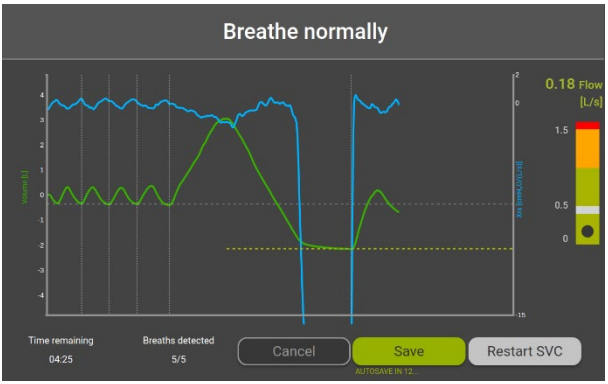


Figure 55 - Slow Spirometry screen: Four stable breaths are followed by a maximal inhalation and exhalation (green trace shows the volume). A drop in the reactance (blue trace) is typical when the patient reaches their closing volume. The dashed yellow line represents the plateau.

Note: for accurate results, the patient must take at least 3 normal (tidal) breaths before beginning the slow spirometry maneuver.

Note: do not instruct the patient to begin the slow spirometry maneuver until the device displays the message **"***You can perform the SVC maneuver***"**. Starting the test before this prompt appears will not permit to save the results.

Note: for accurate results, only one slow spirometry maneuver should be performed per measurement.

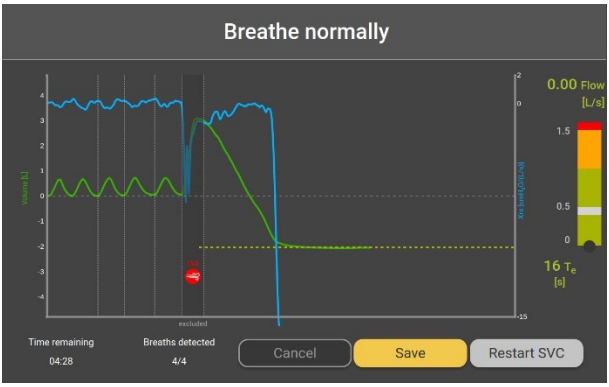


Figure 56 - SVC with invalid IC

Note: if the device displays the warning “Flow too high”, it means the patient’s airflow is above 1.5 L/s. You will need to ask the patient to breathe more slowly and then repeat the maneuver.

Once saved, the device will display a summary of the results (see section below *Results of a measurement session*).

11.6 Results of a measurement session

At the end of each measurement, the results are shown on-screen for immediate review, including FOT data and any available spirometry volumes and charts. To review previously saved sessions, you can browse the database at any time (for further information, see section *Browsing the database*).

Caution! If a caution message appears and you are unable to save the measurement, it means the selected waveform is not accurate (outside 10%) for the patient's impedance measured. You must return to the *Home* page, choose a different waveform designed for higher impedances, and then repeat the test (see section *Criteria for selecting the stimulating waveform*).

11.6.1 Summary of a FOT measurement session

The way results are shown depends on the signal you choose.
At the top of the screen, you will always find the patient's details and the stimulus type that was used.

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

If you select a single frequency waveform (5, 6, 8, or 10 Hz), the resistance and reactance data will look like the example in Figure 57.

Figure 57 - Results of a single frequency measurement

- The bar plot on the left (orange bars) reports the mean and standard deviation of the Resistance (INSPiratory, EXPiratory and TOTal), calculated based on all the accepted breaths of the measurement. The dashed line represents the predicted value of resistance while the solid line is the upper limit of normality (ULN) based on the selected reference equations. If the reference equations are not enabled (see section *Change user settings*), the predicted value and the ULN will not be displayed.
- The bar plot on the right (blue bars) reports the mean and standard deviation of Reactance (INSPiratory, EXPiratory and TOTal), calculated from all the accepted breaths of the measurement. The dashed line represents the predicted value of reactance while the solid line is the lower limit of normality (LLN) based on the selected reference equations. If the reference equations are not enabled (see section *Change user settings*), the predicted value and the LLN will not be displayed.
- If you used a stimulating waveform at 5 Hz or 5-11-19Hz, an additional horizontal bar on the top right of the screen will display as a vertical line the mean ΔXrs calculated from all the accepted breaths of the measurement. ΔXrs is the difference between the mean inspiratory and the mean expiratory reactance at 5Hz 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 red part indicates the presence of expiratory flow limitation.

The device automatically groups single tests into a measurement session. You can review the combined results for the entire session on-screen after your last measurement, or you can access them later from the database at any time (see section *Browsing the database*).

The right side of the screen displays the session information, which includes a header with the session's label, date, and overall Coefficient of Variation (CoV) of the respiratory resistance (total) for consistency, followed by a list of the individual measurements. Although you can perform up to five tests in a single measurement session, a maximum of three tests can be selected at the same time to compute the final result. The device automatically defaults to the three most similar measurements, but you can manually change this selection using the number buttons. The resistance and reactance graphs, along with the session CoV, will update in real-time as you select or deselect different measurements.

Note: as suggested by the Technical Standards for Oscillometry (King et al., Eur Respir J., 2020), the between-measurement CoV of the resistance should be below 10% for adults and 15% for children. The device will display the CoV in red if its value exceeds the respective threshold.

Note: if only one measurement is present in the session, the CoV of the resistance is calculated from that single measurement, representing breath-by-breath variability. If multiple measurements are present, the CoV is computed from the mean values of the resistances of each measurement (between-measurement variability). The Technical Standards recommend taking at least three measurements per session.

You can add a note to the session by pressing the *Comment* button ( ) on the top right corner. A window will open where you can type the note.
You can also open a preview of the clinical report by pressing the *Report preview* button ( ). A window will popup, showing the numerical results of the measurement session as they will be reported in the hardcopy version of the clinical report (Figure 58). For further information on the contents of the clinical reports, see section *Clinical Reports*.

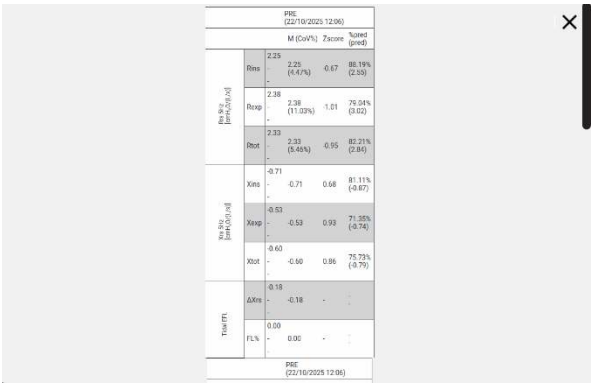


Figure 58 - Popup showing the results of the measurement session as displayed in the clinical report

Note: the measurement session remains active for 20 minutes, during which you can add more individual measurements. See section *Adding a new measurement to the current session* for details.

Press the *Close* ( ) button to exit the summary screen of the measurement session or the *Export* ( ) button to send the entire measurement session results to a printer or to a USB drive (see section *Print, export or share the results*).

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

If you use a multi-frequency signal, you will see the usual results (like in Figure 57), but with an extra graph added to the bottom left of the screen (Figure 59).

Figure 59 - Results of a 5-11-19 Hz measurement

A bar for the selection of the respiratory phase (INSP, EXP, TOT) is displayed on top of the graph. By default, total is selected (TOT) and values of mean total resistance (orange line) and reactance (blue line) at the frequencies of the stimulating waveform are displayed. Upper limit of normal (ULN) and Lower limit of normal (LLN) lines are reported in white. You can change the selection to INSP or EXP by clicking on them.

Note: as suggested by the Technical Standards for Oscillometry (King et al., Eur Respir J., 2020), the between-measurement CoV of the resistance should be below 10% for adults and 15% for children. The device will display the CoV in red if its value exceeds the respective threshold.

Note: if only one measurement is present in the session, the CoV of the resistance is calculated from that single measurement, representing breath-by-breath variability. If multiple measurements are present, the CoV is computed from the mean values of the resistances of each measurement (between-measurement variability). The Technical Standards recommend taking at least three measurements per session.

Pseudo-random noise stimulus (PSRN)

The results are reported as in Figure 60.

Figure 60 - Results of a PSRN measurement

Values of total resistance (orange line) and reactance (blue line) are displayed. Single values are reported as points with the colors of the corresponding measurements.

When a PSRN stimulus is used, the device uses coherence as an index of the quality of the data. If the coherence at one of the PSRN frequencies is <0.95, the device highlights the measurement as these data points must be considered cautiously when interpreting data. This is also highlighted in the final report (see section *Clinical Reports*). Upper limit of normal (ULN) and Lower limit of normal (LLN) lines are reported in white.

11.6.2 Review and edit of single FOT measurement

If you want to review the results of a single measurement, press on the *Edit* button ( ) next to the test you want to review (Figure 59). The results of the single measurement are displayed on screen as reported in Figure 61.

Figure 61 - Result of a single measurement

This screen allows you to manually edit which breaths are included in the final calculation. Any breaths automatically excluded by the device are initially shaded. You can tap a breath to toggle it between included and excluded, and the results on the right will update in real-time. If you wish to undo your changes, press the *Reset* button ( ) to restore the original automatic selection. When finished, press *Save* to keep your edits or *Back* to discard them.

If more than 10 breaths have been taken, the zoom button ( ) allows you to toggle the number of breaths displayed on the screen. Click the double-arrow buttons to turn pages.

If you want to review the reason why the breaths were excluded click on the ( ) symbol.

Figure 62 – Table showing the reasons for breath exclusions.

Breaths are automatically excluded if at least one of the following conditions is met:

- Flow: exceeds 1.5 L/s during either the inspiratory or expiratory phase.
- Impedance anomaly: resistance or reactance is too high or too low compared to physiological values (e.g., due to glottis closure).
- Breathing pattern anomaly: tidal volume, respiratory rate (RR), inspiratory time (Ti), expiratory time (Te), or other parameters outside physiological values.
- Outlier: the breath has characteristics (tidal volume, Rrs, Xrs, etc.) that differ significantly from the other breaths.
- Internal error: a technical error occurred during data collection.
- Manual exclusion/inclusion: the breath has been manually removed (by clicking on it) or was automatically excluded but re-selected manually.

11.6.3 Adding a new measurement to the current session

From the Results panel (Figure 59), you can add a new measurement to the current session by clicking *Add Measurement* (up to five measurements can be included in a single session), or end the current session by pressing the Close button ( ) in the top-right corner.

You can also add new measurements to the current session from the *Home* screen by navigating to the current patient. In this case, the software will ask whether you want to continue the previous session or start a new one.

11.6.4 Loops charts

If enabled in the user settings (see section *Graphs Settings*), press the *LOOPS* tab to switch to the loop charts view. The charts of the selected parameters are displayed as shown in Figure 63.

The breaths from each FOT measurement selected in the *FOT* tab are displayed with the same color.

Figure 63 - Loop Charts

11.6.5 Summary of a slow spirometry measurement session

If the patient has performed a slow spirometry maneuver, the results are reported as in Figure 64 by navigating to the *SVC* tab.

Figure 64 - Results of a Slow Spirometry measurement

This screen summarizes the spirometry results, displaying the session's maximum Slow Vital Capacity (VC) and the mean Inspiratory Capacity (IC), along with their percentages relative to the predicted values (if predictions are enabled).
By default, the device selects the maneuvers with the most similar VC values and displays the highest VC value. The Inspiratory Capacity (IC) is calculated as the average of the IC values from the selected maneuvers.

You can manually change which tests are included in these calculations by using the selection buttons (TEST1, TEST2, etc.) located at the bottom of each graph. The VC and IC results update in real time as you make changes.
Under default conditions, the maneuvers are aligned to their maximum value (TLC).
Additionally, you can enter a Total Lung Capacity (TLC) or Functional Residual Capacity (FRC) value measured with an external medical device and associate it with the slow spirometry maneuvers recorded with the Resmon PRO FULL. To do this, select *Add TLC/FRC* on the Slow Spirometry Results screen (Figure 64) and enter the value (in liters) in the field that appears.
Entering a TLC or FRC value enables the calculation and inclusion of the following parameters in the clinical report, according to the formula shown below:

- FRC = TLC - $IC_{measured}$
- RV = TLC - $VC_{measured}$
- RV/TLC
- sG_{rs}insp = 1/(Rinsp * (FRC + mean volume during inspiration))
- sG_{rs}exp = 1/(Rexp * (FRC + mean volume during expiration))
- sG_{rs}tot = 1/(Rrs * (FRC + mean volume during the whole breath))

Note: for each measurement session, a maximum of three measurements can be selected at the same time.

Note: if the IC of one or more maneuvers is invalid (see section *Measurement of slow spirometry volumes*), the average IC value is calculated only from the maneuvers with valid ICs. If none are valid, the IC is not computed.

Note: if the selected maneuvers have invalid IC values, it may not be possible to compute FRC or TLC.

11.6.6 Closing Volume chart

Press the CVFOT button (

) to compute the Closing Volume of the SVC maneuver. CV_{FOT} is calculated only on the maneuver with the highest VC. After processing, a chart displaying the reactance as a function of the measured VC will appear (Figure 65).

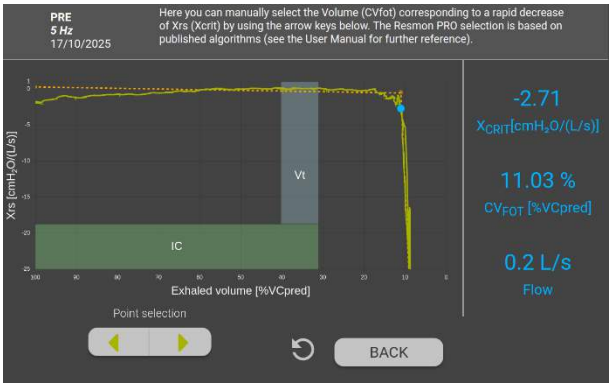


Figure 65 – CVFOT and Xcrit computed automatically.

The key point on the graph, X_{crit}, is detected automatically (Nilsen et al., J Appl Physiol., 2019) but can be manually adjusted using the on-screen arrows or by tapping the graph. The displayed CV_{FOT} and X_{crit} values are color-coded: blue for automatic and purple for manual. Use the SAVE button to confirm your changes, the Reset button to restore the automatic X_{crit} selection, and the BACK button to return to the SVC summary (Figure 64) without saving any applied changes.

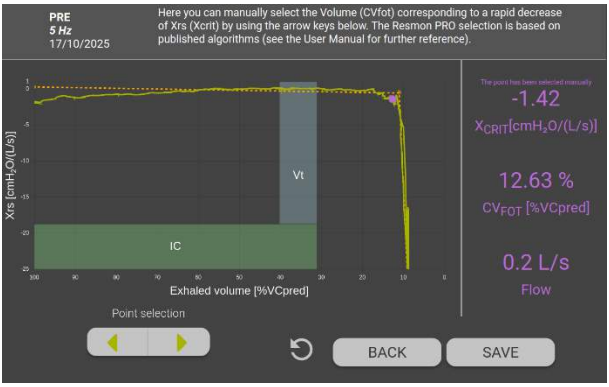


Figure 66 - CVFOT and Xcrit computed by selecting the point manually.

11.6.7 Specific respiratory conductance (sGrs)

The device calculates the sGrs value for a specific measurement only when a valid FRC value is available (either entered manually or computed from TLC and IC).
Furthermore, if multiple FOT and SVC measurements are taken within the same session, you must select at least one corresponding test from both the FOT and SVC measurements for the sGrs value to be calculated.

Once the sGrs value has been computed, it will be included in the clinical report and in all exportable file formats.

11.6.8 Compare results of two measurement sessions

Starting from *FOT* tab (Figure 59) or *SVC* tab (Figure 64) you can compare the current measurement session with another one in two ways: either by starting a *New session* or by choosing a saved one from the database via the *Select another session to compare* button. On the comparison screen, the two sessions are shown in different colors, and you can interactively select or deselect individual measurements from either session to see the results update in real-time (Figure 67).

Figure 67 - List of sessions to compare

11.7 Print, export or share the results

If you press the *Export* button ( ) you can (Figure 68):

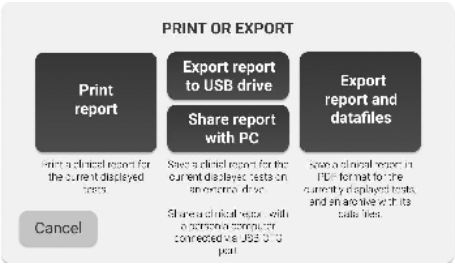


Figure 68 - Print or export the clinical report

- *Print report* to print the clinical report. Be sure to have a compatible USB printer connected the device.

Caution! The printed report may contain confidential data. Make sure to protect its content from unauthorized access following the regulations of your institution.

- *Export report to USB drive* to export the clinical report. Be sure to have a USB memory stick inserted into the device.

Caution! The PDF report may contain confidential data. Make sure to protect its content from unauthorized access following the regulations of your institution.

Note: from software version 21.0.0, the Resmon PRO FULL V3 supports USB drives with AES-XTS encryption.

- *Export report and datafiles* to export the session data together with the PDF report. A JSON file will be created for each session; an archive (.tar.bz2 file) will be exported for each measurement of the session.

Caution! The PDF and JSON file may contain confidential data. Make sure to protect its content from unauthorized access following the regulations of your institution.

Note: from software version 21.0.0, the Resmon PRO FULL V3 supports USB drives with AES-XTS encryption.

Based on the selection made in the *Admin* account (see section *Data Sharing*), you can also share the results of the session with a personal computer or with a third-party software.

- *Share report with PC* to share the clinical report directly with a personal computer. Connect the PC to the USB-OTG port of the device: the Resmon PRO FULL will be detected by the PC as an external drive. Open the external drive folder with a file explorer and the report will be available there.

- *Share with a third-party software* to export the session data through the USB-OTG port or through ethernet cable to a third-party software.

Figure 69 - Share data with third-party software
(Left – using USB-OTG Cable, Right – using ethernet cable)

Note (applicable only when the Resmon PRO FULL is connected to the BreezeSuite third-party software): if you are sharing data with a third-party software through **ethernet cable**, the Clinical Report (PDF) is shared if:

- *"Enable sharing PDF"* is checked in Network Settings (see paragraph *Data Sharing*)
- USB-OTG cable is connected

Note: if you wish to modify the breath selection for a measurement, the measurement selection for the session, or to add information such as notes, TLC/FRC, it is recommended to do so **before** sharing the session with the third-party software. Otherwise, the software will detect the changes and ask you to transfer the data again in order to ensure the third-party data is on par with the device data.

For problems related to printing and exporting the results, refer to section *Troubleshooting*.

11.8 Description of exported data

11.8.1 Single patient data export

From the *Results* screen (see section *Results of a measurement session*) you can export the session data in different formats.

.json file

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

.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 measurements, as reported in the following tables (Table 7, Table 8, Table 9).

Single frequency (5, 6, 8, 10Hz) stimulating waveform	
Column Title	**Parameter**
Pressure	Raw Pressure
Flow	Raw Flow
Filtered flow	Tidal Breathing Flow
Rf	Within-breath Resistance at *f* Hz
Xf	Within-breath Reactance at f Hz
#	Sample Counter

Table 7

Multi frequency (5-11-19Hz) stimulating waveform	
Column Title	**Parameter**
Pressure	Raw Pressure
Flow	Raw Flow
Filtered flow	Tidal Breathing Flow
R5	Within-breath Resistance at 5Hz
X5	Within-breath Reactance at 5Hz
R11	Within-breath Resistance at 11Hz
X11	Within-breath Reactance at 11Hz
R19	Within-breath Resistance at 19Hz
X19	Within-breath Reactance at 19Hz
#	Sample Counter

Table 8

PSRN stimulating waveform	
Column Title	**Parameter**
RP	Raw Pressure
RF	Raw Flow
FF	Tidal Breathing Flow
#	Sample Counter

Table 9

.mxn file

This file is organized in a n-by-18 matrix, where each row represents the n-th breath detected by the device during the FOT measurement. The first four columns contain the sample number correspondent to the beginning of inspiration, end of inspiration, end of expiration, and a flag indicating if the breath was excluded (Figure 70). The remaining 15 columns include binary values that are used by the software to identify measurement artifacts (1: discarded). Unless a breath has been discarded, the beginning of the inspiratory phase coincides with end of expiratory phase of the previous breath. The following table contains the description of each column or why the breath was discarded:

1	2	3	4	5	6	7	8	9
Start of Insp	End of Insp	End of Exp	Breath validity: 0 = valid; 1 = discarded; 2 = discarded but manually selected; 3 = valid but manually discarded	Lost samples	VT	T_tot	T_insp	T_exp
10	**11**	**12**	**13**	**14**	**16**	**16**	**17**	**18**
Ti/Tot	R insp	R exp	R tot	X tot	Flow exp	Flow insp	IC flow	Outlier

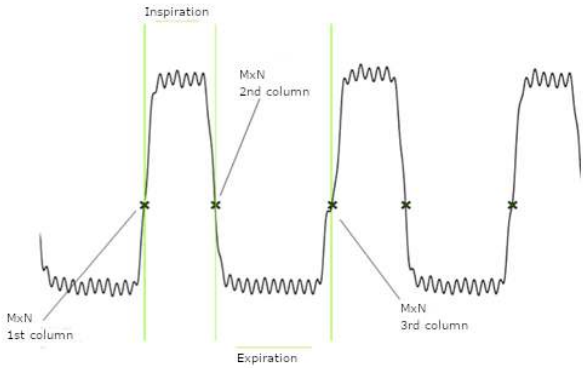


Figure 70 - Flow (from the .dat file) with superimposed mxn points for a breath

.tr file

This file contains the average tracings of Volume, Resistance, Reactance and their standard deviation as a function of time (Figure 71). 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.

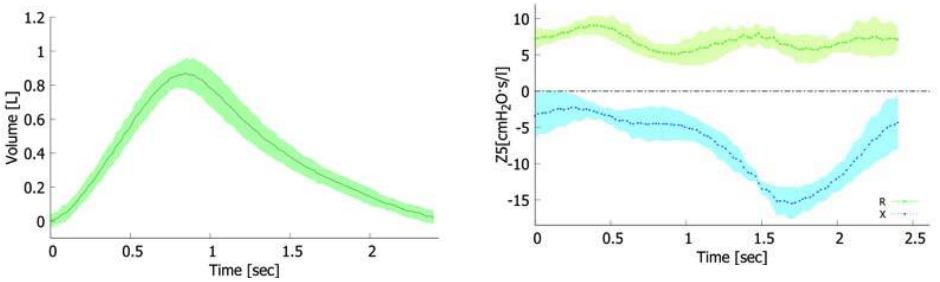


Figure 71 - Left: Average Tidal Volume and Standard deviation. Right: Average Resistance and Reactance and their standard deviations (obtained from a .tr file)

SVC_.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 is reported in the following table (Table 10).

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

Table 10

SVC _.mxn file

This file has the same purpose of the .mxn file of the oscillometry measurement, but it is referred to the slow spirometry measurement.

11.8.2 CSV Measurement and Session files

From the *Home* screen (see section *How to start a new measurement session*), you can export two comma-separated values (.csv) files containing all the measurements and sessions associated with the current account.

To export the .csv files, connect a USB drive to the device and click the Export button ( ).

Once exported, the files can be opened using a text editor or compatible data analysis software.

The *Measurements* .csv file includes all measurement results recorded under the current account, while the *Sessions* .csv file reports the mean values of the measurements within each session (for the selected measurements).

11.9 Browsing the database

From the *Home* screen (Figure 39) press the *Archive* button to enter the database.

11.9.1 Search for a patient and edit their information

A table will be displayed with the list of all patients present in the database (Figure 72).

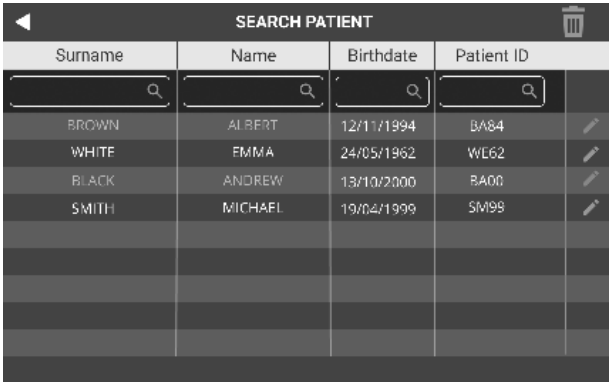


Figure 72 - Patients listing

If the number of patients is large, a scrolling bar will be displayed on the right of the table. You can scroll the list to search for the patient, or perform a patient search by surname, name, birth date, or patient ID. Press on the fields and type the data related to the patient you are looking for. Press the corresponding row of the results table to select the desired

patient. By pressing the *Edit* button ( ) next to each patient, you can edit patient data (Surname, Name, Birth sex, Birthdate, Ethnicity, Patient ID).
To delete patients, tap the *Delete* button ( ). Check the boxes for the patients you want to remove, and then press the **red button** to confirm (Figure 73).

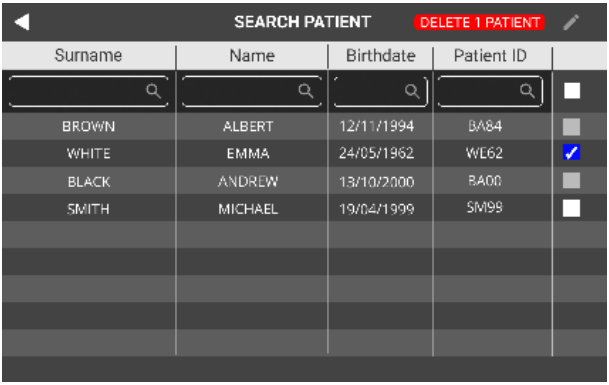


Figure 73 - Delete patient

After pressing the delete button, a window will pop up asking for confirmation before completing this operation.

Note: once confirmed, you cannot undo this operation.

Note: by deleting a patient, you will also delete all his measurements.

11.9.2 Select the measurement session to recall

Once you select a patient from the database, a table will be displayed showing a list of all their measurement sessions (Figure 74). Each session in the list includes details such as the date and time, the waveform type used, the session label, the number of measurements it contains, a note on whether spirometry was performed, and the user who recorded it. To open a session and view its results summary, simply tap on the corresponding row in the table. For more information see section *Results of a measurement session*.

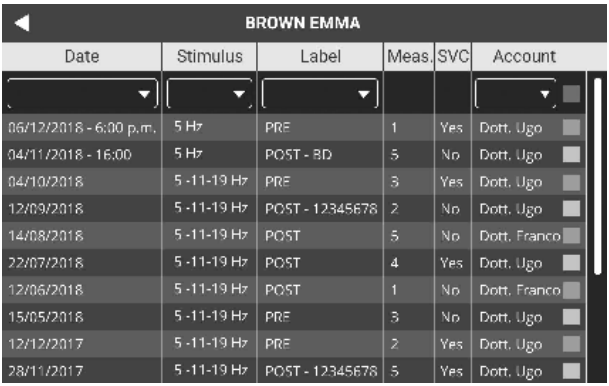


Figure 74 - Session results

11.10 Plot trend graphs

To create trend graphs, first select a patient to see their session history. Use the checkboxes on the right to choose the sessions you want to plot. When you select your first session, the device will automatically select all other sessions that used the same waveform, and a *TRENDS* button will appear in the top-right corner (Figure 75). You can then manually adjust the selection by checking or unchecking individual sessions, or use the master checkbox in the filter line to select or deselect all at once. Press the *TRENDS* button to view up to four graphs, which will display the parameters you've configured in your user *Graphs Settings*.

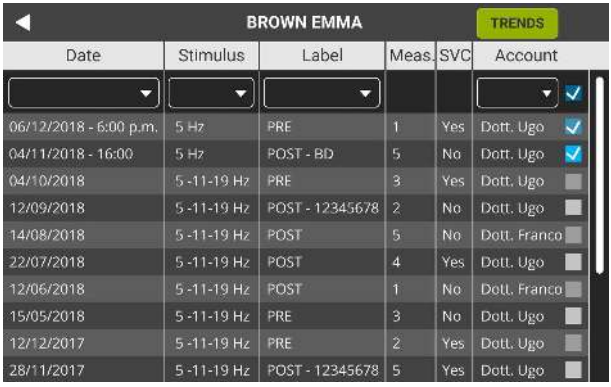


Figure 75 - Selection of sessions to be included in trend graphs

The selection of TRENDS will move you to the trend screen (Figure 76). You can open a preview of the trend report by pressing the *Report preview* button ( ). A window will popup, showing the numerical results of the measurement session as they will be reported in the hardcopy version of the trend report.

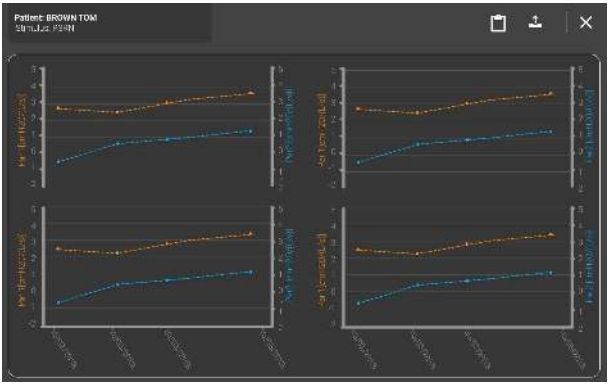


Figure 76 - Trend screen

By pressing the *Export* button ( ), you can print, export or share the results (Figure 68) as indicated in section *Print, export or share the results*.

11.11 Clinical Reports

You can create a clinical report for a single measurement or an entire session, either immediately after the test or by recalling a saved session from the database. The Resmon PRO allows you to export two types of Clinical Reports: the **complete report** and the **simplified report** .

11.11.1 Complete Clinical Report

The report is organized into six sections displays the results of a single session or of a comparison between two different sessions. You can either print the report or export it as a PDF file to a USB stick (see section *Print, export or share the results*).

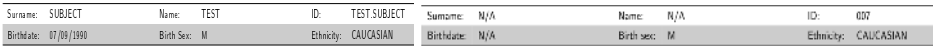
Note: please note that the statistical values (mean, standard deviation – SD - and coefficient of variation - CoV) are calculated differently for each report type. Single-measurement reports reflect **intra-test** (within-breath) variability, while session reports reflect **between-test** variability.

Personal Data

This section reports patient information (Figure 77).

- Surname
- Name

- Birthdate
- Birth sex
- Patient ID
- Ethnicity



Non-anonymized data Anonymized data

Figure 77 - Personal data section

If data are anonymized (Figure 77) in the *Account settings* (see section *Accounts*) the following personal data will not be displayed: Surname, Name, ID and Birthdate.

Measurement details

This section includes details related to the measurement session (Figure 78).

		PRE				
Age [Years]		34.50				
Weight $[kg]$		99.0				
Height $[cm]$		185.0				
BMI $[kg/m^2]$		28.93				
		Date $[dd/mm/yyyy]$	Z filter $[cmH_2O/(L/s)]$	Selection		
				FOT	VC	IC
TEST 1		17/10/2025 09:45	0.42	√	x	√
TEST 2		17/10/2025 09:47	0.42	√	√	-
TEST 3		17/10/2025 10:02	0.42	√	x	√
TEST 4		- -	-	-	-	-
TEST 5		- -	-	-	-	-
Account		ADULT				
Prediction Equation	FOT	Oostveen et al., ERJ, April 2013				
	SVC	GLI 2020, Hall et al., Eur Respir J 2021				
Software version		23.0.0				

Figure 78 - Measurement details section

- Measurement type/label (PRE, POST, BC-POST, BD-POST or Custom Label).
- Age, Weight, Height and BMI at the date of the measurement. Measurement Units are in square brackets.

One row for each measurement of the session reporting:

- The date and time of the measurement
- 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 measurements are selected to calculate the mean values of FOT parameters and slow spirometry volumes (√ = selected, x = not

selected, - Not Available/Not Valid). The selection of measurements can be different between FOT parameters and slow spirometry volumes (IC and SVC)

- Name of the Account used to perform the measurement session
- The equations for predicted values* used to calculate the range of normality of FOT (if enabled, see *Reference equations* paragraph in *Change user settings* section) and slow spirometry volumes (if available)
- The software version used to collect data of the measurement session

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

FOT charts

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

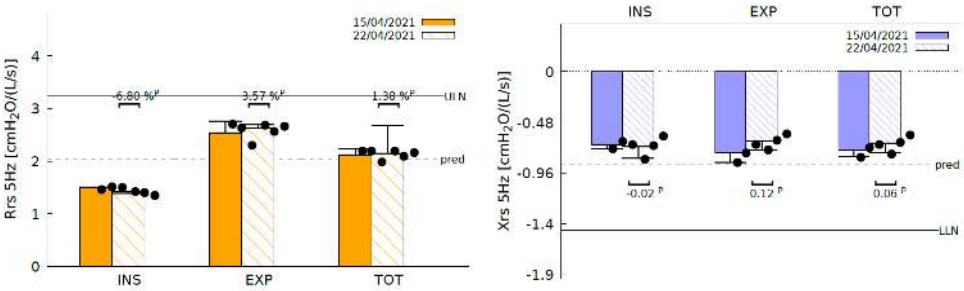


Figure 79 - Bars for resistance and reactance

Referring to Figure 79:

- Bars on the left chart represent the mean and standard deviation of inspiratory (INSP), expiratory (EXP) and total (TOT) resistance calculated from the selected single measurements within a measurement session (see section *Performing a measurement*).
- Bars on the right chart represent the mean and standard deviation of inspiratory (INSP), expiratory (EXP) and total (TOT) reactance calculated based on the selected measurements within a session. The dots on each bar represent the mean values of the FOT parameters of each selected measurements of the session.
- Bars with different color patterns placed side by side are used for paired comparisons between measurement sessions. By default, the measurement session labelled as PRE is plotted first. In case of coinciding labels of the two selected measurement 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 predicted value computed based on the selected reference equations (for further information see previous section).

- If you used 5 Hz or 5-11-19 Hz stimulating waveform, an additional graph on the bottom of the page is displayed (Figure 80). This graph shows as an arrow the mean and standard deviation of ΔXrs calculated over all the measurements of the session. Black dots represent the mean ΔXrs of individual measurements 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 measurement session is reported. Each measurement session is identified by its label.

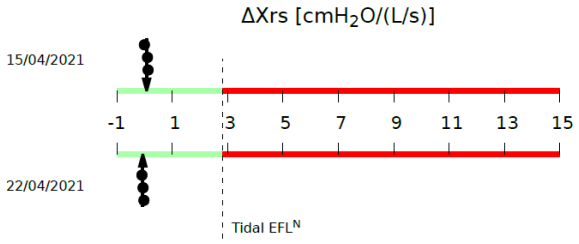


Figure 80 -Expiratory Flow Limitation (EFL) during tidal breathing

If you used the 5–11–19 Hz waveform, an additional chart is displayed at the bottom of the page (Figure 81). The chart displays the resistance (orange solid line) and reactance (blue solid line) values at each frequency of the stimulating waveform. The displayed values may refer to inspiration, expiration, or the entire breath, depending on your selection on the results screen prior to export (see section *How to start a new measurement session*). The default setting is total.

Results from individual measurements are shown as dashed lines. Error bars at each stimulating frequency represent the standard deviation of the selected measurements. Black lines indicate the upper limit of normality for resistance and the lower limit of normality for reactance, based on the selected reference equations (see the previous section for details).

In comparative clinical reports, each session chart is identified by its corresponding label.

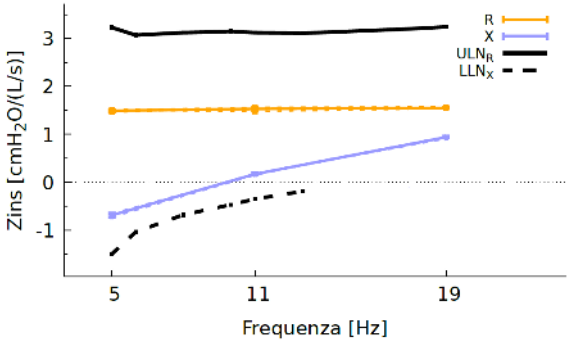


Figure 81 - Inspiratory resistance and reactance spectra

A similar graph is shown when PSRN stimulus is used:

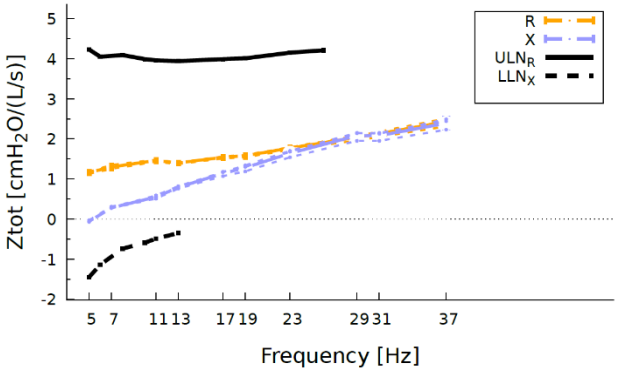


Figure 82 - Inspiratory resistance and reactance spectra in a PSRN measurement

Figure 82 shows an example of the chart included in the clinical report when a PSRN stimulating waveform is used. The solid lines represent the mean inspiratory resistance (orange) and reactance (blue) of the measurement session, while dashed lines represent results from individual measurements. Error bars at each stimulating frequency indicate the standard deviation of the selected measurements. Black solid lines represent the upper limit of normality for resistance and the lower limit of normality for reactance, as defined by the selected reference equations (see the previous section for details).

When a PSRN stimulus is used, the device uses coherence as a data quality index. Data points with coherence values below 0.95 are marked with an “X” symbol. In comparative clinical reports, each measurement session chart is identified by its corresponding label.

Loop charts (optional)

Loop charts are reported in the clinical report only if they have been **enabled** in the **Graph Settings page** (see section *Graphs Settings*). Based on the selection of the parameters to be reported on the x- and y- axes, they report their values from all valid breaths recorded in a single FOT measurement or in FOT sessions. In the latter case, different colors are used for each FOT measurement within a given FOT session (Figure 83).
A maximum of two loops can be reported in the clinical report (see section *Graphs Settings*).

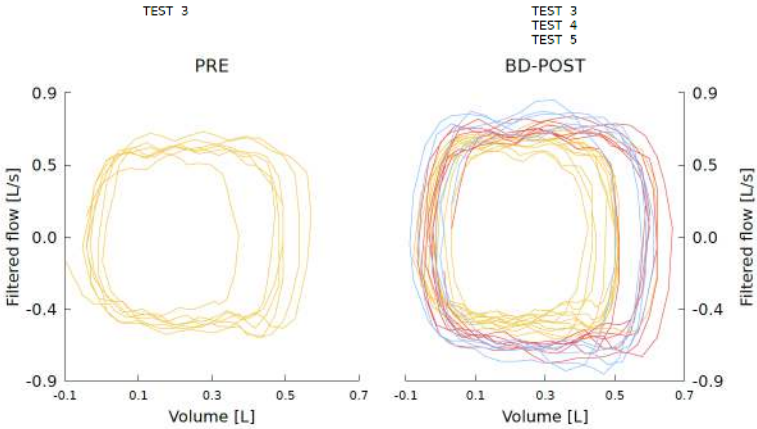


Figure 83 - Loop Charts on Clinical Report

The *Loop page* also includes a table displaying the respiratory resistance and reactance values computed at the end of the inspiratory phase (Rei, Xei), at the end of the expiratory phase (Ree, Xee), and the differences (ΔR, ΔX, respectively) between the end-expiratory and end-inspiratory phases.

Slow spirometry data

This section of the clinical report is available only if at least one slow spirometry maneuver has been performed within the selected measurement session. Slow spirometry data are reported both as a chart and in table format (see Figure 84 for an example). When more than one maneuver is performed, 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 measurement session is identified by the measurement session label. The first session is plotted using black lines, the second session is plotted using red lines.

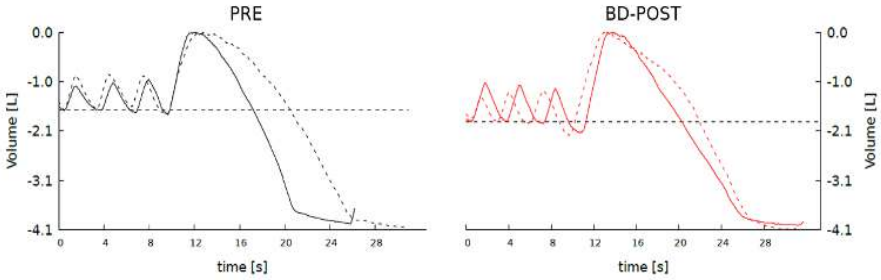


Figure 84 - Slow Spirometry chart

The following parameters will be reported in the table, if available:

VC	Vital capacity in liters
IC	Inspiratory capacity in liters
ERV	Expiratory reserve volume in liters
FRC*	Functional residual capacity in liters
RV*	Residual volume in liters
RV/TLC*	Residual volume to total lung capacity ratio in percentage
TLC*	Total lung capacity in liters
sG_{rs}insp*	Specific conductance of the respiratory system during inspiration in $cmH_2O^{-1}\ s^{-1}$
sG_{rs}exp*	Specific conductance of the respiratory system during expiration in $cmH_2O^{-1}\ s^{-1}$
sG_{rs}tot*	Specific conductance of the respiratory system during whole breath in $cmH_2O^{-1}\ s^{-1}$
CV_{FOT}	Closing Volume (detected by FOT)
Xcrit	Reactance value at CVfot

* values calculated using either the TLC or FRC manually entered by the user and measured with external medical devices

The Slow Vital Capacity (VC) is reported as the maximum VC selected among the three most similar slow spirometry maneuvers within the measurement session.
The Inspiratory Capacity (IC), Functional Residual Capacity (FRC), and Total Lung Capacity (TLC) results are reported as the mean (M) and coefficient of variation (CoV) of the selected slow spirometry maneuvers within the session that have a valid IC.
The Expiratory Reserve Volume (ERV), Residual Volume (RV), and RV/TLC ratios are calculated with respect to the maximum VC.

For all the above parameters, the clinical report also includes:

- Z-score

- Predicted value and percentage of the predicted value, calculated according to the reference equation selected for the session
- If predicted values are not available, the corresponding fields are displayed as N/A

Note: if the IC of the measurement with the highest VC is invalid, some parameters derived from the user-entered FRC or TLC values (e.g., RV, RV/TLC, etc.) may not be displayed in the mean (M) column of the report.

Numerical results

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

- Mean (M) and coefficient of variation (CoV)
- 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 measurement 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).

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

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 measurement has been done with a 5Hz or 5-11-19Hz stimulating waveform.
FL%	Percentage of flow-limited breaths. Available only when the measurement has been done with a 5Hz or 5-11-19Hz stimulating waveform.

$R_{5\text{-}19\ insp/exp/tot}$	Difference between inspiratory/expiratory/total resistance at 5Hz and 19Hz. Available only when the measurement has been done with a 5-11-19Hz stimulating waveform.
$AX_{insp/exp/tot}$	Area of inspiratory, expiratory or total (whole-breath) reactance
$Fres_{insp/exp/tot}$	Resonant frequency of inspiratory, expiratory or total (whole-breath) reactance. Frequency at which reactance is null.

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.
$R_{5\text{-}19}$	Difference between total resistance at 5Hz and 19Hz.
$AX_{insp/exp/tot}$	Area of inspiratory, expiratory or total (whole-breath) reactance
$Fres_{tot}$	Resonant frequency of total (whole-breath) reactance. Frequency at which reactance is null.

Breathing pattern parameters

The accuracy of breathing pattern parameters is reported in section *Technical specifications*.

Caution! Breathing pattern parameters should be used only for an overall evaluation of the quality of the measurement. If you notice abnormal values, it is recommended to repeat the measurement

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.

Footnotes

This section contains an explanation of all the footnotes found within the clinical report.

A: Reference values determined on the following population: [...]

It activates when there are some unfulfilled constraints of the prediction equation like the patient height, his ethnicity or his age: in this case all the prediction equation's constraints will be listed in the brackets.

B: According to patient's data at the time of the most recent test between the two compared ones.

When two tests of a given patient are compared, the reference equations used for both tests are selected from the anthropometric data of the patient at the time of the most recent measurement.

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: Reference values determined on the following population: [...]

This note applies with the same logic as a footnote, but will appear only on the second session's prediction equation (on comparative reports)

E: Reference values determined on the following population: [...]

This note applies with the same logic as A footnote, but will appear on SVC prediction equation(s)

G: No data about normal between-session 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 predicted range according to selected prediction equation

The measured values are out of the normal range according to the chosen reference equation.

J: Resonant frequency calculated by linear extrapolation of the values of Xrs at 11 Hz and 19 Hz. AX calculation limited to 37 Hz

The stimulus is 5-11-19 Hz and the estimated Fres is greater than 19Hz. This also impacts the AX parameter.

K: Resonant frequency above 37 Hz. AX calculation limited to 37 Hz
The stimulus is PSRN and the estimated Fres is greater than 37Hz. This impacts both AX and Fres parameters.

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

M: Within measurement variability > 30%

N: Dellacà et al., ERJ, May 2004

P: Short time repeatability threshold not applicable: tests taken in different days
PRE-POST compared report between two tests not taken in the same day: CHG threshold not applicable

Q: Within session variability > 10% (adults)/ 15%(children)

R: Significative bronchodilator response according to the "Technical Standards for Respiratory Oscillometry", ERS 2020
For a given stimulus frequency, this note appears in comparative reports of sessions “PRE” and “BD-POST” when the change (CHG) for Rtot is 40% for children or 32% for adults (ERS 2022) or the CHG for Xtot is 50% for children and 44% for adults (ERS 2022) (only if the difference is > 0.2) or the CHG for AX is 80%.

S: Variation above the positive bronchodilator threshold at 5 Hz defined by the "Technical Standards for Respiratory Oscillometry", ERS 2020
For 6, 8 and 10 Hz for all breathing phases (insp, exp and tot)
For 5 Hz, 5-11-19 Hz and PSRN stimuli for insp and exp breathing phases

T: Significative bronchodilator response according to the "Technical Standards for Respiratory Oscillometry", ERS 2020
Notice: measurements performed on different days

U: Variation above the positive bronchodilator threshold at 5 Hz defined by the "Technical Standards for Respiratory Oscillometry", ERS 2020
Notice: measurements performed on different days

V: Results based on the value of TLC entered manually by the user
It appears when the results have been derived using a value of TLC manually entered by the user.

W: Results based on the value of FRC entered manually by the user
This note appears when the results have been derived using a value of FRC manually entered by the user

Z: The difference between the two largest maneuvers does not meet repeatability criteria based on ATS/ERS Spirometry Standardization Statement (2019)
This note appears when the difference between the two (selected) largest maneuvers is above the following thresholds:
0.15 L or 10% VC (whichever is smaller) for patients older than 6 years of age, or
0.10 L or 10% VC (whichever is smaller) for those aged 6 years or younger

11.11.2 Simplified Clinical Report

The Simplified Clinical report includes the most significative parameters that can be measured with the Resmon PRO FULL. The following table summarizes the key differences compared to the Complete Report.

Parameter	Complete	Simplified
Surname	✓	✓
Name	✓	✓
ID	✓	✓
Birthdate	✓	✓
Birth Sex	✓	✓
Ethnicity	✓	✓
Age	✓	✓
Weight	✓	✓
Height	✓	✓
BMI	✓	✓
Test(s) Date	✓	✓ (of the first test)
Z Filter	✓ (for each test)	✓ (of the first test)
FOT selection	✓	✓
VC selection	✓	
IC selection	✓	
Account	✓	✓
Pred. Eq. FOT	✓	✓

Pred. Eq. SVC	✓	✓
Rrs 5Hz bar chart	✓	
Xrs 5Hz bar chart	✓	
Fequency dependency of Rrs and Xrs graph	✓	✓
ΔXrs chart	✓	
Loop Graphs	✓	✓
Ree	✓	✓
Rei	✓	✓
Xee	✓	✓
Xei	✓	✓
ΔR	✓	✓
ΔX	✓	✓
Rrs insp (lowest available frequency)	✓ (for each test + mean value + CoV)	✓ (mean value)
Rrs exp (lowest available frequency)	✓ (for each test + mean value + CoV)	✓ (mean value)
Rrs tot (lowest available frequency)	✓ (for each test + mean value + CoV)	✓ (mean value + CoV)
Xrs insp (lowest available frequency)	✓ (for each test + mean value)	✓ (mean value)
Xrs exp (lowest available frequency)	✓ (for each test + mean value)	✓ (mean value)
Xrs tot (lowest available frequency)	✓ (for each test + mean value)	✓ (mean value)
ΔXrs	✓ (for each test + mean value)	✓ (mean value)
FL %	✓ (for each test + mean value)	✓ (mean value)
Ti	✓ (for each test + mean value + CoV)	
Te	✓ (for each test + mean value + CoV)	
Ti/Ttot	✓ (for each test + mean value + CoV)	
RR	✓ (for each test + mean value + CoV)	✓ (mean value)
Vt	✓ (for each test + mean value + CoV)	✓ (mean value)
Vt/Ti	✓ (for each test + mean value + CoV)	
Vt/Te	✓ (for each test + mean value + CoV)	
Ve	✓ (for each test + mean value + CoV)	✓ (mean value)
Accepted breaths	✓	✓
Fres	✓ (for each test + mean value + CoV)	✓ (mean value)
AX	✓ (for each test + mean value + CoV)	✓ (mean value)

R5-19	✓ (for each test + mean value + CoV)	✓ (mean value)
Rrs 11Hz insp	✓ (for each test + mean value + CoV)	
Rrs 11Hz exp	✓ (for each test + mean value + CoV)	
Rrs 11Hz tot	✓ (for each test + mean value + CoV)	✓ (mean value – only with PSRN)
Xrs 11Hz insp	✓ (for each test + mean value)	
Xrs 11Hz exp	✓ (for each test + mean value)	
Xrs 11Hz tot	✓ (for each test + mean value)	✓ (mean value – only with PSRN)
Rrs 19Hz insp	✓ (for each test + mean value + CoV)	
Rrs 19Hz exp	✓ (for each test + mean value + CoV)	
Rrs 19Hz tot	✓ (for each test + mean value + CoV)	✓ (mean value – only with PSRN)
Xrs 19Hz insp	✓ (for each test + mean value + CoV)	
Xrs 19Hz exp	✓ (for each test + mean value)	
Xrs 19Hz tot	✓ (for each test + mean value)	✓ (mean value – only with PSRN)
SVC graph	✓	✓
VC	✓	✓
IC	✓	✓
ERV	✓	✓
FRC	✓	✓
RV	✓	✓
RV/TLC	✓	✓
TLC	✓	✓
sGrs insp (lowest available frequency)	✓	✓
sGrs exp (lowest available frequency)	✓	✓
sGrs tot (lowest available frequency)	✓	✓
Closing Volume (lowest available frequency)	✓	✓
CV FOT	✓	✓
Xcrit (lowest available frequency)	✓	✓
Flow exp during SVC	✓	✓
Rtot, PSRN frequencies	✓ (for each test + coherence + mean value + CoV)	

Xtot, PSRN frequencies	✓ (for each test + coherence + mean value)	

11.12 Trend report

A trend report can be created containing all the sessions selected to plot trend graphs (see *Plot trend graphs*). A trend report can be either printed or exported to a USB memory stick or shared with an external pc using the USB-OTG port. The file format is PDF.
Trend reports are organized into three sections:

1. Personal data
2. Trends charts
3. Numeric results

Personal data

This section reports patient information (Figure 77).

- Surname
- Name
- Birthdate
- Birth sex
- Patient ID
- Ethnicity

Trend charts

The first page of the trend report may present up to 4 trend graphs depending by the user settings (see *Graphs Settings* section and Figure 85).

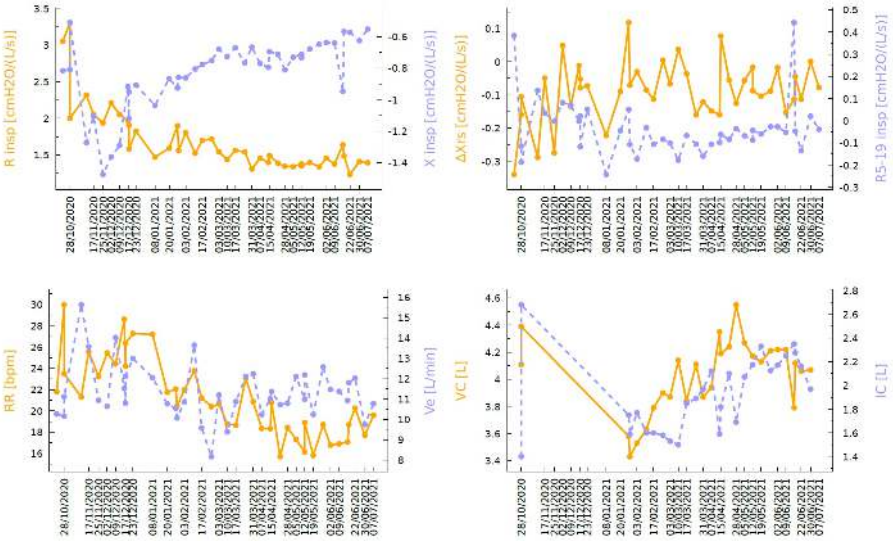


Figure 85 - Example of a set of 4 trend charts with 2 parameters each

Numeric results

This section of the trend report shows a table containing the date/time and the values of all the parameter of the sessions that are reported in the trend charts.
Mean session results are reported for each parameter.

12 Cybersecurity

Note: in case a cybersecurity event related to Resmon PRO FULL is detected or suspected please contact us with the full details at support@restech.it

The Resmon PRO FULL exposes the following interfaces and protocols:

GUI (Graphical User Interface): the device asks for a password at every boot, after presenting a page with a list of accounts; without providing the password, it will not be possible to operate the device or view any data stored on the device. The Admin account can also login from the same page to create new accounts or reset account passwords.

Caution! Ensure passwords are managed (e.g. stored, rotated) according to the user password policy of your institution.
Following a shared responsibility principle, RESTECH protects the passwords while they are stored on the Resmon PRO FULL, while it is not responsible for managing external user password strategies.
The Resmon PRO FULL does not enforce any auto-logout policy. To better protect against unauthorized usage of the device, please logout or shutdown the device when you are not using it.

Note: to guarantee backward compatibility out of the box when restoring data from an older Resmon PRO FULL model, the Resmon PRO FULL supports passwords as short as 5 characters long. In case your institution is not enforcing rules about password length, RESTECH suggests a minimum length of 12 characters when setting new account passwords.

USB-OTG: the port requires a micro-USB data cable used to exchange information with a personal computer directly connected to the device. The interface can be configured in two alternative modes of operation (see also section *Admin account*):

- *Share data with PC*: clinical reports in PDF format can be exported to the personal computer
- *Share data with third-party software*: using the serial protocol over USB, the device can download patient information and upload observation results to a personal computer running a compatible third-party software

Caution! Do not connect the Resmon PRO FULL to an external computer if you suspect it may have been infected by malware.
Following a shared responsibility principle, RESTECH is not responsible for host security of the personal computer running the third-party software or used for reading clinical reports.

NETWORK: the port requires an Ethernet cable that can be used to exchange data (visit/patient information and observation results) from a compatible third-party web service installed on a personal computer or on the local network of the healthcare facility.

The Resmon PRO FULL is not exposing any service over the network; instead, it can initiate connections to a third-party web service as configured in section *Admin account → Data Sharing → Network*).

Two protocols are supported:

- HTTPS is a protocol that enforces data confidentiality, data integrity and target authentication. HTTPS is the recommended protocol to select to enforce cybersecurity in data exchange with the device.
    - HTTPS also supports mutual authentication using TLS certificates, see section *Admin account → Data Sharing → Network* for detailed instructions on how to configure authentication and certificate revocation checks
- HTTP is an insecure protocol which is only supported to guarantee the essential function of the device in situations where the third-party web service is not supporting HTTPS and is running on a personal computer directly connected to the device (isolated network).

Caution! Do not connect the Resmon PRO FULL to an external computer if you suspect it may have been infected by malware. The network interface can also be used to connect the device to a local network, in which case it is expected that the network is following cybersecurity standards, especially in case the insecure HTTP protocol is selected.
Following a shared responsibility principle, RESTECH is not responsible for host security of the personal computer running the web service, nor for network security of the Health IT infrastructure it is eventually connected to.

From a cybersecurity perspective, the intended environment of use of the Resmon PRO FULL is a private Health IT infrastructure where all personal computers directly or indirectly connected to the device run up-to-date anti-malware software, and are verified not to have been compromised. Whenever the device is connected to a network, it is expected that the

network has been properly secured e.g. via the use of network segmentation, isolation and/or firewalling. Network performance even at peak times shall allow data transmission to guarantee the essential function of the device; in case of network unavailability, the Resmon PRO FULL will display a *timeout* error when either downloading the list of patient visits or uploading the observation results.

USB: the USB ports can be used to export some data to a USB drive. Such data can contain confidential information, including medical records and PII (*Personally identifiable information*). The following is a list of operations that end up with data exported to USB drives and what kind of information is then stored inside the USB drive:

- Backup:
    - The FULL Backup contains an encrypted database dump including all medical and personal data, and a list of unencrypted Patient IDs
    - The TECHNICAL Backup does *not* contain any medical or patient personal data
    - Both types of backup contain software log files where all personal data, whenever present, is pseudonymized
- CSV: when you choose to create CSV files with a description of all measurements (from either the Backup menu or the user's home page), data is never encrypted unless you use an encrypted USB drive; when you export a CSV file for an account which has *anonymization* ON (see *Admin account and device settings*), patient names, surnames and birth dates are all removed from the CSV – however, some potential identification data such as height, weight and age at time of test are left intact.
- Session results: when you export to a USB drive the results of a session, the clinical report in PDF format, and the technical files in JSON format are never encrypted unless you use an encrypted USB drive; when you export a observation results for an account which has *anonymization* ON (see *Admin account and device settings*), patient names, surnames and birth dates are all removed from the CSV – however, some potential identification data such as height, weight and age at time of test are left intact.

BACKUP / RESTORE / MERGE: the device keeps automated backups of its internal database (including patient data and observation results) as a measure of responding to certain types of hardware faults. However, this feature will not be able to protect against all kinds of hardware faults, such those involving the memory chip where the backup files are kept. Following a shared responsibility principle, RESTECH is not responsible for weak backup policies and encourage users to perform frequent full backups (see chapter 9.3).

In case of RESTORE operations, all patient data in the device will be overwritten by patient data in the USB memory. If you have patient data on your device that you want to keep, you may want to use the MERGE operation instead.
In case of MERGE operations, data inside the USB drive will be merged with data inside the device. This operation may involve automated and manual decisions on how to manage conflicting information. The results of such decisions may lead to loss of data. See section *Restore a previous backup or Merge*.

The MERGE operation can also be performed from MAINTENANCE personnel: however, in case conflicts on patient data are detected, you will need to perform the operation from the ADMIN account, since patient information is not disclosed to MAINTENANCE accounts.

RESTECH strongly suggests to perform a Full Backup before any operation involving the potential loss of data.

Caution! Make periodic full backups to avoid losing availability of data. Archive backups according to the regulations of your institution.

Caution! Make and archive a full backup before initiating a RESTORE or MERGE operation, to protect patient data from accidental or unforeseeable data loss.

Caution! The USB drive may contain confidential data after backup. Protect its content from unauthorized access following the regulations of your institution.
From software version 21.0.0, the Resmon PRO FULL also supports USB drives with AES-XTS encryption: when used, such drives guarantee encryption at rest for all information exported from the device. Encryption protects confidentiality and integrity of exported data.
Following a shared responsibility principle, RESTECH is not responsible for the confidentiality and integrity of exported data once this leaves the Resmon Pro FULL.

Note: if you use an account with "*Anonymize archive"* set, the name, surname and birthdate of patients will not appear in the exportation of CSV datasets and session results

Note: Patient IDs are always accessible from a full backup both in software log files and in the directory structure of patient data files

PHYSICAL SECURITY: the Resmon PRO FULL is hardened against some kind of physical attacks that may be aimed to violate the confidentiality of data stored or the integrity of the software run by the device. Moreover, the device comes with tamper evident seals on its back and bottom to ensure unauthorized access to hardware internals is detectable. Following a shared responsibility principle, please protect physical access to the device and verify the integrity of seals. In case you suspect a violation (e.g. cracked seals) please contact your local distributor.

SECURE UPDATES: RESTECH provides authenticated (digitally signed) software updates for the Resmon Pro FULL. This ensures that only integral, authorized software can run on your device. Please ask your local distributor to get authenticated software updates or register on the restech.it website.

DEVICE DECOMMISSION: RESTECH provides ways of sanitizing the Resmon PRO FULL of any sensitive, confidential data related to your patients. Please contact your local distributor shall you have this need.

13 Cleaning and disinfection

To prevent the spread of germs and avoid cross-infection between patients, the Resmon PRO FULL device requires proper cleaning and disinfection. The device should not be sterilized but it should undergo a validated reprocessing procedure that ensures the safety of the device for its next use.

Approved wipes 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

Approved wipes 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

Always follow the instructions on the wipe packaging for use and disposal, in addition to your institution's own hygiene and legal regulations. Contact your local distributor if you need help.

Warning! The device must be turned off during cleaning and disinfection procedures.

Warning! Always wear suitable protective gloves, eye protection, and a fluid-resistant gown when cleaning and disinfecting the device.

Warning! Use only EPA (United States Environmental Protection Agency) registered chemicals for cleaning/disinfection of the device.

Warning! The risk of infection can be avoided only if the following instructions are observed and if all the contaminated parts are disinfected carefully.

13.1 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. Perform a visual inspection

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

Bacterial/viral filters and nose clips are single-use items.

Caution! In order to prevent cross-contamination, replace the bacterial/viral filter and the nose clip after each patient!

Caution! To avoid inaccurate measurements, you must use only disposables that comply with the required specifications reported in section *Disposables*.

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.

Warning! The use of a filter reduces the contamination of the parts behind it. However, thorough cleaning and disinfection still have to be performed.

Warning! If you suspect that the device is contaminated (for example because a patient has not used a filter), contact your local distributor. 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.

You will need to use three CaviWipes towelettes.

After each patient, dispense two CaviWipes towelettes and wipe the whole surface of the device until it is wetted to remove debris and bioburden. Do not squeeze the wipes too much

to avoid frothing. Pay particular attention to the parts around the front cover (Figure 86) and the inlet of the device because they are those at higher risk of contamination.

Figure 86 -Front cover

Take a third CaviWipes towelette, remove the front cover and clean it thoroughly on both sides, focusing on crevices, grooves, corners, the areas around the magnets and gasket. Lay the front cover on a clean and disinfected surface.
Clean the area left uncovered after the removal of the front cover. Using a tool such as a 0.8 mm thick spatula (Figure 87, not provided with the device) push the towelette in the interstices between the two parts of the plastic frame.

Figure 87 - Example of tool used for cleaning the interstices

Caution! Never clean the device surface directly with metal brushes, steel, wood or other scrubbing materials.

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

3. Disinfect the device
You will need to use five 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. 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.

- Take the second Super Sani-Cloth towelette and disinfect the (precleaned) interstices between the two parts of the plastic frame, pushing the towelette with the spatula. 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 interstices and the parts around the inlet of the device.
- Dispense the fourth Disinfect both sides of the front cover, allowing treated surfaces to remain wet for two minutes.
- Finally, mount the front cover back in its position and use another Super Sani-Cloth towelette to clean the front region of the device, focusing on the parts around the front cover. Let the treated surface stay wet for at least two minutes.

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

4. Perform 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 and 3).

Carefully inspect the device. If you notice damaged surfaces, deformations, cracked seals, discolorations or corrosions contact Customer Service. For further information, see section *Setup*.

13.2 Instructions to be followed in case of suspected high degree of contamination of internal parts

If you suspect that a high degree of contamination of internal parts has occurred (for example because a patient with tuberculosis breathed into the device without using an antibacterial filter), contact your local distributor for a complete cleaning and disinfection of the device.

14 Maintenance

Caution! With the exception of the cleaning and disinfection procedures indicated in the previous paragraph, service on the device must be performed only by qualified personnel. In case of need, contact your local distributor.

14.1 Calibration check

It is mandatory to verify that the device is calibrated daily using the procedure described in the section *Calibration check*.

Caution! Only use the Test Object provided by the manufacturer to perform the calibration check.

14.2 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.

Warning! Turning the device off before replacing the Air Filter.

To change the filter, turn the cover counterclockwise. 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 your local distributor.

Warning! Do not cover or occlude the Air Filter. This may cause internal heating of the device and may affect the measurement.

Caution! After replacing the Air Filter, verify that the cover is tight. If not, dust might occlude the flowmeter screen and the measurements may be affected.

15 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. If possible, make a full backup of the device. See section *Backup, restore*
2. The device must be thoroughly cleaned in order to remove residues as far as possible. For further information see section *Cleaning and disinfection*.
3. Since parts of the device may have come into contact with biological substances, disinfect it by following the instructions in section *Cleaning and disinfection*.
4. Before shipping the device, **always contact your local distributor** to get the following information:
    a. The address for return
    b. The packing instructions

15.1 Information for disposal for private users, companies and healthcare facilities

15.1.1 Disposal of Electric and Electronic Equipment

The Resmon PRO FULL is electrical equipment that must be disposed of following your local or national regulations. Contact your local distributor for further details.

In the European Union, the device shall be disposed according to WEEE Directive 2012/19/EU.

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

15.1.2 Disposal of packaging

The packaging composition is reported below (Recycling Codes are valid in the European Union only):

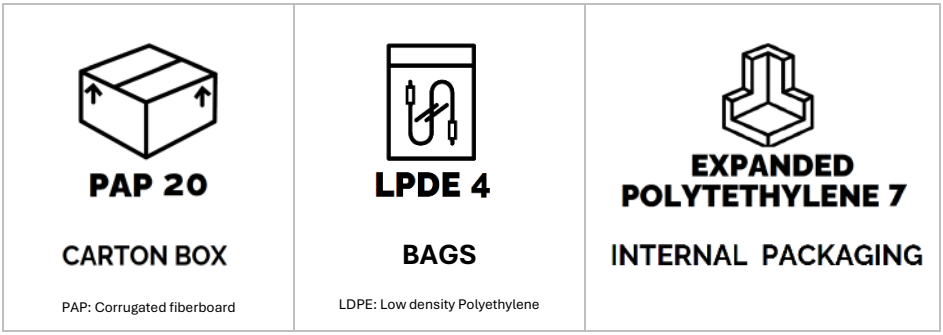


Figure 88 - Packaging composition and disposal

The packaging shall be disposed according to local or national regulation. If you need further information, please contact your local distributor.

16 Operating and Storage Conditions

16.1 Operating Conditions

Temperature: 10 - 27°C
Relative humidity: 30 - 75% non-condensing
Barometric pressure: 700 – 1060mbar

16.2 Storage and Transport Conditions

Temperature: +5 - +40°C
Relative humidity: 30 - 75% non-condensing
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

17 Troubleshooting

This section lists common problems you might encounter during normal use and their solutions. If your problem isn't listed, or if you have other questions, please contact your local distributor.

17.1 Problems related to the results of the measurement

17.1.1 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, the operator is holding his/her cheeks or the patient is breathing through the cheek holder. Make sure there are not leaks from the nose or mouth. Repeat the measurement. If the problem persists, perform a calibration check to exclude any problems with the calibration of the device.

17.1.2 The measured impedance is outside the measurement range of the device. For this reason, this measurement will be discarded

Change the stimulating waveform to change the impedance measurement range of the device, so that it includes the measured impedance of the patient.

17.2 Problems related to the calibration verification

17.2.1 Calibration check failure

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. If the device returns an error with the message "Low amplitude detected", check that the Test Object is connected firmly to the inlet of the device without leaks and retry.

17.2.2 Calibration check required before making new tests. Touch here to perform it now

To perform the calibration check, if you are logged in with an account, you can touch the message on screen or go to Settings and press Calibration check. Then, connect the Test Object and run a verification of the factory calibration.

17.2.3 Volume check for SVC was not executed today. Touch here to perform it now

To perform the calibration check, if you are logged in with an account, you can touch the message on screen or go to Settings and press Calibration check. Then, connect the 3L syringe and run a verification of the factory calibration.

17.3 Problems related to the measurement

17.3.1 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.

17.3.2 Filter impedance very low or missing filter

The device has measured a filter impedance that is lower than $0.1 cmH_2O \cdot s \cdot L^{-1}$.
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.

17.3.3 More contiguous valid breaths are required

This error might appear when using a PSRN stimulus
During the measurement the device has automatically discarded breaths with artifacts (e.g., cough or glottis closure) but the total number of accepted breaths has not reached the minimum required for a PSRN measurement. This number would vary among measurements, so try to repeat the measurement with a good number of accepted breaths in a row.

17.4 Problems related to the creation of new patients

17.4.1 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.

17.5 Problems occurring when browsing the database

17.5.1 No Patients have been created yet

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.

17.5.2 No measurements for patient [PatientID]

A patient has been created but no measurements have been performed on him, therefore no measurement data are available for that patient.

17.5.3 An issue with the device data storage has been detected

Contact your local distributor as soon as possible to avoid losing data. Remember to take regular full backups of your data. Please notice that a full backup taken when an issue with the device data storage has already happened will not include measurement traces.

17.5.4 Storage is almost full

Contact your local distributor as soon as possible. Take a full backup of your device. Notice that in case of memory storage full, the device could experience several issues such as not booting up properly.

17.5.5 Graphs cannot be shown since some data are not available

When opening sessions imported from different devices (e.g. restore or merge from Resmon PRO FULL V2), some information could not be restored. This may happen with volume-related loop graphs.
If you think you should see the graphs, remember to enable the loop graphs from your account settings (see *Change user settings*).

17.6 Problems occurring when exporting data onto a USB drive

17.6.1 Not enough disk space on USB drive

The space on the USB drive is not enough to allow a complete export of the measurement 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.

17.6.2 An error occurred - could not create the file on USB drive / Device not found – Please insert a USB drive and try again

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 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 / exFAT / NTFS
3. Verify that the USB drive is not write-protected
4. Use another USB drive

17.7 Problems related to printing

17.7.1 Printer not found

Connect a postscript USB printer or a printer compatible with the AirPrint or IPP Everywhere protocols to the device and turn it on. Contact your local distributor for the updated list of verified USB printers.

17.8 Problems related to the restore or merge of a backup file

17.8.1 No valid backup files found

There are four possibilities:

1. 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.
2. You are trying to restore from a backup files, but the device did not detect any backup file in the USB drive connected to the device.
3. You copied a full backup on its USB drive correctly, but the backup is not compatible with the device.
    a. Only FULL BACKUP files of Resmon PRO FULL V3 and Resmon PRO FULL V2 are accepted
    b. For Resmon PRO FULL V2 files, only those exported with software version 6 onwards are accepted
4. You copied a full backup on its USB drive correctly, but the backup is compromised or damaged.

17.8.2 Some sessions exist both on your device and on the backup you are trying to restore

During a merge operation, you can try a merge with some data that is already inside the device, at least partially. In this scenario, the software will ask you to decide whether to overwrite the details with data inside the backup, or to keep the version you have inside the device (e.g. because you have made recent changes and you want to keep them).
In case you have sessions that are still open (i.e. so recent you can add new measurements to them) you will be forced to overwrite their details.

17.8.3 Some conflicts on patient data between information on your device and information on the backup file have been found

During a merge operation, the software tries to merge all information automatically. However, it may encounter some conflicting information for which human intervention is necessary. For instance, when merging data from two different devices, the same Patient ID

may belong to different persons, or vice versa the same person may have different Patient IDs.
Follow the UI to solve conflicts manually and make decisions.
The following are examples of situations that would lead to the message appearing:

- The same person has two different Patient IDs: you can merge their data safely
- The same Patient ID belongs to different patients: you will need to create a new patient for importing the new data; you may also pick one patient from your local database and merge the new data into its data
- Demographics for a patient was updated recently and now differs slightly: you may choose the right demographic details for the patient

17.9 Problems related to the use of third-party software

17.9.1 I cannot see the button labeled "Continue using third-party data"

The button will only be displayed when the Resmon PRO FULL is correctly connected to a third-party software (you can verify the connection via the 'Ping' button in the Data Sharing options inside the Admin panel, see section *Admin account and device settings*).
If the connection works correctly, the button will only be displayed when a non-empty list of visits was transferred from the third-party software.
If the connection works correctly and you are sure a non-empty list of visits has been scheduled, please contact your local distributor.

17.9.2 Invalid data in the following fields

The Resmon PRO FULL only supports a well-defined set of data when interacting with the third-party software. If unsupported data is sent through, the device will show a popup indicating explicitly which fields were rejected, so that you can modify their content before trying again. Some examples of unsupported data are most special characters and alphabets other than Greek, Cyrillic and Chinese/Japanese/Korean.

17.9.3 Conflicting Patient ID: would you like to update current data for ID <patientID>?

The third-party software sent data about a patient that is different from the one registered on the device (e.g. different name for patient with the same unique ID). You can proceed and accept the change to update the local patient with the information inside 'New data', or cancel the operation and change the ID remotely before trying again.

17.9.4 Some of the measurements were already present and have not been updated

According to the third-party software in use, some third-party software may not manage duplicate entries, and will refuse an update. You need to delete the observation results from the third-party software and try again, to ensure that the most recent data is sent through. This would only be needed in case you made local modifications (e.g. added notes, changed selection) after first upload the results.

17.9.5 Data synchronization was interrupted due to an unexpected power loss or other external causes

The data remains stored on the Resmon PRO FULL after a *Sync All* operation, or is deleted only once a *Sync and Delete* operation has been successfully completed. If the data transfer is interrupted, restart the synchronization procedure to transfer all data to the third-party software.

17.10 Other problems related to the device

17.10.1 Internal temperature is too high.

Caution! To prevent overheating, the device temporarily restricts the user from performing additional measurements.

The temperature inside the device is above a safety threshold. You are not allowed to make a new measurement. 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.

17.10.2 Account already exists!

If you want to add another user to the device, choose another username. The username must be unique.

17.10.3 Wrong Password

The password to login as a user or admin is incorrect. Try again or reset password. See section *Admin account*.

17.10.4 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.

17.10.5 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.

18 Technical specifications

Flow measurement	Mesh type	
	Range	± 1.5 L/s
	Linearity	< ± 2% in the range ± 1.5L/s
Mouth pressure	Range	± 2.5 kPa
	Linearity	1.5 %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 environmental sensor	Barometric pressure	± 100Pa
	Temperature	± 1°C
	Relative humidity	± 3%
Operating conditions	Temperature: 10 - 27°C Relative humidity: 30 - 75% non-condensing Barometric pressure: 700 – 1060mbar	
Storage / Transport Conditions	Temperature: 5 - +40°C Relative humidity: 30 - 75% non-condensate Barometric pressure: 700 – 1060mbar	
Calibration and calibration check	Factory calibration according to international recommendations + auto-zeroing of the sensors before each measurement 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	0.68 – 0.95 $cmH_2O \cdot s \cdot L^{-1}$ in the frequencies of normal breathing (0.2 – 0.98 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 your local distributor to know the list of verified USB printers. - 1 USB-OTG - Ethernet 10/100/1000 - HDMI	
Display	10.1'' HD color display with capacitive touchscreen	
Electrical specifications	Power supply: 100-240V, 50-60 Hz 60W input AC / 15VDC 3A output power supply (supplied with the device) Stand-by current: 500 mA Average current during the measurement: 1500 mA	
Dimensions	31x29x26 cm (without the cart)	53x53×80(min H) cm (with the cart)
Weight	4.3 kg (9.4 lbs) device only 6.4 kg (14.7 lbs) with device holder; 22 Kg (49.60 lbs) with the Resmon CART and device holder)	
Noise	Type A filter, < 64 dB rms (measured at a distance from the device equal to the average distance of the patient's ear from the device while making a measurement – Phonometer: SL4023 SD – Class II – Time Constant: Slow)	
Internal fuse	2A, fast-type; max voltage rating: 125V; PSE: 100A @ 100VAC	
Service life	7 years	
Compatible third-party software	All third-party software that implements Restech's proprietary protocols versions v1 or v2	
Compatible printers	Printers that support postscript, Airprint or IPP Everywhere protocols	

Table 11

Measurement ranges and accuracy for impedance parameters

Parameter	**Parameter range at specified frequency**		**Accuracy**
Resistance (R) and reactance	5Hz, 6Hz, 8Hz, 10Hz	0 – 25 $cmH_2O \cdot s \cdot L^{-1}$	≤ 0.1 $cmH_2O \cdot s \cdot L^{-1}$ or ≤10% of the measured value
	5-11-19Hz	0 – 25 $cmH_2O \cdot s \cdot L^{-1}$	

(X) (inspiratory, expiratory, total); **X_{crit}**	PSRN (5Hz, 7Hz, 11Hz, 13Hz, 17Hz, 19Hz, 23Hz)	0 – 25 $cmH_2O \cdot s \cdot L^{-1}$	
	PSRN (29, 31 Hz)	0 – 15 $cmH_2O \cdot s \cdot L^{-1}$	
	PSRN (37Hz)	0 – 6.8 $cmH_2O \cdot s \cdot L^{-1}$	
R5-19	/	0-5 $cmH_2O \cdot s \cdot L^{-1}$	≤ 0.5 $cmH_2O \cdot s \cdot L^{-1}$ or ≤20% of the measured value
ΔXrs	5Hz	0-10 $cmH_2O \cdot s \cdot L^{-1}$	≤ 0.5 $cmH_2O \cdot s \cdot L^{-1}$ or ≤20% of the measured value
ΔR, ΔX	5Hz, 6Hz, 8Hz, 10Hz, 11Hz, 19Hz	0 – 25 $cmH_2O \cdot s \cdot L^{-1}$	≤ 0.5 $cmH_2O \cdot s \cdot L^{-1}$ or ≤20% of the measured value
fres (inspiratory, expiratory, total)	/	5-37 Hz	≤ 1.0 Hz or ≤20% of the measured value
sGrs (inspiratory, expiratory, total)	/	n.a. (these parameters need input from another equipment to calculated)	
AX (inspiratory, expiratory, total)	/	1-50 $cmH_2O \cdot L^{-1}$	≤ 2.0 $cmH_2O \cdot L^{-1}$ or ≤20% of the measured value

Table 12

Measurement ranges and accuracy for breathing pattern parameters

Parameter	Range	Accuracy
Vt	0.1 – 2L	≤ 0.05L or ≤2.5% of the measured value
Ti and **Te**	0 – 3s (Ti) and 0-5 (Te)	≤200ms
Ti/Ttot	0.2 – 1	≤0.05
RR	2 – 40 breaths per minute	≤10%
Vt/Ti and **Vt/Te**	0.1 – 1.5L/s	≤10%
Ve	2-30 L/min	≤ 10% of the measured value

Table 13

Measurement ranges and accuracy for volume parameters

Parameter	Range	Accuracy
IC	0 – 5 L	≤ 0.05 L or ≤2.5% of the measured value
SVC, ERV and CV_{FOT}	0 – 9 L	
FRC, TLC, RV	n.a. (these parameters need input from another equipment to be calculated)	
RV/TLC	n.a. (these parameters need input from another equipment to be calculated)	

Table 14

19 Electromagnetic compatibility

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

- The device is intended to measure respiratory impedance of pediatric and adult patients 3 years of age or older.
- 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.
- The device design ensures, according to international recommendations concerning devices, as **essential performance** that the measurement of impedance of the respiratory system by forced oscillation technique, must have an accuracy of 0.1 $cmH_2O \cdot s \cdot L\text{-}1$ or 10% of the measured value.
- In case of electromagnetic disturbances, the operator might observe display flickering.
- 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 Instructions for Use. Portable and mobile RF communications equipment can affect medical electrical equipment.
- Accessories not specified within the Instructions for Use are not authorized. Using other components may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity). In case of electrostatic charges higher than 8kV released on the power supply or higher than 6kV released on the signal connectors (i.e., LAN, USB and HDMI) located in the rear side of the device, this could temporarily turn off for auto-protection. Should this be the case, unplug the power supply from the mains for at least 30 seconds (and up to 15 minutes) before turning the Resmon PRO FULL on again.

Warning! Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally

19.1 Cables

The following cables may be used with the Resmon PRO FULL but are not supplied with it. They can be purchased by the responsible organization and they could affect the compliance of the Resmon PRO FULL with the requirements on electromagnetic emissions and immunity. The following specifications are recommended by the manufacturer of the Resmon PRO FULL for limiting the probability of EMC interference:

Cable	Recommended characteristics
USB cable	USB certified, length < 3 m
HDMI cable	HDMI certified, length < 3 m
LAN cable	Length < 3 m

Table 15

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

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

19.2 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

Harmonic emissions (IEC 61000-3-2)	Complies	establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker (IEC 61000-3-3)	Complies	

Table 16

19.3 Electromagnetic Immunity

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: ± 8 kV Air discharge: ± 15 kV	± 6 kV ± 8 kV (deviations from IEC 60601-1-2)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Note: in case of static discharges higher than the compliance level, the power supply will temporarily turn off for auto-protection. Unplug the power supply from the mains for at least 30 seconds (and up to 15 minutes) before turning the equipment on again.
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:	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.

	± 1 kV		
Power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	30 A/m	30 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)	0% U_T for 0.5 cycle and 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T for 250/300 cycles	0% U_T for 0.5 cycle and 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T for 250/300 cycles	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			

Table 17

Electromagnetic Immunity – Test specifications for enclosure port immunity to RF wireless communications equipment

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.

Test frequency (MHz)	**Band[(a)] (MHz)**	**Service[(a)]**	**Modulation[(b)]**	**Immunity Test Level (V/m)**
385	380-390	TETRA 400	Pulse modulation[b)] 18Hz	27
450	430-470	GMRS 460, FRS 460	FM [c)] +/- 5kHz deviation 1kHz sine wave	28
710	704-787	LTE Band 13, 17	Pulse modulation[b)] 217Hz	9
745				
780				
810	800-960			28

870 930		GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b)] 18Hz	
1720 1845 1970	1700-1990	GSM 1800, 1900, CDMA 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b)] 217Hz	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b)] 217Hz	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation[b)] 217Hz	9

a) For some services, only the uplink frequencies are included
b) The carrier shall be modulated using a 50% duty cycle square wave signal
c) As an alternative to FM modulation, 50% pulse modulation at 18Hz may be used because while it does not represent actual modulation, it would be the worst case

Table 18

20 User Information

20.1 Incident Reporting

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

Model: Resmon PRO FULL (ref. RT1100)

MANUFACTURER

Restech Srl
Via Melchiorre Gioia, 61-63
20124 Milano – Italy

Web: www.restech.it
Email: info@restech.it
Tel: +39 02 3659 3690

20.2 Technical Assistance

For other information and requests of technical support, please contact your local distributor or RESTECH technical assistance at: support@restech.it