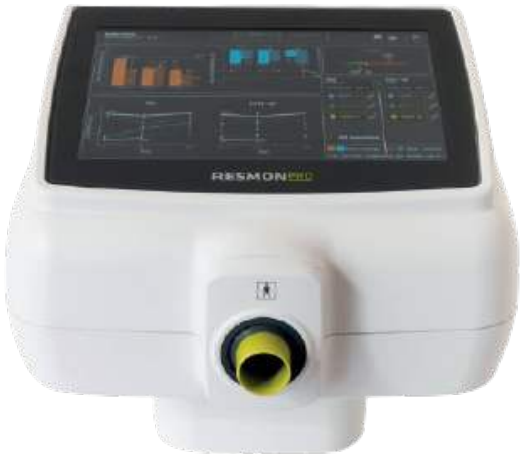
RESTECH
RESPIRATORY TECHNOLOGY

Instructions for Use
Resmon PRO FULL

Version **V3**
(Ref: RT1100)

Oscillometry Device



Please review this document before using the device.

Revision 29– February 2024
Software version: 22.0.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 present device is classified as a medical device class IIa according to the European Regulation MDR 2017/745. The device has been designed in accordance with the requirements of the IEC 60601-1:2007/A1 2012/A2 2020 and its deviation AAMI/IEC 60601-1:2005 + AMD 1:2012, CAN/CSA-C22.2 No. 60601-1:14, JIS T 0601-1:2017.

CE 0051

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

Table of Contents

Symbols in the Instruction Manual

Symbols for notes on safety

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

	**Warning** indicates a potentially hazardous situation, which, if not avoided, may result in it 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.

Labeling / Symbols and icons

The icons on the device labels and used in the Instruction Manual, 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 Labeling		Manufacturer
		Type BF Applied Part
		CE Mark
		Waste of electrical and electronic equipment according to WEEE Directive 2012/19/EU

Where you find it	Symbol	Meaning
	Rx Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
		Consult Instruction Manual
		Direct Current Power Supply
		Class II equipment
	IP20	Degree of Protection
		Catalog Number
		Production Date (YYYY-MM-DD)
		Serial Number
		Medical Device
		UDI GS1 Datamatrix
		Model
Device Back Lid		Ethernet
		USB
		HDMI
		Refer to Instruction for Use
		Direct Current Power Supply
		Power ON/OFF Button
		Do not cover

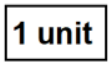
Where you find it	Symbol	Meaning
Front Cover		Type BF applied part
Package Labeling		CE Mark
		Serial Number
		Catalog Number
		Medical Device
	Rx Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
		Manufacturer
		Production Date (YYYY-MM-DD)
		UDI GS1 Datamatrix
		Minimum and maximum allowed storage and transport temperature (degrees Celsius)
		Minimum and maximum allowed storage and transport relative humidity (%)
		Refer to Instruction for Use
		Shipping Information
		Model

Table 1

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
CV	Coefficient of Variation
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
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	Percentage 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	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
X5	Reactance at the Frequency of 5 Hz
Z	Respiratory Impedance
ΔXrs	Difference Between Mean Inspiratory and Mean Expiratory at 5 Hz
ρ	Coherence

Table 2

List of the units of measurement

Physical quantity	Available units of measurements (See also *Change user settings*)			
	Default format	Other available format(s)		
BMI	$kg \cdot cm^{-2}$			
Date format	dd/mm/yyyy	mm/dd/yyyy		yyyy/mm/dd
f	Hz	Hz		
Height	cm	cm		in
R, X, Z, X_{crit}	$cmH_2O \cdot s \cdot L^{-1}$	$cmH_2O \cdot s \cdot L^{-1}$		
sGrs	$cmH_2O^{-1} \cdot s^{-1}$	$cmH_2O^{-1} \cdot s^{-1}$		
Respiratory rate, RR	breaths per minute, bpm	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	$cmH_2O \cdot L^{-1}$			

Table 3

Descriptive Information

Indications for Use

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

Contraindications

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

Description of the device

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

Device structure

Figure 1 - Device front view

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

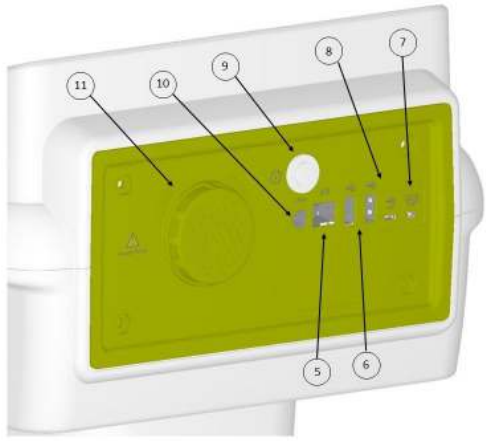


Figure 2 - Device back view

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

Components

1- **Test Object** 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- **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 a Class I medical device (Figure 4**).**

Figure 4 - Resmon CART

Other components supplied with the device:

The Resmon PRO FULL is supplied with the following components:

1. **Power Supply** (see *Power Supply specifications* below)

2. **Device Holder (**Figure 5**):** every device is supplied with a device holder. This component 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.

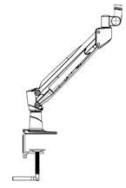


Figure 5 - Device Holder

3. **Calibration and Titration reports**
4. **USB pen drive**
5. **Air blower filte**r (2 pieces), supplied the device for the periodic maintenance activities. See section *Maintenance.*

Power Supply specifications

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 call the distributor.

Caution! Use of accessories other than those provided by the manufacturer or in configurations different from those reported in this manual may alter the performances of the device. If any accessories are damaged or lost contact the distributor.

Disposables

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

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

These items are single use and, therefore, must be changed after each patient. For a proper disposal of filters and nose-clips used during the measurements, follow the safety instructions reported on their instructions for use and the additional provisions and regulations of your hospital or institution.
To increase the comfort of the patient, you may consider connecting a single use, single patient mouthpiece or mask to the filter on the patient's side. Any mouthpiece suitable for pulmonary function measurement or mask that allows the exclusion of the nose and that can be connected to your filters can be used. The use of mouthpieces/masks is not mandatory. For a proper use and disposal of mouthpieces/masks, follow the instructions

for use of their manufacturers and the additional provisions and regulations of your hospital or institution.

Caution! The use of disposables which fail to comply with the specifications indicated above may reduce the accuracy of the measurements. The manufacturer recommends special attention to the patient's posture during the measurement to assure that the upper airways are not partially or completely occluded by the tongue or by the teeth.

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

Shipping Box Composition

The Resmon PRO FULL is shipped as follow:

- 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 Other *components supplied with the device*
- Power Supply	(1 piece)	See section Other *components supplied with the device*
- USB pen drive	(1 piece)	See section Other *components supplied with the device*
- Air Blower filter	(2 pieces)	See section Other *components supplied with the device*
- Instruction for use (this document)	(1 piece)	

Optionally:

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

Warnings

Warning! Connect the device to extension cords and outlet strips only if they are compliant with all the requirements of IEC 60601-1. Do not connect other outlet strips to the outlet strip of the device. Do not put the outlet strip on the floor. Other devices that are not part of the Resmon PRO FULL should not be plugged to the outlet strip

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

Warning! Do not expose the device to condensing humidity

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

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

Warning! Please pay attention to insert the correct birth date on patient data section before starting any measurement.

General precautions

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

- Handle with care. Rough handling or misuse could cause hardware and electrical damage
- Cover the device when not in use, as dust may cause improper function of the device
- Do not occlude openings on the bottom of the device. The occlusion may worsen the quality of the measurement and may cause over-heating of the device
- Pressing hard on the touchscreen could damage the screen and display integrity
- Always use a bacterial/viral filter in order to avoid cross-contamination among patients.
- Ensure that the metal mesh of the flow sensor is not occluded. An occlusion of the mesh could result in a significant change in the measured parameters and produce unreliable results
- If the holder should become damaged, remove the device from the holder and contact the distributor. If the device falls from the holder, this could injure the patient or user and cause malfunctions of the device itself
- Should the chassis be damaged, disconnect it from the power supply and contact the distributor (see section *User Information*)
- In case the display is damaged or malfunctioning, contact the distributor (see section *User Information*). The display buttons and instructions are essential for the proper use of the device
- If the packaging is damaged at the time you receive the device, contact the distributor before using it (see section *User Assistance Information*)
- The use of this device could be contraindicated in patients with known sensitivities or allergies to the following components: ABS (acrylonitrile butadiene styrene), Silicone, Stainless Steel, Polypropylene, Acrylic, Polycarbonate, Nylon, Aluminum and PET (polyethylene terephthalate)
- Do not allow liquids to enter the device. If the device is accidentally hit by water splashes, disconnect the power cord, and immediately clean the device with a soft cloth.
- Do not use the Resmon PRO FULL in an MRI environment

Setup

Choose the right place for setup

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

Caution! Do not place the device in such a position that may hinder the ability to disconnect the device from the power supply.

Resmon PRO FULL with Device Holder

Assembling the holder

Figure 6 shows the holder and its components.

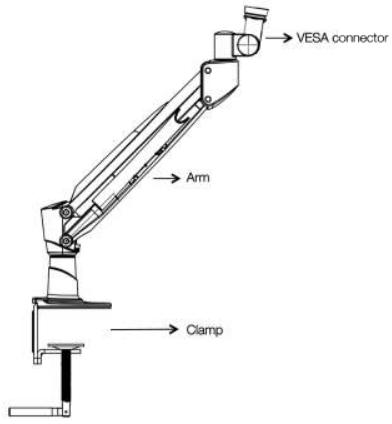


Figure 6 - Arm Bracket

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

Warning! If the holder is not firmly attached to the surface (desk or table) the device may fall causing possible damage to the device or users. Fasten the clamp securely before using the device.

Warning! The desk or table must be of adequate dimensions and weight to securely prevent the device 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 7. To do it, loosen the nut with the tool provided with the device, change the orientation to be between 5 and 10 degrees as shown in Figure 7 and then tighten the nut again.

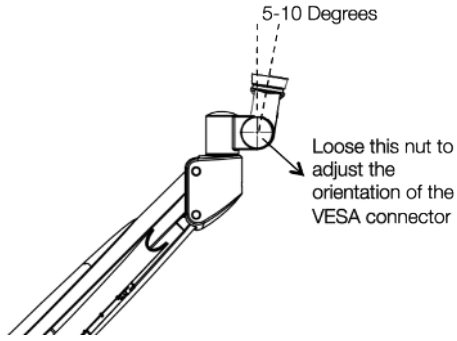


Figure 7 - Adjust the orientation of the VESA connector

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

3. **Fasten the device to the arm**. On the bottom of the device there is a connector (see Figure 8). Pull the round pin and turn it counterclockwise to open. Connect the arm to the connector, turn it clockwise to close and lock it in place. The connector has a shape that allows only one orientation of the device and a complete closing of its lock.

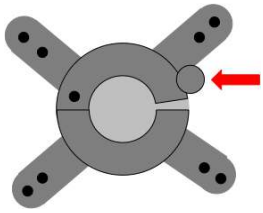


Figure 8 - VESA connector, the arrow indicates the safety locker that should be properly engaged to guarantee a secure connection between the device and the holder

Warning! Make sure that the safety lock is properly locked before using the device.

Warning! If the holder is damaged, do not use the device. Remove the device from the holder and contact the distributor.

Resmon PRO FULL with Resmon CART

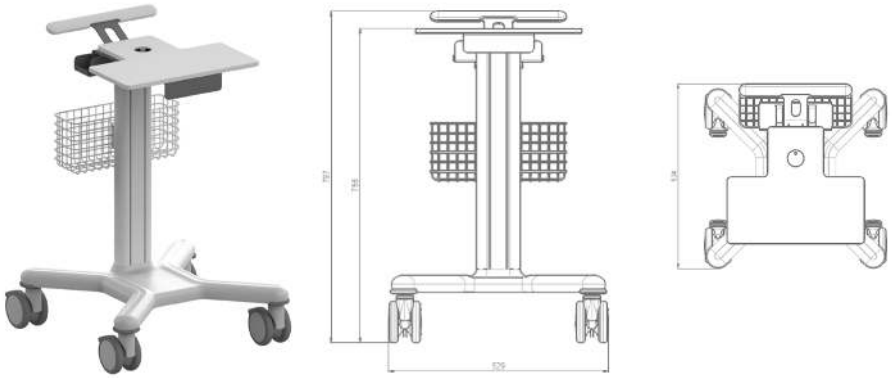


Figure 9 - Resmon CART

Resmon CART is an optional medical device component (Class I) of Resmon PRO FULL useful for transporting the device. Figure 9 reports a picture of the Resmon CART and its dimensions.

Assembling of Resmon CART

The assembly of the Resmon CART **must be performed by authorized personnel only**, following the assembling instructions reported in the **Instructions Manual – Resmon CART**, supplied with the cart.

Turning on/off the device

Turning on the device

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

Warning! If the holder is damaged, do not use the device. Remove the device from the holder and contact the distributor.

Warning! The power supply provided by the manufacturer is compliant with IEC 60601-1. Do not use the device with a non-compliant power supply. In case of damage or loss of the power supply contact the distributor

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

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 7 seconds.

Warning! In order to guarantee electrical safety, when the device is not in use unplug the power supply. The green led “ON” indicates that the power supply is plugged in. This light should be off when the device is not being used.

First log-in and the Admin account

When the device is turned on the log in page will display. At first log-in no accounts are present, only the Admin user is present.

Press the *Admin* button ( ) and insert the admin password to access the *Admin panel* (Figure 10). The default password for ADMIN is *admin.*

The *Admin* is enabled to modify the device settings but not to perform measurements nor to access the database. In order to perform measurements with the device it is necessary to create additional user accounts.

Select Logout in the header bar if you want to exit the *Admin panel*.

Figure 10 - Admin Settings

Caution! To avoid any unauthorized access, it is necessary to change the Admin password during the first access to the Admin Panel. Refer to Accounts paragraph for further information

Info

Press the *Info* icon ( ) to see the distributor contact information, system date, software and firmware versions, first installed version, the serial number of the device and the disk usage (Figure 11).

Figure 11 - Information Page

Accounts

Accounts will be able to perform measurements and browse the available subjects data. Select *Accounts* to create, remove or modify an account.
The following screen will display (Figure 12).

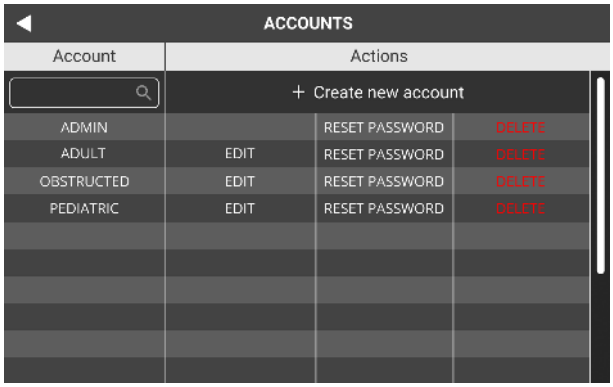


Figure 12 - Account management screen

Select *Create new account* to create a new user. Enter the username (max 25 characters) and password (5-32 digits) and repeat it in the appropriate section. You can choose whether to allow the device to display results also in relation to preset reference equations (see section *Reference equations*) and if the archive will be anonymized by clicking the buttons on the right. By checking *Anonymize archive*, name and surname will not appear on test reports and in all exported files and filenames. By default, the reference equations are enabled and the archive is not anonymized. (Figure 13)

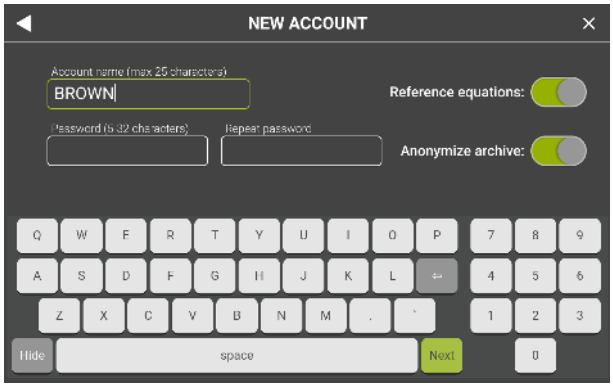


Figure 13 - Create a new account

Press *Next* to confirm.

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

Username already in use.

- Select *Delete* next to the account name to remove the account. Once confirmed, press *OK* to go back to the *Admin panel*.
- Select *Reset password* next to the account name to modify the password of a current user. Insert the new password, repeat it, press *Next* to confirm and go back to the previous page.

Modify Accounts Password (including Admin)

From the Accounts management screen (Figure 12) it is possible to modify Accounts (including Admin) password by selecting on the “Reset Password” button.
The new password and a confirmation of the new password will be requested.

A pop-up on the screen will notify a successful change of the password.

Backup and restore of previous backups

A backup of the device can be saved on a USB drive, or a backup saved on a USB drive can be restored on the device.

Backup to USB

Insert a USB memory stick into the USB port and select *Backup & Restore* and then *Backup to USB* to start copying data from the device (Figure 14).

Figure 14 - Backup and restore

You can choose the type of backup that you want to perform (Figure 15).

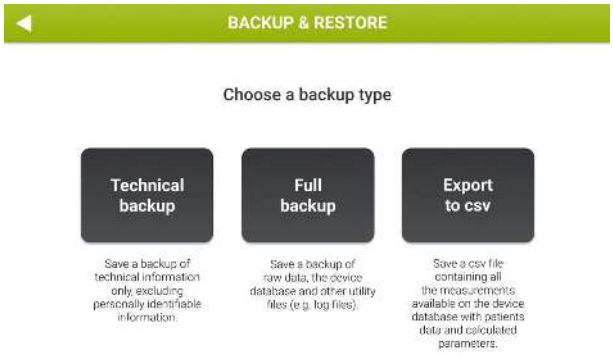


Figure 15 - Backup Options

- Select *Technical backup* to save a backup of technical information only, excluding personally identifiable information.
- Select *Full backup* to backup raw data, the dump of the device database and other utility files (e.g. log files).
- Select *Export to csv* to create two .csv files: one containing all the measurements available on the device database with patients' data and calculated parameters and one containing all sessions available on the device.

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.

Restore a previous backup

Insert a USB memory stick containing a full backup into one of the USB ports. Select *Backup & Restore* and then *Restore from backup*.
You can restore a full backup from a Resmon PRO FULL v2 (you first need to upgrade the device to at least software version 6.1.2) or from a Resmon PRO FULL V3.
If one or more full backups are detected in the USB drive, the device will display the file name, the serial number of the device the backup was taken from, and the backup date.

Only the latest full backup is considered.
Press *Restore* to start the restore from backup, enter the Admin password and confirm. All data will be lost and overwritten by the backup data (Figure 16).

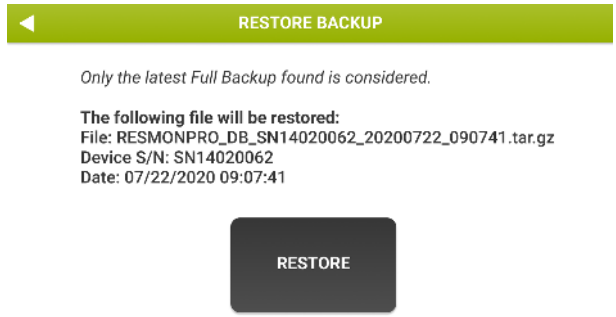


Figure 16 - Restore from backup

If the restore from backup procedure was successful, a success screen reporting the name of the restored file will be displayed.
Press *Reboot* to restart the device.

Software Update

Select *Software update* to install a new software release. The update must be copied in the root of a USB memory stick, which must be plugged in the USB port.
Select the update you want to install, and press *Install.*
Press *OK* when the device displays the message:

Update installed!

Caution! Software updates are digitally signed. Corrupted or tampered software updates will not be displayed.

Date & time

Press Date & time to set the time settings (Figure 17).

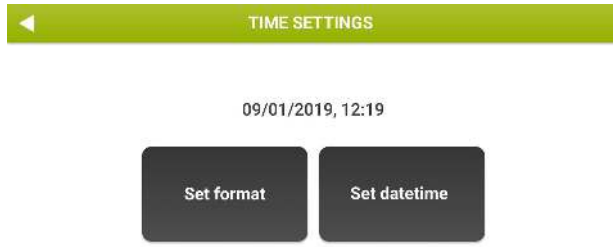


Figure 17 - System date options

Set format allows you to set the date and time format, while *Set datetime* is used to set the date and time of the system.
It is possible to edit the date format (DD/MM/YYYY, MM/DD/YYYY or YYYY/MM/DD) and time format (12-hour or 24-hour). The default display format is *DD-MM-YYYY, 24-hour*. After entering the new date and time, additional controls will be performed by the device; for instance, if you try to insert a system date which is in the past when compared with the latest recorded event, you will get the following message:

System date seems incoherent – is this system date correct?

You will have to double check and confirm the system date, or to go back and adjust its value to the correct one.

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

Language

Press *Language* to change the software language. The default is English. The language will change immediately.

Measurement units

Select *Measurement units* to set (Figure 18):

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

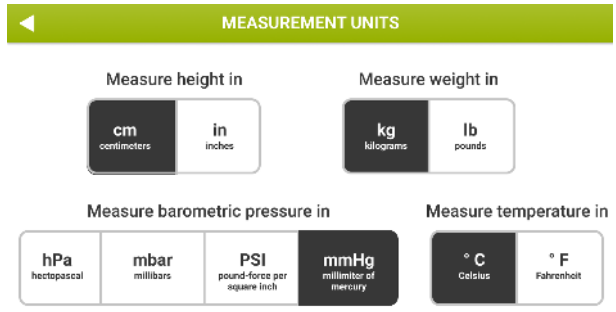


Figure 18 - Measurement units screen

Select the desired Measurement units and press the *Back button* ( ) to return to *Admin panel*.

USB keyboard layout

Press *USB keyboard layout* to select the desired USB keyboard layout to use between the following layout types (Figure 19 - USB keyboard layout screen, 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
pt:	Portuguese keyboard layout
de:	German keyboard layout

Table 4

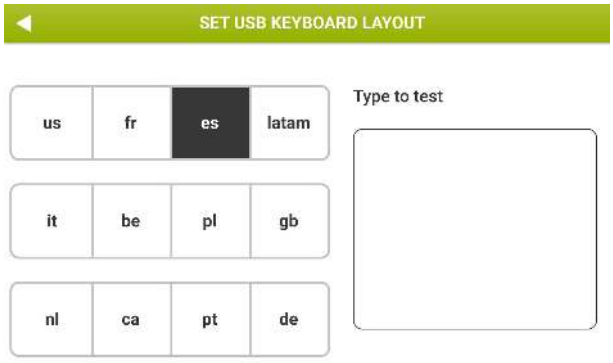


Figure 19 - USB keyboard layout screen

After the selection, connect a corresponding keyboard and use the text box below *Type to test* to verify the selection.

Data Sharing

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*. Insert the new text and press *OK* to confirm.

- **Printer:** press *Printer* to visualize the name of the USB printer connected to the device. Press *Test printer* and to print a test page.

  If the printer is compatible, the test page will be printed correctly.
  If no printer is connected, an error message will be displayed: *Printer not found*

USB-OTG

Press *USB-OTG* to select the preferred method for sharing data via the USB-OTG port (micro-USB data cable). Two options are supported: *Share data with an external personal computer* (default) and *Share data with third party software (ASCENT, Expair)*.

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

Sharing data with an external personal computer. This option allows sharing a clinical report in PDF format with a personal computer connected to the USB-OTG port. This requires no third-party software running on the computer.

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. To enable this functionality:

1. Select *Sharing Data with third party software*
2. Confirm the *Reboot* of the device to make the new configuration effective
3. After reboot, go to the same screen (Admin – Data Sharing – Data Sharing via USB-OTG); three more buttons are now displayed: *Ping*, *Sync* and *Sync and Delete* (Figure 20)
4. 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.

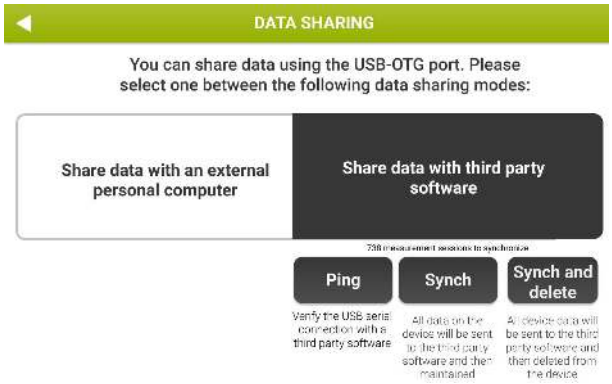


Figure 20 - Options available for sharing data with 3rd party software

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:

5. Select *Sync* to only synchronize data. The synchronization can be performed on measurements of the current day, last week or all data.

6. 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. Once data synchronization is ended the data on the device will be deleted (Figure 21).

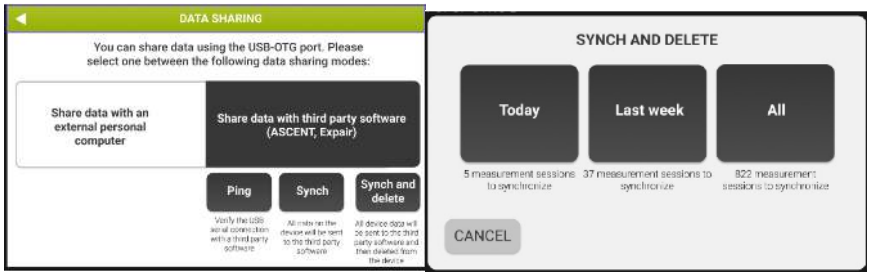


Figure 21 - Synchronization selection

Network

Press Network to share data with third party software (e.g., BreezeSuite) through an Ethernet cable connection.

To connect the device:

1. Enable the network using the slider button on the upper-right side of the display (Figure 22).

2. Insert the information requested to connect the Resmon PRO FULL with the third-party software.
    a. Figure 22 shows the default network parameters; the Resmon Pro will make requests to the third party web service to exchange medical data. The default configuration refers to BreezeSuite default configuration (port 8082)
    b. 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. Simply place a USB drive containing such backup and press the *Import* button.
    c. 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 through the ethernet cable together with the numerical results.
3. Select the Ping button to verify the connection between the device and the third-party software.

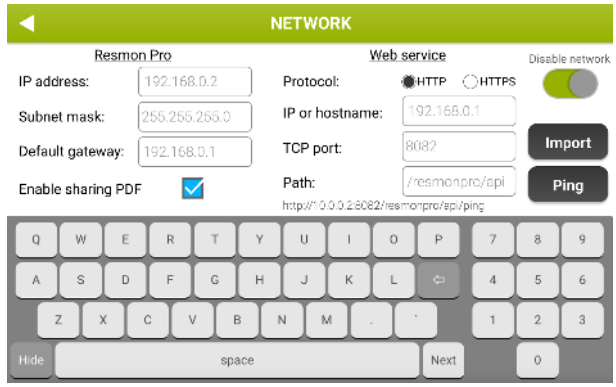


Figure 22 - Network settings

Data imported into the Resmon PRO FULL from a connected third-party software

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)

Verification of the Factory Calibration

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

How to perform the verification of the factory calibration

This option is available in the *Settings panel*. Select *Calibration check* to perform a verification of the factory calibration.

Verification of the FOT factory calibration

Verification of the FOT calibration is accomplished by measuring the resistance and reactance of the Test Object supplied with the device at all stimulating waveforms and comparing them with their counterparts measured during factory calibration.
This Verification is successful when the measured error on impedance at all stimulating waveforms is below 9%. Such value guarantees that the next measurements are accurate within the limits reported in section *Technical specifications*. If the device is not calibrated properly, you will not be allowed to make any FOT measurements on patients. Should this be the case, the device must be recalibrated: contact your local distributor for technical assistance.

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

How to read the code of the Test Object

The resistance and reactance spectra of the Test Object are two lines which theoretical slopes are 0 $cmH_2O \cdot s^2 \cdot L^{-1}$ and 0.17 $cmH_2O \cdot s^2 \cdot L^{-1}$, respectively, and theoretical intercepts of 2.50 $cmH_2O \cdot s \cdot L^{-1}$ and 0 $cmH_2O \cdot s \cdot L^{-1}$, respectively. Their actual values are printed on the Test Object label (the CODE) and are also reported in the Test Object Report supplied with the device.

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

ABCD – EFGH – JKLM – NOPQ – RSTU

where:

A	sign of the resistance spectrum slope (0 = positive, 1 = negative)
BCD	slope of the resistance spectrum (2 digits precision)
E	sign of the resistance spectrum intercept (0 = positive, 1 = negative)
FGH	intercept of the resistance spectrum (2 digits precision)
J	sign of the reactance spectrum slope (0 = positive, 1 = negative)
KLM	slope of the reactance spectrum (2 digits precision)
N	sign of the reactance spectrum intercept (0 = positive, 1 = negative)
OPQ	intercept of the reactance spectrum (2 digits precision)
RSTU	checksum.

For example, this CODE can be:

0000 – 0245 – 0017 – 0001 – 0065

And corresponds to:

Slope of the resistance spectrum	0 $cmH_2O/(L/s^2)$
Intercept of the resistance spectrum	2.45 $cmH_2O/(L/s)$
Slope of the reactance spectrum	0.17 $cmH_2O/(L/s^2)$
Intercept of the reactance spectrum	0.01 $cmH_2O/(L/s)$

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

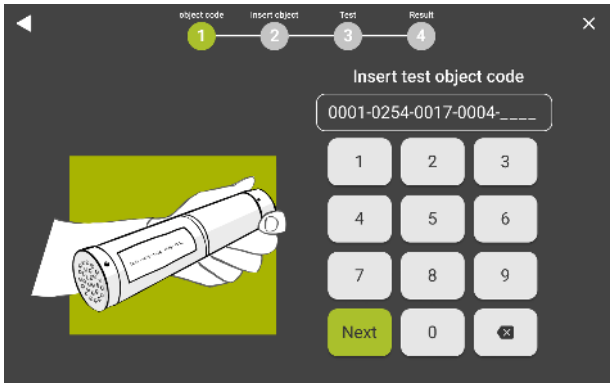


Figure 23 - Insert Code for the Identification of the Test Object

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

Figure 24 - Connection of the Test Object to the device inlet

The duration of the Calibration Verification is 90 seconds + 3 seconds for sensors' zeroing and can be cancelled at any time by pressing *Stop*.
This test is performed for all stimulating waveforms, i.e. 5Hz, 6Hz, 8Hz, 10Hz, 5-11-19Hz and PSRN signals. Then, resistance and reactance spectra are derived and compared with the resistance and reactance spectra measured in factory immediately after calibration and stored into the device.
The Calibration Verification can provide the following results on screen:

- *Test passed*: the FOT Verification has been successful because the measurement has a coherence at all stimulation waveforms that is greater than 95% and the measured impedance has an error within 9%.
- *Failure*: the FOT Verification has not been successful because impedance at least at a given stimulating waveform differs more than 9% from the expected value.

Caution! If the result of the calibration verification is failure or coherence error repeat the test. If it fails again, you will not be allowed to make any measurements on 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 Verification of the Factory Calibration.

The verification of the factory calibration must be checked every day. The verification of the FOT factory calibration is mandatory while the verification of the slow spirometry volumes calibration is optional. If the verification of the FOT factory calibration has not been made yet, you will be noticed to perform it on your Home Screen before starting the measurement session.

Verification of the Slow Spirometry factory calibration (SVC)

The verification of the Slow Spirometry factory calibration consists in measuring increasing flows generated with a 3L calibration syringe and in comparing the resulting volumes with the nominal value of the syringe.
According to the indications of the ATS/ERS guidelines[1] the Verification of the Slow Spirometry factory calibration is successful when the measured error on volume is below 3% of the expected value (i.e. 90 mL in case a 3L calibration syringe is used)
At the end of the FOT calibration check, press the *Make test for SVC* button to start the SVC calibration verification.

The instructions to perform the Slow Spirometry verification will appear on the screen (Figure 25).

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

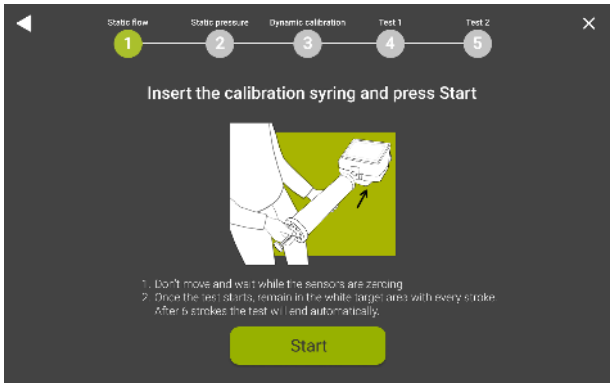


Figure 25 - Instructions for the Slow Spirometry volumes verification

The measurement of the slow spirometry volumes will not be available until a successful verification of the slow spirometry volumes is done.
Connect a 3L volume calibration syringe (not supplied with the device) to the device inlet, make sure that no leaks are present around it and that the syringe is completely empty.

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

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

Press *Start calibration* and wait for 3 seconds during the auto-zeroing of the flowmeter. Move the syringe piston in and out six times and maintain the flow within the highlighted area displayed on screen (Figure 26).
On the right side of the screen a counter will increase automatically at the end of each run together and the calculated inspiration or expiration volume will be displayed in real time. The values of volume outside the recommended accuracy range will be red-colored.

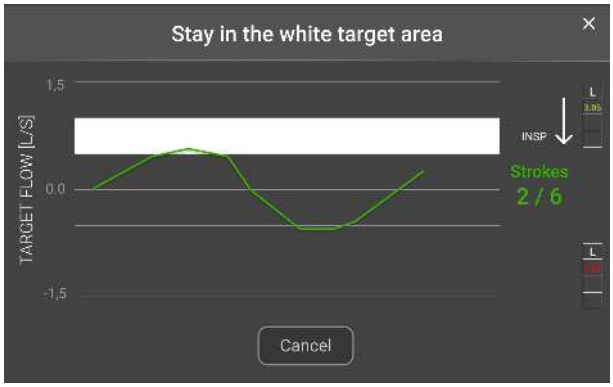


Figure 26 - Example of flow tracing during the slow spirometry volume verification

The verification results are reported as in Figure 27.

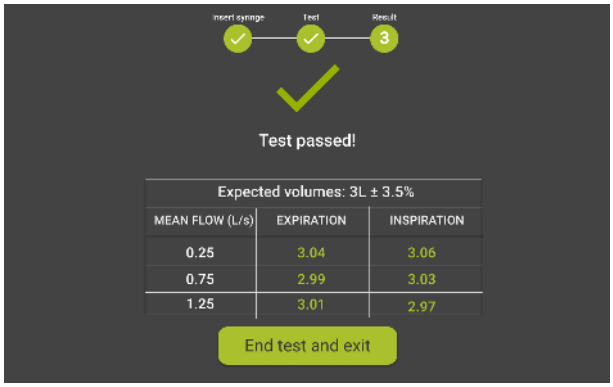


Figure 27 - Slow Spirometry verification results

Results can be:

- *Test passed*: volume measurements are within 90 mL of the 3L syringe, as recommended by international guidelines on volume measurements[2]. Bars on

[2] 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

screen represent the volumes (in liters) measured during each run (Insp = inspiration, corresponds to filling the syringe with air, Exp = expiration, corresponds to emptying the syringe) Press *Continue* to verify FOT calibration.

- *Test failed*: Slow Spirometry volume verification was not successful because at least one of the volumes measured during this procedure was not within 90 mL of the theoretical value (3 L).

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 could be unreliable.

Operating instructions

To perform the user login, select the account you want to use (Figure 28), insert the passcode for the account and press *Next.*

Figure 28 - Account displayed in the Login screen

After the user logs in, the *Home* Screen will be displayed (Figure 29 - Home screenFigure 29). You can always press the *Logout* button ( ) to log-out.

Figure 29 - Home screen

From the *Home* screen:

1. Press the *Settings* button ( ) to change the user settings
2. Press the *Export* button ( ) to export a CSV archive containing all measurement sessions performed with the logged in account

3. Press *Archive* to enter the database.
4. Press *Measurement* to perform a new measurement session.

Change user settings

If you enter the *Settings*, the following page will be loaded (Figure 30):

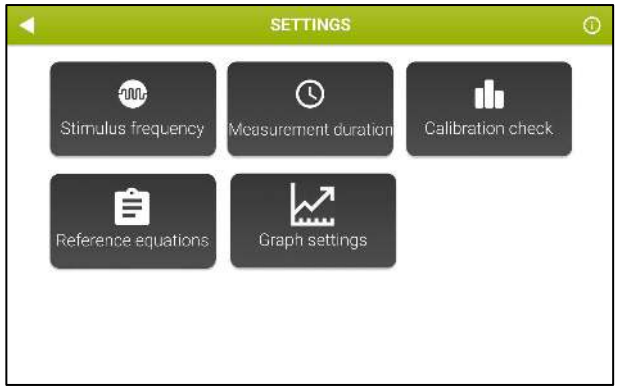


Figure 30 - Settings screen

Stimulus frequency

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

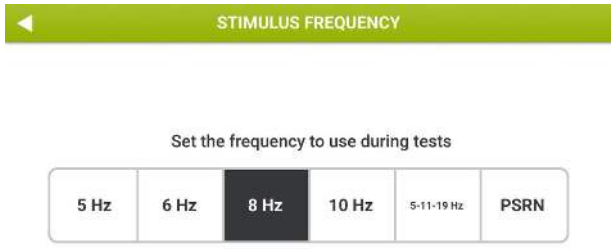


Figure 31 - Selection of the stimulating waveform

The stimulating waveforms available are:

- Sinusoidal signal at 5, 6, 8 or 10 Hz

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

The highlighted button indicates the waveform currently active. Select the desired stimulus and press the *Back button* (◄) to return to *Settings*. The highlighted button corresponds to the current selection. For further information on the choice of the stimulating waveform, see section *Criteria for selecting the stimulating waveform*.

Measurement duration

Press *Measurement duration* to select the maximum duration of the measurement (Figure 32).

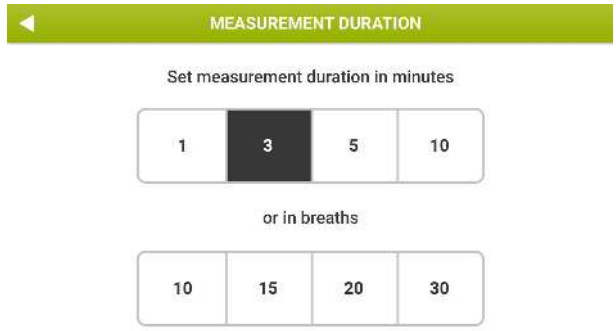


Figure 32 - Selection of the measurement duration

You can select the maximum duration in terms of minutes (available choices are 1, 3, 5 or 10 minutes) or in terms of total number of breaths without artefacts (available choices are 10, 15, 20 or 30 breaths). If you select the latter option (maximum duration in terms of accepted breaths), the measurement will end automatically when the number of breaths set here is reached. The device has a timeout time of 10 minutes if the number of breaths set by the user is not reached.

Note: if the selected stimulus is PSRN, it is not possible to choose the measurement duration, which is instead forced to be 1 minute.

Calibration check

See section *Verification of the Factory Calibration*.

Reference equations

You can choose the set of reference equations used by the device to perform calculations on measured data (Figure 33). For a more in-depth description of the reference equations, see section *Clinical Reports.*

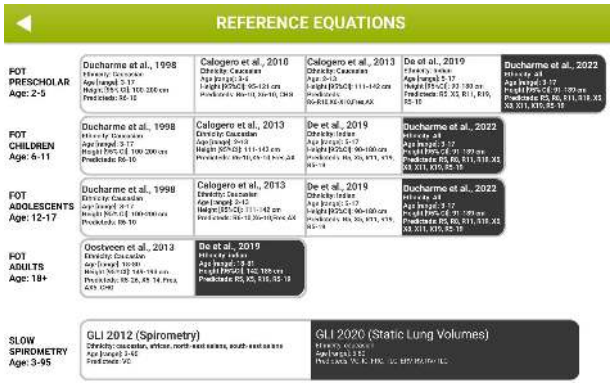


Figure 33 - Choose the set of Reference equations

Info

See section *First log-in and the Admin account*.

Graphs Settings

In this section (Figure 34) you can setup which parameters are to be shown on screen during a FOT measurement and which parameters are to be reported on Trend charts (see section *Trend report*) and Loop charts (see section *Loop representation*).

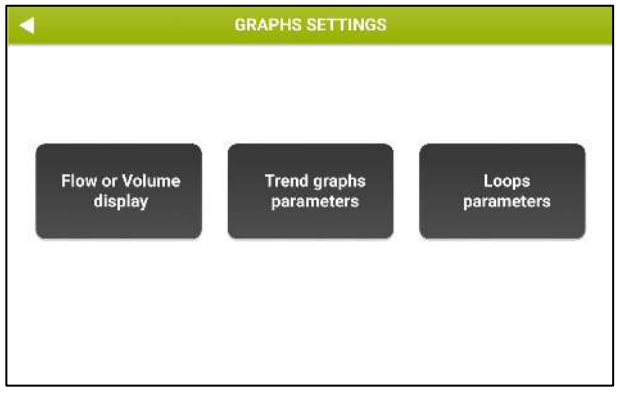


Figure 34 - Graph Settings Options

By selecting *Display Flow or Volume* you can choose to show either Flow or Volume on the screen during the measurement and in the real time measurement screen and in the screen to evaluate the breath selection (see section *Results of a single measurement*).

By selecting *Trend Graph Parameters*, you can choose which parameters are to be displayed on the trend graphs (Figure 35).

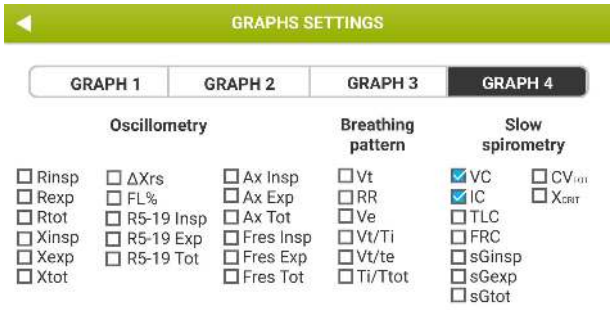


Figure 35 - Trend graph variables selection screen

You can setup up to 4 trend graphs by selecting for each of them 1 or 2 parameters to display.
To select the parameters:

- Press one of the *Graph* buttons
- Select up to 2 variables

If no parameters are selected, the corresponding graph will not be displayed.
The selection will be automatically saved at the closing of the screen.

By selecting *Loops parameters*, you can choose which parameters are to be displayed on the Loops charts (Figure 36).

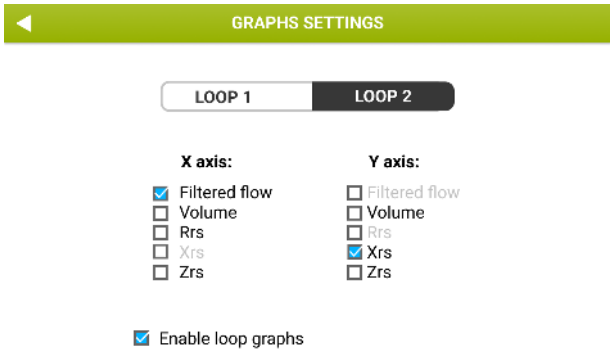


Figure 36 - Loop Parameters setting

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

Note: Before configuring your loops charts, you need to select the *Enable loop graphs* option reported on the bottom part of this screen.

Note: If the *Enable loop graphs* option 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.

Criteria for selecting the stimulating waveform

The default stimulating waveform is 5-11-19 Hz. Single-frequency waveforms (5Hz, 6Hz, 8Hz or 10Hz) allow measuring the within-breath respiratory impedance at three frequencies and, at the same time, provides an estimate of the frequency dependence of resistance and reactance within the limits of accuracy up to 25 $cmH_2O \cdot s \cdot L^{-1}$.
You can change the stimulating waveform from your *Settings* page (see section *Change user settings*) to measure the impedance of the patient at a different frequency.

The choice of the pseudo-random noise stimulating waveform (PSRN) may be useful if you are interested in studying the frequency dependence of resistance and reactance with a frequency resolution higher than that provided by the 5-11-19 Hz signal.

The maximum values of respiratory impedance that can be measured at a specific stimulating waveform within the 10% accuracy limit (as required by international guidelines on FOT equipment) have been established by the manufacturer. They are reported in section Technical specifications and summarized in the Table 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, 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 the measurement, the device notifies you automatically if the limits reported above have been exceeded (see also section *Performing a new measurement* session).

In this case, the measurement is automatically discarded. Repeat the measurement with another stimulating waveform that allows the measurement of impedances higher than those allowed with the current stimulating waveform (see table above). To change the stimulating waveform, press *Settings* from your *Home* page and then *Stimulus frequency* (see *section Change user settings*).

Values of impedance above 25 $cmH_2O \cdot s \cdot L^{-1}$ are unlikely within the intended population. However, if you encounter these values, repeat the measurement and pay attention to the posture of the patient. For further information, see section *Preparing the patient for a measurement*. If you are using a single sinusoidal stimulating waveform or a 5-11-19Hz waveform and the device warns you again that the measured impedance exceeded the limits of accuracy, this measurement has to be considered unreliable and the device should not be used for further FOT measurements on this patient.

Performing a new measurement session

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

A measurement session on a given patient and with a given session label (see below) may be composed of one single measurement or multiple measurements (up to five). If a measurement session includes less than five measurements, you can continue adding new measurements, provided that the last one is performed no later than 20 minutes after the previous one. After this time, the session is automatically closed, and you will need to start a new one.
A session may include the measurement of the slow spirometry volumes only if a successful slow spirometry verification has been performed before during the same day. For further information see section *Verification of the Factory Calibration*.
The measurement of the slow spirometry volumes is not available if the selected stimulating waveform is pseudo-random noise (PSRN).
To perform a new measurement session from the *Home* screen, press the *Measurement* button.
The verification of the factory calibration must be checked every day. The verification of the FOT factory calibration is mandatory while the verification of the slow spirometry volumes calibration is optional.

If the verification of the FOT factory calibration has not been made yet, or if previous verification was unsuccessful (see section *Verification of the Factory Calibration*), you will be noticed to perform it before starting the measurement session (Figure 37).

Figure 37 - Notice to make a calibration check required to make new measurements

You can perform a new measurement session on a new patient or on a patient already in the database.
If the daily verification of FOT calibration has been successful but the slow spirometry verification has not been done or it was not successful, the device will allow you to perform FOT measurements but it will not be possible to carry out slow spirometry measurements. (Figure 38)

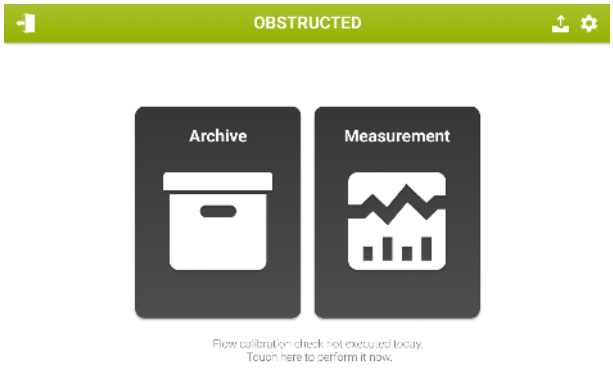


Figure 38 - Notice to make a slow spirometry verification

Performing a measurement session on a patient already in the database

After pressing *Measurement*, the Patient Search screen will be displayed.
Type in the patient information using the keyboard on the screen. You need to enter at least one letter to proceed. Press *Next*. Patients whose surname contains the letters entered are shown in a table format (Figure 39).

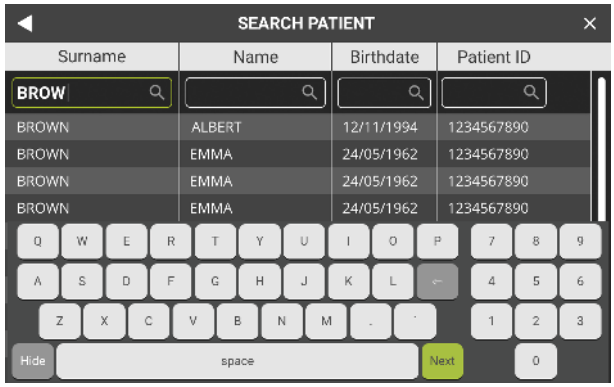


Figure 39 - Results of the patient search

If several results are present, you can scroll down. Press on the row corresponding to the patient to highlight and open the patient file.
Patient's height and weight at the time of the last measurement (these fields are empty in case a new patient has been created) are presented (Figure 40).
To insert or modify data press the correspondent text entry box and enter the new value.
Current room temperature, pressure and relative humidity are provided by the Resmon PRO FULL using the built-in ambient sensors. You can always edit/update these values before proceeding to the next steps.

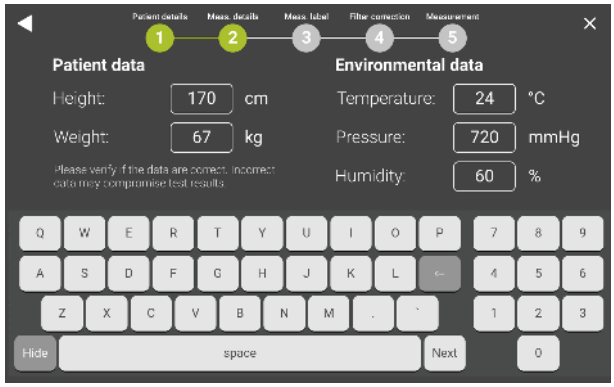


Figure 40 - Edit patient anthropometric data and room conditions

Caution! As recommended by international guidelines, room parameters will be used to apply the BTPS correction to the calculation of slow spirometry volumes. Make sure to enter and/or edit these values correctly to avoid inaccurate results.

Performing a measurement session on a new patient

If the patient is not present in the database, press *Create new patient.* (Figure 41).

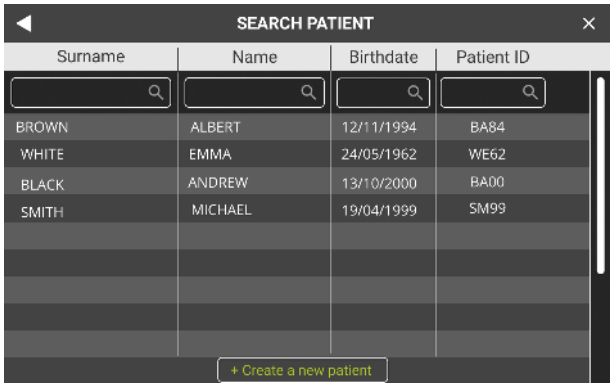


Figure 41 - Archive with the Create new patient button

A new screen allows you to enter the following data for the patient:

- Surname
- Name
- Sex (Male, Female)
- Birthdate (according to the format chosen in *Settings*)
- 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*.

Figure 42 - Patient's data

Press *Next* to accept and to insert the anthropometric data (height and weight) and to edit/update room parameters at the time of visit. Press on the text entry box to activate the

desired field. Current room temperature, pressure and humidity are provided by the Resmon PRO FULL using the built-in ambient sensors. You can always edit/update these values before proceeding to the next steps.
The *Next* button will appear only once both fields are filled up.

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

In case of active connections through USB-cable or ethernet cable with a third-party software with visits scheduled, see *Data Sharing* section, the device will display a screen as in Figure 43.

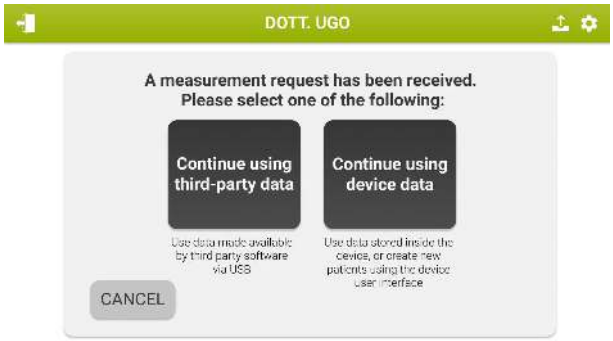


Figure 43 - Visits Scheduled

By pressing the button *"Continue using device data"* it is possible to use the device local database adding a new session of measurements on already existing patients (*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*).

By pressing the button "Continue using third-party data" the scheduled visits will be displayed and can be selected to perform measurements (Figure 44)

Figure 44 - Scheduled Visits

Note: If the "Continue using a third-party software" button has been selected, the list of scheduled and valid visits not yet performed will be maintained on the Resmon PRO FULL even if the ethernet cable gets disconnected thereafter. Every time you press the Measurement button on your Home Screen and some scheduled visits are still awaiting to be performed, the previously described Figure 44 will be shown.

Visits having inconsistency between the third-party software and the Resmon PRO FULL (e.g. Patient ID or credentials) and requiring an action are displayed in red color Figure 45. Selecting those red visits, a pop-up is showed (Figure 45).

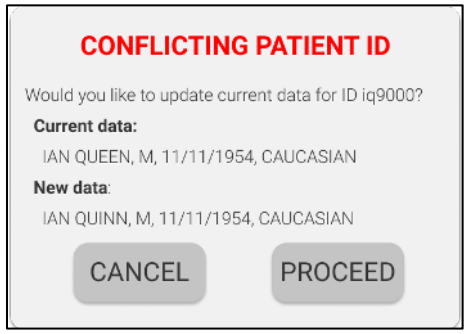


Figure 45 - Pop-up message

Once the measurement session is performed the data **will automatically be saved on the device** ("Archive" session) but **not on the third-party software** where the visits have been scheduled. To share them please refer to *Print, export or share the results*.

Do not modify Patient Credentials on the Resmon PRO FULL, otherwise data sharing of third-party software of such a modified patient session is not permitted, until a new visit is scheduled for the same patient.

Labeling a measurement session

After inserting/reviewing patient and room data, you will enter the screen showed in Figure 46. You can add here a label to the measurement, to easily recognize and recall it later. For example, this label may refer to a measurement performed before or after taking a medication (bronchoconstrictor or bronchodilator).
For further information, see section *Clinical Reports*.

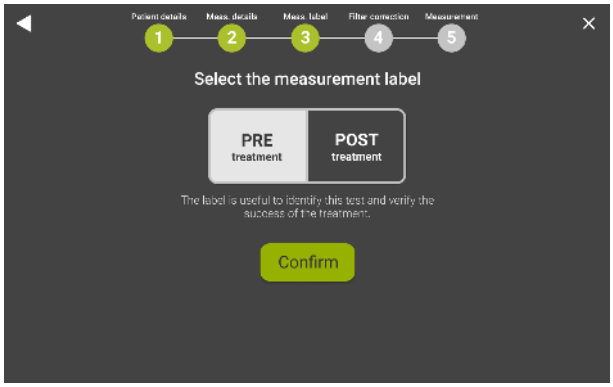


Figure 46 - Measurement Selection Options

Select the desired label for the measurement, PRE or POST; if you select POST, three more options will be displayed: *Bronchoconstrictor*, *Bronchodilator* and *Other…* (Figure 47). Selecting *Other…* will open up a keyboard to type a custom label for this measurement.

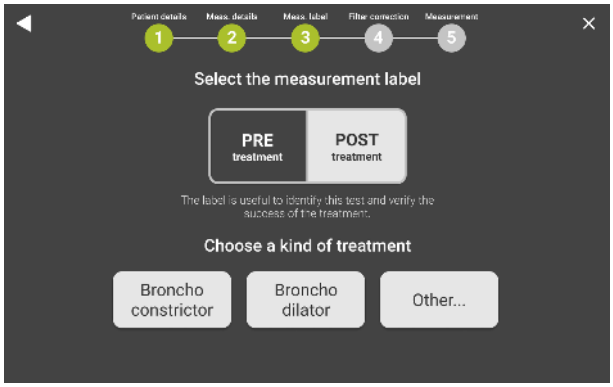


Figure 47 - Post treatment selection options

Note: the device does NOT perform bronchodilation or bronchoprovocation testing.

Preparing the device for a measurement session

You can connect now a single-use bacterial/viral filter to the inlet on the device. The use of bacterial/viral filters is mandatory to perform a measurement.
The selection of a filter with the characteristics reported in section *Disposables* will guarantee a proper connection to the inlet of the device without leaks. To increase the comfort of the patient you may also consider connecting a mouthpiece to the filter with the characteristics reported in section *Disposables*. The use of mouthpieces is not mandatory.
Once the measurement type has been chosen, you access the filter measurement screen (Figure 48). The filter has intrinsic impedance that is added to the patient's own impedance and that can be subtracted at the end of the measurement before displaying the results.

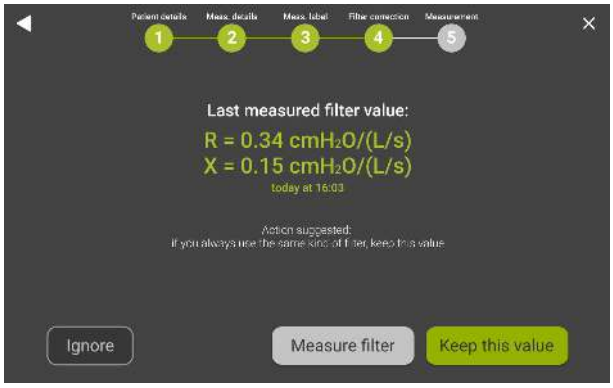


Figure 48 - Filter Measurement

- Select *Keep this value* to apply the filter correction indicated on screen. If N/A is displayed here, no previous value has been measured at the stimulating waveform that you are going to use.
- Select *Measure filter* to measure the impedance of a new filter at the frequency of the stimulating waveform. Insert the filter before pressing this button. Do not attach anything to it. If the measured value is below the range of acceptability (0.1 – 1 $cmH_2O/(L/s)$) you will get the following message: "*Filter impedance very low or missing filter*". If the measured value is above the range of acceptability you will get the following message: "*The filter impedance is outside the recommended range"*.
- Select *Ignore* to not apply the correction for the filter impedance.

Wait for the sensors to reset and filter measurement procedure to complete (Figure 49).

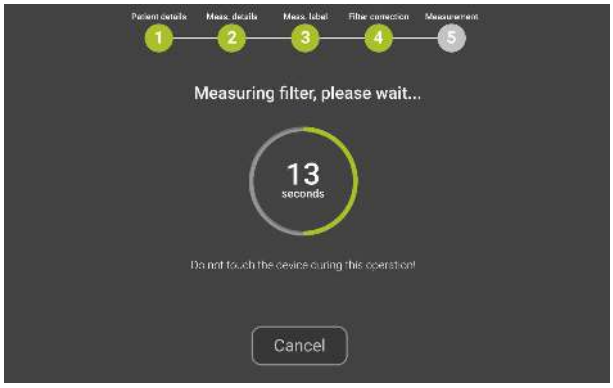


Figure 49 - Sensors auto-zeroing and filter impedance measurement

Caution! Do not touch the device during sensors reset and filter measurement. Do not obstruct the inlet of the device during sensors reset and filter measurement. Any error in sensors reset and filter measurement may cause errors in the identification of breaths, inspirations and expirations, and the computation of breathing pattern parameters.

Caution! If the filter measurement results in a *coherence error,* repeat the measurement. If it still does not succeed, contact the distributor.

Once the sensors are reset successfully and the filter has been measured, the instructions for execution of the measurement will display.
The image and instructions (Figure 50) shown remind you to insert the filter, wear the nose-clip, hold the cheeks, and let the patient breathe normally through the filter. For further information on the use of the filter and the nose-clips please refer to their instructions for use.

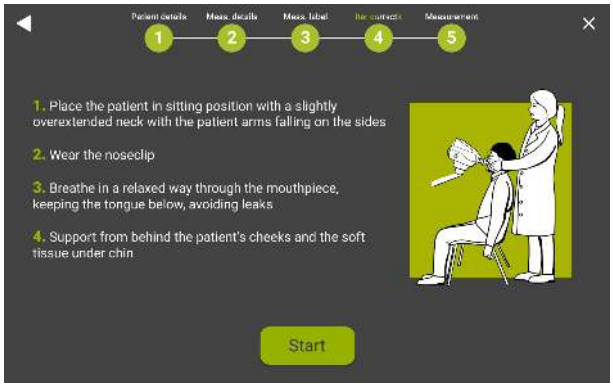


Figure 50 - Instructions for the execution of the measurement

Press *Start measurement* to begin the measurement.

Caution! If the patient fails to use the nose-clip, hold the cheeks or keep proper posture, the measurement may produce inaccurate results. Review the *Correct Posture* section and be aware of the patient's posture for the duration of the measurement.

Caution! Failure to use a filter or using the same filter between patients may cause cross-contamination. If you suspect that the device is contaminated because a patient has not used a filter, contact the distributor. All the components of the breathing circuit can be replaced.

Caution! Throughout the measurement procedure, the actuator will generate the pressure wave stimulus required for lung function measurements. A slight sensation of these oscillations is normal. Moreover, an air blower will continuously remove the exhaled air in order to avoid carbon dioxide accumulation. A slight noise associated with the air moving within the breathing circuit is normal.

Preparing the patient for a measurement session

- Place a chair in front of the device. Be sure a bacterial/viral filter is connected properly to the device.
- The patient should be sitting, back straight and neck slightly flexed upward. Adjust the height of the device so that correct patient position is assured. (Figure 51)

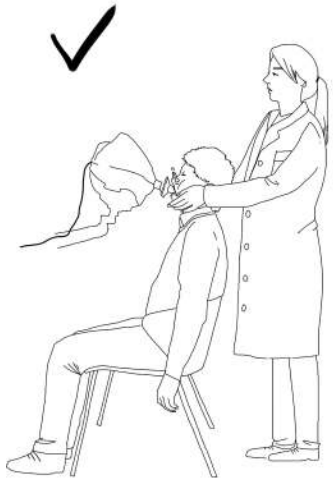


Figure 51 - Correct position for FOT measurement

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.

Caution! Not using the nose-clip may cause inaccurate measurements. If the tidal volumes are much lower than expected, repeat the measurement paying particular attention to avoid leaks from the nose and mouth.

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

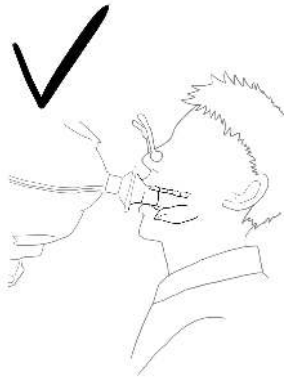


Figure 52 - Correct position of the tongue during the FOT measurement

Caution! If the resistance values are much higher than expected, repeat the measurement paying particular attention to occlusions. Observing large variations in real-time reactance can indicate that the tongue or teeth are obstructing the airway.

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

Caution! Not holding the patient's cheeks may cause inaccurate measurements.

Performing a measurement session

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

For problems related to performing a measurement session, refer to section *Troubleshooting.*

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 53).

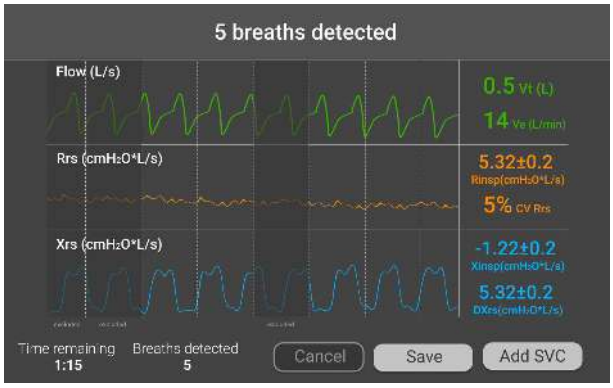


Figure 53 - Real-time tracings for volume and impedance

The plots show, from top to bottom:

- Flow [L/s] or Volume [L] depending by the user settings
- Resistance Rrs [$cmH_2O/(L/s)$]
- Reactance Xrs [$cmH_2O/(L/s)$]

In case of multi frequency stimulating waveform, the tracings displayed on the screen during the measurement are those at the lowest frequency (5 Hz).
On the bottom section of the screen, the following values are reported:

- Remaining time to the end of the measurement (*mm:ss*),
- Number of accepted breaths

On the right section of the screen the following values are reported:

- Mean tidal volume (Vt) of the accepted breaths and mean minute ventilation (Ve)
- Mean inspiratory resistance (Rinsp) of the accepted breaths and the mean coefficient of variation of total resistance (CoV Rrs)
- Mean inspiratory reactance (Xinsp) and the difference between inspiratory and expiratory reactance (ΔXrs) of the accepted breaths.

For these last two parameters, the standard deviation is reported next to the value.

Note: ΔXrs is displayed only if the 5Hz or 5-11-19Hz stimulating waveform are used.

The number of accepted breaths starts from -3, as the first 3 breaths are not used for the calculation of impedance but only to optimize the amplitude of the stimulating waveform to the patient being tested. This also allows the patient to adapt to the device with a normalized breathing pattern.
If a successful slow spirometry verification has been performed on the same day, the device will enable the measurement of the slow spirometry volumes after five breaths are accepted. A button *Add SVC* will appear on the bottom right side of the screen (Figure 53). At this point, you may choose to either continue with the measurement of the FOT parameters until the timer countdown is completed or until you reach the selected number of accepted breaths (see section *Change user settings*) or you can switch to the measurement of slow spirometry volumes (see section *Measurement of slow spirometry*). Any time, you can press *Save* to end the measurement.

Note: the minimum number of breaths required after the amplitude optimization for the results to appear is five. If the measurement is stopped before five accepted breaths an error screen will allow you either to *Restart* the measurement or to *Exit* and return to the *Home* screen.

Note: if the measurement of the slow spirometry volumes is not enabled (i.e. the button measure SVC does not appear on screen after five accepted tidal breaths), please perform a successful slow spirometry verification first (see section *Verification of the Factory Calibration*) and ensure that your device has been enabled for slow spirometry measurements. For further information contact your distributor.

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 until you reach the selected number of accepted breaths or you can switch to the measurement of slow spirometry volumes (see section *Measurement of slow spirometry volumes*). Any time, you can press *Save* to end the measurement.

Note: the minimum duration of a PSRN measurement required for the results to appear is 30 seconds. If the measurement is stopped before 30 seconds an error screen will allow you either to *Restart* the measurement or to return to the *Home* screen.

Note: the measurement of the slow spirometry volumes is not allowed with the PSRN stimulating waveform.

Measurement of slow spirometry volumes

Current slow spirometry volumes calculated and displayed by the device are the inspiratory capacity (IC) and the slow vital capacity (SVC).
After pressing *Add SVC* (see section *Measurement of FOT parameters*) the device will guide you through the measurement of these parameters (Figure 54). The volume tracing will be displayed on the screen as a solid line.

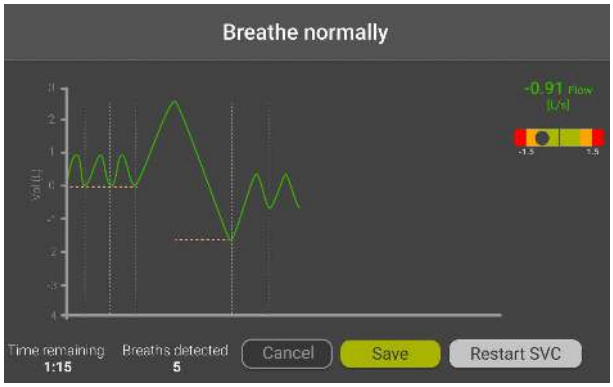


Figure 54 - Slow Spirometry screen

First, the patient is required to make at least three tidal breaths for the calculation of the tidal breathing baseline. When such baseline becomes stable, it will be displayed with a horizontal yellow line and, on top of the screen, the message “Do VC maneuver” will appear, indicating that the device is ready to record the slow spirometry volumes.

Caution! Ensure the patient performs at least 3 tidal breaths before starting the slow spirometry maneuver, otherwise the results may be inaccurate.

Caution! Always wait for the device to display the message “Do VC Maneuver” before asking the patient to start the slow spirometry maneuver, otherwise the results may be inaccurate.

Caution! Do not ask the patient to make more than one slow spirometry maneuver within each measurement, otherwise the results may be inaccurate.

The Slow Spirometry maneuver consists of a gentle deep inspiration from end expiratory volume until maximal volume is reached (this phase is used to calculate the IC), followed by a gentle expiration until no more air can be blown out (this phase is used to calculate the SVC).
A colored panel on the right side of the display will assist you in letting the subject maintaining tidal flows. A little ball moves from right to left (and vice versa) of such panel to show if the flow is getting out of tidal values range (Figure 55). The current flow values are displayed on the top of this panel using the same colored-fashion criteria.

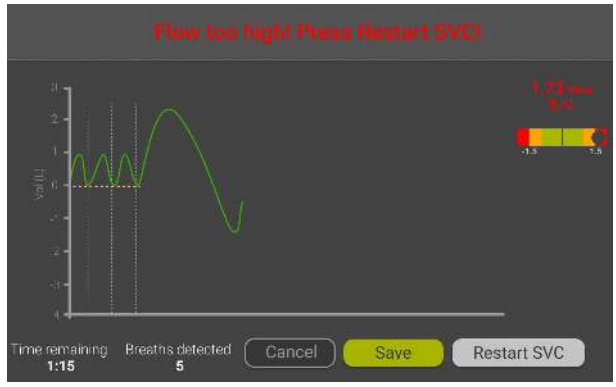


Figure 55 - SVC with high flow

Note: if the patient's airflow is above 1.6 L/s during the maneuver (the flow value is displayed on the right part of the screen), the device will warn you with the following message "*Flow too high*". You need to repeat the maneuver. Ask the patient to breathe more slowly.

At the end of this phase, the patient is required to return to breathe normally at his/her operating volumes and make at least one more tidal breath. When such tidal breath is done, a horizontal yellow line is displayed on screen.
If you need to cancel and to repeat the maneuver, press *Restart SVC*. This will cancel the current maneuver. At any time, you can press *Save* to end the measurement.
At the end of each measurement, a summary of the results will be displayed on the screen. See section *Results of a measurement session*.

Presentation of the results

Results of each measurement can be reviewed on screen at the end of the measurement. The results will include FOT data and, if available, slow spirometry volumes and loops charts.
You can also always review the saved measurement sessions by browsing the database (for further information, see section *Browsing the database*).

Caution! If the measured impedance is outside the 10% accuracy limit at the selected stimulating waveform, at the end of the measurement you will be notified with a caution message and you will not be able to save the measurement. Go to the *Home* page. Select a stimulating waveform that allows the measurement of higher impedances, then repeat the measurement. For further information, see section *Criteria for selecting the stimulating waveform.*

The presentation of resistance and reactance data will vary depending on the selected stimulus. If you have chosen a single frequency stimulating waveform (5, 6, 8 or 10Hz), the results are reported as in Figure 56.

Figure 56 - 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 is the predicted value of resistance while the solid line is the upper limit of normality (ULN) based on the selected reference equations. In case the reference equations have been disabled (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 is the predicted value of reactance

while the solid line is the lower limit of normality (LLN) based on the selected reference equations. In case the reference equations have been disabled (see section *Change user settings*), the predicted value and the LLN will not be displayed.

- If you used a stimulating waveform at 5 Hz, 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 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 green part of the bar represents the normality range, the red part indicates the presence of expiratory flow limitation.

You can add a note to the session by pressing the *Comment* button ( ). 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 57). For further information on the contents of the clinical reports, see section *Clinical Reports*.

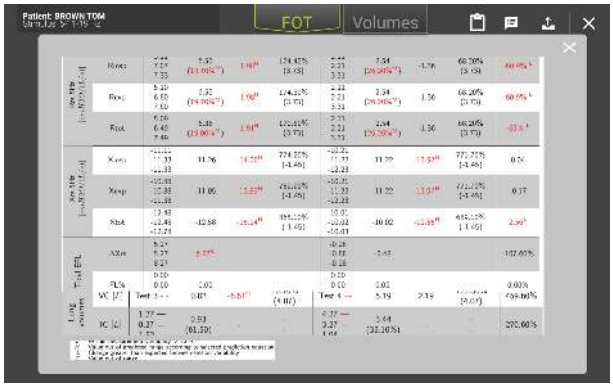


Figure 57 - Popup showing the results of the measurement session as displayed in the clinical report

Note: the measurement session will remain open for 20 minutes and you can still add single measurements to that session.

Adding a new measurement while performing a measurement session

You can add a new measurement to the open session by pressing the button *Add measurement* (up to five measurements can be added to a given session) or end the current session by pressing the *Close* button ( ).

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

In addition to the results displayed for a single frequency stimulating waveform (Figure 56) an additional graph is displayed on the bottom left of the screen (Figure 58).

Figure 58 - 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, inspiration is selected (INSP) and values of mean inspiratory 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.

Pseudo-random noise stimulus (PSRN)

The results are reported as in Figure 59.

Figure 59 - 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.

Results of a measurement session

Each single measurement is automatically added to a measurement session. Pooled results of a measurement session are displayed on screen after reviewing data from each single measurement performed or they can be recalled from the device database.
The results of a measurement session displayed on screen include a summary of FOT parameters measured during the session, a summary of the slow spirometry parameters, if measured, and loop charts of the selected parameters.
Figure 60 shows the results of a FOT measurement session with five single measurements. The top side of the screen reports patient name and the stimulus type used during the measurement session.

Figure 60 - FOT results of a measurement session

The measurement session is identified in the right portion of the screen, with a header consisting of Label and date of the measurement, followed by the Coefficient of variation (CoV) of the session. The reported CoV represents the within-session variability of the session. The single measurements are listed beneath the header.
Even if five measurements are performed, a maximum of three measurements can be selected, and only three dots will be plotted. By default, the three measurements that minimize the within-session variability will be selected.
You can always select or deselect a single measurement by pressing the corresponding button number on the right side of the screen. The resistance and reactance bars will

update automatically and the CoV of Rtot will change based on the selected measurements.

Guide to the selection of the FOT measurements within a session

Note: ERS technical standards on FOT recommended maintaining the *within-session* variability of Rtot below 15% for children and 10% for adults. Values above 15% will be highlighted on screen

The three most reproducible measurements are automatically selected. You can always select or deselect a single measurement by pressing the corresponding button number on the right side of the screen.

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

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.

Results of a single measurement

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

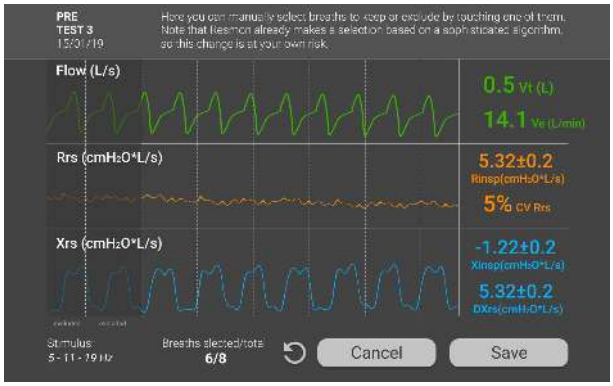


Figure 61 - Result of a single measurement

The breaths that were automatically excluded by the Resmon PRO FULL for the computation of mean parameters are shaded in this screen. You can manually select or deselect breaths to keep or exclude them by tapping them.
The values of the parameters displayed on the right portion of the screen will automatically update when you select/deselect a breath.
You can always reset to the original breath selection made automatically by the Resmon PRO FULL by pressing the Reset button ( ). At the end of the selection you can keep your selection by pressing *Save* or discard it by pressing *Cancel*.

Loops charts

If enabled in the *User Settings* (see section Graphs Settings), press the *Loop* tab to switch from FOT results to Loop charts. The charts of the selected parameters are displayed as in Figure 62.

Figure 62 - Loop Charts

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

Summary of a slow spirometry measurement session

If the patient has performed a slow spirometry maneuver, the results are reported as in Figure 63. Press *SVC* tab to switch from FOT results to SVC results.

Figure 63 - Results of a Slow Spirometry measurement

The maximum Slow Vital Capacity (VC) with its percent predicted value (%pred) and the mean Inspiratory Capacity (IC) among the selected measurements of the session with the correspondent within-session CoV (CoV%) are reported.
By default, the three measurements that minimize within-session CoV of IC will be selected. You can always select or deselect a single measurement by pressing the corresponding button number (*TEST1*, *TEST2*, etc.). The mean VC and IC will update automatically.
Each SVC plot reports also the FRC values as a horizontal dotted line.

By selecting the CV_{FOT} button a chart showing the reactance versus the exhaled volume during a slow spirometry maneuver is displayed (Figure 64).
The Closing Volume measured by FOT (CV_{FOT}) is the volume at which the reactance changes its slope becoming more negative (this reactance value is named X_{crit} and is identified on the chart by a blue dot). CV_{FOT} is the volume capacity point where airways derecruitment initiates.
X_{crit} is calculated automatically following the algorithm described in *Nilsen et al, J App Physiol, 2019*, but can be manually modified by the user, by moving the cursor displayed on the chart on the left or the right using the two arrow buttons on the bottom-left side of the screen or selecting on the graph the desired point. Press SAVE to confirm the selection, BACK to return to the previous screen and the counterclockwise arrow to revert to the automatic selection of X_{crit}.
X_{crit} and CV_{FOT} are displayed on the right side of the chart, in blue if the values are automatically calculated by the device or in purple if they have been recalculated after a manual adjustment of the X_{crit} point.
If more than one slow spirometry maneuver has been performed in a given measurement session, the buttons on the bottom side of the screen allow to move from one maneuver to the other.

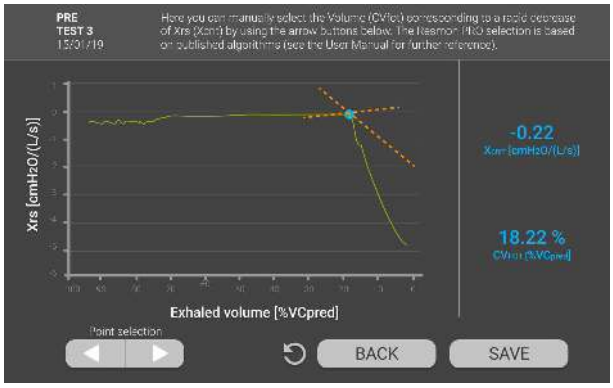


Figure 64 - Results of a Slow Spirometry measurement

Add absolute volumes (TLC or FRC) for the calculation of lung volume and specific Conductance

You can input a value of total lung capacity (TLC) or functional residual capacity (FRC) measured with an external medical device to a measured slow vital capacity maneuver by selecting *Add TLC/FRC* in the screen of the results of a Slow Spirometry measurement and entering the value in liters in the field that will appear on the screen.
The input of TLC will allow the calculation and the inclusion in the clinical report of the following parameters according to the formula reported below:

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

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

By default, the highest measured VC volume is selected among those performed in a measurement session. For the calculation of mean IC, the three most reproducible measurements are automatically selected. You can always select or deselect a single measurement by pressing the corresponding button number at the bottom of each graph.

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

Compare results of two measurement sessions

The results of the current session can be compared with a new session or with a session previously saved in the database.
You can start a new session to compare with the current one by pressing *New session*.
You can compare the current measurement with a previous session by pressing *Select a previous session to compare.* A list of sessions is displayed, identified by Label, date, time, coefficient of variation (CoV) and number of FOT and SVC measurement. You can select a session from the list by pressing on it (Figure 65).

Figure 65 - List of sessions to compare

The results of the two sessions are reported in different colors, following the legend displayed on the bottom right portion of the screen.
You can select or deselect single measurements of both sessions, and the results will update accordingly.

Print, export or share the results

If you press the *Export* button ( ) you can print, export/share the PDF of the clinical report created on the device screen or export all datafiles (Figure 66) of the measurement, including also the PDF of the clinical report.

Figure 66 - Print or export the clinical report

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

Caution! The printed report contains 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.

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

If there is not enough space on the USB memory you will get the following message:

Not enough disk space. Please, free some memory on the USB device and try again or use a different USB memory with more free space.

Press *Back* to get back to the Export Page.

Caution! The USB drive contains 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.

- Select *Export Report and Datafile* to export the session data. An archive (.tar file) will be exported for each measurement of the session.

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

- Select *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.

- Select *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 67 - Share data with third-party software
(Left – using USB-OTG Cable, Right – using ethernet cable)

Note: 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 breath selection of a measurement **Restech** suggests performing it before sharing the session with the third-party software.

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

Description of exported data

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

1. *.json* file

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

2. *.dat* file

This file includes raw data sampled or calculated at 200Hz. The meaning and header of each column change according to the stimulating waveform used for the measurements, as reported in the following tables (Table 6, Table 7, Table 8).

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 6

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 7

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

Table 8

3. *.mxn file*

This file is organized in a n-by-14 matrix, where each row represents the n-th breath detected by the device during the FOT measurement while 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 (flag value: TRUE) or not, respectively (Figure 1Figure 68). The remaining 10 columns reports flags values that are used by the software to identify measurement artifacts. Unless a breath has been discarded, the beginning of the inspiratory phase coincides with end of expiratory phase of the previous breath.

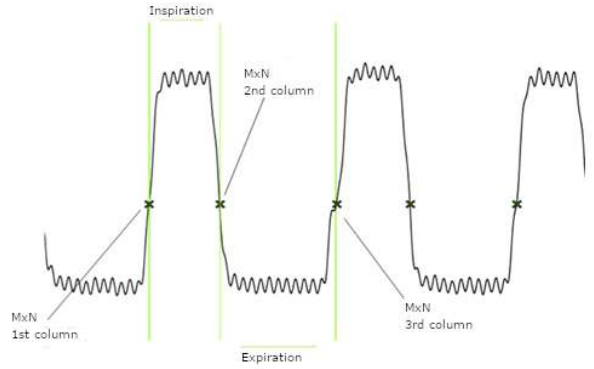


Figure 68 - Flow (from the .dat file) with superimposed mxn points for a breath

4. *.tr file*

This file contains the average tracings of Volume, Resistance, Reactance and their standard deviation as a function of time (Figure 69). 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.

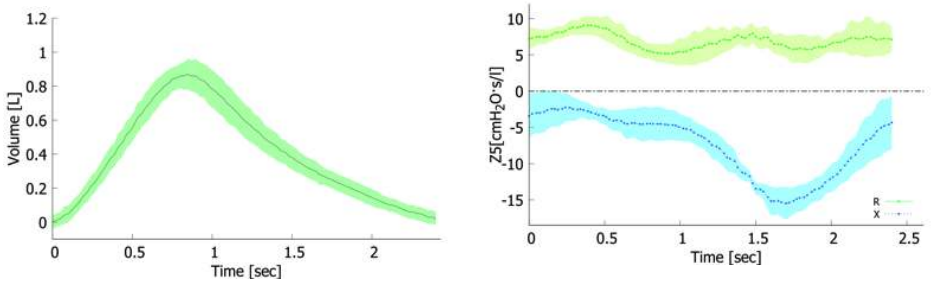


Figure 69 - Left: Average Tidal Volume and Standard deviation. Right: Average Resistance and Reactance and their standard deviations (obtained from a .tr file)

5. _VC.dat file

This file is only present if a slow spirometry maneuver has been performed. It includes raw data sampled or calculated at 200Hz during the maneuver. The meaning and header of each column will change according to the stimulating waveform used for the measurement, as reported in the following tables (Table 9, Table 10). These VC files are not available if a PSRN stimulating waveform was used since it is impossible to perform an SVC maneuver with such stimulus.

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 9

Multi frequency (5-11-19Hz) stimulating waveform	
Column Title	**Parameter**
Pressure	Raw Pressure
Flow FOT	Raw Flow
Flow SVC	Flow calibrated for SVC
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
Volume	Raw Volume
#	Sample Counter

Table 10

6. _VC.mxn file

This file is organized in a n-by-14 matrix, where each row represents the n-th breath accepted by the device during the slow spirometry maneuver, while 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(flag value: TRUE) or not, respectively (Figure 68).The remaining 10 columns reports flags values that are used by the software to identify measurement artifacts.

Browsing the database

From the *Home* screen press the *Archive* button to enter the database.

Search for a patient

A table will be displayed with the list of all patients present in the database (Figure 70 - Patients listing).

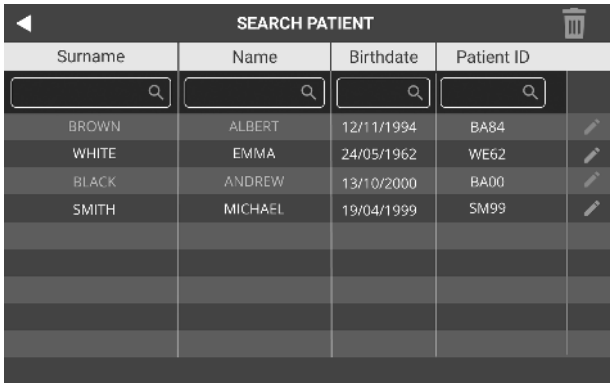


Figure 70 - Patients listing

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, Date, Ethnicity, Patient ID).

By pressing the *Delete* button ( ), you can choose the patients to delete from the database by checking the boxes that will appear next to the patient and then pressing the red button to confirm. (Figure 71)

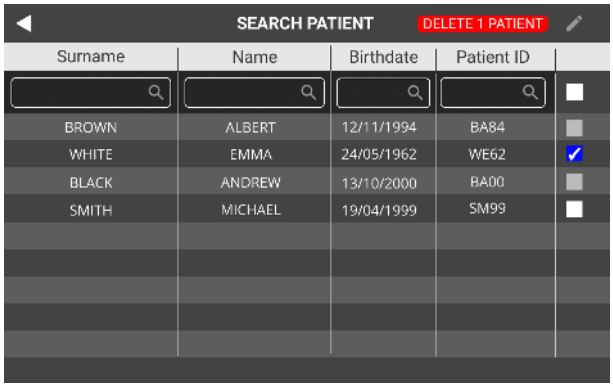


Figure 71 - Delete patient

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

Caution! Once confirmed, you cannot undo this operation.

Caution! By deleting a patient, you will also delete all his measurements.

Select the measurement session to recall

Once you have selected one patient from the database, a table with the list of all the sessions performed by that patient will be displayed.
For each measurement session the following details are reported (Figure 72):

- date and time of the measurement,
- the type of stimulating waveform,
- the session label,
- the number of measurements included in each session
- a note describing if the slow spirometry was performed
- the name of the account that performed the measurement

To select a measurement session, press the corresponding table row. A summary of the measurement session will be displayed. For more information see section *Results of a single measurement*.

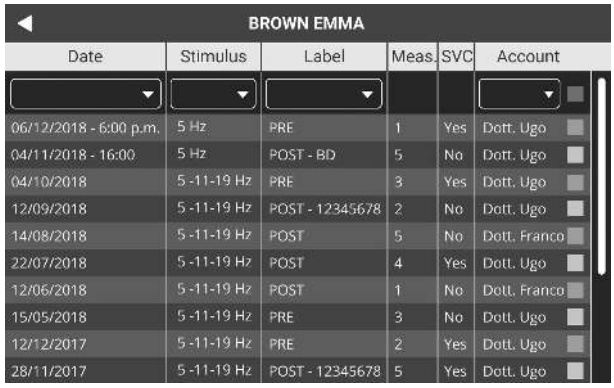


Figure 72 - Session results

For problems related to browsing the database, refer to section *Troubleshooting*.

Plot trend graphs

The device allows you to plot up to 4 trend graphs displaying up to 2 parameters each according to the selection set in the user settings (please refer to section *Graphs* for a detailed description).

To plot trend graphs, select a patient and use the corresponding checkboxes on the right of the table reporting the session results for the selection of the session to include (Figure 72).

After the selection of the first session, the device will automatically select all the other sessions performed using the same stimulating frequency and a *TRENDS* button will appear on the upper right part of the screen (Figure 73). You can deselect a previously included session by touching the checkmark in the checkbox. You can select/deselect all the available measurement using the checkbox that will appear on the filter line of the table.

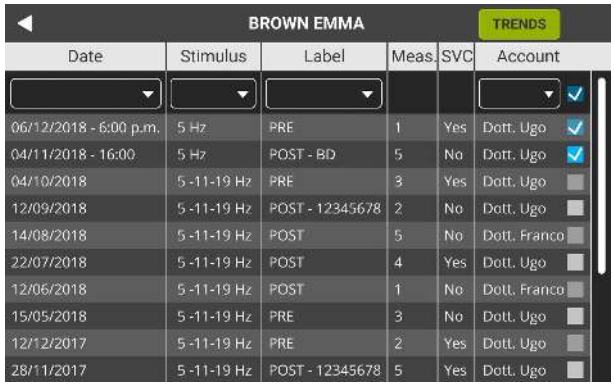


Figure 73 - Selection of sessions to be included in trend graphs

The selection of TRENDS will move you to the trend screen (Figure 74). 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.

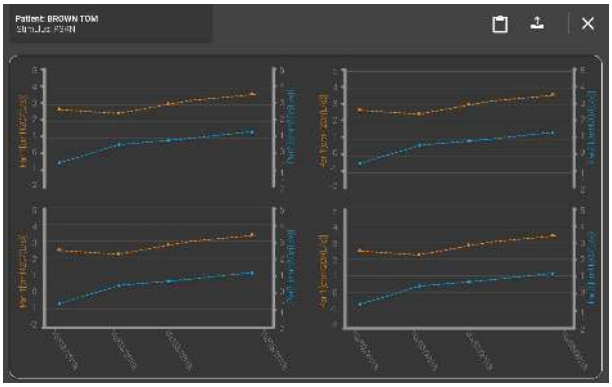


Figure 74 - Trend screen

By pressing the *Export* button ( ), you can print, export/share the PDF of the clinical report created on the device screen or export all datafiles (Figure 66) of the measurement, including also the PDF of the clinical report.

Clinical Reports

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

1. Personal data
2. Measurement details
3. FOT charts
4. Loops charts (optional)
5. Slow spirometry data (optional)
6. Numeric results
7. Footnotes

Note: in single-measurement reports, the mean, standard deviation and coefficient of variation are *intra-test*, in test-session reports they are *between-tests.*

1. Personal data

This section reports patient information (Figure 75).

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

Non-anonymized data Anonymized data

Figure 75 - Personal data section

If data are anonymized (Figure 75) in the *Account settings* (see section *Accounts*) the following personal data will not be displayed: Surname, Name, ID and Birthdate.

2. Measurement details

This section includes information and details related to the measurement session (Figure 76).

		BTPS3				
Age $[Years]$		30.1				
Weight $[kg]$		82.0				
Height $[cm]$		182.0				
BMI $[Kg/m^2]$		24.76				
		Date	Z filter $[cmH2O/(L/s)]$	SELECTION		
				FOT	VC	IC
TEST 1		09/10/2020 15:54	-	√	√	√
TEST 2		- -	-	-	-	-
TEST 3		- -	-	-	-	-
TEST 4		- -	-	-	-	-
TEST 5		- -	-	-	-	-
Account		USABILITY_TESTER				
Prediction Equation	FOT	Oostveen et al. 2013[A]				
	SVC	GLI 2012				
Software version		21.3.0				

Figure 76 - 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). 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 section Change user settings) and slow spirometry volumes (if available)
- The software version used to collect data of the measurement session

Reference equations

Reference equations allow the determination of the normal range of respiratory parameters. Several reference equations are available that cover different age ranges and ethnicities that for the patients, see *Reference equations paragraph* in *Change user settings* section. They are summarized in Table 11 and all of them are taken from studies published on peer reviewed international journals. It is possible to completely disable reference equations for a given account, see section *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, 2019	Children (5-17 yrs old)	- Resistance at 5, 11 and 19Hz - Reactance at 5, 11 and 19Hz - R5-19

Ducharme et al, Chest, 1998 (default)	Adolescents (8-17 yrs old)	- Resistance at 6, 8 and 10Hz
De et al, Lung India, 2019	Adults (18-81 yrs)	- Resistance at 5, 11 and 19Hz - Reactance at 5, 11 and 19Hz - R5-19
Oostveen et al, Eur Respir J., 2013 (default)	Adults (18-84 yrs)	Resistance between 5 and 23Hz Reactance between 5 and 13Hz Resonant Frequency (Fres)
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)
Quanjer et al, Eur Respir J, 2012 (GLI)	Children and Adults (3-95 yrs old)	- Vital Capacity (VC)
Ducharme et al., Pediatr Pulmonol, 2022	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

Table 11

* 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.

3. FOT charts

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

Refer to Figure 77.

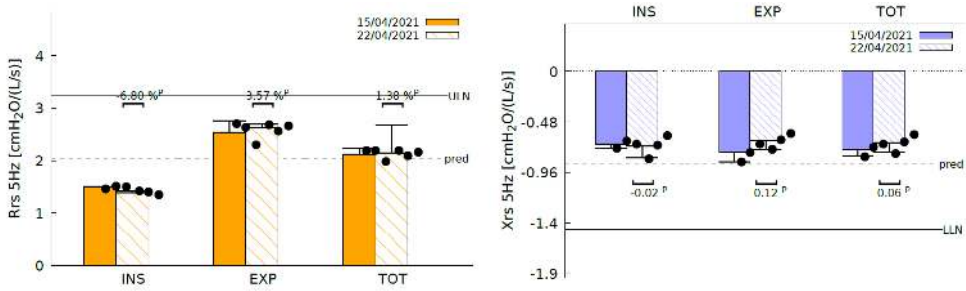


Figure 77 - Bars for resistance and reactance

- Bars on the left chart of Figure 77represent 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 session*).
- 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 a 5 Hz stimulating waveform, an additional graph on the bottom of the page is displayed (Figure 78). 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 cmH2O/(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.

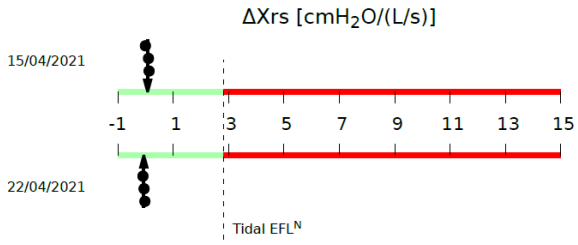


Figure 78 -Expiratory Flow Limitation (EFL) during tidal breathing

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

In addition to the charts reported when a single frequency stimulating waveform is used (Figure 77 and Figure 78) where data are the resistance and reactance at 5Hz), a new chart with values of resistance (orange solid line) and inspiratory reactance (blue solid line) at the frequencies of the stimulating waveform is reported at the bottom of the page (Figure 79). Shown values may refer to the inspiration, expiration or whole breath depending by your selection on the results screen before the exportation (see also section *Performing a new measurement session*). The default setting is inspiration.
Results from the single measurements are reported as dashed lines. Error bars at each stimulating frequency represent the standard deviation of the selected single measurements. Black lines represent the upper limit of normality for the resistance, and the lower limit of normality for the reactance, based on the selected reference equations (for further information see the previous section).
In comparative clinical reports, the chart of each measurement session is identified by its label.

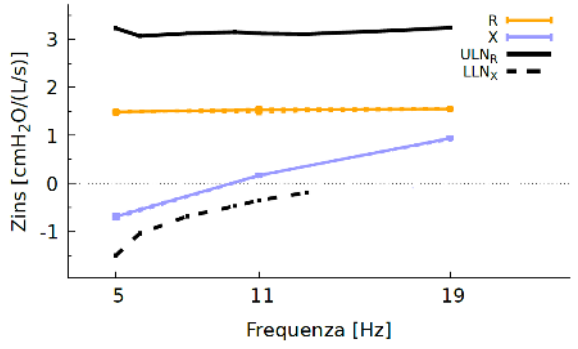


Figure 79 - Inspiratory resistance and reactance spectra

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

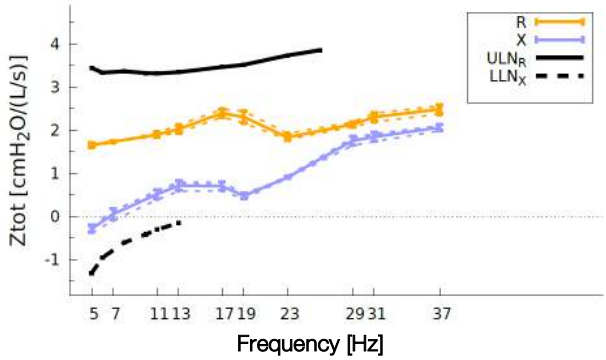


Figure 80 - Inspiratory resistance and reactance spectra in a PSRN measurement

Figure 80 shows an example of the chart reported on the clinical report when a PSRN stimulating waveform has been used. Solid lines represent the mean inspiratory resistance (orange) and reactance (blue) of the measurement session. Results from the single measurements are reported as dashed lines. Error bars at each stimulating frequency represent the standard deviation of the selected measurements. Black solid lines represent the upper limit of normality for the resistance and the lower limit of normality for the reactance, based on the selected reference equations (for further information see the previous section). When a PSRN stimulus is used the device uses the coherence as a data quality index. The symbol *X* indicates the data points with a coherence < 0.95.
In comparative clinical reports, the chart of each measurement session is identified by its label.

4. Loops 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 81).
A maximum of two loops can be reported in the clinical report (see section *Graphs Settings*).

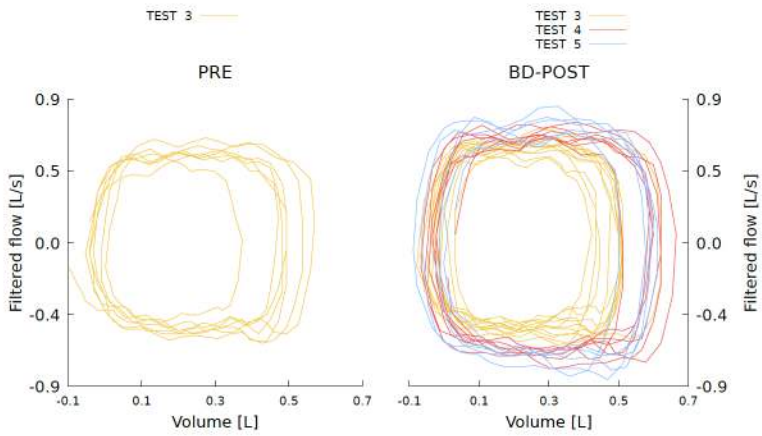


Figure 81 - Loop Charts on Clinical Report

5. Slow spirometry data (optional)

This section of the clinical report is available only if at least one slow spirometry maneuver has been performed within the selected measurement session. Slow spirometry data are reported both as a chart and in table format (see Figure 82 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.

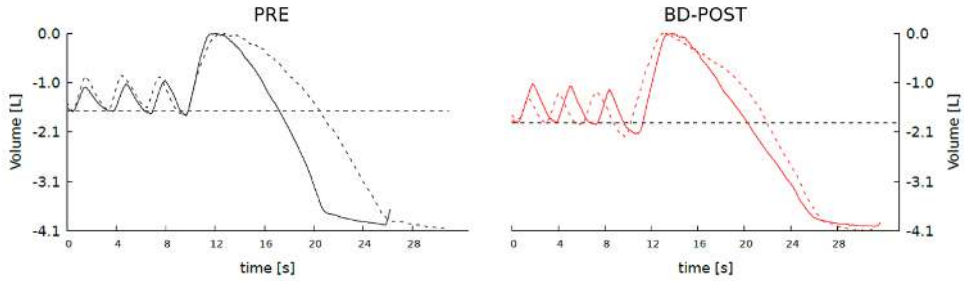


Figure 82 - Slow Spirometry chart

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*

+ if FRC is not manually entered by the user, it is calculated from the other volumes

For the slow vital capacity (VC) and the expiratory reserve volume (ERV), results are reported as follows:

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

For the inspiratory capacity (IC), functional residual capacity (FRC), residual volume (RV) and RV/TLC results are reported as:

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

For the total lung capacity (TLC) results are reported as follows:

- Value manually entered by the user
- 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

6. 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

Caution! The accuracy of breathing pattern parameters is 10%. Breathing pattern parameters should be used only for an overall evaluation of the quality of the 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.

7. 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 subjects 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
(AX, Fres): the stimulus is 5-11-19 Hz and the estimated Fres is greater than 19.

K: Resonant frequency above 37 Hz. AX calculation limited to 37 Hz
(AX, Fres): the stimulus is PSRN and the estimated Fres is greater than 37.

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*
In comparative reports of sessions “PRE” and “BD-POST” when a given frequency has CHG for Rtot :40% and for Xtot: +50% (only if the difference is > 0.2) and AX 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

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

1. Personal data

This section reports patient information (Figure 75).

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

2. Trend charts

The first page of the trend report may present up to 4 trend graphs depending by the user settings (see *Graphs* section and Figure 83).

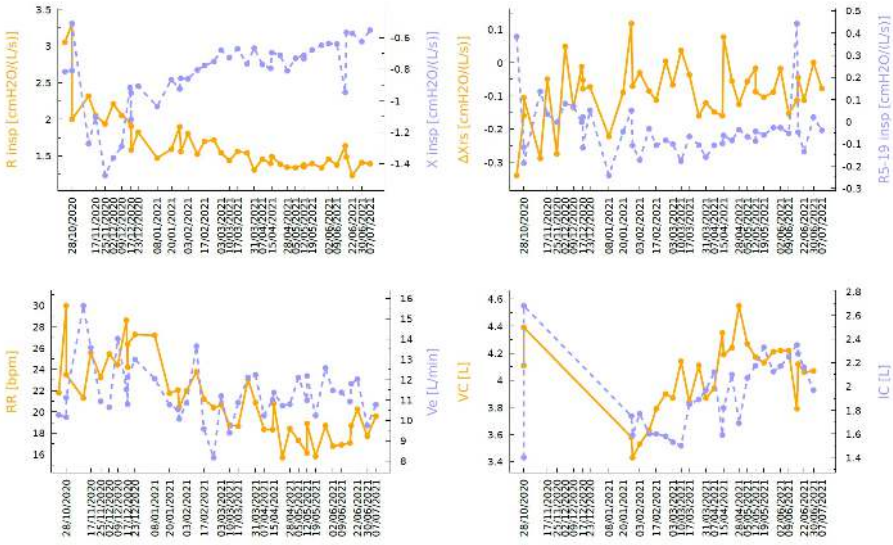


Figure 83 - Example of a set of 4 trend charts with 2 parameters each

3. 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.

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's 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 *First log-in and the 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 (e.g. Expair)

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 download visit/patient information from a compatible third-party web service (e.g. BreezeSuite) installed on a personal computer, and to upload observation results to the same web service, by means of a standard TCP/IP configuration. The intended environment of use is a direct connection (point-to-point network) with the personal computer, i.e. without the need for a separate network infrastructure, like a router or a switch. 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 *First log-in and the 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.
- 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.

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.

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Note:
When HTTPS is selected, the Resmon PRO FULL will verify certificates and only allow connections from trusted certificates. In case you need support for self-signed certificates, please contact your local distributor (see section *User Information*).

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: while *technical backup* files do *not* contain any medical or personal information, when you export a *full backup,* the following data is included:
    - The encrypted database dump including all medical and personal data
    - Software log files where all personal data 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 neither encrypted nor pseudonymized;
- Session results: when you export to a USB drive the results of a session, the clinical report in PDF format, and the eventual technical files in JSON format are neither encrypted nor pseudonymized

Caution! Make periodic full backups to avoid losing availability of data. Archive backups 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. 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

Cleaning and disinfection

In the course of lung function measurements some parts of the device can be contaminated by germs and may cause cross-infection among patients. The device should not be sterilized. An effective cleaning and disinfection procedure in most cases sufficient.
The reprocessing instructions described in this section have been successfully validated by the manufacturer and render the Resmon PRO FULL, if previously used or contaminated, fit for a subsequent single use.

The following wipes have been successfully tested by Restech for the ***cleaning*** of the device:

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

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

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

Before using the above towelettes and for a proper disposal after their use, read the instructions for use reported on the package insert. Make sure to observe the safety precautions of the manufacturer.
In addition to the instructions given in this section, observe the legal provisions and hygiene requirements of your institution.
Should you require further assistance, contact the distributor.

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

Warning! When cleaning and disinfecting the device, use legally marketed gloves of appropriate type and length, eye protection and fluid-resistant gowns.

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.

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. Replace the bacterial/viral filter and the nose clip after each patient!

The use of a bacterial/viral filter with the characteristics indicated in section *Disposables i*s mandatory to perform a measurement. You can use any filter for pulmonary function measurement having the specifications reported in section *Disposables*. The use of a nose clip is mandatory to perform a measurement.

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 the 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 84) and the inlet of the device because they are those at higher risk of contamination.

Figure 84 -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 (not provided with the device) push the towelette in the interstices between the two parts of the plastic frame. (Figure 85)

Figure 85 - 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.*

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 the distributor for a complete cleaning and disinfection of the device.

Maintenance

Maintenance procedures to be done by the user

Calibration Verification

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

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

Replacement of the Air Filter

The air filter is located on the back side of the device, closed by its cover.
The air filter keeps the interior of the unit free of dust.
It is recommended to change the air filter yearly.
To change the filter, turn the cover clockwise. Remove the filter and place the new one on the inside of the cover. Then, place the cover in its original housing and rotate it counterclockwise, following the direction indicated by the arrow "*CLOSE*".

Caution! Use only air filters provided by the distributor.

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

Caution! When replacing the air filter, verify that the cover is tight. If not, dust might occlude the pneumotachograph screen and the measurements may be affected.

Maintenance procedures to be done by qualified personnel

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

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

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

Information for disposal for private users, companies and healthcare facilities

Disposal of Electric and Electronic Equipment

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

The symbol above is valid only in the European Union.
The device shall be disposed according to WEEE Directive 2012/19/EU (European Union) or according to local and national regulation (extra UE).
For a proper disposal contact your local distributor.

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

Figure 86 - Packaging composition and disposal

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

Operating and Storage Conditions

Operating Conditions

Optimal temperature: 10 - 27°C
Optimal relative humidity: 30 - 75% non-condensing
Optimal barometric pressure: 700 – 1060mbar

Storage and Transport Conditions

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

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

Troubleshooting

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

Problems related to the results of the measurement

The patient's resistance or reactance are different (higher or lower) than the values that you expected

Be sure that the patient maintains a correct posture, is wearing a nose clip, is holding his/her cheeks, or the operator is holding his/her cheeks. Make sure there are not leaks from the nose or mouth. Repeat the measurement. If the problem persists, perform a calibration check to exclude any problems with the calibration of the device.

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.

Problems related to the calibration verification

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.

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.

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.

Problems related to the measurement

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.

Filter impedance very low or missing filter

The device has measured a filter impedance that is lower than 0.1cm$H_2O{\cdot}s{\cdot}L^{-1}$.
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.

Flow spike detected

The device can detect a flow spike if the filter is not inserted. In this case, the filter measurement would stop. Repeat the filter measurement using a filter.

Caution: selecting *Ignore* the additional impedance of the filter will be ignored!

If you press IGNORE the measured parameters will also include the filter value. No automatic correction will be applied.

No valid breath detected

This error might appear when using a PSRN stimulus, when no breaths have been performed during the measurement.
During the measurement the device has automatically discarded breaths with artifacts (cough, glottis closure, etc.) and the total number of accepted breaths has not reached the minimum required for a PSRN measurement. Repeat the measurement and make sure that the breath counter on the screen has reached at least 1 valid breath.

Problems related to the insertion of new patients

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.

Problems occurring when browsing the database

No Patients

You are browsing the database, but no patients have been inserted yet.
Be sure to confirm the insertion of a new patient before browsing the database.

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.

An issue with the device data storage.

An issue with the device data storage has been detected. You can still use the device regularly and save new measurements, but some things may not work as expected (e.g. you will not be able to see and edit the traces of old measurements).
Contact your distributor as soon as possible to not lose data.

Problems occurring when exporting data onto a USB drive

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.

An error occurred - could not create the file on USB drive

This is an unexpected error that might happen when the device is trying to save a clinical report on the USB drive.
Try to export again the data on the same USB drive. If the problem persists:

1. Use the other USB port of the device
2. Verify that the USB drive is formatted FAT32
3. Verify that the USB drive is not write-protected
4. Use another USB drive.

Device not found – Please insert a USB drive and try again

Check that the USB drive is correctly inserted into one of the two USB slots. Then, wait a few seconds a repeat the operation. If the problem persists:

1. Use the other USB port of the device

2. Verify that the USB drive is formatted FAT32
3. Verify that the USB drive is not write-protected
4. Use another USB drive.

Problems related to printing

Printer not found

Connect a postscript USB printer to the device and turn it on. Contact the local distributor for the updated list of verified USB printers.

Problems related to the restore of a backup file

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 system 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 its device.
4. You copied a full backup on its USB drive correctly, but the backup is compromised or damaged.

Other problems related to the device

Internal temperature is too high. Please turn off the device, wait five minutes and try again

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

Account already exists!

If you want to add another user to the device, choose another username. The username must be unique. Otherwise, login as the existing one.

Wrong Password

The password to login as a user or admin is incorrect. Try again or reset password. See Section *First log-in and the ADMIN account.*

Once you have plugged the device into an electrical outlet, it does not turn on

Be sure the power cord is connected to the device properly, that the cable is properly connected to the power supply, and that the power-on button has been pressed for at least a half second.

The device or the touch screen do not respond to your inputs

Wait a few seconds. If the device fails to respond, turn it off by pressing the power-on button for at least seven seconds, and then turn it on again.

Technical specifications

Flow measurement	Mesh type	
	Range	± 2L/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	Optimal temperature: 10 - 27°C Optimal relative humidity: 30 - 75% non-condensing Optimal barometric pressure: 700 – 1060mbar	
Storage / Transport Conditions	Recommended temperature: 5 - +40°C Recommended relative humidity: 30 - 75% non-condensate Recommended 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 the 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	

Table 12

Measurement ranges and accuracy for impedance parameters

Parameter	Parameter range at specified frequency		Accuracy
Resistance (R) and reactance (X) (inspiratory, expiratory, total); **X_{crit}**	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 $cmH_2O \cdot s \cdot L^{-1}$	
	PSRN (5Hz, 7Hz, 11Hz, 13Hz, 17Hz, 19Hz, 23Hz, 29Hz, 31Hz)	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
fres (inspiratory, expiratory, total)	/	18-37 Hz	≤ 0.5 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)	/	6-50 $cmH_2O \cdot L^{-1}$	≤ 0.5 $cmH_2O \cdot L^{-1}$ or ≤20% of the measured value

Table 13

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 14

Measurement ranges and accuracy for volume parameters

Parameter	Range	Accuracy
IC	0 – 4 L	≤ 0.05 L or ≤2.5% of the measured value
SVC, ERV and CV_{FOT}	0 – 8 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 15

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 4 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, this could temporarily turn off for auto-protection. Should this be the case, unplug the power supply for at least 30 seconds 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

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 16

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

Electromagnetic Emissions

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

Table 17

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 for at least 30 seconds 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: ± 1 kV	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	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 18

Electromagnetic Immunity			
The Resmon PRO FULL is intended for use in the electromagnetic environment specified below. The customer or the user of the Resmon PRO FULL should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF RF coupled into lines (IEC 61000-4-6)	150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Resmon PRO FULL, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. **Recommended separation distance** - d=1.2/√P - d=1.2/√P 80 MHz to 800 MHz - d=2.3√P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF (IEC 61000-4-3)	10 V/m 80 MHz – 2.7 GHz	10 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. [a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Resmon PRO FULL is used exceeds the applicable RF compliance level above, the Resmon PRO FULL should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Resmon PRO FULL. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 19

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**[a]	**Max power** (W)	**Distance** (m)	**Immunity Test Level** (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] +/- 5kHz deviation 1kHz sine wave	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation[b] 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800, 1900, CDMA 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation[b] 217Hz	0.2	0.3	9
5500						
5785						
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 20

Recommended Separation Distances

The customer or the user of the Resmon PRO FULL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment as described.

Recommended separation distances between portable and mobile RF communications equipment and the equipment			
The Resmon PRO FULL is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Resmon PRO FULL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (i.e. transmitters) and the Resmon PRO FULL as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitters in meters		
	150 kHz – 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800MHz $d=1.2\sqrt{P}$	800 MHz to 2.7 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. *NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.* *NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*			

Table 21

User Information

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: support@restech.it
Tel: +39 02 3659 3690

Other User Assistance Information

For other information and requests of technical support, please contact your local distributor:

TECHNICAL ASSISTANCE / LOCAL DISTRIBUTOR
(Contacts and/or company's stamp)