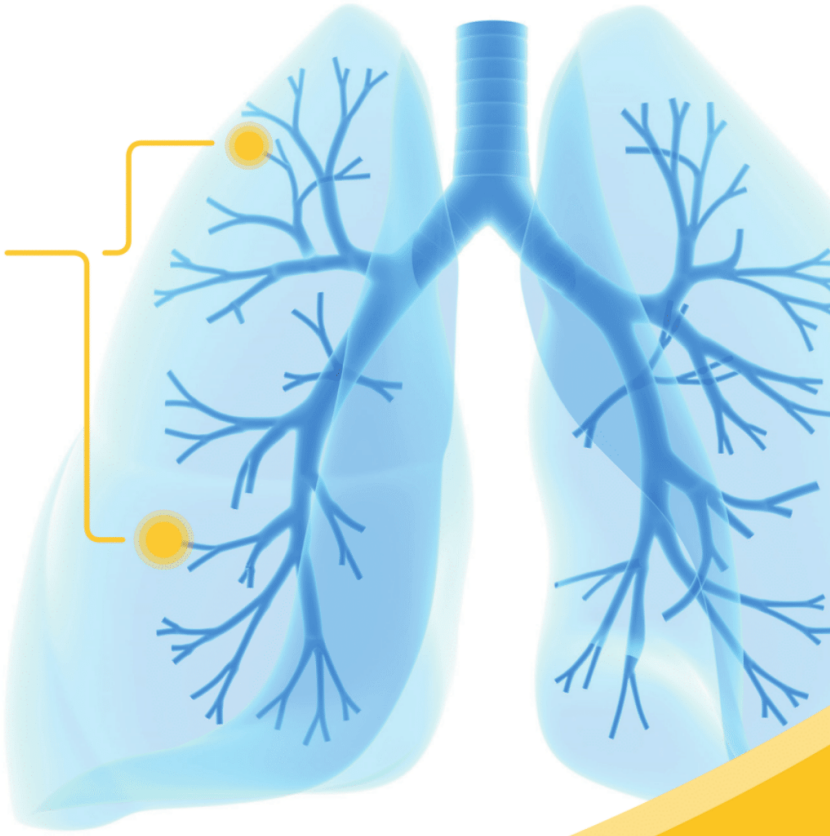
User Manual

English Edition

tremoflo®

Airwave Oscillometry

Fast, Easy, Portable



THORASYS

“tremoflo C-100 Airwave Oscillometry System
User Manual

English (p/n 101648), Rev. AJ, Effective 2021-01-21

	*Caution: Please read this manual in its entirety before using your tremoflo C-100 Airwave Oscillometry System or the tremoflo software. Failure to read and respect the content of this manual may lead to equipment damage or potential health risks.*

 ONLY

The tremoflo C-100 Airwave Oscillometry System is manufactured by

THORASYS Thoracic Medial Systems Inc.
6560 Avenue de l’Esplanade, Suite #103
Montreal, Quebec H2V 4L5
Canada

Represented in Europe by

THORASYS Europe GmbH
Tscheulinstr. 21
D-79331 Teningen
Germany

Symbols

	Type BF medical device.
	Read all instructions carefully before use.
CE 2797	This device complies with the Medical Devices Directive of the European Economic Community.
	Do not mix this device with general waste upon disposal. For proper treatment, recovery and recycling, please contact your dealer or supplier for further information.
	Intertek has tested this product to conform to safety standards for Canada and USA.
	Manufacturing date
	Manufacturer
REF	Part Number
SN	Serial Number
EC REP	Authorized Representative (Europe)
⎓	Direct Current (DC)
IP20	Protected from touch by fingers and objects greater than 12 millimeters. Not protected from liquids. Or This device *meets the requirements specified by the standard IEC 60529:2013 for ingress protection against solid foreign object and access to hazardous parts.*
	Warning or Caution
℞ ONLY	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

	*ESD sensitive device*
	*Non-sterile product, do not use in a sterile field*
	*Single use only do not reuse*
	*Fragile, Handle with Care*
	*Keep Dry*
	*Temperature sensitive keep package within specified temperature limits*
	*Humidity sensitive keep package within specified relative humidity limits*
	*Expiration Date*
	*This Way Up*
	*Use No Hooks*

Warnings & Cautions

	*To avoid risk of electric shock, the tremoflo C-100 must be connected to supply mains with protective earth.*
	*Stop using the tremoflo C-100 immediately if the device emits smoke. Inhaling smoke can cause lung irritation.*
	*If any part of the tremoflo C-100 or its accessories and cables, appears damaged, do not use the device. Use of a damaged device could cause injury to the patient or operator.*
	*The tremoflo C-100 is not suitable for use in the presence of explosive or flammable gasses.*
	*Do not position the tremoflo C-100 in a way that would make it difficult to disconnect the power cord in an emergency.*
	*Do not modify the tremoflo C-100 in any way. Modification to the device may make it unsafe or cause measurement error.*
	*A qualified medical practitioner must interpret test results from the tremoflo C-100. Test results are not sa substitute for examination and qualified diagnosis. Before using the tremoflo C-100, users must read and understand this manual and all product labels and markings.*
	*Only qualified persons may service the tremoflo C-100. Do not open the device as this may lead to damage or inaccuracy.*
	*Do not insert anything into the tremoflo C-100's opening, damage to the mesh screen inside may cause measurement errors.*
	*Testing with the tremoflo C-100 should not interfere with patient breathing; stop testing if the patient shows or reports signs of discomfort.*
	Use only the accessories and cables provided with your tremoflo C-100. Use of other accessories or cables may have undesirable effects on the performance of the device or on the test results.

	*If function stops during electrostatic discharge to the device, reset the system by unplugging the device waiting for several seconds then plugging back in and following normal start-up procedures.*

License & Operating Conditions

By using the tremoflo C-100 Airwave Oscillometry System and the tremoflo Software, you agree to the THORASYS License and Operating Conditions, a copy of which is available upon request.

Copyright Notice

Patents

The tremoflo Airwave Oscillometry System is protected by U.S. and International Patents. Contact THORASYS for detailed patent number listings.

Customer Service & Technical Support

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Table of Contents

1 Introduction

1.1 Welcome to the tremoflo!

Welcome, and congratulations on your acquisition of a new tremoflo C-100 Airwave Oscillometry System (AOS)!

This user manual applies to these variants of the tremoflo C-100:

- tremoflo Model 101336 compatible with clearFlo filters;
- tremoflo Model 101596 compatible with LEMON Medical GMBH Pulmosafe model 1011 filters (available in certain regions only);
- tremoflo Model 101490 compatible with Bird Healthcare Suregard model RJVKB8 (available in Australia and New-Zealand only).

	*The tremoflo C-100 is factory calibrated and intended to be used with specific types of filters. To verify which type of filter is compatible with your tremoflo C-100, check the model (REF) number on the label under the device and refer to the list above.*

1.2 Intended Use/Indications for Use

The tremoflo Airwave Oscillometry System (AOS) is a portable medical device intended to monitor lung function and assess human respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD) in adults and children. The device produces measures of airway resistance, reactance and other lung function parameters to assist physicians in diagnosis, treatment selection and evaluation of treatment efficacy. The principle technology of the AOS is based on a compact implementation of the Forced Oscillation Technique (FOT), a non-invasive technique that assesses lung function by superimposing a multi-frequency airwave on top of the patient's spontaneous breathing.

1.2.1 Indications for use

The technique requires virtually no patient effort: patients breathe normally into the tremoflo for a short period of time while supporting their cheeks and blocking nasal airflow with a nose clip. Cheek support may be provided by a parent or medical assistant for patients who require assistance (e.g. children, elderly). All tests are performed via an anti-viral/bacterial mouthpiece or nasal adapter connected to the device. Test results are displayed in the software and available in a printable report.

The tremoflo may be used in seated, standing or supine orientations and is safe for use in all patients capable of spontaneous breathing, including geriatric, pregnant, and mobility impaired patients as well as children as young as 2 years of age with and without respiratory illness. Young or sick patients may require rest between measurements; abnormal breathing, such as hyperventilation, may cause errors in test results and normal breathing must be restored before testing patients experiencing breathing difficulty. Patients that experience shortness of breath, tightness in the chest, chronic cough, wheezing, or exposure to dust or chemicals must be capable of sustaining normal breathing for the duration of a measurement. Provocations and/or reversibility testing may be evaluated through the assessment of key parameters before and after administration of bronchoconstrictor or bronchodilator drugs.

Measurements are performed by specialized users, such as respiratory therapists, pulmonologists, researchers or other health practitioners, under the direction of a trained physician. The tremoflo is intended for use in a hospital environment, pulmonary function testing clinic/laboratory, physician’s office or similar settings.

2 Operating Principles

2.1 Airwave Oscillometry

Airwave Oscillometry (AO), also referred to as the Forced Oscillation Technique in relevant literature, is one of the most advanced implementations of oscillometry. AO measures pulmonary function, more specifically respiratory mechanics, by superimposing a gentle oscillatory pressure and flow wave onto the patient's spontaneous breathing. The frequencies of oscillation are higher than those contained in normal quiet breathing, but lower than audible sound waves.

As illustrated in Figure 2.1, breathing is a slow oscillatory process. The tremoflo C-100 Airwave Oscillometry System (AOS) superimposes a small, higher frequency oscillation onto the breathing waveforms. The oscillatory waves are sometimes referred to as "pseudo-random noise" in recognition of the fact that the resulting waveforms have the appearance of a "noisy" breathing waveform. Sophisticated signal processing techniques are then used to separate the recorded waveforms into their slower breathing pattern components and their faster respiratory mechanics components.

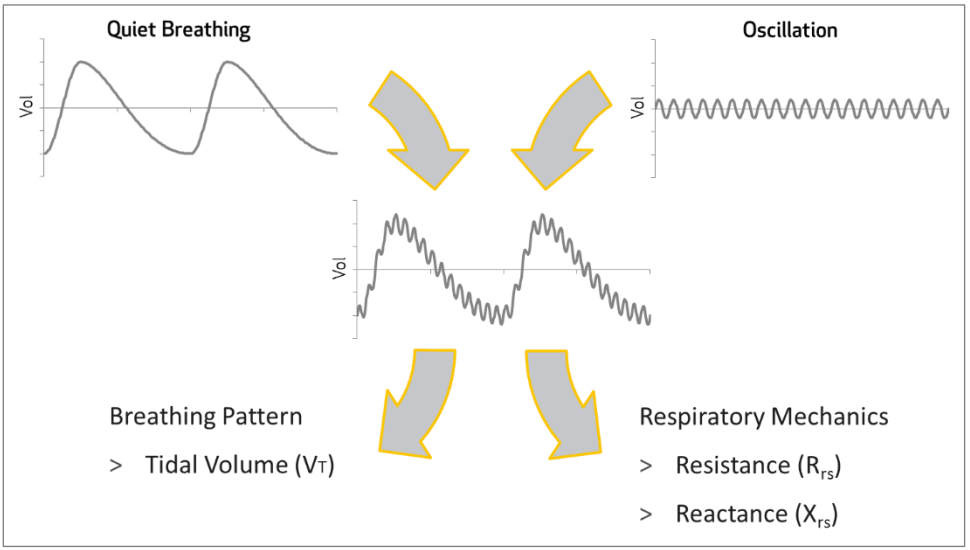


Figure 2.1: Illustration of Airwave Oscillometry.

2.2 Waveforms

The tremoflo C-100 offers the following multi-frequency waveforms for measuring airway function as per established FOT techniques [1]:

- AOS 5 to 37 Hz (adults)
- AOS 7 to 41 Hz (pediatric)

These multi-frequency waveforms comprise of multiple sinusoidal prime frequency signals summed together to form a “noisy” composite air waveform (airwave), as seen in Figure 2.1. The tremoflo software reports respiratory system resistance and reactance at each sinusoidal frequency within your waveform. Waveforms are configured to maximize the performance of your tremoflo device. The waveforms can be used for intra-breath and whole breath analysis. The multi-frequency waveforms allow for the analysis of the lung mechanics over the range of frequencies it covers. For further support or information on which waveform to choose, please contact our Technical Support team.

2.3 Resistance & Reactance

The primary non-parametric outcome of Oscillometry is a pair of curves referred to as Resistance (R) and Reactance (X), each of which is plotted against frequency.

Resistance (R) is a measure of the energy dissipation in the respiratory system. A large portion of R can be attributed to the friction within the breathing gases as they make their way through the airways. Here, resistance is defined as the ratio of the pressure drop across an airway segment and the flow through that segment. However, overall R also contains contributions from energy dissipation in the lung and chest wall tissues [5].

Reactance (X) captures energy conservation in the respiratory system, which includes both the elastic fibres in the lung, i.e. those elements determining lung compliance (C), and the inertive forces related to the acceleration and deceleration of the column of air in the airway tree as well as the lung tissues [5].

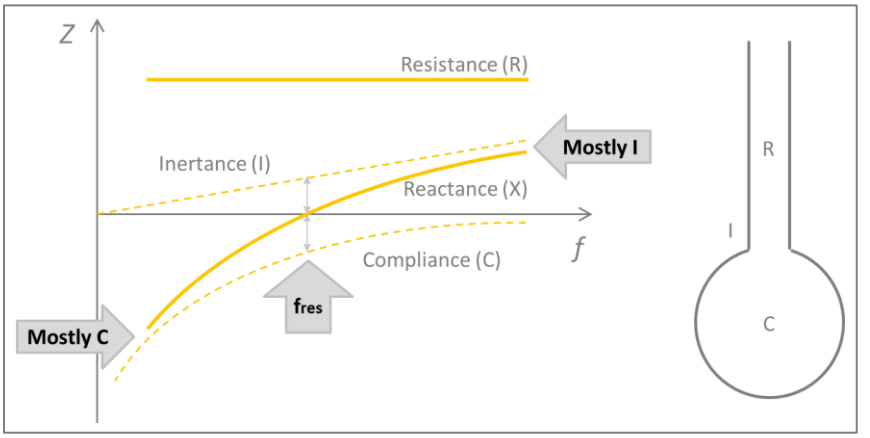


Figure 2.2: Resistance & Reactance

As illustrated in Figure 2.2, R is normally expected to be frequency-independent for an adult lung [5,6], resulting in a horizontal line. On the other hand, X is a negative number at low frequencies, but crosses into positive territory as frequency increases. If X were determined by C only, it would remain entirely negative. In contrast, if C were absent and X were entirely determined by the inertance (I) of the mass being oscillated, X would be positive only. Since C and I coexist in reality, and given their individual characteristics, studies [5] have found that in the normal lung,

- at low frequencies, X is dominated by C;
- at high frequencies, X is dominated by I; and
- there exists an intermediate frequency called the resonance frequency (fres) at which C and I make equal and opposite contributions to X, so that X becomes equal to zero [5].

2.4 Assessment of Small Airways

A variety of studies along with computer simulations [2,3,4] have demonstrated that R and X change in different patterns depending on the type of airway obstruction.

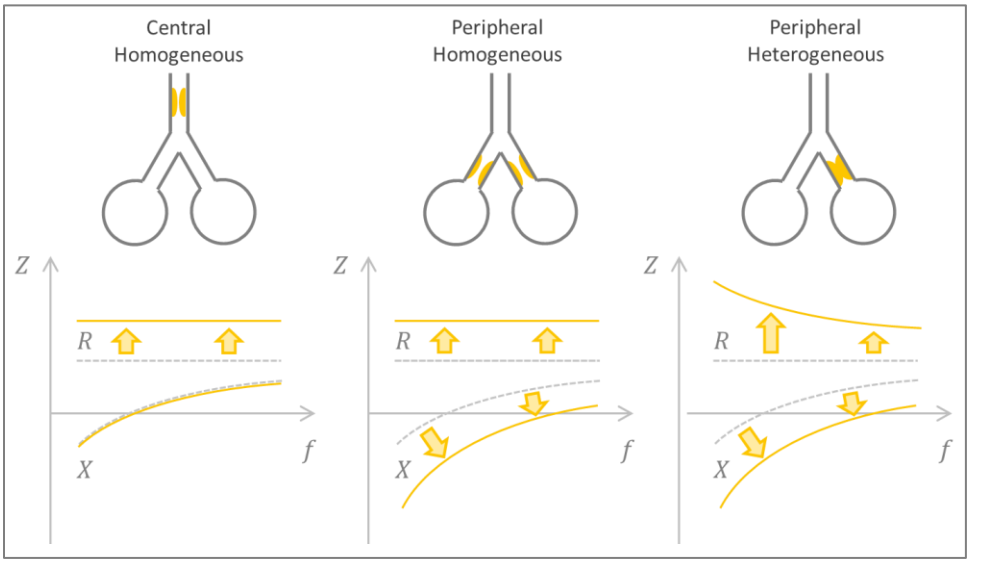


Figure 2.3: Assessment of Small Airways

Specifically, as illustrated in Figure 2.3,

- **Central Obstruction** leads to a frequency-independent increase in R, i.e. a parallel upward shift, without significant changes to X;
- **Homogeneous Peripheral Obstruction** may cause a similar frequency-independent change in R that is accompanied by a downward-and-right shift in X;
- **Heterogeneous Peripheral Obstruction** also results in a downward-and-right shift in X, but in this case the increase in R is greater at low frequencies than at higher frequencies, therefore R becomes characteristically frequency-dependent.

Therefore, Oscillometry can uniquely and distinctly capture peripheral obstruction as indicated by a shift in X, and the heterogeneity of such peripheral obstruction as indicated by a newly introduced or greatly amplified frequency-dependence of R.

2.5 Outcome Parameters

A variety of numerical outcome parameters may be derived from the non-parametric measurements of R and X. The most commonly reported key outcome parameters are listed in Table 2.1 and their relationship to the R and X curves is illustrated in Figure 2.4.

Table 2.1: Key Impedance Parameters of Airwave Oscillometry

Impedance Parameter*	Abbr.	Units**	Indicative of
Resistance at 5 Hz or 7 Hz	R_5, R_7	cm H_2O.s/L	Overall respiratory system resistance
Resistance at 20 Hz	R_{20}	cm H_2O.s/L	Central airway resistance
Frequency dependence of Resistance, 5 – 20 Hz or 7-20 Hz	R_{5-20} or R_{7-20}	cm H_2O.s/L	Heterogeneity of airway obstruction
Reactance at 5 Hz or 7 Hz	X_5, X_7	cm H_2O.s/L	Compliance, small airway obstruction
Reactance Area	AX_5, AX_7	cm H_2O/L	Small airway obstruction
Resonance Frequency	F_{res}	Hz	Small airway obstruction

Note that values at 20 Hz are obtained by linear interpolation between neighbouring prime number frequencies (19 and 23 Hz) for the AOS 5-37 and AOS 7-41 waveforms.

*The above table lists the most commonly reported outcome parameters. Further outcome parameters such as the resistance and reactance values at other

measurement frequencies are also available for display and reporting. Contact THORASYS or your closest representative for details.

**Other units are available and listed in Appendix B.

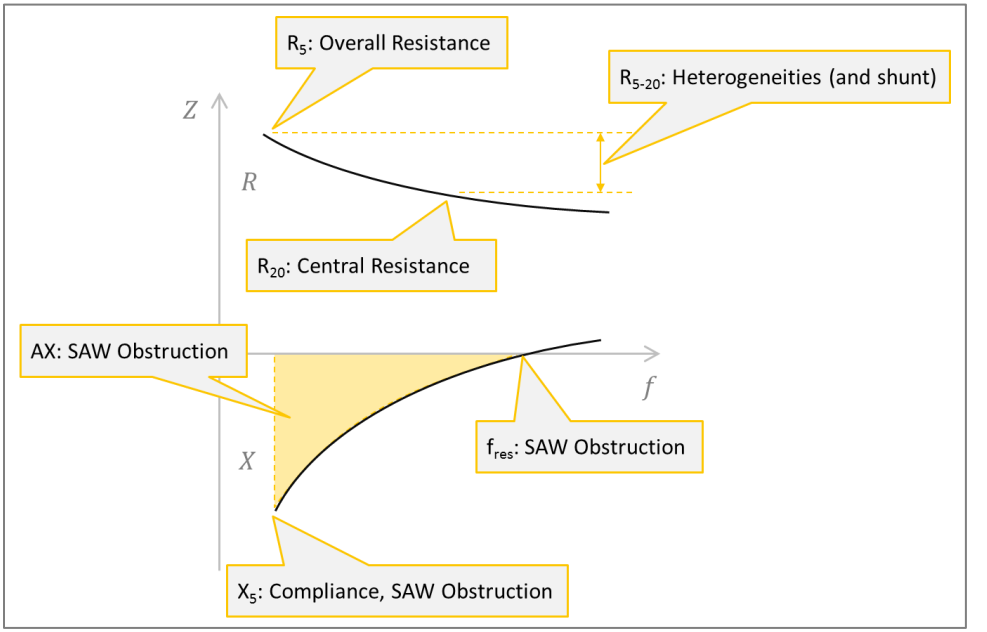


Figure 2.4: Key Outcome Parameters of Airwave Oscillometry (SAW = Small Airways)

Breathing pattern parameters are listed in Table 2.2.

Table 2.2: Breathing Pattern Parameters

Parameter	Abbr.	Units	Description
Respiratory Rate	RR	Breaths per minute (BPM)	Number of breaths taken per minute
Tidal Volume	VT	L	Volume of air between inspiration and expiration
Inspiration Time	T.in	S	Length of inspiration
Expiration Time	T.ex	S	Length of expiration
Respiratory Duty Cycle	Ti/Ttot	No units	Ratio of inspiration time over the total respiratory cycle time (Ttot)
Minute Ventilation	Ve	L/min	Product of the respiratory rate times the tidal volume

2.6 Quality Control Parameters

2.6.1 Coefficient of Variation

The primary test for the goodness of a patient test as per the 2003 ERS guideline for Oscillometry [1] is that the coefficient of variation (CV) between three valid measurements must not exceed 15%.

2.6.2 Coherence

Coherence (COH) is found in the literature as an optional quality control parameter [1]. COH is calculated during tremoflo analysis and captures the stability of the relationship between the different raw data waveforms used for analysis.

3 Setup Instructions

3.1 Unpacking & System Components

3.1.1 Unpacking & Inspection

Before opening, inspect the tremoflo packaging for damage during shipping. If the box appears damaged, do not open the box and immediately contact THORASYS Technical Support or your local representative.

Open the tremoflo packaging carefully without allowing sharp objects to protrude into the box. Remove packing foam and carefully remove all items from the box. Be sure to take out the tremoflo C-100 cradle and handheld unit together. Visually inspect all items, and make sure that you obtained all system components (see below).

	*If any part of the tremoflo C-100, or its accessories and cables, appears damaged, do not use the device. Use of a damaged device could cause injury to the patient or operator.*

3.1.2 tremoflo C-100 AOS Components

The tremoflo C-100 AOS system includes the parts listed in Table 3.1. These are all re-usable components. Accessories and other required compatible components are listed in Table 3.2. These are provided separately for the system and include single-use components as indicated in the table. Note that the system is to be used and controlled by a standard computer system (PC) as described in Section 3.3.

Table 3.1: tremoflo System Components

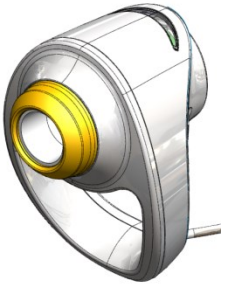
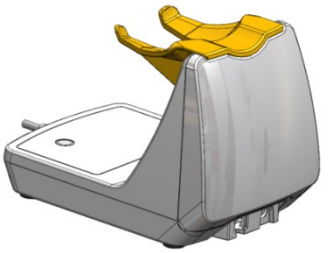
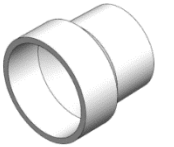
Description	Image
Handheld Unit (HU) Core component of the tremoflo C-100 AOS. Contains the patented vibrating mesh oscillator as well as all sensors required to obtain measurements. Permanently attached to the Cradle by a highly flexible cable. Supplied with a dust cap. **Cradle** Contains electronics and supports the HU during calibration or when the system is not in use.	 
Power Supply External medical grade power supply with wide input range for safe connection to mains in any locale.	
Power Supply Cord Medical grade power supply cord, as indicated by green dot, according to the standards of your locale.	
Ethernet Cable Ethernet cable used to connect the Cradle to the computer system.	

Table 3.2: System Accessories

Description	Image
Calibration Test Load (accessory) Calibrated mechanical test load used for Field Calibration. Supplied with two red dust caps.	
Test Load Adapter (accessory) Adapter to permit insertion of the test load into the HU during Field Calibration.	
Bacterial/Viral Filters & Nose Clips (compatible components) Depending on the model number, the tremoflo C-100 is designed to mate with specific types of filters through which the patient breathes into the tremoflo device (single use Bacterial/Viral PFT Filter). The clearFlo filters (part number 101421) are available from THORASYS. The LEMON Medical GMBH Pulmosafe model 1011 filters are available from third party suppliers. The Bird Healthcare Suregard model RJVKB8 is available from Bird Healthcare.	
A Nose Clip device (single use) is needed to ensure the patient breathes through the mouth into the tremoflo. Nose clips (part number 101422) are available from THORASYS.	
USB to Ethernet adapter (optional) may be used to connect the ethernet cable to the laptop for laptops without an ethernet port.	

3.2 Hardware Installation

3.2.1 Operating Conditions

The tremoflo C-100 AOS is intended for indoor testing at elevations below 2000 m, temperatures between 10 and 35°C, and relative humidity between 15 and 95%, non-condensing. Please contact THORASYS for information on acceptable electromagnetic environments.

3.2.2 Electrical Safety

	*If the computer used with the tremoflo is not connected to a power outlet with medical grade insulation, it must be located at least 1.5 m away from the patient. If this minimum distance cannot be maintained, such equipment must be connected to the power outlet via medical grade isolation transformers. The tremoflo can be used within 1.5 m of the patient as it includes an appropriate medical grade power supply.*
	*Use only the power supply provided with your tremoflo C-100. Use of another power supply may damage the device or put patients at risk.*
	*Use only the Ethernet cable provided with your tremoflo C-100 and only connect the device directly to a supported PC. Use of another cable, an indirect connection of the device to the PC through network devices or a connection of the tremoflo C-100 to other unsupported devices may damage the device or put patients at risk.*

3.2.3 Placement

Place the tremoflo C-100 Handheld Unit and Cradle on a desk or other flat surface within easy reach of the intended patient location during a measurement, as shown in Figure 3.1. Place the computer system at least 1.5 m away from the intended patient location. Orient the computer such that the operator can easily view the patient and the computer screen simultaneously.

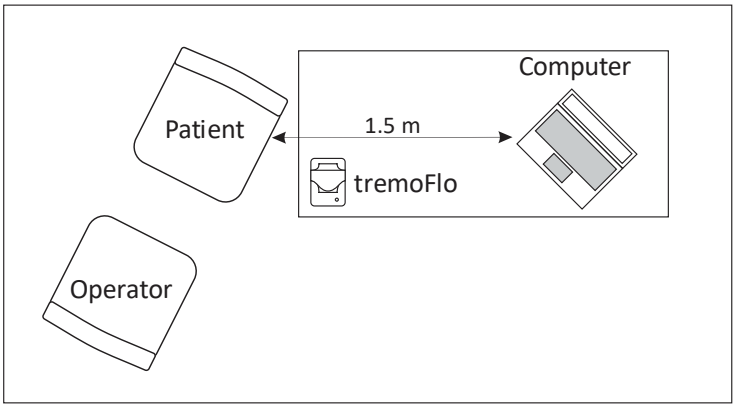


Figure 3.1: Patient environment

3.2.4 Connections

To provide interconnections between the tremoflo system components, computer and power outlets, proceed as follows:

1. Connect one end of the Ethernet cable to the Ethernet port on the tremoflo Cradle. Note that the tremoflo's Ethernet port features medical grade isolation.
2. Connect the other end of the Ethernet cable to the Ethernet port of your computer. If the computer has multiple Ethernet cards make sure to connect the cable to the port that is configured for use with the tremoflo. Alternatively, if your laptop does not have an ethernet port and you have purchased a Radicom USB to Ethernet adapter distributed by THORASYS (XS-EAU-00), connect the other end of the ethernet cable to the USB to ethernet adapter.
3. Connect the tremoflo power supply to the power port of the tremoflo Cradle.
4. Connect the device end of the medical grade power supply cord to the tremoflo power supply.
5. Connect the other end of the medical grade power supply cord to a suitable wall outlet.
6. Connect the power supply of the computer as per the instructions of the computer manufacturer, subject to the warnings, minimum distances and electrical safety instructions provided above.

3.3 Software Installation

3.3.1 Ethernet Adapter Settings

The *tremoflo C-100* requires a dedicated Ethernet port on your computer or, altenatively, a Radicom USB to ethernet adapter may be used. In most cases the drivers will be available as part of the Windows operating system and the adapter will be immediately recognized upon connection. In case of missing drivers, please refer to the manufacturer's documentation and CD provided with your USB to ethernet adapter.

1. Go to the Windows Control Panel and click the Network and Sharing Center icon
2. Click Change Adapter Settings
3. Right click the icon for the Ethernet Adapter you wish to use with *tremoflo* and select Properties from the list.
4. Select Internet Protocol Version 4 (TCP/IPv4) from the list and click the properties button. See Figure 3.2.
5. Click on the option Use the following IP address
6. Fill in the IP address field with 192.168.1.241
7. Fill in the Subnet mask field with 255.255.255.0
8. Leave the remaining fields blank, as shown in Figure 3.3 and click OK
9. Close the control panel windows

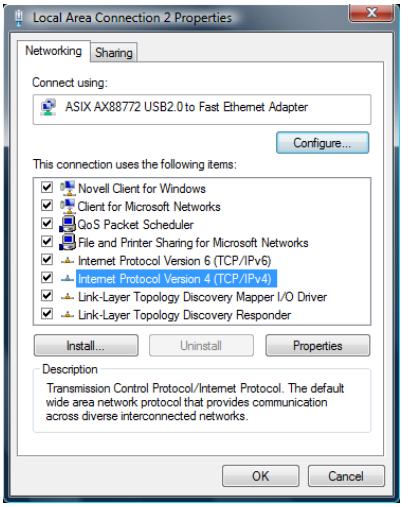


Figure 3.2 Local Area Connection Properties window

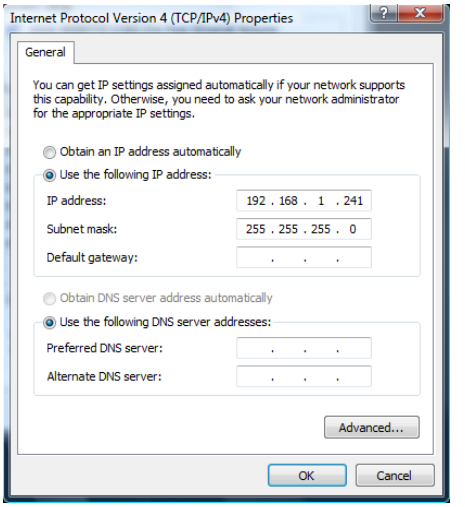


Figure 3.3 Internet Protocol Version 4 properties window

3.3.2 Software Installation

We recommend that you install *tremoflo* Airwave Oscillometry Software on a dedicated computer for operating your *tremoflo C-100*. See the minimum system requirements for the dedicated computer in Appendix D. *tremoflo* software is licensed to one computer only, be sure you are installing the software on the computer you wish to use for testing. If you require additional software licenses please contact sales@thorasys.com for quotation.

⚠	*Ensure you have administrator privileges on the computer before beginning the installation process. Software installation may not complete if you do not have administrator privileges.*

1. Right-click the setup file and choose the option **Run as administrator**.
2. You will see the welcome screen showing the version of *tremoflo* software. Please check that the version is the one you wish to install and click **Next** to proceed.
3. The next step asks for the User Name and Organization to whom you wish to register the software. Enter the name and organization, and then click **Next** to proceed.

4. The next step asks for the folder where you wish to install *tremoflo* software. Click the **Next** button to accept the default folder or **Browse** button to select a new folder.
5. The next step asks where you wish to create the shortcut to the software. Click the **Next** button to accept the default folder or **Browse** button to select a new folder.
6. The next step in the setup process asks if you wish to install additional shortcut icons. *tremoflo* will create a desktop icon or a Quick Launch icon if the **Create a desktop icon** or **Create a Quick Launch icon** options are selected. Click the **Next** button to proceed.
7. A summary screen will show all of the installation options you have selected. Review the options and click **Install** to accept the options and proceed or click **Back** to make a change.
8. During the installation process, the *tremoflo* software and all required third party software utilities (i.e. Firebird database application) will be installed. A dialog message may be displayed saying 'An existing 2.1 Server is running' if an existing Firebird installation was found. If you previously installed Firebird using a *tremoflo* software installer, you can click OK and complete the installation. Otherwise, we recommend you uninstall the current version of Firebird and re-start the *tremoflo* software installer.
9. The final screen confirms if the software has finished installing. Click **finish** to close it.

3.4 Software Registration

3.4.1 Software Registration Components

Registration of *tremoflo* software has three components: a Registration Code, a System Identifier and an Unlocking Key.

3.4.1.1 Registration Code

The Registration Code is a 23-character alphanumeric code that is generated when you purchase a license. It is unique to your software license and determines the features that are available once the software is registered. You can find the Registration Code(s) for your software on the label located on your *tremoflo* installation DVD pouch.

Sample Registration Code: 1234567-FW2L-VC3Z-PQ32-ZDEB

3.4.1.2 System Identifier

The System Identifier (ID) is a 6 character alphanumeric code that identifies your workstation. It is unique to the workstation and is displayed by the software registration wizard. The registration wizard is initiated anytime unregistered *tremoflo* software is launched, so to obtain your System ID, launch the *tremoflo* software. You may launch the software by double-clicking the shortcut placed during installation or by going to the *Start* menu → *All Programs* → *Thorasys* → *tremoflo 1.0* → *tremoflo.exe*. The System ID is automatically recognized by the registration wizard and is grayed out as it is not modifiable.

Sample System ID: ZX1YZX

3.4.1.3 Unlocking Key

The Unlocking Key is a 6 character alphanumeric code that completes the software registration and allows you use the software's features. It is obtained by contacting THORASYS Technical Support.

3.4.2 Registration of your software license

To register your tremoflo license launch the tremoflo software by clicking the tremoflo software icon. The tremoflo software you will then prompt you to enter your registration code as shown in Figure 3.4.

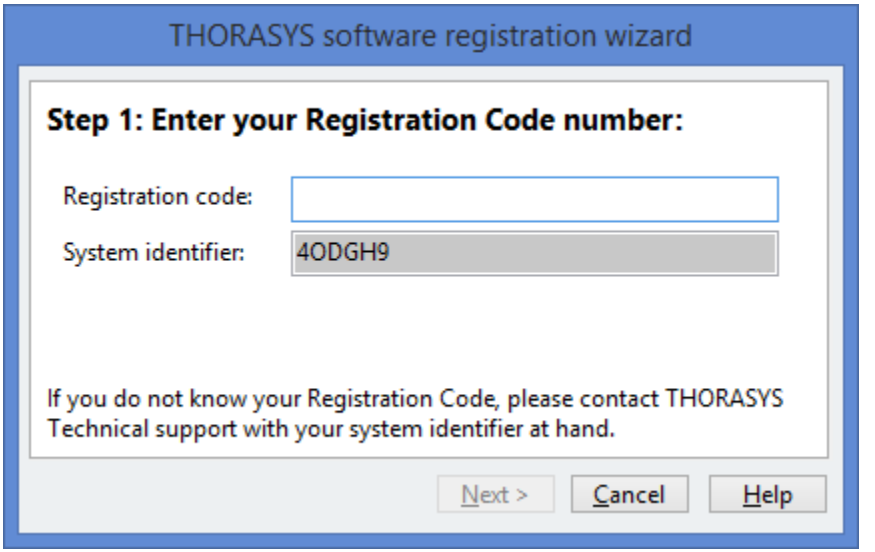


Figure 3.4: Software Registration Dialog Step 1

Enter the Registration Code on step 1 of the software registration wizard, and then click *Next*. Be careful when entering codes to avoid confusion between the letter O and number 0.

3.4.3 Workstation License Unlocking

To unlock the license on your workstation you need an unlocking key. Please contact THORASYS technical support with your registration code and System identifier to obtain your unlocking key. After you have obtained an unlocking key from THORASYS you may proceed to registration of your license on the workstation. Enter the Unlocking Key on step 2 of the software registration wizard, and then click *Next*.

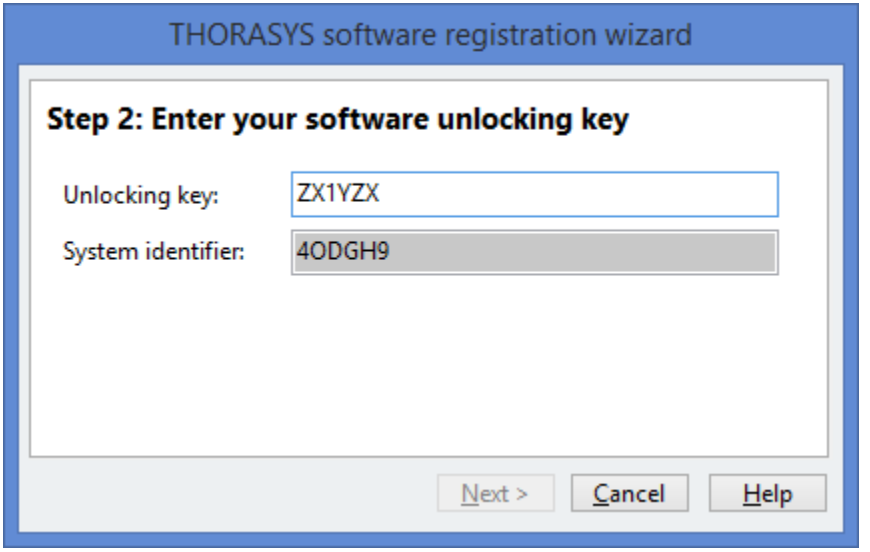


Figure 3.5: Software Registration Dialog Step 2

The registration summary is now displayed. To complete the registration, click *Close*.

3.4.4 User Management

Once the software registration is complete the software will take you to the User Management Dialog as shown in Figure 3.6. To preserve data-confidentiality *tremoflo* requires a user name and password for each person using the software. At least one user profile must be created to use the tremoflo software.

In the User management Dialog, enter the user's first name, last name, and ausername and password that will be needed for future logins. Select the **Administrator** privilege level for the primary user; this person will have some additional options within the software. You are now ready to use your software.

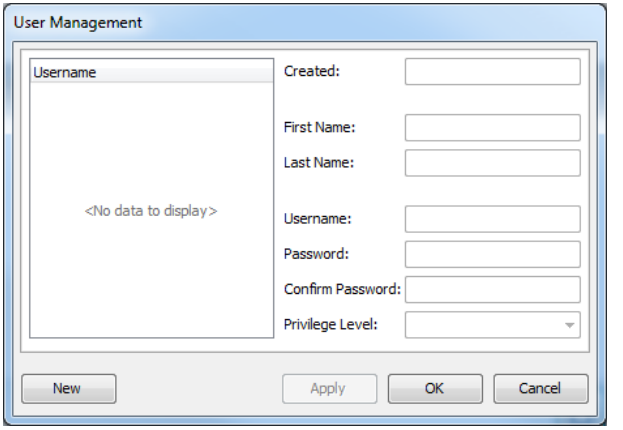


Figure 3.6: User Management Dialog

In addition, you should create an account for each person who will use the software. You may do this now, or at any time in the future by selecting **User Management** from the main menu (*tremoflo* tab).

Note that you may uninstall *tremoflo* software at any time by clicking the uninstall icon in the **tremoflo** folder of the start menu. Your patient data and software registration will remain on the computer after you have uninstalled the software.

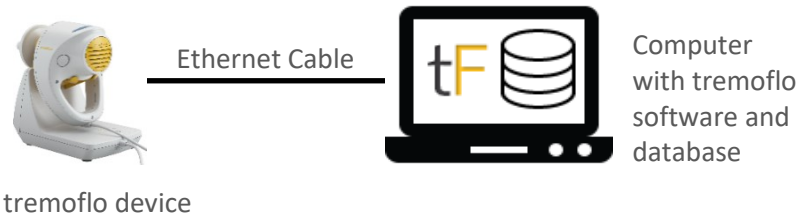
3.5 Network Configuration

The purpose of connecting the tremoflo to the computer and configuring the computer's network settings is to ensure raw data collected by the tremoflo device can be transferred to the tremoflo software for analysis.

In addition to this, the software can then save and refresh data to and from a database stored either on the same computer the tremoflo software is installed on, or to and from a database stored on another computer on the same network. The database components are installed and configured automatically during tremoflo software installation.

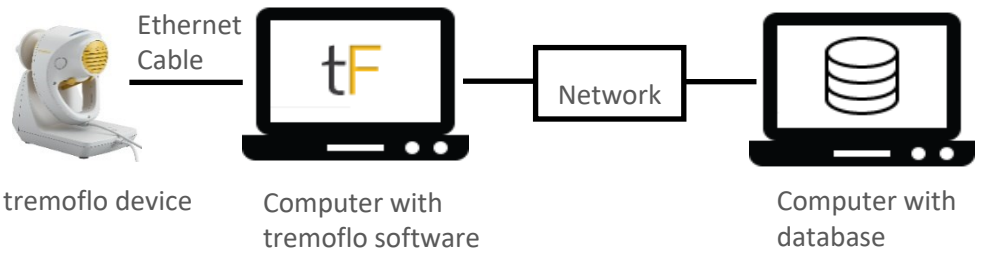
The following describes these two possible configurations of collecting and storing data using the tremoflo. Note that the requirements of each computer and network being used must meet those listed in Appendix D (Computer System Requirements).

3.5.1 Local Network Setup



In this network setup, the tremoflo software and database components are installed on a single computer and the tremoflo device collecting data connected to that computer. In this case, data is not transmitted across a separate network or across other devices. No additional configuration is required for this setup.

3.5.2 Remote Network Setup

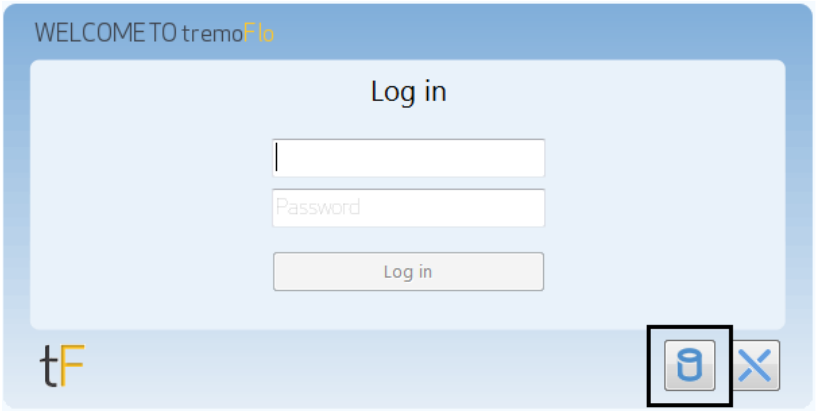


In this setup, the tremoflo software is installed on a separate computer than the database. The tremoflo software communicates with the tremoflo device via a direct Ethernet connection to the tremoflo device as with the local setup, however the analyzed data, created Tests and encrypted Patient information is saved to and refreshed from the remotely located database. The network must be secured to prevent unauthorized access to data transmitted across the network including using a firewall to protect the network from outside it (e.g. if the network is also connected to the Internet) and preventing access to the computers to only users requiring them.

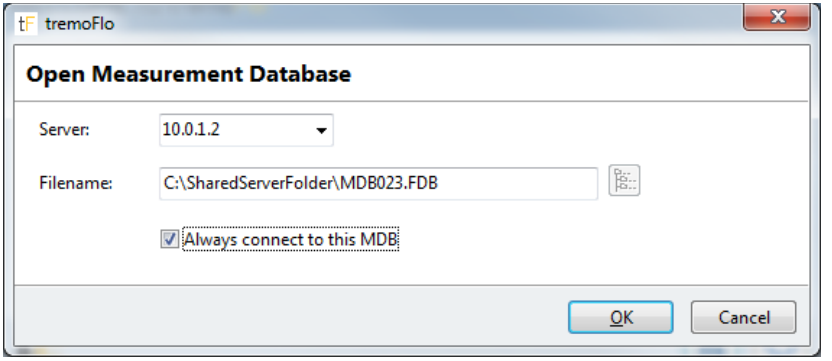
⚠	*The network used, and any changes made to the network (i.e. changes in the configuration, connection of other unmentioned items to the network setup, disconnection of items, equipment updating and upgrading), should be analyzed to identify, analyze and evaluate any unforeseen risks to Patients, Operators or third parties.*

To setup the computer with the tremoflo software to connect to the computer with the database, follow these steps.

1. Make sure the tremoflo software is installed on both computers being used (one where the tremoflo software is installed and connected to the tremoflo device, and the second where the database is to be installed). This ensures that all necessary database components are installed and setup for use with the tremoflo software. Software Installation instructions can be found in section 3.3.
2. Open the tremoflo software, then click the database icon on the Login dialog.



3. Enter the IP address or Host Name of the remote server where the database is located, as well as the local path on that server to the database file.



4. Select the 'Always connect to this MDB' checkbox if you wish to make it the default database, then click OK. If the connection is successful, the User Creation or Login Dialog should then appear.

4 Operating Instructions

4.1 Power Switch & Indicators

To power up the tremoflo system, briefly press the power button on the tremoflo Cradle. The power button will light up, briefly alternating between green, yellow and red before settling to a steady yellow colour.

The tremoflo C-100 AOS has two power indicator lights. On the cradle, a power and status indicator light around the power button can light up in green, yellow or red, wherein each colour has the significance indicated in Table 4.1. The second power indicator, located on the top of the Handheld Unit, lights up in blue when power is supplied to the Handheld Unit and does not change colour with system status.

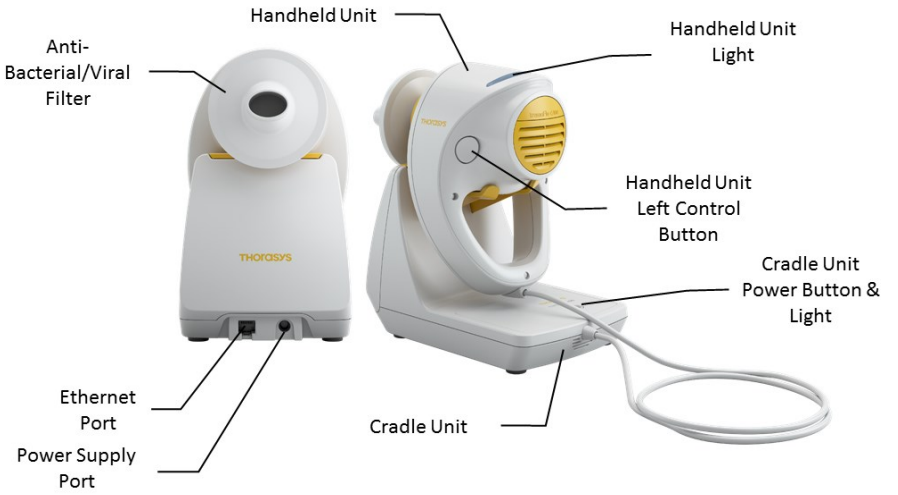


Figure 4.1: tremoflo C-100 Diagram

Table 4.1: Significance of colours, Cradle power indicator and status light

Colour	Status	Details
Unlit/Gray	Off	The tremoflo is powered down.
Flashing	Starting	The tremoflo firmware is booting.
Green	Ready	The tremoflo is powered up, communicating with the software, fully initialized and ready for use.
Yellow	Standby	The tremoflo is powered up and either waiting to connect to the software or being initialized.
Red	Error	The tremoflo is powered up, but a critical error has occurred and the system is not ready for use. Refer to Appendix A for possible causes and solutions.

4.2 Software Start-up Sequence

4.2.1 Starting the Software

With the computer running, start the tremoflo software by either clicking the tremoflo icon in the task bar or by double-clicking the tremoflo icon on the desktop.

4.2.2 User Logon

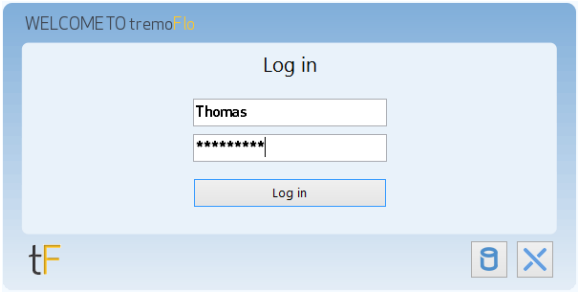


Figure 4.2: User Logon Dialog

Upon startup, the tremoflo software will display a user logon dialog as shown in Figure 4.2. Enter your user name and password, then click the *Log in* button. All

data collected during the session will be associated with the user account corresponding to the credentials entered on this screen.

4.2.3 Welcome Dialog

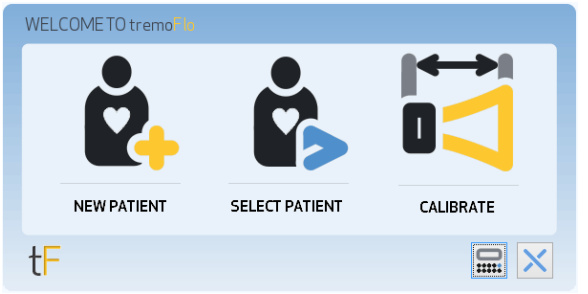


Figure 4.3: Welcome Dialog

Next, the software shows a Welcome Dialog (Figure 4.3) offering three main actions:

- **Calibrate:** Click to perform Field Calibration (see section 4.3) before patients are to be measured. If you omit this step at the start of a session, the software will automatically prompt you prior to the first measurement.
- **New Patient:** Click to add and test a new patient (see section 4.4).
- **Select Patient:** Click to select an existing patient from the database to either perform a new test on that patient or review previously collected test data (see section 4.4).

4.3 Field Calibration

4.3.1 Overview

Each tremoflo system is factory calibrated to provide measurement accuracy. The tremoflo's sensors and electronics possess long-term stability characteristics, therefore calibration factors do not change significantly under normal circumstances. Nonetheless, it is good practice to perform a quick Field Calibration on a daily basis to ensure continued system accuracy and detect any change or damage to the system that may inadvertently have occurred.

The tremoflo software contains features to regularly prompt the user for Field Calibration in predefined intervals, typically daily. A Field Calibration Wizard guides

the user through the calibration process, which typically takes less than a minute to complete.

4.3.2 Step 1: Waveform Selection

Step 1 of the Field Calibration allows you to enter the Calibrator ID if you are performing the Field Calibration for the first time, or if you are changing test loads. Enter the Calibrator ID as shown in Figure 4.4. Note that each Calibration Test Load has a unique Calibrator ID that communicates to the software the exact characteristics and expiry date of this particular Calibration Test Load. The Test Load is valid for one (1) year. During field calibration, the expiration date of the test load is verified and reported by the software as shown in Figure 4.5. If the test load is expired by more than 30 days, you will not be able to proceed with calibration. Contact THORASYS if your test load is due for re-calibration.

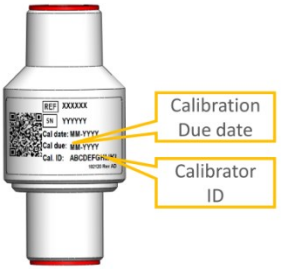


Figure 4.4: Test Load Calibrator ID and Calibration Due Date

The Calibrator ID contains a checksum to protect against typographic errors, and a green checkmark is displayed when a valid Calibrator ID is entered. If you have already performed Field Calibration with the same Calibration Test Load, the software has retained the Calibrator ID.

Step 1 also displays the Oscillometry waveforms that are loaded in the current configuration along with the time since last calibration for each waveform as shown in Figure 4-5. If calibration is required, the waveform will be displayed in red as shown below. Make sure the checkboxes are checked next to the waveforms you intend to calibrate and use for measurement, then click *Next*.

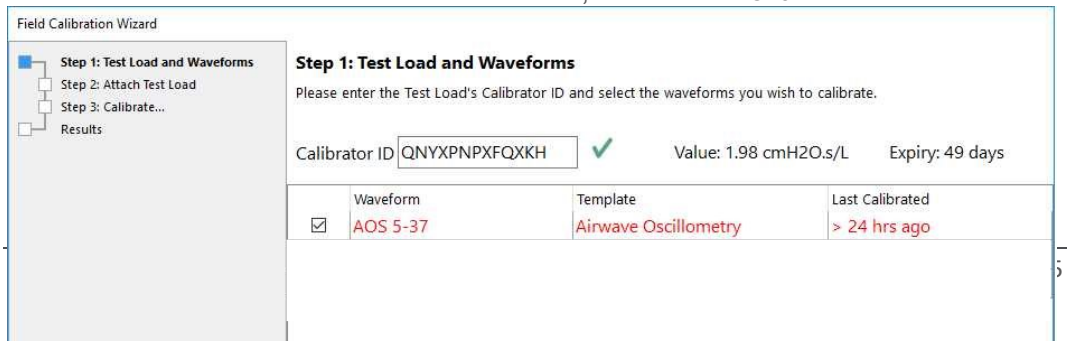


Figure 4.5: Field Calibration Wizard, Step 1

4.3.3 Step 3: Calibration Test Load Attachment

In Step 2 (Figure 4.6), the Field Calibration Wizard reminds you to attach the Calibration test load to the tremoflo. Make sure to remove the two red dust caps from the Calibration test load prior to attaching it to the tremoflo system, then click *Next* to start the calibration.

Note: the Calibration Test Load is not to be breathed into.

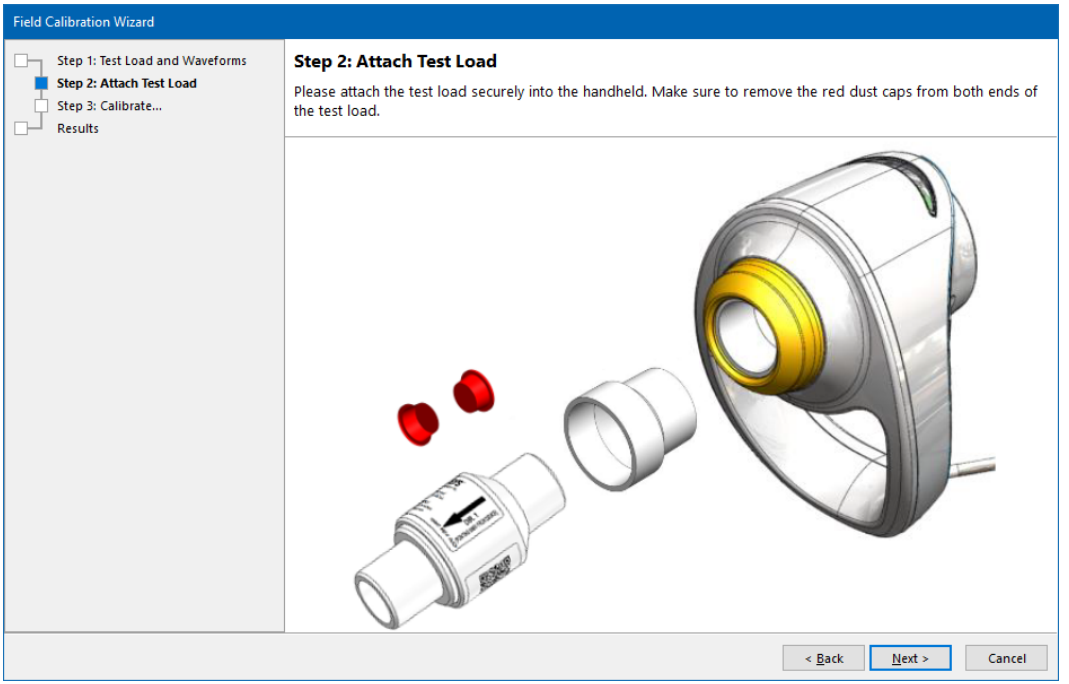


Figure 4.6: Field Calibration Wizard, Test Load Reminder Screen

4.3.4 Step 3: Calibration

In Step 3, the tremoflo software measures the Calibration Test Load (Figure 4.7). This step typically takes 8-16 seconds for each waveform that is loaded. Upon completion of this step, the software automatically proceeds to the Results screen.

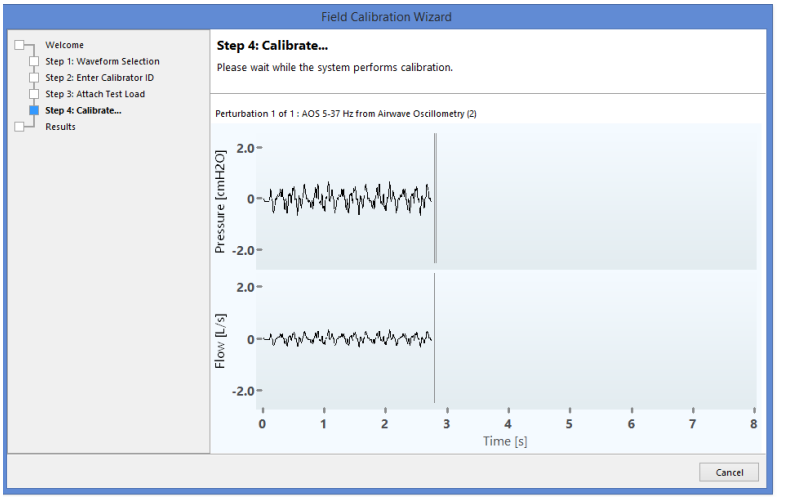


Figure 4.7: Field Calibration Wizard, Calibration Screen

4.3.5 Results

The final screen of the Field Calibration Wizard displays the results of the Field Calibration. If the measured values for the Calibration Test Load match the nominal values contained in the Calibrator ID based on predefined acceptance criteria, the software displays a green checkmark (Figure 4.8). At this point you may print the calibration history log by clicking on *Report.* Click *Finish* to complete the calibration.

If the Calibration fails, a warning message will pop up, and a red X will be displayed instead of the green checkmark. In this case, you can click on each waveform to visualize additional details for troubleshooting and technical support purposes. Provided that the cause of failure is readily identified (see Appendix A), you can click *Start Over* to restart the calibration.

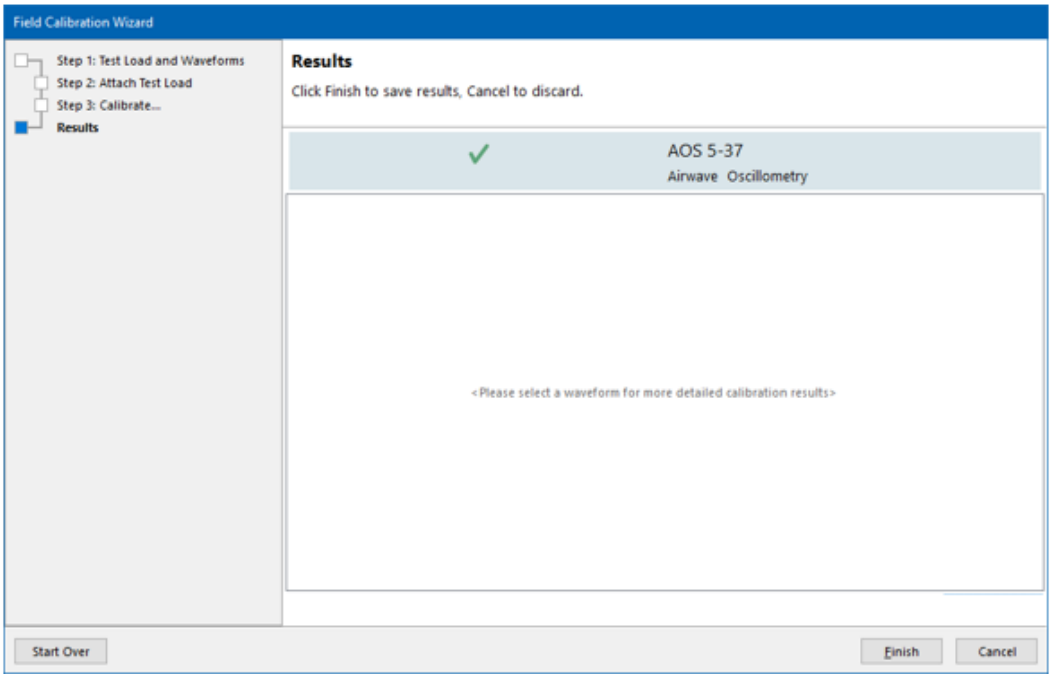


Figure 4.8: Field Calibration Wizard, Results Screen

4.3.6 End of Calibration

When you click *Finish* on the Results screen of the Field Calibration Wizard, the calibration is stored into the database and the wizard closes.

If the Field Calibration was started from the Welcome Dialog (see section 4.2), the tremoflo software will return to the Welcome Dialog so that the user can continue to add a new patient to the database or select an existing patient to be tested anew.

4.4 Starting a Patient Test

4.4.1 About Patient Tests

The tremoflo software is designed to assess respiratory function in accordance with the 2003 ERS guideline for Oscillometry. Thus, a complete tremoflo patient test is required to include at least three separate, valid measurements. The overall results of a test are calculated as the average of the three measurements.

Accordingly, the tremoflo software maintains constructs for Patients, Patient Tests and Measurements, where each patient can have a multitude of Patient Tests, and each Patient Test can contain a multitude of Measurements.

4.4.2 Adding Patients to the Database

The first step when starting a patient test is to add the patient to be measured to the database, or to select an existing patient.

If the patient you intend to assess is not yet in the database, select New Patient either from the Welcome Dialog or from the tremoflo toolbar on the Patient tab to display the New Patient Dialog (Figure 4.9). Enter the patient information as per Table 4.2.

Table 4.2: Completion of Patient Details dialog

Field	Information Entered	Format
First Name	Patient's first name	Alphanumeric Text
Last Name	Patient's last name	Alphanumeric Text
Subject Code	Custom Code	Alphanumeric Text
Sex	Male/Female	From drop-down list
Date of Birth	Date Of Birth	As per regional settings
Weight	Body Weight	See table Table 4.3
Height	Body Height	See table Table 4.3
Ethnicity	Patient's Ethnicity	From drop-down list

Note that the tremoflo AOS uses metric units in most situations, but the software can interpret other commonly used unit types. If using a unit type other than the default; ensure that the unit is supported. For instance, the following entries will be treated the same by the tremoflo software:

Table 4.3: Units conversion

75	=	75 kg	=	165 lb
1.7 m	=	67 in	=	5 ft 7 in
1.5	=	1.5 hrs	=	90 min

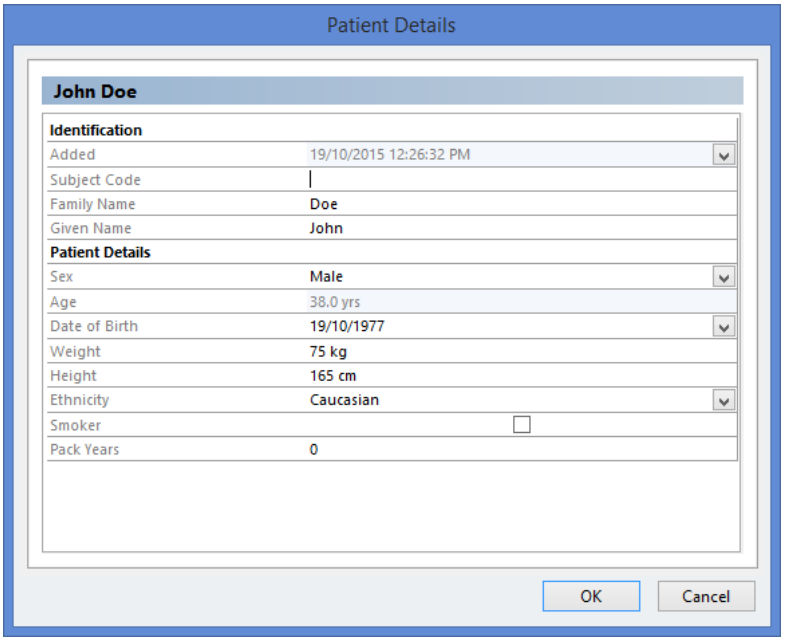


Figure 4.9: New Patient Dialog

4.4.3 Selecting Existing Patients

If the patient you wish to study is already in the database, choose Select Patient either on the Welcome Dialog or on the tremoflo toolbar on the Patient tab to display the Patient List Dialog (Figure 4.10).

A selection of display modes may be selected at the top of the Patient List Dialog to facilitate rapidly locating the desired record. Available choices include:

- **All Patients** – all patients are displayed.
- **Recently Tested Patients** – the specified number of recently test patients are displayed.
- **Search Patient** – patients whose first name, last name or subject code starts with the specified search string are displayed.

In addition, the buttons at the top left of the Patient List Dialog permit adding a new patient, editing the selected record or deleting a patient for whom no measurements are contained in the database. Patients with measurement data cannot be deleted.

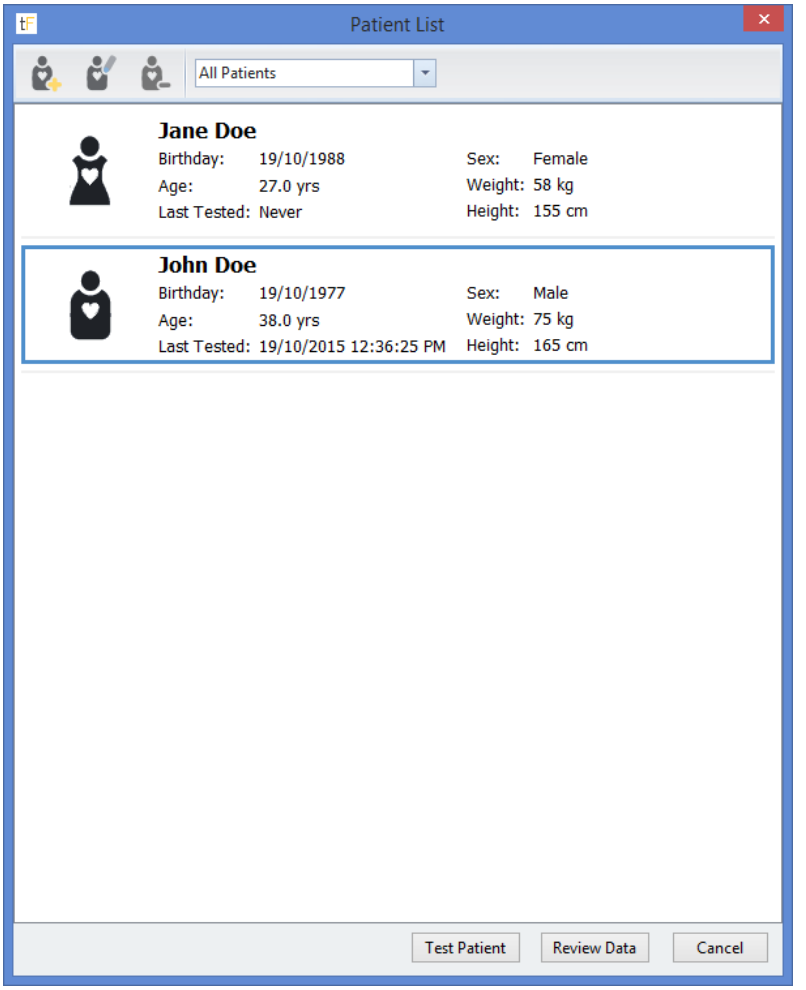


Figure 4.10: Patient List Dialog

Once the correct patient record is selected, the buttons on the bottom of the Patient List Dialog may be used to select one of the following two actions:

- **Test Patient** – Start a new Patient Test for the selected Patient. Note that if a recent open patient test exists, the software will ask whether you prefer to continue that test or start a new one.
- **Review Data** – Review historic Patient Tests for the selected Patient. Note that the software may stay in offline mode, and the light on the tremoflo may remain yellow in this case.

4.4.4 Choosing the test type for a new test

When choosing to test a patient the test type dialog will appear with a choice of two test types currently supported by the tremoflo software: the *Standard Test* for standard baseline measurements and the *Bronchodilator Test* for reversibility testing.

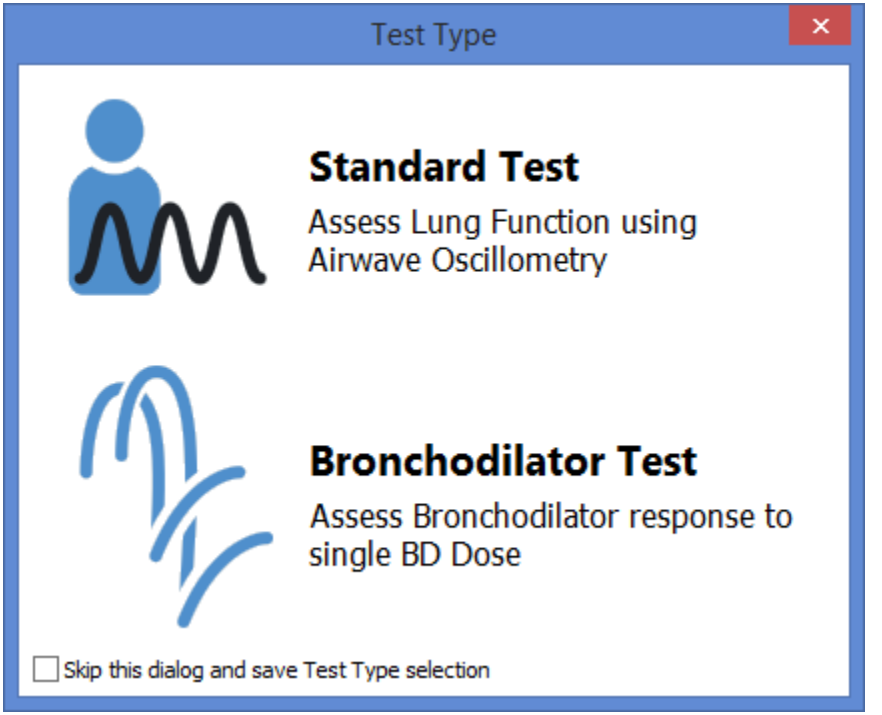


Figure 4.11: Test Type dialog

4.4.5 Test Properties

Once you selected your test type, the Test Properties Dialog is displayed (Figure 4.12). In this dialog you may give your test a title, chose the reference dataset and fill in the other fields as required.

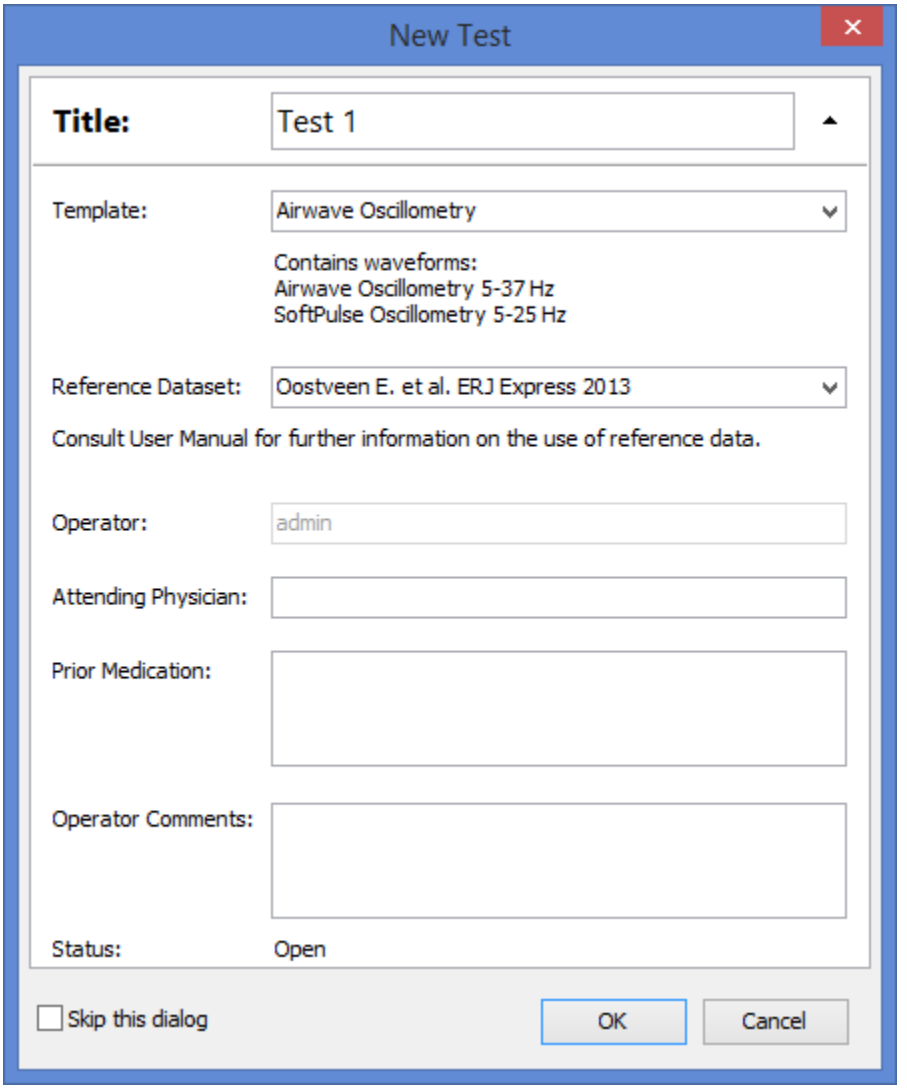


Figure 4.12: Test Properties Dialog

Closing the Test Properties Dialog completes the start-up sequence of the tremoflo software. At this point, the device will connect to the software and be initialized. Once the system initialization is complete the screen will display the main window of the tremoflo software in the Test Tab. At this point you are ready to take your first measurement.

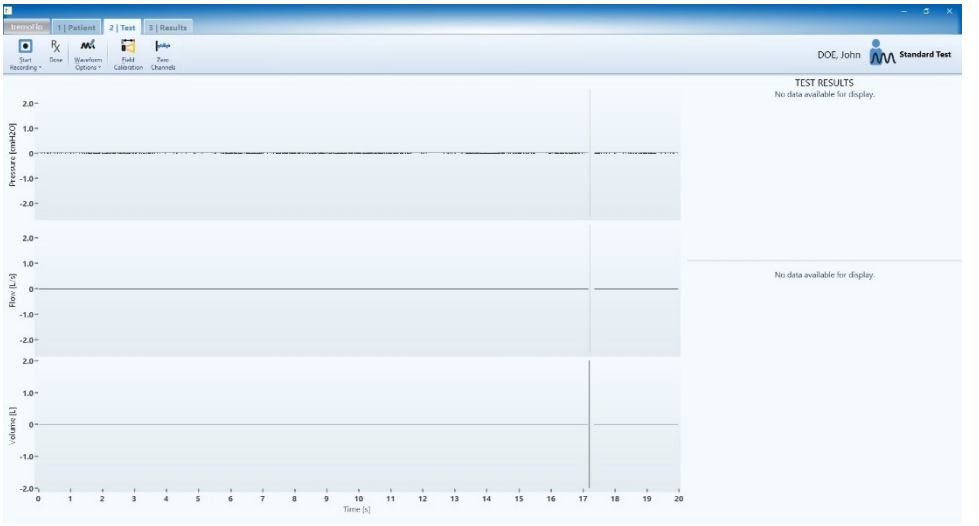


Figure 4.13: Test View of a new patient test.

4.4.6 Reviewing data

If you have chosen to review data instead of testing a patient the software will automatically display the main window in the Patient Tab. From there you can review the results under the Results tab for the current patient or select another patient.

4.5 tremoflo Main Window

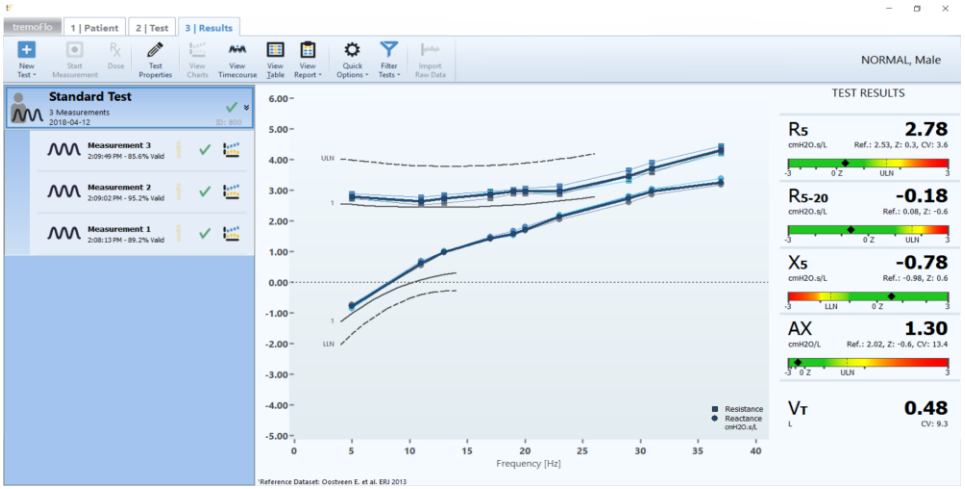


Figure 4.14: tremoflo Main Window (Results Tab, Chart View)

4.5.1 Screen Layout

The tremoflo main window features a tabbed “ribbon” toolbar at the top of the screen as shown in Figure 4.14. The Ribbon has three tabs labelled 1 | Patient, 2 | Test and 3 | Results. Below the Ribbon is the large client area that changes appearance depending on which tab is selected on the Ribbon, but generally displays a combination of graphical or tabular data, selected numerical readouts and meta-data.

4.5.2 1 | Patient

When this tab is selected, the Ribbon offers buttons to add, select or edit patients, or to start a new Patient Test. The client area displays historic test results for the current patient, which may be formatted as graphs or table views.

4.5.3 2 | Test

This tab is used to collect new measurements (described in further detail in section 4.6). The Test tab is only available when an open test exists for the current patient. The client area on this tab shows a live data feed from the tremoflo system. Once available, the software may also display real-time measurement outcomes, along with data from previous measurements in the same test. The toolbar on the Test

tab displays commands to control the measurement or repeat calibrations if needed.

4.5.4 3 | Results

The Results tab is designed to review complete test results, review data for quality control, drill down into individual measurements as needed and produce final reports.

As shown in Figure 4.14, the client area for the Results tab features a vertical side bar on the left side of the screen allowing users to navigate between current and historical patient tests and measurements for the current patient. Depending on the display mode selected, the remainder of the client area may show a chart showing R and X versus frequency, timecourse charts permitting visualization of intra-breath variation, a table of outcome parameters or a report preview. For the two graphical display modes, a vertical side bar on the right side of the screen displays selected outcome parameters relative to their normal values on green-to-red gauge scales.

The Ribbon on the Results tab provides a variety of different commands as needed to perform these tasks and described in detail in sections 4.7 and 4.10.

4.5.5 tremoflo Menu

To the left of the Patient tab, the tremoflo software features a pull-down menu that can be accessed by clicking the word “tremoflo”. This menu provides access to less frequently used features, such as motor calibration and user management.

4.6 Measurement Collection

4.6.1 Measurement Preparation

After you have added and/or selected the patient and started a new patient test as in Section 4.4, perform the following steps in order to prepare the patient for the measurement. Upon completion of these steps, the patient should be positioned and prepared as shown in Figure 4.15, and the patient’s breathing should be visible on screen as shown in Figure 4.16.

1. **Test Screen -** Make sure that the tremoflo software is showing the Test screen. To switch to the Test screen, click the corresponding tab or press one of the buttons on the tremoflo Handheld Unit. Note: Upon entering the Test screen, the software may re-zero the flow and volume channels, therefore the patient must not be breathing through the device at that time.

2. **Use of Gloves –** Use examination gloves when handling the tremoFlo C-100 during patient tests to avoid any possible contact reaction due to material hypersensitivity and to minimize contamination risks.
3. **Mouthpiece -** Remove a new, originally packaged bacterial/viral filter from its wrapping. Without touching the mouthpiece portion, insert the opposite end into the corresponding port on the cradled tremoflo Handheld Unit.

	*Use only the recommended filter with your device. Other filter types may cause inaccurate results.*

4. **Posture -** Place the patient in an upright seated position.
5. **Nose Clip -** Provide a nose clip to the patient and instruct the patient to apply the nose clip to fully seal the nasal passage.
6. **Cheek Support -** Instruct the patient to use both hands to support facial soft tissues, such that the thumbs support the mouth floor while the remaining fingers support the cheeks. Elbows should be relaxed and aiming slightly outward, without pressure against the chest. In patients unable to support their own cheeks such as young children, cheek support may be provided by a third person standing behind the patient, such as a parent or another health care professional.
7. **Mouth Seal -** Take the tremoflo Handheld Unit off the Cradle and hold it in front of the patient's mouth, so that the patient can take place and seal his or her lips around the mouthpiece without leak or discomfort.
8. **Tongue placement -** Instruct the patient to put his tongue under the mouthpiece to ensure that the tongue does not obstruct the breathing pathway and
9. **Face 15° Upward -** Gently position the tremoflo such that the patient faces approximately 15° upwards from the horizontal plane to ensure that there is no compression on the upper airways that could lead to elevated resistance readings.
10. **Three Quiet Breaths -** Once the above steps have been completed, observe the patient's breathing. If the patient's breathing is unusually shallow, heavy or otherwise abnormal, ask the patient to correct accordingly. Abort and restart if needed.

11. **Inform the Patient & Perform Measurement -** Once the patient is breathing steadily and quietly through the device for at least three breaths as shown in Figure 4.16, inform the patient that they will soon feel a gentle oscillation, then press one of the two buttons on the tremoflo Handheld Unit to start the measurement.

12. **Repeat the above Step 10 & 11 to complete at least three Measurements for a complete test -** Between each repetition, the unit is removed from the patient's mouth and the patient is requested to breathe normally and relax for a few moments before repeating the steps.

⚠	*Proper cheek support is an essential element of a properly performed Oscillometry measurement. Failure to properly support the cheeks may lead to measurement errors and invalid measurements that may be difficult to detect post-hoc.*
⚠	*Compression on upper airways, glottis and/or vocal cords may lead to abnormally elevated resistance values. Ensure that patient faces approximately 15° upward to prevent such errors.*
⚠	*Perform oscillometry before forced respiratory manoeuvres if possible. Allow for at least three (3) minutes of rest, more as needed, if a forced respiratory manoeuvre has been made before taking oscillometry measurements.*

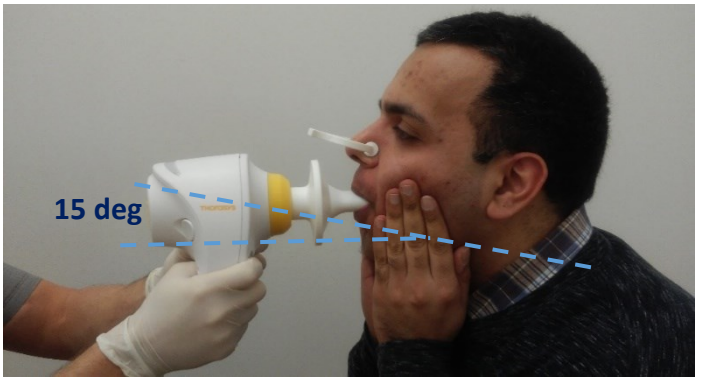


Figure 4.15: Patient preparation showing upright posture facing slightly upwards, nose clip, seal around the mouthpiece, tongue under the mouthpiece and cheek support.

Figure 4.16: Quiet breathing in preparation for a measurement.

4.6.2 Measurement Collection

Measurements are initiated by briefly pressing one of the two buttons on the device, or by clicking the corresponding button on the Ribbon toolbar. Upon initiating a measurement, a mesh inside the tremoflo that is within the patient's flow pathway starts oscillating gently according to a carefully designed multi-frequency waveform. The oscillation is both audible and perceivable by the patient and the operator, but it should be neither loud nor unpleasant to either person.

At the beginning of the measurement, the screen on the tremoflo software resets, and the horizontal axis is scaled to the configured measurement duration. Therefore, a complete measurement will exactly fill the chart from left to right, as shown for a 2 second measurement in Figure 4.17. Numerical readings are displayed live on the right side of the screen. During the measurement, coach the patient to continue breathing quietly and steadily with a normal tidal volume.

The tremoflo automatically ceases oscillating when the measurement is complete. Measurement data are automatically stored without need for user intervention.

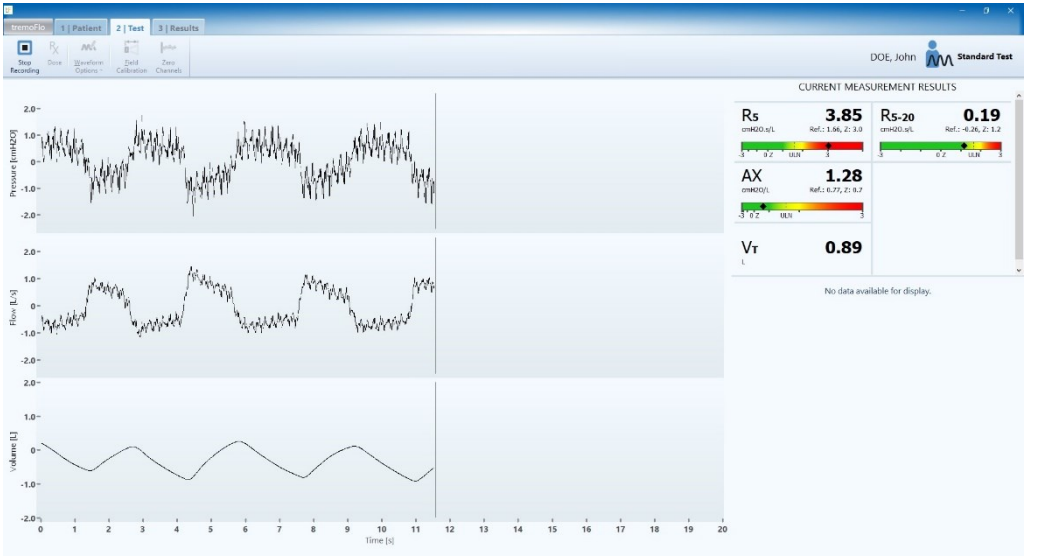


Figure 4.17: Measurement Acquisition

4.6.3 Measurement Analysis

Following measurement acquisition, collected data is analyzed to calculate the measurement's Impedance. As per the 2003 ERS guideline, the measurement's Impedance (Zrs) is calculated as follows:

$$\boldsymbol{Zrs}\ (\boldsymbol{f}) = \frac{\boldsymbol{P}(\boldsymbol{\omega})}{\dot{\boldsymbol{V}}(\boldsymbol{\omega})}$$

The measurement's Resistance (Rrs) is represented by the real part of Zrs, where the measurement's Reactance (Xrs) is represented by the imaginary of Zrs. The measurement's Impedance, Resistance and Reactance are all functions of the frequency of oscillation.

Before calculating a measurement's Impedance, the collected Pressure ($P(\omega)$) and Flow ($\dot{V}(\omega)$) signals are bandpass filtered around the frequency of interest. Following this, the filtered signals are then split into 'windows' (i.e. segments of equal length). The Impedance of each window is calculated, the results of which are averaged to calculate the measurement's Impedance. Each Window has the following properties:

Window Length Amount of data used during the above-mentioned Impedance calculation	0.4 sec
Window Overlap Portion of each Window overlapped by the subsequent Window	75 %
Number of Windows Number of Windows in a 20 second Measurement (with first and last 0.5 seconds excluded from analysis)	181

In addition, the measurement's Coherence is also calculated

$$P_{xy}(f) = P(\omega) \times \dot{V}^*(\omega)$$

$$P_{xx}(f) = \dot{V}(\omega) \times \dot{V}^*(\omega)$$

$$P_{yy}(f) = P(\omega) \times P^*(\omega)$$

$$\boldsymbol{Coherence\ (f) = \frac{P_{xy} \times P_{xy}{}^*}{P_{xx} \times P_{yy}}}$$

$\dot{V}^* = Complex\ Conjugate\ of\ \dot{V}$

$P^* = Complex\ Conjugate\ of\ P$

$P_{xy}{}^* = Complex\ Conjugate\ of\ P_{xy}$

4.6.4 Repetitions

According to the 2003 ERS guideline, a minimum of three valid Measurements is required for a valid Patient Test. Especially in more difficult and/or severe patients, it is common practice to collect additional Measurements and exclude possible outliers. Remove the mouthpiece from the patient's mouth between measurements to allow for a moment of relaxation.

4.6.5 Artefacts

The tremoflo software has the ability to isolate and exclude well-delimited artefacts originating from brief episodes of swallowing, speaking, laughing, light coughing or letting go of the mouth seal. In many cases, the remainder of datasets containing such artefacts can be analyzed to produce a valid Measurement. However, Measurement should be excluded if too large a portion of the Measurement is affected by artefacts, and often such exclusions will happen automatically.

The occurrence of a strong cough during a Measurement may interfere with the operation of the tremoflo and result in an error message. Such cases are detected by the software and indicated by an error message on the screen, and the device needs to be reset before further Measurements can be attempted.

4.6.6 Aborted Measurement

Measurements may be cut short or aborted by pressing one of the two buttons on the tremoflo Handheld Unit for a second time while the measurement is ongoing. In such cases, the tremoflo software will prompt the user whether the partial measurement should be stored or discarded. Note that a configuration-dependent minimum amount of valid data is required, otherwise the measurement will be automatically and irrevocably excluded.

4.6.7 Closing a Patient Test

When the patient test has been completed, the test should be marked as closed in the tremoflo software. The software will automatically prompt for closing of the test if a new test is started, a different patient is selected or the software is shut down.

4.6.8 Disposal of Supplies

Upon completion of a patient test, also be sure to dispose the single-use supplies, namely the bacterial/viral filter and the nose clip, in a suitable waste collection container as per your institutions guidelines and regulations.

	*Filters are one-time-use only; do not attempt to clean or reuse a filter for more than one patient or patient test. Filters must be disposed after use. Filter reuse increases the risk of cross-infection and/or contamination between patients. Repeat use may increase air resistance and lead to incorrect measurements.*

	The main electrostatic filter membrane component is made of a porous polymer away of access within the outer casing. This prevents the device from being cleaned without adversely affecting its filtration performance and resistance, which in turn would affect the system performance and accuracy in addition to the cross-contamination effect. Moreover, the use of heat, if heat sterilization would be attempted, would likely either melt down the membrane and/or affect its filtration characteristics, again preventing the use of the device and affecting its performance.

4.7 Data Review

4.7.1 Overview

As briefly mentioned in section 4.5, the Results tab of the tremoflo software offers comprehensive functionality to review test results and overread data for quality control before producing final reports. Data review can be performed during or immediately after a test as well as at a later time.

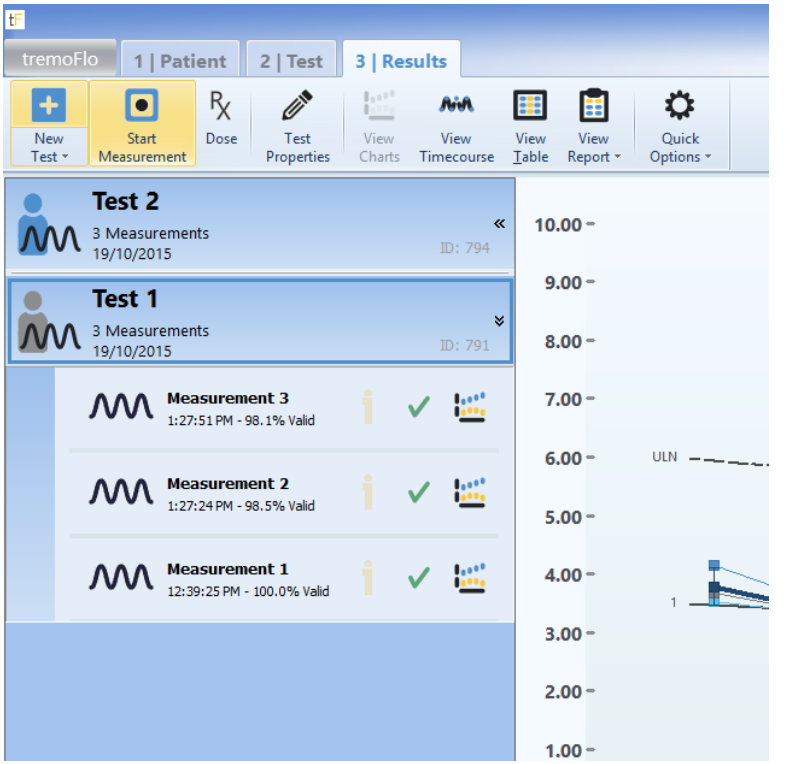


Figure 4.18: Results Navigation Pane and Toolbar

When first navigating to the Results screen, the tremoflo software shows the Chart View shown in Figure 4.14. Using the buttons on the toolbar (Figure 4.18), you may then navigate to the Timecourse View, Table View or Report Preview. The first three views are described in detail in the remainder of this section, and the Report Preview is detailed in section 4.10.

4.7.2 Navigation Pane

The Navigation Pane is a vertical side bar on the left side of the Results screen that displays a blue rectangular card for each patient tests that exists for the currently loaded patient (Figure 4.18). Tests are sorted in reverse chronological order, so that the most recent test appears at the top. Once a test is selected, it is "expanded" to show additional lighter coloured cards for each measurement contained in the test.

As shown in Figure 4.18, the cards representing tests and measurements display a variety of meta-data such as titles and timestamps. Measurement cards also include three controls permitting the actions listed in Table 4.4 to be taken with respect to the corresponding measurement.

Table 4.4: Measurement Card Actions

Icon	Action	Details
	Add/Edit Comment	Add a comment to a measurement, or edit an existing comment. Icon appears darker when a comment is available.
	Include/Exclude	Controls inclusion of the measurement in the test average. Set by automatic validation, but may be changed to force inclusion or exclusion.
	Show/Hide	Show or hide the selected measurement.

4.7.3 Gauge Scales and Reference Data

In a variety of views and reports, the tremoflo software uses green-to-red Gauge Scales (Figure 4.19) to easily visualize the state of a patient's respiratory mechanics relative to their normal values according to tabulated user-selectable reference data. Gauge scales are typically located on the right side of the screen and may be configured via the program options.

Each Gauge Scale Card visualizes the abbreviation and value for one single outcome parameter in large font. A text line in smaller font further provides the units, reference value, Z score and in select cases, the coefficient of variation (CV) of that parameter. Finally, a diamond indicator on a horizontal gauge ranging from green to yellow to red visually illustrates the patient's outcome relative to normal (user-selectable reference data). The significance of the individual colours is as follows:

- **Green –** Outcome well within the 95% confidence interval of normal.
- **Yellow –** Close to the upper or lower limit of normal, as defined by 95% confidence interval around normal value.

- **Red –** Outside of the 95% confidence interval around normal value, i.e. above the upper limit of normal (ULN) or below the lower limit of normal (LLN).

Published equations for healthy patients are available for use in tremoflo software for adults and children aged 2-18 years (refer to Appendix E for literature references).

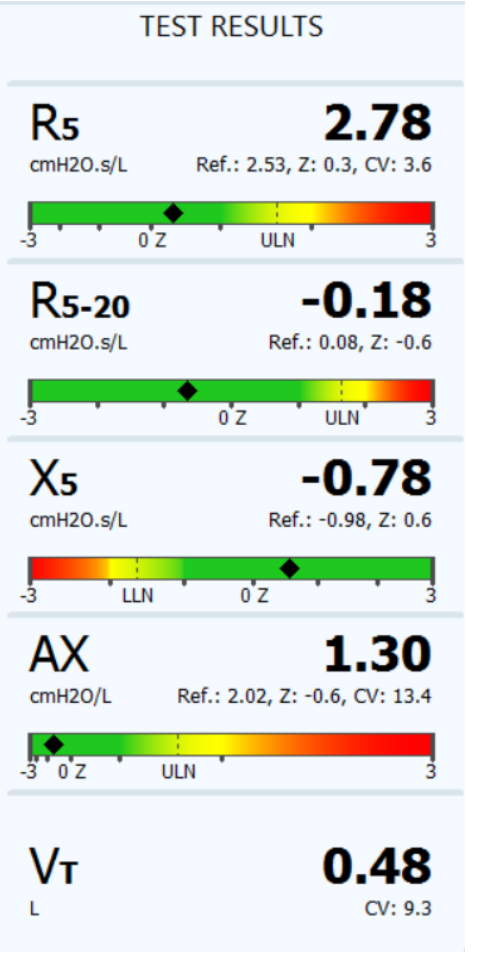


Figure 4.19: Gauge Scales

When a Patient Test is selected in the Navigation Pane, as shown in Figure 4.18, the Gauge Scales display the average outcome values for this test. In this case,

the title at the top of the Gauge Scale Pane reads “TEST RESULTS”, as shown in Figure 4.19.

When a Measurement is selected in the Navigation Pane, the Gauge Scales will display the outcome values for the selected measurement only. Accordingly, the title at the top of the Gauge Scale Pane reads “SELECTED” in this case (not shown).

4.7.4 Impedance Chart

When in Chart View, a graph visualizing R and X versus frequency is displayed between the Navigation Pane and the Gauge Scale Pane. As illustrated in Figure 4.20, this impedance chart contains the following graphical elements:

- **Measurements –** Each individual measurement contained in the selected test is represented by uniquely coloured symbols connected with thin hairlines.
- **Test Average –** The test average is represented by dark blue symbols connected by a thicker line.
- **Normal Values –** The normal values for the patient’s age, sex, height and weight is displayed as a thin black line. The source of the reference values is displayed at the bottom of the chart.
- **Limits of Normal –** The ULN for R and LLN for X are displayed as dashed lines.

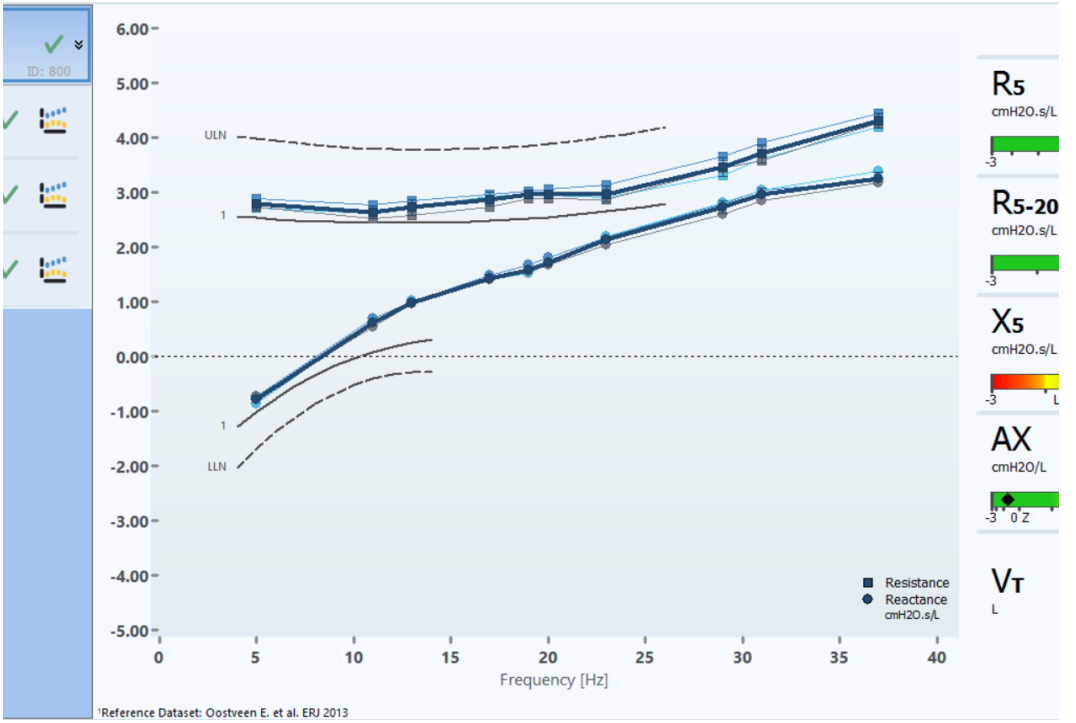
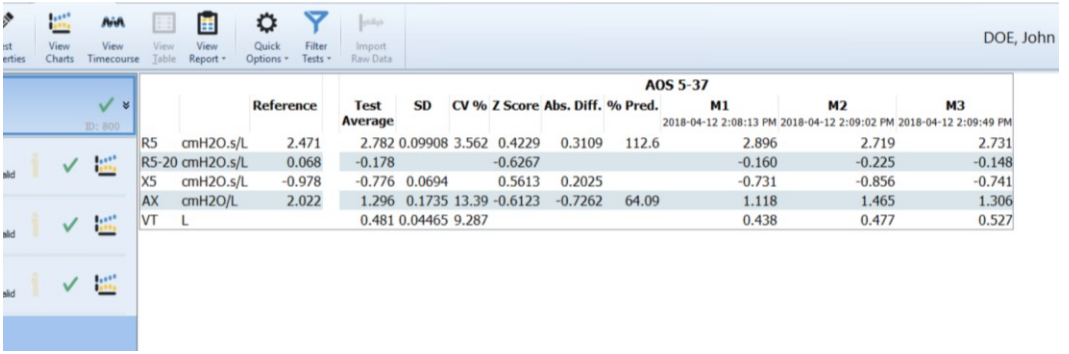


Figure 4.20: Impedance Chart

4.7.5 Table View

The Table View permits visualization of the numerical outcome values for the selected patient test. As shown in Figure 4.21, the parameter abbreviations, units and reference values are shown in the leftmost section of the table, followed by the test average, standard deviation, coefficient of variation, Z-score and % predicted. The individual measurements are shown in the rightmost columns of the table.

Note that some oscillometry outcome parameters such as reactance values may have normal values very close to zero. CV and % predicted cannot be evaluated for these parameters because they would not be meaningful and risk divisions by zero. Moreover, Z-scores and % predicted can be evaluated only for parameters for which reference values exist.



AOS 5-37

		Reference	Test Average	SD	CV %	Z Score	Abs. Diff.	% Pred.	M1 2018-04-12 2:08:13 PM	M2 2018-04-12 2:09:02 PM	M3 2018-04-12 2:09:49 PM
R5	cmH2O.s/L	2.471	2.782	0.09908	3.562	0.4229	0.3109	112.6	2.896	2.719	2.731
R5-20	cmH2O.s/L	0.068	-0.178			-0.6267			-0.160	-0.225	-0.148
X5	cmH2O.s/L	-0.978	-0.776	0.0694		0.5613	0.2025		-0.731	-0.856	-0.741
AX	cmH2O/L	2.022	1.296	0.1735	13.39	-0.6123	-0.7262	64.09	1.118	1.465	1.306
VT	L		0.481	0.04465	9.287				0.438	0.477	0.527

Figure 4.21: Table View

4.7.6 Timecourse View

The Timecourse View permits the visualization of the raw pressure, flow and volume waveforms as well as the temporal variations in R and X over the course of a measurement (Figure 4.22). The Timecourse View is valuable both for quality control and to visualize intra-breath changes in R and X.

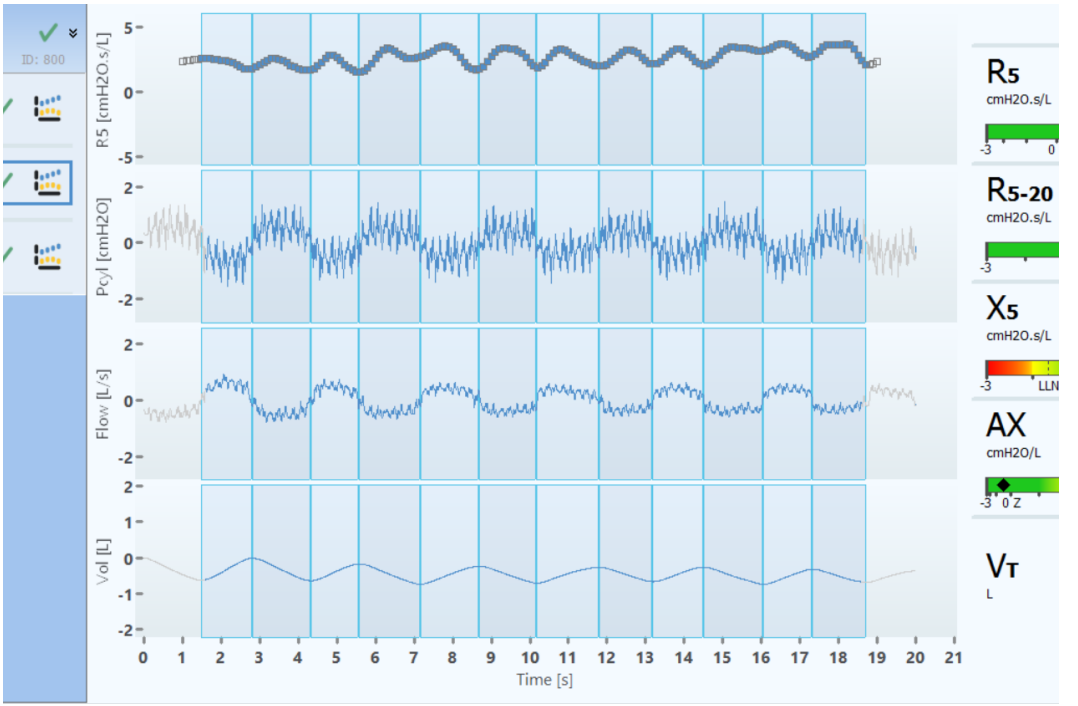


Figure 4.22: Timecourse view (normal patient).

4.8 Quality Control

4.8.1 Overview

The tremoflo software employs a number of different criteria to automatically assess the quality of data as they pass through the different stages of data analysis. These algorithms are designed to detect and exclude most common artefacts while avoiding excessive data exclusion that would lead to unnecessary repetitions.

However, because we are dealing with living systems, automated validation and the resulting inclusion/exclusion decisions will not be perfect in all circumstances, and some degree of human assessment and adjustment is required to achieve the best possible results.

This section describes the validation and exclusion mechanisms contained in the tremoflo software as well as the means available to adjust and override automated decisions.

4.8.2 Raw Data Validation

In the first stages of data analysis, the tremoflo software assesses the quality of the raw data collected from the tremoflo system. If a problem such as a clipped raw data channel is detected, the measurement is automatically excluded.

Raw data validation errors are rare, but when they occur they typically prevent further analysis, and they cannot be overridden.

4.8.3 Artefact Detection

To identify artefacts contained within a measurement, the tremoflo scans the resistance and reactance curve for irregularities such as negative and excessive outlier resistance (by default set to anything larger than three standard deviation from the mean resistance). Such irregularities typically signify the presence of one of the artefacts listed in Table 4.5. Most of these artefacts can be readily identified visually in the Timecourse View, as shown in Figure 4.23.

Table 4.5: Common Artefacts

Artefact	Appearance
Swallowing, Tongue Blockage	Flat flow and volume curves; suppressed oscillation amplitude on flow; large random swings in R and X.
Leak	Flat volume curve; increased oscillation amplitude on flow; R and X near zero.
Cough	Large swings in flow, volume, R and X.
Vocal Expression	Irregular breathing pattern with extended, noisy expiration; random excursions in R and X; negative R values

The automatic artefact identification and exclusion may be edited and overridden in the Timecourse View as follows:

- To exclude an artefact not detected by the software, click into a valid (blue) part of the curve and drag the mouse to mark the bad segment.

- To include a data segment incorrectly marked as artefact, click into an excluded (gray) part of the curve and drag the mouse to mark the segment to be included.

You must click Apply on the Ribbon toolbar to apply your changes and recalculate the measurement and test outcomes. Click Undo if you do not wish to apply your changes, or to reset prior edits.

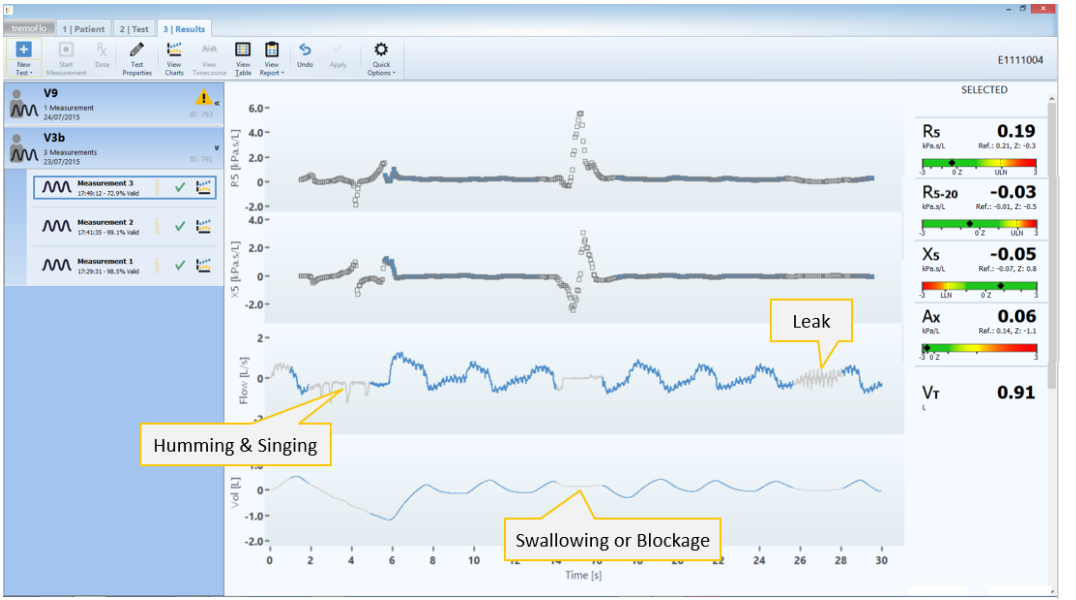


Figure 4.23: Timecourse view, with artefacts

4.8.4 Measurement Validation

Next, the tremoflo software will either exclude the measurement or issue a warning based on the criteria shown in Table 4.6. Note that the measurement will only be automatically excluded if the minimum duration criteria is not met. Visualization of the measurement validation criteria in the Chart View is illustrated in Figure 4.24.

Table 4.6: Measurement Validation Criteria

Criterion	Pass Criteria	Comments
Minimum Duration	≥ 6 sec.	Total valid data as shown in Timecourse. Automatic exclusion if the measurement duration is less than 6 seconds.
Valid Percentage	≥ 70%	Portion of valid data points across all frequencies. Exclusion is not automatic.
Coherence	≥ 0.7	See section 2.6. Exclusion is not automatic.

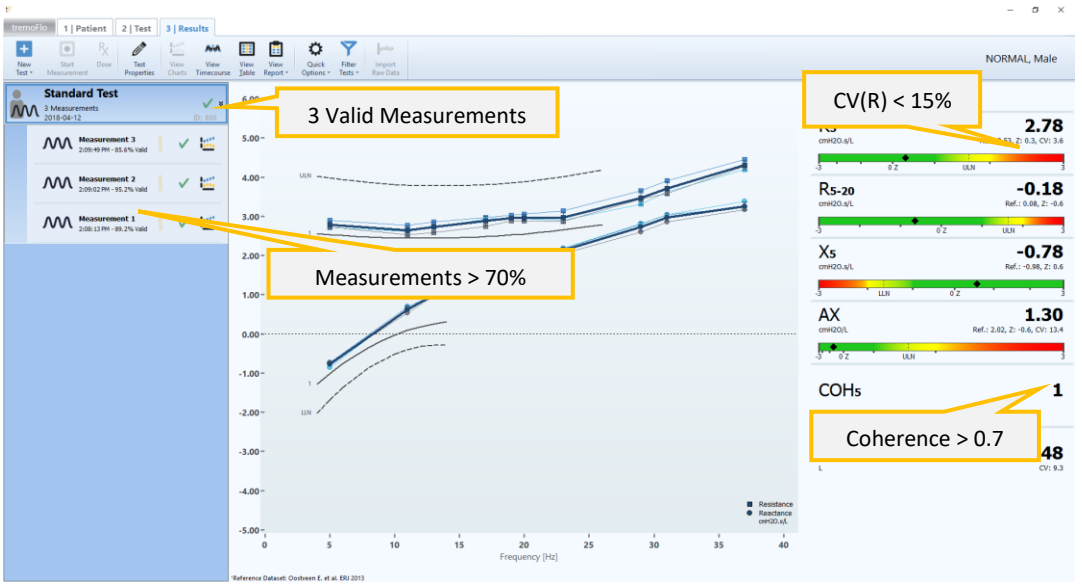


Figure 4.24: Quality Control Parameters on Chart View

4.8.5 Test Validation

Finally, the tremoflo software validates the patient test based on the criteria shown in Table 4.7. A failure to meet these criteria will result in a warning triangle being

displayed on the test's card in the Navigation Pane, Figure 4.24 whereas if the criteria are met a green checkmark is displayed on the test card (not shown).

Table 4.7: Test Validation Criteria

Criterion	Pass Criteria	Comments
Valid Measurements	≥ 3	After measurement validation.
Coefficient of Variation	≤ 15%	After exclusion of outliers measurements.

4.9 Bronchodilator Test

With your tremoflo you can also compare patient test data before and after the administration of a bronchodilator through the Bronchodilator Test which can be accessed by:

1) Choosing the bronchodilator testing in the test type dialog (see Figure 4.11) when starting a new patient test
   or
2) Clicking on the *Dose* button in an open Standard Test after the collection of baseline measurements.

After completing Measurement collection for the Pre BD Test, select *Bronchodilator Dose* to enter details on the administered dose and to automatically create the Post BD Test.

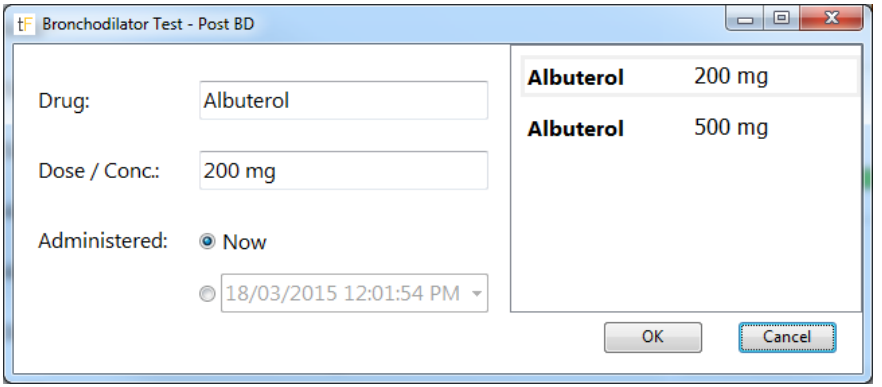


Figure 4.25 Bronchodilator Dose Administration with applicable fields on the left and recently administered doses on the right

During Measurement collection for the Post BD Test (until the Post BD Test is closed), the time since the Dose was Administered is displayed in the right side of the ribbon. After completing Measurement collection for the Post BD Test, click *End Test* to automatically return to Results View and view the comparison results for the Bronchodilator Test.

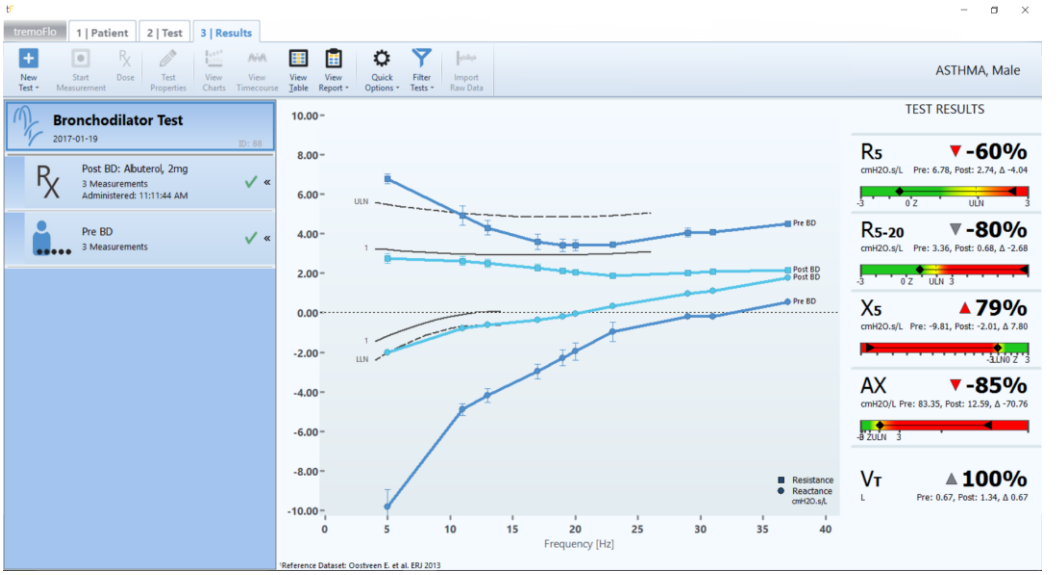


Figure 4.26 Bronchodilator Test Comparison Results

When a Bronchodilator Test is selected, the Results View will display the averaged results on the charts for Resistance and Reactance for both the Pre and Post BD Tests (as in Figure 4.26). The Values Panel will show the change in average value for each Parameter as well as the average values for the Pre and Post BD Tests.

The steps above can also be performed for a bronchoconstriction test.

4.10 Generating Reports

To generate a report click the View Report button on the Results tab of the Ribbon toolbar. A preview of the report for the selected patient test will be displayed in the client area of the main window, as shown in Figure 4.27.

To produce and save a copy of the report in Portable Document Format (PDF), click the Print button on the Ribbon toolbar. Note that by default, tremoflo reports are saved to the folder “C:\Users\Public\Documents\Thorasys\tremoflo 1.0\Reports”.

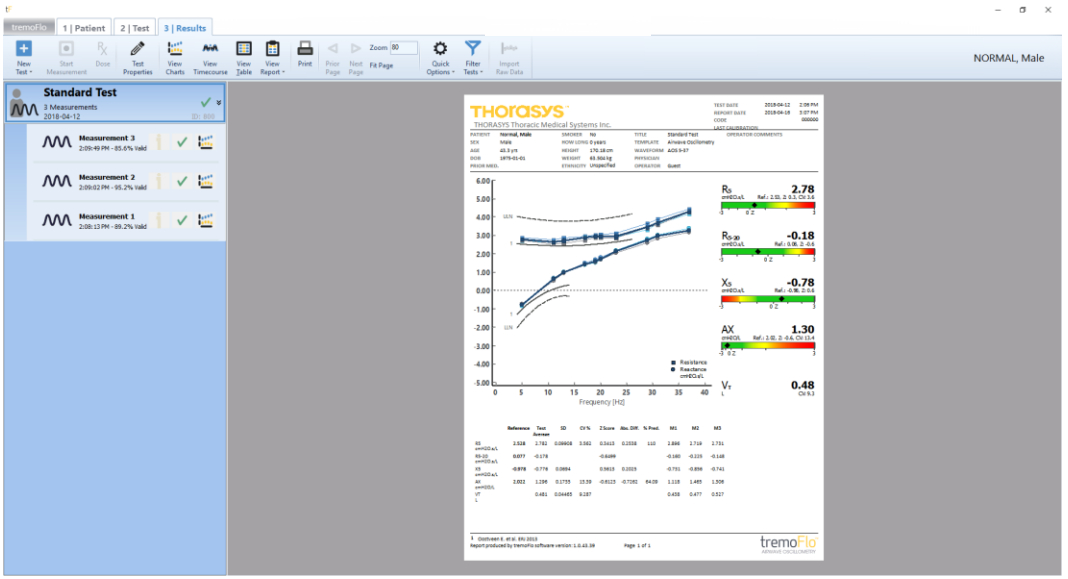


Figure 4.27: Report Preview

4.11 System Shut-Down

4.11.1 Closing the Software

To close the software, click the red X on the top right corner of the tremoflo screen, or select Exit from the tremoflo menu. There is no need to click Save before closing the software, all data are stored automatically as soon as they are collected.

4.11.2 Hardware Power-Down

When you are done with your tremoflo session and after you have closed down the tremoflo software, the power/status indicator on the Cradle should return to yellow. At this point, press and hold the power button on the Cradle for three to five seconds, until all power indicators turn off.

5 Software Reference Manual

5.1 Data Storage & Management

5.1.1 Database Storage

The tremoflo software stores data in a relational Client/Server database. For standard stand-alone installation, the database is typically located in the Windows Program Data area under C:\ProgramData\Thorasys\Database. This directory is not readily visible and accessible to Windows users unless they have administrator or similar privileges.

5.1.2 Backups & Data Transfers

The tremoflo software includes a database utility that permits database backups as well as transfer of selected types of data, including individual patient tests, from or to another database. The database utility is accessed from the System Settings menu.

5.1.3 Data Storage Locations

Default data storage locations are provided in Table 5.1. The file locations for reports and data export can be modified under Customize Reports and in the Export Wizard, respectively. Note that a shortcut to the reports folder is provided on the Windows desktop.

During normal operation, there should not be a need to directly access database or log files. Information contained in these files is normally accessed and maintained via the tremoflo software.

Table 5.1: Data Storage Locations

File Type	Folder
Reports	C:\Users\Public\Public Documents\Thorasys\tremoflo 1.0\Reports
Exported Data	C:\Users\Public\Public Documents\Thorasys\tremoflo 1.0\Export
Study Database	C:\ProgramData\Thorasys\Database

File Type	Folder
Database Template	C:\ProgramData\Thorasys\Database\Empty
System Log File	C:\ProgramData\Thorasys\tremoflo 1.0

6 Care & Maintenance

6.1 Storage & Transport

6.1.1 Dust Cover & Packaging

When the tremoflo system is not used for an extended period of time, be sure to place the dust cover over the filter port on the Handheld Unit. For long-term storage or transport, please retain and use the original tremoflo packaging.

	*Ensure that you insert the plastic dust cap into the tremoflo C-100 before storing for any length of time or transportation. Allowing the inner parts of the device to become dusty may potentially decrease measurement accuracy.*

6.1.2 Environmental Conditions

Store the tremoflo C-100 in a location where the temperature is between -25 and 50 degrees Celsius and the relative humidity is between 10 and 85%, non-condensing. Do not store the tremoflo C-100 in direct sunlight. The above environmental conditions apply for both transport and storage. Do not subject the tremoflo C-100 to impact or excessive vibration during transport and storage.

6.1.3 Acclimatization

After storing or transporting your tremoflo in a cold, or warm environment, allow at least 1 hour for the device to acclimatize to room temperature before taking any measurements. This will ensure maximum accuracy of reported results. In doubt, perform a field calibration in order to ensure the accuracy of the system after exposing it to varying environmental conditions.

6.2 Routine Cleaning

The use of a disposable anti-bacterial/anti-viral filter prevents transmission of diseases and infection between patients during regular use of the device. Proper use and disposal of the filters means that it is not necessary to perform special cleaning procedures to disinfect your tremoflo.

However, it is important to regularly clean the exterior surfaces of the tremoflo C-100 using a mild detergent of neutral pH. Detergents that assist in the removal of organic soil are ideal. Use warm tap water with the detergent to moisten a clean,

soft cloth. Wipe the exterior body and the edges of the tremoflo's filter port, but take care not to press against or otherwise damage the mesh screen inside. Do not use harsh chemical or abrasive cleaners as these may damage your device.

	*Do not immerse any part of the tremoflo C-100 in liquid or sterilize any part with hot water, steam, ETO or Gamma Rays; doing so may damage the device.*
	*Filters are one-time-use only; do not attempt to clean or reuse a filter for more than one patient or patient test. Filters must be disposed after use. Filter reuse increases the risk of cross-infection and/or contamination between patients. Repeat use may increase air resistance and lead to incorrect measurements.*

6.3 Maintenance

Regular maintenance of the tremoflo C-100 is not required. Routine field calibration ensures the accuracy of the outcomes as well as that the device is operating normally.

6.4 Expected Lifetime

The expected lifetime of the device is expected to be about 7 years under normal usage conditions.

6.5 Disposal

At the end of product's life dispose of the tremoflo in accordance with all local regulations regarding electrical and electronic waste. Where required, return the tremoflo to the place of purchase for safe disposal.

7 Warranty Policy

THORASYS warranties products against manufacturing defects by a one (1) year limited parts and labour warranty. Some restrictions apply. Disposables are covered by a three (3) month replacement warranty, including anti-viral/bacterial filters. We do not offer any other warranties, expressed or implied. Exact terms and details of the warranty coverage for specific items are available upon request. THORASYS does not offer refunds, credits or upgrades.

If you feel your THORASYS component is faulty or requires replacement, please contact Technical Support:

North America 1-855-THORASYS (1-855-846-7279) ext. 4

International +1-514-384-8555 ext. 4

techsupport@thorasys.com

Appendix A. Troubleshooting

Power Problems

Problem	Possible Cause	Solution
Unit does not turn on, all power indicators remain unlit.	Power cable not connected.	Verify all power connections.
	No power on outlet.	Verify that power is available, try a different outlet.
	Power button not fully pressed.	Press the power button for one full second.
Only one power indicator (Cradle or Handheld Unit) turns on while the other remains unlit.	Internal error (rare).	Disconnect and reconnect power supply, reboot the tremoflo. Contact Technical Support if the problem persists.
Power/status indicator on Cradle is yellow.	Software is not running.	Start the software and complete the software start-up sequence.
	Software is not fully initialized.	Complete the software start-up sequence.
	Software is in offline mode (reviewing historic data).	Start a new patient test.
Power/status indicator on Cradle is red.	Ethernet cable disconnected.	Reconnect Ethernet cable, software normally recovers and light returns to green.
	Software error.	Check error messages on screen and proceed accordingly.
	Internal error (rare).	Disconnect and reconnect power supply, reboot the tremoflo. Contact Technical Support if the problem persists.

Calibration Problems

Problem	Possible Cause	Solution
Unable to attach Calibration Test Load.	Dust cap still on unit.	Remove the dust cap before attaching the test load.
	Incorrect Calibrator Adapter.	Verify that the calibrator adapter matches the filter diameter.
Calibration produces error message.	No Calibration Test Load attached.	Attach the calibration test load (without dust caps) and click Start Over.
	Dust caps still on Calibration Test Load.	Remove the dust caps, reattach the test load and click Start Over.
	None of the above.	Click Start Over and try again. If the problem persists, contact Technical Support.
	Device too cold or too warm due to extreme environmental condition exposure.	Wait a few minutes for the device to acclimatize to the room temperature and repeat the calibration.

Appendix B. List of Units

Acceptable units are shown in the table below

Measurement	Units
Mass	kg, g, oz, lb
Length	m, cm, mm, in, ft
Volume	L, cL, mL, uL, cc, m3
Pressure	Pa, hPa, kPa, bar, mbar, mmH2O, cmH2O, mmHg, inHg, psi
Time	ms, s, sec, min, h, hrs, d, days

Appendix C. Electromagnetic Compatibility

Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility and needs to be installed and put into service according to the EMC information provided below.

<table>
<tr><th colspan="4">Guidance and Manufacturer's Declaration – Electromagnetic Emissions</th></tr>
<tr><td colspan="4">The tremoflo C-100 is intended for use in the electromagnetic environment specified below. The customer or the user of the tremoflo C-100 should ensure that it is used in such an environment.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td colspan="2">Electromagnetic Environment – Guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td colspan="2">The tremoflo C-100 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td colspan="2" rowspan="3">The tremoflo C-100 is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage Fluctuations/ Flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
<tr><td>  </td><td colspan="3">Warning: The tremoflo Airwave Oscillometry System should not be used adjacent to or stacked with other equipment, and that if adjacent or stacked use is necessary, the tremoflo should be observed to verify normal operation in the configuration in which it will be used.</td></tr>
<tr><td colspan="4">Guidance and Manufacturer's Declaration – Electromagnetic Immunity</td></tr>
<tr><td colspan="4">The tremoflo C-100 is intended for use in the electromagnetic environment specified below. The customer or the user of the tremoflo C-100 should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 Test Level</td><td>Compliance Level</td><td>Electromagnetic Environment - Guidance</td></tr>
</table>

Electrostatic discharge (ESD) EN 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient /burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input /output lines	± 2 kV for power supply lines ± 1 kV for input /output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2kV line(s) to earth	± 1 kV line(s) to line(s) ± 2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0%Un during half cycle 0%Un during 1 cycle 70%Un during 25 cycles (at 50Hz) 70%Un during 30 cycles (at 60Hz) Short interruptions: 0%Un during 250 cycles (at 50Hz) 0%Un during 300 cycles (at 60Hz)	Voltage dips: 0%Un during half cycle 0%Un during 1 cycle 70%Un during 25 cycles (at 50Hz) 70%Un during 30 cycles (at 60Hz) Short interruptions: 0%Un during 250 cycles (at 50Hz) 0%Un during 300 cycles (at 60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *tremoflo C-100* requires continued operation during power mains interruptions, it is recommended that the *tremoflo C-100* be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The *tremoflo C-100* is intended for use in the electromagnetic environment specified below. The customer or the user of the *tremoflo C-100* should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz 385MHz: 27V/m 710MHz,745MHz, 780MHz: 9V/m 450MHz, 810MHz, 870MHz, 930MHz: 28V/m 1.72GHz, 1.845GHz, 1.97GHz, 2.45GHz : 28V/m 5.24GHz, 5.5GHz, 5.785GHz: 9V/m	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz 385MHz: 27V/m 710MHz,745MHz, 780MHz: 9V/m 450MHz, 810MHz, 870MHz, 930MHz: 28V/m 1.72GHz, 1.845GHz, 1.97GHz, 2.45GHz : 28V/m 5.24GHz, 5.5GHz, 5.785GHz: 9V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *tremoflo C-100*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance d = $1.2\sqrt{P}$ d = $1.2\sqrt{P}$ 80 MHz to 800 MHz d = $2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in 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: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TB 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 *tremoflo C-100* is

used exceeds the applicable RF compliance level above, the *tremoflo C-100* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *tremoflo C-100*.

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the *tremoflo C-100*

The *tremoflo C-100* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *tremoflo C-100* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *tremoflo C-100* as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter in Watts	Separations Distance According to Frequency of Transmitter		
	150 kHz to 80 MHz d = $1.2\sqrt{P}$	80 MHz to 800 MHz d = $1.2\sqrt{P}$	800 MHz to 2.5 GHz d = $2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

Appendix D. tremoflo C-100 Technical Specifications

Principle of Operation

Measurement Principle	Oscillometry (Forced Oscillation Technique)
Oscillator Technology	Breathe-through Vibrating Mesh Technology (Patented)
Oscillator Frequency Range	DC - 41 Hz or higher, depending on amplitude requirement
Typ. Used Frequency Range	5 – 37 Hz (adult), 7 - 41 Hz (pediatric)
Patient Connection	Via disposable mouthpiece and bacterial/viral filter
Patient Cooperation	Quiet breathing, no voluntary manoeuvres required
Effective Deadspace	35 ml
Measurement Duration	User programmable, typically 20 sec., min. 10 sec., max. ≥ 10 min.
Measurement Repetitions	Typically 3, as per guidelines
Device Type	Portable medical device for use with tablet, laptop or desktop computer
Device Support	Handheld or on optional adjustable support arm (in preparation)

Measurements

Raw Data

Flow	Nominal Range	± 2.5 L/s
	Resolution	0.0014 L/s
	Linearity	< 2% up to 1 L/s
	Total Pathway Resistance	1.0 ± 5% $cmH_2O.s/L$
Volume		Integration of flow.
Mouth Pressure	Nominal Range	± 10 cmH_2O
	Resolution	0.0053 cmH_2O
	Linearity	< 0.25%
	Typical Swings[1]	1.6 cmH_2O peak-to-peak
Sampling	Low level sampling rate	>10 kHz
	Raw data storage rate	256 Hz
	AD accuracy	12 bit native, > 16 bit oversampled
Calibration	Reference Test Load	Nominal 2 $cmH_2O.s/L$ reference test load provided with system
	Calibration Duration	Typ. < 1 min.
	Calibration Frequency	Typ. once daily

[1] Mouth pressure swings depend on patient and oscillation waveform used.

Oscillation Waveforms

AOS 5-37	Adult	Non-harmonic composite Airwave™	5, 11, 13, 17, 19, 23, 29, 31 & 37 Hz
AOS 7-41	Pediatric	Non-harmonic composite Airwave™	7, 11, 13, 17, 19, 23, 29, 31, 37 & 41 Hz

Impedance Data

Abbr.	*Title*	*Description*
R(f)	Resistance as a function of frequency	Increases as the airways narrow. Heterogeneous constriction and/or disease of the small airways commonly leads to characteristic changes in the shape (i.e. frequency dependence) of Resistance.
X(f)	Reactance as a function of frequency	Reflects the compliance and the inertive properties of the respiratory system. Reactance becomes more negative in lung disease and is particularly sensitive to obstructions in the small airways.
Coh(f)	Coherence at each frequency	Quality control parameter ranging from +1 (ideal) to -∞

Accuracy Performance Limits

Nominal Measurable Impedance Range: 0 to 25 cmH2O.s/L

Nominal Measurable Impedance Accuracy: 10% or 0.1 cmH2O.s/L, whichever is greater over the oscillatory frequency range.

Outcome Parameters

Title	AOS 5-37	AOS 7-41	Description
Target Population	Adult	Pediatric	
Low frequency Resistance	R5	R7	Indicative of overall resistance of the respiratory system.
Mid-frequency Resistance[2]	R19 or R20	R19 or R20	Indicative of resistance of the conducting airways.
Frequency Dependence of Resistance[2]	R5-19 or R5-20	R7-19 or R7-20	Indicative of changes in the shape of R(f) that are typically associated with heterogeneous obstruction and small airway disease.
Low-frequency Reactance	X5	X7	Indicative of overall stiffening (i.e. loss of compliance) of the lungs and obstruction of small airways.
Resonance frequency	fres	fres	The frequency at which X(f) is zero. Indicative of overall stiffening of the lungs and obstruction of small airways.
Reactance Area	AX		Area enclosed by the negative portion of X(f), from the lowest measurement frequency to fres. Indicative of overall stiffening of the lungs and obstruction of small airways.
Tidal Volume	Vt		Patient's tidal volume
Respiratory Rate	RR		Patient's respiratory rate

[2] Mid-frequency values may be evaluated at 19 or 20 Hz depending on user preference. 20 Hz values interpolated from neighbouring frequencies contained in the oscillatory waveform.

Note: The above table lists the most commonly reported outcome parameters. Further outcome parameters such as the resistance and reactance values at other measurement frequencies are also available for display and reporting. Contact THORASYS or your closest representative for details.

Normative Data

Reference	*Demographics*	*Parameters*	*Comments*
Oostveen et al. 2013 *Eur. Resp. J.* 42.6: 1513-1523.	Adults 18-80 yrs.	R(f), X(f), f_{res}, AX at 5Hz	Predominantly Caucasian Cohort BD response thresholds provided
Brown et al. 2010 *Resp. Physiol. & Neurobiol.* 172.3: 162-168.	Adults 18-92 yrs.	R(f), X(f)	Predominantly Caucasian Cohort
Calogero et al. 2013 *Ped. Pulmonol.* 48.7: 707-715.	Children 2-13 yrs.	R(f), X(f), f_{res}, AX at 6Hz	Predominantly Caucasian Cohort BD response thresholds provided
Nowowiejska et al. 2008 *Ped. Pulmonol.* 43.12: 1193-1197.	Children 3-18 yrs.	R(f), X(f), f_{res}	Predominantly Caucasian Cohort

Physical Device

Ratings & Connectivity

Electrical Ratings	Cradle	24V, 1.25 A
	External Power Supply	100-240Vac, 47-63Hz, 30W
Power Lights	Cradle	With status indicator: Yellow – Standby, Green – Ready, Red – Error
	Handheld	Blue – Powered On
Acoustic Noise Emission	Patient Location	< 60 dB(A)
Patient Connectivity		Via Bacterial/Viral Filter with integrated mouthpiece
Computer Connectivity		Isolated Ethernet

Dimensions & Weight

Dimensions - WxDxH	Handheld	19 x 13 x 14 cm	7.5 x 5.1 x 5.5 in
	Cradle	21 x 14 x 15 cm	8.3 x 5.5 x 5.9 in
	Handheld on Cradle	21 x 14 x 24 cm	8.3 x 5.5 x 9.4 in
	Shipping Package	31 x 31 x 22 cm	12 x 12 x 8.5 in

Weight	Handheld Only	0.7 kg	1.5 lb
	Handheld & Cradle	1.7 kg	3.7 lb
	Shipping Weight	3.5 kg	7.7 lb

Certifications & Regulatory

Health Canada	Class II	Medical Device License 92761
European MDD/CE	Class IIa	CE Mark 607250
US FDA	Class II	510(k) K170185
Australia TGA	Class IIa	ARTG Certificate 220187
Electrical Safety		Protection Class I ES60601-1:2005 + A2012 (IEC60601-1, Edition 3.1)
Applied Parts		Class BF
Performance Guidelines		Meets and exceeds applicable ERS Guidelines[1]
Country of Origin		Canada

Computer System Requirements

Type		Desktop, All-in-One, Laptop or Tablet
Operating System	tremoflo Software	Windows 7/8/8.1/10, 32 or 64-bit

	Database	Windows 7/8/8.1/10/Server from Windows 2008 and above, 32 or 64-bit. Port 3050 open (for Firebird Database communication)
CPU		Dual-core 1.6 GHz or more
Memory		Min. 500 GB HDD, 3 GB RAM
Screen Resolution		1280 x 800
Connectivity		RC-45 Ethernet or USB-to-Ethernet (10/100/1000 Mbps), Wireless where permitted

Data Storage

Data Storage	File Type	Relational patient database, royalty-free
	Location	Local or remote server (no dedicated server required)
	Initial File Size	Approx. 2.8 MB
	Data Volume	Typ. <1 MB per patient test
	Encryption	Patient data in proprietary binary format, not Human-readable
Electronic Logs	Access Log	Time-stamped electronic log file of user actions
	Exception Log	Time-stamped exception log file for technical support purposes

Appendix E. References

[1] Oostveen E., et. al., 2003.The forced oscillation technique in clinical practice: methodology, recommendations and future developments. European Respiratory Journal, 22: 1026-41.

[2] Tgavalekos, Nora T., et al. "Identifying airways responsible for heterogeneous ventilation and mechanical dysfunction in asthma: an image functional modeling approach." *Journal of Applied Physiology* 99.6 (2005): 2388-2397.

[3] Lutchen, Kenneth R., et al. "Airway constriction pattern is a central component of asthma severity: the role of deep inspirations." American Journal of Respiratory and Critical Care Medicine 164.2 (2001): 207-215.

[4] Kaminsky DA, Irvin CG, Lundblad L, et al. Oscillation mechanics of the human lung periphery in asthma. *J Appl Physiol* 2004;97:1849-58.

[5] Bates, Jason HT. Lung mechanics: an inverse modeling approach. Cambridge University Press, 2009.

[6] Oostveen E., et. al., 2013. Respiratory impedance in healthy subjects: baseline values and bronchodilator response. European Respiratory Journal: Epub 2013 Apr 18.