tremoFlo® C-100 Technical Specifications (English)

1 Overview

The THORASYS® tremoFlo® C-100 Airwave Oscillometry System™ (AOS) is a handheld, portable medical device to measure pulmonary function without patient effort in quietly breathing patients. Compared to traditional lung function measurements, the tremoFlo uniquely combines of non-invasiveness, ease of use and new outcomes that potentially provide earlier detection of lung disease and exacerbations, and better insight into disease mechanisms and small airway disease.

This document applies to Part Numbers 101336 and 101490 used in combination with tremoFlo Software Version 1.0.

The tremoFlo is protected by US and international patents.

2 Principle of Operation

Measurement Principle	Oscillometry (Forced Oscillation Technique)
Oscillator Technology	Breathe-through Vibrating Mesh Technology (Patented)
Oscillation Frequency Range	DC - 37 Hz or higher, depending on amplitude requirement
Patient Connection	Via disposable mouthpiece and bacterial/viral filter
Patient Cooperation	Quiet breathing, no voluntary manoeuvres required
Measurement Duration	User programmable, typically 16 to 30 sec., min. 8 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)

3 Measurements

3.1 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		By 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.

3.2 Oscillation Waveforms

AOS 5-37	Adult	Non-harmonic composite Airwave™	5, 11, 13, 17, 19, 23, 29, 31 & 37 Hz
AOS 5-11-19	Adult	Sparse non-harmonic composite Airwave™	5, 11 and 19 Hz
S-IOS 5-25	Adult	Harmonic Soft Impulse Oscillometry™ signal	5, 10, 15, 20 and 25 Hz
SFO 5	Adult	Single-frequency (sinusoidal) Oscillometry signal	5 Hz (other frequencies upon request)
AOS 7-37	Pediatric[2]	Non-harmonic composite Airwave™	7, 11, 13, 17, 19, 23, 29, 31 & 37 Hz
AOS 7-13-19	Pediatric[2]	Sparse non-harmonic composite Airwave™	7, 13 and 19 Hz
SFO 7	Pediatric[2]	Single-frequency (sinusoidal) Oscillometry signal	7 Hz (other frequencies upon request)

Custom oscillation waveforms are available on request.

3.3 Impedance Data

Abbr.	*Title*	*Waveforms*	*Description*
R(f)	Resistance as a function of frequency	All	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	All	Reflects the compliance and the intertive 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	All	Quality control parameter ranging from +1 (ideal) to -∞

Nominal Impedance Range: 0.5 to 15 cmH2O.s/L

Nominal Impedance Accuracy: 10% or 0.1 cmH2O.s/L, whichever is greater

[2] Pediatric waveforms in preparation

3.4 Outcome Parameters

Title	*AOS 5-37*	*AOS 5-11-19*	*S-IOS 5-25*	*SFO 5*	*AOS 7-47*	*AOS 7-13-19*	*SFO 7*	*Description*
	adult				*pediatric*			
Low frequency Resistance	R_5				R_7			Indicative of overall resistance of the respiratory system.
Mid-frequency Resistance	R_{19}		R_{20}	-	R_{19}		-	Indicative of resistance of the conducting airways.
Frequency Dependence of Resistance	R_{5-19}		R_{5-20}	-	R_{7-19}		-	Indicative of changes in the shape of R(f) that are typically associated with heterogeneous obstruction and small airway disease.
Low-frequency Reactance	X_5				X_7			Indicative of overall stiffening (i.e. loss of compliance) of the lungs and obstruction of small airways.
Resonance frequency	f_{res}			-	f_{res}		-	The frequency at which X(f) is zero. Indicative of overall stiffening of the lungs and obstruction of small airways.
Reactance Area	AX_5			-	AX_7		-	Area enclosed by the negative portion of X(f), from 5 Hz to f_{res}. Indicative of overall stiffening of the lungs and obstruction of small airways.
Reactance Difference	ΔX_5				ΔX_7			Difference between low frequency inspiratory and expiratory resistance.
Tidal Volume	V_t							Patient's tidal volume
Respiratory Rate	RR							Patient's respiratory rate

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.

3.5 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_5	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_6	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

4 Physical Device

4.1 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	Yes
Acoustic Noise Emission	Patient Location	< 60 dB(A)
Patient Connectivity		Via Bacterial/Viral Filter with integrated mouthpiece
Computer Connectivity		Isolated Ethernet

4.2 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

4.3 Certifications & Regulatory

Health Canada	Class II	Medical Device License 92761
European MDD/CE	Class IIa	CE Mark 607250
US FDA	Class II/510(k)	Pending
Australia TGA	Class IIa	ARTG Certificate 220187
Electrical Safety		Protection Class I
Applied Parts		Class BF
Performance Guidelines		Meets and exceeds applicable ERS Guidelines[3]
Country of Origin		Canada

4.4 Computer System Requirements

Type		Desktop, All-in-One, Laptop or Tablet
Operating System		Windows 7/8/8.1, 32 or 64-bit
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, Wireless where permitted

4.5 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

[3] Oostveen et al., Eur Respir J 2003; 22: 1026-1041.