

Total Lung Capacity (TLC) MiniBox™ vs. Body Plethysmography

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INTRODUCTION

The MiniBox system is based on a novel technique for the measurement of lung volumes. The system is designed to measure lung volumes without the utilization of gases or a Plethysmographic cabin. The system sits on a desk and allows a rapid and user-friendly measurement.

The MiniBox technique has been validated in a prospective multi-center study on over 134 subjects, in Israel.

The purpose of this study, as well as others to come, is to test the accuracy of the measurement on different populations, in different geographies, against several Body Plethysmography devices.

METHOD

This study was held at a private practice in Boston, and included 27 subjects. Each of the patients enrolled was measured at the same day in random order on the MiniBox and the reference Body Plethysmography device, manufactured by Morgan Scientific, Inc.

DISCUSSION

Our results show that TLC_MiniBox is remarkably accurate compared to TLC_Pleth across the entire population studied. Among our prospective cohort of 27 subjects, who were healthy or had varying severities of obstructive and restrictive diseases, TLC_MiniBox correlated well with TLC_Pleth (adjusted r2 = 0.85).

Furthermore, the study showed a CV (Coefficient of Variation) of 10.9%, lower than the CV shown in our multi-center study (134 subjects) of 12.1%, or the CV shown by O'Donnell et al (CHEST, 2010) between Helium Gas Dilution and Computerized Tomography (CT) versus Body Plethysmography of 18.9% and 15.6%, respectively.

STUDY DATA	
No. subjects	27
Male / Female	14 / 13
Age (years)*	67.6
Height (cm)*	167.5
Weight (Kg)*	78.5
No. Healthy	12
No. Unhealthy	15

* Mean

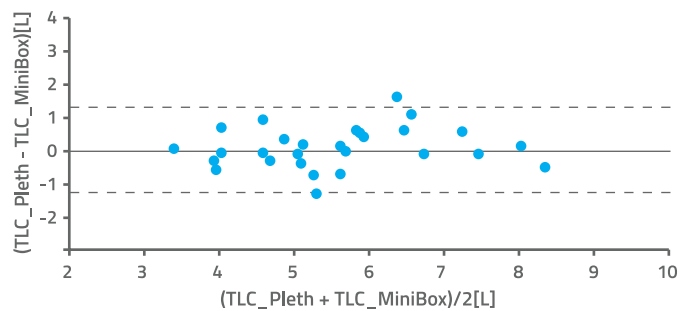


Figure 1: Associated Bland-Altman plots comparing MiniBox™ TLC (TLC_MiniBox) to Plethysmographic TLC (TLC_Pleth) for all subjects. The solid lines represent the mean bias while the dashed lines represent the upper and lower limits ($\pm 1.96 * SD$). The mean coefficient of variation (CV) is displayed within each graph.

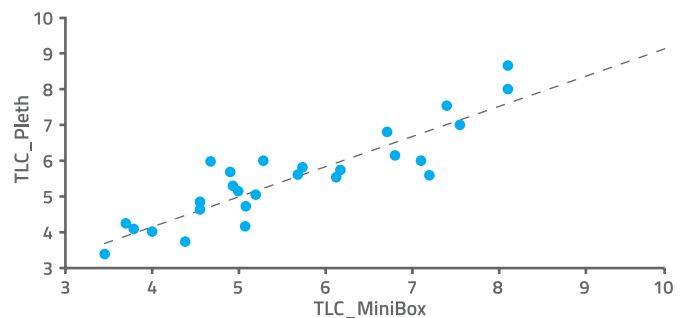


Figure 2: Scatter plots of plethysmographic TLC (TLC_Pleth) vs. MiniBox™ TLC (TLC_MiniBox) for all subjects. For subjects that were measured more than once on the device, the TLC is presented as the average value of all measurements. The dashed lines represent the unity line and the dotted lines represent the confidence intervals. The linear regression equation and the adjusted R2 are displayed within each graph.

COMPARATIVE STUDIES RESULTS VERSUS BODY PLETHYSMOGRAPHY

	MiniBox multi-center study, in Israel	MiniBox Boston study	O'Donnell et al. (CHEST, 2010) – Helium Gas Dilution	O'Donnell et al. (CHEST, 2010) – CT
No. subjects	134	27	149	149
CV [%]	12.1%	10.9%	18.9%	15.6%