

Total Lung Capacity (TLC) with the MiniBox® vs. Body Plethysmography: Accuracy, Measurement Time, and Testing Errors

Study conducted at the Specialist Medical Centre, Verona, Italy

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 non-sponsored study was held at the Specialist Medical Centre, Verona, Italy and included 134 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 MGC Diagnostics, USA. Simultaneously, time was recorded to measure reproducible lung volume data and DLCO values.

DISCUSSION

Our results show that TLC_MiniBox is remarkably accurate compared to TLC_Pleth across the entire population studied. Among our prospective cohort of 134 subjects, who had varying severities of obstructive and restrictive diseases, TLC_MiniBox correlated well with TLC_Pleth (adjusted $r^2 = 0.92$).

Furthermore, the study showed a CV (Coefficient of Variation) of 7.9%. Time to measure reproducible lung volumes and DLCO was 13.3 and 5.6 minutes on the MGC device vs. 6.9 and 1.4 minutes with the MiniBox.

STUDY DATA	MGC	MiniBox
Average Test Time (min) TLC and DLCO	13.3 and 5.6	6.9 and 1.4
Number of test errors or tests with no results	27 (7 TLC, 20 DLCO)	11 (0 TLC, 11 DLCO)
	20.1%	8.2%

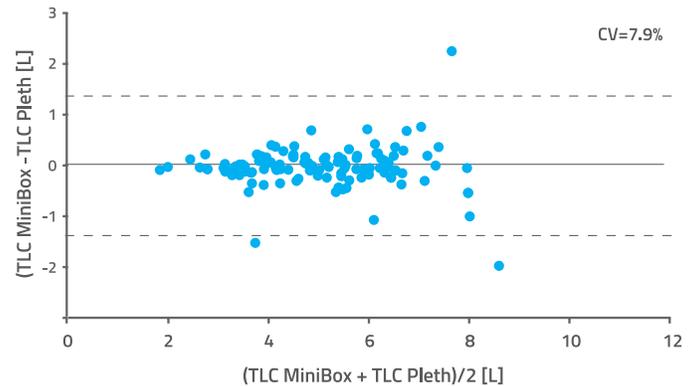


Figure 1: Associated Bland-Altman plots comparing MiniBox TLC (TLC_MiniBox) to Plethysmographic TLC (TLC_Pleth) for all subjects. The solid lines represent the mean bias while the dashed lines represent the upper and lower limits ($\pm 1.96 \times SD$). The mean coefficient of variation (CV) is displayed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

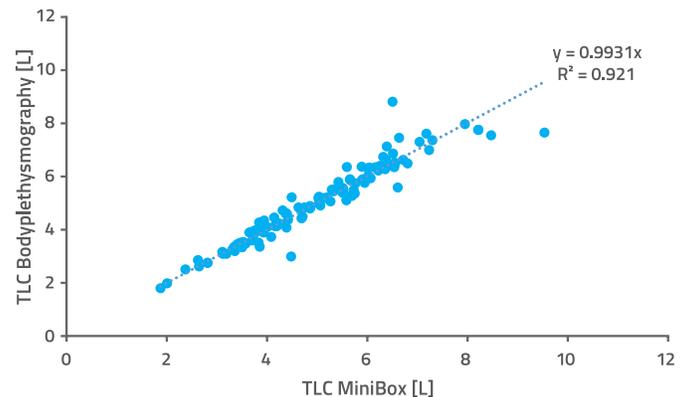


Figure 2: Scatter plots of plethysmographic TLC (TLC_Pleth) vs. MiniBox TLC (TLC_MiniBox) for all subjects. For subjects that were measured more than once on the device, the TLC is presented as the average value of all measurements. The dotted line represents the line of identity. The linear regression equation and the adjusted R^2 are displayed within the graph.

STUDY DATA		
No. subjects	134	
MiniBox device	No. Healthy	0
MGC Body Plethysmograph	No. Unhealthy	134

Comparative study results over time: MiniBox vs. Body Plethysmography

	MiniBox multi-center study, Israel, 2014	MiniBox Boston study, USA, 2017	MiniBox Cincinnati study, USA, 2017	MiniBox Verona study, Italy, 2019	MiniBox Enschede study, Netherlands, 2019
No. subjects	134	27	50	134	30
CV [%]	12.1%	10.9%	9.1%	7.9%	7.8%