

ISO 26782 Compliance Assessment of FlowMIR Plus: A study on Accuracy, Repeatability, Pneumatic Impedance, and Linearity in Spirometry Testing

Adriano Mencarini, Luca Pomella, Marco Pennacchiotti, Massimo Pistolesi
MIR - Medical International Research

Abstract

In accordance with *ATS/ERS* guidelines, spirometry measurements must adhere to stringent criteria. Standard *ISO 26782* is considered to provide a practical degree of safety for spirometers intended to assess lung function in individuals over 10 kg¹. This study evaluates the compliance of the FlowMIR Plus turbine technology developed by MIR with current guidelines, demonstrating its suitability for spirometry testing.

MIR laboratory conducted the validation tests using the FlowMIR Plus disposable turbine, the Spirobank II Plus professional spirometer (recipient of the *Good Design Award 2024*), and a pulmonary waveform generator compliant with *ATS/ERS*. Measurements were performed without BTPS correction to ensure realistic evaluation of

sensor readings. The testing protocol included three trials per spirometry parameter (FEV_1 , FEV_6 , FVC), across 13 expiratory curves representing prototypical patient profiles, as defined by *ISO*.

The results confirm that FlowMIR Plus measurements meet the *ISO 26782* requirements for accuracy, repeatability, pneumatic impedance, and linearity. Therefore, the findings highlight the reliability of turbine technology, with particular regard to the FlowMIR Plus turbine by MIR, sustaining its value in spirometry applications.

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¹ ISO 26782. *Anaesthetic and respiratory equipment: Spirometers intended for the measurement of time forced expired volumes in humans* (International Organization for Standardization, 2009).

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1. Introduction

Spirometry is among the fundamental medical exams to assess lung function and monitor respiratory conditions. To ensure reliable and clinically meaningful measurements, the equipment used – spirometer and its technology – must meet strict accuracy, repeatability, expiratory impedance, and linearity conditions. In particular, the *ISO 26782* international standard establishes performance requirements for spirometers intended for the measurement of time-forced expired volumes in humans.

In this study, we considered the mentioned criteria to assess whether the FlowMIR Plus turbine aligns with the requested benchmarks for spirometry performance.

2. Standard ISO 26782: Performance Requirements

Standard *ISO 26782* defines specific performance requirements to ensure consistent, reliable, and clinically valid spirometry measurements. These criteria are defined in relation to a set of profiles, represented by 13 expiratory curves.

2.1. Defined Test Profiles C1-C13

To evaluate spirometry device performance, the *ISO 26782* standard defines a series of test profiles that simulate the forced expiratory maneuvers observed in clinical practice. These profiles aim to represent heterogeneous expiratory patterns in patients.

Previous approaches – such as the 24 ATS test profiles – were based on real human exhalations. However, these profiles revealed themselves to be limited, leading to redundant data and an artificial structure that required smoothing when used with mechanical pump systems. To address these issues, the *ISO 26782* standard adopts a more systematic approach, focusing on the key characteristics of spirometry waveforms. The test profiles are mathematically defined

using exponential equations to mimic real-life expiratory patterns while eliminating artifacts. The methodology accounts for different lung volumes (vital capacity) ranging from 1.0 L to 8.0 L, and exponential time constants (τ) varying from 0.5 s to 2.5 s.

The profiles are further refined by incorporating:

- A start phase, reproducing the gradual increase in expiratory flow observed in humans. This step ensures an accurate back-extrapolated volume calculation and the correct identification of FEV₁ and FEV₆.
- A controlled end phase, simulating either a prolonged finish, as observed in patients with airflow limitation, or an abrupt termination, as occurs in younger individuals where chest wall mechanics limit expiration.

These 13 standardized test profiles, known as *Defined Test Profiles C1-C13*, are designed to comprehensively assess spirometer performance,

Figure 1.
Defined Test Profile C2

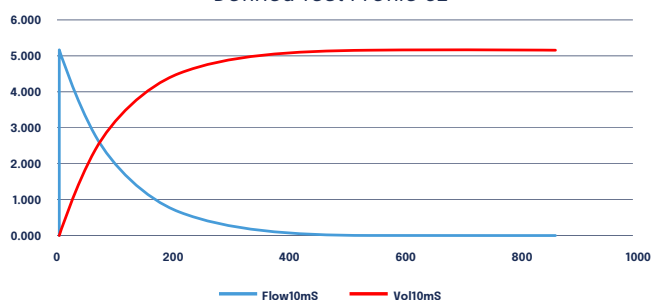
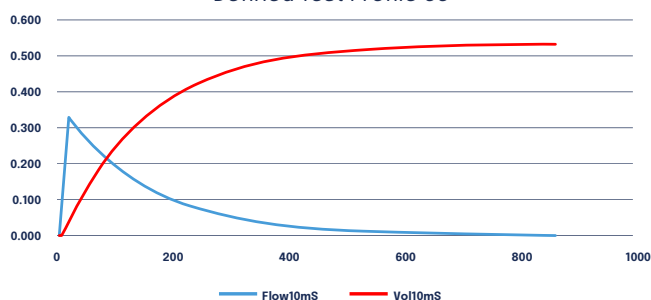


Figure 2.
Defined Test Profile C8



covering many expiratory behaviors found in patients. By testing spirometers against this panel of profiles, the standard ensures that devices provide valid measurements across various respiratory conditions².

Based on this classification of expiratory curves, we evaluated the assessment of FlowMIR Plus in accordance with the criteria analyzed in this study.

2.2. Accuracy

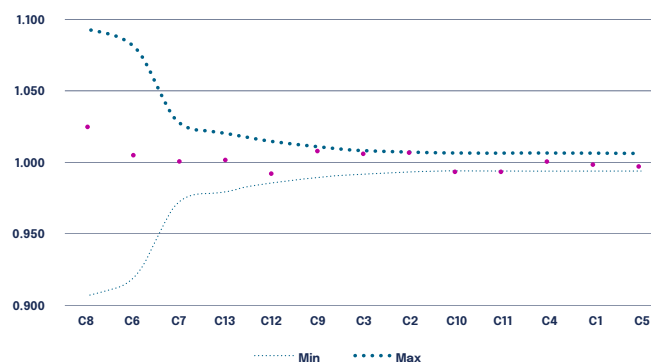
Establishing accuracy limits helps minimize potential errors that could impact clinical assessments.

According to the standard, the maximum permissible error for spirometric volume measurements must not exceed $\pm 3.0\%$ of the reading or 0.05 L, whichever is greater. This threshold applies under specific environmental conditions³.

In *Figure 3*, we illustrate the comparison between the actual volume measurements obtained using FlowMIR Plus (Actual) and the standard reference values (Standard). The data points (each representing an individual measurement) follow the diagonal trend, demonstrating a high adherence to the standard.

Finally, *Figure 4* highlights the measured values in relation to standard tolerance ranges, verifying compliance with accuracy thresholds.

Figure 4. Volume measurement within tolerance limits



2.3. Repeatability

The repeatability metric requires that spirometer readings remain within 0.05 L or 3% of the mean value. This condition implies that when the same test is performed multiple times under the same status, the variations between measurements should not exceed these limits⁴.

Figure 5 presents the repeatability analysis of FlowMIR Plus, displaying the percentage deviation of repeated measurements for different test conditions (C1–C13). The bars indicate the variation from the mean, with positive and negative deviations accounting the measurement spread. As shown, all values remain within the $\pm 3.0\%$ threshold, demonstrating that the turbine maintains a high level of repeatability, aligning with *ISO 26782*.

Figure 3.

Accuracy of FlowMIR Plus compared to the standard

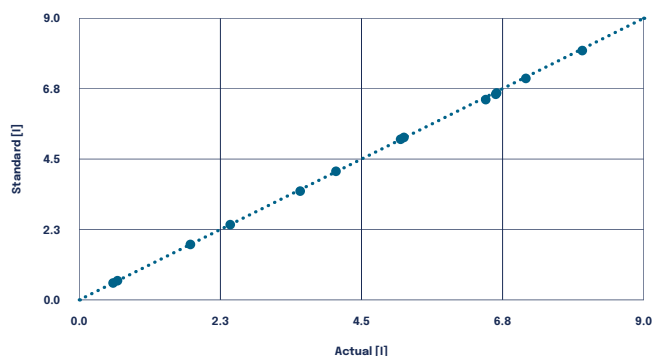
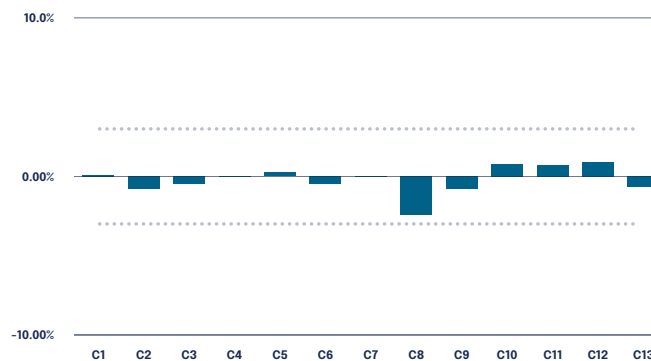


Figure 5.

Repeatability of FlowMIR Plus compared to the standard



² ISO 26782. *Anaesthetic and respiratory equipment: Spirometers intended for the measurement of time forced expired volumes in humans*, Annex A (International Organization for Standardization, 2009).

³ ISO 26782. *Anaesthetic and respiratory equipment: Spirometers intended for the measurement of time forced expired volumes in humans*, Section 7.1. Accuracy (International Organization for Standardization, 2009).

⁴ ISO 26782. *Anaesthetic and respiratory equipment: Spirometers intended for the measurement of time forced expired volumes in humans*, Section 7.8. Repeatability (International Organization for Standardization, 2009).

2.4. Expiratory impedance

Expiratory impedance, also referred to as pneumatic impedance to flow, is critical to assess the performance of a spirometer, including that of its accessories (e.g., standard or pediatric mouthpiece, antibacterial filter, etc). The expiratory impedance shall not exceed 0.15 kPa/(L/s), corresponding to 1.53 CmH₂O/(L/s), for a curve with flows of 14 L/s.

Given that expiratory impedance (Z_s) can be represented as

$$Z_s = \frac{\text{CmH}_2\text{O}}{\text{L/s}}$$

the tests determined the following impedance values:

Table 1.
Expiratory impedance of FlowMIR Plus

CmH ₂ O	L/s	CmH ₂ O/(L/s)
10.9	14	0.77

Maintaining expiratory impedance within the established limits minimizes airflow resistance. Indeed, demonstrating that FlowMIR Plus complies with this criterion enhances the overall performance of spirometry testing.

2.5. Linearity

The last point of the standard that we will analyze is linearity. The linearity error of the spirometer, including its accessories and detachable components, shall not exceed 3% when measured at incremental steps between 0.4 L and 0.6 L, covering the entire measurement range of the device for the defined test profiles.

Table 2.
Linearity of FlowMIR Plus compared to the standard

		Vref	Measured	Verr	Linearity	Max error
C8	FEV1	0.260	0.273	0.013	2.38	±3%
C6	FVC	0.607	0.610	0.003	-0.36	±3%
C7	FEV1	1.243	1.237	0.006	0.35	±3%
C7	FVC	1.769	1.770	0.001	0.02	±3%
C13	FVC	2.406	2.407	0.001	-1.04	±3%
C2	FEV1	3.273	3.303	0.030	-0.03	±3%
C12	FVC	3.518	3.487	0.031	-0.04	±3%
C9	FVC	4.087	4.120	0.033	0.63	±3%
C10	FEV1	4.628	4.633	0.005	-0.37	±3%
C3	FVC	5.110	5.133	0.023	-0.15	±3%
C11	FEV1	5.588	5.557	0.031	0.30	±3%
C5	FEV1	5.889	5.903	0.014	-0.58	±3%
C10	FVC	6.477	6.427	0.050	0.64	±3%
C1	FVC	7.120	7.113	0.007	-0.17	±3%
C5	FVC	8.023	8.003	0.020	0.49	±3%

3. Methodology

To validate the compliance of the FlowMIR Plus turbine with the accuracy, repeatability, expiratory impedance, and linearity criteria defined by ISO 26782, a series of tests were conducted using a FlowMIR Plus turbine, a Spirobank II Plus spirometer, and a waveform generator compliant with ATS/ERS guidelines.

The study validated turbine performance by testing the 13 Defined Test Profiles (C1-C13), as per the standard. Each of the 13 Defined Test Profiles was executed three times to assess the turbine's consistency across different breathing patterns (see Tables 3, 4, and 5). The evaluation focused on three key spirometric parameters: Forced Expiratory Volume in 1 Second (FEV₁), Forced Expiratory Volume in 6 seconds (FEV₆), and Forced Vital Capacity (FVC).

The maximum error was calculated within the standard parameters of 0.05 L or 3%. In addition, no BTPS correction has been applied to the measurements, ensuring that the testing conditions closely mirrored actual scenarios. This approach aimed at attainably reflecting the turbine's actual performance without external adjustments, thus providing an objective assessment of its functionality. The collected data were processed and analyzed, and graphical representations were generated in accordance with the established evaluation criteria.

Table 3.
Tests on FEV1

	Standard	Average measurement	Accuracy	Accuracy %	FEV1 1	FEV1 2	FEV1 3
C1	4,895	4,913	0,018	0,37	4,91	4,92	4,91
C2	3,273	3,303	0,030	0,93	3,3	3,31	3,3
C3	2,490	2,473	-0,017	-0,67	2,47	2,47	2,48
C4	4,090	4,107	0,017	0,41	4,11	4,1	4,11
C5	5,889	5,903	0,014	0,24	5,9	5,9	5,91
C6	0,526	0,517	-0,009	-1,77	0,52	0,52	0,51
C7	1,243	1,237	-0,006	-0,51	1,24	1,23	1,24
C8	0,261	0,273	0,012	4,73	0,27	0,28	0,27
C9	1,992	1,983	-0,009	-0,44	1,98	1,99	1,98
C10	4,628	4,633	0,005	0,12	4,63	4,64	4,63
C11	5,588	5,557	-0,031	-0,56	5,56	5,56	5,55
C12	2,098	2,050	-0,048	-2,29	2,05	2,05	2,05
C13	1,374	1,357	-0,017	-1,26	1,36	1,36	1,35

Table 4.
Tests on FEV6

	Standard	Average measurement	Accuracy	Accuracy %	FEV6 1	FEV6 2	FEV6 3
C1	7,120	7,113	-0,007	-0,09	7,11	7,12	7,11
C2	5,167	5,217	0,050	0,96	5,22	5,22	5,21
C3	5,026	5,033	0,007	0,15	5,03	5,03	5,04
C4	6,635	6,640	0,005	0,08	6,64	6,64	6,64
C5	8,023	8,003	-0,020	-0,25	8,01	8	8
C6	0,607	0,610	0,003	0,49	0,61	0,61	0,61
C7	1,769	1,767	-0,002	-0,13	1,77	1,76	1,77
C8	0,527	0,540	0,013	2,47	0,54	0,54	0,54
C9	4,021	4,037	0,016	0,39	4,04	4,04	4,03
C10	6,323	6,337	0,014	0,22	6,34	6,33	6,34
C11	6,637	6,593	-0,044	-0,66	6,59	6,59	6,6
C12	3,342	3,333	-0,009	-0,26	3,33	3,33	3,34
C13	2,406	2,403	-0,003	-0,11	2,4	2,41	2,4

Table 5.
Tests on FVC

	Standard	Average measurement	Accuracy	Accuracy %	FVC 1	FVC 2	FVC 3
C1	7,120	7,113	-0,007	-0,09	7,11	7,12	7,11
C2	5,174	5,217	0,043	0,82	5,22	5,22	5,21
C3	5,110	5,133	0,023	0,46	5,13	5,13	5,14
C4	6,647	6,650	0,003	0,05	6,65	6,65	6,65
C5	8,023	8,003	-0,020	-0,25	8,01	8	8
C6	0,607	0,610	0,003	0,49	0,61	0,61	0,61
C7	1,769	1,770	0,001	0,06	1,77	1,77	1,77
C8	0,527	0,540	0,013	2,47	0,54	0,54	0,54
C9	4,087	4,120	0,033	0,81	4,12	4,12	4,12
C10	6,477	6,427	-0,050	-0,78	6,42	6,43	6,43
C11	6,637	6,427	-0,210	-3,17	6,42	6,43	6,43
C12	3,518	3,487	-0,031	-0,89	3,48	3,49	3,49
C13	2,406	2,407	0,001	0,03	2,4	2,41	2,41

3.1. Data Analysis

The turbine's performance was analyzed based on four key aspects. To visually interpret the results, several representations were generated in accordance with the predefined evaluation criteria.

- Accuracy, assessed by comparing the measured values against the expected reference values from the waveform generator. (Figure 3, Figure 4)
- Repeatability, determined by evaluating the variability of measurements across repeated tests. (Figure 5)
- Expiratory impedance, analyzed by measuring the pressure drop of the turbine compared to the prescribed limit. (Table 1)
- Linearity, examined by verifying that the measurement error does not exceed 3% when comparing turbine flow and volume readings to reference values. (Table 2)

4. Conclusions

The results of this research confirm that the FlowMIR Plus turbine meets the performance requirements outlined in *ISO 26782*. The graphical analysis supports this conclusion by demonstrating compliance with the prescribed limits for accuracy, repeatability, expiratory impedance, and linearity. By not applying correction factors, this study provides a realistic assessment of the turbine's actual performance in controlled conditions. The results suggest that FlowMIR Plus is a reliable tool for spirometric measurements, reinforcing its suitability for clinical and research applications. Future studies may explore additional testing conditions to further validate its scope.

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