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ORIGINAL RESEARCH

# Test-retest reliability and concurrent validity of a digital manovacuometer

*Reprodutibilidade teste-reteste e validade concorrente de manovacuômetro digital*

*La reproducibilidad de test-retest y la validez concurrente del manovacuometro digital*

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**ABSTRACT |** The manovacuometer is a simple, quick and non-invasive test which measures the maximal respiratory pressures (MRS). Guidelines recommend the use of a digital manovacuometer due to its high accuracy. The purpose of this study was to assess the test-retest reliability and concurrent validity of a digital manovacuometer in measuring the maximal inspiratory and expiratory pressures (MIP/MEP) and nasal inspiratory pressure while sniffing (SNIP). A total of 30 healthy subjects were assessed (20–30 years old) using the UFMG and MicroRPM® (Micro Medical, UK) digital manovacuometers. To assess reliability, Intraclass Correlation Coefficient (ICC) and Student's t test it was used for dependent samples. For the validity assessment, the following were used: Pearson correlation, Student's t test for dependent samples, linear regression and the Bland-Altman method. The level of significance was set at 5% (p<0.05). The ICC values were significant and showed a good magnitude (0.76 to 0.89) and no significant differences were found between the means of the variables of the UFMG digital manovacuometer analyzed within two days (p>0.05); the correlation between observed values from the two instruments was of high magnitude for all variables (0.82 to 0.85); no significant difference was found between the values obtained for both instruments (p>0.05); a strong association was observed between measures of MIP and MEP obtained by the two methods and Bland-Altman analysis showed no systematic overestimation or underestimation of maximal respiratory pressures and SNIP. In conclusion, the results suggest that the UFMG manovacuometer is a reliable and valid instrument for assessing MIP, MEP and SNIP in healthy subjects.

**Keywords |** Respiratory Muscles; Respiratory Function Tests; Reproducibility of Results.

**RESUMO |** A manovacuometria é um teste simples, rápido e não invasivo que mensura as pressões respiratórias máximas (PRM). Diretrizes recomendam o uso do manovacuômetro digital devido à sua alta precisão. O objetivo deste estudo foi avaliar a reprodutibilidade teste-reteste e a validade concorrente de um manovacuômetro digital na mensuração das pressões inspiratórias e expiratórias máximas (PImáx e PEmáx) e da pressão inspiratória nasal durante o fungar (SNIP). Foram avaliados 30 indivíduos saudáveis (20–30 anos) utilizando os manovacuômetros digitais UFMG e MicroRPM® (*Micro Medical, UK*). Para avaliar a reprodutibilidade, foi utilizado o Coeficiente de Correlação Intraclasse (CCI) e teste *t* de *student* para amostras dependentes. Para análise da validade foram utilizados: a correlação de *Pearson*, o teste *t* de *student* para amostras dependentes, a análise de regressão linear e o método Bland-Altman. O nível de significância considerado foi de 5% (p<0,05). Os valores de CCI foram significativos e de boa magnitude (0,76 a 0,89) e não foram encontradas diferenças significativas entre as médias das variáveis do manovacuômetro UFMG analisadas nos dois dias (p>0,05). A correlação entre os valores observados nos dois instrumentos foi de alta magnitude para todas as variáveis (0,82 a 0,85); não houve diferença significativa entre os valores médios obtidos nos dois instrumentos (p>0,05); foi observada forte associação entre as medidas das PRM obtidas pelos dois métodos e a análise de Bland-Altman não demonstrou superestimação ou subestimação sistemática das PRM e do SNIP. Em conclusão, os resultados sugerem que o manovacuômetro UFMG é confiável e válido para avaliação das PRM e SNIP em indivíduos saudáveis.

**Descritores |** Músculos Respiratórios; Testes de Função Respiratória; Reprodutibilidade dos Testes.

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**RESUMEN |** La manovacuometría es una prueba sencilla, rápida y no invasiva que mide las presiones respiratorias máximas (PRM). Directrices recomiendan el uso del manuvacuómetro digital debido a su alta precisión. El objetivo de este estudio fue evaluar la reproducibilidad test-retest y la validez concurrente de un manuvacuómetro digital para medir las presiones inspiratoria y espiratoria máximas (PImáx y PEmáx) y de la presión inspiratoria nasal durante la aspiración (SNIP). Se evaluaron 30 sujetos sanos (20–30 años) por medio de los manovacuómetros digitales UFMG y MicroRPM® (*Micro Medical*, *UK*). Para evaluar la reproducibilidad, se utilizó el coeficiente de correlación intraclase (CCI) y el test *t* de *student* para muestras dependientes. Para el análisis de la validez se utilizaron: la correlación de *Pearson*, el test *t* de *student* para muestras dependientes, el análisis de regresión lineal y el método Bland-Altman. El nivel de significación considerado fue del 5% ($p<0,05$). Los valores de CCI fueron significativos y de buena magnitud (0,76 a 0,89) y no se encontraron diferencias significativas entre las medias de las variables del manovacuómetro UFMG analizadas en los dos días ($p>0,05$). La correlación entre los valores observados en los dos instrumentos fue de alta magnitud para todas las variables (0,82 a 0,85); no hubo diferencia significativa entre los valores medios obtenidos en los dos instrumentos ($p>0,05$); Se observó una fuerte asociación entre las medidas de las PRM obtenidas por los dos métodos y el análisis de Bland-Altman no demostró sobreestimación o subestimación sistemática de las PRM y del SNIP. En conclusión, los resultados sugieren que el manovacuómetro UFMG es fiable y válido para la evaluación de las PRM y SNIP en sujetos sanos.

**Palabras clave |** Músculos Respiratorios; Pruebas de Función Respiratoria; Reproducibilidad de Resultados.

## INTRODUCTION

Measurement of Maximal Respiratory Pressures (MRP) is the most widely used noninvasive method in the clinic for evaluation of respiratory muscle strength (RMS)[1,2]. The classic maneuvers of MRP are those in which subjects generate maximum inspiratory (MIP) and expiratory (MEP) efforts against an occluded mouthpiece[2,3]. An alternative and/or complementary test to assess inspiratory force is the SNIP test (sniff nasal inspiratory pressure)[4], which records nasal inspiratory pressure during sniff.

Manovacuometry is used to evaluate RMS under different conditions[2,5-7]. The SNIP test is important to quantify the decline in inspiratory force due to weakness of the orofacial muscles, as in amyotrophic lateral sclerosis[8,9].

According to Montemezzo *et al*.[10], he most widely used type of manovacuometer in Brazil is the analog, despite the digital equipment presenting considerable advantages[2,3,5]. The digital manovacuometer frequently reported for the measurement of MRPs and SNIP is MicroRPM® (Micro Medical, UK)[11-16]. Reproducibility was evaluated by Dimitriadis *et al*.[7], who observed a high value of intraclass correlation coefficient (ICC) for both MIP (0.78 and 0.87, respectively) and for MEP (0.82 and 0.90, respectively).

Because the applicability of a measure in research and in clinical decision-making depends on the extent to which the data are reproducible and accurate[17], the aim of this study was to assess the test-retest reliability of MRP and SNIP measured by a digital manovacuometer developed in Universidade Federal de Minas Gerais (UFMG)[18], as well as the concurrent validity of these measures in relation to those obtained by the MicroRPM® manovacuometer.

## METHODOLOGY

### Sample

The convenience sample was composed of volunteers of both sexes, who met the following inclusion criteria: age between 20 and 30 years; with body mass index (BMI) within normal or overweight ($18.5\ kg/m^2 \leq BMI \geq 29.9\ kg/m^2$)[19] and presenting normal pulmonary function according to what was predicted by Pereira *et al*.[20]. Exclusion criteria were: inability to understand or perform the maneuver requested, report of current or former smoking; neuromuscular, respiratory and/or heart diseases; deviated nasal septum or previous nasal surgery; presence of fever in the previous three weeks and/or flu in the week before the test; blood pressure (BP) at rest greater than or equal to 160/110 mmHg[21] and/or hemoglobin saturation ($SpO_2$) of less than 90% and/or heart rate (HR) greater than 85% of maximal HR before the execution of maneuvers. As a criterion for discontinuation, the report of respiratory and/or muscle discomfort during testing was considered. The study was approved by the Institutional Ethics Committee (CAAC 0425.0.203.000-10) and participants signed a free and informed consent form.

## Measurement instruments

*Digital manovacuometer – UFMG*

To measure RMS, a digital manovacuometer developed at UFMG through a partnership between the Laboratory for Evaluation and Research in Cardiorespiratory Performance (LabCare) and the Center for Studies and Research in Biomedical Engineering[18,22], with an operating range of 500 $cmH_2O$[18], was used. A Diver nozzle, with a 2 mm diameter escape hole and the nose clip were used to measure RMS[1,2,22]. For the SNIP test, a 60 cm silicone extension and a conical-shaped nasal plug were used. The RMS were operationalized by Manovac 4.1 software, using the variable maximum average pressure (MAP) Peak pressure (PIP) and plateau pressure (Pplat), and SNIP was operationalized by PIP[4,22,23].

*MicroRPM® manovacuometer*

This equipment has an operating range of ±300 $cmH_2O$[24]. For measures of RMS, a diver-type nozzle was used. For the SNIP test, the equipment offers four polyethylene nasal plugs of different sizes. The PUMA PC (Micro Medical, Rochester, Kent, UK) software operationalized the MIP, MEP and SNIP variables. In this study, these variables were used to analyze the concurrent validity of MMP (mean maximum pressure, inspiratory and expiratory) and SNIP variables.

## Measurement of maximal respiratory pressures and SNIP

For measurement of MRP, subjects remained in a sitting position, with their feet on the ground and trunk backed up, using a nose clip. For the measurement of MIP and MEP, a previously described procedure was used[3,22]. The minimum time of the maneuvers was 1.5 s, so that the maximum pressure sustained by 1 s could be observed[2]. The measurement of pressures was terminated when the participant performed three acceptable maneuvers (with no air leak between the lips and with at least a second and a half in length)[3] with three of them reproducible (one with variation less than or equal to 10% and the other with a maximum variation of 20% to the one of highest value)[2,3]. The largest measure could not be the last, considering the learning effect[3]. The MMP, PIP and Pplat variables were selected from the maneuver with the largest MMP value between reproducible maneuvers.

For the SNIP test, participants were positioned sitting with arms resting, and the receiver was inserted into one unobstructed nostril, according to individual perception. The contralateral nostril remained without occlusion. The participant was asked to breathe at the level of the functional residual capacity (FRC) and perform, to verbal command, a rapid maximal inspiration through the non-occluded nostril. Ten measures with a 30 s interval between each were performed, being selected the PIP variable with the higher value[2,4].

## Procedures

The study was conducted in two days, with an interval of at least 2 and at most 15 days, subjects were evaluated in the same period (morning or afternoon). All procedures were performed by a single examiner.

On the first day, the following variables were evaluated: personal data, body mass and height (Filizola Ind. Ltda, Brazil.), blood pressure (stethoscope by BD, USA, and sphygmomanometer by Tycos, USA); HR and $SpO_2$ (Nonim, USA). After that, the pulmonary function test (Pony FX®, Italy) was performed according to the criteria proposed by the Brazilian Society of Pneumology and Tisiology (SBPT)[25]. After resting for about 10 minutes, subjects performed a random measurement of MIP, MEP and SNIP, with the UFMG manovacuometer.

On the second day, after a draw was performed to identify what would be the order of use of instruments (UFMG and MicroRPM®), a randomization of the MIP, MEP and SNIP tests was performed. A 10-minute rest was established between the measurements in the two instruments.

## Data reduction

For reproducibility, values of MMP, PIP and Pplat (inspiratory and expiratory), as well as SNIP values obtained with the UFMG manovacuometer on the first day (test) and on the second day (retest), were compared. For the concurrent validity, MMP (inspiratory and expiratory) and SNIP obtained with UFMG and MicroRPM manovacuometers (obtained on the first day) were analyzed.

## Statistical analysis

To assess the distribution of data, the Shapiro-Wilk test was used. For the test-retest reproducibility of the inspiratory and expiratory variables (MMP, PIP and

Pplat) and of SNIP, the intraclass correlation coefficient and Student's t test were used for dependent samples. For concurrent validity, the Pearson correlation test was used (between inspiratory and expiratory MMP, as well as the SNIP obtained from both instruments). Student's *t* test was used for dependent samples, as well as the Bland-Altman method and regression analysis. A linear regression analysis was used to assess the degree of association (coefficient of determination $r^2$) between the RMS and SNIP values assessed by two manovacuometers. A linear regression equation was determined considering the MIP (operationalized by inspiratory MMP), MEP (operationalized by expiratory MMP) and SNIP (inspiratory PIP) from the UFMG manovacuometer as dependent variable (Y) and MIP, MEP and SNIP from the MicroRPM® manovacuometer as independent variable (X). SPSS version 15.0 and GraphPad Prism 5 statistical packages were used. Data were presented as measures of central tendency, dispersion and confidence interval were used. A significance level of 5% was considered.

## RESULTS

Initially, 31 individuals, of which one was excluded for presenting changes in pulmonary function, were recruited. Thus, the final sample consisted of 30 participants.

Table 1 shows the demographic and anthropometric characteristics and spirometric data of the participants.

Table 2 presents data on the reliability of the UFMG manovacuometer. All the ICC values were significant and presented good magnitude (≥0.76). No significant differences were found between the values obtained in the two test days, demonstrated in the analysis of the 95%CI.

Table 3 presents comparing data between the two manovacuometers. There was no significant difference in any of the variables.

In the analysis of the correlation (r) between measurements obtained with both manovacuometers, values of high magnitude and significant for the variables inspiratory MMP, expiratory MMP and SNIP (0.85, 0.83 and 0.82, p=0.000, respectively) were observed.

The regression equation of MIP values obtained by the UFMG manovacuometer and by the MicroRPM® manovacuometer was: UFMG MIP=11.87+0.86x (MicroRPM® MIP); (p=0.000). An $r^2$ of 0.83 was observed. The regression equation for the MEP was: UFMG MEP=0.97+0.98x (MicroRPM® MEP) (p=0.000); with an $r^2$ of 0.83. The regression equation for the SNIP was: SNIP=22.87+0.75x (MicroRPM® SNIP); (p=0.000), with an $r^2$ of 0.67.

The Bland-Altman analysis found the MIP for the mean of the differences found a bias between the two instruments equal to -3 $cmH_2O$ (Figure 1A); for the MEP, a bias equal to -2 $cmH_2O$ (Figure 1B) was found, and, for the SNIP, there was a bias of 0.6 $cmH_2O$ (Figure 1C).

Table 2. Variables of test-retest reliability of the UFMG manovacuometer analyzed in the 30 participants

| Variables ($cmH_2O$) | 1st day Mean (SD) | 2nd day Mean (SD) | 95%CI | ICC |
|---|---|---|---|---|
| Maximal Inspiratory Pressure | | | | |
| MMP | 108.74 (29.08) | 106.73 (29.40) | -3.05–7.06 | 0.89 |
| PIP | 120.90 (32.36) | 118.17 (30.93) | -3.02–8.49 | 0.88 |
| Pplat | 100.73 (26.62) | 95.47 (30.25) | -2.08–12.60 | 0.76 |
| Maximal Expiratory Pressure | | | | |
| MMP | 130.92 (37.76) | 135.78 (40.78) | -13.28–3.56 | 0.84 |
| PIP | 139.47 (39.77) | 143.60 (43.64) | -13.12–4.86 | 0.83 |
| Pplat | 122.40 (38.04) | 125.80 (38.40) | -12.05–5.25 | 0.82 |
| SNIP | | | | |
| SNIP | 90.37 (24.04) | 94.33 (23.01) | -9.83–1.90 | 0.78 |

ICC: intraclass correlation coefficient; MMP: mean maximum pressure; Pplat: plateau pressure; PIP: peak pressure; SNIP: sniff nasal inspiratory pressure test; SD: standard deviation

Table 1. Demographic, anthropometric and spirometric data of the participants

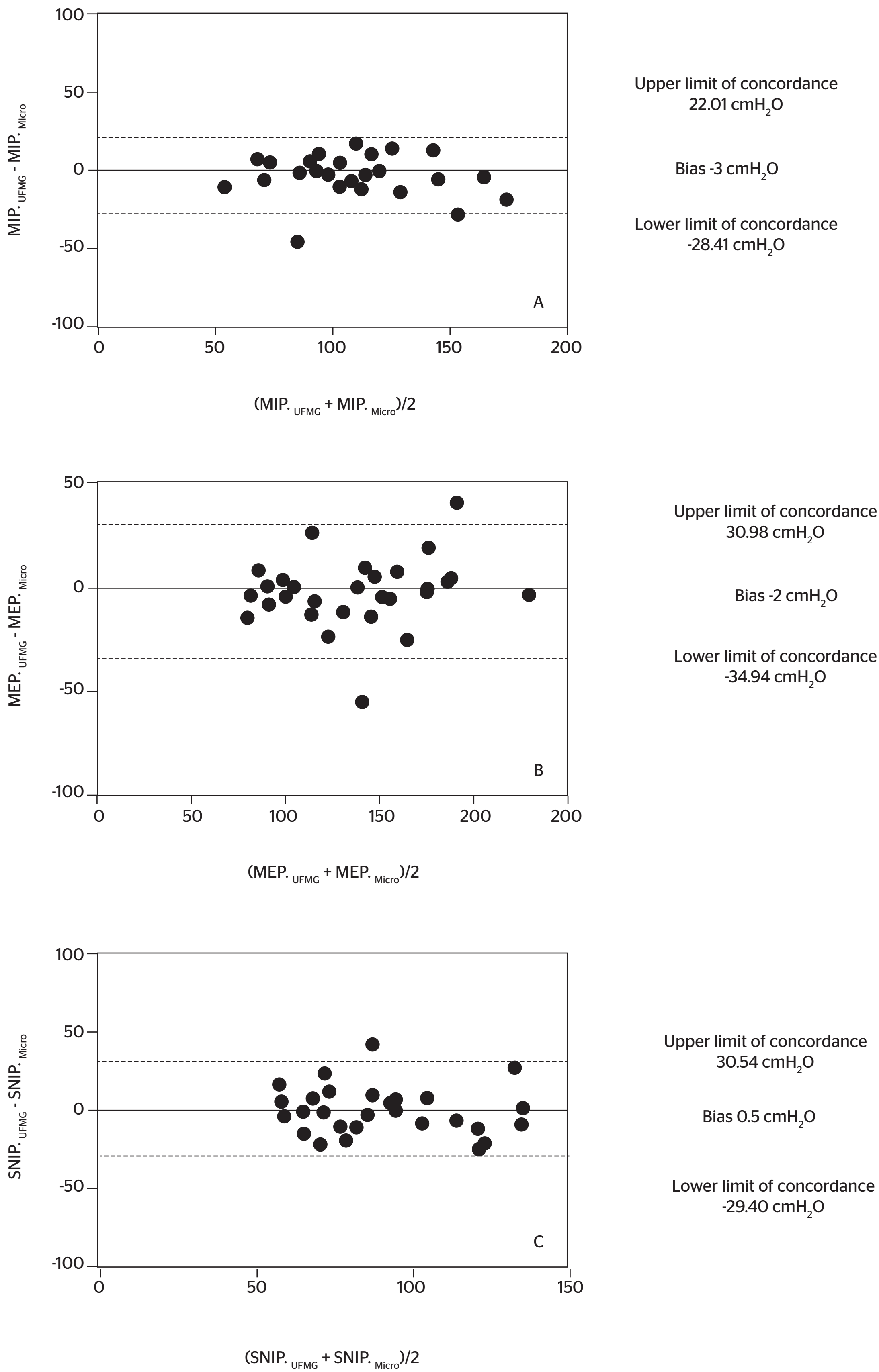
| Variables | Mean (SD) |
|---|---|
| Gender | 15M/15F |
| Age (years) | 23.50 (1.3) |
| BMI (kg/m$^2$) | 22.80 (2.70) |
| $FEV_1$ (L) | 3.80 (0.69) |
| $FEV_1$ (expected %) | 115.93 (0.62) |
| FVC (expected %) | 112.15 (0.70) |
| $FEV_1$/FVC | 85.88 (4.34) |

M: male; F: female; BMI: body mass index; $FEV_1$: Forced expiratory volume in one second; FVC: forced vital capacity; $FEV_1$/FVC ratio of forced expiratory volume in one second and forced vital capacity; SD: standard deviation

Table 3. Comparison between UFMG and MicroRPM® manovacuometers

| Variables ($cmH_2O$) | UFMG manov. Mean (SD)# n =30 | MM manov. Mean (SD) n=30 | 95%CI |
|---|---|---|---|
| MMP (Inspiratory) | 108.74 (29.08) | 109.93 (31.02) | -7.48–5.09 |
| MMP (Expiratory) | 130.92 (37.76) | 137.77 (37.98) | -15.05–1.35 |
| SNIP | 90.37 (24.04) | 89.80 (26.15) | -5.14–6.28 |

UFMG manov.: UFMG manovacuometer; MM manov.: MicroRPM® manovacuometer; MMP: mean maximum pressure; SNIP: sniff nasal inspiratory pressure test. # Mean of measurements collected on the first day




UFMG: UFMG manovacuometer; Micro: MicroRPM® manovacuometer

Figure 1. Bland-Altman analysis between measurements of maximal inspiratory pressure (MIP-A), maximal expiratory pressure (MEP-B) and sniff nasal inspiratory pressure (SNIP-C) in both equipments

## DISCUSSION

The main results of this study were: 1) The test-retest reliability of measurements of the UFMG manovacuometer was adequate and 2) All values obtained for the variables of the UFMG and MicroRPM® manovacuometers showed good agreement and no significant difference.

Regarding the reliability of the MRP (operationalized by MMP), the results of this study are similar to those of Dimitriadis *et al.*[7], who evaluated the test-retest reliability of the MicroRPM® manovacuometer. A total of 15 healthy adults were evaluated in sitting and standing positions, with values reported considered appropriate for reliability (ICC>0.80). The discussion of the reproducibility of the variables (Pplat and PIP) of the UFMG manovacuometer is hampered by the lack of studies that have operationalized these variables. However, it is noteworthy that all ICC values were greater than 0.75, reflecting good agreement between the measurements[17].

With regard to the assessment of concurrent validity, no significant difference was observed between the mean MIP, MEP and SNIP obtained by the two manovacuometers; excellent correspondence between the variables and $r^2$ from moderate (SNIP) to high magnitudes (RMS). The Bland-Altman analysis of the MIP, MEP and SNIP values obtained between the two manovacuometers showed a low bias between measurements, and the absence of systematic error in the measurements could be verified, since the differences were uniformly and randomly distributed. Thus, the values of MRPs and SNIP were not overestimated or underestimated systematically.

Severino *et al.*[11] showed no significant difference between the values obtained in the SNIP measures between two digital devices (MVD300® by Globalmed, Brazil and MicroRPM®) in 18 healthy subjects aged between 18 and 35 years (p>0.05). Furthermore, a significant correlation of moderate magnitude between measurements (r=0.63) was demonstrated. The Bland-Altman analysis showed a bias of 7 $cmH_2O$, SD=32.9 $cmH_2O$ and 95%CI -57.5–71.5 $cmH_2O$. For the SNIP measure, the value of bias observed between the manovacuometers in the present study was lower than that observed by Severino *et al.*[11]. Moreover, the limits of agreement of 95% were more appropriate, suggesting that there was a better agreement between measurements made by the UFMG manovacuometer in relation to MVD300®, given that, in both studies, the MicroRPM® was used as the gold standard instrument.

A limitation of this study is the absence of individuals with respiratory dysfunction or different age groups. Future studies with this objective are needed.

## CONCLUSION

The results of this study demonstrate that the UFMG digital manovacuometer showed appropriate values of test-retest reliability, as well as concurrent validity, in relation to MicroRPM®, in the MIP, MEP and SNIP measurements, indicating that it can be used both in clinical practice and in research.

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