Translated by E.V. Trushina

Research Article

https://doi.org/10.23934/2223-9022-2024-13-3-514-521

Creation and Preclinical Testing of a Spirometer with Extended Functionality

V.S. Shabaev[1] ✉, V.A. Onoshko[2], A.S. Galushko[2], V.A. Mazurok[1], I.V. Orazmagomedova[1], L.G. Vasilyeva[1], D.A. Aleksandrova[1]

Department with Resuscitation and Intensive Care Wards No. 8
[1] V.A. Almazov National Medical Research Center
Akkuratova Str. 2, Saint-Petersburg, Russian Federation 197341
[2] Krasnogvardeets
Truda Str. 7/5, lit. A, Saint-Petersburg, Kolpino, Russian Federation 196655

✉ **Contacts:** Vitaly S. Shabaev, Anesthesiologist-Resuscitator, Anesthesiology-Resuscitation Department with Resuscitation and Intensive Care Wards No. 8, V.A. Almazov National Medical Research Center. Email: shabaev_vitaliy@mail.ru

RELEVANCE We present the results of preclinical testing of an upgraded portable AR-1 gas flow analyzer produced by JSC Krasnogvardeets (Saint Petersburg) in order to create import-substituting technologies and develop practical and scientific spheres of healthcare.

THE AIM OF THE STUDY was to substantiate the possibility of clinical use of the upgraded device, originally intended for testing ventilators and inhalation anesthesia devices, as a monitor of the external respiration apparatus function.

MATERIAL AND METHODS The preclinical study of the upgraded gas flow analyzer was conducted at the V.A. Almazov National Medical Research Center in comparison with devices for conventional (Bellavista 950, Berner Ross Medical, Russia) and high-frequency (IPV-2C, Intrapulmonary Percussive Ventilation, Percussionaire Corporation, USA) mechanical ventilation in volume- and pressure-controlled modes using an artificial lung. The following reflected spirometry parameters were compared: tidal and minute volume under inhalation and exhalation, respiratory rate, maximum and minimum flows, peak and positive end expiratory pressure, fraction of inspired oxygen.

RESULTS A high accuracy of parameter matching shown by the gas flow analyzer and ventilators was demonstrated.

CONCLUSION The upgraded model of the gas flow analyzer can be used clinically as a portable spirometer at the prehospital and hospital stages.

Keywords: spirometer, ventilator, verification, gas flow rate

For citation Shabaev VS, Onoshko VA, Galushko AS, Mazurok VA, Orazmagomedova IV, Vasilyeva LG, et al. Creation and Preclinical Testing of a Spirometer with Extended Functionality. *Russian Sklifosovsky Journal of Emergency Medical Care.* 2024;13(3):514–521. https://doi.org/10.23934/2223-9022-2024-13-3-514-521 (in Russ.)

Conflict of interest Authors declare lack of the conflicts of interests

Acknowledgments, sponsorship The study had no sponsorship

Affiliations

Vitaly S. Shabaev	Anesthesiologist-Resuscitator, Anesthesiology-Resuscitation Department with Resuscitation and Intensive Care Wards No. 8, V.A. Almazov National Medical Research Center; https://orcid.org/0000-0002-5336-003X, shabaev_vitaliy@mail.ru; 22%, data collection, research design, statistical data analysis, article writing
Valery A. Onoshko	Software Engineer, Krasnogvardeets; on_work@mail.ru; 21%, creation of the spirometer model, modernization of the spirometer model
Aleksey S. Galushko	Head, Special Design and Technology Bureau, Krasnogvardeets; https://orcid.org/0009-0000-3057-9816, galushka00@mail.ru; 20%, creation of the spirometer model, modernization of the spirometer model
Vadim A. Mazurok	Doctor of Medical Sciences, Full Professor, Head, Department of Anesthesiology and Resuscitation with the Clinic, V.A. Almazov National Medical Research Center; https://orcid.org/0000-0003-3917-0771, vmazurok@mail.ru; 19%, modernization of the spirometer model, study design, text writing, proofreading of the article
Indira V. Orazmagomedova	Head, Anesthesiology-Resuscitation Department with Resuscitation and Intensive Care Wards No. 8, V.A. Almazov National Medical Research Center; https://orcid.org/0000-0001-9629-4450, o.i.v-st@mail.ru; 7%, data collection
Lyudmila G. Vasilyeva	Anesthesiologist-Resuscitator, Department of Anesthesiology and Resuscitation for Adults with Intensive Care Units, Perinatal Center, V.A. Almazov National Medical Research Center; https://orcid.org/0000-0001-9611-9222, vasileva.lg21@gmail.com; 6%, data collection

Daria A. Aleksandrova Resident, Anesthesiologist-Resuscitator, V.A. Almazov National Medical Research Center;
https://orcid.org/0000-0002-0734-7344, aleksand-dasha@yandex.ru;
5%, data collection

FiO2 — inspiratory oxygen fraction
HF — high-frequency
MV – mechanical ventilation
MVE — minute volume of expiration
MVI — minute volume of inspiration
PC — personal computer
PCV — pressure-controlled ventilation
PEEP — positive end-expiratory pressure
Pmax — maximum airway pressure
RR — respiratory rate
TVE — tidal volume of expiration
TVI — tidal volume of inspiration
VCV — volume-controlled ventilation

INTRODUCTION

The life of a patient depends on the adequate operation of the mechanical ventilation device [1]. The regulations for checking respiratory equipment are defined by standards and precise indications of compliance with application possibilities [2, 3]. This type of testing is carried out by certified technical specialists with the necessary skills. The AR1 Pneumatic Meter (hereinafter referred to as the Meter) is originally intended for such work — checking the main functions of respiratory equipment: ventilators and inhalation anesthesia devices. In particular, the device is capable of directly measuring gas consumption (flow), pressure dynamics, assessing gas temperature and humidity, and oxygen concentration. The measurements are performed after the Meter is installed in the breathing circuit. Given that the indicators reflected by the Meter are very close to those assessed during conventional clinical breathing monitoring, the idea of its practical use in this capacity by medical personnel arose.

An analysis of the relevance of creating such a device revealed the existence of its imported analogue [4] — the CITREX H5 flow analyzer (IMT Analytics AG, Switzerland). The basic functionality of the European model is comparable, while the technical capabilities are superior to the Meter. At the same time, it has a number of significant limitations, primarily its high price and expensive maintenance.

The COVID-19 pandemic has made portable devices for assessing the condition of the external respiration apparatus in demand — a kind of spirometers with extended functionality, the creation of which has become an urgent task [1]. The practical application of such spirometers is seen not only (and not even so much) in intensive care units, but at the pre-hospital stage: in an ambulance, at home, in a clinic. Finally, the import substitution strategy adopted in the Russian Federation [5] makes it obligatory to develop domestic equipment models, including those in the premium segment.

The above determined **the aim** of the current stage of our research - to determine the convenience and feasibility of the clinical use of the modernized Meter based on a comparative assessment of external respiration indicators reflected by conventional and high-frequency ventilators.

MATERIAL AND METHODS

A preclinical study of the Meter developed jointly with engineers from JSC Krasnogvardeets (St. Petersburg) was conducted at the V.A. Almazov National Medical Research Center. Initially, the device was adjusted and checked according to the state standard of gas consumption for compliance with the accepted standard of error of ±2% for these devices [2].

To implement clinical use, design changes were made to the Meter, allowing one to: 1) analyze parameters in dynamics, 2) accumulate and 3) transfer digital information to a mathematical editor with a customizable averaging interval of 1, 2, 4, 5 and 10 minutes. In addition, 4) the scheme of switching on the Meter for conducting research work was changed; 5) the ability to evaluate the bidirectional gas flow (from -200 to +200 l/min), and 6) measure its pressure (from -20 to 120 cm H_2O) in real time has been added. Finally, 7) the calculation of inhalation and exhalation time constant has been implemented, based on 8) the original principle of averaging parameters.

OPERATING PRINCIPLE OF THE METER

Measurement of the volumetric flow rate in the device is based on the assessment of the pressure drop formed when gas flows through a grid woven

from thin steel wire with a small (0.05×0.05 mm) cell (Fig. 1).

The dependence of the pressure drop on the volumetric flow rate is described by the formula:

$\Delta P = A \times \mu \times Q + B \times \rho \times Q^2$,

where A and B are constants characterizing the geometric dimensions of the grid through which the gas flows; μ is the dynamic viscosity of the gas; ρ is the density of the gas; Q is the gas flow.

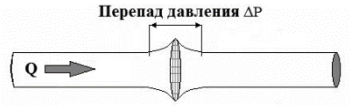

Fig. 1. Scheme of operation of the flow measurement channel

The pressure is recorded by a strain gauge. Oxygen concentration is measured using a galvanic oxygen sensor. The relative humidity in the high-flow channel is measured by a capacitor with an insulator that changes its permittivity with changes in humidity. The gas flow temperature is measured using the analog voltage signal from a sensor installed in the device channel. All parameters are digitized using an analog-to-digital converter and transformed into digital values by the device's built-in software.

The device measures the following parameters: low and high gas flows, humidity and gas temperature in high flow, volumetric oxygen content and excess pressure in high flow, low and high differential pressure, and atmospheric pressure. Spirometry parameters include: respiratory rate, duration of inhalation and exhalation, maximum inhalation flow and minimum exhalation flow, tidal and minute volumes during inhalation and exhalation, maximum and end-expiratory pressures, pressure during inspiratory pause, and mean pressure during the respiratory cycle, work performed.

The devices used for comparison were conventional (low-frequency) and high-frequency ventilators.

The conventional ventilation device was the Bellavista 950 (Berner Ross Medical, Russia). The choice of this device was dictated by a number of its technical capabilities: 1) digital recording of indicators in a wide time range - from 20 seconds to 24 hours; 2) storing information for up to 30 days with the highest (3 seconds) discreteness. Finally, 3) the ability to transfer accumulated data to external media for a period from one day to a year. This device is duly certified and has a registration certificate.

The IPV-2C (Intrapulmonary Percussive Ventilation, Percussionaire Corporation, USA) operating in pressure controlled mode was selected as the high-frequency (HF) ventilator. The IPV-2C (hereinafter referred to as the Percussioner) provides high-frequency mechanical ventilation (RR 60–330 breaths/min) designed to enhance diffusion gas exchange in the lungs, increase functional residual capacity (alveolar recruitment), improve airway clearance and remove carbon dioxide. The respirator can be used either independently or in combination with low-frequency breathing equipment.

In the case of conventional mechanical ventilation, the following spirometric parameters were compared: tidal volume of inspiration (TVI) and expiration (TVE), respiratory rate (RR), minute volume of inspiration (MVI) and expiration (MVE), maximum and minimum flows (F_{max}, F_{min}), minimum, corresponding to positive end-expiratory pressure (PEEP), as well as maximum airway pressure (P_{max}) and fraction of oxygen during inspiration (FiO_2).

The accumulation of indicators was performed on a model with an artificial lung in forced modes: VCV (volume-controlled ventilation) and PCV (pressure-controlled ventilation). The Meter was sequentially integrated into the breathing circuit of the Bellavista 950 device, observing the necessary technical connections (Fig. 2).

Fig. 2. Option for connecting the Meter to the ventilator circuit
Note: Meter with test lung (right), Bellavista 950 ventilator (middle), laptop with developed Meter software (left)

The implementation of HF mechanical ventilation, including with the help of the Percussioner, has design features. Considering that one of the tasks of a HF ventilator is to create an average pressure in the airways without a significant difference between the peak inspiratory pressure and the end-expiratory pressure, those devices usually do not have the ability to adjust and track respiratory volumes and flow rates. Among the main indicators

shown on the Percussioner display are the following: respiratory rate and inspiratory support pressure, while inspiratory time and inspiratory flow are set by the control knob on a nominal scale from 1 to 11 (hereinafter referred to as "nominal") without reference to the usual systems of calculation: seconds and liters per minute.

Taking into account the above, the integration of the Meter into the Percussioner circuit was aimed at: 1) obtaining volumetric ventilation indicators, and 2) comparison of pressometric parameters reflected by the Percussioner and the Meter. The research was performed at the minimum and maximum respiratory rates set on the Percussioner. The integration of the Meter into the Percussioner circuit is shown in Fig. 3.

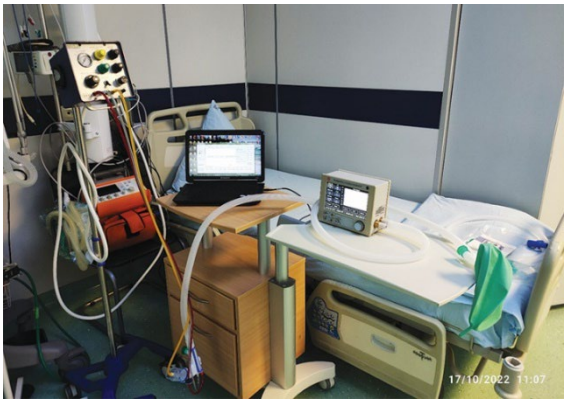

Fig. 3. Option for connecting the Meter to the Percussioner circuit: left — Percussioner; middle — laptop with software connected to the Meter; right — Meter with test lung

Fig. 4 and 5 show the graphic and digital parameters presented on the display of the Meter and a personal computer equipped with the original software.

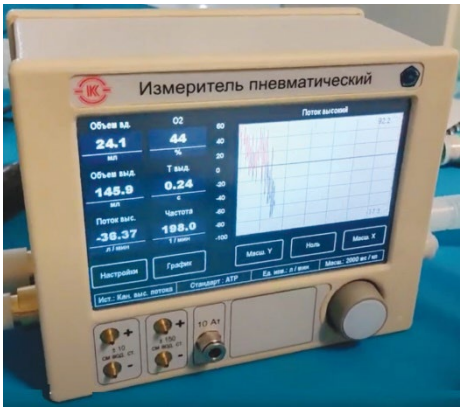

Fig. 4. View of the front panel of the Meter during the receipt of graphic and digital information

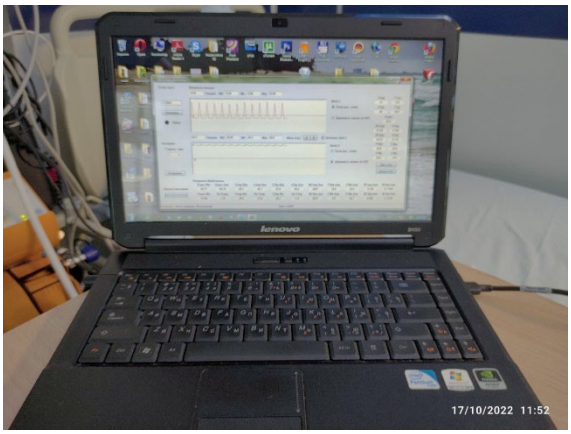

Fig. 5. Screen view of the software on a personal computer, developed for digitizing and accumulating data obtained using the Meter

Statistical analysis of the collected data was performed using STATISTICA-10. The Kolmogorov–Smirnov and Shapiro–Wilk statistical tests were used to determine the nature of the distribution; a power analysis of the study was performed; comparison of two samples was carried out using the Mann–Whitney U-test. The data are presented as median and quantiles (25; 75): median (Q1; Q3). Differences were considered statistically significant at $p \leqslant 0.05$.

RESULTS

The number of compared respiratory cycles with conventional (low-frequency) ventilation was 124 (for PCV) and 92 (for VCV), which corresponded to the power of the study equal to 1.0 and minimized the risk of type I and type II errors. The analysis of the nature of the distribution of the variants showed that the data in the samples differed from the normal distribution, which determined the choice of the Mann-Whitney criterion as a satisfying nonparametric indicator for these conditions.

Absolute numerical comparable indicators for conventional mechanical ventilation in PCV mode are presented in Table 1, statistical analysis of the obtained data is presented in Table 2.

Considering that the RR and FiO_2 of the compared devices were absolutely equal and had no variability, they are not included in the statistical calculation and are not presented in Table 2. The remaining data obtained show that there are statistically significant differences between the Meter and the ventilator, which, however, are hardly clinically significant (Table 3).

Table 1

Spirometry parameters during conventional pressure-controlled mechanical ventilation

Parameter	N	Mean M±SD	Median	Minimum	Maximum
Bellavista 950					
RR, beats/min	124	12.0±0	12.0	12.0	12.0
TVI, ml	124	263.4±2.4	263.2	260.1	268.1
TVE, ml	124	292.9±5.9	294.2	280.5	302.1
PEEP, cm H_2O	124	5.2±0.1	5.2	5.1	5.3
P_{max}, cm H_2O	124	20.4±0.0	20.4	20.4	20.4
MVI, ml/min	124	3176.5±172.2	3197.0	2116.0	3323.0
MVE, ml/min	124	3486.3±146.2	3517.0	2476.0	3594.0
FiO_2, %	124	21.0±0.0	21.0	21.0	21.0
Meter					
RR, beats/min	124	12.0±0.0	12.0	12.0	12.0
TVI, ml	124	275.7±11.5	277.6	194.0	283.1
TVE, ml	124	265.7±10.8	266.4	156.9	296.7
PEEP, cm H_2O	124	5.0±0.2	5.0	5.0	7.0
P_{max}, cm H_2O	124	21.0±0.1	21.0	20.0	21.0
MVI, ml/min	124	3415.2±197.8	3330.9	3288.6	4369.1
MVE, ml/min	124	3276.1±165.0	3207.2	3175.8	3653.1
FiO_2, %	124	21.0±0.0	21.0	21.0	21.0

Notes: TVI — tidal volume of inspiration; TVE — tidal volume of expiration; MVI — minute volume of inspiration; MVE — minute volume of expiration; PEEP — positive end-expiratory pressure; RR — respiratory rate; FiO_2 — the fraction of inspired oxygen; P_{max} — maximum pressure

Table 2

Comparison of spirometry parameters during conventional pressure-controlled mechanical ventilation using the Mann-Whitney U-test, median (Q1; Q3)

Parameter	Meter	Bellavista 950	*p*
TVI, ml	263.2 (261.1; 265.4)	277.6 (276.6; 278.4)	0.0001
TVE, ml	294.2 (288.0; 297.9)	266.4 (264.9; 267.6)	0.0001
PEEP, cm H_2O	5.2 (5.1; 5.2)	5.0 (5.0; 5.0)	0.0001
P_{max}, cmH_2O	20.4 (20.4; 20.4	21.0 (21.0; 21.0)	0.0001
MVI, ml/min	3197.0 (3165.0; 3238.0)	3330.9 (3319.5; 3337.4)	0.0001
MVE, ml/min	3517.0 (3456.0; 3558.5)	3207.2 (3186.1; 3224.4)	0.0001

Notes: TVI — tidal volume of inspiration; TVE — tidal volume of expiration; PEEP — positive end-expiratory pressure; MVI — minute volume of inspiration; MVE — minute volume of expiration; P_{max} — maximum pressure

Table 3

Difference in mean values of compared parameters obtained on the Meter and the conventional mechanical ventilation device

Parameter	Difference between averages on the Meter and the Ventilator, n (%)
TVI, ml	12.33 (5)
TVE, ml	27.14 (9)
PEEP, cm H_2O	0.14 (3)
P_{max}, cm H_2O	0.58 (3)
MVI, ml/min	238 (8)
MVE, ml/min	210 (6)

Notes: TVI — tidal volume of inspiration; TVE — tidal volume of expiration; PEEP — positive end-expiratory pressure; MVI — minute volume of inspiration; MVE — minute volume of expiration; P_{max} — maximum pressure

According to the data presented in Table 3, the absolute differences in TVI and TVE between the Meter and the Ventilator are 12 and 27 ml, respectively, which in proportion ratio does not exceed 9% (TVI/TVE – 263/292, and 275/265 on the Meter and the Ventilator, respectively); and in pressure – 0.14 and 0.58 cm H2O, i.e. no more than 3%. The minute ventilation rates for inhalation and exhalation differed by 238 and 210 ml/min, respectively (the difference in proportional ratio was within 8%: 238 from 3415 ml/min and 210 from 3486 ml/min). Thus, the obtained data fall within the 10% error range defined by the State System for Ensuring the Uniformity of Measurements [2] and specific safety requirements for ventilators [3].

Absolute numerical comparable indicators for conventional mechanical ventilation in VCV mode are presented in Table 4, statistical analysis of the obtained data is presented in Table 5.

Considering that in the VCV mode, both RR and FiO_2 of the compared devices were absolutely equal, they are not included in the statistical calculation, and are not presented in Table 5. The remaining data obtained show that there are also statistically significant differences between the Meter and the Ventilator, which can be considered clinically insignificant (Table 6).

Table 4

Spirometry parameters during conventional volume-controlled mechanical ventilation

Parameter	N	Mean	Median	Minimum	Maximum
Bellavista 950					
RR, beats/min	92	12.00±0.00	12.00	12.00	12.00
TVI, ml	92	353.99±1.04	354.00	350.60	355.80
TVE, ml	92	396.29±2.00	396.35	388.90	399.60
F_{max}, l/min	92	80.38±2.00	80.35	80.10	80.90
F_{min}, l/min	92	16.21±0.07	16.20	16.10	16.40
PEEP, cm H_2O	92	5.14±0.05	5.10	5.10	5.20
P_{max}, cm H_2O	92	26.42±0.05	26.40	26.30	26.50
MVI, ml/min	92	4192.27±416.19	4235.00	425.00	4267.00
MVE, ml/min	92	4743.12±58.08	4749.00	4247.00	4787.00
FiO_2, %	92	21.00±0.00	21.00	21.00	21.00
Meter					
RR, beats/min	92	12.00±0.00	12.00	12.00	12.00
TVI, ml	92	405.74±1.50	405.92	396.49	408.25
TVE, ml	92	394.64±1.64	394.74	390.97	404.63
F_{max}, l/min	92	83.21±0.94	83.15	80.51	85.61
F_{min}, l/min	92	19.03±0.46	18.97	18.22	20.58
PEEP, cm H_2O	92	5.00±0.00	5.00	5.00	5.00
P_{max}, cm H_2O	92	26.00±0.00	26.00	26.00	26.00
MVI, ml/min	92	4880.08±34.45	4866.78	4860.10	5012.41
MVE, ml/min	92	4712.66±97.33	4735.19	4322.61	4800.67
FiO_2, %	92	21.00±0.00	21.00	21.00	21.00

Notes: TVI — tidal volume of inspiration; TVE — tidal volume of expiration; MVI — minute volume of inspiration; MVE — minute volume of expiration; PEEP — positive end-expiratory pressure; RR — respiratory rate; F_{max} — maximum flow; F_{min} — minimum flow; FiO_2 — the fraction of inspired oxygen; P_{max} — maximum pressure

According to the data presented in Table 6, the absolute differences in the respiratory volumes on inhalation and exhalation were 51.7 and 1.7 ml, respectively (the difference was no more than 15%), and in pressure - 0.1 and 0.4 cm H_2O (difference of no more than 10%).The minute ventilation rates for inhalation differed by 16%, for exhalation – by 1%.Thus, the obtained data were generally less than the range of permissible errors of ±10% defined the State System for Ensuring the Uniformity of Measurements [2] and ±15% defined by specific safety requirements for ventilators [3].

Table 5

Comparison of spirometry parameters during conventional volume-controlled mechanical ventilation using the Mann–Whitney U-test, median (Q1; Q3)

Parameter	Meter	Bellavista 950	*p*
TVI, ml	354.0 (353.1; 354.7)	405.9 (404.9; 406.6)	0.0001
TVE, ml	396.4 (395.2; 397.5)	394.7 (393.8; 395.1)	0.0001
F_{max}, l/min	80.35 (80.2; 80.5)	83.15(82.6; 83.6)	0.0001
F_{min}, l/min	16.20 (16.2; 16.3)	18.97 (18.7; 19.2)	0.0001
PEEP, cm H_2O	5.1 (5.1; 5.2)	5.0 (5.0; 5.0)	0.0001
P_{max}, cm H_2O	26.4 (26.4; 26.5)	26.0 (26.0; 26.0)	0.0001
MVI, ml/min	4235.0 (4229.0; 4245.0)	4866.8 (4865.6; 4872.0)	0.0001
MVE, ml/min	4749.0 (4734.0; 4763.0)	4735.2 (4731.7; 4741.0)	0.0001

Notes: TVI — tidal volume of inspiration; TVE — tidal volume of expiration; MVI — minute volume of inspiration; MVE — minute volume of expiration; PEEP — positive end-expiratory pressure; F_{max} — maximum flow; F_{min} — minimum flow; P_{max} — maximum pressure

Table 6

Difference in mean values of compared parameters obtained on the Meter and the mechanical ventilation device

Parameter	Difference between averages on the Meter and the Ventilator: absolute values, n (%)
TVI, ml	51.7 (15)
TVE, ml	1.7 (0)
F_{max}, l/min	2.83 (3)
F_{min}, l/min	2.77 (14)
PEEP, cm H_2O	0.1 (3)
P_{max}, cm H_2O	0.4 (2)
MVI, ml/min	687 (16)
MVE, ml/min	30 (1)

Notes: TVI — tidal volume of inspiration; TVE — tidal volume of expiration; MVI — minute volume of inspiration; MVE — minute volume of expiration; PEEP — positive end-expiratory pressure; F_{max} — maximum flow; F_{min} — minimum flow; P_{max} — maximum pressure

It should be noted, however, that the traditional ventilator we selected for comparison is not strictly a standard, since it itself has a regulated (permissible) error of 15% [3]. Therefore, the obtained data allow us to conclude that the upgraded Meter meets the technical requirements regarding the accuracy of the measurements it performs.

The next objective of our study was to evaluate the possibility of clinical application of the Meter during HF mechanical ventilation. The results are presented in Tables 7 and 8.

Table 7

Comparison of the parameters reflected on the Meter and Percussioner at a given respiratory rate of 60 breaths per minute

Parameters	Meter	Percussioner
RR per hour of measurement	3960	–
RR per minute	66±0	60
Average inspiratory volume, ml	38±0.19	–
Minimum inspiratory volume, ml	35.2±1.6	–
Maximum inspiratory volume, ml	46.0±01.73	–
Average expiratory volume, ml	45.5±0.36	–
Minimum expiratory volume, ml	43.4±2.7	–
Maximum expiratory volume, ml	48.4±0.39	–
Minimum flow, l/min	4.9±0.06	–
Maximum flow, l/min	17.5±0.14	–
Minimum pressure, cm H_2O	24.0±0.03	25.0±0.5
Maximum pressure, cm H_2O	26.0±0.03	–
Duration of inhalation, s	0.2±0.0003	Nominally (1)
Duration of exhalation, s	0.6±0.019	Nominally (1)
MVI, ml/min	2489.9±19.9	–
MVE, ml/min	2992.9±23.5	–

Notes: MVI — minute volume of inspiration; MVE — minute volume of expiration; RR — respiratory rate

Considering that the Percussioner does not provide for accumulation, transfer and digitalization of data, we conducted an actual assessment of the indicators set and presented on the display with their subsequent analysis in the form of descriptive statistics. From the data presented in Tables 7 and 8 it is evident that the parameters specified and strictly regulated by the Percussioner settings coincide with those displayed on the Meter. Thus, the Meter demonstrated the high-precision capabilities of its application: all respiratory cycles were recorded with automatic calculation of the necessary respiratory parameters, including the extremely small recorded respiratory volume of 0.5 ml.

Table 8

Comparison of the parameters reflected on the Meter and Percussioner at a given respiratory rate of 330 per minute

Parameters	Meter	Percussioner
RR per hour of measurement	17350	-
RR per minute	377.2±19.4	330
Average inspiratory volume, ml	0.5±0.05	-
Minimum inspiratory volume, ml	0.8±0.5	-
Maximum inspiratory volume, ml	6.7±2.2	-
Average expiratory volume, ml	3.6±0.2	-
Minimum expiratory volume, ml	0.5±0.23	-
Maximum expiratory volume, ml	42.6±10.55	-
Minimum flow, l/min	2.4±0.16	-
Maximum flow, l/min	6.0±0.29	-
Minimum pressure, cm H_2O	45.1±0.49	46±0
Maximum pressure, cm H_2O	46.8±0.54	-
Duration of inhalation, s	0.8±0.0005	Nominally (11)
Duration of exhalation, s	0.1±0.07	Nominally (11)
MVI, ml/min	166.6±16.4	-
MVE, ml/min	1132.7±45.4	-

Notes: MVI — minute volume of inspiration; MVE — minute volume of expiration; RR — respiratory rate

DISCUSSION

The basic version of the Meter (AR1 Pneumatic Meter) is intended for testing ventilators. The conducted preclinical study of the upgraded Meter revealed good reproducibility and accuracy of the parameters displayed by the device, which gives grounds to assume the prospects of its clinical use by medical staff as a high-precision portable spirometer. Firstly, at the pre-hospital stage, during the first contact with the patient (at home, in an ambulance, in a clinic). Secondly, already at the hospital stage, in almost any clinical (pulmonology, therapy, cardiology, etc.) departments. And finally, in the intensive care unit - for extended monitoring of mechanical ventilation in conjunction with respirators with limited respiratory monitoring capabilities.

In our opinion, the modernized Meter is especially valuable due to its ability to accumulate digital data with the highest discreteness (from breath to breath), as well as their automatic averaging for selected 1, 2, 4, 5 and 10-minute intervals. The objective information collected in this way allows for dynamic monitoring of the functional state of the external respiratory apparatus.

The possibility of transferring accumulated digital data to a personal computer (PC) using Notepad, a text editor that comes pre-installed on Windows computers, and further transfer of data to statistical programs for their mathematical analysis may prove to be very interesting for research purposes, an example of which is the present work.

The Meter has a compact size (length 250 mm, width 125 mm, depth 170 mm), light weight (2.2 kg), is very easy to use and, most importantly, does not require consumables. The inlet and outlet fittings of the Meter correspond to the diameter of the respiratory circuit hoses, which eliminates the need to use adapters to install it into the latter.

CONCLUSION

During preclinical testing, the upgraded AR-1 Pneumatic Meter demonstrated satisfactory performance characteristics. Among them: 1) high-precision accumulation and 2) mathematical analysis of the collected digital data. The presence of a convenient and intuitive interface, as well as small dimensions, allow us to consider the Meter as a mobile device for clinical and scientific use. Further studies are needed to assess the practical convenience of using the Meter at the pre-hospital and hospital stages.

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Received on 03/06/2023
Review completed on 10/11/2023
Accepted on 05/06/2024