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Assessment of accuracy and applicability of a new electronic peak flow meter and asthma monitor

K. Richter*, F. Kanniess*, B. Mark+, R.A. Jörres*, H. Magnussen*

Assessment of accuracy and applicability of a new electronic peak flow meter and asthma monitor. K. Richter, F. Kanniess, B. Mark, R.A. Jörres, H. Magnussen. ©ERS Journals Ltd 1998.

ABSTRACT: The aim of this study was to assess the accuracy and applicability of a portable electronic peak flow meter combined with an asthma monitor (AM1, Jaeger, Germany) which measures peak expiratory flow (PEF), forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC).

The technical accuracy in PEF, FEV_1 and FVC measurement was tested according to American Thoracic Society (ATS) criteria for monitoring devices using a flow generator. In addition, the effect of connecting a heated screen pneumotachograph (PT) to the AM1 was determined and the accuracy in FEV_1 determinations was evaluated by simultaneous measurements in 49 normal volunteers.

The devices tested fulfilled all ATS criteria for monitoring devices with respect to the accuracy of PEF, FEV_1, and FVC measurements. The conditions of intra- and interdevice variability were satisfied in all cases. Compared with the PT, the AM1 showed about 4% lower values in FEV_1, as measured in the 49 subjects.

In conclusion, the electronic peak flow meter and asthma monitor AM1 yielded valid measurements of peak expiratory flow and forced expiratory volume in one second, which matched the accuracy criteria of the American Thoracic Society standards for monitoring devices.

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*Krankenhaus Grosshansdorf, Zentrum für Pneumologie und Thoraxchirurgie, LVA Freie und Hansestadt Hamburg, D-22927 Grosshansdorf, Germany. +Erich Jaeger Co., D-97204 Höchberg, Germany.

Correspondence: K. Richter
Krankenhaus Grosshansdorf
Zentrum für Pneumologie und Thoraxchirurgie
Wöhrendamm 80
D-22927 Grosshansdorf
Germany
Fax: 49 4102692295

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Measuring peak flow is an inexpensive and easy method for monitoring airflow obstruction in patients with bronchial asthma and is constantly recommended in international guidelines for asthma management [1–3].

Several studies which evaluated a number of portable peak flow meters have shown major discrepancies between recorded values and laboratory-generated peak flow rates [4, 5]. To achieve quality control, the American Thoracic Society (ATS) and the European Respiratory Society (ERS) recently published standards for the calibration of portable peak flow meters as monitoring devices [6, 7].

In the present study the accuracy was tested of a recently available electronic peak flow meter and asthma monitor (AM1; Jaeger Co., Höchberg, Germany) which measures peak expiratory flow (PEF), forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC). All data are stored with date, time and optional information about symptoms, medication and events. The additional measurement of FEV_1 and FVC may increase the versatility of the device, provided the required quality criteria are satisfied [8].

The study design comprised three experiments. Firstly, the accuracy and reproducibility of the AM1 regarding PEF, FEV_1 and FVC were assessed according to the ATS standards for monitoring devices using a mechanical test rig [6]. Secondly, the effect of connecting a heated screen pneumotachograph (PT) to the AM1 was determined; and thirdly, the accuracy of FEV_1 determinations was evaluated by simultaneous measurements in a group of volunteers.

For editorial comment see page 261

Material and methods

Description of the electronic peak flow meter and asthma monitor (AM1)

The pocked-sized electronic peak flow meter and asthma monitor (weight 145 g, length 112 mm) contains a fixed turbine that is driven by the exhaled air of the patient. The rotational flow of the turbine is converted by optical scanning of half revolutions into PEF, FEV_1 and FVC. The data are displayed digitally on a liquid crystal screen, with the best blow within 10 min being stored in the memory. Medication, symptoms and events can be scored from 0 to 3 and fed into the system, which stores them with date and time. An optional alarm reminds the patient to perform the test at the proper time. Coupling with a personal computer enables the generation of a report for different time periods. For quality-control purposes, a flow-volume curve drawn from five values (PEF, maximal expiratory flow at 75, 50 and 25% of FVC (MEF_{75}, MEF_{50}, MEF_{25}, respectively) and FVC) can be displayed for every measurement. Up to 460 measurements can be stored in the

memory. The device is operated with batteries, which last for approximately 200 days if five measurements are performed daily. Changing batteries does not lead to a loss of data. The average life time of the rotational flow turbine is 1 yr. Measurement ranges for the AM1 are 60–840 L·min^{-1} for PEF, 0.5–8 L for FEV_1, and 0.5–8 L for FVC. The resolution is 1 L·min^{-1} in the low flow range and 10 L·min^{-1} in the high flow range for PEF, and 15 mL for FEV_1 and FVC. The resistance of the device depends on flow rate and increases approximately linearly from 7.0 Pa·L^{-1}·s at a rate of 1 L·s^{-1} to 64.3 Pa·L^{-1}·s at a rate of 14 L·s^{-1}. An external adjustment for body temperature and ambient pressure, and saturated with water vapour (BTPS) conditions is not considered to be necessary, as only forced expiratory flows and volumes are measured.

Experiment 1: testing according to the ATS standards

The accuracy, reproducibility (intradevice variability) and interdevice variability of the AM1 were evaluated according to ATS standards [6]. A mechanical flow generator that was capable of generating accurate flows between 0–900 L·min^{-1} (0.1–15.7 L·s^{-1}) was used. The device generated flows by a motor-driven piston under computer control and could generate the 24 ATS flow-volume curves and 26 ATS flow-time curves with an accuracy in peak flow rate of ð0.5%, which is below the ATS criterion of ±2%. The time needed to increase the flow to 12 L·s^{-1} was below 30 ms; the resolution was 4.88 mL·s^{-1} in flow and 0.785 mL in volume. The AM1 was attached directly to the flow generator. Two devices were selected from the routine production at random without screening before the validation testing. Each AM1 underwent five manoeuvres using each of the 26 flow-time ATS waveforms for PEF accuracy testing. Accordingly, for FEV_1 and FVC, five manoeuvres were performed for each of the 24 volume-time curves. The average for each waveform was taken for analysis. Absolute and percentage deviation from target values were calculated according to formulae B3 and B4 of the ATS testing criteria [6]. Acceptable performance for PEF was defined as fewer than three errors out of the total 52 tests (26 waveforms, two meters). The accuracy criterion was ±12% or 25 L·min^{-1} of target values, whichever was the greater. Corresponding criteria for FEV_1 and FVC were ±5.5% or ±0.1 L, with fewer than three errors out of 48 tests (24 waveforms, two devices).

For testing intra- and interdevice variability, 10 AM1 were randomly selected from the routine production. Wave-form numbers 1, 4, 8 and 25 of standard flow-time waveforms were used for PEF testing and numbers 1, 3, 6 and 11 of standard volume-time waveforms for FEV_1 and FVC testing, respectively. Three flows of each waveform were performed for each meter. Absolute and percentage ranges were calculated according to formulae B1 and B2 of the ATS [6]. The criteria for intradevice variability and acceptable performance were defined, for PEF, as <6% or 15 L·min^{-1} intradevice variability and fewer than six errors out of 120 trials (10 devices, four waveforms, three flows each). Those for interdevice variability were <11% or 25 L·min^{-1} and no errors, while FEV_1 and FVC required <3.5% or 0.1 L intradevice variability and fewer than six errors out of 120 trials and <11% or 0.2 L interdevice variability without any errors.

Experiment 2: influence of a series connection of PT and AM1 in test rig experiments

As the PEF device was tested in series connection with a PT, it was essential to check whether the performance of the PT or the PEF device was disturbed by the presence of the other device. Therefore, the AM1 was attached directly after the PT. The pneumotachometer device (Masterscope; Jaeger Co., Höchberg, Germany) used as the reference system had been validated in earlier studies [9]. For one AM1 device randomly taken from the routine production, five flow manoeuvres were performed with all 24 ATS volume-time waveforms and with numbers 1, 3, 4, 5, 8, 12 and 26 of flow-time waveforms for the AM1 and the PT, alone as well as in series connection. A graphical analysis of PT and AM1 values for PEF, FEV_1 and FVC was performed according to the proposals of BLAND and ALTMAN [10]. Percentage differences in PEF, FEV_1, and FVC between the two experimental set-ups were expressed relative to the average value from both devices.

Experiment 3: comparison of simultaneous FEV_1 measurements by PT and AM1 in human subjects

Forty-nine volunteers (mean age (SD) 37 (9) yrs; 13 female, 36 male) were selected at random from the staff for this part of the study. The AM1 was attached in series after the PT, as described above. The subjects had to perform three technically satisfactory FVC manoeuvres according to the ATS standards [6]; all three manoeuvres were re-corded. A complete inspiration was performed before connecting to the mouthpiece in order to exclude an effect of airflow direction on the AM1. Percentage differences in FEV_1 values between PT and AM1 were calculated relative to the average of both values. As in experiment 2, a graphical analysis of PT and AM1 values for FEV_1, was performed according to the proposals of BLAND and ALTMAN [10].

Results

Experiment 1: testing according to the ATS standards

Table 1 shows the results of accuracy testing, with mean (SD) PEF values for the two tested devices and percentage differences relative to the target values. With PEF, the ATS criteria for monitoring devices were fulfilled for every waveform in both devices. Mean percentage differences (SD) from target values were -1.27 (1.82)% for device 1 and 0.34 (2.02)% for device 2. Tables 2 and 3 present the corresponding values for FEV_1 and FVC. Accuracy criteria for monitoring devices in FEV_1 and FVC were fulfilled for every waveform in both devices, mean (SD) deviations from target values being 1.74 (1.53)% for device 1 and 2.29 (1.71)% for device 2. Corresponding values for FVC were 1.61 (2.17)% and 0.83 (2.58)%.

Furthermore, in 10 randomly selected devices, ATS criteria for intra- and interdevice variability were satisfied for PEF, FEV_1, and FVC. Mean ranges (SD) for intra- and interdevice variability in PEF were 0.57 (0.69)% and 0.67 (0.45)%, respectively. Corresponding values for FEV_1 were 0.39 (0.42) and 0.90 (1.73)%, and for FVC 0.90 (0.63) and 2.06 (2.42)%.

Table 1. – Peak expiratory flow (PEF) values of two AM1 devices obtained using 26 American Thoracic Society standard flow-time waveforms and differences between AM1 and target values

Waveform no.	PEF Target L·min^{-1}	PEF Device 1 L·min^{-1}	PEF Device 2 L·min^{-1}	Difference 1* L·min^{-1}	Difference 1* %	Difference 2* L·min^{-1}	Difference 2* %
1	446.7	443.4 (2.19)	451.4 (2.19)	-3.3	-0.7	4.7	1.1
2	651.6	642.6 (3.58)	657.0 (0.00)	-9.0	-1.4	5.4	0.8
3	287.6	284.0 (0.00)	294.2 (1.79)	-3.6	-1.3	6.6	2.3
4	264.1	256.0 (0.00)	260.0 (0.00)	-8.1	-3.1	-4.1	-1.5
5	217.8	216.0 (0.00)	220.0 (0.00)	-1.8	-0.8	2.2	1.0
6	185.3	182.4 (0.55)	183.2 (0.84)	-2.9	-1.6	-2.1	-1.1
7	150.5	145.2 (0.84)	145.8 (0.84)	-5.3	-3.6	-4.7	-3.2
8	139.7	130.4 (0.89)	133.0 (0.00)	-9.3	-6.6	-6.7	-4.8
9	315.5	316.6 (2.19)	319.0 (0.00)	1.1	0.3	3.5	1.1
10	284.0	275.2 (1.79)	276.0 (0.00)	-8.8	-3.1	-8.0	-2.8
11	412.2	412.2 (1.79)	416.2 (3.35)	0.0	0.0	4.0	1.0
12	641.0	647.4 (3.58)	659.4 (5.37)	6.4	1.0	18.4	2.9
13	288.2	282.0 (8.22)	291.8 (1.79)	-6.2	-2.2	3.6	1.2
14	229.3	225.6 (2.19)	225.6 (2.19)	-3.7	-1.6	-3.7	-1.6
15	477.4	477.0 (0.00)	485.0 (0.00)	-0.4	-0.1	7.6	1.6
16	315.1	311.8 (1.79)	319.0 (0.00)	-3.3	-1.0	3.9	1.3
17	350.5	346.2 (1.79)	351.0 (4.00)	-4.3	-1.2	0.5	0.1
18	515.6	513.8 (4.38)	525.0 (4.90)	-1.8	-0.4	9.4	1.8
19	417.2	418.6 (3.58)	428.2 (1.79)	1.4	0.3	11.0	2.6
20	445.8	441.8 (1.79)	449.8 (1.79)	-4.0	-0.9	4.0	0.9
21	238.4	232.0 (0.00)	236.0 (0.00)	-6.4	-2.7	-2.4	-1.0
22	202.6	203.2 (1.79)	205.6 (2.19)	0.6	0.3	3.0	1.5
23	487.9	485.0 (0.00)	493.0 (0.00)	-2.9	-0.6	5.1	1.0
24	249.3	240.8 (1.79)	244.0 (0.00)	-8.5	-3.4	-5.3	-2.1
25	851.6	875.6 (8.76)	882.0 (0.00)	24.0	2.8	30.4	3.6
26	695.7	686.0 (0.00)	702.8 (6.57)	-9.7	-1.4	7.1	1.0
			Mean	-2.69	-1.27	3.59	0.34
			SD	6.71	1.82	8.13	2.02

PEF values from devices 1 and 2 are presented as mean (SD) of five measurements. *: difference between target PEF and PEF of devices 1 and 2.

Table 2. – Forced expiratory volume in one second (FEV_1) values of two AM1 devices obtained using 24 American Thoracic Society standard volume-time waveforms and differences between AM1 and target values

Waveform no.	FEV_1 Target mL	FEV_1 Device 1 mL	FEV_1 Device 2 mL	Difference 1* mL	Difference 1* %	Difference 2* mL	Difference 2* %
1	4262	4389.0 (8.22)	4404.0 (8.22)	127.0	3.0	142.0	3.3
2	4574	4638.0 (24.65)	4716.0 (13.42)	64.0	1.4	142.0	3.1
3	1188	1239.0 (8.22)	1248.0 (6.71)	51.0	4.3	60.0	5.1
4	1371	1433.4 (13.92)	1461.0 (8.23)	62.4	4.6	90.0	6.6
5	3868	3885.0 (0.00)	3936.0 (8.22)	17.0	0.4	68.0	1.8
6	3027	2981.0 (8.22)	2999.2 (6.83)	-46.0	-1.5	-27.8	-0.9
7	2519	2570.2 (12.91)	2574.0 (0.00)	51.2	2.0	55.0	2.2
8	1615	1651.0 (6.71)	1654.0 (0.00)	36.0	2.2	39.0	2.4
9	3772	3810.0 (42.43)	3807.0 (16.43)	38.0	1.0	35.0	0.9
10	3031	3079.0 (0.00)	3109.2 (0.45)	48.0	1.6	78.2	2.6
11	1811	1876.5 (8.22)	1895.3 (6.71)	65.5	3.6	84.3	4.7
12	1621	1657.2 (7.16)	1660.4 (8.76)	36.2	2.2	39.4	2.4
13	3834	3771.4 (25.20)	3805.2 (31.90)	-62.6	-1.6	-28.8	-0.8
14	3053	3109.0 (0.00)	3121.8 (7.16)	56.0	1.8	68.8	2.3
15	5304	5337.0 (6.71)	5412.0 (6.71)	33.0	0.6	108.0	2.0
16	3896	3945.0 (0.00)	3969.0 (13.42)	49.0	1.3	73.0	1.9
17	2597	2677.8 (7.16)	2691.0 (6.71)	80.8	3.1	94.0	3.6
18	3155	3225.0 (18.37)	3195.0 (0.00)	70.0	2.2	40.0	1.3
19	2512	2552.0 (29.88)	2552.0 (13.42)	40.0	1.6	40.0	1.6
20	2563	2591.8 (16.71)	2597.8 (13.86)	28.8	1.1	34.8	1.4
21	3549	3540.0 (0.00)	3540.0 (0.00)	-9.0	-0.3	-9.0	-0.3
22	2813	2874.0 (8.22)	2889.0 (8.22)	61.0	2.2	76.0	2.7
23	1360	1394.0 (0.00)	1394.0 (0.00)	34.0	2.5	34.0	2.5
24	922	945.0 (0.00)	945.0 (0.00)	23.0	2.5	23.0	2.5
			Mean	39.8	1.74	56.6	2.29
			SD	38.6	1.53	43.9	1.71

FEV_1 values from devices 1 and 2 are presented as mean (SD) of five measurements. *: difference between target FEV_1 and FEV_1 of devices 1 and 2.

Table 3. – Forced vital capacity (FVC) values of two AM1 devices obtained using 24 American Thoracic Society standard volume-time waveforms and differences between AM1 and target values

Waveform no.	FVC Target mL	FVC Device 1 mL	FVC Device 2 mL	Difference 1* mL	Difference 1* %	Difference 2* mL	Difference 2* %
1	6000	5952 (51.23)	5979 (22.75)	-48	-0.80	-21	-0.35
2	4999	5046 (22.75)	5127 (40.25)	47	0.94	128	2.56
3	3498	3390 (15.00)	3384 (8.22)	-108	-3.09	-114	-3.26
4	1498	1578 (6.71)	1584 (8.21)	80	5.34	86	5.74
5	5132	5139 (17.10)	5067 (12.55)	7	0.14	-65	-1.27
6	4011	4044 (43.21)	3966 (22.75)	33	0.82	-45	-1.12
7	3169	3246 (34.53)	3189 (27.25)	77	2.43	20	0.63
8	1993	2076 (13.42)	2061 (22.75)	83	4.16	68	3.41
9	4854	4914 (39.12)	4848 (32.52)	60	1.24	-6	-0.12
10	3843	3915 (33.54)	3879 (22.75)	72	1.87	36	0.94
11	2735	2820 (18.37)	2778 (26.83)	85	0.03	43	0.02
12	2002	2073 (6.71)	2073 (19.56)	71	3.55	71	3.55
13	4896	4899 (73.94)	4905 (51.96)	3	0.06	9	0.18
14	3786	3822 (37.35)	3837 (40.25)	36	0.95	51	1.35
15	5937	6006 (29.24)	6027 (24.65)	69	1.16	90	1.52
16	5458	5526 (25.10)	5484 (29.24)	68	1.25	26	0.48
17	5833	5895 (81.47)	5634 (67.58)	62	1.06	-199	-3.41
18	4343	4428 (16.43)	4332 (12.55)	85	1.96	-11	-0.25
19	3935	4083 (38.83)	3849 (39.12)	148	3.76	-86	-2.19
20	2881	2937 (19.56)	2928 (6.71)	56	1.94	47	1.63
21	4477	4512 (30.74)	4512 (30.74)	35	0.78	35	0.78
22	3857	4005 (48.61)	3978 (12.55)	148	3.84	121	3.14
23	3419	3369 (20.12)	3369 (20.12)	-50	-1.46	-50	-1.46
24	1237	1320 (10.61)	1329 (8.21)	83	6.71	92	7.44
			Mean	50	1.61	14	0.83
			SD	58	2.17	78	2.58

FVC values from devices 1 and 2 are presented as mean (SD) of five measurements. *: difference between target FVC and FVC of devices 1 and 2.

Experiment 2: influence of a series connection of PT and AM1 in test rig experiments

Figure 1 shows the differences in PEF values between measurements obtained by AM1 and AM1 in series connection with the PT. Values are plotted against average PEF from both measurements as obtained in seven ATS flow-time curves. For each flow-time curve a mean value of five single measurements was calculated. Mean (SD) differences were 1.14 (10.2) L·min^{-1} or 0.96 (2.63)%, respectively. Limits of agreement were -19.18 to +21.46 L·min^{-1}, with the 95% confidence interval for the bias being - 8.25 to +10.54 L·min^{-1}. Figure 2 shows the corresponding differences of FEV_1 as obtained in 24 volume-time curves. Mean (SD) differences were -11.3 mL (15.1) or -0.43 (0.52)%. Limits of agreement were +18.9 to -41.5 mL, with the 95% confidence interval for the bias being -4.9 to -17.7 mL. Corresponding mean (SD) differences for measurement of FVC (figure not shown) were +39.5 (64.8) mL or 0.84 (1.7)%. Limits of agreement were -90.1 to +169.2 mL, with the 95% confidence interval for the bias being +12.2 to +66.9 mL. All differences referred to measurements in series.

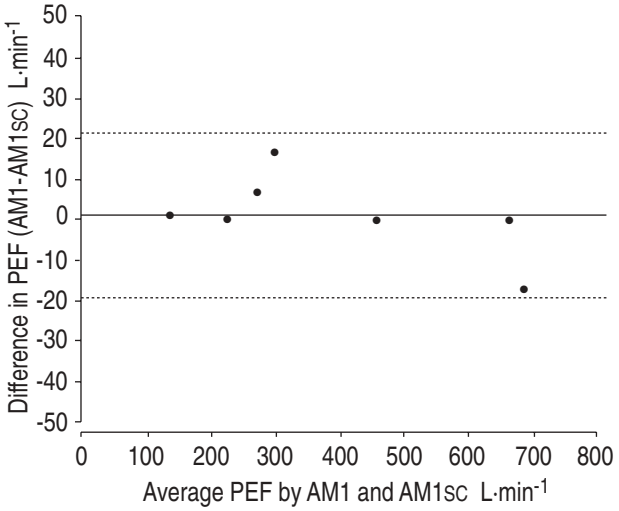

Fig. 1. – Differences in peak expiratory flow (PEF) values between measurements obtained by the electronic peak flow meter (AM1) and AM1 in series connection (AM1SC) with the pneumotachograph. Values are plotted against average PEF from both measurements. ——: mean; ------- : ±2SD.

Experiment 3: comparison of simultaneous FEV_1 measurements by PT and AM1 in human subjects

Figure 3 shows individual differences of FEV_1 values between PT and AM1 measurements plotted against average FEV_1 from both measurements as obtained in 49 volunteers. All 3 pairs of values per volunteer were plotted. Corresponding mean (SD) differences were 0.166 (0.142) L or 4.33 (3.49)%, respectively. Limits of agreement were -0.112 to + 0.444 L, with the 95% confidence interval for the bias being +0.143 to +0.189 L. It has to be mentioned that the difference found was only valid for measurements in series.

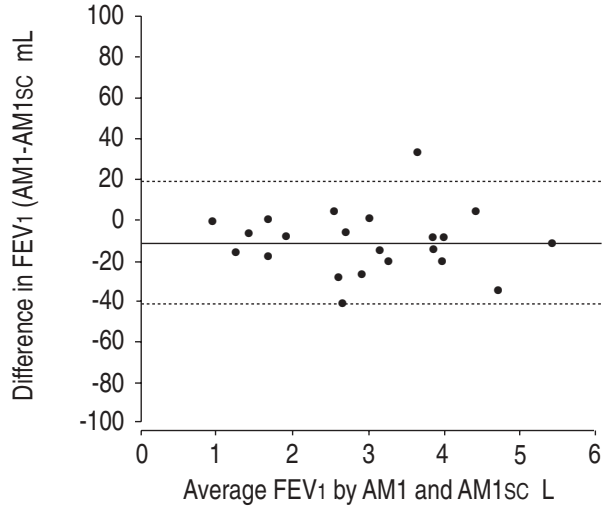

Fig. 2. – Differences in forced expiratory volume in one second (FEV_1) values between measurements obtained by the electronic peak flow meter (AM1) and AM1 in series connection ($AM1_{SC}$) with the pneumotachograph. Values are plotted against average FEV_1 from both measurements. ——: mean; ------- : $\pm 2_{SD}$.

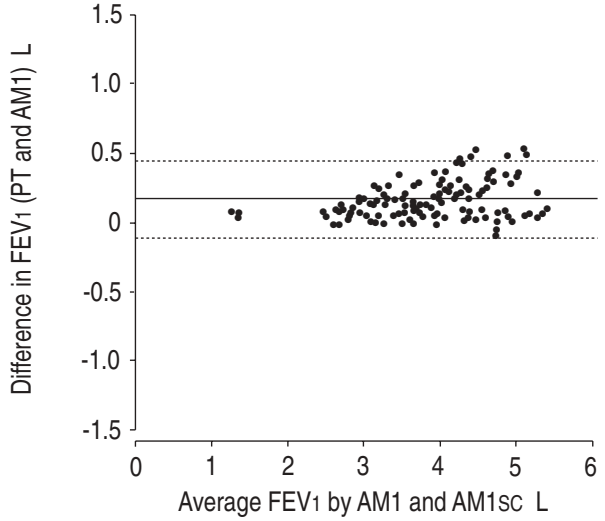

Fig. 3. – Individual differences in forced expiratory volume in one second (FEV_1) between values obtained by the pneumotachograph (PT) and the electronic peak flow meter (AM1) against the average from both values. Values were obtained by series connection of the PT and AM1. ——: mean; ------- : $\pm 2_{SD}$.

Discussion

This study demonstrated that the measurement of PEF, FEV_1 and FVC by the electronic asthma monitor AM1 satisfied the criteria for monitoring devices set by the ATS, including the criteria for inter- and intradevice variability. Several studies have validated PEF monitoring devices [4, 5, 11], including one electronic device which showed ac-ceptable performance for the measurement of FEV_1 [12]. In the present study, ATS criteria for testing the AM1 device were applied, as these standards were available at the time of the study and ATS waveforms cover a broad range of relevant flow patterns. In order to achieve as strict as possible an evaluation, the complete set of testing criteria were checked. The variety of flow profiles includes those with fast rise times, which are suitable for testing the frequency response of the device, particularly in view of the fact that a peak flow meter is primarily designed to be used in subjects with normal or deteriorated lung function. Therefore, a potential distortion at extremely high flow rates is probably not relevant. The mechanical test rig used in this study generated known accurate flow rates with adequate power to yield the required acceleration, even for higher flow rates.

Criteria for the accuracy of peak flow meters differ between various recommendations. The USA National Asthma Education Program recommends an accuracy of ±10% of the true reading, which is compatible with the ATS criteria [13], whilst the official ERS statement on peak expiratory flow measurement recommends that the accuracy of PEF meters should be ±5% or 5 $L \cdot min^{-1}$, whichever is the greater [14]. The present data demonstrate that these more stringent criteria for measurement of PEF were missed in only one of 52 testings (table 1).

The accuracy in FEV_1 measurement using the AM1 was also tested. FEV_1 measurements proved to be reliable when using the flow generator as a calibration device. However, when FEV_1 values were measured in series connection with a PT in human subjects, the AM1 showed an underestimation by about 4% compared with the PT. Hence, measurements by the PT and the AM1 device were not interchangeable. At present, the reason for this is unknown, because the fact that no BTPS correction has been applied should lead to an error of only 1% [6]. Furthermore, in the experimental set-up the influence of the series connection of the two devices was much smaller than other sources of error in FEV_1 measurements. Other important issues for the evaluation of monitoring devices, such as patients' long-term compliance with the device or the usefulness of additional information about symptoms or intake of medication, were not part of this study and may be investigated in future studies. Because compliance with asthma therapy may be poor and completion of diary cards inaccurate, if they are filled in at all [15, 16], it is certainly useful to have a hard copy printout of the measurements, including a time and date stamp. This could significantly improve asthma control and management.

In summary, it can be concluded from the present data that the electronic peak flow meter and asthma monitor AM1 yields valid measurements of peak expiratory flow and forced expiratory volume in one second, which match the accuracy criteria of the American Thoracic Society for monitoring devices. In this respect, the AM1 is applicable for the monitoring and treatment control of airway diseases.

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