

This checklist shows the text of the Standard and the manner in which the product is shown to comply.

Summary

The PiKo-1 has been adjusted to be compliant with the frequency response requirements of the new EN 13826:2003 standard. The device has been on sale in Europe for two years as a CE marked ATS scale meter. Its measurement range is compliant by design.

4 General Requirements

4.1 Electrical safety

PEFM that are defined as Medical Electrical Equipment (see sub-clause 2.2.15 of EN 60601-1) shall, in addition to the requirements in this standard, meet the applicable requirements in EN 60601-1.

The environmental conditions given in clause 7.1 of this standard replace those given in sub-clause 10.2.1 of EN 60601-1.

See appendix 1 EN 60601-1 certification

4.2 Mechanical safety

Rough surfaces, sharp corners and edges, which can cause injury or damage shall be avoided or covered.

In particular, attention shall be paid to flange or frame edges and the removal of burrs.

Compliance is checked by inspection

This is complied with

5 Identification, marking and documents.

5.1 Marking of the scale or display

a) The scale or display shall be marked in units of litres per second or litres per minute.

Litres per minute is used

b) For PEFM with a graduated scale the increment between any two adjacent graduation lines shall represent a difference in peak flow no greater than 10 L/min (0,15 L/s) at flows of 700 L/min (11 L/s) or below, and 20 L/min (0,3 L/s) at flows above 700 L/min (11L/s)

Not applicable

For PEFM with a digital display the incremental step shall be no greater than 5 L/min or 0,02 L/s.

1 l/min increments (in the digital display) are used throughout

NOTE 5 L/min and 0,02 L/s are not exact equivalents because digital displays do not usually register to three decimal places.

c) The numbering and graduation lines on a scale or digital display shall be clearly legible with normal vision. (i.e. a visual acuity of 1, corrected if necessary, at a distance of 0,5m at the intended operators position and at an ambient illuminance in the range 100 Lx to 1500 Lx.

complies

d) The numbering on a scale shall appear at intervals no greater than 50 l/min (1,0L/s) up to 700 L/min (11,0 L/s) and 100 L/min (1,7 L/s) thereafter.

Not applicable

e) The numbering on a scale or digital display shall not exceed the measurement range. (see clause 6)

The range is 60 to 800LPM and only measured numbers display

5.2 Marking of PEFM or packaging

5.2.1 Marking of the PEFM

The PEFM and/or its components shall be clearly and legibly marked with the following:

a) an arrow showing the direction of flow for any operator detachable components that are flow direction sensitive unless designed in such a way that prevents incorrect assembly;

Not applicable

b) the name or trademark and address of the manufacturer;

The word 'Ferraris' is marked on the bezel. The address appears on the rear label

c) where appropriate, either the serial number or batch code preceded by the symbol 'Lot' in accordance with EN 980;

The device is both serialised, and LOT numbered on the box

5.2.2 Marking of the packaging:

a) details to enable the user to identify the PEFM and the contents of the packaging;

The box shows picture, name, part number, and description

b) If appropriate, the symbol

STERILE

 in accordance with EN 980;

- Not applicable**
- c) if appropriate, the symbol for 'USE BY'
Not applicable
- d) where appropriate, an indication that the PEFM is for single patient use (See EN 980);
stated on front of box
- e) any special storage and/or handling instructions;
Not applicable
- f) the intended purpose of the PEFM.
Front of box states 'For effective asthma management'

5.3 Accompanying Documents

The accompanying documents shall include the following:

- a) the intended purpose of the PEFM including any restrictions for its use;
Stated in intended use section of user manual
- b) a statement, if applicable, that the performance of the PEFM can be affected by the patient spitting or coughing into the PEFM during expiration or by extremes of temperature, humidity and altitude;
complies
- c) if the PEFM is intended to be dismantled by the user, the correct method of reassembly;
not applicable
- d) details of what the user should do if unusual readings are obtained;
shown in intended use under blow quality
- e) recommended storage conditions;
in specification
- f) methods of cleaning, disinfection and sterilization, if appropriate;
section in user manual
- g) the highest resistance to flow within the measurement range of the PEFM and the flow at which this occurs;
in specification
- h) details of the nature and frequency of any maintenance and/or calibration needed to ensure that the PEFM operates properly and safely.
section in user manual

5.4 Technical Description

The technical description shall include the following:

- a) specification of the signal input/output part, if applicable;
Not applicable
- b) limits of accuracy of the measured value (see 7.1);
6%/4% quoted in specification
- c) a statement to the effect that the values displayed by the instrument are expressed as BTPS values;
in section on ' measurement scale' with definition
- d) any correction factors to be applied for changes in ambient conditions.
Add 1.5% per 1000 feet of altitude stated in warnings

6 PEFM measurement ranges

The range shall be from no greater than 60 L/min (1,0 L/s) to not less than 800 L/min (13,3 L/s) and expressed at BTPS conditions.

Complies

7 Performance requirements

7.1 Error of measurement

When tested in accordance with Annex A, the maximum permissible error for flow in the measurement range shall be:

± 10 L/min ($\pm 0,15$ L/s) or 10% of the reading whichever is the greater. This applies under the following environmental conditions:

- Ambient temperature range from 10 °C to 35 °C.
- Relative humidity range from 30 %RH to 75 %RH.
- Altitude range from 0 m to 1400 m (atmospheric pressure range from 1060 hPa to 850 hPa)

NOTE: The maximum permissible error values do not take into account the error limits of the test apparatus specified in Annex A.

Complies

7.2 Linearity

When tested in accordance with Annex A, the difference between the mean error at any two consecutive test flows (see annex A) shall not exceed 5% of the larger of the two test flows.

The linearity tolerances do not take into account the error limits of the test apparatus specified in annex A

When tested in accordance with annex A and under ambient conditions, the span of the PEFM readings at any set peak flow in the measurement range shall not vary by more than 10 L/min (0,15 L/s) or 5% of the mean of the readings, whichever is the greater.

The repeatability tolerances do not take into account the tolerances of the test apparatus specified in annex A

Complies (electronic linearisation)

7.3 Resistance to flow

When tested in accordance with annex A the resistance to flow across the measurement range of the PEFM shall not exceed 0,35 kPa/L/s (0,006 kPa/L/min)

Stated in spec as $<2.5\text{cmH}_2\text{O/l/s}$ (0.249kPa/l/s)

7.4 Frequency Response

When tested in accordance with annex B the difference between the measurement values for Profiles A and B (see fig B1) shall not exceed 15 L/min (0,25 L/s) or 12% whichever is the greater.

3% difference measured - see appendix 2

NOTE: This tolerance does take into account the tolerances of the test apparatus specified in appendix B

8 Dismantling and reassembly

8.1 If intended for dismantling by the user, the PEFM shall be designed or marked to indicate correct reassembly when all parts are mated.

Not applicable

8.2 When tested in accordance with annex C after dismantling and reassembly in accordance with the manufacturer's instructions, the PEFM shall meet the requirements of clause 7 and its readings shall not have changed by more than 10% or 10 L/min (0,15 L/s), whichever is the greater.

Not applicable

9 Effects of mechanical ageing

If the PEFM has moving parts as part of the flow sensing/indicating system then after being tested in accordance with annex C, the PEFM shall meet the requirements of clause 7 and its readings shall not have changed by more than 10% or 10 L/min (0,15 L/s), whichever is the greater.

Complies – shown by 50,000 cycle test

NOTE In the test in annex C the PEFM is operated 2000 times to simulate normal use of three times per day over 2 years.

10 Effects of dropping hand-held PEFM

When tested in accordance with annex C hand-held PEFM shall meet the requirements of clause 7

complies

Annex A (normative)

Method of determining accuracy, repeatability and resistance to flow of peak expiratory flow meter output

A1 Principle

A waveform of known peak flow is discharged through the PEFM and the output compared with the set reference peak flow.

A.2 Apparatus

A 2.1 An air flow source capable of producing a peak flow accurate to within $\pm 3\%$ of maximum flow or ± 3 L/min, a repeatability tolerance within $\pm 3\%$ or 3 L/min (0,05 L/s whichever is the greater, and a linearity tolerance not exceeding $\pm 1\%$ when producing a flow profile with a slow rise time (>100 ms) and long dwell time (>100 ms).

Profile A: having a RT between 120ms and 140 and a DT between 100ms and 120 ms

Rigid, smooth-bore coupling of not more than 100mm in length.

A 3 Procedure

A 3.1 Carry out the procedure with the device equilibrated at one set of environmental conditions within the range given in 7.1,

A 3.2 Connect the air flow source to the outside of the PEFM mouthpiece using the rigid coupling, ensuring that the PEFM is orientated in accordance with the manufacturer's instructions.

A 3.3 Prepare the PEFM for use according to the manufacturer's instructions.

A 3.4 Using profile A (see Figure B.1) discharge gas that is at the chosen ambient conditions, through the PEFM and record the PEFM output and peak pressure at:

100; 150; 200; 300; 450; 600; 720 L/min and at 150 L/min intervals thereafter. (1,7); (2,5); (3,3); (5,0); (7,5); (10,0); (12,0) L/s and at (2,5) L/s intervals thereafter.

A 3.5 Repeat A.3.3 and A.3.4 four more times (i.e. a total of five times), at each flow.

NOTE: A.3.5 can be carried out during A.3.4 for each waveform.

A 3.6 Repeat A.3.3 and A.3.4 five times at 300 and 600 l/min (5,0 and 10,0 L/s) but this time discharge gas at a temperature of $34 \pm 2^\circ\text{C}$ and a relative humidity above 90%.

A 4 Calculations

If the manufacturer indicates that the output of their PEFM is known to vary according to ambient conditions and/or the characteristics of the gas flowing through it, then all results from the PEFM must be adjusted with appropriate correction factors (with removal of BTPS correction for tests in A 3.4, where appropriate) to account for the set of ambient conditions and different test gas conditions in A.3.4 and A.3.6.

A 4.1 Accuracy

Calculate the accuracy of the PEFM for each reference peak flow, which is expressed as the error from the following equation

$$\text{error} = \text{mean of 5 recorded PEF} - \text{reference PEF}$$

A 4.2 Output Repeatability

Calculate the span of PEFM readings for each reference peak flow from the following equation:

$$\text{span} = \text{maximum PEFM reading} - \text{minimum PEFM reading}$$

A 4.3 Resistance to flow

Calculate the resistance to flow for each of the reference flows from the following equation:

$$\text{Resistance} = \text{peak pressure} \div \text{reference flow}$$

A 4.4 Linearity

Calculate the difference for each of the reference flows RF_n (n = Number of flows) from the following equation:

$$\text{Difference \%} = [\text{mean error}_{\text{RF}_n} (\text{L/min}) - \text{mean error}_{\text{RF}_{n+1}} (\text{L/min})] \times 100 \div [\text{mean displayed flow for } n + 1]$$

A 5 Test report

The report shall include a reference to this test and the following:

For the data from A 3.4 and A 3.5

- a) the 5 readings for each of the flows tested;
- b) the span of these 5 readings (repeatability);
- c) the error for each of the 5 readings for each flow tested and their mean (accuracy);

d) the error for each of the 5 readings expressed as a percentage of the reference flow for each of the flows tested, and their mean (accuracy);

e) the difference% (vide supra, A4.4) for each pair of consecutive flows tested (A3.4) across the range (linearity);

f) the peak pressure reading in kPa, and the derived resistance, at each of the flows tested. (resistance):

For the data from A 3.6:

g) the 5 readings for each of the 2 flows tested;

h) the error for each of the 5 readings for the 2 test flows and their mean;

A 6 Pass/ Fail criteria

To meet this standard any error of PEFM reading shall be less than the sum of the stated permissible error in this standard and the known error of the test apparatus (which must be less than stated in A.2).

Annex B (normative)

Method of determining frequency response

B 1 Principle

Two specially chosen artificial profiles (see Fig B.1) are delivered to PEFM to determine their frequency response.

NOTE: Many PEFM do not give an analogue output signal to allow frequency response to be measured by spectral analysis. It is therefore necessary to check that PEFM accurately read PEF from flow profiles that span the range of frequency content found in the client population who use these PEFM. These two artificial profiles are chosen to span the 90% confidence limits for the rise time and dwell time for PEF.

B 2 Apparatus

B 2.1 An air flow source capable of delivering the two profiles given in Fig B1 with a flow reproducibility of $\pm 3\%$.

(see annex D for an example of such an airflow source)

B 2.2 Profile B : Having a RT of between 24 ms and 36 ms and a DT of between 12ms and 18ms

B 2.3 A rigid, smooth bore coupling of no more than 100mm in length if required.

B 3 Procedure.

B 3.1 Using the mouthpiece and rigid, smooth-bore coupling, if required, attach the PEFM to the airflow source.

B 3.2 Measure, five times, the PEFM reading at three different flows using profile A and B.

NOTE: These flows should be at 25, 50 and 75% of the top of the measurement range

B 4 Calculations for Frequency Response

Calculate at each flow the mean difference in reading between profile A and B and express as a percentage of the reading for profile A

B 5 Test report

The report shall include for each of the three flows:

- a) the mean of the readings, for profile A and B;
- b) the difference between the mean readings for profile A and B;

c) the difference expressed as a % of reading for profile A.

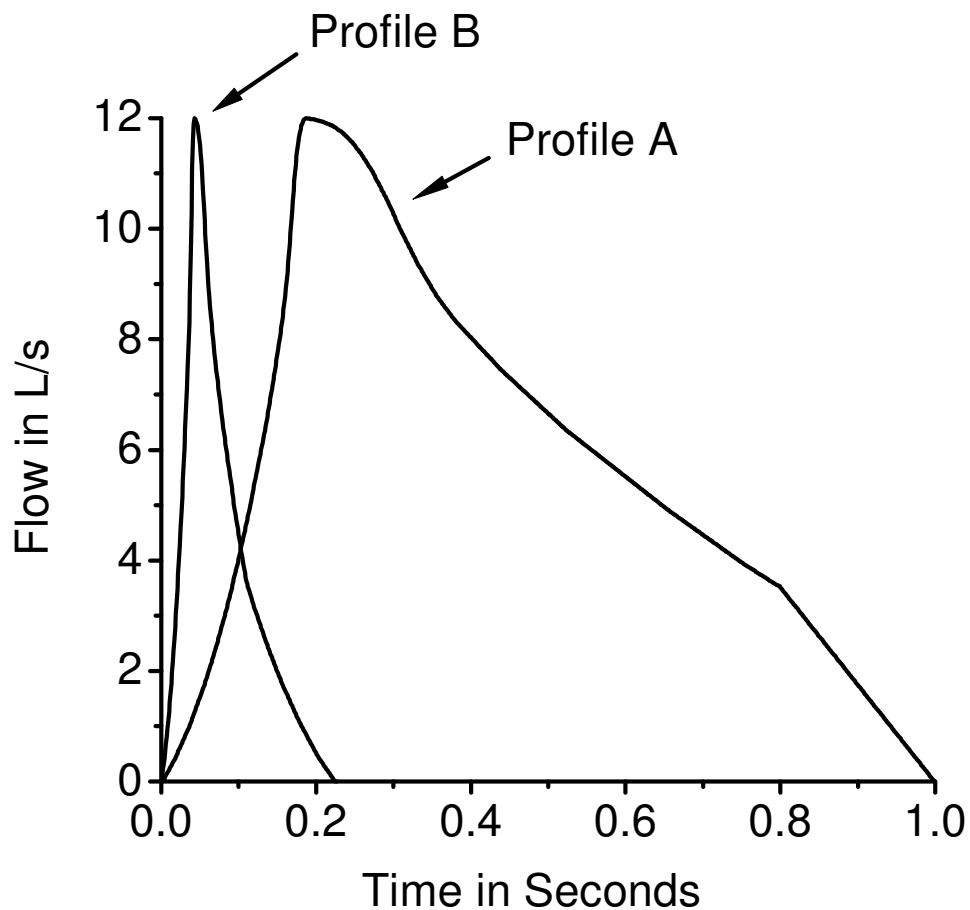


Figure B1. Flow time plots of Profile A, which should have a rise time (RT) between 120 to 140 ms and dwell time (DT) between 100 to 120 ms, and Profile B, which should have an RT between 24 to 36 ms and DT between 12 to 18 ms.

NOTE: Profiles are available in digital format from the European Respiratory Society.

Annex C (normative)

Method of determining the effects of dismantling, ageing and dropping.

C 1 Principle

To assess the effects of, mechanical ageing, by simulating 2 years usage, dropping hand-held devices, and dismantling and reassembling PEFM.

C 2 Apparatus

- a) An airflow source that supplies a profile, at ambient conditions, with a rise time of 24 to 36ms and a dwell time of no more than 140 ms at a flow of $90\% \pm 5\%$ at the maximum of the measurement range of the PEFM.
- b) A rigid smooth bore coupling of no more than 100mm in length, if required.

C 3 Procedures

C 3.1 Procedure for testing PEFM that may be dismantled and re-assembled by the user

Dismantle and re-assemble the PEFM (if applicable) according to the manufacturers instructions, and then carry out the procedure in annexe A and annex B. Calculate the effects of dismantling and re-assembling in accordance with C.4

C 3.3 Procedure for testing the effects of mechanical ageing

C.3.2.1 Using the mouthpiece and rigid, smooth bore coupling, if required, attach the PEFM at its recommended working orientation to the outlet of the test apparatus. Ensure that the peak flow from the airflow source does not exceed the measurement range of the PEFM.

C 3.2.2 Prepare the PEFM according to the manufacturer's instructions.

C 3.2.3 Actuate the airflow source.

C 3.2.4 Repeat C.3.2.2 4 to C.3.2.3 2000 times.

C 3.2.5 Carry out the procedures in annex A and B after a period of at least 1h. after the last repeat of C.3.2.4. Calculate the effects of mechanical aging in accordance with C.4

C.3.3 Procedure for testing the effects of dropping hand held PEFM

Drop the hand held PEFM in accordance with the test given in clause 21.5 of of EN 60601-1:1990 and then carry out the procedure in annex A and annex B. Calculate the effects of dropping in accordance with C.4

C 4 Calculation of effects

Calculate the difference before and after dropping dismantling and re-assembling using the formula:

$$\text{Difference} = \frac{\text{post (drop/age/dismant')} \text{ reading} - \text{pre (drop/age/dismant')} \text{ reading}}{\text{True value}}$$

C 5 Test report

The report shall include the following information:

- a) the information listed in annex A.5 and B.5
- b) the mean PEF readings at each flow (as tested in Annex A) before and after ageing, dropping and dismantling, their difference and that difference expressed as a % of the reference flow
- c) reference to this test method

APPENDIX 1 CE Certification (including EN60601)



EC Declaration of Conformity

We

Manufacturer

Pulmonary Data Services, Inc.
908 Main Street
Louisville CO 80027
U.S.A.

Authorized representative

Ferraris Respiratory Europe, Ltd.
Harforde Court, John Tate Road
Hertford SG13 7NW
U.K.

declare under our sole responsibility that the

PIKo-1 EU/ATS Electronic Peak Flow Meter


and its PiKoTrend data-communication cradle and software program to which this declaration relates are in conformity with the provisions of the Council of the European Communities Directive 93/42/EEC of 14 June 1993 concerning medical devices that apply to them. The devices are classified as Class I devices under Rule 12 of Annex IX of the Directive and perform a measuring function.

In addition, we declare that the design, production, packaging, and labeling of this product conform to the requirements of the following standards:

Quality management: ISO 13485:1996 [Certificate FM 76889, BSI]
Safety: EN 60601-1, Safety general
EN 60601-1-1, Safety of electrical systems
EN 60601-1-2, Electromagnetic compatibility
Performance standards: PEF: EN 13826:2003
FEV1: ATS Standardization of Spirometry:1994

EC Certificate CE 01942 issued by British Standards Institute (Notified body 0086) attests to compliance with the procedures referred to in Annex V of the Directive for those aspects of manufacture concerned with the conformity of products with the metrological requirements.

Year in which "CE" mark affixed: 2003



J. W. Lewis
Vice President, Operations



Date of Issue

APPENDIX 2 Functional test results

Profiles A and B from the Explosive Decompression device

DEVICE (del press bar)	WAVEFORM	Peak flows at two rates for six readings each	% diff
150001	1.5	A 556	556 556 556 556 0.0 0 0.0
		B 535	535 535 527 535 533.4 3.6 8 1.5
			diff diff% ---> 22.6 4.1
	0.5	A 280	280 280 280 280 0.0 0 0.0
		B 275	270 275 270 270 272 2.7 5 1.8
			diff diff% ---> 8 2.9
150006	1.5	A 556	564 556 556 556 557.6 3.6 8 1.4
		B 542	549 556 527 549 544.6 11.0 29 5.3
			diff diff% ---> 13 2.4
	0.5	A 270	270 270 270 270 0.0 0 0.0
		B 275	275 275 270 270 273 2.7 5 1.8
			diff diff% ---> -3 -1.1
150011	1.5	A 556	556 549 556 556 554.6 3.1 7 1.3
		B 549	542 527 527 542 537.4 9.9 22 4.1
			diff diff% ---> 17.2 3.2
	0.5	A 274	274 274 274 268 272.8 2.7 6 2.2
		B 274	264 274 274 274 272 4.5 10 3.7
			diff diff% ---> 0.8 0.3
150017	1.5	A 542	549 535 535 535 539.2 6.3 14 2.6
		B 513	520 527 520 520 520 4.9 14 2.7
			diff diff% ---> 19.2 3.6
	0.5	A 268	268 264 268 268 267.2 1.8 4 1.5
		B 268	268 268 264 268 267.2 1.8 4 1.5
			diff diff% ---> 0 0.0
150022	1.5	A 547	540 533 540 540 540 4.9 14 2.6
		B 533	526 520 526 526 526.2 4.6 13 2.5
			diff diff% ---> 13.8 2.6
	0.5	A 268	268 268 268 268 0.0 0 0.0
		B 264	264 268 268 268 266.4 2.2 4 1.5
			diff diff% ---> 1.6 0.6

Mean % difference in A/B waveforms

1.9

ATS 26 flow profiles from the pump

ATS No	TRUE	PIKO 150001					Error	Error%	Mean	BTPS	BTPS	SD	Span	Span%
		Mean	Mean	error %										
1	446	477	477	477	477	484	32.4	7.3	478.4	456.87	-2.44	3.13	7	1.46
2	651	658	658	658	658	658	7	1.1	658	628.39	3.47	0.00	0	0.00
3	287	294	294	294	294	294	7	2.4	294	280.77	2.17	0.00	0	0.00
4	264	275	275	275	275	275	11	4.2	275	262.63	0.52	0.00	0	0.00
5	217	232	232	232	232	232	15	6.9	232	221.56	-2.10	0.00	0	0.00
6	185	185	185	185	185	185	0	0.0	185	176.68	4.50	0.00	0	0.00
7	150	153	153	153	153	153	3	2.0	153	146.12	2.59	0.00	0	0.00
8	139	144	144	144	144	144	5	3.6	144	137.52	1.06	0.00	0	0.00
9	315	318	318	318	318	318	3	1.0	318	303.69	3.59	0.00	0	0.00
10	283	294	299	299	299	299	15	5.3	298	284.59	-0.56	2.24	5	1.68
11	412	433	433	433	433	433	21	5.1	433	413.52	-0.37	0.00	0	0.00
12	641	696	686	686	686	686	47	7.3	688	657.04	-2.50	4.47	10	1.45
13	288	304	299	299	299	299	12	4.2	300	286.5	0.52	2.24	5	1.67
14	229	242	242	242	247	242	14	6.1	243	232.07	-1.34	2.24	5	2.06
15	477	513	513	513	513	520	37.4	7.8	514.4	491.25	-2.99	3.13	7	1.36
16	315	322	322	322	322	322	7	2.2	322	307.51	2.38	0.00	0	0.00
17	355	368	368	368	361	368	11.6	3.3	366.6	350.1	1.38	3.13	7	1.91
18	515	549	549	549	556	549	35.4	6.9	550.4	525.63	-2.06	3.13	7	1.27
19	417	440	440	440	440	440	23	5.5	440	420.2	-0.77	0.00	0	0.00
20	445	477	477	477	484	477	33.4	7.5	478.4	456.87	-2.67	3.13	7	1.46
21	238	251	251	251	251	251	13	5.5	251	239.71	-0.72	0.00	0	0.00
22	202	213	218	213	218	218	14	6.9	216	206.28	-2.12	2.74	5	2.31
23	487	527	520	520	527	520	35.8	7.4	522.8	499.27	-2.52	3.83	7	1.34
24	249	261	261	261	261	261	12	4.8	261	249.26	-0.10	0.00	0	0.00
25	851	915	904	915	904	904	57.4	6.7	908.4	867.52	-1.94	6.02	11	1.21
26	695	696	717	696	707	707	9.6	1.4	704.6	672.89	3.18	8.85	21	2.98

mean span error 0.85

CONCLUSION

PiKo-1 complies with the response time requirements of EN13826 with a difference of 1.9% between the peak flows of waveforms A and B (up to 12% acceptable)

PiKo-1 complies with the accuracy of measurement showing a maximum span error of 2.98% and a mean error of 0.8% (up to 10% is allowed)

G.M.Peck
 Technical Manager
 Ferraris Respiratory Europe Ltd
 August 2004