# Physikalisch-Technische Bundesanstalt

**Braunschweig und Berlin**

PTB

# Prüfschein

*Test certificate*

| | |
|---|---|
| Ausgestellt für:<br>*Issued to:* | Hans Rudolph, Inc.<br>7205 Central<br>Kansas City, Missouri 64114<br>U.S.A. |
| Prüfgrundlage:<br>*In accordance with:* | DIN EN 13826 Peak expiratory flow meters (2003) |
| Gegenstand:<br>*Object:* | Flow / Volume Simulator, Series 1120<br>for testing of medical pulmonary equipment |
| Kennnummer:<br>*Serial number:* | SN 112-011 |
| Prüfscheinnummer:<br>*Test certificate number:* | **PTB 1871/05** |
| Datum der Prüfung:<br>*Date of Test:* | August 2005 |
| Anzahl der Seiten:<br>*Number of pages:* | 10 |
| Geschäftszeichen:<br>*Reference No.:* | PTB – 8.12-PA-17/05 |

Im Auftrag
*By order*
W. Riedel

Berlin, 17.08.2005

Siegel
*Seal*

Hinweise siehe letzte Seite der Anlage, die Bestandteil des Prüfscheines ist.
*For notes, see last page of the Annex which forms an integral part of the test certificate.*

## 1 General

The Flow / Volume Simulator was checked for compliance with European standard DIN EN 13826 (Peak Expiratory Flow meters) for a peak flow of 12 L/s with different flow resistances.

Used terms and abbreviations:

| | |
|---|---|
| FVS: | Flow / Volume Simulator, Series 1120, Hans Rudolph, Inc., USA |
| FVP: | Target profile for the drive control of the FVS |
| PF: | Peak flow |
| RT: | Rise time of air flow from 10 % to 90 % of the PF |
| DT: | Dwell time of air flow being higher than 90 % of the PF |
| PTB-FM: | PTB flow meter<br>Utilized as reference flow sensor, traced to the National Volume Flow Standard. |
| s: | Measurement uncertainty |
| u: | Extended measurement uncertainty (k=2) |

## 2 Description of the device checked

The device consists of a cylinder-piston pump, driven by a linear motor with integrated magnetic incremental position sensor. The position sensor supports electronic commutation of the motor and is used for speed and position control of the piston. The pump is controlled by an internal micro-processor. The control data are downloaded from a PC via USB-interface. The process data are acquired by the controller and transferred back to the PC via the USB.

Technical specifications of the pump given by the manufacturer:

| | |
|---|---|
| Cylinder diameter: | 152.4 mm |
| Maximum volume: | 8.5 L |
| Maximum volume flow: | 16 L/s |
| Flow resolution: | 35 µL |
| Software version: | 4.5.1 |

## 3 Measurement Instrumentation

PTB-Flowmeter (PTB-FM):

| | |
|---|---|
| Manufacturer: | VIASYS Healthcare, Inc., Höchberg, Germany |
| Type: | Jaeger 20 L/s, Pneumotachograph<br>modified by a custom-designed wide-band amplifier,<br>electrical Bessel-type low-pass filter, 100 Hz |
| Calibrated by: | PWG-6, MH Custom Design, USA, No. 711, traced back to the German National Volume Flow Standard, s = 0.12 % |
| Measurement uncertainty: | s = 0.28 % |

Data acquisition:

| | |
|---|---|
| Manufacturer: | ADDI-DATA GmbH, Ottersweier, Germany |
| Type: | APCI-3120 (16 bit ADC, 14 bit DAC, PCI add-in card) |
| Measurement uncertainty: | s = 0.02 % |
| Time base: | Quartz time base of the ADC (10 kHz sampling frequency) |
| Measurement uncertainty: | s = 0.003 % |
| Software: | Delphi-program "DAprj.exe", PTB, Rel. 2005-08-08 |

Data interpretation and statistical evaluation:

| | |
|---|---|
| Software | Delphi-program "PeakFlow", PTB, Rel. 2005-08-03/Ch4 |

Pneumatic resistors:

| | |
|---|---|
| Manufacturer: | VIASYS Healthcare, Inc., Höchberg, Germany |
| Calibrated: | PTB Berlin at 5 L/s (July 2005) |

The resistors are fitted to the outlet of the PTB-FM by means of an adapter tube.
In the tables, the following designations are used:

R0: No additional flow resistance. Base value of sensor = 42 Pa/(L/s)

R2: 207 Pa/(L/s) added pneumatic resistor, total 258 Pa(L/s) with tube.

Pressure sensor #1 for the measurement of flow resistances:

| | |
|---|---|
| Manufacturer: | HUBER Instrumente |
| Type: | PRE 3026.240.S |
| Serial no.: | 491 122 |
| Measurement uncertainty: | s = 0.2 mmHg (F.S. 300 mmHg) |

Pressure Sensor #2 for calibrating internal pressure sensors and air-tightness tests:

| | |
|---|---|
| Manufacturer: | Druck Limited |
| Type: | DPI 261 |
| Serial no.: | 606 / 92-7 |
| Measurement uncertainty: | s = 0.04 % F.S. (F.S. 1300 mbar) |

Temperature and humidity sensor:

| | |
|---|---|
| Manufacturer: | T&D Messtechnik GmbH, Düsseldorf, Germany |

| | |
|---|---|
| Type: | DH 50.B |
| Serial no.: | 19 230/01 |
| Measurement uncertainty: | s = 0.2 K; 5 % Rel. Humidity |

## 4 Description of the measuring set-up

The volume flow was measured by means of the PTB-FM, a modified pneumotachograph Jaeger 20 L/s, originally manufactured by VIASYS and equipped with a fast pressure sensor and an electronic low pass filter with approximately 100 Hz bandwidth. The overall bandwidth was verified by comparing the pneumatic step responses of the PTB-FM with that of a hot-wire anemometer (bandwidth > 1kHz). The PTB-FM signal was recorded by a Pentium-PC equipped with an ADC-card.

The PTB-FM has a minimum pneumatic flow resistance of 42 Pa/(L/s) at 5 L/s. All measurements were performed with either this resistance or with an additional pneumatic resistor of 208 Pa/(L/s) to simulate the pneumatic resistance of a peak-flow-meter.

A silicone tube (28 mm internal diameter) was applied to connect the pump and the PTB-FM. The distance from the FVS outlet to the PTB-FM's entrance is 20 mm, to the sensor 60 mm (Fig. 1, 2).

The PTB-FM was calibrated by means of stationary flows of a Pulmonary Waveform Generator PWG-6. The volume flow of the PWG-6 is traced back to the German National Flow Standard in the Physikalisch-Technische Bundesanstalt (PTB), with a measurement uncertainty of s = 0.12 %. The PTB-FM was calibrated at air temperatures of 18 °C and 27 °C. The actual air temperature was measured with a resistance thermometer, having a bandwidth of 20 Hz .. 50 Hz, depending of the air velocity. The temperature dependence on the PTB-FM was corrected according to the measured temperature by linear interpolation between 18 °C and 27 °C.

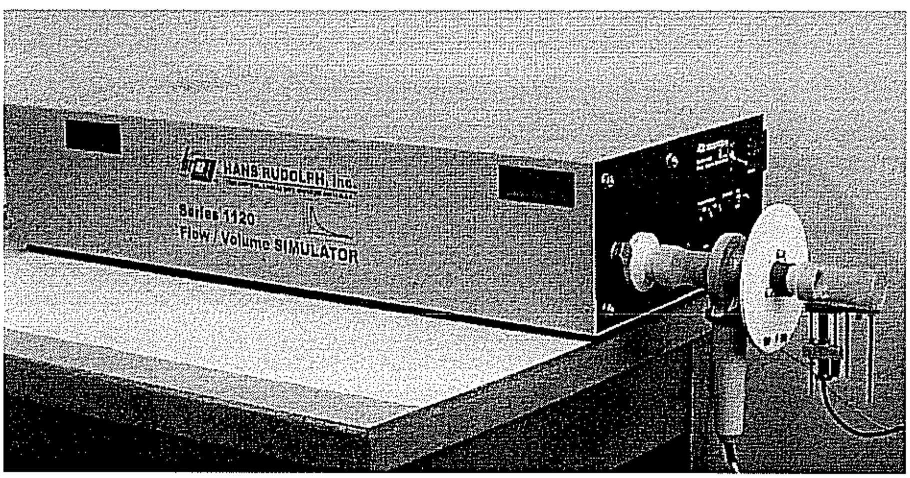


**Fig. 1** The Flow / Volume Simulator with attached PTB-FM and temperature sensor

The calibration state of the PTB-FM was checked on a daily basis by means of the PWG-6.

The air-tightness of the test set up of FVS, PTB-FM and temperature sensor was checked at rest by measuring the pressure decay of the hermetically sealed system at overpressure.

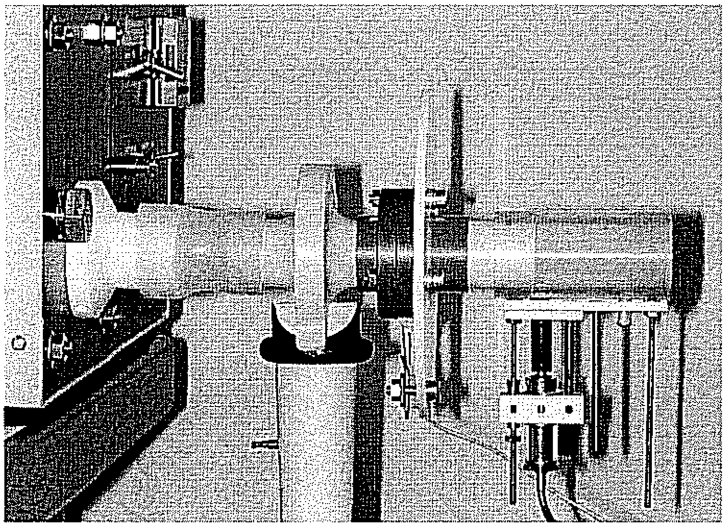

**Fig. 2** The Flow-sensor PTB-FM, temperature-sensor and Hot-wire anemometer

## 5 Measurements

Performance of the FVS was checked by its capability to generate the flow profiles A and B defined in DIN EN 13826. The generated flow was measured by means of the PTB-FM connected to a computer described above.

In preparation of the detailed test at 12 L/s, the operation of the FVS was checked with target PFs between 1.7 L/s and 13.33 L/s without statistical evaluation and without assessment of measurement deviation. The measurements showed, that the FVS, using appropriate control profiles FVP, is able to generate flow profiles required by the EN 13826.

Profiles A and B were repeated 10 times each for statistical evaluation. The target PF was 12 L/s at flow resistances of approximately 40 Pa/(L/s) and 260 Pa/(L/s). The "Adjust" command of the FVS-Software was executed two times before each measurement series in order to activate the FVS's pressure compensation.

The 10 measurements with identical parameter settings are statistically evaluated by means of the averaged measured values, and the standard deviation of the measured values.

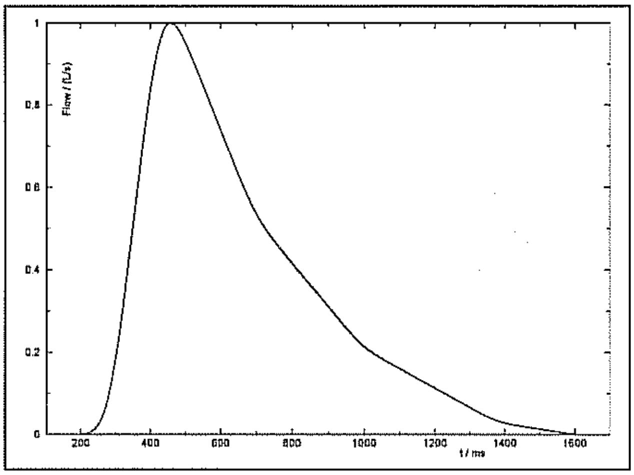


**Fig. 3:** Nominal profile CEN A
(RT = 131 ms; DT = 114 ms)
normalized to 1 L/s.

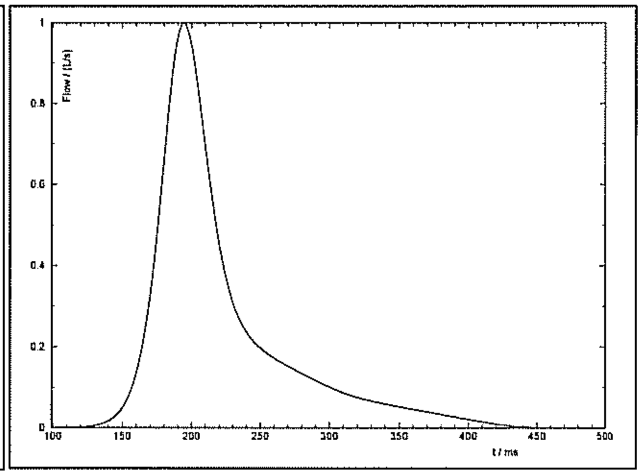


**Fig. 4:** Nominal profile CEN B
(RT = 30.1 ms; DT = 15.6 ms)
normalized to 1 L/s.

The flow profiles, here labeled "CEN A" and "CEN B" (Fig. 3, 4), comply with the DIN EN 13826: They are centered in the tolerance ranges of the RT and DT.

The piston drive has to be controlled by target profiles which approximate the flow profiles above. The target profiles for the FVS are labeled FVP A and FVP B.

The FVP A and B were sampled with the native sampling time of 3.90625 ms of the FVS to apply them without changes as target flow profiles for the motion controller.

As a first approach, the FVP A and B are copies of the respective CEN A and B profiles.

FVP A medium: RT=131 ms, DT=114 ms;
FVP B medium: RT=30.1 ms, DT=15.5 ms.

They are labeled "medium", because they are in the middle of the tolerance range for RT and DT.

Initial measurements indicated that faster target profiles would be required at higher PFs. Therefore, a second set of Profiles A and B, labeled "fast", was generated with

FVP A fast: RT=128 ms, DT=110 ms,
FVP B fast: RT=26.2 ms, DT=11.4 ms.

Its time parameters allow the inertia of the FVS to be pre-compensated.

Both, FVP A and FVP B in the fast version were applied as target profile for this measurement at 12 L/s, because the measured profiles of FVP B medium exceeded the tolerances of RT of the EN 13826.

Ambient conditions during the measurements were: Room temperature: 23.0 °C .. 23.9 °C, relative humidity: 38 % .. 45 %, ambient air pressure: 1003 mbar .. 1011 mbar.

The FVS indicated an internal temperature of 4 K .. 8 K above room temperature. The actual outlet temperature was measured dynamically and applied to compensate the temperature dependence of the PTB-FM.

The following parameters are evaluated:

- the peak flow
- the rise time (RT) of the flow from 10 % to 90 % of the measured peak flow
- the dwell time (DT) during which the flow remains above 90 % of its measured peak flow.

The target PF is quoted without assessing the difference to the measured PF: It deviates, for example, due to the air compressibility. This has to be taken into account for application of the FVS. The corresponding values of target PF and measured PF are given to alleviate the scaling of the target PF in future applications.

## 6 Data interpretation

The flow was measured by means of the PTB-FM with a sampling frequency of 10 kHz.
Data interpretation was facilitated by a purpose-written Delphi-program "PeakFlow". It calculates two polynomial fits for the measured data: One $5^{th}$ order fit around the measured peak determines the peak flow and the two 90 % intersections, defining the DT of the normally noisy profile. The other fit of $3^{rd}$ order at the lower rising edge relieves the determination of the 10 % intersection which defines the start of RT. The fit results were checked using a graphical interface, but without manual interaction, except to discard severe waveform errors. Some preliminary experiments e. g. on the polynomial degrees and the range of the fits were carried out to determine the usability of the fits.

## 7 Results

Table 1: Peak flow for FVP A and B

| Target peak flow | FVP | PR | Measured peak flow | | | | |
|---|---|---|---|---|---|---|---|
| | | | PF | sd | | $u_{PTB}$ | $u_{k=2}$ |
| L/s | | | mL/s | mL/s | % | % | % |
| 12 | A fast | R0 | 11696 | 21 | 0.2 | 0.28 | 0.68 |
| | | R2 | 11608 | 20 | 0.2 | 0.28 | 0.68 |
| | | | | | | | |
| | B fast | R0 | 11793 | 98 | 0.8 | 0.28 | 1.68 |
| | | R2 | 11529 | 72 | 0.6 | 0.28 | 1.30 |

Table 2: Rise Time for FVP A and B. (EN13826: RT: A=120 ms..140 ms, B=24 ms..36 ms)

| Target peak flow | FVP | PR | Rise time RT | | | | |
|---|---|---|---|---|---|---|---|
| | | | min | max | mean | sd | |
| L/s | | | ms | ms | ms | ms | % |
| 12 | A fast | R0 | 128.4 | 131.0 | 129.7 | 1.0 | 0.76 |
| | | R2 | 132.1 | 134.3 | 133.5 | 0.7 | 0.50 |
| | | | | | | | |
| | B fast | R0 | 24.7 | 25.5 | 25.1 | 0.3 | 1.03 |
| | | R2 | 26.9 | 27.2 | 27.1 | 0.2 | 0.84 |

Table 2: Dwell Time for FVP A and B. (EN13826: DT: A=100 ms..120 ms, B=12 ms..18 ms)

| Target Peak flow | FVP | PR | Dwell Time DT | | | | |
|---|---|---|---|---|---|---|---|
| | | | min | max | mean | sd | |
| L/s | | | ms | ms | ms | ms | % |
| 12 | A fast | R0 | 108.4 | 113.8 | 111.4 | 1.8 | 1.6 |
| | | R2 | 107.3 | 111.5 | 109.0 | 1.5 | 1.4 |
| | | | | | | | |
| | B fast | R0 | 15.3 | 17.1 | 16.3 | 0.59 | 3.6 |
| | | R2 | 15.3 | 16.4 | 16.0 | 0.34 | 2.1 |
| | | | | | | | |

PR: Pneumatic Resistance, R0 is 42 Pa/(L/s), R2 is 258 Pa/(L/s)

sd: standard deviation

$u_{PTB}$: uncertainty of the measurement device and procedure, the uncertainty of time measurements (Chapter 8) was estimated as 1 % and assigned to the $u_{PTB}$.

$u_{k=2}$: extended uncertainty of the measurement

## 8 Measurement Uncertainty

The measurement uncertainty *u* was determined by geometrical addition of the uncertainty of the test apparatus and the test procedure $u_{PTB}$ to the standard deviations $sd_{meas}$ from mean and by multiplying the result with *k*=2 according to the "Guide to the Expression of Uncertainty in Measurement" ("GUM"; BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML, 1995; ISBN 92-67-10188-9) to achieve a confidence level of 95 %:

$$u = 2 \cdot \sqrt{u_{PTB}^2 + sd_{meas}^2}$$

The uncertainty of the flow meter was estimated with 0.28 %. This is the combined calibration uncertainty (0.12 %) and the experimentally influence due to the data evaluation.

The usability of the fit functions of the data sets described in chapter 6, depends on the noise content of the data sets. Especially bumps, excited by acoustic resonance have a great influence around the peak region of profiles B. The uncertainty of PF was estimated with 0.25 % by means of variations of the fit parameters and by comparison of different profiles.

The measurement uncertainty of the RT and DT is less than that of the PF, since the 10 % and 90 % levels refer to the measured PF. Residual influences result from the curvature of the data set adjacent to the 10 % and 90 % levels. This and the specification of the tolerance ranges in EN 13826 leads to another interpretation: The span of time measurements (maximum minus minimum for RT and DT) and $u_{PTB}$ has to be related to the tolerance specified in the standard.

The standard deviation is given for completeness.

## 9 Summary

The Flow / Volume Simulator, Series 1120, of the Hans Rudolph, Inc. was tested for compliance with the DIN EN 13826 at a peak flow of 12 L/s.

It meets the requirements to generate the profiles A and B as demanded by the standard.

In preparation of the detailed test at 12 L/s, the operation of the FVS was checked with target PFs between 1.7 L/s and 13.33 L/s without statistical evaluation and without assessment of measurement deviation. The measurements show, that the FVS — with appropriate target profiles — can be applied for tests according to EN 13826.