

PiKo[®] Monitors

Electronic Patient Monitoring



Redefining Patient Care Beyond Expectations

Performance and simplicity go beyond expectations to create the world's most effective home health monitor for managing asthma and other respiratory conditions at home.

Redefining Patient Care — Diagnostic Confidence

PiKo[®] monitors measure peak flow, FEV₁, FEV₆, and FEV₁/FEV₆, giving you a reliable solution for asthma and COPD management. Sophisticated features include automatic test quality alerts and electronic data storage of 96 tests. Data can be reviewed via a single operating button, eliminating the errors associated with paper diaries. All tests can be easily downloaded to the companion PiKoNET software.

Redefining Patient Care — Improving Outcomes

As a part of our family of asthma and disease management products, PiKo monitors embody years of dedication to advancing the quality of lung health.

We continue redefining patient care so that you can achieve improved patient outcomes, more efficiently, more profitably.

Redefining Patient Care — Proven Technology

- **Portable.** PiKo-1[™] is the world's first pocket sized electronic peak flow and FEV₁ meter. In addition to FEV₁, the new PiKo-6[™] measures FEV₆ and FEV₁/FEV₆.
- **Ease of Use.** Single operating button simplifies testing, while electronic data storage eliminates errors. Color zone personalization, red, yellow, and green zones are automatically displayed.
- **Intelligent Design.** Features test quality alerts and electronic storage of the last 96 readings.
- **Affordable.** Not only the highest performing home health monitor of its type, PiKo is cost comparable to traditional mechanical peak flow meters.
- **Optional Software.** PiKoNET[™] for tracking and trending. Available in Professional and Personal versions.



PiKo Monitors

PiKo-1™

Electronic Peak Flow & FEV₁ Meter

PiKo-1 measures peak flow and FEV₁, considered by many asthma specialists to be a more reliable indicator of an impending asthma attack.

Recognized as the Best Over-the-Counter and Self Care Product at the US Medical Design Excellence Awards in 2003, PiKo-1 provides the most accurate peak flow measurement when compared to mechanical peak flow meters and is ATS/EU scale compliant.

PiKo-6™

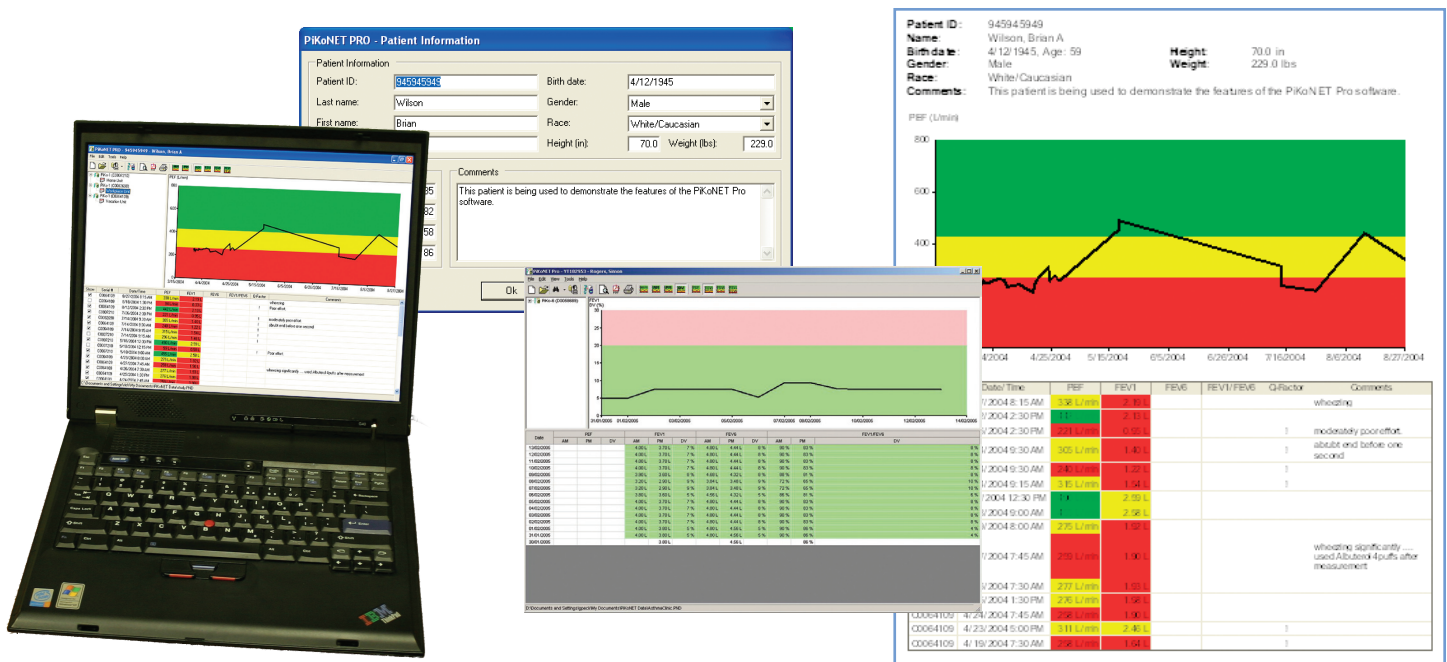
Electronic FEV₆, & FEV₁/FEV₆ Meter

PiKo-6 goes one step further measuring FEV₁, FEV₆, and FEV₁/FEV₆, bringing a new level of effectiveness to the monitoring of COPD, asthma, cystic fibrosis, and lung transplant patients.

An easy and cost-effective solution to patient screening and monitoring, PiKo-6 acts as a reliable indicator of the need for full spirometry and provides continuous assessment of lung function.



(Actual Size)



PiKoNET™ Software

PiKoNET™ Software Tracking & Trending Software

Easy-to-use, Windows® based PiKoNET software allows viewing and trending of PiKo results for effective monitoring and management of asthma and COPD.

Featuring a small USB interface cradle, PiKoNET software allows single or multiple patient data to be downloaded onto a computer for tracking and trending. All data can be presented in graphical and tabular format and is date and time stamped, eliminating the need for record cards.

- **Simplicity.** Easily download data via infrared ports on PiKo and cradle.
- **Graphical Customization.** Viewed parameters selectable for table and graphs as well as dates, data, scales, and zones. Graphical data selectable for morning, afternoon, or all day.
- **Intelligent Design.** PiKoNET configures PiKos with zones and reference values. Automatically calculates diurnal variation and links serial number(s) of PiKo(s) to the patient record.
- **Reporting.** Reports include patient data, tables, and graphs that can be previewed on screen, printed, or saved as a PDF file on the patient's record.
- **Records.** Patient Records include ID, patient demographics, and reference values.
- **Security.** Password protected databases can be created for storing patient records in groups or for trials.

Redefining Accuracy. Beyond Expectations.



Technical Specifications

PiKo-1 & PiKo-6

Sensor:

Pressure/flow sensor technology, (patented)

Memory:

96 patient test scores

Memory Type:

Non-volatile

Color Zone:

3 Color Zones (Green, Yellow, Red)

Reference Values:

User defined

Quality Factor:

Warning & indicator for cough or abnormal blow

Sounds:

Four patterns for different indications and warnings

Communication:

Bi-directional IR port (RS232 format)

Battery Life:

PiKo-1: One year (based on average of 6 blows per day)

PiKo-6: Six months (based on average of 6 blows per day)

Battery Type:

2 x type 357 silver oxide button cells (or equivalent)

Dimensions:

75 x 35 x 20 mm; 35 grams

Resistance:

<2.5 cmH₂O/l/sec at 14 LPS or lower

Operating Temp:

10°C to 38°C (50°F to 100°F)

Storage Temp:

-20°C to 60°C (-4°F to 140°F)

Humidity:

0 - 100% relative humidity

Barometric:

550 to 780 mm Hg

Performance:

ATS 1994 (monitoring), AS/NZS-4237: 1994, EN13826: 2003

Safety:

EN60601-1, EN60601-1-1, EN60601-1-2, and IPX4

Regulatory:

PiKo-6 FDA 510(k); PiKo-1 FDA 510 (k) for OTC; CE 0086, Class I with measurement function

Contracts:

GSA V797P-4063a; UK NHS Drug Tariff prescribable on FP10

Patent:

US #6,447,459 B1

Warranty:

Six months (batteries not included)

PiKo-1**PEF:**

Range 15 - 999 LPM (1 LPM resolution)

Accuracy 5% or +/- 20 LPM (whichever is greater)

FEV₁:

Range 0.15 - 9.99 liter (0.01 liter resolution)

Accuracy +/- 3.5% or 0.1 liter (whichever is greater)

PiKo-6**FEV₁:**

Range 0.15 - 9.99 liter (0.01 liter resolution)

Accuracy +/- 4% or 0.1 liter (whichever is greater)

FEV₆:

Range 0.15 - 9.99 liter (0.01 liter resolution)

Accuracy +/- 4% or 0.1 liter (whichever is greater)

PiKoNET software**Definition:**

PiKoNET is a reporting package that reads data from a PiKo-1 or PiKo-6 and presents the data in trend format against time. With PiKo-1, PEF and FEV₁ are reported. PiKo-6 does not measure PEF.

Parameters reported:

PEF, FEV₁, FEV₆, FEV₁/FEV₆, reference values, zone thresholds, diurnal variation (difference between best am and best pm readings for selected parameter). Reference values are used for comparison and the graphs show banded zones relating to percentages of reference values achieved.

Operating Systems:

Windows 98, Windows ME, Windows 2000, Windows XP.

Hardware Requirement:

Minimum of Pentium III, 600 MHz, 64MB RAM, 500MB free space. Supports USB connection to PiKo.

Networks:

This is a single computer-based product; however, if the computer is part of a network, installation requires that the user be logged in as an administrator.

Software Required:

The following will be installed at the installation if required. NET Framework version 1.1 or higher, MDAC version 2.6 or higher, or JET version 4.0 or higher.

Databases:

Multiple databases supported, unlimited patients. Uses Microsoft generic high security format with password protection.

Output:

-PDF: Creates an Adobe Acrobat Portable Document of the entire patient report.

-TXT: Creates as Tab Delimited Text File useful for importing into word processing documents.

-CSV: Creates a comma separated variables text file, suitable for importing easily into Excel or other spreadsheets, databases and statistical analysis programs.

-Inbuilt report preview and print.

Program facility:

Allows PC to program reference and zone thresholds into PiKo.

Study Record:

Allows entry of site ID, study code and comments.

Quality Standards:

Facility to record study properties, for trials etc.

Contact Information

US

Phone: + 1.800.574.7374

Email: sales@nspirehealth.com

UK

Phone: + 44 (0) 1992 526300

Email: info@nspirehealth.com

Germany

Phone: + 49 (0) 9736/8181-0

Email: vertrieb@nspirehealth.com

www.nspirehealth.com



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