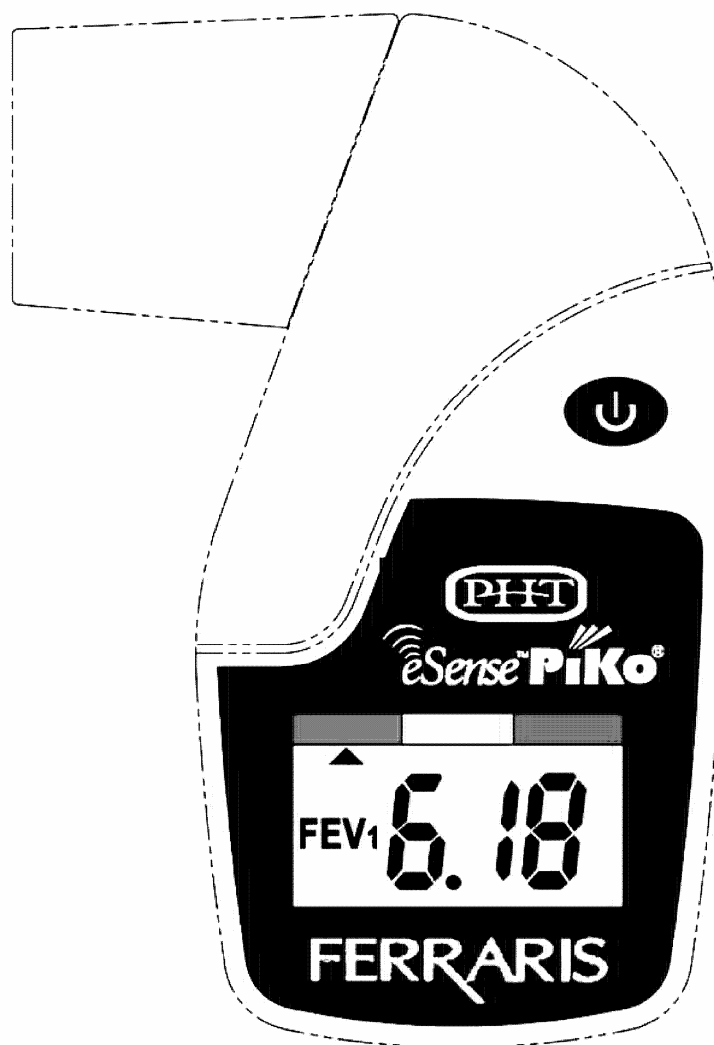# USER'S MANUAL

eSense™ PiKo®

Ferraris Respiratory, Inc.

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eSense^{TM} Piko®
User's Manual

<u>Intended Use</u>

The **eSense^{TM} Piko®** is used for monitoring respiratory conditions such as COPD and Asthma.

The **eSense^{TM} Piko®** measures the Peak Expiratory Flow (PEF) and the Forced
Expiratory Volume in the first second of expiration (FEV1).

It displays the test results and also shows the respective color-zone relative to the patient's PEF or FEV1 reference values.

In addition, the blow quality is evaluated to notify the patient to repeat the test in case of a cough or any suspect blow.

PEF - the fastest speed a person can blow air out of their lungs.
FEV1 - the amount of air blown out in the first second of a forced exhalation.
Color Zones - display the test results in a "traffic light" color format relative to the patient's reference PEF or FEV1.
Q Factor - Quality Factor notifies the patient to repeat the test in case of a cough or any suspect blow.
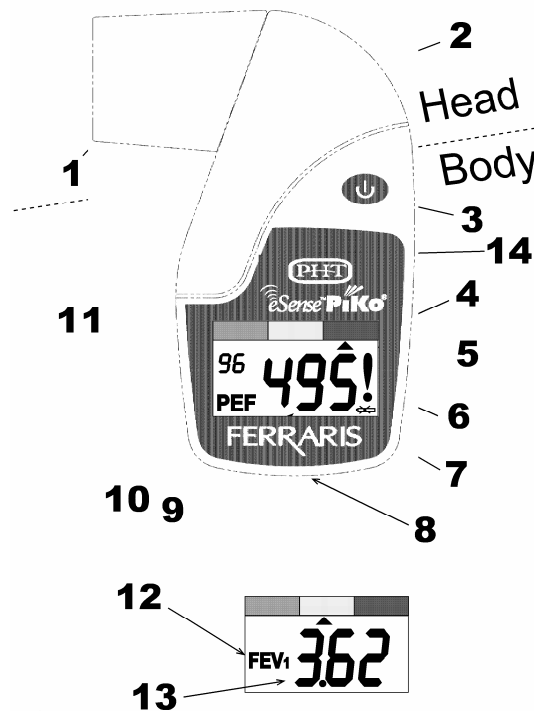
⚠ <u>Warnings</u>

Note: Please read all the information in this manual before using the **eSense^{TM} Piko®.**

- The user should be under the care of a licensed healthcare professional. Healthcare professionals may recommend the **eSense^{TM} Piko®** as part of a disease management treatment plan.

- Regardless of displayed test results, if signs or symptoms of chest tightness, shodness of breath, coughing or wheezing occur, contact your healthcare professional immediately.

- The **eSense^{TM} Piko®** is intended for use by a single person. Follow instructions carefully to get a correct reading.

- If you use the **eSense^{TM} Piko®** above 1,000 feet elevation (300m), adjust your values by adding 1.5%. To do this, multiply the PEF & FEV1 by 1.015.

- The **eSense^{TM} Piko®** is not designed or intended to be used as a primary diagnostic tool for asthma, COPD, or any other pulmonary disease.
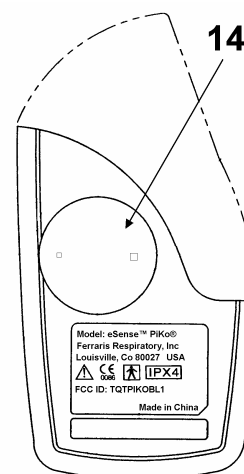
eSense^{TM} Piko® Description

1. Removable Mouthpiece
2. Vent holes
3. Operate Button
4. Colored Zones
5. Zone indicator
6. Q-Factor indicator
7. Low battery indicator
8. IR Communication window
9. PEF data, (Liter per minute)
10. PEF indicator
11. Memory counter
12. FEV1 indicator
13. FEV1 data, (Liters)
14. Battery cover, (behind)

Front View

Note: The PEF data, items 9 & 10, and the FEV1 data, items 12 & 13, alternate at 2 second intervals.

Note: The display turns blank if the operate button is not pressed for 3 minutes. Upon pressing once the operate button, the display will show the last test results.

Back View

Perform Test

If the display is blank, press the operate button once. The display will show the last test results.

1. **Stand** up. **Hold** the **eSense^{TM} Piko®** in your hand. **Do not** cover the vent holes.

2. Bring the **eSense^{TM} Piko®** up with the mouthpiece towards your mouth.

3. Press the operate button. A short beep will confirm the action.

4. Wait to hear the second beep. The blow animation will indicate that the test can begin.
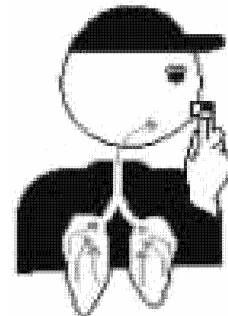
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5. Inhale as fully as you can.
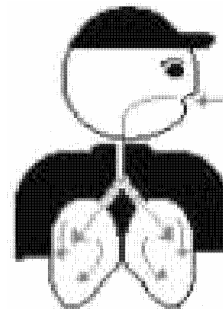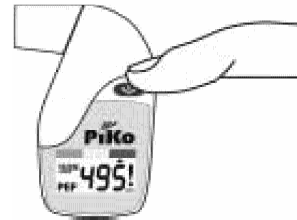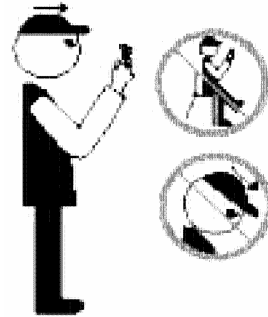
6. Place the mouthpiece in your mouth and blow as hard as you can for several seconds.

7. Your test results are displayed as soon as you complete the test.

8. If a reference value was set, a zone indicator will show your color zone.

9. You may want to perform 3 Tests.

10. The **eSense^{TM} Piko®** will select and save only the best results for any tests performed within 3 minutes.

<u>Setting Reference Values</u>

Setting a Reference PEF or FEV1 for color-zone display:

1. Press the Operate button quickly 4 times during 2 seconds. The PEF or FEV1 indication starts blinking. The display will show the stored reference value, (000 for first time setting).

2. Release the button, then each press will advance the display by 10 LPM for PEF, or 0.10 Liter for FEV1.

3. Hold the button for more than 5 seconds to save the desired reference value. The PEF or FEV1 indicator will stop blinking and a beep will sound.

4. The display will show briefly the new reference value and return to show the last test results.

Notes:

- During the reference setting process, if the button is not pressed within 5 seconds, the unit will exit the Setting Mode without modifying the old reference. The display will return to the last test results.

- The color-zone and relative warning indicator in the memory review mode will reflect the new reference value.

- The entire memory bank can be erased by setting the PEF reference to 10, or the FEV1 reference to 0.10.

- The optional accessory software can be used to toggle between displaying the color-zone relative to the PEF or FEV1 reference.

- The optional accessory software can be used to modify each color-zone limits, in 10% increments.

Memory Review

The **eSense^{TM} Piko®** memory bank can store the last 96 PEF & FEV1 tests. Each memory location contains also the warning indicators and a time/date stamp of the test.
To scroll through the memory bank, follow these steps:

1. Press and hold the Operate button for 5 seconds. The display will show the last test results containing the PEF, FEV1, color-zone and warning indicator.
    It will also show the respective memory counter location.

2. Release the button. Each press of the button will now display the next oldest stored test.

3. There are 2 ways to exit the Memory Review Mode:
    • Press and hold down the Operate button for 5 seconds
    • Avoid pressing the Operate button for 20 seconds.
    The unit will then display the latest test result and will be ready for a new test.

Note:The entire memory bank can be erased by setting the PEF reference to 010, or the FEV1 reference to 0.10

Note:The time/date stamp of each test is accessible by the optional accessory software for displaying trends and other information. It is not displayed in the Memory Review Mode.

<u>Additional Information</u>

A reference PEF or FEV1 value is usually the best result you achieve when you are not having symptoms.

Reference PEF or FEV1
To turn ON the color-zone indicator, you or a healthcare professional must set a reference value (see page 6).
The following are color-zone descriptions:

G   Y   R

Default Settings:
G   Green = test results **over 80%** of the set value
Y   Yellow = test results **between 50 - 80**% of the set value
R   Red = test results **under 50%** of the set value

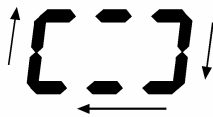⚠ **Note**: If your test result falls in the Red Zone, contact your healthcare professional immediately.

Q Factor Indicator
Indicates to repeat the test since one or more of the following occurred:
- A cough was detected.
- The blow effort was too short.
- The blow effort had a slow start.
- The result was unnaturally low or high for your reference.

Downloading Data

The memory bank can be downloaded to a PC using an IR Cradle and the PiKoNet software. The following is a description of the steps involved:

1. To start downloading, press the Operate button. The downloading progress is indicated by the cycling segments on the display.

2. Upon completion of the downloading, the memory bank is cleared and the display turns to show the latest test results.

3. The PiKoNet software shows trends and other relevant information, (refer to the Manual of the optional program).

Note: It is possible to interrupt the downloading process at any time by removing the **eSense^{TM} Piko®** from the IR cradle.

The memory bank can also be downloaded to a LogPad (Palm PDA) via Personal Area Network using the built-in transceiver. Please see LogPad manual for instructions downloading **eSense^{TM} Piko®** data.

Sound Patterns

- Pressing Operate Button: Short beep
- Error During Initialization: Long beep
- Blow Command: Short beep
- Result within Green Zone: No beep
- Result within Yellow Zone: 2 short beep
- Result within Red Zone: Long beep
- Any result containing (!):   Long beep

Maintenance

Note: This product is **NOT** user serviceable.

Cleaning:
   Note: Do not submerge the **eSense^{TM} Piko®** in water.

1.   Detach the mouthpiece by sliding it sideways.

2.   Wash the mouthpiece with a liquid dish soap in cold water, rinse and dry thoroughly. **DO NOT** use heat to dry.

3.   The **eSense^{TM} Piko®** can be cleaned as follows:
   • Rinse with low-flow pressure water at room temperature.
   • Only the Head Section may be cleaned with a solution of 5% liquid dish soap in cold water, followed by rinsing.
   • Hold the unit upside down and shake to remove the water.
   • Wipe exterior with a clean, dry towel.
   • Air dry completely before further use or storage.

4.   To avoid damage to the unit:
   • **DO NOT immerse in water or use a dishwasher.**
   • **DO NOT use a high pressure water flow.**
   • **DO NOT use any sort of active solvent for cleaning.**
   • **DO NOT dry by heat, hair dryer, or a dishwasher.**
   • **DO NOT insert anything into the Vent Holes or the Mouthpiece opening.**

Battery Replacement:
1.   Replace batteries when "Low Battery" indicator appears.
2.   Open the battery door using the special tool supplied with the **eSense^{TM} Piko®**.
3.   Use TWO, type 357 Silver Oxide button cell batteries, or equivalent.

Technical Specifications

PEF	Range 15 - 999 LPM, (1 LPM resolution)
FEV1	Range 0.15 - 9.99 Liter, (0.01 Liter resolution)
Accuracy	PEF: +/-5% or 10 LPM, (whichever is greater) FEV1 : +/-3~5% or 0.05 Liter, (whichever is greater)
Sensor	Pressure/flow sensor technology (US Patent 6,447,459)
Memory	96 Tests containing: PEF, , Color Zone, Quality Factor, Time/Date Stamp (15 mm. resolution)
Memory type	Nonvolatile
Color Zones	3 color Zones, (Green, Yellow, Red)
Reference values	User settable for PEF or FEV1
Quality Factor	Warning & indicator for cough or abnormal blow
Sounds	4 patterns for different indications and warnings
Communication	Bi-Directional IR port, (RS232 format) RF via proprietary protocol
External settings	Possible settings using the optional software: - Each Color Zone limits, (in I 0% increments) - Select Coior Zones to relate to PEF or FEV1
Battery	2, type 357 Silver Oxide button cells, (or equivalent)
Battery life	0.5 year (based on average of 3 Tests/day), or approximately 5,400 consecutive Blows.
Dimensions	75 X 35 X 20 mm, (3 X 1.3 X 0.8 inch)
Weight	35 gm, (1 .25 oz)
Back pressure	1.5 cm H_2O/LPS @ 14 LPS or lower
Operating Temp.	10 to 38 ℃, 50 to 100 ℉
Storage Temp.	-20 to 60 ℃, -4 to 140 ℉
Humidity	0 - 100% relative humidity
Barometric	550 to 780 mmHg
Standard	ATS1994, (monitoring devices)
Compliance	AS/NZS-4237: I 994 EN60601, EN60601-1-1, EN60601-1-2
Regulatory	FDA - 510(k) for OTC CE (0086) - Class I, with measurement function FCC Part 15

Warranty

Ferraris Respiratory, Inc.(FRI) warrants each hardware product it manufactures to be free from defects in material and workmanship. Under this warranty, FRI will repair or replace at its option, any hardware product or part thereof within 6 months of purchase. Examination of the product must disclose to FRI that the product is defective This warranty does not apply to any product or part that has been repaired or altered in any way that, in FRI's judgment, affects its durability or reliability or any product or part subjected to misuse, negligence or accident. THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES OF MERCHANTABILITY AND FITNESS. A copy of the receipt must accompany a warranty claim. If the product should become defective within the warranty period, return to FRI at 901 Front Street, Louisville CO 80027 USA.

Safety

AS/NZS-4237:1994
EN60601
EN60601-1-1
EN60601-1-2

Type BF patient applied part.
Ordinary equipment (not protected against harmful ingress of moisture).
Not suitable for use with flammable anesthetics.
Suitable for continuous operation.

This symbol indicates that the user must read and understand all instructions and warnings.

This symbol indicates that this Class I equipment with measurement function complies with the European Union Medical Device Directive.

This symbol indicates that this device provides a certain level of protection against electrical shock.

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