SECTION 12

SUMMARY OF SAFETY AND EFFECTIVENESS

K963550

NOV - 1 1996

RESPIRONICS INC.®
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October 21, 1996

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Classification Name	21 CFR 874.5550, 77 ETP
Common/Usual Name	Powered Nasal Irrigator
Proprietary Name	RinoFlow Micronized E.N.T. Wash System
Predicate Devices	Puls-ator Irrigator Lavage - K821481 Ethicare P.O. Box 5027 Fort Lauderdale, FL 33310

Reason for Submission

The RinoFlow Micronized E.N.T. Wash System is a new device.

Substantial Equivalence

This premarket notification section 510(k) submission demonstrates that the RinoFlow Micronized E.N.T. Wash System is substantially equivalent to the Ethicare Puls-ator Irrigator Lavage (K821481), which is used to irrigate the nasal and sinus passages and humidify the upper respiratory tract.

Testing was performed to demonstrate that the performance of the RinoFlow Micronized E.N.T. Wash System in its intended environment is as safe and effective as that of the legally marketed predicate device. The safety and effectiveness of the RinoFlow Micronized E.N.T. Wash System were verified through performance-related testing that consisted of Electrical Safety, Electromagnetic Compatibility, Mechanical and Environmental Testing. The RinoFlow Micronized E.N.T. Wash System was tested and found compliant with the standards referenced in the "Draft FDA Reviewer Guidance for Premarket Notifications," November 1993.

General Technical Description

Intended Use/Indications for Use

RinoFlow Micronized E.N.T. Wash System aerosolizes solutions intended for nasal and sinus irrigation and humidification of the upper respiratory tract. RinoFlow is used to treat conditions and disorders of the upper respiratory tract where homeostasis of the nasal mucosa is disturbed, resulting in symptoms such as catarrh, and mucopurulent or crusty secretions. Such conditions and disorders include:

- Rhinitis
- Both Acute and Chronic Sinusitis

RinoFlow Micronized E.N.T. Wash System should be used with a physiological saline solution. "Tap" water is not recommended.

Contraindications

The following pre-existing conditions contraindicate the use of the RinoFlow System:

- Operations to the tympanum (eardrum), including plastic operations on the tympanum
- Other pathologies of the tympanic area
- Injuries or recent surgery that may have fractured or disturbed the cribriform plate

Patient Population

Adults and pediatrics (age ≥3).

Environment of Use

Hospital, clinic, physician's office, or home by prescription.

Manufacturer

The RinoFlow Micronized E.N.T. Wash System is manufactured by Mefar (Italy) and distributed in the United States by Respironics, Inc.

Summary of the Device Description

The RinoFlow Micronized E.N.T. Wash System (Figure 12-1) provides aerosol irrigation with positive pressure. The device has two settings that facilitate a two-phase procedure for nasal irrigation and upper respiratory tract humidification. Phase One washes the nasal cavity and nasopharynx by hydrating and softening the mucus with a stream of large-particle aerosol, causing drainage to occur. Phase Two applies the aerosol stream with higher velocity that reaches the paranasal sinuses.

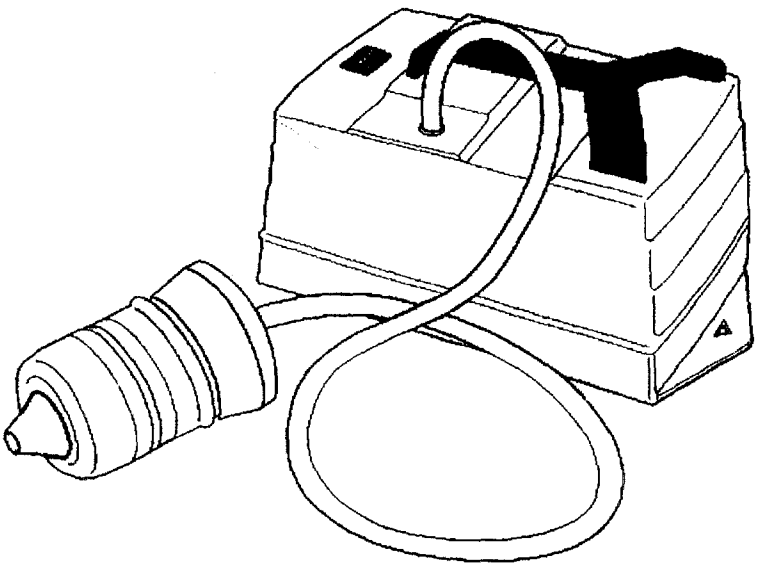

Figure 12-1. The RinoFlow Micronized E.N.T. Wash System

Technical Description

The RinoFlow E.N.T. Wash System consists of a Micronizer-Chamber connected by a length of tubing to a lubricant-free, sealed piston compressor. The compressor incorporates a reciprocating power pump design. Internal functions of the RinoFlow are diagrammed in Figure 12-2.

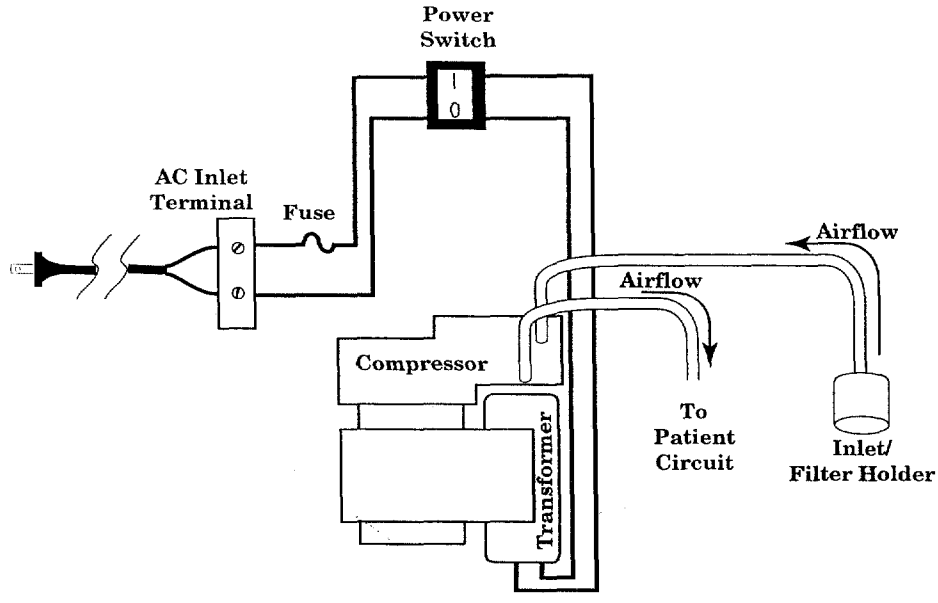

Figure 12-2. Schematic Drawing of Internal Functions

The Micronizer-Chamber (Figure 12-3), made of synthetic, washable polycarbonate material, is in four essential parts: the body, the inner shell, the outer shell, and the baffle. Tubing is connected at the bottom of the body. At the top of the body is an air injector covered by a baffle. The bell-shaped inner shell surrounds the air injector and baffle and tapers to an outlet at the top for the aerosol stream to exit. The rim at the bottom of the shell fits in a groove at the top of the body. The space inside the inner shell forms the inner chamber, where the liquid is micronized. The outer shell fits over the body, surrounding the inner shell and its contents. The outer shell is cylindrical and tapers to an outlet at the top. The outer shell can be rotated to two different positions, gliding vertically over the body. In the first position, the outer shell's outlet is vertically aligned slightly above that of the inner shell. The space between the outer shell and the inner shell forms the outer chamber, where the drainage is collected. This chamber is sealed at the bottom by an O-ring. The space between the very tops of the inner and outer shells forms an opening for the drainage to descend into the outer chamber during Phase 1. Four holes around the rim at the top of the outer shell provide the primary means for excess nasal drainage to enter the outer chamber. These holes also provide an outlet for patient exhalation.

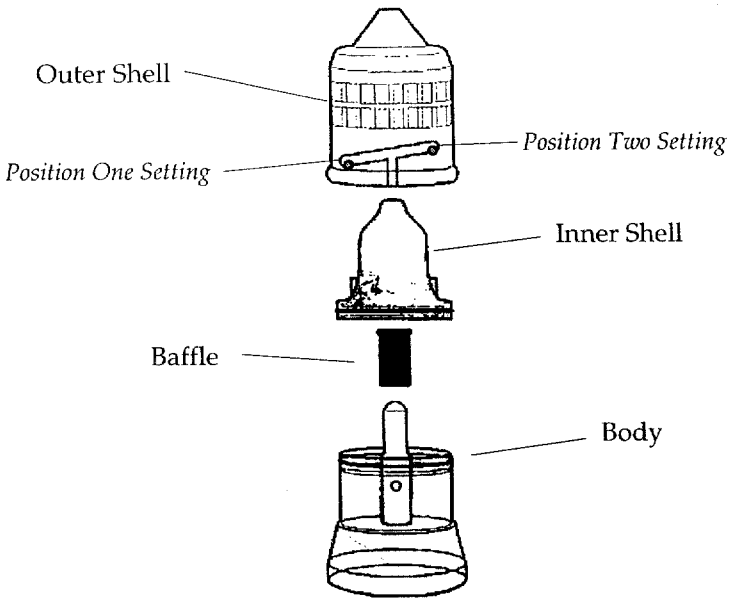

Figure 12-3. Exploded View of Micronizer-Chamber

When rotated to the second position, the outer shell lowers so its outlet meets that of the inner shell, joining the holes to create a single outlet. This configuration increases the velocity of the aerosol stream. The outer chamber is unaffected by this change in shell configuration, and any residual drainage will continue to enter the chamber via the four holes along its rim.

Principles of Operation

The Micronizer-Chamber is set for irrigation of the nasal cavity by rotating the outer shell to the first setting as indicated. Liquid is placed into the inner chamber of the Micronizer-Chamber. The outlet of the outer shell is placed in the opening of one nostril and held in that position. When the power button is pressed on, the compressor pressurizes the liquid via the air injector, creating a large-particle aerosol stream that is delivered through the outlet into the nasal cavity and nasopharynx. The irrigation of the mucous membranes softens and thins the mucus, facilitating its drainage. The drainage enters the space between the very tops of the inner and outer shells and descends into the outer chamber. Any drainage that does not enter the opening between the inner and outer shells is guided into the rim at the top of the outer shell. From there, the drainage descends through the four rim holes into the outer chamber. Because of the delivery pressure of the micronized wash solution, the nasal drainage cannot

enter the inner chamber and mix with the washing fluid (Figure 12-4). The pressure generated by the patient's exhalation is released through the four holes on the outer shell. The procedure is repeated with the other nostril.

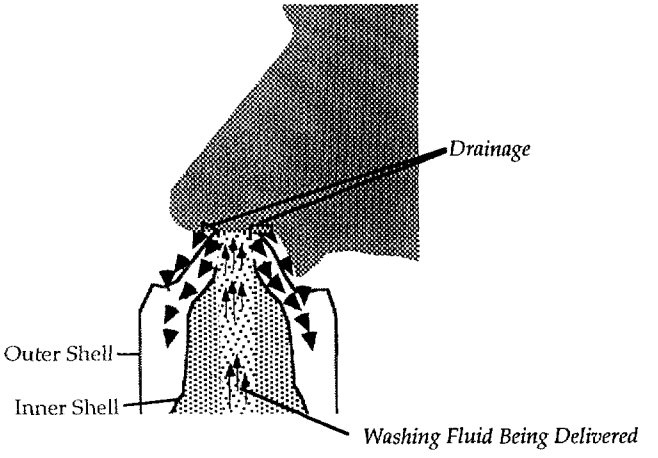

Figure 12-4. Nasal Drainage Enters Outer Chamber Only

Once the wash is complete and the Micronizer-Chamber has been rinsed, the Micronizer-Chamber can be set for irrigation of the paranasal sinuses by rotating the outer shell to the second setting as indicated. This setting increases the velocity of the aerosol stream to reach the paranasal sinuses. The outlet of the outer shell is placed lightly against the opening of one nostril and held in that position. During treatment, the patient closes the contralateral nostril and periodically swallows and holds his or her breath for a brief period. This process is akin to Politzer's method, which can cause inflation of the Eustachian tube and middle ear. Any drainage that leaks from the nostril will continue to enter the chamber via the four holes along its rim. The pressure generated by the patient's exhalation is released through the four holes on the outer shell. The procedure is repeated with the other nostril.