

Research Article**A New Spacer Device with Best Quality for
Asthma and COPD (RESPIPARD)****Mehdi Ghahramanifar^{1,2,3,4}, Hossein Marioryad⁵,****Ali Ghadimi Moghadam⁶ and Abdolkarim Ghadimi Moghadam^{1,3,4,7,*}**¹Asian Electro Medical Company (Knowledge Base Company), Yasuj, Iran.²Faculty of Medicine, Yasuj University of Medical Sciences, Yasuj, Iran.³Medicinal Plants Research Center, Yasuj University of Medical Sciences, Yasuj, Iran.⁴Cellular and Molecular Research Center, Yasuj University of Medical Sciences, Yasuj, Iran.⁵Social Determinants of Health Research Center.

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INTRODUCTION

The Knowledge-Based Products is one of the criteria that is considered in the process of evaluation and identification of knowledgeable companies. Therefore, a list of examples of services and Knowledge-Based Products is provided for this purpose. But during the appraisal and qualification process of companies there may be commodity and services that are not mentioned in the "List of commodity / services of knowledgeable". Qualifying companies can choose and maintain a process called "Other Proposed Products in the Product Information and Services" category in order to be completed after careful examination of the products that they do not have.

Applicants are strongly advised to carefully review the "Catalog of Products / Services" and list their product on this list and may also refrain from choosing the "other proposed products" route, as this process requires an accurate assessment and expertise. It is therefore time consuming and prolongs the process of evaluating companies.

Examples of the most similar systems:

1. Damyar (Iranian company)

2. Damsaz (Iranian company)

3. Zerostat VT (Cipla Company)

In order to produce this product in the research and development phase, there were several studies, experiments and studies:

- Beta 2 agonists and corticosteroids are the first line treatment for asthma and COPD in children and adults (1).

Corticosteroids are a potent anti-inflammatory drug that reduces excessive respiratory bronchus, improves lung function, and reduces asthma symptoms and drug use in patients (1, 4). Spacer devices were developed to use pressure sprays using pressure spray metering-dose inhalers, and to increase efficacy and prevent spray losses and thereby improve efficacy in Patients and their problems in the use of sprays are made. In addition, spacers keep large particles of the drug, which are usually accumulated at the beginning of the oropharynx, thereby reducing the side effects of corticosteroid drugs, such as oral and pharyngeal (5 and 6). Also, the rate of systemic absorption reduces some of the corticosteroids (6,7). The Global Initiative for Asthma, "GINA"

recommends that patients of all ages who use moderate to high corticosteroid inhalers should use a spacer device (1). In recent discussions, ADMIT (Aerosol Drug Management Improvement Team) is considered to be an asthma management that the use of sprays is essential. The patient's ability to survive the best response and control of asthma and the effort to raise awareness of the proper use of tools for successful treatment is critical (8, 13).

In a study done by Giraud et al. In 2002, 21 studies were observed and found that among those who received inappropriate sprays, the inappropriate spray technique had a share of 14-90% (with an average of 50%) among these patients (14). As well as in asthmatic patients, improper use of spray with instability and non-control of asthma has been associated. In a 2003 study by Lee Young et al., Only 5% of medical interns were able to correctly use sprays that were substantially increased with one-to-one training session essentially using the correct spray between them (15). In a 2003 study by Guevara et al. In a systematic education program for self-management of asthma in children and adolescents, education along with improved lung function, reduced absenteeism in school, reduced number of days with less activity and less visitation At Emergency Centers (16). A study by Thomas et al. in 2009 also suggested that changing the type of spray in patients can reduce control and require training in the technique of their use, and if not accompanied by training, it causes confusion and loss of use for spray (17). In the study of Price and colleagues in 2012, it was found that the mistakes of using spray and spacers, the difficulties and difficulties of using the spacers and the inefficiency of some of the spacers are the most common mistakes in the use of sprays

and the uncontrolledness of the disease of individuals. (18). Oral sprays are considered as one of the medical therapies in the medical field and are used in emergency and non-emergency situations. The therapeutic effects of respiratory sprays used in patients due to inappropriate use (especially children and elderly patients), as well as the adhesion of powder to the oral mucosa, are significantly reduced. On the other hand, the sprayers used in the market have problems such as low volume of the compartment (the powder is lost in the system) and the inability to separate the tail flow from exhalation and thereby reduce the spray efficiency. The use of these spacers, despite the training of the patient due to educational problems in the elderly and children, continues to be due to the aforementioned problems by reducing the efficacy of respiratory sprays. Inappropriate use in addition to reducing the efficacy can be associated with complications such as the potential for oral fungal infections and other digestive problems. The existence of a system that can simplify the use of respiratory sprays by increasing the efficacy and cost-effective and cost-effective can actually be a step toward improving the treatment with respiratory sprays.

Initially, the Spacers used in the country were tested as shown below. These Spacers do not have the ability to separate the flow of the exhaust pipe, and most importantly, they do not even have a spray Puffy (as shown below - Figure A with a cap and B picture without a cap). However, in most medical editions, two puffs are prescribed for spraying each time. On the other hand, the caps of these Spacers are not attached to the Spacer themselves, and the loss of the cover increases the likelihood of Spacer contamination.



Figure A

To solve all the problems presented to improve the efficiency of respiratory sprays, an electronic system was designed and manufactured by Asia



Figure B

Electroteb Company that by spraying the patient's tail, the patient's tail was synchronized with puff spray. The system lost its efficacy in

some cases, such as short tail or tail cramps. On the other hand, due to high prices and the need for charging, it could not actually be a good market. After several testing steps, the company succeeded in designing a fully mechanical system that solved all problems associated with the use of respiratory sprays and defects in the previous system.

Approvals and tests performed:

- Perform frequent tests for system efficiency and review the quality and performance of the system and compare it with the best available market examples
 - Obtaining approval from the University of Medical Sciences
 - Registration in the Office of Industrial Property
1. This product consists of the following components and sub-systems (parts):
 - a) Partitioned plastic enclosure
 - b) Three one-way valves
 - c) Spray Spacer
 - d) Oral Spacer and separate mask (for use in infants and children)
 - e) Connecting the lid to the system (to avoid Spacer contamination)

The three-valve respipard has a compartment of suitable volume for spray accumulation and an enclosure for exhaust-flow. With this mechanism, the patient can enter the compartment by pushing the spray, and when the tail is inserted, the drug enters the lungs, and when exhaling, the expiratory flow is removed from an outlet from the first chamber. These two valves always flow through the air in the opposite direction, thus preventing the flow of tail flow from exhalation. In addition, another valve is used to replace the air sucked out by air, which prevents the drug from leaving the compartment (at each stage of respiration). This system, with its proper volume for the drug, improves the flow of air to one side, increases the efficacy of the spray to over 300% of normal. The use of the three-valve respipard is such that the patient first attaches the spray through the sprayer, attaches to the respipard, and the mouth spacer (In children and infants, respipard mask attaches to mouth spacer) is inserted into the mouth. Then, spraying and pushing the drug into the lungs after taking the

medication. It should be noted that the time of spraying is independent of the duration of the operation, and therefore prevents spray efficacy in patients, especially children and the elderly. On the other hand, the use of antibacterial plastics in the production sample is another feature of the system. The lid of the system is attached to the system itself, preventing the loss of the cap and the increased likelihood of a spacer. The three-valve respipard eliminates the need for patient training (with regard to the moment of use of spray during tail) by means of a one-way flow of air (fully mechanized and without using electronic circuits). In addition, the air flow is one-way. Along with the proper compartment volume; the spray powder is prevented from wasting. On the other hand, the antibacterial properties of plastics used in the manufacture of respipard prevent recurrence of diseases, such as COPD, from the remobilization of microbial agents after treatment of lung infection. The actual sample of this product was made and tested in a practical way on the patient. Construction of this sample from a prototype to an industrial sample took about six months. The cost of designing and manufacturing various samples (from pilot to industrial samples) was about 2500 Dollars (design, construction and purchase of 3D printers and laser devices, and practical tests). The price of the industrial sample of this product will be between 1 to 2 Dollars depending on the materials used. Production of the first industrial prototype of the product by the main members and contractor of the company in the fields of medicine, mechanics and industrial designer, and by faculty members of specialized and internal specialized departments, cardiology, pediatrics, anesthesia, women, neurology and infectious diseases. The opinion of the university presidency (a total of 16 people) has been approved. According to the application of the product (the delivery of the maximum possible amount of the drug to the lung) and that respipard has the highest efficiency with mechanical separation of the tail flow from the exhalation, than the rest of the products, the research of the Asia Electroteb Company continues to produce better performance

products, especially in Children under the age of two will work.

Due to the high price of foreign samples, the samples are not sold in the country. Visiting the AsiaElectroteb Company at the annual Asthma and Allergy Exhibition (2016), the external specimen of this product (Zerostat VT) from Cipla Company was reviewed. The strengths of this product are not the capacity of a Puff Spray (the current internal specimen does not contain a puff) and the use of high quality materials. The weaknesses of this product were the lack of concurrent two puffs and having only one valve. On the other hand, the price of this product was 10Dollars, which is four times the price of a four-way respipard. On the other hand, respipard with three valves regulates the flow of drug to the lung with the highest efficacy and prevents drug loss.

The manufactured plastics are of the type intended for respipard are of the medical bayer type, which also have anti-bacterial properties. The most common cause of COPD attacks is bacterial infections. On the other hand, these patients, like asthmatic patients, permanently use bronchodilator sprays and corticosteroids. The antibacterial properties of plastics used in the manufacture of respipard prevent recurrence of diseases such as COPD and prevent the remobilization of microbial agents after treatment of lung infection. The cover of this system is also unlike the external system attached to the system, thereby preventing the loss of the cap and the increased likelihood of a spacer.



Zerostat VT

Innovations have been about increasing the volume to a puff and the use of high-quality plastic. But the number of valves and the mechanism of drug guidance to the lung have not changed. Because of the fear and cry of

patients under the age of two when using respipard or other spacers, the company intends to solve this problem in the future by using the following.

- 1) Use the pacifier inside the mask
- 2) The use of animated puppets on the respipard for the attention of the child
- 3) Use an outlet for connecting the mask and respipard (to prevent the child from seeing the system)

Asia Electroteb Company (Knowledge Base) with the registration number 7786 and the national ID 14005519501 to the Director of Mehdi Ghahramanifar National Number 1640089306

Reg No: 93186 International
Classification: B05B 15/00 A61L 9/00



Impressions of the Respire

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