

Review of Two Vibrated Respiratory Devices

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Overview Reports

<http://www.regence.com/trgmedpol/dme/dme62.html> 13:10 19-0406

Description

Pulmonary complications are major causes of morbidity and mortality for patients with compromised airway clearance mechanisms. Conditions such as high spinal cord injuries, neuro-muscular deficits, or severe fatigue associated with intrinsic lung disease can diminish the effectiveness of a cough, or eliminate the ability to cough altogether. Other conditions such as cystic fibrosis, bronchiectasis, and pneumonia can affect the ability of the lungs to manage secretions and influence the viscosity and amount of sputum produced. Several adjunctive techniques and devices have been used to assist those who are otherwise unable to clear pulmonary secretions effectively. (2)

Passive interventions include nebulized bronchodilating medication, postural drainage combined with chest percussion and/or vibration (P/PD or PDPV), and possibly diaphragmatic (or "quad") coughing maneuvers. Active interventions consist of autogenic drainage or breathing and coughing techniques such as forced expiratory technique ("huff" coughing), active cycle breathing (deep breathing or breath stacking), and pursed lip breathing (creates positive expiratory pressure.) Usually, several of these mechanisms are utilized in an effective pulmonary toilet program. (3)

Several devices exist that are proposed as an adjunct or alternative to one or more of the mechanisms described above.

The FLUTTER® mucous clearance device and Acapella™ device are small handheld devices that provide positive expiratory pressure (PEP.) Exhaling through the device creates oscillations, or "flutter" in pressures in the airway resulting in loosening of mucous. Other PEP devices are used with a small volume nebulizer, and function in conjunction with medication delivery.

Mechanical Insufflator-Exsufflator (CoughAssist) is a portable electric device which utilizes a blower and a valve to alternately apply a positive and then a negative pressure to a patient's airway in order to assist the patient in clearing retained bronchopulmonary secretions. Air is delivered to and from the patient via a breathing circuit incorporating a flexible tube, a bacterial filter and either a facemask, a mouthpiece, or an adapter to a tracheostomy or endotracheal tube.

Intrapulmonary Percussive Ventilator (IPV) is a type of mechanized chest physical therapy. Instead of a caretaker clapping or cupping the patient's chest wall, the IPV device delivers high-flow jets of air to the airways by a pneumatic flow interrupter at a rate of 100-300 cycles/minute

via a mouthpiece. The patient controls variables such as inspiratory time, peak pressure, and delivery rates.

Intermittent positive pressure breathing (IPPB) devices use pressure to passively fill the lungs when a breath is initiated. An incorporated manometer and mechanical valves serve to terminate the flow of inspired air when a predetermined pressure is reached on inhalation. IPPB breathing circuits are designed to nebulize inhaled medication. Most IPPB devices are powered by compressed air and are not suitable for home use.

Mechanical percussors are typically electrical devices used in lieu of a caretaker's hands for chest percussion and/or vibration.

Note: The ABI Vest, formerly known as the ThAIRapy Vest is addressed in a separate medical policy: High Frequency Chest Compression Systems for the Treatment of Cystic Fibrosis and Other Respiratory Disorders (DME Policy No. 45)

Policy/Criteria

Small hand-held positive expiratory pressure devices, such as the FLUTTER® or Acapella™ devices, may be considered medically necessary as an adjunct to airway clearance in patients who can demonstrate effective use of the device and when other mechanisms have proven inadequate or ineffective in mobilizing pulmonary secretions.

Mechanical percussors may be considered medically necessary when the patient or operator of the powered percussor has received appropriate training by a physician or therapist.

An Insufflator-Exsufflator device, such as the CoughAssist, may be considered medically necessary in a small subset of patients with neuromuscular disease resulting in an inability to adequately clear their airways using standard airway clearance mechanisms (as noted in the description above). There should be evidence of significantly low forced expiratory flow and vital capacity not associated with obstructive disease.

Intrapulmonary percussive ventilators (i.e., Percussionaire and Percussive Tech HF devices) and Intermittent Positive Pressure Breathing (IPPB) devices are considered investigational for home use.

Scientific Background

The published literature included a number of small, randomized studies that compared different mucus clearance techniques, typically in crossover studies. (4,5) Pulmonary function and weight of expectorated sputum are typically analyzed immediately after treatment. (6) Thus these small short-term studies focus on intermediate outcomes, and do not include any data regarding long-term stabilization or improvement of lung function or a decrease in pulmonary exacerbations resulting in hospitalization. The reliability and validity of sputum weight as a proxy for health outcome is still unresolved.

The sparse data that are available do not suggest that any one alternative, including the various oscillatory devices, autogenic drainage, or positive expiratory pressure, is superior to another. The Flutter device, autogenic drainage and positive expiratory pressure are simple devices or maneuvers that can be learned by most patients.

Mechanical Insufflation-Exsufflation as an Expiratory Muscle Aid

The published data suggest that mechanical insufflation-exsufflation (MI-E) can improve the intermediate outcome of peak cough expiratory flow. Data regarding its role in the clinical management of the patient consist of case series (7-13). In some studies, patients have served as their own control, with a decreased incidence of hospitalization among patients who switch from tracheostomy to a noninvasive approach, which may include MI-E as one component. While controlled trials would ideally further delineate who is most likely to benefit from MI-E, particularly those who would benefit from having a device in the home, such trials are logistically difficult. The heterogeneous nature of the patients, even among those with similar diseases, almost mandates a case by case approach for these patients. For example, the clinical utility of MI-E would not only depend on the physiologic parameters of lung function, but also on the

tempo of the disease course, the availability of home caregivers, and patient preference and motivation. The non-investigational status for the MI-E device is based on these considerations.

Intrapulmonary Percussive Devices

The clinical data regarding the Percussionaire device are sparse. One early randomized trial of 16 cystic fibrosis patients reported no difference in spirometric measures or number of hospitalizations, suggesting that the Percussionaire device was equivalent to chest physical therapy. (4) Subsequent updated literature searches in 2005 and 2006 based on MEDLINE did not return any published clinical studies that alter the policy conclusions regarding intrapulmonary percussive ventilation devices. Toussaint and colleagues in a randomized, cross-over study compared assisted mucus clearance techniques with and without intrapulmonary percussive ventilation (IPV). (14) Eight patients received five consecutive days of treatment with IPV with nebulization and assisted-clearance techniques and five days without IPV. At the end of each sequence mucus production was weighed. The mean mucus production was significantly higher following the sequence with IPV ($p=0.01$). Marks and colleagues compared pulmonary function and sputum production following a single treatment with PercussiveTech HF IPV with changes following a standard chest physiotherapy treatment performed by a respiratory therapist. There were 10 patients with stable cystic fibrosis in this cross-over study. Pulmonary function parameters were not significantly different at four hours following either therapy. There was a slight trend toward more sputum production following the PercussiveTech HF IPV treatment; however, the difference was not statistically significant. (15) No other studies were found which address intrapulmonary percussive ventilator devices. The small number of patients and lack of long term outcomes do not allow conclusions concerning the effectiveness and clinical significance of IPV on the overall health outcomes of the patient. Therefore, the policy is unchanged.

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Cross References

High Frequency Chest Compression Systems for the Treatment of Cystic Fibrosis and Other Respiratory Disorders, TRG Medical Policy Manual, DME, Policy No. 45

Codes	Number	Description
HCPCS	E0480	Percussor, electric or pneumatic; home model
	E0481	Intrapulmonary percussive ventilation system and related accessories
	E0482	Cough stimulating device, alternating positive and negative pressure
	E0484	Oscillatory Positive expiratory pressure device, non-electric, any type, each
	E0500	IPPB machine, all types, with built-in nebulization; manual or automatic valves; internal or external power source

The Flutter Device

Manufactured by Scandipharm

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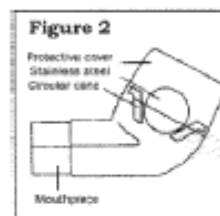
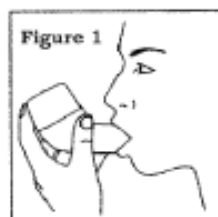
About Scandipharm

Axcan Scandipharm, Inc. is a Birmingham-based pharmaceutical company marketing gastrointestinal and related products for cystic fibrosis. Axcan Scandipharm Inc. is a subsidiary of Axcan Pharma Inc., a Canadian pharmaceutical company involved in the development and distribution of pharmaceutical products mainly in the field of gastroenterology. Axcan is one of the ten largest publicly traded healthcare companies in Canada and is listed on the Montreal and Toronto Stock Exchanges under the AXP symbol.

FLUTTER[®] Mucus Clearance Device

Product Description / Intended Use

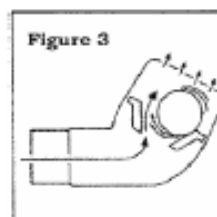
The FLUTTER[®] mucus clearance device is a small handheld device that provides positive expiratory pressure (PEP) therapy for patients who have chronic obstructive pulmonary disease (COPD) such as asthma, bronchitis, cystic fibrosis, atelectasis, or other conditions producing retained secretions. It is shaped like a pipe with a hardened plastic mouthpiece at one end, a plastic, protective, perforated cover at the other end, and a high-density stainless steel ball resting in a plastic circular cone on the inside (Figures 1 and 2).



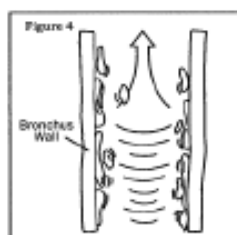
Principles of Operation

The principle of the FLUTTER[®] as a mucus clearance device is based on its ability to: vibrate the airways (which loosens mucus from the airway walls); intermittently increase endobronchial pressure (which helps maintain the patency of the airways during exhalation, so that mucus does not become trapped as it moves up the airways); accelerate expiratory airflow (which facilitates the upward movement of mucus through the airways so that it can be more easily cleared).

The FLUTTER[®] effect occurs during the expiratory phase of respiration. Before exhalation, the steel ball blocks the conical canal of the FLUTTER[®]. During exhalation, the actual position of the steel ball is the result of an equilibrium between the pressure of the exhaled air, the force of gravity on the ball, and the angle of the cone where the contact with the ball occurs. As the steel ball rolls and bounces up and down, it creates an opening and closing cycle which repeats itself many times throughout each exhalation (Figure 3).



The net result is that oscillations in expiratory pressure and airflow are produced. When the oscillation frequency approximates the resonance frequency of the pulmonary system, endobronchial pressure oscillations are amplified and result in vibrations of the airways. The vibrations produced by these oscillations cause the "fluttering" sensation from which the FLUTTER[®] derived its name. These vibrations loosen mucus from the airway walls. The intermittent increases in endobronchial pressure decrease the collapsibility of the airways during exhalation, increasing the likelihood of clearing mucus from the tracheobronchial tract. The airflow accelerations increase the velocity of the air being exhaled, facilitating the movement of mucus in the airways (Figure 4).



The FLUTTER[®] produces a range of oscillation frequencies between 6 and 20 Hz, which corresponds to the range of the pulmonary resonance frequencies in humans. Attaining oscillation frequencies in this range is fundamental to the efficacy of the FLUTTER[®]. The individual pulmonary resonance frequency of each patient is dependent on many factors, including lung volume, lung elasticity, and degree of airway obstruction. The frequency of oscillation that produces the best transmission of vibrations in a given patient corresponds to the pulmonary resonance frequency for that patient. When the resonance frequency of the pulmonary system is achieved, the pressure variations are amplified, maximizing the vibrations of the airway wall. These vibrations, coupled with increases in expiratory pressure and airflow, facilitate the clearance of mucus.

The oscillation frequency produced by the FLUTTER[®] when its stem is in the horizontal position is approximately 15 Hz. This frequency can be modulated by changing the inclination of the FLUTTER[®] slightly up (higher frequency) or down (lower frequency) from its original horizontal position. Adjusting the FLUTTER[®] to the resonance frequency is easily accomplished by the patient who selects the angle tilt that results in the best transmission of vibrations to his/her airways.

Clinical Study Results

Cystic fibrosis, bronchitis and bronchiectasis are characterized by abnormally thick mucus. Inhaled bacteria can become imbedded in these secretions, resulting in inflammation, which leads to destructive disease of the lungs.

The efficacy of the FLUTTER[®] in facilitating mucus clearance in cystic fibrosis has been reported. The average amount of sputum expectorated with the FLUTTER[®] was over three times the amount expectorated after conventional postural drainage with percussion and vibration. Every patient expectorated more mucus with the FLUTTER[®] than with conventional postural drainage.¹

Indications

The FLUTTER[®] provides positive expiratory pressure (PEP) therapy for patients who have chronic obstructive pulmonary disease (COPD) such as asthma, bronchitis, cystic fibrosis, atelectasis, or other conditions producing retained secretions.

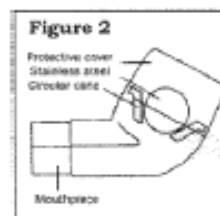
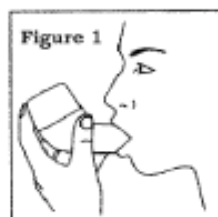
Contraindications

Patients with pneumothorax or overt right-sided heart failure.

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Product Description / Intended Use

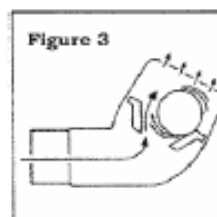
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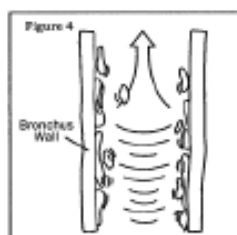
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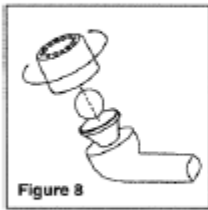
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Contraindications

Patients with pneumothorax or overt right-sided heart failure.

Cleaning the Flutter

The FLUTTER® is recommended for single patient use only. Instruct your patients to clean their FLUTTER® after each session to remove moisture and/or mucus (Figure 8). Disassemble and rinse all components with tap water; wipe with a clean towel, reassemble, and store in a clean, dry location. Every two days, patients should disassemble and clean their FLUTTER® in a solution of mild soap or detergent. Chlorine bleach or other chlorine-containing products (e.g., dishwashing detergent) should not be used. Rinse, dry, reassemble, and store. Also, at regular intervals, your patients should thoroughly disinfect their FLUTTER®. They can do this at home by disassembling and placing the already-cleaned components in a solution of 1 part alcohol to 3 parts tap water for 15 minutes. Again, rinse, wipe, reassemble, and store.



Note to Physicians and Healthcare Professionals

The FLUTTER® provides positive expiratory pressure (PEP) therapy for patients who have chronic obstructive pulmonary disease (COPD) such as asthma, bronchitis, cystic fibrosis, atelectasis, or other conditions producing retained secretions. PEP therapy, combined with forced expiratory technique (FET), or "huff" coughing, may be used for airway clearance, bronchial hygiene, or as an alternative to conventional chest physical therapy (CPT) and pursed lip breathing. PEP therapy will help prevent accumulation of secretions; improve mobilization of secretions; promote effective breathing patterns and improve gas exchange and distribution of ventilation; improve central and peripheral airway function; prevent or reverse atelectasis; and improve bronchodilation when used in combination with respiratory drug delivery via nebulizer or MDI spacer devices.

Reference:

1. Konstan MW, Stern RC, Doershuk CF. Efficacy of the FLUTTER® device for airway mucus clearance in patients with cystic fibrosis. J Pediatrics May 1994; 124:689-693.

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FLUTTER®)))))))
MUCUS CLEARANCE DEVICE

FLUTTER® is a secretion removal device for Hands-Free CPT that effectively and efficiently removes harmful secretions from the airways of patients with mucus producing respiratory conditions. FLUTTER® is indicated for the following conditions: atelectasis, bronchitis, bronchiectasis, cystic fibrosis, chronic obstructive pulmonary diseases (COPDs) such as asthma, and other conditions producing retained secretions.

FLUTTER® is the only mucus clearance device that provides:

- Positive Expiratory Pressure (PEP) - holds airways open
- Airway Oscillation - vibrates mucus from airway walls
- Intermittent Flow Acceleration - pushes mucus upward for expectoration

FLUTTER® is easy to use, fully portable, and very durable

The Acapella Device

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DHD Healthcare of Wampsville, N.Y., a maker of products for respiratory care, identified a large base of patients for whom a self-administered therapy would be effective, but in many cases was difficult because of their lack of mobility. Those patients needed a product they could administer, whether they were sitting, standing, or reclining. Such a product, in addition to increasing a patient's comfort, would greatly decrease the cost of treatment by shortening the time of therapy and reducing the need for assistance from therapists or other healthcare providers.

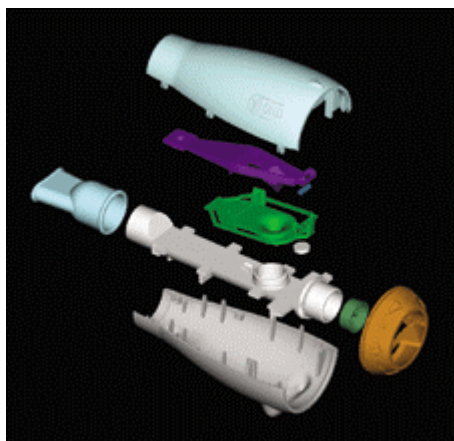
Individuals suffering from diseases such as chronic bronchitis, emphysema, asthma, and cystic fibrosis experience impaired breathing because excess mucus accumulates in the lungs and blocks the airways. The new product, as envisioned by DHD, would incorporate two therapies for that condition: positive expiratory pressure, or PEP, therapy and vibration therapy.

The therapeutic device called acapella lets patients administer pressure and vibration to clear congested lungs and airways.

In PEP therapy, the patient draws air through a device with a one-way valve and exhales into a resistance in that device to create positive pressure in the lung, moving the accumulated mucus to larger airways where it can be coughed out. With vibration therapy, the mucus is further loosened by various external and internal forms of vibration and then expelled.

The respiratory treatment, combining PEP and vibration therapy, would be self-administered by patients, many with limited mobility. The patient could not be required to adopt a specific position to use the device. For a new at-home product to serve such patients it had to work independent of gravity.

Remembering that patients would be treating a serious health problem by themselves, DHD Healthcare wanted to market a product that was both easy to use and non-intimidating. Simplicity of operation is important in giving the doctor or prescribing clinician the confidence that the patient will perform the treatment correctly. Also, the device had to be easy for the patient to clean at home.



The product, now marketed by DHD under the brand name acapella, had to accommodate the differences in breathing flow rate and areas of congestion, because patients range widely in age and size, as well as in the severity of their disease.

The company wanted the device to have a low cost of manufacture to widen its availability on the market. Yet, it had to meet the FDA's quality and reliability requirements and DHD Healthcare's own ISO 9001 standards.

With the broad design goals identified, DHD assembled a product development team that included professionals from the company's staff as well as individuals from Product Genesis Inc. of Cambridge, Mass., a firm specializing in product development.

The companies believe quality product development usually results from a team whose members bring widely different disciplines to the project. DHD and Product Genesis contributors came from fields as diverse as bioengineering, mechanical engineering, materials science, industrial design, human factors engineering, and ergonomics.

Work styles varied, as well. Some people were more comfortable and effective in the early research phase of the project, when the process would be more iterative and unpredictable; others were better suited to the later development phase, when the work was more sequential and predictable.

From Brainstorm to Breadboard

Modifying or improving an existing product, or even creating a next-generation model, follows a relatively straightforward path of development. DHD, however, had set a number of strict criteria for its product, and meeting all the requirements left room for few preset formulas or standards. Facing a challenge that required start-from-scratch engineering, team members engaged in broad product brainstorming, followed by bench testing of promising ideas. From there a breadboard, or rough prototype, was constructed and subjected to early human testing.

Bob Elden, a mechanical engineer at Product Genesis, spent many hours blowing into the thing. He tried the device at different flow rates as the team measured pressures.

In order to determine the critical parameters and the minimum number of working parts, we tested nearly 100 configurations of the functional components, with different contact diameters, curvatures, sizes, and so forth, in order to determine the critical parameters and the minimum number of parts needed to meet DHD's requirements. Three basic design concepts received extensive testing and evaluation before the team settled on the final system.

Developed over the course of eight months, the final product consists of 10 injection-molded parts that assemble inside a snap-shut housing.

A valve, looking like a cone in a doughnut, opens under pressure when a user breathes into the device. The cone lifts out of the doughnut to open the valve and pressure is released. As the pressure reduces, the flow rate increases, creating a Venturi effect, pulling the cone back into the doughnut. The cone is mounted on a rocker. A magnet keeps the valve closed when the device is not in use and allows for adjustment of the resistance.

A doctor prescribes the device and works with the patient to establish correct use of the product and to determine which level of resistance best meets the patient's needs.

Some parts of the product solution flowed naturally, building on the prior experience of team members and past projects. We used a comfortable and confident grip, made the device small enough to fit in any user's hand, and designed a dial that makes it easy for the patient to regulate flow resistance. The acapella's materials and colors were selected to produce a pleasant, non-threatening appearance. The translucent outer housing was chosen to let the user quickly confirm that the inside of the acapella was dry after cleaning.

To achieve production standards and cost targets, all components of the product were designed for injection molding. The product incorporates just 10 pieces. The two pieces of the enclosure snap together without the need for ultrasonic welding. It can be assembled without tools in a matter of minutes, thereby achieving the company's cost targets. The price to a hospital is about \$40.

Other aspects of designing the acapella proved to be more challenging, leading to first-time applications of various technologies and testing multiple alternatives. Here are examples of some of the design challenges we encountered, along with our solutions.

Excess friction: Our early design concepts created too much friction in the internal operating system, preventing the desired oscillation. To solve the problem, we went to a rocker design that centralized the friction at the pivot.

Pressure spikes: One of our first versions of the rocker system attained the average pressures necessary for effective PEP therapy, but we encountered unacceptable spikes in pressure. After further exploration, the development team came up with a solution based on a principle from Physics 101—the Venturi effect. To produce the Venturi force, we designed the floating cone and doughnut ring configuration. It worked. The design balanced the pressure, creating just the right amount of opening at the orifice for even control.

Variable flow ranges: Rather than a one-size-fits-all solution, we created two color-coded versions of the acapella—green for high airflow (13 to 30 liters per minute) and blue for low flow (10 to 15 lpm), more appropriate for children and patients with limited lung capacity.

The acapella made its successful market debut after eight months in development.

Although product development does not require genius, it clearly requires the right combination of applied technical ability and a fertile imagination to produce designs that have to operate effectively and flawlessly. In DHD's case, the acapella has enhanced the company's market position and, more importantly, it has provided a low-cost, at-home therapy that greatly improves the quality of many patients' lives.

<http://www.dhd.com/catalog/bronchial/acapellaChoice.asp> 13:25 19-04-06

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acapella[®] choice



Vibratory Positive Expiratory Pressure System

Like the original acapella[®], acapella[®] choice can be used in any spatial orientation to open airways and mobilize secretions. What's more, it disassembles into four, easy-to-clean parts that withstand autoclaving, boiling, and dishwashing. Your patients get all the benefits of vibratory PEP therapy, in the home or hospital, with a convenient, easy-to-clean device (single patient use).



Respiratory Accessories:

Inspiratory Muscle Trainer



The Trainer is designed to strengthen respiratory muscles through the use of resistance during the inspiratory effort. Features include 6 color coded resistors for setting the resistance level, port for monitoring pressures or delivering oxygen, and noseclip. 15 mm ID connection allows direct application to the endotracheal airway.

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[Randomised crossover study of the **Flutter device** and the active ...](#)

BACKGROUND: Airway clearance techniques are an important part of the routine care of patients with b...

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Conclusions: Daily use of the **Flutter device** in the home is as effective as

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