

URGENT MEDICAL FIELD SAFETY NOTICE

Portex® Acapella® DH (Green) Vibratory PEP Device with Mouthpiece

Affected Device: Portex Acapella DH Vibratory Positive Expiratory Pressure (PEP) Device

Type of Action: Removal

Date: January 4, 2021

Attention: Clinical Users of, and Distributors of the Portex Acapella DH (Green) Vibratory PEP Device with Mouthpiece

Affected Devices: **The following Product Number and Lot Number is potentially affected by this issue:**

Model Number	Name	Lot/Serial Number
21-1530	Portex Acapella DH (Green) Vibratory PEP Device with Mouthpiece	3988435

Dear Customer,

The purpose of this Field Safety Notice is to advise you that Smiths Medical has initiated a Field Action for one lot of Portex Acapella DH (Green) Vibratory PEP Device with Mouthpiece products listed in the table above. A total of 4,440 devices are included in this Field Action.

REASON FOR FIELD ACTION

Smiths Medical became aware that one lot of Portex Acapella DH (Green) Vibratory PEP Device with Mouthpiece shipping boxes incorrectly contained Portex Acapella DM (Blue) Vibratory PEP Device with Mouthpiece devices.

This Field Action is being performed with the knowledge of the appropriate regulatory authorities.



RISK TO HEALTH:

The Acapella vibratory PEP system is a single patient use device that provides Positive Expiratory Pressure (PEP) Therapy for patients who have Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems, and patients with atelectasis. The Acapella devices, blue and green, are designed to meet specific patient lung performance parameters. Acapella DH (Green) is recommended for patients able to maintain an expiratory flow of 15 liters per minute or greater for 3 seconds. Acapella DM (Blue) is recommended for patients who can maintain an expiratory flow of less than 15 liters per minutes for 3 seconds.

The risk to health of receiving the Acapella DM (Blue) when an Acapella DH (Green) is required could be delay in initiation of therapy until the correct model of device is obtained. The risk to health of using the Acapella DM (Blue) when an Acapella DH (Green) is required could be the device may not function optimally for the therapy.

Smiths Medical has received zero (0) reports of death or serious injury related to this issue.

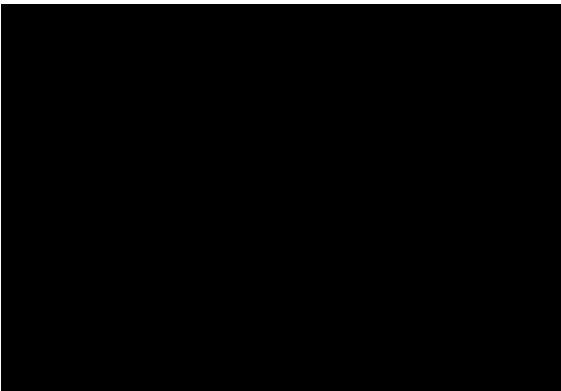
INSTRUCTIONS TO CUSTOMERS AND DISTRIBUTORS:

1. Identify and quarantine affected product in your possession by referring to the table on page 1 of this Field Safety Notice.
2. Determine the number of affected devices in your possession and complete the attached Field Safety Notice Response Form (Attachment 1) within 10 days of receipt, returning it to fieldactions@smiths-medical.com. The Response Form must be returned even if you do not have any affected product in your possession.
3. Smiths Medical will contact you to provide instructions on returning the product following the receipt of your Response Form. All impacted product within your possession must be returned. When returning product please include a copy of the Response Form (Attachment 1) inside EACH BOX.
4. Product credit will be processed once the impacted product and Response Form (Attachment 1) has been received and processed.
5. DISTRIBUTORS: if you have distributed potentially affected product to your customers, please immediately notify them of this Field Action with the editable Distributor Response Form for your customers (Attachment 1a) to respond appropriately.

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may cause.

If you have any questions regarding this notification, please contact Smiths Medical via email at fieldactions@smiths-medical.com.

Sincerely,



Enclosure: Attachment 1 – Field Safety Notice Response Form (and Attachment 1a – Distributor Response Form if applicable)

