TECHNICAL SUMMARY SHEET

Acapella™ DM (Blue) Vibratory PEP System

Device Classification

GMDN: 43947
Classification: Class IIa

Product Description

The Acapella DM vibratory PEP system is a single-patient use device that provides positive expiratory pressure (PEP) therapy for patients who have cystic fibrosis, COPD, asthma, lung diseases with secretory problems and patients with atelectasis. All patients must be capable of following instructions for positive expiratory pressure therapy.

The Acapella DM vibratory PEP system consists of:

- Removable mouthpiece
- Acapella DM vibratory PEP device with 22 mm male fittings including:
  - Expiratory resistance/frequency adjustment dial
  - One-way inspiratory valve
  - Patient end which adapts to a mouthpiece or mask.
  - Mouthpiece (detachable)

The Acapella DM vibratory PEP System is recommended for patients capable to maintain an expiratory flow of less than 15 litres per minute for 3 seconds.

Indications

The Acapella DM vibratory PEP is intended for use as a positive expiratory pressure (PEP) device. It may also be used simultaneously with nebulised aerosol drug delivery.

Contraindications

Although no absolute contraindications to the use of PEP therapy have been reported, the following should be carefully evaluated before a decision is made to initiate therapy:

- Inability to tolerate increased work of breathing
- Haemodynamic instability
- Intracranial pressure (ICP) › 20 mm Hg
- Acute sinusitis
- Recent facial, oral or skull surgery or trauma
- Epistaxis
- Oesophageal surgery
- Active haemoptysis
- Untreated pneumothorax
- Nausea
- Known or suspected tympanic membrane rupture or other middle ear pathology

Precautions

- Bleach is not recommended for use on the Acapella DM vibratory PEP system. It may deteriorate the nickel-plated mechanism located in the interior of the device.
- DO NOT MICROWAVE. The metal and magnet might ignite.
- It is the responsibility of the user to ensure all sterility verification(s).
- Visually inspect the device to ensure that the unit is free of contamination and foreign objects.
- Verify all connections are secure.

Components Composition

Mouthpiece: styrene butadiene copolymer
Platform donut: polypropylene, glass filled
Knob: styrene butadiene copolymer
Housing top and bottom: styrene butadiene copolymer
Rocker/dowel assembly: polypropylene, glass filled, stainless steel
Tube/adaptor assembly: styrene butadiene copolymer, silicone rubber
Magnet: Sintered neodymium iron boron coated with electrolytic nickel plating

This device is not made with natural rubber latex.

This device is not manufactured using derivatives of tissues or cells of animal origin.

Warning: This product contains DEHP.

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Manufacturing Site Name and Address

ICU Medical, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442, USA

Country of Origin

USA

Sterilisation Method

Non-sterile

Shelf-Life

5 years

Labelling and Packaging

Acapella DM (blue) Vibratory PEP Systems				
Product code	Packaging system	Length (cm)	Width (cm)	Height (cm)
21-1015	Single Unit (Polybag)	28,0	17,8	N/A
	Transit Carton (10 Units)	26,2	20,8	14,4
21-1016	Single Unit (Box)	17,9	6,7	6,7
	Transit Carton (10 Units)	35,6	14,3	18,6

One (1) product unit is packaged per each in a polybag (21-1015) or in box (21-1016). The polybag/box is printed with product information to aid identification of the product. Ten (10) units are packed per transit carton.

The lot number, manufacturing date and expiration date are located on the bag and box labels. Instructions are included in the packaging. Product is non-sterile, free from latex and intended for use by a single patient. Product should not be used if packaging is open, wet or damaged.

Product Range and Features

Acapella DM (blue) Vibratory PEP Systems		
Product code	Description	Units/Case
21-1015	Device with mouthpiece	10
21-1016	Device with mouthpiece (individually boxed devices)	10

The product complies with current legislation and has the corresponding CE marking.
For additional information, warnings and/or safety precautions, refer to the manufacturer's Instructions for Use.

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