



Freevent® DualCare™ is both a speaking valve and a Heat and Moisture Exchanger (HME), enabling hands-free speech and supporting the lungs with important heat and moisture.

Providing patients the ability to speak

Speech is our most important means of communication, so losing one's voice after going through a tracheostomy highly affects the patient's life.

Freevent DualCare gives your patient back the ability to speak hands-free and can be used as soon as the patient can breathe spontaneously¹.

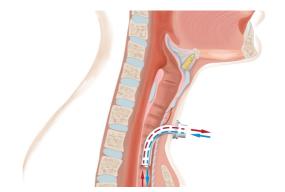
Better pulmonary health

After a tracheotomy, the upper airway is bypassed and the patient breathes directly through the tracheostomy tube. Thus, the inhaled air is not heated, moisturized, or filtered. The use of Heat and Moisture Exchangers (HMEs) by tracheostomized patients provides heat and moisture of the inspired air and gives patients positive pulmonary effects such as decreased viscosity of mucus secretions, less coughing, and improvements in respiratory functions^{1-4a}.

An HME is an exchange system, saving heat and moisture when exhaling, and giving it back when inhaling

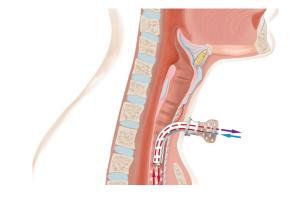
To get the HME exchange effect the patients need to both inhale and exhale through the device. When exhaling through an HME, the natural heat and moisture of the air are retained by the HME system. Heat and moisture are released from the HME during inhalation, and as a result, the inhaled air is heated and moisturized².

Breathing without an HME



- · When exhaling, moisture and heat are lost.
- When inhaling, unconditioned air enters the lower airways, leading to tracheobronchial dryness.

Breathing with Freevent DualCare in HME mode



- When exhaling, moisture and heat are retained by the HME system.
- When inhaling, moisture and heat are given back to the respiratory tract.

With Freevent DualCare, the patient gets the HME effect with a simple twist of the lid of the speaking valve¹!

^aPost-market clinical study, sponsored by Atos Medical (2010). Data on file.



Freevent DualCare enables hands-free speech and provides the lungs with important heat and moisture.

Freevent DualCare consists of two parts that are assembled together, a speaking valve and an HME, providing patients the ability to speak along with the benefits of an HME. The switch between the speaking mode and HME mode is done with a simple twist of the lid¹.

The HME is available both with 15 mm and 22 mm interfaces to fit different tube connections. The speaking valve can be cleaned and re-used for 2 months whereas the HME needs to be replaced at least every 24 hours.



Speaking mode

Freevent DualCare is put into speaking mode by twisting the lid of the speaking valve until it clicks into speaking mode position and the flexible membrane covers the openings of the valve. Freevent DualCare is a bias closed valve and the membrane will only open on inhalation. When exhaling the membrane is closed and the air will be guided through the vocal cords enabling speech.

HME mode

Freevent DualCare is put into HME mode by twisting the lid of the speaking valve until it clicks into a position indicating the windows are open without the membrane visible. In the HME mode, the user breathes both in and out through the HME, saving heat and moisture when breathing out, and giving heat and moisture back when inhaling.

Using Freevent DualCare on a tube with a deflated cuff

When the patient is using a tracheostomy tube with a cuff, the cuff must always be completely deflated when using the Freevent DualCare speaking valve. There should be sufficient space around the tube and the deflated cuff to allow exhaled air to pass around the tube; otherwise, the patient will not be able to breathe.

The Blue Edition

The Blue Edition is specially developed to make it easy for clinicians, hospital staff, and home care staff to see when a patient is using the Freevent DualCare speaking valve. This Speaking valve is bright blue with a colored membrane, which makes it possible to see when Freevent DualCare is being used. It can also easily be seen if the device is in speaking mode or HME mode.



For pulmonary health, an HME should be used day and night

The pulmonary climate changes rapidly after application and removal of an HME ⁵. Clinical studies show that the improvement in tracheal climate only occurs when the HME is used. It has also been shown that adherence to HME use is needed to obtain a substantial reduction in coughing and mucus production ⁶⁻⁸. Thus, optimal pulmonary rehabilitation is only reached when an HME is regularly both day and night.

Freevent DualCare system makes it possible for the patient to use an HME both day and night. Freevent HMEs fit with both the speaking valve to be used during daytime and with the HME DigiTop to be used during sleep.

IMPORTANT: Do not use the speaking valve during sleep since the airway could be blocked unintentionally. During sleep, use the HME DigiTop instead.

HME DigiTop

Since the speaking valve cannot be used during sleep, HME DigiTop was developed as a solution for nighttime use to be able to provide heat and moisture to inspired air during sleep. HME DigiTop should be used together with Freevent HME 15 or 22 and is included when buying a Freevent DualCare speaking valve.

HME DigiTop can be occluded with two fingers for speaking when the cuff is deflated or a tracheostomy tube without a cuff is used.

If there is a preference to use HME DigiTop also during the day that is perfectly fine.

HME DigiTop $\rm O_2$ is available as a separate product and has an oxygen port that allows for integrated administration of supplemental oxygen, up to 3-4 L/min with minimal impact on the HME performance. Use oxygen tubing of 1/8 inch (3.2 mm) diameter.





Facts & performance

HME media	Foam impregnated with hygroscopic salt
Moisture loss	
Freevent HME 15	VT = 500 ml: 21.5 mg/l
	VT = 1000 ml: 22.5 mg/l
Freevent HME 22	VT = 500 ml: 21 mg/l
	VT = 1000 ml: 22 mg/l
Pressure drop, Freevent DualCare with Freevent HME 15	
HME mode	
	30 l/min: 35 Pa
	60 I/min 125 Pa
Speaking mode	30 l/min: 125 Pa
Pressure drop, Freevent DualCare with Freevent HME 22	
HME mode	
	30 l/min: 50 Pa
	60 I/min 150 Pa
Speaking mode	30 I/min: 140 Pa
Dead space	
Freevent HME 15 + speaking valve	4.1 ml
Freevent HME 22 + speaking valve	4.6 ml
Oxygen Supply	Possible with HME DigiTop O ₂
Recommended tidal volume	>50 ml
Made in	Sweden

Precautions

- Do always check before each use that the Speaking Valve rotates properly between the two modes. The Speaking Valve may get stuck in one of the modes due to the presence of mucus. If this occurs, clean the device thoroughly and if the problem persists stop using the device and replace it.
- Do check the device if you experience increased breathing resistance as this might be a sign of blockage (e.g., by mucus).
- Do consult your clinician if there is a problem in connection with the device.

- Do not use humidifiers or heated humidified oxygen via a mask over the tracheostoma while using the device since it will cause the HME to become too wet. If oxygen therapy is required, use only non-heated humidified oxygen.
- Do not administer medicated nebulizer treatment over the tracheostoma while using the device. The medication can become deposited in the HME, and medications may also adversely affect the Speaking Valve membrane. If the device is inadvertently used during a medicated nebulizer treatment, the device must be removed immediately. The HME must be discarded, and the Speaking Valve and the HME DigiTop must be cleaned thoroughly to remove all medication residues.

Ordering Information		REF	Rx*
@808j	Freevent DualCare Set 15**: 30 pcs Freevent HME 15 Regular + 1 pc Speaking Valve + 1 pc Freevent HME DigiTop + 1 pc Removal Aid + 1 pc Connection Strap	7741	Rx
	Freevent DualCare Set 22**: 30 pcs Freevent HME 22 Regular + 1 pc Seaking Valve + 1 pc Freevent HME DigiTop + 1 pc Removal Aid + 1 pc Connection Strap	7740	Rx
	Freevent DualCare Speaking Valve: 1 pc Speaking Valve + 1 pc Freevent HME DigiTop + 1 pc Connection Strap	7744	Rx
	Freevent HME 15** Regular, 30 pcs	7742	Rx
	Freevent HME 22** Regular, 30 pcs	7747	Rx
	Removal Aid, 2 pcs	7745	
	Freevent Connection Strap, 2 pcs	7746	
6 6	Freevent DualCare Speaking Valve Blue: 1 pc Freevent DualCare Speaking Valve Blue + 1 pc Freevent HME DigiTop Blue + 1 pc Connection Strap	7755	Rx
•	1 pc HME DigiTop O2 Blue	7756	Rx

^{*} US only.

 $Always\ read\ the\ Instructions\ for\ use\ (IFU)\ before\ starting\ to\ use\ any\ of\ the\ products,\ available\ at\ www.atosmedical.com.$

References

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Contact us for more information

We develop products in close cooperation with leading institutions, doctors, physicians, nurses, speech-language pathologists, and patients from all over the world, to improve patients' quality of life through smart and innovative solutions.

For more information about our assortment please visit <u>www.atosmedical.com.</u>

^{**} Freevent DualCare is available in sizes 15mm and 22mm.

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