



MT-2009-2008

Filter/HMEs: Supporting daily clinical routine

SAFESTAR®
CARESTAR®
HUMIDSTAR®
TWINSTAR®



Clinical Challenges

The utilization of heat and moisture exchangers (HMEs) and breathing system filters in the OR, the ICU as well as other settings is an approach to address concerns commonly associated with mechanical ventilation: proper humidification of inspired air and cross-infection.

Humidification

Humidification of the inspired gas in mechanical ventilation has been shown to contribute to the prevention of ventilator-associated pneumonia (VAP).¹ Passive humidification as performed by heat and moisture exchangers additionally decreases condensation and moisture accumulation in the breathing system.¹ Assessing the efficacy of HMEs in reducing bacterial growth and prevention of VAP, various randomized controlled studies observed slightly lower VAP rates, suggesting that the use of HMEs might decrease VAP rates.^{2,3,4,5,6,7}

VAP is the most important nosocomial infection in intensive care units, accounting for 9 cases/1,000 ventilation days or about 30,000 cases annually in Germany alone.⁸ VAP leads to an attributable mortality rate of up to 71 %⁹, increased average duration of mechanical ventilation¹⁰, increased

length of hospital stay¹¹, and higher treatment costs¹².

The use of HMEs may decrease not only the incidence of VAP in patients eligible for these devices, but also the associated workload and cost.¹ Late-onset VAP, occurring after five or more days of mechanical ventilation, is often due to multiresistant organisms such as Methicillin-Resistant *Staphylococcus Aureus* (MRSA)^{13,14} or Aerobic Gram-negative bacteria such as *Pseudomonas aeruginosa*, the latter originating 50 % from endogenous sources and 50 % from cross-contamination.¹

Cross Infection

As a preventive measure for infection prophylaxis and avoiding the risk of cross-infection in anesthesia, various expert committees recommend the use of a breathing system filter, to be attached to the Y-piece and replaced after every patient.^{15,16,17,18}



In several countries national medical associations have already put forth guidelines recommending the utilization of breathing system filters.

In its November 2002 publication “Infection Control in Anaesthesia”¹⁵, the Association of Anaesthetists of Great Britain and Ireland recommends using a new breathing system filter for each patient. There is evidence that breathing circuits are often contaminated with transmissible microorganisms and blood.^{19,20} Furthermore, the possibility of cross-infection of Hepatitis C²⁰ and the occurrence of multiple-resistant tuberculosis pathogens have also been cited.

The Hygiene recommendations in anesthesia¹⁶ by the French Working Group for Hygiene in Anesthesia advise using a breathing system filter on the Y-piece and replacing it after every patient to prevent the risk of possible cross-infection.

An update of these recommendations¹⁷ in June 2002, authored by the Comité Technique National des Infections Nosocomiales, stresses the need to protect the anesthesia circuit with a filter. This requirement was derived from publications on cross-infections that actually occurred or were considered possible during anesthesia.^{21,22,23,24,25,26}

Furthermore, the French Society of Anesthesia and Intensive Care recommends the use of a hydrophobic, mechanical filter for anesthesia which withstands at least a minimum water pressure of 49 mbar.²⁷

The Centers for Disease Control and Prevention in the United States recommend the use of a breathing system filter during anesthesia in patients with confirmed or suspected tuberculosis.^{28,29}

The Ministry of Health and Long-Term Care of the Canadian province of Ontario has constituted the use of a hydrophobic, mechanical filter in all confirmed and suspected cases of SARS between the patient and the ventilator.³⁰

According to the Recommendations for Prevention of Nosocomial Pneumonias¹⁸ published in Germany in 2000, by the Commission of Hospital Hygiene and Infection Prevention at the Robert Koch Institute, an anesthesia breathing circuit with breathing system filters shall be replaced once daily. If breathing system filters are not used, the anesthesia hoses must be replaced or disinfected for each new patient. Breathing system filters should be inserted between the tracheal tube and the Y-piece.

Bibliography

- 1 Kola A, Eckmanns T, Gastmeier P, 2005.; Efficacy of heat and moisture exchangers in preventing ventilator-associated pneumonia: meta-analysis of randomized controlled trials, *Intensive Care Medicine*,31:5
- 2 Martin C et al., 1990, Heat and moisture exchangers and vaporizing humidifiers in the intensive care unit, *Chest*, 97:144
- 3 Dreyfuss D et al., 1995, Mechanical ventilation with heated humidifiers or heat and moisture exchangers: effects on patient colonization and incidence of nosocomial pneumonia, *Am J Respir Crit Care Med*,151:986
- 4 Branson RD et al., 1996, Comparison of three humidification techniques during mechanical ventilation: patient selection, cost and infection considerations, *Respir Care*, 41:809
- 5 Kirton OC et al., 1997, A prospective, randomized comparison of an in-line heat moisture exchanger filter and heated wire humidifiers: rates of ventilator-associated early-onset (community-acquired) or late-onset (hospital-acquired) pneumonia and incidence of endotracheal tube occlusion, *Chest*, 112:1055
- 6 Boots RJ et al., 1997, Clinical utility of hygroscopic heat and moisture exchangers in intensive care patients, *Crit Care Med*, 25:1707
- 7 Memish ZA et al., 2001, A randomized clinical trial to compare the effects of a heat and moisture exchanger with a heated humidifying system on the occurrence rate of ventilator-associated pneumonia, *Am J Infect Control*, 29:301
- 8 Gastmeier P et al., 2003, Five years working with the German nosocomial infection surveillance system (Krankenhaus Infektions Surveillance System), *Am J Infect Control*, 31:316
- 9 Powers J (2006): Managing VAP effectively to optimize outcomes and costs, *Nurs Manage*, 37(11):48A-48F
- 10 Rello J et al., (2002, Epidemiology and Outcomes of Ventilator-Associated Pneumonia in a large US Database, *Chest*, 122:2115-21
- 11 Kollef MH, 1999, The Prevention of Ventilator-Associated Pneumonia, *N Engl J Med*, 340:627
- 12 Craven DE, 2006, Preventing Ventilator-Associated Pneumonia in Adults – Sowing Seeds of Change, *Chest*, 130:251-60
- 13 Chastre J, Fagon JY, 2002, Ventilator-associated pneumonia, *Am J Respir Crit Care Med*, 165:867
- 14 Cook D, 2000, Ventilator associated pneumonia, *Intensive Care Med*, 26:31
- 15 Wallace PGM et al., 2002, *Infection Control in Anaesthesia*, The Association of Anaesthetists of Great Britain and Ireland: London
- 16 Groupe de travail sur l'hygiène en anesthésie, 1998, *Recommandations concernant l'hygiène en anesthésie*, *Annales françaises d'anesthésie et de réanimation*, 10(17)
- 17 Comité technique national des infections nosocomiales, Groupe permanent de réflexion et vigilance sur la désinfection, *Sous-groupe désinfection en Anesthésie Réanimation*, 2002, *Désinfection des dispositifs médicaux en anesthésie et en réanimation*, Ministère de la santé, de la famille, et des personnes handicapées
- 18 Kommission für Krankenhaushygiene und Infektionsprävention beim Robert Koch-Institut: *Prävention der nosokomialen Pneumonie*, 2000, *Bundesgesundheitsblatt – Gesundheitsforschung – Gesundheitsschutz*, 43:302
- 19 Miller DH et al., 2001, Presence of protein deposits on cleaned reusable anaesthetic equipment, *Anaesthesia*, 56:1069
- 20 Chrisco JA, Devane G, 1992, A descriptive study of blood in the mouth following routine oral endotracheal intubation, *Journal of the American Association of Nurse Anesthetists*, 60:379–383
- 21 Olds JW et al., 1972, *Pseudomonas aeruginosa* respiratory tract infection acquired from a contaminated anesthesia machine, *Am Rev Respir Dis*, 105:629
- 22 Herwaldt LA, Pottinger J, Coffin SA, 1996, "Nosocomial infections associated with anesthesia", in Mayhall CG (ed.), *Hospital epidemiology and infection control*: 655–675, Williams and Wilkins: Baltimore
- 23 Hovig B, 1981, Lower respiratory tract infections associated with respiratory therapy and anaesthesia equipment, *J. Hosp Infect*, 2:301
- 24 Nielsen H et al., 1980, Cross-infection from contaminated anaesthetic equipment. A real hazard?, *Anaesthesia*, 35:703
- 25 Chant K et al., 1994, Investigation of possible patient-topatient transmission of hepatitis C in a hospital, *New South Wales Public Health Bulletin*, 1994, 5:47
- 26 Knoblanche GK, 1996, Revision of the anaesthetic aspects of an infection control policy following reporting of hepatitis C nosocomial infection, *Anesth Intensive Care*, 1996, 24:169
- 27 Hajjar J, Loctin H, Gouillet D. Technical requirements for buying a heat and humidity exchanger for ventilation during anesthesia, *Annales françaises d'anesthésie et de réanimation*, 19(7):556
- 28 Sehulster L, Chinn RYW, 2003, Guidelines for Environmental Infection Control in Health-Care Facilities - Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), *MMWR* 52(RR10)
- 29 Jensen PA et al., 2005, Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, *MMWR* 54(RR17):1-141
- 30 Ministry of Health and Long-Term Care, 2004, *Directive to all Ontario Health Care Facilities/Settings for High-Risk Aerosol-Generating Procedures under Outbreak Conditions*, Directive HR04-13

Dräger Filters/HMEs - for all Clinical Applications and Needs



SafeStar® Family



CareStar® Family



HumidStar® Family



TwinStar® Family

The Dräger Solution

The HMEs and breathing system filters of Dräger's extensive portfolio offer the following features:

- For different tidal volumes and/or different deadspace needs all products are available in different sizes
- Equipped with a Luer-Lock connector for gas sampling
- Sampling port in convenient 45° angle
- With a tethered luer cap in order to prevent any loose parts from falling into the breathing system*
- Transparent housing of the products allows for visual inspection at any time while in use
- Fast and easily identified due to their color coding and clear labeling
- Standardized connectors provide proper and easy connection with other components of the ventilation circuit

In order to support the clinician to properly address the specific challenges, Dräger offers an extensive portfolio of high-performing HMEs and breathing system filters.

SafeStar® Family

The new SafeStar mechanical HEPA breathing system filters from Dräger meet high standards for infection prophylaxis in ventilation. The active medium of these mechanical filters is a hydrophobic filter membrane of coated glass fibers developed specifically for this purpose. Due to the hydrophobicity SafeStar cannot be passed by potentially contaminated fluids (e.g. blood, sputum, condensate) under normal pressure conditions of mechanical ventilation. Therefore, SafeStar can inhibit the passage of fluidborne microorganisms. Furthermore, SafeStar's mechanical medium with very high bacterial and viral filtration efficiency rates reduces the passage of airborne microorganisms to a considerable extent. This significantly helps to reduce the risk of possible cross-infection.

* for further information please refer to: Department of Health, 2004, Protecting the breathing circuit in anaesthesia, Report to the Chief Medical Officer of an Expert Group on blocked anaesthetic tubing, Department of Health Publications: London, UK

CareStar® Family

The CareStar breathing system filters from Dräger provide an excellent and cost-efficient alternative. Due to its high-performing electrostatic filtration medium, CareStar supports protection of the patient from potentially present microorganisms in the inspired air as well as safe-guarding the ventilator and the ventilator breathing system from airborne microorganisms that the patient exhales. This also helps to reduce the risk of possible cross-infection.

HumidStar® Family

The HME medium of HumidStar heat and moisture exchangers from Dräger consists of a new microporous polymer foam that was specially developed for this application and returns a high degree of heat and moisture. In addition to the HumidStars for mechanical ventilation Dräger offers the HumidStar Trach for tracheostomized patients which features an oxygen port and a safety valve.

TwinStar® Family

The TwinStar breathing system filters/HMEs from Dräger combine all the advantages of the CareStar and the HumidStar or the SafeStar and the HumidStar. They efficiently humidify and heat the inspired air of the ventilator dependent patient. Additionally, with their high bacterial and viral filtration efficiency rates they exceptionally sustain infection-prevention since TwinStar supports protection of the patient from potentially present microorganisms in the inspired air as well as safe-guarding the ventilator breathing system from airborne micro-organisms that the patient exhales. A highlight is the TwinStar HEPA which contains a hydrophobic filter membrane of coated glass fiber. This membrane cannot be passed by potentially contaminated fluids (e.g. blood, sputum, condensate) under normal pressure conditions of mechanical ventilation.

Four families - one goal: Supporting daily clinical routine



MT-3219-2008

SafeStar® Family



MT-2864-2008

CareStar® Family



MT-2763-2008

HumidStar® Family



MT-3840-2008

TwinStar® Family

Dräger consumables are tested and manufactured to meet the highest standards in medical technology and their functionality is convincing.

Product Overview Filters / HMEs

FILTERS AND HMEs



Product name	Filter/HME TwinStar® 90	Filter/HME TwinStar® 55	Filter/HME TwinStar® 65A	Filter/HME TwinStar® 25	Filter/HME TwinStar® 8	Filter/HME TwinStar® 10A	Filter/HME TwinStar® HEPA	Filter SafeStar® 80	Filter SafeStar® 55
Part no.	MP01800	MP01805	MP01810	MP01815	MP01820	MP01825	MP01801	MP01785	MP01790
Deadspace (ml)	90	55	65	25	8	10	55	80	55
Recommended patient	adult	adult	adult	pediatric	neonatal	neonatal	adult	adult	adult
Recommended tidal volume (ml)	300 - 1500	300 - 1500	300 - 1500	75 - 500	30 - 200	30 - 200	300 - 1500	300 - 1500	300 - 1500
Bacterial retention ¹ (%)	99.999	99.999	99.999	99.999	99.9	99.9	99.9999	99.9999	99.9999
Viral retention ¹ (%)	99.999	99.99	99.99	99.99	99.9	99.9	99.9999	99.9999	99.9999
Filtration method	electrostatic	electrostatic	electrostatic	electrostatic	electrostatic	electrostatic	mechanical (HEPA ²)	mechanical (HEPA ²)	mechanical (HEPA ²)
Fluid breakthrough at (mbar)	-	-	-	-	-	-	151	87.5	96
Moisture loss ³ (mg H ₂ O/l air) (@ Vt 500ml)	4.7	7.2	6.9	5.8	6.1	6.4	9.8	-	-
Moisture output (mg H ₂ O/l air)	39.3	36.8	37.1	38.2	37.9	37.6	34.2	-	-
Resistance (mbar)	1.0 at 30 l/min 2.2 at 60 l/min 3.6 at 90 l/min	0.9 at 30 l/min 2.0 at 60 l/min 3.5 at 90 l/min	1.1 at 30 l/min 2.4 at 60 l/min 4.2 at 90 l/min	1.3 at 15 l/min 1.8 at 20 l/min 2.8 at 30 l/min	0.6 at 5 l/min 1.6 at 10 l/min 3.0 at 15 l/min	0.4 at 5 l/min 1.0 at 10 l/min 1.6 at 15 l/min	1.3 at 30 l/min 2.7 at 60 l/min 4.3 at 90 l/min	1.4 at 30 l/min 3.2 at 60 l/min 5.5 at 90 l/min	1.3 at 30 l/min 2.9 at 60 l/min 4.6 at 90 l/min
Maximum duration of use	24h	24h	24h	24h	24h	24h	24h	24h	24h
Housing material	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent
Housing height (mm)	81.6	78.5	89.9	72.0	50.5	58.2	85.1	81.6	81.5
Housing diameter (mm)	80.0	68.5	68.5	48.1	36.8	36.8	68.5	80.0	68.5
Product	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free
Weight (g)	37	28	30	18	9	9	40	47	39
Sampling port	Luer lock	Luer lock	Luer lock	Luer lock	Luer lock	Luer lock	Luer lock	Luer lock	Luer lock
Cap of sampling port	tethered	tethered	tethered	tethered	tethered	tethered	tethered	tethered	tethered
Connector patient side	22M / 15F	22M / 15F	22M / 15F	22M / 15F	22M / 15F	22M / 15F	22M / 15F	22M / 15F	22M / 15F
Connector machine side	22F / 15M	22F / 15M	22F / 15M	22F / 15M	15M / 8.5M	15M	22F / 15M	22F / 15M	22F / 15M
Shelf life	3 years	3 years	3 years	3 years	3 years	3 years	5 years	5 years	5 years
Colour code	Blue	Blue	Blue	Blue	-	-	Blue	Red	Red
Units/package (pcs.)	50	50	50	50	50	50	50	50	50

¹ According to Nelson Laboratories, Inc., Salt Lake City, USA

² According to EN 1822-1:1998

³ According to ISO EN 9360-1 (2000)

FILTERS AND HMES



Product name	Filter SafeStar® 60A	Filter CareStar® 45	Filter CareStar® 40A	Filter CareStar® 30	HME HumidStar® 55	HME HumidStar® 25	HME HumidStar® 10A	HME HumidStar® 2	HME HumidStar® Trach
Part no.	MP01795	MP01755	MP01765	MP01770	MP01730	MP01735	MP01740	MP01745	MP01750
Deadspace (ml)	60	45	40	30	55	25	10	2	8
Recommended patient	adult	adult	adult	adult/ pediatric	adult	pediatric	neonatal	neonatal	adult
Recommended tidal volume (ml)	300 - 1500	300 - 1500	300 - 1500	100 - 1500	300 - 1500	75 - 500	30 - 200	10 - 30	100 - 1500
Bacterial retention ¹ (%)	99.9999	99.999	99.999	99.999	-	-	-	-	-
Viral retention ¹ (%)	99.9999	99.999	99.99	99.99	-	-	-	-	-
Filtration method	mechanical (HEPA ²)	electrostatic	electrostatic	electrostatic	-	-	-	-	-
Fluid breakthrough at (mbar)	117	-	-	-	-	-	-	-	-
Moisture loss ³ (mg H ₂ O/l air)	-	-	-	-	6.3 (@ Vt 500ml)	6.2 (@ Vt 250ml)	6.4 (@ Vt 50ml)	6.4 (@ Vt 50ml)	10.8 (@ Vt 500ml)
Moisture output (mg H ₂ O/l air)	-	-	-	-	37.7	37.8	37.6	37.6	33.2
Resistance (mbar)	1.5 at 30 l/min 3.2 at 60 l/min 5.4 at 90 l/min	0.7 at 30 l/min 1.7 at 60 l/min 3.2 at 90 l/min	1.0 at 30 l/min 2.2 at 60 l/min 3.7 at 90 l/min	0.6 at 30 l/min 1.5 at 60 l/min 2.6 at 90 l/min	0.4 at 30 l/min 1.0 at 60 l/min 2.1 at 90 l/min	0.2 at 15 l/min 0.3 at 20 l/min 0.4 at 30 l/min	0.1 at 5 l/min 0.2 at 10 l/min 0.3 at 15 l/min	0.5 at 5 l/min 1.1 at 10 l/min 1.9 at 15 l/min	0.2 at 30 l/min 0.3 at 60 l/min 0.2 at 90 l/min
Maximum duration of use	24h	24h	24h	24h	24h	24h	24h	24h	24h
Housing material	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent	Polypropylene transparent	Styrene-butadiene transparent	Polypropylene transparent
Housing height (mm)	93.1	65.1	78.4	67.1	78.5	72.0	58.2	36.6	29.6
Housing diameter (mm)	68.5	80.0	68.5	68.5	68.5	48.1	36.8	19.0	34.0
Product	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free	PVC free Latex free
Weight (g)	42	29	25	23	28	18	9	3.5	4.5
Sampling port	Luer lock	Luer lock	Luer lock	Luer lock	Luer lock	Luer lock	Luer lock	-	O ₂ port
Cap of sampling port	tethered	tethered	tethered	tethered	tethered	tethered	tethered	-	-
Connector patient side	22M / 15F	22M / 15F	22M / 15F	22M / 15F	22M / 15F	22M / 15F	22M / 15F	15F	15F
Connector machine side	22F / 15M	22F / 15M	22F / 15M	22F / 15M	22F / 15M	22F / 15M	15M	15M	-
Shelf life	5 years	3 years	3 years	3 years	5 years	5 years	5 years	5 years	5 years
Colour code	Red	Red	Red	Red	Green	Green	-	-	-
Units/package (pcs.)	50	50	50	50	50	50	50	50	50

¹ According to Nelson Laboratories, Inc., Salt Lake City, USA

² According to EN 1822-1:1998

³ According to ISO EN 9360-1 (2000)

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