



Preventing  
healthcare associated infections  
with our *filter* portfolio





# High mortality caused by nosocomial infections and ventilation-induced lung damage

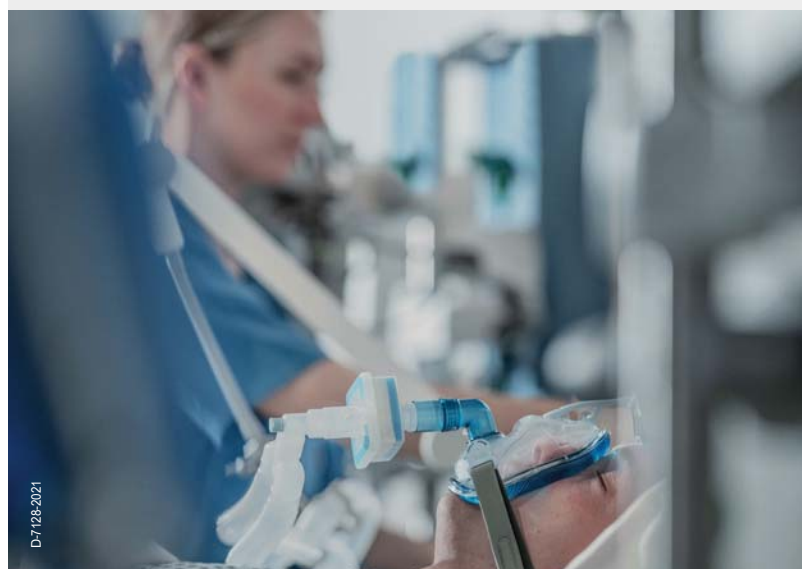
Minimising the risk of healthcare associated infections (HCAs) and avoiding the extra workload, stress and costs caused by HCAs is at the heart of improving your clinical outcomes and maintaining the hospital's reputation. To help address these concerns and decrease financial burdens, as Your Specialist in Acute Care, we support you in your fight against HCAs and assist you in improving staff and patient safety—through the entire patient pathway.

## Nosocomial infections

- Of every 100 hospitalised patients at any given time, 7 in developed and 10 in developing countries will acquire at least one health care-associated infection<sup>[1]</sup>
- 10 000–20 000 end fatally<sup>[2]</sup>
- 20–30 % of nosocomial infections could be prevented by improved hygiene<sup>[3]</sup>
- Nosocomial infections prolong hospital stay by an average of 10 days + excess cost of \$15,275 for confirmed hospital-acquired infection<sup>[4]</sup>

## Ventilator-induced lung damages

- Ventilation-induced lung injury can contribute significantly to morbidity and mortality in critically ill patients<sup>[5]</sup>
- The lack of humidification of medically administered gases leads to ventilation-induced lung damage and increased risk of infection<sup>[6]</sup>







# Reducing nosocomial infections



As a preventive measure for infection prophylaxis and avoiding the risk of cross-infection, various expert committees recommend the use of a breathing system filter

In order to avoid cross-contamination and microorganisms from entering the breathing circuit, it is advisable to place a barrier between the patient and the breathing circuit, especially when the device comes in contact with more than one patient. To protect you and your patients from getting in contact with contiguous bacteria and viruses, this barrier must be a filter which lets air pass but holds back microorganisms to the highest possible degree. Moreover, to ensure that your device is functioning at its most optimal against microorganisms, a filter is recommended on the device side whenever possible, thus protecting your staff at all times.

## Filtration Efficiency

In order to protect your patient and their surroundings, filtration efficiency is a significant parameter that ensures the avoidance of cross-contamination and infection prophylaxis. Filters have two main parameters: bacterial filtration efficiency (BFE) and viral filtration efficiency (VFE). Those two parameters are both decisive for the filtration efficiency as they indicate different things. BFE refers to how efficient the medium is in filtrating bacteria (larger in size), whereas VFE refers to how efficient the medium is in filtrating viruses (smaller in size).

## Dead space

When administering artificial ventilation, dead space is a vital parameter to monitor. This is because it represents the volume of ventilated air that does not participate in gas exchange. Therefore, the design of filters and HME (Heat and Moisture Exchanger) must ensure a small dead space while at the same time permit high filtration and HME performance with minimal resistance. We design our filters and HME with these requirements in mind so as to ensure a high-performance beneficial flow.

# Humidification to support lung-protective ventilation



Why is humidity important in ventilation therapies?

It's all about giving patients the most comfortable treatment to improve patient comfort and safety. Thus the right humidification of inspired gas in mechanical ventilation is an essential part in your daily routines. In patients receiving respiratory support therapy, the natural humidification process is often overwhelmed or even completely bypassed.

## Challenges possibly caused by dry inspired air

- ① Drying out of mucosa and hypothermia, resulting in viscous mucus
- ② Slowdown of the mucociliary transport system (contaminants aren't removed)
- ③ Higher infection risk
- ④ Impairment of surfactant activity
- ⑤ Higher risk of air trapping, hyperinflation and atelectasis
- ⑥ Possible degradation of gas exchange due to changes in lung
- ⑦ Compliance and airway patency
- ⑧ Increased airway workload

To improve outcomes in patients requiring ventilation therapy, all types of mechanical ventilation, artificial humidification, and warming of the inhaled air are recommended.





## Medical gas for ventilation has a low temperature and low humidity

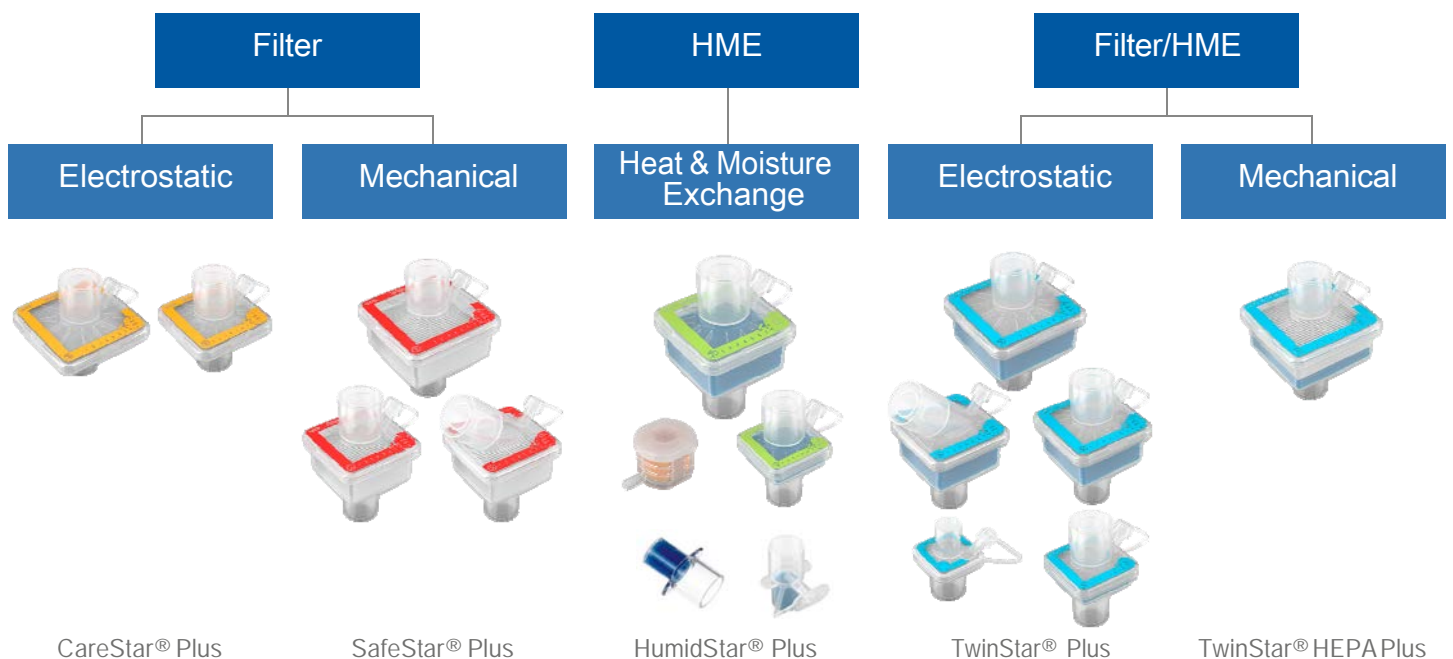
In some cases, patients receiving respiratory support therapy, the natural humidification process is often bypassed. During mechanical ventilation, the breathing gas used is much colder ( $\sim 15^{\circ}\text{C}$ ) and dryer than the ambient atmosphere. When patients are intubated near the carina, this gas enters the lungs at a much lower temperature level. At this point, the gas can no longer be substantially humidified before it is distributed further into the lungs. This can have a negative effect on the pulmonary immune system: secretions tend to thicken, inhibiting their gas transport and clearance. Surfactant function is also negatively influenced, and the overall airway workload is increased.<sup>[7]</sup> To address these concerns and improve outcomes, the sufficient humidification and warming of breathing gas can significantly help counteract these negative effects and reduce the rate of ventilator-associated lung injuries (VALI).<sup>[8]</sup>

With the utilisation of our technologies like the heat and moisture exchanger (HME), you can support your patient with a safe protective lung ventilation strategy. HMEs collect and store moisture from the expiratory phase of breathing and return a portion of both to the breathing gas during the inspiratory phase. This enables you to remarkably improve the conditions of inhaled gas (gas temperature:  $\sim 25\text{-}30^{\circ}\text{C}$ , increased humidity) and protect the respiratory epithelium.<sup>[9]</sup>

# Our filters/HMEs for all your clinical applications and needs

## Filter/HME for all applications

Choosing the right filter application can have a significant impact on the success of patient ventilation therapies and recovery. As your Specialist in Acute Care, we offer you an extensive portfolio of high-quality breathing system solutions for all applications—supporting you with all your clinical needs.



## Manufacturing quality

- 1 Ensured quality thanks to fully automated production
- 2 Fully automated testing of every filter during the production processes
- 3 Clean room classified production (clean room class 8, acc. ISO 14644-1)
- 4 Sustainable production thanks to optimised production and logistic processes to reduce emissions
- 5 Production based in Lübeck, Germany



ST-5499-2016

# Quality at every corner

## Specialist quality

As a healthcare professional, you value quality when delivering ventilation therapy. This is why we test our products extensively for both quality and compatibility. As Your Specialist in Acute Care, we look back on more than 130 years of experience and expertise in the field of filtration. In order to protect your patients, staff and medical equipment from bacterial and viral contaminants, we know how important reliable filtration is in lung protection strategies.

## Product quality

Being able to rely on the quality of medical equipment is a needed prerequisite to fully concentrate on the application of therapies. We provide you with high quality filters for different fields of application.

- High bacterial -/ viral retention rates of up to >99.9999 %
- Standardised connectors provide proper and easy connection with other components of the ventilation circuit to simplify workflows
- Equipped with a 45° angled Luer-Lock connector for gas sampling to facilitate handling for clinical staff
- 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
- Writable surface to easily document time of filter application and usage time to improve operating lives of system components and to ensure high filtration performance
- Lightweight product design to enhance patient comfort

## Portions quality

We make it possible for you to enable high quality therapy—all from a single source. Freeing you of routine tasks by streamlining and facilitating your hospital processes and workflows, reducing staff stress and unnecessary costs by offering you tailor-made solutions, at the end of the day it means giving you more time to care for your patients' wellbeing and recovery.

## Innovation quality

Our common goal is to optimise your workflows by equipping you with innovative medical equipment that facilitates clinical processes so as to save you time and simplify handling. That's why we put much effort into the innovation and design of our filters—to help you achieve these goals:

### Application safety



### Variety of applications



- Clear visibility of filter type and clear visibility of deadspace to ensure the right filter for each application

### Infection prevention



### Innovation



- Clear visibility of single use disposable product and writable surface to easily document time of filter application



# Reliable quality for every emergency

D-7145-2021



CareStar® Plus Electrostatic Filter Family



red dot winner 2022

## Managing cost of high quality care with CareStar® Plus

Managing cost of care and at the same time delivering high quality therapies to improve patient outcomes are two main objectives in today's hospital environment. Together with you, we assist you in combining these objectives so that you can focus more on caring for your patients. Our CareStar Plus breathing system filters provide an excellent and cost-efficient solution. Due to its highperforming electrostatic filtration medium, CareStar Plus protects the patient from potentially present microorganisms in the inspired air as well as the ventilator breathing system from airborne microorganisms that the patient exhales. This reduces the risk of possible cross-infection and promotes patient and staff safety.

### Emergency handling

- Blister packaging for quick application
- Lightweight to improve patient comfort
- Clear color coding
- Simple secure LuerLock port for quick connection of the Sample Line



### Economically attractive

- Cost-effective filter for protection
- Very good filtration performance
- Bacterial retention:  $\geq 99.99\%$
- Viral filtration:  $\geq 99.9\%$

# Increased safety to avoid cross- contamination



D-7/15-2021



SafeStar® Plus Mechanical Filter Family



## Improve patient outcomes by preventing HCAI

Preventing patients from acquiring a healthcare associated infection (HCAI), especially when they are that their most vulnerable, is a major undertaking in your daily work. It is also an issue that carries an immense financial burden for your institution. Our new SafeStar Plus mechanical HEPA breathing system filters meet high standards for infection prophylaxis in ventilation. The active medium here is a hydrophobic filter membrane of coated glass fibres developed specifically for this purpose. Due to its hydrophobicity, potentially contaminated fluids (e.g. blood, sputum and condensate) cannot pass through SafeStar Plus filters under the normal pressure conditions of mechanical ventilation. As a result, SafeStar Plus can inhibit the passage of fluid-borne microorganisms. Furthermore, SafeStar Plus' mechanical medium has high bacterial and viral filtration efficiency rates that considerably reduce the passage of airborne microorganisms. This significantly helps to decrease the risk of possible cross-infection. We aim to support you to achieve the goals of preventing HCAI and managing cost of care—at the same time.

### Performance

- Excellent bacterial filtration:  $\geq 99.999\%$
- Excellent virus filtration rate:  $\geq 99.999\%$

### Application variety

- Wide range of applications depending on application to Y-piece, inspiratory port or expiratory port
- Extensive coverage of different tidal volumes



### Safety

- Outstanding product performance
- Cleanroom classification ISO8 (acc. ISO 14644-1)
- Safe, clean blister packaging
- Writable pad printing for safe application time

# Mechanical vs electrostatic filters



Find the right filter for your individual needs

Which is the right filter for your specific needs? Choosing the appropriate filter can be an overwhelming decision. That is why we want to help you have a clear understanding of the differences between these filter varieties.

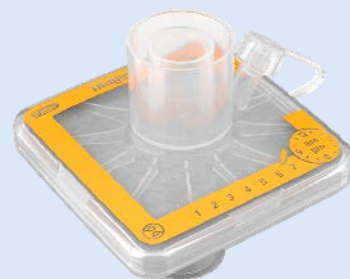
## Mechanical filters = high performance

- Irregular grid of fibrers
- No defined average pore size
- Rather tightly woven
- Typically glass/ceramic fibrers, resin bound
- Thin filter paper, pleated to yield high surface area (often named “pleated” filter)



## Electrostatic filters = good performance

- Irregular grid of fibres
- No defined average pore size
- Rather loosely woven
- Polymeric fibrers
- One “thick” layer
- Additionally: Polarisation of fibres resulting in an electrical charge



# Our contribution to a better tomorrow

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We designed our new filter portfolio to combine quality and sustainability. This is our commitment, this is the responsibility we have for a healthier environment.



New production in Germany with European suppliers leads to a **90% reduction in annual carbon dioxide equivalent (CO<sub>2</sub>e) transport emissions**

Improved product design saves **>13 tonnes of glue** per year

All our filters are **latex, PVC, BPA and DEHP free**

Sustainable design results in **35% weight reduction** per filter housing, **saving >75 tonnes of plastic** per year

# Humidification to protect the respiratory system



HumidStar® Plus HME Filter Family



red dot winner 2022

## Humidification prevents ventilator induced lung damages

Effectively prevent lung damage induced by mechanical ventilation that involves cold and dry gases. To protect patients' respiratory system from drying out and ensuing lung damage, our HumidStar Plus HME supports to passively humidificate the air they inhale. The HME medium of our HumidStar® Plus HMEs consists of a new microporous polymer foam that was specially developed for this application as it returns a high degree of moisture. In addition, we offer the HumidStar Trach Plus for tracheostomised patients to ensure a lung protective ventilation for all patients.

### Application comfort

- Easy-to-use alternative to active humidification
- Cost effective alternative to active humidification



### Infection prevention

- Disposable product for the reduction of infection sources
- Passive humidification for lung-protective ventilation

# Increased safety and lung protection support combined

D-7/41-2021



TwinStar® Plus Combined Filter Family



## Improve your patient outcomes: Filtration and humidification at the same time

Offering patients a comfortable and quick recovery while managing cost of care are clinical goals you strive for every day. As Your Acute Care Specialist, we designed our TwinStar Plus breathing system filters/HMEs to combine all the advantages of our filter and HME portfolio—to help you save on costs and promote patient healing. 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. Our TwinStar Plus portfolio supports the protection of your patient from potentially present microorganisms in the inspired air as well as safeguards the ventilator breathing system from airborne microorganisms that the patient exhales. To further increase patient safety, the TwinStar HEPA Plus is highlighted by a hydrophobic filter membrane of coated glass fibre.

### Optimal combination

- Economic solution through combination of HME and electrostatic/mechanical filter
- Excellent filtration and highly effective humidification performance combined

### Application variety

- Wide range of applications depending on application to Y-piece, inspiratory port or expiratory port
- Extensive coverage of different tidal volumes depending on patient group








### HEPA classification






- High-efficiency particulate filter with very good separation efficiency for increased safety

Product name		Filter SafeStar® 55 Plus	Filter SafeStar® 60A Plus	Filter SafeStar® 90 Plus	Filter/HME TwinStar® 90 Plus	Filter/HME TwinStar® HEPA Plus
Part-no.		MP05790	MP05795	MP05785	MP05800	MP05801
Patient category		Adult	Adult	Adult	Adult	Adult
Recommended tidal volume		300 - 1500 mL	300 - 1500 mL	300 - 1500 mL	300 - 1500 mL	300 - 1500 mL
PVC & DEHP free?		Yes	Yes	Yes	Yes	Yes
Latex free?		Yes	Yes	Yes	Yes	Yes
Lead (Pb) free?		Yes	Yes	Yes	Yes	Yes
Polyester free?		Yes	Yes	Yes	Yes	Yes
Reusable / Disposable?		Disposable	Disposable	Disposable	Disposable	Disposable
Reprocessing / Cleaning		No	No	No	No	No
Maximum duration of use (hours)		24	24	24	24	24
Performance Data	Deadspace (ml)	55	60	90	90	90
	Filtration Efficiency (%) (Non-Conditioned)*	≥99.709%	≥99.906 %	≥99.904 %	≥99.00 %	≥99.891 %
	Bacterial retention (%)	≥99.999 %	≥99.999 %	≥99.9999 %	≥99.99 %	≥99.9999 %
	Viral retention (%)	≥99.999 %	≥99.9999 %	≥99.999 %	≥99.9 %	≥99.9999 %
	Moisture Loss (mg H <sub>2</sub> O/L air)	---	---	---	≤5.9 at VT=500 mL	≤10.9 at VT=500 mL
	Moisture Output (mg H <sub>2</sub> O/L air)	---	---	---	≥38.1 at VT=500 mL	≥33.1 at VT=500 mL
	Filtration method	Mechanical	Mechanical	Mechanical	Electrostatic	Mechanical
	Leakage @70mbar (ml/min)	≤5	≤5	≤5	≤5	≤5
	Compliance @60mbar	≤1	≤1	≤1	≤1	≤1
	Compliance @30mbar	≤1	≤1	≤1	≤1	≤1
	Resistance 2.5 L/min	≤0.3 mbar	≤0.3 mbar	≤0.3 mbar	≤0.3 mbar	≤0.3 mbar
	Resistance 5 L/min	≤0.4 mbar	≤0.4 mbar	≤0.3 mbar	≤0.3 mbar	≤0.4 mbar
	Resistance 15 L/min	≤1.1 mbar	≤1.1 mbar	≤0.7 mbar	≤0.6 mbar	≤0.8 mbar
	Resistance 30 L/min	≤2 mbar	≤2 mbar	≤1.3 mbar	≤1 mbar	≤1.6 mbar
Resistance 60 L/min	≤4.2 mbar	≤4.2 mbar	≤2.8 mbar	≤2 mbar	≤3.3 mbar	
Resistance 90 L/min	≤6.7 mbar	≤6.7 mbar	≤4.6 mbar	≤3.5 mbar	≤5.2 mbar	
Sampling port	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap	
Connections towards device		22F/15M	22F/15M	22F/15M	22F/15M	22F/15M
Connections towards patient		22M/15F	22M/15F	22M/15F	22M/15F	22M/15F
General comment on connections		---	angled connector	---	---	---
Length (mm)		55	55	64	64	64
Width (mm)		55	55	64	64	64
Height (mm)		80.8	91.5	76.8	76.8	76.8
Weight (g)		20.8	22.8	27.3	22.2	26.8
during operation	Temperature range	5 to 40 °C (41 to 104 °F)	5 to 40 °C (41 to 104 °F)	5 to 40 °C (41 to 104 °F)	5 to 40 °C (41 to 104 °F)	5 to 40 °C (41 to 104 °F)
	Relative humidity range	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)
	Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)
	Temperature range	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)
	Relative humidity range	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)
	Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)
	Temperature range	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)
	Relative humidity range	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)
	Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)
Is the packaging material PVC free?		Yes	Yes	Yes	Yes	Yes
Is the packaging material Latex free?		Yes	Yes	Yes	Yes	Yes
Sterile? Non-Sterile?		non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**
Hygienic production and packaging conditions						
Packing unit		100	100	100	100	100
Country of origin		Germany	Germany	Germany	Germany	Germany
Overall Shelf Life of the product (in years)		5	5	5	3	5

\*filters tested in unused state | \*\*product is manufactured in clean room class ISO 8 acc. EN 14644-1:2015






For more details see IFU of the products - Not all articles are available worldwide

Product name		Filter/HME TwinStar® 55 Plus	Filter/HME TwinStar® 60A Plus	Filter/HME TwinStar® 25 Plus	Filter/HME TwinStar® 9 Plus	Filter CareStar® 20 Plus
						
Part-no.		MP05805	MP05810	MP05815	MP05820	MP05770
Patient category		Adult	Adult	Pediatric	Pediatric/Neonatal	Adult/Pediatric
Recommended tidal volume		300 - 1500 mL	300 - 1500 mL	100 - 500 mL	30 - 150 mL	100 - 500 mL
PVC & DEHP free?		Yes	Yes	Yes	Yes	Yes
Latex free?		Yes	Yes	Yes	Yes	Yes
Lead (Pb) free?		Yes	Yes	Yes	Yes	Yes
Polyester free?		Yes	Yes	Yes	Yes	Yes
Reusable / Disposable?		Disposable	Disposable	Disposable	Disposable	Disposable
Reprocessing / Cleaning		No	No	No	No	No
Maximum duration of use (hours)		24	24	24	24	24
Performance Data	Deadspace (ml)	55	60	25	9	20
	Filtration Efficiency (%) (Non-Conditioned)*	≥98.46 %	≥98.80 %	≥98.74 %	≥97.07 %	≥99.551 %
	Bacterial retention (%)	≥99.99 %	≥99.99 %	≥99.98 %	≥99.99 %	≥99.99 %
	Viral retention (%)	≥99.9 %	≥99.9 %	≥99.9 %	≥99.9 %	≥99.9 %
	Moisture Loss (mg H <sub>2</sub> O/L air)	≤9.4 at VT=500 mL	≤6.3 at VT=500 mL	≤11.8 at VT=250 mL	≤10.3 at VT=50 mL	---
	Moisture Output (mg H <sub>2</sub> O/L air)	≥34.6 at VT=500 mL	≥37.7 at VT=500 mL	≥32.2 at VT=250 mL	≥33.7 at VT=50 mL	---
	Filtration method	Electrostatic	Electrostatic	Electrostatic	Electrostatic	Electrostatic
	Leakage @70mbar (ml/min)	≤5	≤5	≤5	≤5	≤5
	Compliance @60mbar	≤1	≤1	≤1	≤1	≤1
	Compliance @30mbar	≤1	≤1	≤1	≤1	≤1
	Resistance 2.5 L/min	≤0.3 mbar	≤0.3 mbar	≤0.3 mbar	≤0.3 mbar	≤0.3 mbar
	Resistance 5 L/min	≤0.3 mbar	≤0.3 mbar	≤0.4 mbar	≤0.6 mbar	≤0.3 mbar
	Resistance 15 L/min	≤0.7 mbar	≤0.7 mbar	≤1.1 mbar	≤1.5 mbar	≤0.7 mbar
	Resistance 30 L/min	≤1.3 mbar	≤1.3 mbar	≤1.8 mbar	≤3.3 mbar	≤1.3 mbar
Resistance 60 L/min	≤3 mbar	≤3 mbar	≤3.8 mbar	≤7.2 mbar	≤2.8 mbar	
Resistance 90 L/min	≤4.9 mbar	≤4.9 mbar	≤6.2 mbar	≤12.3 mbar	≤4.8 mbar	
Sampling port	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap	
Connections towards device		22F/15M	22F/15M	22F/15M	22F/15M	22F/15M
Connections towards patient		22M/15F	22M/15F	22M/15F	22M/15F	22M/15F
General comment on connections		---	angled connector	---	---	---
Length (mm)		55	55	44	34	55
Width (mm)		55	55	44	34	55
Height (mm)		62	87.5	76.8	43.8	62
Weight (g)		17.6	19.3	12.4	7.1	14
during operation	Temperature range	5 to 40 °C (41 to 104 °F)	5 to 40 °C (41 to 104 °F)	5 to 40 °C (41 to 104 °F)	5 to 40 °C (41 to 104 °F)	5 to 40 °C (41 to 104 °F)
	Relative humidity range	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)
	Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)
during storage	Temperature range	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)
	Relative humidity range	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)
	Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)
during transport	Temperature range	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)
	Relative humidity range	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)
	Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)
Is the packaging material PVC free?		Yes	Yes	Yes	Yes	Yes
Is the packaging material Latex free?		Yes	Yes	Yes	Yes	Yes
Sterile? Non-Sterile?		non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**
Hygienic production and packaging conditions						
Packing unit		100	100	100	100	100
Country of origin		Germany	Germany	Germany	Germany	Germany
Overall Shelf Life of the product (in years)		3	3	3	3	3

Product name		Filter CareStar®35Plus	HME HumidStar®55Plus	HME HumidStar®25Plus	HME HumidStar® 2 Plus	HME HumidStar® 2 Plus Luer-Lock	
							
Part-no.		MP05755	MP05730	MP05735	MP05845	MP05840	
Patient category		Adult	Adult	Pediatric	Neonatal	Neonatal	
Recommended tidal volume		300 - 1500 mL	300 - 1500 mL	100 - 500 mL	10 - 50 mL	10 - 50 mL	
PVC & DEHP free?		Yes	Yes	Yes	Yes	Yes	
Latex free?		Yes	Yes	Yes	Yes	Yes	
Lead (Pb) free?		Yes	Yes	Yes	Yes	Yes	
Polyester free?		Yes	Yes	Yes	Yes	Yes	
Reusable / Disposable?		Disposable	Disposable	Disposable	Disposable	Disposable	
Reprocessing / Cleaning		No	No	No	No	No	
Maximum duration of use (hours)		24	24	24	24	24	
Performance Data		Deadspace (ml)	35	55	25	2	
		Filtration Efficiency (%) (Non-Conditioned)*	≥99.217 %	---	---	---	---
		Bacterial retention (%)	≥99.99 %	---	---	---	---
		Viral retention (%)	≥99.9 %	---	---	---	---
		Moisture Loss (mg H2O/L air)	---	≤7.8 at VT=500 mL	≤9.3 at VT=250 mL	≤11.5 at VT = 45 mL	≤11.5 at VT = 45 mL
		Moisture Output (mg H2O/L air)	---	≥36.2 at VT=500 mL	≥34.7 at VT=250 mL	≥32.5 at VT=45 mL	≥32.5 at VT=45 mL
		Filtration method	Electrostatic	none	none	none	none
		Leakage @70mbar (ml/min)	≤5	≤5	≤5	≤1	≤2
		Compliance @60mbar	≤1	≤1	≤1	≤1	≤1
		Compliance @30mbar	≤1	≤1	≤1	≤1	≤1
		Resistance 2.5 L/min	≤0.3 mbar	≤0.3 mbar	≤0.3 mbar	≤0.3 mbar	≤0.3 mbar
		Resistance 5 L/min	≤0.3 mbar	≤0.3 mbar	≤0.3 mbar	≤1 mbar	≤1 mbar
		Resistance 15 L/min	≤0.6 mbar	≤0.3 mbar	≤0.3 mbar	≤1.2 mbar	≤3.5 mbar
		Resistance 30 L/min	≤0.9 mbar	≤0.6 mbar	≤0.3 mbar	≤3.2 mbar	≤3.5 mbar
Resistance 60 L/min	≤2 mbar	≤1 mbar	≤0.9 mbar	≤11.5 mbar	≤12 mbar		
Resistance 90 L/min	≤3.5 mbar	≤2 mbar	≤1.5 mbar	≤25 mbar	≤27 mbar		
Sampling port	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap	---	Luer-Lock with tethered cap		
Connections towards device		22F/15M	22F/15M	22F/15M	15M	15M	
Connections towards patient		22M/15F	22M/15F	22M/15F	15F	15F	
General comment on connections		---	---	---	---	---	
Length (mm)		64	55	44	---	---	
Width (mm)		64	55	44	---	---	
Height (mm)		62	80.8	76.8	---	---	
Weight (g)		16.8	17	12.2	2.8	3.2	
during operation		Temperature range	5 to 40 °C (41 to 104 °F)	5 to 40 °C (41 to 104 °F)	5 to 40 °C (41 to 104 °F)	5 to 40 °C (41 to 104 °F)	
		Relative humidity range	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	
		Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	
during storage		Temperature range	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	
		Relative humidity range	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	
		Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	
during transport		Temperature range	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	
		Relative humidity range	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	
		Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	
Is the packaging material PVC free?		Yes	Yes	Yes	Yes	Yes	
Is the packaging material Latex free?		Yes	Yes	Yes	Yes	Yes	
Sterile? Non-Sterile?		non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	---	non-sterile; assembled in clean environment**	
Hygienic production and packaging conditions		---	---	---	---	---	
Packing unit		100	100	100	100	100	
Country of origin		Germany	Germany	Germany	Sweden	Sweden	
Overall Shelf Life of the product (in years)		3	5	5	5	5	

\*filters tested in unused state | \*\*product is manufactured in clean room class ISO 8 acc. EN 14644-1:2015

For more details see IFU of the products - Not all articles are available worldwide

Product Information in General		HME HumidStar® Trach Plus	CombiStar Filter HME	CombiStar Filter HME flex	CombiStar F-HME HEPA flex	CombiStar mechanical Filterflex	
Product name							
Part-no.		MP05750	MP12060	MP12061	MP12062	MP12063	
Patient category		Adult/Pediatric	Adult	Adult	Adult	Adult	
Recommended tidal volume		100 - 1500 mL	---	---	---	---	
PVC & DEHP free?		Yes	Yes	Yes	Yes	Yes	
Latex free?		Yes	Yes	Yes	Yes	Yes	
Lead (Pb) free?		Yes	Yes	Yes	Yes	Yes	
Polyester free?		Yes	Yes	Yes	Yes	Yes	
Reusable / Disposable?		Disposable	Disposable	Disposable	Disposable	Disposable	
Reprocessing / Cleaning		No	No	No	No	No	
Maximum duration of use (hours)		24	24	24	24	24	
Performance Data	Deadspace (ml)	6	Check individual components	Check individual components	Check individual components	Check individual components	
	Filtration Efficiency (%) (Non-Conditioned)*	---	≥98.46%	≥98.46%	≥99.891%	≥99.709%	
	Bacterial retention (%)	---	≥99.99 %	≥99.99%	≥99.9999 %	≥99.999 %	
	Viral retention (%)	---	≥99.9 %	≥99.9 %	≥99.9999 %	≥99.999 %	
	Moisture Loss (mg H <sub>2</sub> O/L air)	≤10.8 at Vt=250 mL ≤14.4 at Vt=500 mL	≤9.4 at VT=500 mL	≤9.4 at VT=250 mL	≤10.9 at VT=50 mL	---	
	Moisture Output (mg H <sub>2</sub> O/L air)	≥29.6 at VT=500 mL	≥34.6 at VT=500 mL	≥34.6 at VT=250 mL	≥33.1 at VT=50 mL	---	
	Filtration method	none	Electrostatic	Electrostatic	Mechanical	Mechanical	
	Leakage @70mbar (ml/min)	n/a	Check individual components	Check individual components	Check individual components	Check individual components	
	Compliance @60mbar	n/a					
	Compliance @30mbar	n/a					
	Resistance 2.5 L/min	n/a					
	Resistance 5 L/min	n/a					
	Resistance 15 L/min	n/a					
	Resistance 30 L/min	≤0.1					
Resistance 60 L/min	≤0.3						
Resistance 90 L/min	≤0.6	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap		
Sampling port	---	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap		
Connections towards device		---	22F/15M	22F/15M	22F/15M	22F/15M	
Connections towards patient		15F	22M/15F	22M/15F	22M/15F	22M/15F	
General comment on connections		---	---	---	---	---	
Length (mm)		---	---	---	---	---	
Width (mm)		---	---	---	---	---	
Height (mm)		---	---	---	---	---	
Weight (g)		6	---	---	---	---	
during operation	Temperature range	5 to 40 °C (41 to 104 °F)	10 to 40 °C (50 to 104 °F)	10 to 40 °C (50 to 104 °F)	10 to 40 °C (50 to 104 °F)	10 to 40 °C (50 to 104 °F)	
	Relative humidity range	5 to 95% (non-condensing)	5 to 95 % (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	
	Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	
	during storage	Temperature range	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)
		Relative humidity range	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)
		Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)
	during transport	Temperature range	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)	-20 to 60 °C (-4 to 140 °F)
		Relative humidity range	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)	5 to 95% (non-condensing)
		Air pressure range	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)	570 to 1200 hPa (8.3 to 17.4 psi)
Is the packaging material PVC free?		Yes	Yes	Yes	Yes	Yes	
Is the packaging material Latex free?		Yes	Yes	Yes	Yes	Yes	
Sterile? Non-Sterile?		---	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	
Hygienic production and packaging conditions		---	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	non-sterile; assembled in clean environment**	
Packing unit		100	25	25	25	25	
Country of origin		Sweden	Check individual components	Check individual components	Check individual components	Check individual components	
Overall Shelf Life of the product (in years)		5	2	2	2	2	

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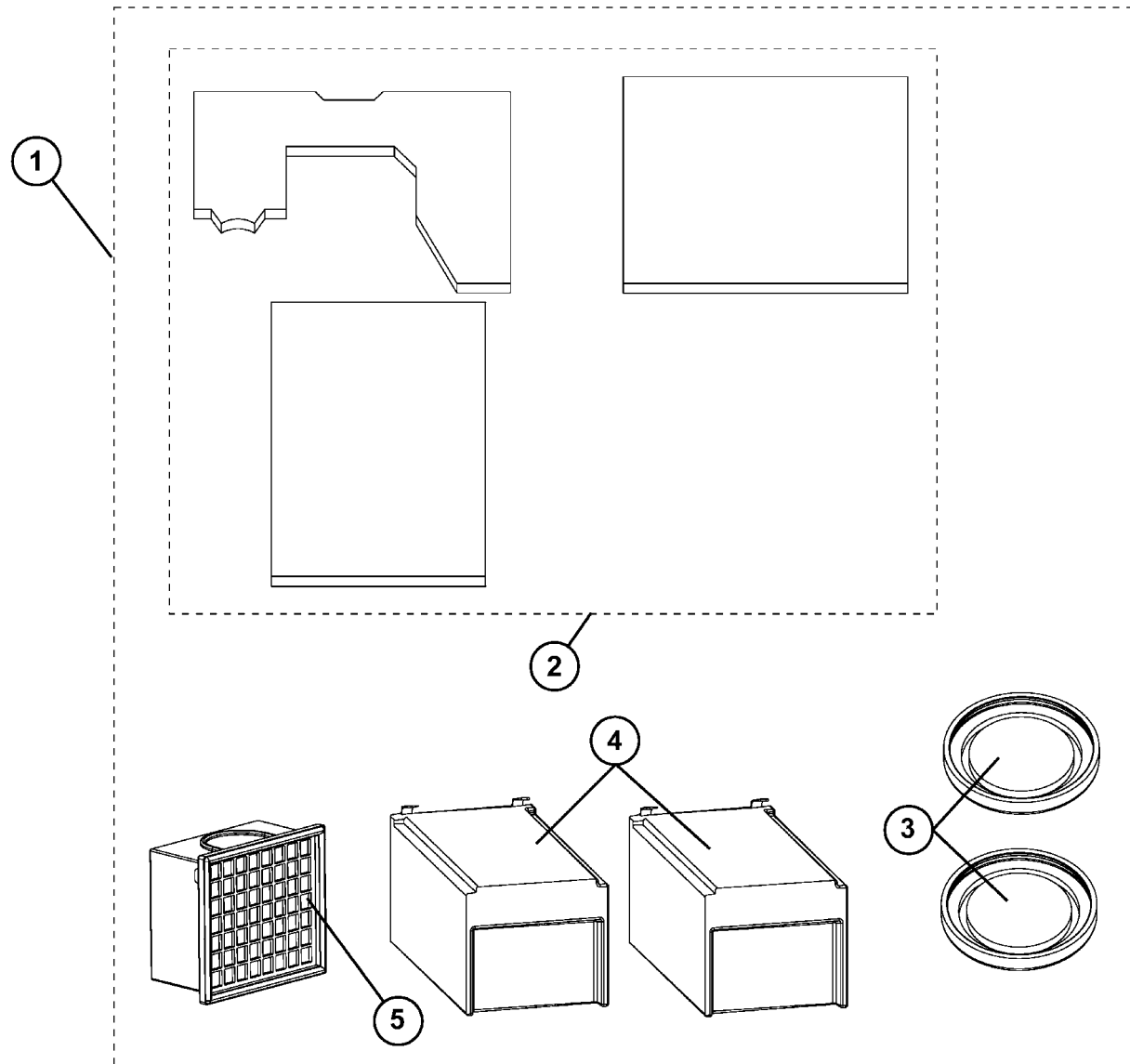
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