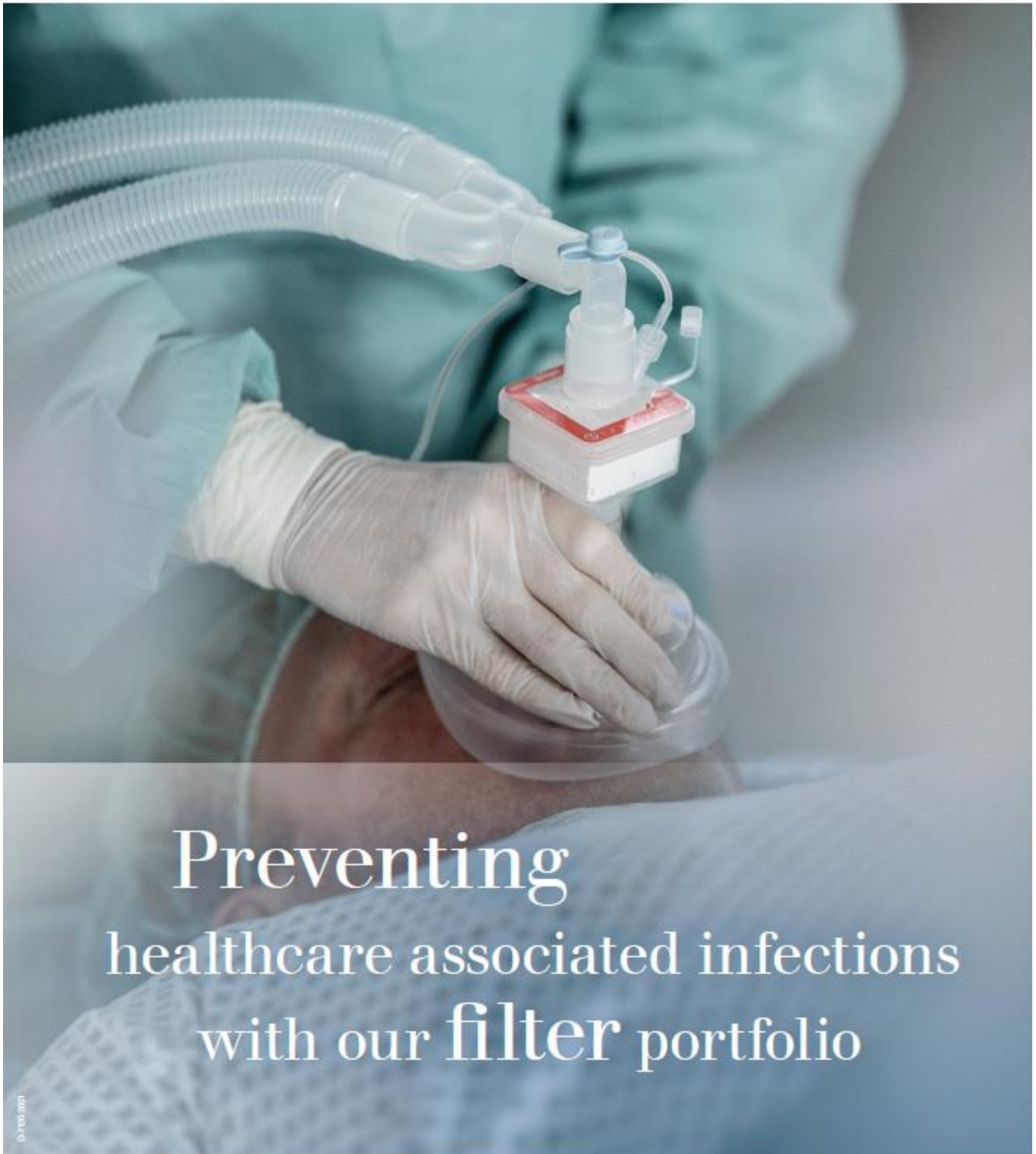
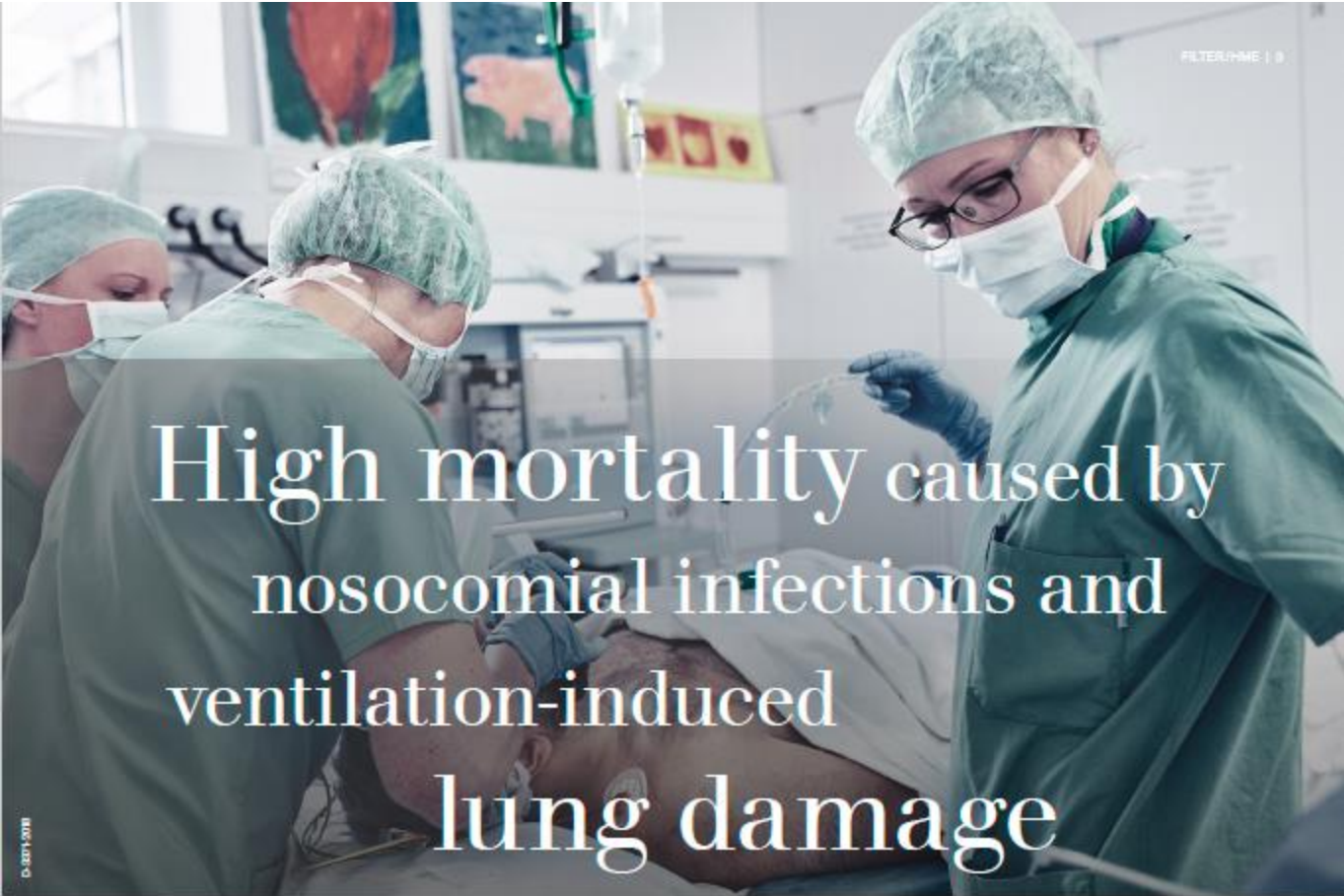




Preventing
healthcare associated infections
with our filter portfolio





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

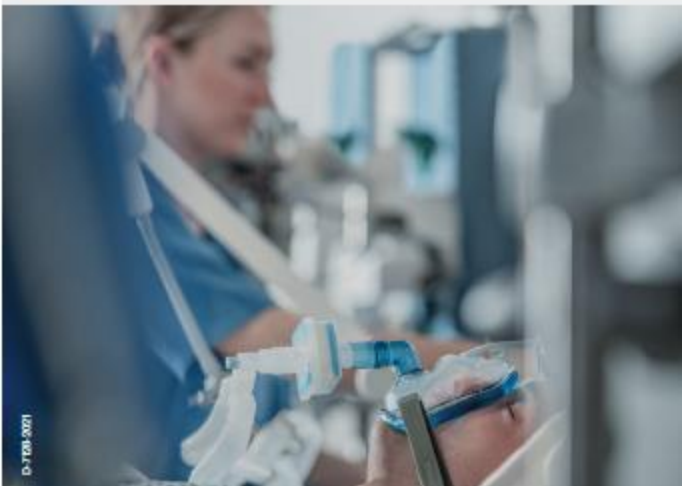
Minimising the risk of healthcare associated infections (HCAIs) and avoiding the extra workload, stress and costs caused by HCAIs is at the heart of improving your clinical outcomes and maintaining the hospital's reputation. To help address these concerns and decrease financial burdens, as Your Specialist in Acute Care, we support you in your fight against HCAIs 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^[1]
- 10 000–20 000 end fatally^[2]
- 20–30 % of nosocomial infections could be prevented by improved hygiene^[3]
- Nosocomial infections prolong hospital stay by an average of 10 days + excess cost of \$15,275 for confirmed hospital-acquired infection^[4]

Ventilator-induced lung damages

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



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

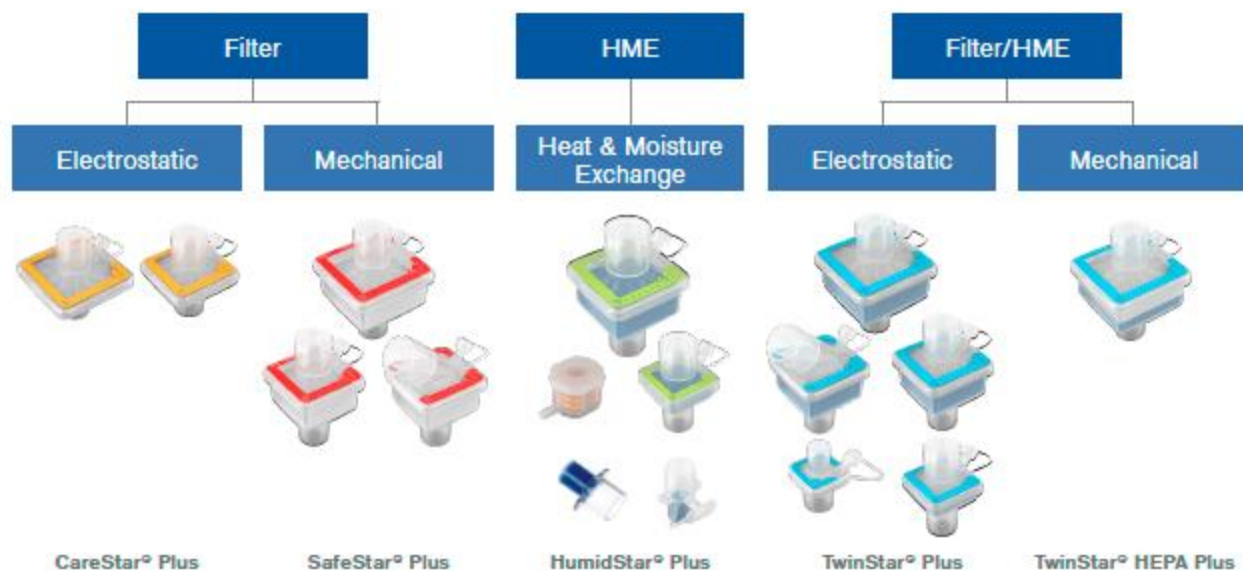
In some cases, patients receiving respiratory support therapy, the natural humidification process is often bypassed. During mechanical ventilation, the breathing gas used is much colder ($\sim 15^{\circ}\text{C}$) and dryer than the ambient atmosphere. When patients are intubated near the carina, this 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.^[7] 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).^[8]

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.^[9]

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.



Reliable quality for every emergency

0-1165 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

D71165031



SafeStar® Plus Mechanical Filter Family



reddot winner 2022

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 ISO 8 (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.

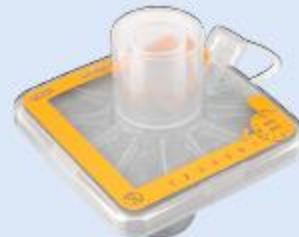
Mechanical filters = high performance

- 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 fibers resulting in an electrical charge



Humidification to protect the respiratory system



HumidStar® Plus HME Filter Family



reddot 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



TwinStar® Plus Combined Filter Family



reddot winner 2022

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 Information in General		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
Product specific information						
Performance Data	Deadspace (ml)	55	60	90	90	90
	Filtration Efficiency (%) (Non-Conditioned)*	≥99.700 %	≥99.906 %	≥99.904 %	≥99.00 %	≥99.801 %
	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 ₂ O/L air)	---	---	---	≤5.9 at VT=500 mL	≤10.9 at VT=500 mL
	Moisture Output (mg H ₂ 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
Connection	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	---	---	---
Product Size	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
Environmental conditions	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)
Packaging/Logistics	Is the packaging material PVC free?		Yes	Yes	Yes	Yes
	Is the packaging material Latex free?		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
	Country of origin		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 Information in General		Product name					
		Part-no.	MP05805	MP05810	MP05815	MP05820	MP05770
		Patient category	Adult	Adult	Pediatric	Pediatric/Neonatal	Pediatric
		Recommended tidal volume	300 - 1500 mL	300 - 1500 mL	100 - 500 mL	30 - 150 mL	100 - 500 mL
		PVC & DEHP free? Latex free? Lead (Pb) free? Polyester free?	Yes Yes Yes Yes	Yes Yes Yes Yes	Yes Yes Yes Yes	Yes Yes Yes Yes	Yes Yes Yes Yes
Use	Reusable / Disposable?	Disposable	Disposable	Disposable	Disposable	Disposable	
	Reprocessing / Cleaning	No	No	No	No	No	
	Maximum duration of use (hours)	24	24	24	24	24	
Product specific information	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 H2O/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 H2O/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 Compliance @30mbar	≤1 ≤1	≤1 ≤1	≤1 ≤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
Connection	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	---	---	---	
Product Size	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	
Environmental conditions	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)
Packaging/Logistics	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? 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**	non-sterile; assembled in clean environment**
	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 Information in General			Filter CareStar® 35 Plus	HME HumidStar® 55 Plus	HME HumidStar® 25 Plus	HME HumidStar® 2 Plus	HME HumidStar® 2 Plus Luer-Lock	
								
Part-no.			MP06755	MP05730	MP06735	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? Latex free? Lead (Pb) free? Polyester free?			Yes Yes Yes Yes	Yes Yes Yes Yes	Yes Yes Yes Yes	Yes Yes Yes Yes	Yes Yes Yes Yes	
Use			Disposable	Disposable	Disposable	Disposable	Disposable	
Reprocessing / Cleaning			No	No	No	No	No	
Maximum duration of use (hours)			24	24	24	24	24	
Product specific information								
Performance Data			Deadspace (ml)	35	55	25	2	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 Compliance @30mbar	≤1 ≤1	≤1 ≤1	≤1 ≤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	
Connection								
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			---	---	---	---	---	
Product Size								
Length (mm)			64	65	44	---	---	
Width (mm)			64	65	44	---	---	
Height (mm)			62	80.8	76.8	---	---	
Weight (g)			16.8	17	12.2	2.8	3.2	
Environmental conditions								
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)
Packaging/Logistics								
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		Product name	HME HumidStar® Trach Plus	CombiStar Filter HME	CombiStar Filter HME flex	CombiStar F-HME HEPA flex	CombiStar mechanical Filter flex
							
		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
Use	Reusable / Disposable?		Disposable	Disposable	Disposable	Disposable	Disposable
	Reprocessing / Cleaning		No	No	No	No	No
	Maximum duration of use (hours)		24	24	24	24	24
Product specific information	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%	≥99.991%	≥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 H2O/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 H2O/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				
		Sampling port	---	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap	Luer-Lock with tethered cap
Connection	Connections towards device		---	22F/15M	22F/15M	22F/15M	22F/15M
	Connections towards patient		16F	22M/15F	22M/15F	22M/15F	22M/15F
	General comment on connections		---	---	---	---	---
Product Size	Length (mm)		---	---	---	---	---
	Width (mm)		---	---	---	---	---
	Height (mm)		---	---	---	---	---
	Weight (g)		6	---	---	---	---
Environmental conditions	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)
Packaging/Logistics	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	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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