

SODA LIME AND RELATED ACCESSORIES

SODA LIME

A	Soda lime Drägersorb 800+, for CO₂ absorption, canister, 5 l, 2 pcs.	MX00001
B	Soda lime Drägersorb Free, for CO₂ absorption, canister, 5 l, 2 pcs.	MX50050
C	Canister opener, for canisters MX00001 and MX50050, 5 pcs.	MX10209





Drägersorb Free – Soda Lime Consumables and Accessories

Click and connect with 100% reliability. As one of the leading manufacturers of anaesthesia equipment, we believe in leading the way to producing high-quality soda lime that ensures your patients' and staff's safety to the highest degree. Drägersorb is more than just a formula, it is absorption efficiency – you can trust.

Benefits

Drägersorb Free

Soda lime is invaluable in removing CO₂ when administering anaesthesia. Moreover, ensuring the safety and comfort for both staff and patient plays a critical goal, as volatile anaesthetic compounds are used to induce patients during surgical procedures.

To optimise both safety and performance, we are the only manufacturer of anaesthesia machines that also develops and produces its own soda lime. That's why in Dräger systems, our soda lime formula is specifically designed to meet the latest requirements of anaesthesia equipment.

With Drägersorb Free, we provide you with a product that has been tested and tried to give you improved performance, while keeping your staff and patients safe during life-saving procedures.

In addition, Drägersorb Free delivers you:

- Advanced CO₂ absorption
- No formation of compound A or carbon monoxide.
- No channel formation.
- Low abrasion level, to significantly reduce dust formation.
- The elimination of decomposition products (e.g., formaldehyde).

In combination with our Drägersorb CLIC, you can improve your workflows and protect your investments, saving you costs in the long run.

Generates no Compound A

Protecting your patients from potential health risks when administering the volatile anaesthetic sevoflurane is of utmost priority. Clinical research has shown that there is a substantial drawback to using any conventional soda lime with sevoflurane due to the fact that this combination produces the toxin compound A, which studies have found to have nephrotoxic effects in animals. ²

With this safety topic in mind, we have developed Drägersorb Free. Thanks to its chemical composition, when using Drägersorb Free, you will completely eliminate the generation of compound A, regardless of the degree of humidity in the soda lime. Its optimised formula delivers you safety-conscious quality to the highest levels.

Generates no carbon monoxide: under any clinical condition

Another serious threat to patient and staff well-being is the formation of a toxic, colourless, and odourless gas – carbon monoxide. When volatile anaesthetics are used with any conventional dry soda lime, the combination results in the production of carbon monoxide. Since carbon monoxide is not measured by anaesthesia machines, it cannot be detected by your clinical staff. This toxic by-product poses a serious hazard to your induced patients.

Drägersorb Free eliminates this concern. Under any and all clinical conditions, our Drägersorb Free does not generate carbon monoxide. ^{1,2} No matter the degree of humidity in the soda lime, you can rest assured that your patients are protected through the entire induction process.

Benefits

High CO₂ absorption capacity

Safety you can see, results you can rely on. When working with patients in a critical environment, you need to count on equipment and the accessories that complement them – 100% of the time.

Our unique soda lime pellet design took us years of dedicated research and engineering. The result is an optimal shape that gives you even and effective absorption of CO₂. Our hemispherically-shaped pellet with its high porosity is designed to prevent channel formations, thus allowing optimised cartridge performance which results in long-term savings. Moreover, thanks to its clear colour change, you have a clear indication of the level of absorption and exhaustion. Our Drägersorb Free has the highest CO₂ absorption^{1,2,3} of all safe absorbents.

Practical packaging

To save you time and help you manage costs, Drägersorb Free comes in our disposable Drägersorb CLIC absorber, which can be used in all of our modern Dräger anaesthesia workstations. It is a fast, clean, and simple single-use solution that offers you flexibility and high-quality results.

You and patient are protected by:

- Zero-contact with the soda lime.
- No exposure to dust.
- Better use of absorber filling that can be changed at any time, including during surgery, thanks to its non-return valve.

Drägersorb Free is available in our disposable Drägersorb CLIC Free cartridge as well as in our 5 L refillable canister.

For anaesthesia machines with blower technology, such as Zeus Infinity Empowered or Perseus A500 from Dräger, the use of a dust filter to protect the blower technology is recommended when refillable soda lime absorbers are used.

Benefits

Helping to shape a more sustainable future

As a manufacturer of medical technology for over 130 years, we are committed to provide excellence in the quality of our products. And we are also committed and believe in taking responsibility in creating sustainable products.

We designed our Drägersorb products to combine patient safety and sustainability. That's why our Drägersorb products are free of natural latex and do not contain PVC or phthalates, e.g. DEHP (which is possibly carcinogenic to humans⁴), and why production is located in Germany with sourcing from local suppliers in Europe, to minimize the carbon footprint and related environmental impact. Furthermore we have established a recycling programme for soda lime in Germany which saves CO₂ emissions (33 tons in 2021).

This is our commitment, this is the responsibility we have for a healthier environment.

¹ Dr. Bito, Hamamatsu Med. University, Japan Journal of Clinical Anaesthesia 15:33-37, 2003

² Production of compound A and carbon monoxide in circle systems: an in vitro comparison of two carbon dioxide absorbents M.M.R.F. Struys, et al.; Anaesthesia, 2004, 59, S. 584-589

³ J. Baum, H. J. Woehlck Best Practice & Research Clinical Anaesthesiology, Vol. 17 (2003) S. 63-76

⁴ World Health Organization. Guidelines for drinking-water quality. World Health Organization. 2017. 424-425. ISBN 978-92-4-154995-0.

Details



D-27640-2017

Dust filter

Technical Data

Dust filter	MX50115
Material:	
Housing	PP Polypropylen
Fleece	Polyolefine

Ordering Information

Description	Order no.
Drägersorb Free 5-L canister	MX50050
CLIC Absorber Free (6 absorbers per box)	MX50100
Drägersorb CLIC adapter	MX50090
Infinity ID CLIC Absorber Free, disposable, 1.2 l, 6 pcs.	MX50120
Canister opener, for canisters MX00001 and MX50050, 5 pcs.	MX10209
Dust filter, 5 pcs.	MX50115

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www.draeger.com/contact

Fișa cu date de securitate în conformitate cu Regulamentul (CE) nr.1907/2006 (REACH)

000090300063_RO_RO **Drägersorb Free**

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Versiune 4.5 (ro,RO)
Înlocuiește versiunea de 02.08.2021 (4.4)

SECȚIUNEA 1: Identificarea substanței/amestecului și a societății/întreprinderii

1.1 Element de identificare a produsului

Numele comercial/denumirea **Drägersorb Free**
Art-Nr. 000090300063_RO_RO
Prod-Nr **MX50050 (5L)**; MX50100 (1,2L); MX50120 (1,2L)

Componentele periculoase pentru etichetare
hidroxid de calciu, hidroxid de sodiu

1.2 Utilizări relevante identificate ale substanței sau amestecului și utilizări contraindicate

Categoriile de utilizare

SU20 Servicii pentru sănătate
SU0 Altele

Categoriile de produse [PROC]

PROC8a Transfer de substanțe sau amestecuri (încărcare și descărcare) în unități nespecializate
Profesional:
PROC0 Altele

Categoriile de degajare în mediu [ERC]

ERC11a Utilizare larg răspândită de articole cu eliberare redusă (la interior)

Categoriile de produse [AC]

AC2 Mașini, aparatură mecanică, articole electrice/electronice

Utilizarea substanței/preparatului

Ca un absorbant de dioxid de carbon
Agenți adsorbanti și absorbanti

Utilizări nerecomandate

Nu utilizați pentru scopuri private (în gospodărie).

Remarcă

Pochlaniane dwutlenku wegla z powietrza
nici una

1.3 Detalii privind furnizorul fișei cu date de securitate

Furnizor

Dräger Romania SRL
Str. Daniel Danielopolu nr. 42 A
RO-14134 Bucharest
E-mail info@draeger.com

Domeniul responsabil cu informațiile:

Dräger Global EHS Management
Telefon +49 451 882 6979
Pagina web www.draeger.com

E-mail (persoana competentă în domeniu):

sds@draeger.com

1.4 Număr de telefon care poate fi apelat în caz de urgență

Centre anti-Poisons, National, Institute of Legal Medicine: Sos. Vitan (401) 6 34 38 90/ 1 35
Birzesti 9, Sector 4, 75669 B

SECȚIUNEA 2: Identificarea pericolelor

2.1 Clasificarea substanței sau a amestecului

Clasificare conform Procedura de clasificare
Regulamentului / Ordonanței (EG)
Nr. 1272/2008 [CLP]

Skin Irrit. 2, H315

Eye Dam. 1, H318

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Atenționari privind pericolele asupra sănătății

H315 Provoacă iritarea pielii.
H318 Provoacă leziuni oculare grave.

Remarcă

Amestecul este clasificat ca fiind periculos în acord cu Regulamentul (CE) NR. 1272/2008 [CLP].
nici una

2.2 Elemente pentru etichetă

Marcare conform Ordonanței (EG) Nr. 1272/2008 [CLP]

Componentele periculoase pentru etichetare

hidroxid de calciu, hidroxid de sodiu

Pictograme pericole



GHS05

Cuvânt de avertizare

Pericol

Frazele de pericol

H315 Provoacă iritarea pielii.
H318 Provoacă leziuni oculare grave.

Fraze de precauție

P102 A nu se lăsa la îndemâna copiilor.
P103 Citiți cu atenție și urmați toate instrucțiunile.
P260 Nu inspirați praful/fumul/gazul/ceața/vaporii/spray-ul.
P280 Purtați mănuși de protecție/îmbrăcăminte de protecție și echipament de protecție a ochilor/echipament de protecție a feței.
P301 + P330 + P331 ÎN CAZ DE ÎNGHIȚIRE: clătiți gura. NU provocați vomă.
P302 + P352 ÎN CAZ DE CONTACT CU PIELEA: spălați cu multă apă/....
P305 + P351 + P338 ÎN CAZ DE CONTACT CU OCHII: clătiți cu atenție cu apă timp de mai multe minute. Scoateți lentilele de contact, dacă este cazul și dacă acest lucru se poate face cu ușurință. Continuați să clătiți.
P410 A se proteja de lumina solară.
P411 Pastrati la temperaturi care nu depasesc 50 ° C.

Criterii de pericol suplimentare

EUH066 Expunerea repetată poate provoca uscarea sau crăparea pielii.

Reguli speciale privind elementele suplimentare de etichetare pentru anumite amestecuri

nedeterminat

Instrucțiuni speciale pentru marcarea produselor de protecție a plantelor

nu aplicabile

Instrucțiuni speciale pentru ambalare

nedeterminat

Altă marcare

nu aplicabile

2.3 Alte pericole

Posibile efecte daunatoare fizico-chimice

nedeterminat

Posibile efecte daunatoare asupra omului și simptome posibile

Pe baza valorii pH (vezi secțiunea 9) nu este de exclus o iritare a pielii și ochilor.
După inhalarea prafului se poate ajunge la iritații ale căilor respiratorii.

Posibile efecte daunatoare asupra mediului

nedeterminat

Alte efecte adverse

nedeterminat

Rezultatele evaluării PBT și vPvB

nedeterminat

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SECȚIUNEA 3: Compoziție / informații privind componentii

3.1 Substanțe

nu aplicabile

3.2 Amestecuri

Material conținând substanțe periculoase

CAS-numar	CE-Nr.	Numele substanței	Concentrație	Clasificare conform Regulamentului / Ordonanței (EG) Nr. 1272/2008 [CLP]	SCL/ M/ ATE
1305-62-0	215-137-3	hidroxid de calciu	78 - 84 %	Skin Irrit. 2; H315 Eye Dam. 1; H318 STOT SE 3; H335	
7732-18-5	231-791-2	Apa	14 - 18 %		
10043-52-4	233-140-8	calcium chloride	3 - 5 %	Eye Irrit. 2; H319	
1310-73-2	215-185-5	hidroxid de sodiu	0.5 - 2 %	Met. Corr. 1; H290 Skin Corr. 1A; H314	Skin Corr. 1A; H314: C>=5% Skin Corr. 1B; H314: 2%<=C<5% Skin Irrit. 2; H315: 0.5%<=C<2% Eye Irrit. 2; H319: 0.5%<=C<2%
2390-59-2	219-231-5	Etil violet	< 0.1 %	Skin Irrit. 2; H315 Eye Dam. 1; H318 STOT SE 3; H335	
Nr.-REACH		Numele substanței			
01-2119475151-45-033		hidroxid de calciu			
-		Apa			
01-2119457892-27-xxxx		hidroxid de sodiu			
-		Etil violet			

Remarcă
nici una

SECȚIUNEA 4: Măsuri de prim ajutor

4.1 Descrierea măsurilor de prim ajutor

Informații generale

Dezbrăcați imediat îmbrăcămintea contaminată, imbibată.

Dupa inspirație

Scoateți pe cel afectat la aer, țineți-l liniștit la cald.
Solicitați un tratament medical în cazul apariției unor tulburări.

Dupa contactul cu pielea

Se va spăla imediat cu:
Apă
În caz de iritare a pielii se va consulta un medic.

Dupa contactul cu ochii

Dupa contactul cu ochii clătiți ochii cu apă suficient de mult cu pleoapele deschise, apoi consultați imediat medicul.

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Dupa inghitire

NU provocați vomă.

Dati sa bea apa din abundenta in inghitituri mici (efect de dilutie).

4.2 Cele mai importante simptome și efecte, atât acute, cât și întârziate

Simptome

nedeterminat

Efecte

perforarea stomacului

4.3 Indicații privind orice fel de asistență medicală imediată și tratamentele speciale necesare

Indicații pentru medic

nedeterminat

SECȚIUNEA 5: Măsurile de combatere a incendiilor

5.1 Mijloace de stingere a incendiilor

Mijloace de stingere necorespunzătoare

Dioxid de carbon (CO₂)

5.2 Pericole speciale cauzate de substanța sau amestecul în cauză

Produse de ardere periculoase

nedeterminat

5.3 Recomandări destinate pompierilor

Echipament special de protecție la combaterea incendiilor

nici una

Informații suplimentare

Produsul însuși nu arde.

Măsurile de stingere corespund zonei.

Colectați separat apa de stingere contaminată. Nu lăsați să ajungă în canalizare sau în apele de suprafață.

SECȚIUNEA 6: Măsurile de luat în caz de dispersie accidentală

6.1 Precauții personale, echipament de protecție și proceduri de urgență

Pentru personalul care nu este implicat în situații de urgență

Evitarea formării de praf.

Utilizați echipament personal de protecție.

În caz de acționare a vaporilor, pulberii sau aerosolilor purtați aparat de respirație.

6.2 Precauții pentru mediul înconjurător

Se va reține apa/agentul de stingere contaminat.

Nu se va lăsa să ajungă în canalizare sau în ape, curgătoare sau nu.

6.3 Metode și material pentru izolarea incendiilor și pentru curățenie

Pentru reținere

Resturile se vor curăța cu apă.

Se va colecta mecanic și se va preda la punctele de colectare deșeurilor.

Pentru curățare

Evitarea formării de praf.

6.4 Trimiteri către alte secțiuni

Debarasare și depozitare deșeurilor: vezi secțiunea 13

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SECȚIUNEA 7: Manipularea și depozitarea

7.1 Precauții pentru manipularea în condiții de securitate

Măsuri de protecție

Stația de umplere se va aspira în timpul umplerii, reumplerii sau turnării produsului.
Evitați formarea și depunerea prafului.
Nu sunt necesare măsuri deosebite.
Se vor folosi numai echipamente rezistente la baze.
Resturile nu se vor pune în recipientele de depozitare.
Se vor respecta măsurile de precauție uzuale în timpul manipulării substanțelor chimice.
Produsul nu este:

Arde

Nu sunt necesare măsuri deosebite.

Măsuri uzuale de protecție și prevenirea incendiilor.

Evitați:

Producerea/formarea de praf

Contactul cu ochii

Contactul cu pielea

A nu se inspira praful.

Informații privind igiena generală ocupatională

Nu se va mânca, bea, fuma, fuma, trage pe nas la locul de muncă.
Dezbrăcați imediat îmbrăcămintea contaminată, imbibată.
Înainte de a face pauze și la sfârșitul lucrului spălați temeinic mainile și fața, eventual faceți dus.

7.2 Condiții de depozitare în condiții de securitate, inclusiv eventuale incompatibilități

Cerințe de spații de depozitare și recipiente

Păstrați/depozitați numai în containerul original.
A se păstra ambalajul închis ermetic.

Clasa de depozitare

13 Corpuri solide necombustibile ce nu pot fi alocate niciunei clase de depozitare descrise mai sus

Materiale de evitat

Nu depozitați împreună cu:
Acid

Alte informații referitoare la condițiile de depozitare

Păstrați numai în ambalajul original, într-un loc răcoros, bine ventilat.
Țineți departe de:
Acid
Recipientii se închid bine și se pastrează în loc răcoros, bine aerisit.
Temperatura maximă de depozitare este de 50 °C.
Se va păstra la o temperatură de 5-40 °C.
După prelevarea probelor, recipientul se va închide etanș la umezeală.
Termen redus de valabilitate; vezi fișa de date produs.

7.3 Utilizare finală specifică (utilizări finale specifice)

Recomandare:
nedeterminat

Soluții specifice branșei
nedeterminat

SECȚIUNEA 8: Controale ale expunerii/protecția personală

8.1 Parametri de control

Valori limita la locul de muncă

CAS-numar	CE-Nr.	Substanța	valoare limita la locul de muncă
1305-62-0	215-137-3	Dihidroxid de calciu	1 Respirable fraction [mg/m ³] Termen scurt(mg/m ³) 4 Respirable fraction 2017/164/EU

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CAS-numar	CE-Nr.	Substanța	valoarea limita la locul de munca
1305-62-0		Calcium hydroxide	1 (1) [mg/m ³] Termen scurt(mg/m ³) 4 (1)(2) (1) Respirable fraction (2) 15 minutes average value (RO)
1310-73-2		Sodium hydroxide	1 [mg/m ³] Termen scurt(mg/m ³) 3 (1) (1) 15 minutes average value (RO)
1305-62-0	215-137-3	hidroxid de calciu	- [ml/m ³ (ppm)] 5 [mg/m ³] Termen scurt(ml/m ³) - Termen scurt(mg/m ³) - EU

8.2 Controlul expunerii

Controale tehnice corespunzătoare

Măsuri tehnice pentru prevenirea expunerii
nedeterminat

Echipament de protecție personal

Protecția ochilor/-fetei

Nu purtați lentile de contact.
Ochelari de protecție etanși

Protecția mainilor

Mănuși (rezistente la baze)

Full contact: Glove material: nitrile rubber, glove thickness: 0.11 mm, Breakthrough time:> 480 min

The above breakthrough times were measured with samples of the recommended glove types of KCL in laboratory tests to EN374.

This recommendation applies only to the product stated in the safety that comes from us and the purpose specified by us. When dissolving in or mixing with other substances and under different conditions of the EN 374, you need to contact the supplier of CE-approved gloves (eg KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de)

Protecția corpului:

Echipament de protecție ușor

Protecție respiratorie

Echipament adecvat de protecție respiratorie:

Semimască cu filtru de particule, filtru P2

Puneți masca de protecție în cazul în care s-a degajat praful.

The operator has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the manufacturer and documented accordingly.

Controlul expunerii mediului

Măsuri tehnice pentru prevenirea expunerii

Not be released into drains.

Indicații complementare

Methods for measurement of the workplace atmosphere must correspond to the requirements of DIN EN 482 and DIN EN 689.

Technical measures and appropriate working operations have priority over the use of personal protective equipment.

Protective clothing should be selected specifically for the working place, depending on concentration and quantity.

The resistance of the protective equipment should be inquired at the respective supplier.

Change contaminated clothing.

Protect skin.

After work, wash hands and face.

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SECȚIUNEA 9: Proprietățile fizice și chimice

9.1 Informații privind proprietățile fizice și chimice de bază

Starea fizică

solid

Culoare

alb

Miros

fara miros

Date relevante privind siguranța

	Valoare	Metoda	Sursa, Remarcă
Pragul de acceptare a mirosului:	nedeterminat		
Punctul de topire/punctul de înghețare	nedeterminat		
Punctul de fierbere sau punctul inițial de fierbere și intervalul de fierbere	nedeterminat		
inflamabilitatea	solid		nu aplicabile
inflamabilitatea	sub forma de gaz		nu aplicabile
Limita inferioară și superioară de explozie	Limită superioară de explozie		nu aplicabile
Limita inferioară și superioară de explozie	Limita inferioara de explozie		nu aplicabile
Punctul de aprindere			nu aplicabile
Temperatura de autoaprindere			nedeterminat
Temperatura de autoaprindere			nedeterminat
Temperatura de descompunere		nedeterminat	nedeterminat
pH	in starea de livrare circa 12		suspensie în apă
Viscozitate	nefolosibil		
Viscozitate	nefolosibil		
Solubilitatea (solubilitățile)	Solubilitate in apa circa 1 g/L		
Solubilitatea (solubilitățile)	nedeterminat		
Coeficientul de partiție n-octanol/apă (valoare log)			nu aplicabile
Presiunea vaporilor			nedeterminat
Densitate si/sau densitate relativa			nedeterminat
Densitate si/sau densitate relativa	Densitatea în vrac circa 730- 930 kg/m ³		
Densitatea relativa a vaporilor caracteristicile particulelor	nedeterminat		nu aplicabile

9.2 Alte informații

Alte caracteristici de siguranță

	Valoare	Metoda	Sursa, Remarcă
Conținut de solvenți			nu aplicabile
Conținutul de apă	circa 14- 18 %		

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	Valoare	Metoda	Sursa, Remarcă
Conținutul de corpuri solide			nu aplicabile
cifra acidului			nedeterminat
Verificarea separării solventului			nu aplicabile
Proprietăți explozive:			nici una
Proprietăți care stimulează arderea			nici una
Alte informații			
nici una			

SECȚIUNEA 10: Stabilitate și reactivitate

10.1 Reactivitate

nedeterminat

10.2 Stabilitate chimică

nedeterminat

10.3 Posibilitatea de reacții periculoase

nedeterminat

10.4 Condiții de evitat

Reacționează cu acizii.
Reacționează foarte exoterm cu acizii.
Reacționează cu metalele ușoare la umiditate și degajă hidrogen.
Reacționează cu metalele nenobile și degajă hidrogen.
În soluție apoasă, la contactul cu metalele, se formează hidrogen.
Se va degaja căldură sub efectul acizilor
Reacționează cu aluminiul la temperaturi înalte.

10.5 Materiale incompatibile

Metale ușoare
Formarea de:
Hidrogen

10.6 Produse de descompunere periculoase

nedeterminat

Indicații complementare

nici una

SECȚIUNEA 11: Informații toxicologice

11.1 Informații privind clasele de pericol definite în Regulamentul (CE) nr. 1272/2008

Toxicitate acută

Date despre animale

	Doza efectivă	Metoda, Evaluare	Sursa, Remarcă
Toxicitate acută orală	Specii nedeterminat	nedeterminat	nici una nedeterminat
Toxicitate dermală acută	Specii nedeterminat	nedeterminat	nici una nedeterminat
Toxicitate inhalativă acută	Specii nedeterminat	nedeterminat	nici una nedeterminat

Corodarea/iritarea pielii

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Date despre animale

Rezultat / Evaluare	Metoda	Sursa, Remarcă
neiritant. Specii lepuri	OCDE 404	nici una

Lezarea gravă/iritarea ochilor

Date despre animale

Rezultat / Evaluare	Metoda	Sursa, Remarcă
Risc de leziuni oculare grave. Specii lepuri	OCDE 405	nici una

Sensibilizarea căilor respiratorii

Evaluare/clasificare
nedeterminat

Sensibilizare cutanată

Date despre animale

Rezultat / Evaluare	Doza / Concentrație	Metoda	Sursa, Remarcă
nedeterminat	Specii nedeterminat	nedeterminat	nici una

cancerogenitatea

Date despre animale

	Valoare	Metoda	Rezultat / Evaluare	Remarcă
cancerogenitatea	Specii nedeterminat	nedeterminat	nici una	nedeterminat

Toxicitate pentru reproducere

Date despre animale

	Valoare	Metoda	Rezultat / Evaluare	Remarcă
Toxicitate pentru reproducere	Specii nedeterminat	nedeterminat	nici una	nedeterminat

STOT (toxicitate asupra organelor țintă specifice) – expunere unică

STOT SE 1 și 2

Date despre animale

	Doza efectivă	Metoda	efecte specifice:	Organe afectate:	Sursa, Remarcă
Toxicitate specifică la ingerare asupra unui organ țintă (expunere unică)	Specii nedeterminat	nedeterminat			nici una nedeterminat
Toxicitate asupra unui organ țintă specific prin expunere cutanată (expunere unică)	Specii nedeterminat	nedeterminat			nici una nedeterminat
Toxicitate specifică la inhalare asupra unui organ țintă (expunere unică)	Specii nedeterminat	nedeterminat			nici una nedeterminat

STOT (toxicitate asupra organelor țintă specifice) – expunere repetată

Date despre animale

	Doza efectivă	Metoda	efecte specifice:	Organe afectate:	Sursa, Remarcă
Toxicitate specifică la ingerare asupra unui organ țintă (expunere repetată)	Specii nedeterminat	nedeterminat			nici una nedeterminat
Toxicitate specifică la ingerare asupra unui organ țintă (expunere repetată)	Specii nedeterminat	nedeterminat			nici una nedeterminat

Fișa cu date de securitate în conformitate cu Regulamentul (CE) nr.1907/2006 (REACH)

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	Doza efectivă	Metoda	efecte specifice:	Organe afectate:	Sursa, Remarcă
Toxicitate asupra unui organ țintă specific prin expunere cutanată (expunere repetată)	Specii nedeterminat	nedeterminat			nici una nedeterminat
Toxicitate asupra unui organ țintă specific prin expunere cutanată (expunere repetată)	Specii nedeterminat	nedeterminat			nici una nedeterminat
Toxicitate specifică la inhalare asupra unui organ țintă (expunere repetată)	Specii nedeterminat	nedeterminat			nici una nedeterminat
Toxicitate specifică la inhalare asupra unui organ țintă (expunere repetată)	Specii nedeterminat	nedeterminat			nici una nedeterminat

11.2 Informații privind alte pericole

Nu sunt date disponibile

Alte informații

nici una

Într-o utilizare destinată nu vor apărea prafuri care pot provoca iritații ale membranelor mucoase ale tractului respirator.

SECȚIUNEA 12: Informații ecologice

12.1 Toxicitate

Toxicitate acvatică

	Doza efectivă	Metoda, Evaluare	Sursa, Remarcă
Toxicitatea acută a peștilor (pe termen scurt)	Specii nedeterminat	nedeterminat	nici una
Toxicitatea cronică (pe termen lung) a peștilor	nedeterminat		
Toxicitate acută (pe termen scurt) pentru crustacee	Specii nedeterminat	nedeterminat	nici una
Toxicitate cronică (pe termen lung) pentru nevertebrate acvatice	nedeterminat		
Toxicitate acută (pe termen scurt) pentru alge și cianobacterii	Specii nedeterminat	nedeterminat	nici una
Toxicitatea pentru alte plante/organisme acvatice	nedeterminat		
Toxicitate pentru microorganisme	Specii nedeterminat	nedeterminat	nici una

12.2 Persistență și degradabilitate

	Valoare	Metoda	Sursa, Remarcă
Biodegradare		nedeterminat	nici una nedeterminat
Biodegradare		nedeterminat	nici una nedeterminat

12.3 Potențial de bioacumulare

Nu sunt date disponibile

12.4 Mobilitate în sol

Evaluare/clasificare
nedeterminat

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12.5 Rezultatele evaluării PBT și vPvB

nedeterminat

12.6 Proprietăți de perturbator endocrin

Nu sunt date disponibile

12.7 Alte efecte adverse

Informații ecotoxicologice suplimentare

	Valoare	Metoda	Sursa, Remarcă
Cererea de oxigen chimic (COC)		nedeterminat	nici una nedeterminat
Cererea de oxigen biochimic		nedeterminat	nici una nedeterminat
Carbon organic total (TOC):		nedeterminat	nici una nedeterminat
AOX			nefolosibil

Informații suplimentare

Pe baza consistenței produsului nu este posibilă o împărțire dispersă în mediul înconjurător.
Pe baza consistenței și a solubilității reduse a produsului nu este probabilă o biodisponibilitate.
Produsul nu conduce la un consum biologic de oxigen.
Date ecologice inexistente.
Nu lăsați să ajungă produsul lipsit de control în mediul înconjurător.

SECȚIUNEA 13: Considerații privind eliminarea

13.1 Metode de tratare a deșeurilor

Coduri deseuri/Denumiri deseuri conform EAK/AVV

Chei deseuri produs	Denumirea deșeurilor
160303 *	deșeuri anorganice cu conținut de substanțe periculoase
160507 *	substanțe chimice anorganice de laborator expirate, constând din sau conținând substanțe periculoase
180106 *	chimicale constând din sau conținând substanțe periculoase

Eliminarea corectă a deșeurilor / Produs

Îndepărtarea conform reglementărilor autorităților.
Debarasare conform "Kreislaufwirtschaftsgesetz (KrWG)".

Eliminarea corectă a deșeurilor / Ambalaj

Ambalajele necontaminante și golite de resturi pot fi transportate pentru revalorificare.
Valorificați ambalajele de vânzare prin DSD (Duales System Deutschland)

Remarcă

Poate să fie înălțat la o platformă de gunoi menajer.
Pachetele sunt de preferat cu privire la, de reglementările locale / naționale de re folosire sau pentru reciclare.
Recipient HDPE sau pungă de plastic PE, clătiți cu apă și reciclarea ca grad de plastic.

SECȚIUNEA 14: Informații referitoare la transport

	Transportul în țară (ADR/RID)	Transport maritim (IMDG)	Transport aerian (ICAO-TI / IATA-DGR)
14.1 Numărul ONU sau numărul de identificare	-	-	-
14.2 Denumirea corectă ONU pentru expediție	-	-	-
14.3 Clasa (clasele) de pericol pentru transport	-	-	-
14.4 Grupul de ambalare	-	-	-

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	Transportul în țară (ADR/RID)	Transport maritim (IMDG)	Transport aerian (ICAO-TI / IATA-DGR)
14.5 Pericole pentru mediul înconjurător	Nu	Nu	Nu

14.6 Precauții speciale pentru utilizatori

nici una

14.7 Transportul maritim în vrac în conformitate cu instrumentele OMI

nu aplicabile

Toate mijloacele de transport

Drăger sifon var nu este higroscopica și conține mai puțin de 4% NaOH. El nu este în conformitate cu UN1907.

Transportul în țară (ADR/RID)

Remarcă

Neclasificat pentru această cale de transport.

Transport maritim (IMDG)

Remarcă

Neclasificat pentru această cale de transport.

Transport aerian (ICAO-TI / IATA-DGR)

Remarcă

Neclasificat pentru această cale de transport.

SECȚIUNEA 15: Informații de reglementare

15.1 Regulamente/legislație în domeniul securității, sănătății și al mediului specifice (specifică) pentru substanța sau amestecul în cauză

Dispoziții-EU

Autorizații

nu aplicabile

Restricții de întrebuințare

nici una

alte Reglementări-EU

De reținut:

Directiva (CEE) Nr. 259/93 asupra supravegherii și controlului aducerii de reziduuri pe teritoriul, în și din Uniunea Europeană.

15.2 Evaluarea securității chimice

Reglementări naționale

Nu au fost efectuate evaluări securității chimice substanțelor din acest amestec.

SECȚIUNEA 16: Alte informații

Importante referințe în literatura sau surse de date
nedeterminat

Instrucțiuni de școlarizare
nedeterminat

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Indicații complementare

Se vor respecta legile naționale și locale referitoare la substanțele chimice.

Informațiile din această foaie informativă de siguranță corespund celor mai noi cercetări științifice în momentul tipării. Informațiile trebuie să vă dea reținerile pentru manipularea sigură a produsului numit în această foaie de siguranță în timpul depozitării, prelucrării, transportului și neutralizării. Informațiile nu pot fi transferate asupra altor produse. În situația în care produsul se amestecă sau se prelucrează cu alte materiale, vagy megmunkálásnak vetik alá, az úgy készített új anyagra nem vihetők át ennek a biztonsági adatlapnak az adatai, amennyiben ebből nem adódik kifejezetten valami más.

Conform frazelor H- și EUH (Numat și text complet)

- | | |
|------|--|
| H290 | Poate fi corosiv pentru metale. |
| H314 | Provoacă arsuri grave ale pielii și lezarea ochilor. |
| H315 | Provoacă iritarea pielii. |
| H318 | Provoacă leziuni oculare grave. |
| H319 | Provoacă o iritare gravă a ochilor. |
| H335 | Poate provoca iritarea căilor respiratorii. |



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^[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

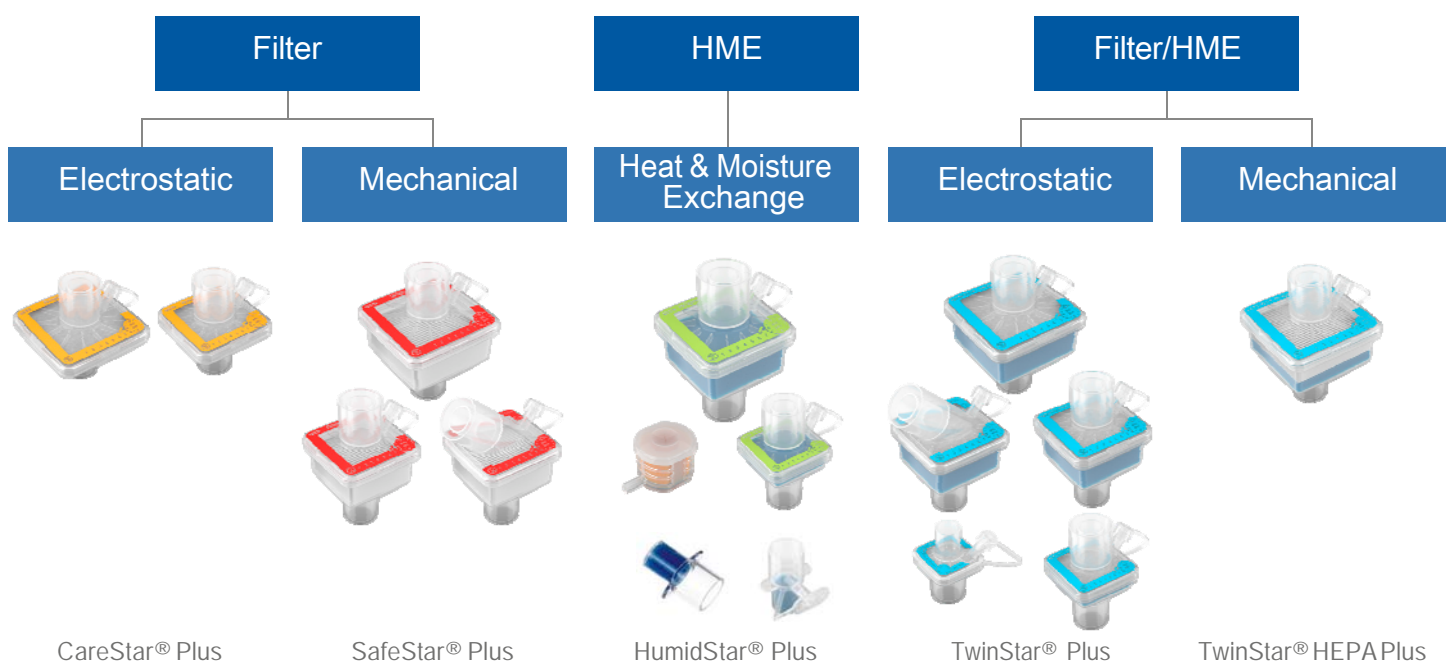
In some cases, patients receiving respiratory support therapy, the natural humidification process is often bypassed. During mechanical ventilation, the breathing gas used is much colder ($\sim 15^{\circ}\text{C}$) and dryer than the ambient atmosphere. When patients are intubated near the carina, this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



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

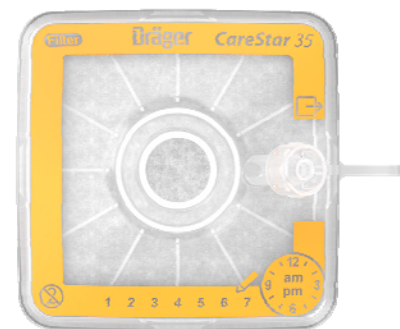


Managing cost of high quality care with CareStar® Plus

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-7/115-2021



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.

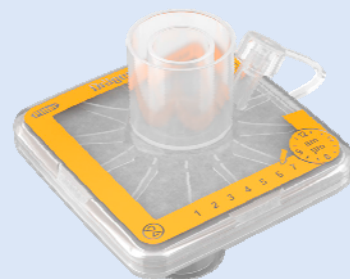
Mechanical filters = high performance

- 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 fibers resulting in an electrical charge



Our contribution to a better tomorrow

D:\2024-2022



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 (CO₂e) 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 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		
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)	
	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)		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 ₂ 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 ₂ 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		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 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)	5 to 95% (non-condensing)
		Air pressure range	570 to 1200 hPa (8.3 to 7.4 psi)	570 to 1200 hPa (8.3 to 7.4 psi)	570 to 1200 hPa (8.3 to 7.4 psi)	570 to 1200 hPa (8.3 to 7.4 psi)	570 to 1200 hPa (8.3 to 7.4 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)	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)	
		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		---	---	---	---	---	
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 ₂ 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 ₂ 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)
	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**
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

Bibliography

- ^[1] (WHO Health care-associated infections FACT SHEET)
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D	Catheter mount ErgoStar CM 55, disposable, 15 cm, straight, 50 pcs.	MP01855
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