Guideline
Breathing System Filter

April 2020, Lübeck
Mechanical vs. Electrostatic Filter

**Mechanical Filter**
- Highly hydrophobic medium will not allow water to pass the membrane
- Optimal filtration performance due to highly efficient pleated glass fiber based filtration medium
- Higher resistance due to tightly woven filter medium
- Higher dead space due to the minimum required filtration area

**Electrostatic Filter**
- Good filtration performance but only in the systems without humidification caused by a humidifier or the chemical reaction in Soda Lime during Anesthesia
- Lower resistance due to loosely woven filtration medium

**Heat and Moisture Exchanger (HME)**
- Available with mechanical / electrostatic filtration medium or without bacterial filtration
- Alternative for active humidification
Overview Breathing System Filter & HME

**FILTER**

**ELECTROSTATIC**
- CareStar®
  - CareStar® 45 (MP01755)
  - CareStar® 40A (MP01765)
  - CareStar® 30 (MP01770)

**MECHANICAL**
- SafeStar®
  - SafeStar® 80 (MP01785)
  - SafeStar® 60A (MP01795)
  - SafeStar® 55 (MP01790)

**HME**

**HEAT & MOISTURE EXCHANGE**
- HumidStar®
  - HumidStar® 55 (MP01730)
  - HumidStar® 25 (MP01735)
  - HumidStar® 10A (MP01740)
  - HumidStar® 2 (MP01745)
  - HumidStar® Trach Plus (MP05750)

**FILTER/HME**

**ELECTROSTATIC**
- TwinStar®
  - TwinStar® 90 (MP01800)
  - TwinStar® 65A (MP01810)
  - TwinStar® 55 (MP01805)
  - TwinStar® 25 (MP01815)
  - TwinStar® 10A (MP01825)
  - TwinStar® 8 (MP01820)

**MECHANICAL**
- TwinStar® HEPA (MP01801)

**NOTE:** The number indicates the dead space, DEHP & PVC free, “A” indicates Angled port, “HME” means Heat & Moisture Exchange filter, “Trach” means Tracheostomy.

Shelf life: 3 years (TwinStar®, CareStar®), 5 years (SafeStar®, HumidStar®), Maximum Duration of use = 24hrs (Single Patient Use)
# Overview Expiratory Valves & compatible Expiratory Heated Filter

<table>
<thead>
<tr>
<th>Device</th>
<th>Expiratory Valve</th>
<th>Reusable/Disposable</th>
<th>Adult</th>
<th>Pediatric</th>
<th>Neonatal</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evita® Infinity V500</td>
<td>8416750 Expiratory valve for Evita Infinity® V500, reusable</td>
<td>Reusable</td>
<td>EHF</td>
<td>P</td>
<td>A</td>
<td>Expiratory Heated Filter (EHF)</td>
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<tr>
<td>Evita® V300</td>
<td>8416750 Expiratory valve for Evita Infinity® V500, reusable</td>
<td>Reusable</td>
<td>EHF</td>
<td>P</td>
<td>A</td>
<td>Expiratory Heated Filter (EHF)</td>
</tr>
<tr>
<td>Savina®</td>
<td>8413660 Expiratory valve for Savina®, reusable</td>
<td>Reusable</td>
<td>EHF</td>
<td>P</td>
<td>A</td>
<td>Expiratory Heated Filter (EHF)</td>
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<tr>
<td>Savina® 300</td>
<td>8417050 Expiratory valve for Savina® 300, reusable</td>
<td>Reusable</td>
<td>EHF</td>
<td>P</td>
<td>A</td>
<td>Expiratory Heated Filter (EHF)</td>
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<td>Babylog® VN500</td>
<td>8415270 Expiratory valve for Babylog® VN 500, reusable</td>
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<td>EHF</td>
<td>N</td>
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<td>Babylog® 8000 Plus</td>
<td>8408950 Expiratory valve for Babylog® 8000 Plus, reusable</td>
<td>Reusable</td>
<td>EHF</td>
<td>N</td>
<td>P</td>
<td>Expiratory Heated Filter (EHF)</td>
</tr>
<tr>
<td></td>
<td>MP01060 Disposable RFID expiratory valve</td>
<td>Disposable</td>
<td>EHF</td>
<td>P</td>
<td>A</td>
<td>Expiratory Heated Filter (EHF)</td>
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</tr>
<tr>
<td></td>
<td>MP01061 Expiratory valve (single use)</td>
<td>Disposable</td>
<td>EHF</td>
<td>P</td>
<td>A</td>
<td>Expiratory Heated Filter (EHF)</td>
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</table>

**NOTE:** The Expiratory Heated Filter have a Maximum Duration of Use of 7 days.

For more details see IFU or PI

Not all articles are available worldwide.

EHF = Expiratory Heated Filter
- Infinity ID Expiratory Filter (MP01780)
- Expiratory Filter (MP01781)
## Filtration Efficiency

<table>
<thead>
<tr>
<th></th>
<th>Bacterial retention*</th>
<th>Viral retention**</th>
<th>NaCl retention***</th>
</tr>
</thead>
<tbody>
<tr>
<td>CareStar® 45 (MP01755)</td>
<td>≥ 99.9999%</td>
<td>≥ 99.9999%</td>
<td>≥ 98.5%</td>
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<tr>
<td>CareStar® 40A (MP01765)</td>
<td>≥ 99.9999%</td>
<td>≥ 99.9999%</td>
<td>≥ 98.1%</td>
</tr>
<tr>
<td>CareStar® 30 (MP01770)</td>
<td>≥ 99.99%</td>
<td>≥ 99.99%</td>
<td>≥ 95.3%</td>
</tr>
<tr>
<td>SafeStar® 80 (MP01785)</td>
<td>≥ 99.9999%</td>
<td>≥ 99.9999%</td>
<td>≥ 99.99%</td>
</tr>
<tr>
<td>SafeStar® 55 (MP01790)</td>
<td>≥ 99.9999%</td>
<td>≥ 99.9999%</td>
<td>≥ 99.7%</td>
</tr>
<tr>
<td>SafeStar® 60A (MP01795)</td>
<td>≥ 99.9999%</td>
<td>≥ 99.9999%</td>
<td>≥ 99.97%</td>
</tr>
<tr>
<td>TwinStar® 90 (MP01800)</td>
<td>≥ 99.999%</td>
<td>≥ 99.999%</td>
<td>≥ 97.8%</td>
</tr>
<tr>
<td>TwinStar® HEPA**** (MP01801)</td>
<td>≥ 99.999%</td>
<td>≥ 99.9999%</td>
<td>≥ 99.8%</td>
</tr>
<tr>
<td>TwinStar® 55 (MP01805)</td>
<td>≥ 99.999%</td>
<td>≥ 99.99%</td>
<td>≥ 96.1%</td>
</tr>
<tr>
<td>TwinStar® 65A (MP01810)</td>
<td>≥ 99.999%</td>
<td>≥ 99.99%</td>
<td>≥ 97.3%</td>
</tr>
<tr>
<td>TwinStar® 25 (MP01815)</td>
<td>≥ 99.999%</td>
<td>≥ 99.99%</td>
<td>≥ 98.0%</td>
</tr>
<tr>
<td>TwinStar® 8 (MP01820)</td>
<td>≥ 99.9%</td>
<td>≥ 99.9%</td>
<td>≥ 79.1%</td>
</tr>
<tr>
<td>TwinStar® 10A (MP01825)</td>
<td>≥ 99.9%</td>
<td>≥ 99.9%</td>
<td>≥ 79.1%</td>
</tr>
<tr>
<td>Infinity ID Expiratory Filter**** (MP01780)</td>
<td>≥ 99.9999%</td>
<td>≥ 99.9999%</td>
<td>-</td>
</tr>
<tr>
<td>Expiratory Filter**** (MP01781)</td>
<td>≥ 99.9999%</td>
<td>≥ 99.9999%</td>
<td>-</td>
</tr>
</tbody>
</table>

* BFE  According to Nelson Laboratories, Inc. Salt Lake City, USA. The mean particle size (MPS) of the challenge aerosol must be maintained at 3.0 ± 0.3 µm. The average percent bacterial filtration efficiency (%BFE) for the reference material must be within the upper and lower control limits established for the BFE test.

** VFE  According to Nelson Laboratories, Inc. Salt Lake City, USA. The mean particle size (MPS) of the challenge aerosol must be maintained at 3.0 ± 0.3 µm. The average percent virus filtration efficiency (%VFE) for the reference material must be within the upper and lower control limits established for the VFE test.

*** NaCl  According to Nelson Laboratories, Inc. Salt Lake City, USA. The filter tester produces a particle size distribution with a count median diameter of 0.075 ± 0.02 µm and a standard geometric deviation not exceeding 1.86 µm as determined with a scanning mobility particle sizer (SMPS).

**** HEPA  HEPA filter class H13 according to DIN EN 1822-1:1998 / DIN EN 1822-1:2011 at 0.1 µm. Our SafeStar® filter are designed with the same filtration medium as our TwinStar® HEPA.
FAQ regarding SARS COV-2

What specification is the minimum required in a breathing circuit filter (HMEF or Filter only) to prevent passage of the SARS COV-2 virus?
It always depends on the application. Generally, mechanical filters (like SafeStar® or TwinStar® HEPA) are always safer because they are less sensitive against humidity and they do have a really good filtration efficiency in their Most Penetrating Particle Size (MPPS). MPPS means: The filtration efficiency acts like parabola at its minimum most particles pass through.
- MPPS of electrostatic filtration medium ~ 0.04-0.08 µm (the filtration efficiency could be ≤ 99%)
- MPPS of mechanical filtration medium ~ 0.2 µm (the filtration efficiency should still be ≥ 99%)
On the other hand, the tightly woven glass fiber based filtration medium requires a minimum filtration area for optimal filtration efficiency. This leads to relatively higher resistance as well as higher dead space which is not recommended for pediatric or neonatal patients at the Y-piece.

Are the differences (≥99.9% or ≥99.99% or ≥99.999%) important when trying to protect patients from the SARS COV-2 virus?
Since no filter can promise 100% efficiency, there remains always a small risk of cross contamination. For enhanced safety, there is sometimes the opportunity to place a mechanical filter at the y-piece as well as the expiratory valve/port.
Exceptions:
- Mechanical filters are only allowed at the expiratory valve (never place it at the Y-piece), if the patient is a neonate or child. This is due to the dead space of the product. Smaller mechanical filters are so far not possible to produce because the area of the filtration medium is decisive for the filtration efficiency.
- No filter is allowed at the Y-piece during active humidification in the ICU because the resistance would increase and the patient would not receive enough humidity.
- More information regarding the set-up and warnings could be found in the corresponding Instruction for Use.
Overview Application Areas

OVERVIEW

ANESTHESIA
- HIGH FRESHGAS FLOW
- MINIMAL / LOW FLOW

RESPIRATORY
- INTENSIVE CARE UNIT (ICU)
- EMERGENCY / TRANSPORT
  - < 3 HOURS
  - > 3 HOURS

ACTIVE HUMIDIFICATION
PASSIVE HUMIDIFICATION
Anesthesia - enhanced safety

For anesthesia cases according to the intended use of anesthesia devices

- **HIGH FRESHGAS FLOW**
  - Adult: TwinStar HEPA / (55)*
  - Pediatric: TwinStar 25 / 10A / 8
  - Neonatal: HumidStar 2
  - Adult: SafeStar 55 / 60A
  - Pediatric: SafeStar 55
  - Neonatal: Optional: HumidStar 2

- **MINIMAL / LOW FLOW**
  - Adult: TwinStar 25 / 10A / 8
  - Pediatric: SafeStar 55
  - Neonatal: Optional: HumidStar 2

**Y-Piece**
- Optional: SafeStar 55 / 80

**Inspiratory Port**
- Optional: SafeStar 55 / 80
- Optional: SafeStar 55 / 60A
- Optional: SafeStar 55
- None**

**Expiratory Port**
- Optional: SafeStar 55 / 80
- Optional: SafeStar 55 / 60A
- Optional: SafeStar 55
- SafeStar 55
- SafeStar 55
- SafeStar 55

* Mechanical filters at the inspiratory as well as expiratory port are recommended and the hose system must be disposed after each patient.
** Mechanical filter at the inspiratory port would lead to condensation issues. Still enhanced safety level due to mechanical filter at the Y piece.
Intensive Care Unit – enhanced safety

For ventilated patients according to the intended use of ventilators

Y-Piece

ACTIVE HUMIDIFICATION

- Adult
  - None
- Pediatric
  - None
- Neonatal
  - None

PASSIVE HUMIDIFICATION

- Adult
  - TwinStar 55 / HEPA eF
  - SafeStar 55 / 80 or EHF mF
- Pediatric
  - TwinStar 25 / 10A / 8 eF
  - SafeStar 55 / 80 or EHF mF

Expiratory Valve

- SafeStar 55 or EHF
- Off-Label Use SafeStar 55 with adapter

Y-Piece

- Electrostatic Filter eF
- Mechanical Filter mF
- Heat-and-Moisture-Exchanger HME
Emergency Care

EMERGENCY/TRANSPORT

< 3 HOURS

Adult

CareStar 30 / 40A / 45

Pediatric

CareStar 30

> 3 HOURS

Adult

TwinStar 55 / HEPA

Pediatric

TwinStar 25 / 10A / 8

Y-Piece

Y-Piece

Electrostatic Filter

Heat-and-Moisture-Exchanger
Many thanks

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