



GVS M35672NL Vent Filters and Sets Instruction Manual

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GVS M35672NL Vent Filters and Sets



Product Information

- **Product Name:** Vent Filters and Sets
- **Manufacturer:** GVS Filter Technology UK Ltd.
- **Address:** NFC House, Vickers Industrial Estate, Mellishaw Lane, Morecambe, Lancashire, United Kingdom, LA3 3EN
- **Contact:** tel. +44 (0)1524 847600
- **Website:** www.gvsuk@gvs.com

Intended Use

The Vent Filters and Sets are filters, both hydrophobic and non-hydrophobic, designed for use within oxygen concentrators and other medical equipment such as ventilators. These filters are typically inserted into the gas sampling line to prevent contamination of the measuring equipment and its system, reducing the risk of patient cross-contamination.

CAUTION:

A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in harm to the patient.

- The use of the medical device requires full understanding and strict observation of all portions of the Instructions for Use.
- The medical device may only be used for the purpose specified under Intended Use.
- Observe all CAUTION statements throughout this manual and all statements on medical device labels.
- The manufacturer disclaims any liability for patient injury caused by noncompliance with these statements.

Installation

After installation of the filter, check that all connections are secure.

Availability of Instructions for Use

The Instructions for Use are not available for each individual filter. Only one copy of the Instructions for Use is included in the distribution package and should therefore be kept in an accessible location for users.

User Responsibility

The medical device is only to be used by healthcare professionals. The user has the responsibility to report any serious incidents related to the medical device to the manufacturer, EC REP, and the competent authority of the Member State.

Product Handling

- To avoid contamination and soiling, the product should remain packaged until ready to be used.
- Do not use the product if the packaging and/or product is damaged.
- Store the product at room temperature, in a dry place, free of dust, and not exposed to direct sunlight.
- Handle the filter with care. Abusive handling can damage the filter.

Safety Precautions

- Before installation, check that all system components are free of obstructions and foreign bodies. Otherwise, use is limited, or faulty operation is possible.
- Inappropriate connection to other devices can result in a patient hazard.
- The medical device products are designed, tested, and manufactured exclusively for disposable use and for a period of use not exceeding 24 hours following the first opening of the primary packaging.
- Do not use after the expiry date stated on the primary packaging.

Monitoring and Replacement

- Monitor filter performance during use. If any changes to filter performance or appearance are observed, change the filter to a new one.
- Always keep a spare filter ready to exchange with the one in use if any of the following are observed:
 - Increase in resistance
 - Filter is visibly soiled or damaged or if it rattles
 - Excessive condensation
 - Associated alarm

Product Disposal

The products must not be reused, cleaned, or sterilized after use in order to re-use. Exceptions from this rule will be stated within the Instruction For Use for the particular product code if applicable. Reuse, cleaning, or sterilization may lead to failure of the products, risk infection, and injury to the patient.

Specifications

- Manufacturer: GVS Filter Technology UK Ltd.
- Intended Use: Filters for use within oxygen concentrators and other medical equipment
- Types: Hydrophobic and non-hydrophobic filters
- Storage: Store at room temperature, in a dry place, free of dust, and not exposed to direct sunlight
- Handling: Handle with care to avoid damage

- Disposable: Designed for single-use only
- Maximum Use Duration: Not exceeding 24 hours following the first opening of the primary packaging

FAQ

- Can the filters be reused?
- No, the filters are designed for single use only and should not be reused.
- What should I do if I observe changes in filter performance or appearance?
- If any changes in filter performance or appearance are observed, replace the filter with a new one.
- How should I handle the filters?
- The filters should be handled with care to avoid damage.
- Can the product be sterilized after use?
- No, the product should not be sterilized after use. It is designed for single use only.

Vent Filters and Sets

Intended use:



Filters, hydrophobic and non-hydrophobic for use within oxygen concentrators and other medical equipment such as ventilators. Filters are typically inserted into the gas sampling line to prevent measuring equipment and its system from becoming contaminated to reduce the risk of patient cross-contamination.

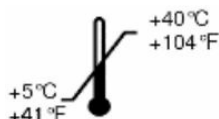
CAUTION:


The CAUTION statement provides important information about a potentially hazardous situation that, if not avoided, may result in harm to the patient. Any use of the medical device requires full understanding and strict observation of all portions of these Instructions for Use. The medical device may only be used for the purpose specified under "Intended Use". Observe all CAUTION statements throughout this manual and all statements on medical device labels. The manufacturer disclaims any liability for patient injury caused by noncompliance with these statements.

Following installation of the filter, check that all connections are secure. The medical device IFU is not available for each filter. Only one copy of the Instructions for Use is included in the distribution package and should therefore be kept in an accessible location for users.

Safety Instructions

-  Medical devices are only to be used by healthcare professionals.
- The user has the responsibility to report any serious incident that has occurred about the medical device, to the manufacturer,
- EC REP and the competent authority of the Member State in which the user and/or the patient is established.
- To avoid contamination and soiling, the product should remain packaged until ready to be used.
-  Do not use the product if the packaging and/or product is damaged.
- If the product was kept outside the stated storage temperature, product functionality cannot be guaranteed.
 - **Storage Temperature:** +5°C to 40°C.





-  Store the product at room temperature, in a dry place, free of dust and not exposed to direct sunlight.
- Handle filter with care. Abusive handling can damage the filter.

For Your Safety

Your Patients, follow the Instructions for the Use of the Machine!

- Before installation, check that all system components are free of obstructions and foreign bodies. Otherwise, use is limited, or faulty operation is possible.
- Inappropriate connection to other devices can result in a patient hazard.
- Medical device products have been designed, tested, and manufactured exclusively for disposable use and for a period of use not exceeding 24 hours following the first opening of the primary packaging.
- Do not use after the expiry date stated on the primary packaging. Use the product if the packaging and/or product is damaged.






-  Manufacturing date
-  Expiry date

Monitor filter performance during the use. If any changes to filter performance or appearance are observed, change the filter to a new one. Always keep a spare filter ready to exchange with the one in use, if any of the below are observed:

- Increase in resistance;
- The filter is visibly soiled or damaged or if it rattles;
- Excessive condensation;
- Associated alarm.



The products must not be reused, cleaned, or sterilized / not to be sterilized after use in order to re-use. Exceptions from this rule will be stated within the Instruction For Use for the particular product code if applicable. Reuse, cleaning or sterilization may lead to failure of the products, risk of infection, and injury to the patient.

-  This product is for single-patient use only.
-   This product is latex and PHT-free.
-  Batch code symbol.
-  Prescription only.

Following use, the products must be disposed of by the local hospital hygiene and waste disposal regulations for hazardous infectious clinical waste.

Shelf Life: 5 years.

Instructions For Use

Product Code	Product Description	Inlet/Outlet Connectors	Approximate Dimensions	Weight	Special Features	Sterilization	Product Supplied	Ambient Conditions	Temperature During Storage
2000/01X XXX	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/02X XXX	Vent Filter Autoclavable	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter, Autoclavable filter	Autoclave (25 mins at 134°C)	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/05X XXX	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/05B AKX XXX	Vent Filter Set	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/05D LKX XXX	Vent Filter Set	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/06X XXX	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/07X XXX	Vent Filter Autoclavable	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	Autoclave (25 mins at 134°C)	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/08X XXX	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/09X XXX	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A

Product Code	Product Description	Inlet/Outlet Connectors	Approximate Dimensions	Weight	Special Features	Sterilization	Product Supplied	Ambient Conditions	Temperature During Storage
2000/12X XXX	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/12D XXX X	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/12P XXX X	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/14X XXX	Vent Filter Autoclavable	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	Autoclave (25 mins at 134°C)	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/14S XXX X	Vent Filter Autoclavable	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	Autoclave (25 mins at 134°C)	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/15X XXX	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/15C XXX X	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/15D XXX X	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/15F XXX X	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A

Product Code	Product Description	Inlet/Outlet Connectors	Approximate Dimensions	Weight	Special Features	Sterilization	Product Supplied	Ambient Conditions	Temperature During Storage
2000/15S XXX X	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/16X XXX	Vent Filter	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	None	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/18X XXX	Vent Filter Autoclavable	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	Autoclave (25 mins at 134°C)	Non-Sterile	5 to 40 °C (41-104 °F)	N/A
2000/18B XXX X	Vent Filter Autoclavable	OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.	54mm diameter x 53.3mm height	11g (approx.)	Bidirectional filter	Autoclave (25 mins at 134°C)	Non-Sterile	5 to 40 °C (41-104 °F)	N/A

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Modifications from the previous issue:

13 languages added and intended use amended. GVS Filter Technology UK Ltd., NFC House, Vickers Industrial Estate, Mellishaw Lane, Morecambe, Lancashire, United Kingdom, LA3 3EN, **tel.** +44 (0)1524 847600

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Documents / Resources

	GVS M35672NL Vent Filters and Sets [pdf] Instruction Manual M35672NL Vent Filters and Sets, M35672NL, Vent Filters and Sets, Filters and Sets, and Sets, Sets
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References

- [User Manual](#)