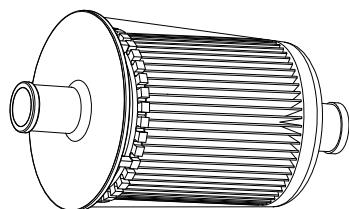


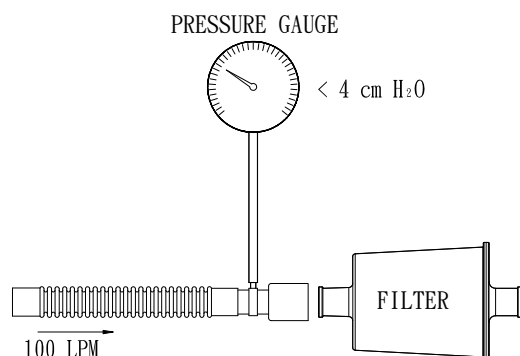


Manifold-Filter® Main Flow Bacteria Filter

Manifold-Filter with 22 mm ID Connector Silicone Tubing



Pressure Drop Test Setup



As the picture shown, when connect the filter into connector pressure should be lower than 4.0 cm H₂O before putting into service

These symbols appear on the Manifold-Filter Main Flow Bacteria Filter.	
Symbol	Meaning
	Refer to these instructions.
	"Use by" mark; anticipated retirement date
	Indicates flow direction, filter is designed for use only in this orientation.
G M P	The Filter complies with the requirements of GMP

The Filter is recommend to have 1 year expiration after first use .

Golden Hygeia International Co., Ltd.

Manufacture Date :

Use By :

INSTRUCTIONS

Description

Designed as a main flow and/or exhalation filter in a heated exhalation system. The transparent plastic casing allow easy monitoring and inspection of the filter. When used as a main flow filter, Manifold-Filter minimizes particles and bacteria delivered to the patient, and reduces the possibility of bacteria reentering the ventilator, where the reinfection or cross-infection might result. Used as an exhalation filter in a heat exhalation system, Manifold-Filter minimizes bacteria in exhaled gas from venting to room air. The filter also protects the ventilator's exhalation and spirometry systems, and is designed for repeated autoclavings.

Caution - Using the filter in the exhalation limb of a patient circuit while using a nebulizer will trap unused medication aerosol, and cause premature buildup of resistance. This will shorten the life of the filter. To ensure proper installation, observe the flow direction markings on the filter.

Maintenance

Inspect and check the pressure drop across the filter before every reuse, and after 15 days of continuous use in the exhalation limb. Replace if cracked, if it rattles, or if its case is broken. Maximum allowable pressure drop across the filter is 4 cmH₂O (0.06 psi) at 100 L/min.

Warning - Remove filter from service if pressure drop is greater than 4 cmH₂O (indicating filter medium is occluded). Failure to pressure test the filter, or to perform a ventilator check, may allow a ventilator/filter malfunction to go undetected, resulting inadequate patient ventilation.

Filtration service life cycle (pressure drop) is depended by the operating environment condition and will reduce its usage in times when Filter is used in medication or contamination from surrounding. Marking the expiration (1 year after first use) on the Filter Label when use the first time. It is normal the filter material changes the color by medication and repeatedly sterilization.

Warning - Failure to detect a blocked filter may result (depending on use) in increased inspiratory or expiratory resistance, causing elevated baseline pressure. If undetected, this will block the inspiratory/expiratory path completely and cause patient injury.

Caution - Abusive handling can damage filter medium. Discard any filter that rattles, or that has bulk liquid or debris visible inside the filter shell (visible bulk liquid may indicate breakdown of the hydrophobic barrier), or visible rips or tears (the seam in the filter medium is not defect). Disinfect filters before disposal.

Cleaning Instruction

If it is necessary to clean the filter housing, wipe with a damp cloth. Any cleaning solution used for external wipe-down must be compatible with polysulfone (the filter housing material).

Warning - To avoid damage, do not immerse filter in liquid, or scrub or touch the filter medium.

Warning - Do not use ethylene oxide (ETO) to disinfect bacteria filters. Always follow your hospital's infection control guidelines for handling infectious materia.

The filter is not sterile, and should be disinfected before use. It is designed for steam autoclaving only, at temperatures not to exceed 135°C (275°F). Note that effective disinfection occurs at a minimum cycle of 133 - 135°C (270 - 275°F) for 20 minutes for gravity-displacement cycles, or 4 minutes for prevacuum cycles.

Separate Silicone Tubing from filters, and wrap them in muslin or equivalent paper wrapper before autoclaving. Follow the steam autoclave manufacturer's instruction.

Note - Golden Hygeia recognizes that cleaning, sterilization, sanitation, and disinfection practices vary widely among health care institution. It is not possible for Golden Hygeia to specify practices that will meet all needs, or to be responsible for the effectiveness of cleaning, sterilization, and other practices carried out in the patient care setting. Golden Hygeia recommends that user of its products who require cleaning and sterilization/disinfection consider the Standard and Recommended Practices for sterilization published by the Association for the Advancement of Medical Instrumentation (AAMI), as well as the following Center Disease Control (CDC) publication: Guideline for Prevention of Nosocomial Pneumonia.

Specifications

Connections:	Barbed fittings for patient circuits for 7200 Series, MA-1, MA-2 Series, and other ventilator applications.
Size:	3.5 in. diameter x 6.0 in. length (8.9 cm x 14.6 cm).
Filter medium:	Over 250 square in. of hydrophobic filter medium.
Filter medium: Efficiency:	When new, minimum efficiency of 99.999% retention of 0.3 μ m and larger particles at a flow of 100 Lpm, and pressure drop of approximately 2.5 cmH ₂ O at 100 Lpm. Maximum allowable pressure drop across the filter is 4 cmH ₂ O (0.06 psi) at 100 Lpm.